PBRER Appendix 1 Reference Information (AstraZeneca Core Data Sheet)	
Medicinal Product	VAXZEVRIA (ChAdOx1-S [recombinant])
Period covered	29 June 2022 to 28 December 2022
Date	17 February 2023

Appendix 1

Reference Information (AstraZeneca Core Data Sheet)

Core Data Sheet in effect at the end of the reporting period: Core Data Sheet Dated 08 November 2022

CDS	
Drug Substance	COVID-19 Vaccine (ChAdOx1-S [recombinant])
Doc ID	Doc ID-004450132
Version	21.0
Date	08 November 2022
Supersedes	31 August 2022

Core Data Sheet
Vaxzevria, solution for injection

Use of this data sheet must conform to the current AstraZeneca Global SOP "4-P40-cv-X Development and Management of the Content of Core Product Information and Market Product Information"

Instructions for local marketing companies:

- *Special instructions are included throughout the document to guide marketing companies. These special instructions and the black border (outlining the special instructions) are NOT to be included in local labels.*

1 NAME OF THE MEDICINAL PRODUCT

Vaxzevria

COVID-19 Vaccine (ChAdOx1-S [recombinant])

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Note to local Marketing Company: To enable flexibility in local labels, the CDS includes viral particles (vp) and infectious units (Inf.U) as units of quantification. This is in alignment with the approved specification.

If use of vp as the units of quantification is not accepted by local health authorities then either both (vp and Inf.U) should be used or as a worst case, Inf.U only. The clinical experience is all based on vp and therefore only using Inf.U in your MPI as units of quantification may complicate the description of the studied dose level in the efficacy section.

It should be noted that vp cannot be converted to Inf.U and vice versa.

One dose (0.5 ml) contains :

COVID-19 Vaccine (ChAdOx1-S* recombinant) 5×10^{10} viral particles (vp)**

*Recombinant, replication-deficient chimpanzee adenovirus vector encoding the SARS-CoV-2 Spike (S) glycoprotein. Produced in genetically modified human embryonic kidney (HEK) 293 cells.

**Corresponding to not less than 2.5×10^8 infectious units (Inf.U)

This product contains genetically modified organisms (GMOs).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Note to local Marketing Company: If your local Health Authority requests that the pharmaceutical form is described as "suspension for injection" rather than "solution for injection" then this may be accepted. However, please consider impact to supply chain or any shared packs first before accepting.

Clear to slightly opaque, colourless to slightly brown, particle free, pH 6.6, solution for injection.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Vaxzevria is indicated for active immunisation of individuals ≥18 years old for the prevention of coronavirus disease 2019 (COVID-19).

4.2 Posology and method of administration

Posology

The Vaxzevria primary vaccination course consists of two separate doses of 0.5 ml each. The second dose should be administered between 4 and 12 weeks after the first dose (see section 5.1).

It is recommended that individuals who receive a first dose of Vaxzevria complete the primary vaccination course with Vaxzevria (see section 4.4).

A booster dose (third dose) of 0.5 ml may be given to individuals who completed the primary vaccination course with Vaxzevria or another authorised COVID-19 vaccine (see sections 4.8 and 5.1). The third dose should be administered at least 3 months after completing the primary vaccination course.

Special populations

Elderly population
No dosage adjustment is required in elderly individuals ≥65 years of age.

Paediatric population
The safety and efficacy of Vaxzevria in children and adolescents (aged <18 years old) have not yet been established. No data are available.

Method of administration

Vaxzevria is for intramuscular (IM) injection only, preferably in the deltoid muscle.

For instructions on administration, see section 6.6.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Patients who have experienced major venous and/or arterial thrombosis in combination with thrombocytopenia following vaccination with any COVID-19 vaccine.

4.4 Special warnings and special precautions for use

Hypersensitivity including anaphylaxis

Hypersensitivity reactions including anaphylaxis and angioedema have occurred following administration of Vaxzevria.

Appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following the administration of the vaccine.

An additional dose of the vaccine should not be given to those who have experienced a severe hypersensitivity reaction to a previous dose of Vaxzevria.

Concurrent illness

As with other vaccines, administration of Vaxzevria should be postponed in individuals suffering from an acute severe febrile illness. However, the presence of a minor infection, such as cold, and/or low-grade fever should not delay vaccination.

Coagulation disorders

- *Thromboembolism in combination with thrombocytopenia*
  A very rare and serious combination of thrombosis and thrombocytopenia including thrombosis with thrombocytopenia syndrome (TTS), in some cases accompanied by bleeding, has been observed following vaccination with Vaxzevria during post-authorisation use. This includes cases presenting as venous thrombosis, including unusual sites such as cerebral venous sinus thrombosis, splanchnic vein thrombosis, as well as arterial thrombosis, concomitant with thrombocytopenia. The majority of the events occurred within the first 21 days following vaccination and some events had a fatal outcome. The reporting rates after the second dose are lower compared to after the first dose. See also section 4.3. Healthcare professionals should consult applicable guidance and, if available, seek advice from specialists (e.g., haematologists, specialists in coagulation) to diagnose and treat this condition.

  Whilst specific risk factors for thromboembolism in combination with thrombocytopenia have not been identified, cases have occurred in patients with a previous history of thrombosis, as well as in patients with autoimmune disorders, including immune thrombocytopenia. The benefits and risks of vaccination should be considered in these patients.

- *Cerebrovascular venous and sinus thrombosis without thrombocytopenia*
  Events of cerebrovascular venous and sinus thrombosis without thrombocytopenia have been reported very rarely following vaccination with Vaxzevria, although a causal relationship has not been established. These events can be fatal and may require different treatment approaches than TTS. Healthcare professionals should consult applicable guidance.

- *Thrombocytopenia*
  Cases of thrombocytopenia, including immune thrombocytopenia (ITP), have been reported following vaccination with Vaxzevria, typically within the first four weeks after vaccination. Very rarely, these presented with very low platelet levels (<20,000 per μL) and/or were associated with bleeding. Some of these cases occurred in individuals with a history of immune thrombocytopenia or thrombocytopenia. Cases with fatal outcome have been reported. In individual with a history of a thrombocytopenic disorder, such as immune thrombocytopenia, the risk of developing low platelet levels should be considered before vaccination and platelet monitoring is recommended after vaccination.

Healthcare professionals should be alert to the signs and symptoms of thromboembolism and thrombocytopenia, as well as coagulopathies. Vaccinated individuals should be instructed to seek immediate medical attention if they develop symptoms such as a severe or persistent headaches, blurred vision, confusion, seizures, shortness of breath, chest pain, leg swelling, leg pain, persistent

abdominal pain, spontaneous bleeding or unusual skin bruising and or petechia a few days after vaccination.

Individuals diagnosed with thrombocytopenia within 21 days of vaccination with Vaxzevria, should be actively investigated for signs of thrombosis. Similarly, individuals who present with thrombosis within 21 days of vaccination should be evaluated for thrombocytopenia.

Risk of bleeding with intramuscular administration

As with other intramuscular injections, Vaxzevria should be given with caution to individuals with thrombocytopenia, any coagulation disorder or to persons on anticoagulation therapy, because bleeding or bruising may occur following an intramuscular administration in these individuals.

Neurological events

Very rare events of demyelinating disorders, including Guillain-Barré syndrome (GBS), have been reported following vaccination with Vaxzevria. A causal relationship has not been established.

As with other vaccines, the benefits and potential risks of vaccinating individuals with Vaxzevria should be considered.

Immunocompromised individuals

It is not known whether individuals with impaired immune responsiveness, including individuals receiving immunosuppressant therapy, will elicit the same response as immunocompetent individuals to the vaccine regimen.

Duration and level of protection

The duration of protection has not yet been established.

As with any vaccine, vaccination with Vaxzevria may not protect all vaccine recipients.

Interchangeability

There are limited safety, immunogenicity and efficacy data available regarding the interchangeability of Vaxzevria with other COVID-19 vaccines. For the available data on the use of Vaxzevria as a booster dose following primary vaccination with another COVID-19 vaccine, see sections 4.8 and 5.1.

4.5 Interaction with other medicinal products and other forms of interaction

The safety, immunogenicity and efficacy of co-administration of Vaxzevria with other vaccines have not been evaluated.

4.6 Pregnancy and lactation

Pregnancy

Data from more than 400 case reports of pregnant women or women who became pregnant after receiving Vaxzevria do not suggest unusual patterns of pregnancy complications or foetal/neonatal

outcomes. No increased risk of maternal thrombosis in combination with thrombocytopenia has been observed.

Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/foetal development, parturition or post-natal development (see section 5.3).

Use of Vaxzevria may be considered during pregnancy when the benefits of vaccination outweigh the potential risks.

Breastfeeding

Anti-SARS-CoV-2 S antibodies are excreted in breast milk of mothers vaccinated with Vaxzevria. In animal studies, lactational transfer of anti-SARS-CoV-2 S antibodies from maternal female mice to pups was observed (see section 5.3). It is unknown whether the vaccine itself is excreted in human milk. In animal studies no quantifiable levels of the vaccine were detected in the mammary gland in female mice.

Available non-clinical, clinical and post-marketing data do not suggest a risk to breastfed newborns/infants.

Fertility

Animal studies do not indicate direct or indirect harmful effects with respect to fertility.

4.7 Effects on ability to drive and use machines

Vaxzevria has no or negligible influence on the ability to drive and use machines. However, some of the adverse reactions mentioned under section 4.8 may temporarily affect the ability to drive or use machines.

4.8 Undesirable effects

Overall summary of the safety profile

Primary vaccination course

The overall safety of Vaxzevria is based on an analysis of pooled data from four clinical trials (COV001, COV002, COV003, and COV005) conducted in the United Kingdom, Brazil, and South Africa. At the time of analysis, 24,244 participants ≥18 years old had been randomised and received either Vaxzevria or control. Out of these, 12,282 received at least one dose of Vaxzevria, with a median duration of follow-up of 4.5 months.

Demographic characteristics were generally similar among participants who received Vaxzevria and those who received control. Overall, among the participants who received Vaxzevria, 89.8% were aged 18 to 64 years and 10.2% were 65 years of age or older. The majority of recipients were White (75.5%), 9.8% were Black and 3.7% were Asian; 55.8% were female and 44.2% male.

The most frequently reported adverse reactions were injection site tenderness (>60%); injection site pain, headache, fatigue (>50%); myalgia, malaise (>40%); pyrexia, chills (>30%); and arthralgia,

nausea (>20%). The majority of adverse reactions were mild to moderate in severity and usually resolved within a few days of vaccination.

Following vaccination, recipients may experience multiple adverse reactions occurring at the same time (for example, myalgia/arthralgia, headache, chills, pyrexia and malaise). If a recipient reports persistent symptoms, alternative causes should be considered.

When compared with the first dose, adverse reactions reported after the second dose were milder and reported less frequently. Adverse reactions were generally milder and reported less frequently in older adults (≥65 years old).

Booster dose (third dose)

In study D7220C00001, 367 participants who had previously received a 2-dose primary vaccination course with Vaxzevria, and 322 participants who had previously received a 2-dose primary vaccination course with an mRNA vaccine received a single booster dose (third dose) of Vaxzevria. The safety profile observed in participants who received a booster dose (third dose) was consistent with the known safety profile of Vaxzevria. The reactogenicity observed in participants who had previously received primary vaccination with an mRNA vaccine was similar to the reactogenicity observed in participants receiving a first dose of Vaxzevria in previous clinical studies.

In the COV001 study, the observed reactogenicity in participants who received a booster dose (third dose) following a 2-dose primary vaccination course with Vaxzevria was consistent with the known reactogenicity profile of Vaxzevria, and was lower after the third dose compared with after the first dose.

In the externally sponsored study RHH-001, 304 participants received a single booster dose (third dose) of Vaxzevria following a 2-dose primary vaccination course with an inactivated whole-virion SARS-CoV-2 vaccine. The reported reactogenicity profile was consistent with the known reactogenicity profile of Vaxzevria.

No new safety concerns, as compared with adverse reactions reported for the primary vaccination course with Vaxzevria, have been identified in individuals receiving a booster dose of Vaxzevria.

Analgesic and/or anti-pyretic medicinal products (e.g. paracetamol-containing products) may be used to provide symptomatic relief from post-vaccination adverse reactions.

Adverse drug reactions

Note to local Marketing Company: The ADR table includes the lower level terms for both feverishness and fever, as both these events could have been reported as solicited events. Feverishness is the subjective feeling of increased body temperature; fever is a recorded body temperature of ≥38.0°C/100.4°F. Both fever and feverishness fall under the preferred term of pyrexia.

The CDS includes ADR frequencies as both CIOMS categories and reported percentage (%) frequencies for the pooled data set, both vaccine-treatment and control arms, for completeness.

Marketing companies should incorporate the ADR frequencies, CIOMS or %, and control as per local regulations.

ADR frequencies in Table 1 are provided for participants in Dose 1 SD for Safety Analysis Set.

Adverse drug reactions (ADRs) are organised by MedDRA System Organ Class (SOC). Within each SOC, preferred terms are arranged by decreasing frequency and then by decreasing seriousness. Frequencies of occurrence of adverse reactions are defined as: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1000); very rare (<1/10,000) and not known (cannot be estimated from available data).

Table 1 – Adverse drug reactions[a] based on an analysis of pooled data from COV001, COV002, COV003, and COV005

MedDRA SOC	**Adverse reaction[b]**	**Vaxzevria (N= 10,317)**	**Control[c] (N= 10,141)**
Blood and lymphatic system disorders	Lymphadenopathy[d]	Uncommon (0.3%)	Uncommon (0.3%)
Nervous system disorders	Headache	Very common (52.7%)	Very common (39.8%)
	Dizziness[d]	Uncommon (0.7%)	Uncommon (0.7%)
	Somnolence[d]	Uncommon (0.5%)	Uncommon (0.3%)
Gastrointestinal disorders	Nausea	Very common (22.2%)	Very common (13.4%)
	Vomiting	Common (1.8%)	Uncommon (0.9%)
	Diarrhoea[d]	Common (1.6%)	Common (1.5%)
	Abdominal pain[d]	Uncommon (0.6%)	Uncommon (0.4%)
Skin and subcutaneous tissue disorders	Hyperhidrosis[d]	Uncommon (0.4%)	Uncommon (0.2%)
	Pruritus[d]	Uncommon (0.3%)	Uncommon (0.3%)
	Rash[d]	Uncommon (0.2%)	Uncommon (0.3%)
	Urticaria[d]	Uncommon (0.1%)	Uncommon (0.1%)
Musculoskeletal and connective tissue disorders	Muscle pain (Myalgia)	Very common (43.9%)	Very common (22.3%)
	Joint pain (Arthralgia)	Very common (26.6%)	Very common (13.0%)
	Pain in extremity[d]	Common (1.3%)	Uncommon (0.8%)

MedDRA SOC	Adverse reaction[b]	Vaxzevria (N= 10,317)	Control[c] (N= 10,141)
General disorders and administration site conditions	**Local**		
	Injection site tenderness	Very common (63.8%)	Very common (40.1%)
	Injection site pain	Very common (54.3%)	Very common (37.5%)
	Injection site warmth	Very common (17.9%)	Very common (15.2%)
	Injection site itch (Injection site pruritus)	Very common (13.1%)	Common (7.8%)
	Injection site swelling	Common (3.4%)	Common (1.6%)
	Injection site redness (Injection site erythema)	Common (3.1%)	Common (1.4%)
	Systemic		
	Fatigue	Very common (53.0%)	Very common (38.6%)
	Malaise	Very common (44.4%)	Very common (21.0%)
	Feverishness[e] (Pyrexia)	Very common (33.5%)	Very common (11.0%)
	Chills	Very common (32.2%)	Common (8.4%)
	Fever[e] (Pyrexia)	Common (7.6%)	Common (1.5%)
	Influenza-like illness[d]	Common (1.1%)	Uncommon (0.7%)

[a] Frequencies of ADRs are reported from the safety analysis set where participants received the recommended dose (5×10^{10} vp) as their first dose.
[b] Solicited event reporting terms, where applicable MedDRA preferred terms are given in parentheses.
[c] Control was either meningococcal vaccine or saline solution.
[d] Unsolicited adverse reaction.
[e] Defined as: Feverishness, (subjective) a self-reported feeling of having a fever; Fever, (objective) ≥38°C/100.4°F.

Summary of safety data from D8110C00001

Additional safety of Vaxzevria was established in a randomised phase III clinical trial conducted in the United States, Peru and Chile. At the time of the analysis, 32,379 participants ≥18 years old had received at least one dose, including 21,587 in the Vaxzevria group and 10,792 in the placebo group.

Demographic characteristics were generally similar among participants who received Vaxzevria and those who received placebo. Overall, among the participants who received Vaxzevria 77.6% were 18 to 64 years and 22.4% were ≥65 years of age. Seventy-nine percent of the participants were White, 8.3% were Black, 4.4% were Asian, 4.0% were American Indian or Alaska Native, 0.3% were Native Hawaiian or Other Pacific Islander, 2.4% were of multiple races and 1.7% were not reported or unknown; 44.4% were female and 55.6% male.

The safety profile observed in this Phase III study was consistent with pooled analysis of data from the United Kingdom, Brazil and South Africa (COV001, COV002, COV003, and COV005). Adverse reactions seen in this Phase III trial were observed at similar frequencies as seen in the pooled analysis except the following: feverishness (pyrexia) (0.7%), arthralgia (1.1%), injection site warmth (<0.1%) and injection site pruritus (0.2%). These adverse reactions were solicited adverse events in the COV001, COV002, COV003, and COV005 studies whereas the D8110C00001 study did not include these as solicited symptoms to report.

Summary of post-authorisation data

The following adverse reactions have been identified during post-authorisation following spontaneous reporting during worldwide use of Vaxzevria.

Blood and lymphatic system disorders: Thrombocytopenia (frequency: very rare). The majority of reported events occurred in individuals aged 18-59 years old.
Immune thrombocytopenia (frequency: not known).

Immune system disorders: Anaphylactic reaction (frequency: not known).

Nervous system disorders: Paraesthesia and hypoaesthesia (frequency: uncommon). Many of these events were co-reported with reactogenicity events.

Ear and labyrinth disorders: Tinnitus (frequency: uncommon).

Vascular disorders: A very rare and serious combination of thrombosis and thrombocytopenia including thrombosis with thrombocytopenia syndrome (TTS), in some cases accompanied by bleeding, has been observed with a frequency less than 1/100,000. This includes cases presenting as venous thrombosis, including unusual sites such as cerebral venous sinus thrombosis, splanchnic vein thrombosis, as well as arterial thrombosis, concomitant with thrombocytopenia (see section 4.4).

Skin and subcutaneous tissue disorders: Angioedema (frequency: not known), cutaneous vasculitis (frequency: not known).

4.9 Overdose

Experience of overdose is limited.

There is no specific treatment for an overdose with Vaxzevria. In the event of an overdose, the individual should be monitored and provided with symptomatic treatment as appropriate.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Mechanism of action

Vaxzevria is a monovalent vaccine composed of a single recombinant, replication-deficient chimpanzee adenovirus (ChAdOx1) vector encoding the S glycoprotein of SARS-CoV-2. Following administration, the S glycoprotein of SARS-CoV-2 is expressed locally stimulating neutralizing antibody and cellular immune responses.

Clinical efficacy

Primary analysis of pooled data from COV001, COV002, COV003, and COV005

Vaxzevria has been evaluated based on pooled data from four on-going randomised, blinded, controlled trials: a Phase I/II Study, COV001 (NCT04324606), in healthy adults 18 to 55 years of age in the UK; a Phase II/III Study, COV002 (NCT04400838), in adults ≥18 years of age (including the elderly) in the UK; a Phase III Study, COV003 (ISRCTN89951424), in adults ≥18 years of age (including the elderly) in Brazil; and a Phase I/II study, COV005 (NCT04444674), in adults aged 18 to 65 years of age in South Africa. The studies excluded participants with severe and/or uncontrolled cardiovascular, gastrointestinal, liver, renal, endocrine/metabolic disease, and neurological illnesses; as well as those with severe immunosuppression. All participants are planned to be followed for up to 12 months, for assessments of safety and efficacy against COVID-19 disease.

In the pooled analysis for efficacy, participants ≥18 years of age received two doses of Vaxzevria (N=8,597) or control (meningococcal vaccine or saline) (N=8,581). Participants randomised to Vaxzevria received either two standard doses [SD] (5×10^{10} vp per dose) or one low dose [LD] (2.2×10^{10} vp) followed by one SD (5×10^{10} vp), administered via IM injection. Overall, the majority of participants (83.8%) received two SD.

Because of logistical constraints, the interval between dose 1 and dose 2 ranged from 3 to 28 weeks, with 77.0% of participants receiving their two doses within the interval of 4 to 12 weeks.

Baseline demographics were well balanced across Vaxzevria and control treatment groups. In the pooled analysis, among the participants who received Vaxzevria, 91.8% of participants were 18 to 64 years old (with 8.2% aged 65 or older); 56.0% of subjects were female; 74.9% were White, 10.1% were Black and 3.7% were Asian. A total of 3,056 (35.5%) participants had at least one pre-existing comorbidity (defined as a BMI ≥30 kg/m^2, cardiovascular disorder, respiratory disease or diabetes). At the time of primary analysis the median follow-up time post-dose 1 and post-dose 2 was 4.7 months and 2.7 months, respectively.

Final determination of COVID-19 cases were made by an adjudication committee, who also assigned disease severity according to the WHO clinical progression scale. A total of 332 participants had SARS-CoV-2 virologically confirmed COVID-19 occurring ≥15 days post second dose with at least one COVID-19 symptom (objective fever (defined as ≥37.8°C), cough, shortness of breath, anosmia,

or ageusia) and were without evidence of previous SARS-CoV-2 infection. Vaxzevria significantly decreased the incidence of COVID-19 compared to control (see Table 2).

Table 2 – Vaxzevria efficacy against COVID-19 in COV001, COV002, COV003 and COV005[a]

Population	Vaxzevria		Control		Vaccine efficacy % (95% CI)
	N	Number of COVID-19 cases[b], n (%)	N	Number of COVID-19 cases[b], n (%)	
Primary analysis population					
Overall (SDSD + LDSD)	8,597	84 (0.98)	8,581	248 (2.89)	66.73 (57.41, 74.01)
Licensing regimen					
SDSD	7,201	74 (1.03)	7,179	197 (2.74)	63.09 (51.81, 71.73)

N = Number of subjects included in each group; n = Number of subjects having a confirmed event; CI = Confidence Interval; LD = Low dose; SD = Standard dose

[a] Primary study endpoint was based on confirmed COVID-19 cases in subjects aged 18 years and over who were seronegative at baseline, who had received two doses (SDSD or LDSD) and were on-study ≥15 days post second dose.

[b] Virologically confirmed SARS-CoV-2 and at least one of the following symptoms: objective fever (defined as ≥37.8°C), cough, shortness of breath, anosmia, or ageusia. Confirmed by adjudication committee.

The level of protection gained from one SD of Vaxzevria was assessed in an exploratory analysis that included participants who had received one dose of SD. Participants were censored from the analysis at the earliest time point of when they received a second dose or at 12 weeks post-dose 1. In this population, vaccine efficacy from 22 days post-dose 1 was 71.42% (95% CI: 51.11, 84.08 [Vaxzevria 18/9,335 vs control 63/9,312]).

Exploratory analyses showed that increased vaccine efficacy was observed with increasing dose interval, see Table 3.

Table 3 – Vaxzevria efficacy by dosing interval in COV001, COV002, COV003 and COV005[a]

Dosing interval	Vaxzevria		Control		Vaccine efficacy % (95% CI)
	N	Number of COVID-19 cases[b], n (%)	N	Number of COVID-19 cases[b], n (%)	
<6 weeks	3,905	35 (0.90)	3,871	76 (1.96)	55.09 (32.99, 69.90)
6-8 weeks	1,124	20 (1.78)	1,023	44 (4.30)	59.72 (31.68, 76.25)
9-11 weeks	1,530	14 (0.92)	1,594	52 (3.26)	72.25 (49.95, 84.61)
≥12 weeks	2,038	15 (0.74)	2,093	76 (3.63)	79.99 (65.20, 88.50)

N = Number of subjects included in each group; n = Number of subjects having a confirmed event; CI = Confidence Interval; LD = Low dose; SD = Standard dose

[a] Primary study endpoint was based on confirmed COVID-19 cases in subjects aged 18 years and over who were seronegative at baseline, who had received two doses (SDSD or LDSD) and were on-study ≥15 days post second dose.
[b] Virologically confirmed SARS-CoV-2 and at least one of the following symptoms: objective fever (defined as ≥37.8°C), cough, shortness of breath, anosmia, or ageusia. Confirmed by adjudication committee.

Note to local Marketing Company: Table 3 above uses the following definitions for the dosing intervals: < 6 weeks (≤ 41 days); 6 to 8 weeks (≥ 42 to ≤ 62 days); 9 to 11 weeks (≥ 63 to ≤ 83 days); ≥ 12 weeks (≥ 84 days).

Efficacy against COVID-19 hospital admission and severe COVID-19 disease

Vaxzevria reduced COVID-19 hospitalisation (WHO severity grading ≥4).

In participants who had received two doses of Vaxzevria (SDSD + LDSD, ≥15 days post-dose 2) as compared to control, there were 0 (N=8,597) vs 9 (0.10%; N=8,581) cases of hospitalised COVID-19, respectively. Corresponding to a vaccine efficacy of 100% (97.5% CI: 50.19, Not Evaluable).

In all participants who received SD as a first dose, as from 22 days post-dose 1, the vaccine efficacy was 100% (97.5% CI: 69.92, Not Evaluable) with 0 (N=9,335) cases of COVID-19 hospitalisation in participants who received Vaxzevria, when compared to 14 (0.15%, N=9,312) cases reported for control. Two of the COVID-19 cases reported for control (≥22 days post-dose 1) were severe (WHO severity grading ≥6).

Efficacy against COVID-19 in subgroups

Participants who had one or more comorbidities had a vaccine efficacy of 62.71% (95% CI: 44.79, 74.82); 34 (1.11%) vs 93 (3.00%) cases of COVID-19 for Vaxzevria (SDSD + LDSD, ≥15 days post-dose 2, N=3,056) and control (N=3,102), respectively; which was similar to the vaccine efficacy observed in the overall population.

In participants ≥65 years old who had received 2 doses of Vaxzevria (SDSD + LDSD, ≥15 days post-dose 2, N=703), there were 4 cases of COVID-19 compared to 8 cases for control (N=680), corresponding to a vaccine efficacy of 51.91% (95% CI: -59.98, 85.54). A large proportion (89.6%) of older adults received their second dose <6 weeks after their first. In older adults (≥65 years old) who had received SD as a first dose (≥22 days post-dose 1), there were 6 cases of COVID-19 for Vaxzevria (N=945) compared to 13 for control (N=896), with 0 vs 2 cases in the Vaxzevria and control groups, respectively, leading to hospitalisation (WHO severity grading ≥4).

Analysis of efficacy data from D8110C00001

Vaxzevria has been evaluated based on an analysis from a randomised, double-blinded, placebo-controlled Phase III trial conducted in the United States, Peru and Chile. The trial randomised 32,451 healthy adults or those with medically stable chronic diseases ≥18 years of age. The study excluded participants with severe and/or uncontrolled cardiovascular, gastrointestinal, liver, renal, endocrine/metabolic disease, and neurological illnesses; as well as those with severe

immunosuppression. All participants are planned to be followed for up to 1 year for assessments of efficacy against COVID-19 disease.

In the updated primary efficacy analysis 26,212 participants received two doses of Vaxzevria (N=17,662) or placebo (N=8,550). Participants randomised to Vaxzevria received (5×10^{10} vp per dose) administered via IM injection on Day 1 and Day 29 (-3 to +7 days). The median dose interval was 29 days and the majority of participants received the second dose ≥26 to ≤36 days (95.7% and 95.3%, respectively) after dose 1.

Baseline demographics were balanced across the Vaxzevria and the placebo groups. Of the participants who received Vaxzevria, 79.1% were aged 18 to 64 years and 20.9% were ≥65 years of age; 43.8% of subjects were female. Of those randomized, 79.3% were White, 7.9% were Black, 4.2% were Asian, 4.2% were American Indian or Alaska Native, 0.3% were Native Hawaiian or Other Pacific Islander, and 2.4% were of multiple races (1.7% were unknown or not reported). A total of 10,376 (58.8%) participants who received Vaxzevria versus 5,105 (59.7%) who received placebo had at least one pre-existing comorbidity. At the time of analysis the median follow-up time post-dose 2 was 61 days.

Comorbidity was defined as a chronic kidney disease, chronic obstructive pulmonary disease (COPD), lower immune health because of a solid organ transplant, history of obesity (BMI >30), serious heart conditions, sickle cell disease, type 1 and 2 diabetes, asthma, dementia, cerebrovascular diseases, cystic fibrosis, high blood pressure, liver disease, scarring in the lungs (pulmonary fibrosis), thalassemia, history of smoking.

Final determination of COVID-19 cases was made by an adjudication committee. A total of 203 participants had SARS-CoV-2 virologically confirmed COVID-19 occurring ≥15 days post second dose and met either the Category A or Category B criteria, and had no prior evidence of a previous SARS-CoV-2 infection.

Category A: One or more of the following:

- Pneumonia diagnosed by chest x-ray, or computed tomography scan
- Oxygen saturation of ≤94% on room air or requiring either new initiation or escalation in supplemental oxygen
- New or worsening dyspnoea/shortness of breath

Category B: Two or more of the following:

- Fever >100°F (>37.8°C) or feverishness
- New or worsening cough
- Myalgia/muscle pain
- Fatigue that interferes with activities of daily living
- Vomiting and/or diarrhoea (only one finding to be counted toward endpoint definition)
- Anosmia and/or ageusia (only one finding to be counted toward endpoint definition)

Vaxzevria significantly decreased the incidence of COVID-19 compared to placebo (see Table 4).

Table 4 – Vaxzevria efficacy against COVID-19[a]

	Vaxzevria		Placebo		Vaccine efficacy % (95% CI)
	N	Number of COVID-19 cases[b], n (%)	N	Number of COVID-19 cases[b], n (%)	
Updated primary efficacy analysis[c]					
Symptomatic illness	17,662	73 (0.4)	8,550	130 (1.5)	73.98 (65.34, 80.47)
Key secondary efficacy analyses					
Symptomatic illness regardless of evidence of prior COVID-19 infection	18,563	76 (0.4)	9,031	135 (1.5)	73.68 (65.13, 80.13)
Severe or critical symptomatic COVID-19[d]	17,662	0 (0.0)	8,550	8 (<0.1)	100.0 (71.62, NE)[e]
COVID-19 emergency department visits	17,662	1 (<0.1)	8,550	9 (0.1)	94.80 (58.98, 99.34)
Post-treatment response for SARS-CoV-2 nucleocapsid antibodies[f]	17,662	156 (0.9)	8,550	202 (2.4)	64.32 (56.05, 71.03)

N = Number of subjects included in each group; n = Number of subjects having a confirmed event; CI = Confidence Interval;
[a] Based on confirmed COVID-19 cases in subjects aged 18 years and over who were seronegative at baseline, who had received two doses and were on-study ≥15 days post second dose.
[b] Virologically confirmed SARS-CoV-2 using the Category A and B criteria.
[c] Updated primary analysis included all outstanding adjudicated events.
[d] Based on laboratory-confirmed COVID-19, plus any of the following: clinical signs at rest indicative of severe systemic illness (respiratory rate ≥30 breaths per minute, heart rate ≥125 beats per minute, oxygen saturation ≤93% on room air at sea level, or partial pressure of oxygen to fraction of inspired oxygen ratio <300 mmHg); or respiratory failure (defined as needing high-flow oxygen, non-invasive ventilation, mechanical ventilation, or extracorporeal membrane oxygenation), evidence of shock (systolic blood pressure <90 mmHg, diastolic blood pressure <60 mmHg or requiring vasopressors); or significant acute renal, hepatic, or neurological dysfunction; or admission to an intensive care unit, or death.
[e] 97.5% CI
[f] Negative at baseline to positive post treatment with study intervention.

In the pre-specified primary efficacy analysis, based on 190 adjudicated cases, there were 65 (0.4%) COVID-19 cases in participants receiving Vaxzevria (N=17,817) and 125 (1.5%) COVID-19 cases in participants receiving placebo (N=8,589), with a vaccine efficacy of 76.0%, (95% CI: 67.6, 82.2).

When cumulative incidence of viral shedding was examined with cases occurring ≥15 days post-dose 2, time to clearance of SARS-CoV-2 in saliva samples in Vaxzevria participants was notably shorter (11 vs 16 days).

Efficacy in subgroups

Participants with one or more comorbidities who received the Vaxzevria ≥15 days post-dose 2 had an efficacy of 75.24% (95% CI: 64.18, 82.88) and participants without comorbidities had a vaccine efficacy of 71.81% (95% CI: 55.5, 82.14).

In participants ≥65 years old who had received Vaxzevria (≥15 days post-dose 2 N=3,696), there were 5 (0.1%) cases of COVID-19 compared to 14 (0.8%) cases for placebo (N=1,812), corresponding to a vaccine efficacy of 83.5% (95% CI: 54.17, 94.06).

Updated efficacy analyses

In the 6-month follow-up analysis, updated efficacy analyses were performed with additional confirmed COVID-19 cases accrued during blinded placebo-controlled follow-up, with a median follow-up time post second dose of 78 days in participants who received Vaxzevria and 71 days in participants who received placebo. Overall vaccine efficacy against symptomatic COVID-19 illness was 66.98% (95% CI: 58.87, 73.50) with 141 (0.80%) cases of COVID-19 reported in participants who had received two doses of Vaxzevria (N=17,617) and 184 (2.16%) cases reported in participants who had received placebo (N=8,528). In participants ≥65 years old there were 6 (0.16%) cases reported in the Vaxzevria group (N=3,696) compared with 19 (1.05%) cases in the placebo group (N=1,816), corresponding to a vaccine efficacy of 86.35% (95% CI: 65.79, 94.55).

In individuals with or without prior evidence of SARS-CoV-2 infection, vaccine efficacy against symptomatic COVID-19 illness was 66.96% (95% CI: 58.94, 73.41) with 144 (0.78%) versus 189 (2.11%) cases of COVID-19 in the Vaxzevria (N=18,450) and placebo (N=8,960) groups, respectively.

Against severe or critical symptomatic COVID-19 illness, vaccine efficacy was 95.69% (95% CI: 66.33, 99.45) with 1 (0.01%) case reported in the Vaxzevria group (N=17,617) and 10 (0.12%) cases reported in the placebo group (N=8,528). There were 2 (0.01%) versus 15 (0.18%) cases of COVID-19-related emergency department visits in the Vaxzevria (N=17,617) and placebo (N=8,528) groups, respectively, corresponding to a vaccine efficacy of 94.17% (95% CI: 74.49, 98.67).

The prevention of SARS-CoV-2 infection (symptomatic and asymptomatic) was evaluated by the occurrence of SARS-CoV-2 nucleocapsid antibodies ≥15 days post second dose. In the 6-month follow-up analysis, there were 295 (1.67%) SARS-CoV-2 infections in the Vaxzevria group (N=17,617) and 323 (3.79%) infections in the placebo group (N=8,528), corresponding to a vaccine efficacy of 61.01% (95% CI: 54.35; 66.70).

Immunogenicity

Primary analysis of pooled data from COV001, COV002, COV003, and COV005

Following vaccination with Vaxzevria, in participants who were seronegative at baseline, seroconversion (as measured by a ≥4-fold increase from baseline in S-binding antibodies) was

demonstrated in ≥98% of participants at 28 days after the first dose and >99% at 28 days after the second. Higher S-binding antibodies were observed with increasing dose interval (Table 5).

Generally similar trends were observed between analyses of neutralising antibodies and S-binding antibodies. An immunological correlate of protection has not been established; therefore the level of immune response that provides protection against COVID-19 is unknown.

Table 5 – SARS-CoV-2 S-binding antibody response to Vaxzevria (SDSD)[a]

Population	Baseline[b]	28 days after dose 1	28 days after dose 2
	GMT (95% CI)	GMT (95% CI)	GMT (95% CI)
Overall	(N=1,538) 57.1 (53.8; 60.6)	(N=1,466) 8,358.0 (7,879.2; 8,866.0)	(N=1,511) 30,599.8 (29,137.1; 32,135.9)
Dose Interval			
<6 weeks	(N=578) 61.4 (55.3; 68.0)	(N=578) 8,184.5 (7,423.9; 9023.1)	(N=564) 21,384.2 (19,750.7; 23,152.8)
6-8 weeks	(N=339) 56.1 (49.6; 63.3)	(N=290) 9,103.9 (8,063.1; 10,279.1)	(N=331) 28,764.8 (25,990.8; 31,834.9)
9-11 weeks	(N=331) 53.6 (47.5; 60.4)	(N=309) 8,120.9 (7,100.2; 9,288.4)	(N=327) 37,596.1 (34,494.2; 40,976.8)
≥12 weeks	(N=290) 54.3 (47.6; 61.9)	(N=289) 8,249.7 (7,254.5; 9,381.4)	(N=289) 52,360.9 (47,135.2; 58,165.9)

N = Number of subjects included in each group; GMT = Geometric mean titre; CI = Confidence interval; S = Spike

[a] Immune response evaluated using a multiplex immunoassay.

[b] Individuals were seronegative at baseline.

The immune response observed in participants with one or more comorbidities was consistent with the overall population.

High seroconversion rates were observed in older adults (≥65 years) after the first SD (97.3% [N=149, 95% CI: 93.3, 99.3]) and the second SD (100.0% [N=156, 95% CI: 97.7, Not Evaluable]). The majority of older adults had a dose interval of <6 weeks. The increase in S-binding antibodies for older adults with a dose interval of <6 weeks (28 days after second SD: GMT=18,759.6 [N=126, 95% CI: 15,764.8, 22,323.3] was comparable to all participants who received their second dose after an interval of <6 weeks (see Table 4).

In participants with serological evidence of prior SARS-CoV-2 infection at baseline (GMT=10,979.1 [N=36; 95% CI: 6,452.7, 18,680.5]), S-antibody titres peaked 28 days after dose 1 (GMT=139,010.4 [N=35; 95% CI: 95,429.0, 202,495.1]) but did not increase further after the second dose.

Spike-specific T cell responses as measured by IFN-ɣ enzyme-linked immunospot (ELISpot) assay are induced after a first dose of Vaxzevria. Geometric mean responses are generally similar across age strata and regardless of presence of comorbidity. These do not rise further after a second dose. Th1 cytokines are induced by Vaxzevria with cells expressing IFN-γ, IL-2, and/or TNFα which are generally similar between age categories.

Study D7220C00001, immunogenicity of a booster dose following primary vaccination with Vaxzevria or an mRNA COVID-19 vaccine

D7220C00001 is a phase II/III partially double-blind, active-controlled study in which 367 participants ≥18 years old previously vaccinated with Vaxzevria and 322 participants ≥18 years old previously vaccinated with an mRNA vaccine received a single booster dose of Vaxzevria at least 90 days after receiving the second dose of their primary vaccination course. Immunogenicity was assessed in 342 participants previously vaccinated with Vaxzevria and 294 participants previously vaccinated with an mRNA vaccine, all of whom were seronegative at baseline. Participants previously vaccinated with Vaxzevria were older than participants previously vaccinated with an mRNA vaccine with 45.9% and 26.9% being ≥65 years of age in the two groups, respectively. Approximately 47% of the participants had at least one pre-existing comorbidity (defined as BMI ≥30 kg/m^2, significant cardiovascular disease, chronic lung disease, or diabetes).

The effectiveness of Vaxzevria administered as a single booster dose in participants previously vaccinated with Vaxzevria was demonstrated by evaluating non-inferiority of the immune response of neutralising antibody titres against the ancestral strain compared to that elicited by a 2-dose primary vaccination course in a subset of matched participants in study D8110C00001.

Non-inferiority for GMT ratio was demonstrated when comparing neutralising antibody titres 28 days after the booster dose to titres 28 days after the primary vaccination course (see Table 6).

Table 6: Neutralising antibody titres against the ancestral strain following booster dosing with Vaxzevria in participants previously vaccinated with Vaxzevria

	28 days after primary vaccination course with Vaxzevria[a]	**28 days after booster dose**	**GMT ratio[b]**	**Met non-inferiority objective (Y/N)**
n	508	327	327/508	
GMT[c]	242.80	248.89	1.03	Y[d]
(95% CI)	(224.82, 262.23)	(229.53, 269.89)	(0.92, 1.15)	

n = Number of subjects in analysis; GMT = Geometric mean neutralising antibody titre; CI = Confidence interval; GMT Ratio = Geometric mean titre ratio

[a.] Based on analyses from a matched cohort of participants in study D8110C00001.

[b.] GMT 28 days after booster dose to GMT 28 days after the second dose of the primary vaccination course.

[c.] Reported results have been adjusted using an ANCOVA model including fixed-effect terms for visit window, time since previous vaccination (for booster), baseline comorbidities, sex, age and a random subject effect.
[d.] Non-inferiority was demonstrated if the lower limit of the 2-sided 95% CI of the GMT ratio of the comparator group and the reference group is >0.67.

Vaxzevria was also shown to be effective in eliciting antibody responses in participants who had previously received primary vaccination with an mRNA vaccine. In these participants, a single booster dose of Vaxzevria resulted in increased humoral responses, with geometric mean fold rise (GMFR) of 3.77 (95% CI: 3.26, 4.37) in neutralising antibody titres against the ancestral strain from pre-booster to 28 days after the booster dose.

Booster dosing with Vaxzevria increased humoral responses also in participants with serological evidence of prior SARS-CoV-2 infection at baseline, and against all analysed variants, i.e. Alpha, Beta, Gamma, Delta and Omicron.

COV001 Immunogenicity of a booster dose (third dose) following primary vaccination with Vaxzevria

COV001 included 90 participants aged 18-55 years who received a booster dose with Vaxzevria. Antibody responses were assessed in 75 participants who had received their two doses of the primary vaccination course within an 8-16 week interval, followed by a booster dose administered between 28-38 weeks after the second dose. Spike IgG antibody titres after the booster dose were significantly higher than after the second dose (median total IgG titre was 1792 EUs [IQR 899–4634] at 28 days after the second dose vs 3746 EUs [2047–6420] 28 days after the booster dose; pairwise comparison in 73 participants for whom samples were available using Wilcoxon signed rank test; p=0.0043).

RHH-001 immunogenicity of a booster dose (third dose) following primary vaccination with an inactivated whole-virion COVID-19 vaccine

The externally sponsored RHH-001 was a phase IV single-blind, randomised study, in which antibodies were assessed in 296 Brazilian participants >18 years old who received a booster dose of Vaxzevria 5-7 months after receiving the second dose of an inactivated whole-virion COVID-19 vaccine.

At 28 days after receipt of a booster dose of Vaxzevria there was a substantial increase from baseline in spike IgG antibody titres (Day 28 GMT 335213 [95% CI: 295598, 380136], baseline GMT 3745 [95% CI: 3252, 4313]). The GMFR from baseline to Day 28 was 90 (95%, CI: 77, 104). Participants who had received a booster dose of Vaxzevria had spike IgG antibody titres at Day 28 that were statistically superior to those induced by a booster dose of the inactivated whole-virion COVID-19 vaccine. Geometric mean ratio (GMR) for Vaxzevria booster dose versus the inactivated COVID-19 vaccine booster dose was 7.0 (95% CI 6.1, 8.1, p<0,0001). Booster dosing with Vaxzevria also increased neutralisation antibody titres against the Delta and Omicron variants.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Toxicity and local tolerance studies

In a repeat-dose toxicity study in mice, IM administration of Vaxzevria was well tolerated. Non-adverse, mixed and/or mononuclear cell inflammation was observed in the subcutaneous tissues and skeletal muscle of the administration sites and adjacent sciatic nerve consistent with the anticipated findings after IM injection of vaccines. There were no findings in the administration sites or sciatic nerves at the end of the recovery period, indicating complete recovery of the Vaxzevria-related inflammation.

Mutagenicity and carcinogenicity

Vaxzevria is a vaccine, as such, genotoxicity (mutagenicity) and carcinogenicity studies have not been conducted.

Reproductive toxicity

Biodistribution studies conducted in mice did not show measurable distribution of Vaxzevria to the gonads (testes, ovaries) following IM injection.

In a reproductive and development toxicity study, Vaxzevria did not induce maternal or developmental toxicity following maternal exposure during the pre-mating, gestation or lactating periods. In this study, vaccine elicited detectable anti-SARS-CoV-2 S-glycoprotein maternal antibodies were transferred to the foetuses and pups, indicating placental and lactational transfer, respectively.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

L-Histidine
L-Histidine hydrochloride monohydrate
Magnesium chloride hexahydrate
Polysorbate 80
Ethanol
Sucrose
Sodium chloride
Disodium edetate dihydrate (EDTA)
Water for injection

(The names of inactive ingredients may vary according to geographical region)

6.2 Incompatibilities

In the absence of compatibility studies, this vaccine must not be mixed with other medicinal products.

6.3 Shelf-life

Unopened multidose vial

Note to local Marketing Company: Please include the shelf-life specified in Module 3.2.P.8.1 Stability and Conclusions of your local dossier.

The following information is intended to guide healthcare professionals only in case of an unforeseen temporary temperature excursion. It is not a recommended storage or shipping condition.

The shelf-life of unopened vials includes the following unforeseen excursions from refrigerated storage (2°C – 8°C) for a single period of:

- 12 hours up to 30°C (86°F)
- 72 hours down to -3°C (27°F)

Unopened vials must always be returned to refrigerated storage (2 to 8ºC [36 to 46°F]) following an unforeseen temperature excursion.

The occurrence of an unforeseen temperature excursion for unopened vials does not impact how the vials should be stored after first opening (first vial puncture).

Opened multidose vial

After first opening, chemical and physical in-use stability has been demonstrated from the time of vial puncture to administration for no more than:

- 6 hours at room temperature, up to 30ºC (86°F), or
- 48 hours in a refrigerator (2 to 8ºC [36 to 46°F]).

The vial can be re-refrigerated, but the cumulative storage time at room temperature must not exceed 6 hours, and the total cumulative storage time must not exceed 48 hours.

6.4 Special precautions for storage

Unopened multidose vial

Store in a refrigerator (2 to 8ºC [36 to 46°F]).

Do not freeze.

Store in outer carton in order to protect from light.

Opened multidose vial

For storage conditions after first opening of the medicinal product, see section 6.3.

6.5 Nature and contents of container

Multidose vial

- 5 ml of solution in a 10-dose vial (clear type I glass) with stopper (elastomeric with aluminium overseal). Packs of 10 vials.

- 4 ml of solution in an 8-dose vial (clear type I glass) with stopper (elastomeric with aluminium overseal). Packs of 10 vials.

Not all pack sizes may be marketed.

6.6 Instructions for use, handling and disposal

Note to local Marketing Company:

Include the wording "Do not shake the vial" with the administration instructions **if** your printed vial labels and outer cartons have been printed in advance and state "Do not shake".

If vial label and carton have not already been printed, there is no need to include the statement "Do not shake" in local PI or on printed vial labels and outer cartons.

If it is a requirement in your market, you may elevate the sentence related to traceability up to a more prominent section of the label, for example 4.4 Warnings & Precautions.

Administration

Vaxzevria is a colourless to slightly brown, clear to slightly opaque solution. The vaccine should be inspected visually for particulate matter and discolouration prior to administration. Discard the vial if the solution is discoloured or visible particles are observed.

Each vaccine dose of 0.5 ml is withdrawn into a syringe for injection to be administered intramuscularly. Use a separate sterile needle and syringe for each individual.

Each vial contains at least the number of doses stated. It is normal for liquid to remain in the vial after withdrawing the final dose. When low dead volume syringes and/or needles are used, the amount remaining in the vial may be sufficient for an additional dose. Care should be taken to ensure a full 0.5 ml dose is administered. Where a full 0.5 ml dose cannot be extracted, the remaining volume should be discarded. Do not pool excess vaccine from multiple vials.

The vaccine does not contain any preservative. After first opening, use the vial within:

- 6 hours when stored at room temperature (up to 30ºC [86°F]), or
- 48 hours when stored in a refrigerator (2 to 8ºC [36 to 46°F]).

The vial can be re-refrigerated, but the cumulative storage time at room temperature must not exceed 6 hours, and the total cumulative storage time must not exceed 48 hours. After this time, the vial must be discarded.

To facilitate the traceability of the vaccine, the name and the batch number of the administered product should be clearly recorded for each recipient.

Disposal

Vaxzevria contains genetically modified organisms (GMOs). Any unused vaccine or waste material should be disposed of in accordance with local requirements. Spills should be disinfected with an appropriate antiviral disinfectant.

PBRER Appendix 2 Summary Tabulations from Clinical Trials and Marketed Experience	
Medicinal Product	VAXZEVRIA (ChAdOx1-S [recombinant])
Period covered	29 June 2022 to 28 December 2022
Date	17 February 2023

Appendix 2

Cumulative Summary Tabulation of Serious Adverse Events from Clinical Trials

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Interval/Cumulative Summary Tabulations of Serious and Non-Serious Adverse Reactions from Marketed Experience

1 GENERAL CONSIDERATIONS

The summary tabulations presented here contain the case reports that were received and evaluated by AstraZeneca and entered into the AstraZeneca global safety database before the end of the PBRER reporting period. The interval counts presented in Table 2 represent new case reports or previously reported case reports with significant new or changed information that were received and processed during the PBRER reporting period.

The numbers of events are presented at the Medical Dictionary for Regulatory Activities (MedDRA), Preferred Term (PT) and System Organ Class (SOC) level.

Within a given case report, where 2 events code to the same MedDRA PT, they have been counted as 1 event at the PT level in the tabulations (except in Table 2 if seriousness differs for each event).

2 TABLE 1 - CUMULATIVE SUMMARY TABULATION OF SERIOUS ADVERSE EVENTS FROM CLINICAL TRIALS

Table 1 includes case reports containing Serious Adverse Events (SAEs) from AstraZeneca-sponsored interventional clinical trials from the Development International Birth Date (DIBD) to the data lock point.

Cumulative counts of SAEs are presented under the following treatment column headings: Investigational product (AZD1222), Blinded, Study procedure, Active comparator, and Placebo / No study product.

Each SAE within a case included in the tabulation is assigned to one of the treatment columns, based on the primary study treatment associated with the SAE as judged by AstraZeneca. The Active comparator column includes SAEs associated with study treatment(s) not otherwise categorised in the tabulation.

Note: When there is at least one blinded study, where end of study unblinding has not yet taken place:

- Case reports containing a Suspected Unexpected Serious Adverse Reaction (SUSAR) are unblinded by AstraZeneca, and the event counts are presented in the table under the appropriate unblinded column heading.
- Case reports containing only expected Suspected Serious Adverse Reactions (SSARs) remain blinded, and the event counts are presented under the Blinded column heading.

3 TABLE 2 - NUMBERS OF ADVERSE DRUG REACTIONS BY TERM FROM POST-MARKETING SOURCES

Table 2 presents numbers of adverse reactions from spontaneous notifications and from non-interventional post-marketing studies for AZD1222 from the International Birth Date (IBD) to the data lock point. This includes cases reported on AstraZeneca brand(s) and case reports on the non-proprietary name of the product (including reports on brands maintained by any licence partners, if applicable).

Spontaneous data include case reports from healthcare professionals, consumers, scientific literature, and worldwide regulatory authorities. This is irrespective of the causality assessment made by the reporter and so will include those events for which the reporter did not consider that there is a reasonable possibility of causal relationship with the AstraZeneca drug. Interval and cumulative adverse reaction counts are presented for serious and non-serious reactions.

Note: Any adverse events from Spontaneous sources where reporter did not consider that there was a reasonable possibility of a causal relationship with the AstraZeneca drug are summarised in Table 2a. The data presented in this table is a subset of the spontaneous data presented in Table 2 and is included for transparency purposes.

The data presented for non-interventional post-marketing studies also include reports from other non-interventional solicited sources. Case reports are included where either the reporter or AstraZeneca has considered there was a reasonable possibility of a causal relationship with the medicinal product, or a causality assessment is unavailable from both the reporter and AstraZeneca. Interval and cumulative counts are presented for serious adverse reactions.

Table 1 - Cumulative Summary Tabulations of Serious Adverse Events from Clinical Studies

System Organ Class Preferred Term	Total Up to 28-DEC-2022 Investigational Product	Blinded	Study Procedure	Active Comparator	Placebo / No Study Product
Infections and infestations	**97**	**417**	**0**	**0**	**8**
Abdominal abscess	0	1	0	0	0
Abdominal wall abscess	0	1	0	0	0
Abortion infected	0	0	0	0	1
Abscess	0	1	0	0	0
Abscess limb	0	4	0	0	0
Anal abscess	1	1	0	0	0
Appendicitis	14	45	0	0	1
Appendicitis perforated	1	6	0	0	0
Arthritis bacterial	1	0	0	0	0
Asymptomatic COVID-19	0	1	0	0	0
Asymptomatic bacteriuria	2	0	0	0	0
Atypical pneumonia	1	0	0	0	0
Bacteraemia	0	2	0	0	0
Bacterial infection	0	1	0	0	0
Bacterial pyelonephritis	0	1	0	0	0
Balanitis candida	0	1	0	0	0
Bartholinitis	1	0	0	0	0
Biliary sepsis	1	0	0	0	0
Breast abscess	1	0	0	0	0
Breast cellulitis	1	0	0	0	0
COVID-19	21	58	0	0	1

Table 1 - Cumulative Summary Tabulations of Serious Adverse Events from Clinical Studies

System Organ Class Preferred Term	Total Up to 28-DEC-2022 Investigational Product	Blinded	Study Procedure	Active Comparator	Placebo / No Study Product
COVID-19 pneumonia	5	47	0	0	0
Campylobacter colitis	1	1	0	0	0
Cellulitis	1	16	0	0	0
Cholecystitis infective	0	2	0	0	0
Chronic sinusitis	0	1	0	0	0
Clostridium difficile colitis	0	3	0	0	0
Clostridium difficile infection	0	1	0	0	0
Coccidioidomycosis	0	2	0	0	0
Colonic abscess	0	2	0	0	0
Complicated appendicitis	0	2	0	0	0
Coronavirus infection	1	1	0	0	0
Cystitis	0	1	0	0	0
Dengue fever	1	0	0	0	0
Device related infection	0	5	0	0	0
Device related sepsis	1	2	0	0	0
Diverticulitis	5	8	0	0	0
Diverticulitis intestinal perforated	0	3	0	0	0
Ear lobe infection	0	1	0	0	0
Elsberg syndrome	0	1	0	0	0
Enterobacter sepsis	0	1	0	0	0
Enterococcal bacteraemia	0	2	0	0	0

Table 1 - Cumulative Summary Tabulations of Serious Adverse Events from Clinical Studies

System Organ Class Preferred Term	Total Up to 28-DEC-2022 Investigational Product	Blinded	Study Procedure	Active Comparator	Placebo / No Study Product
Enterococcal sepsis	0	1	0	0	0
Epididymitis	0	1	0	0	0
Escherichia urinary tract infection	0	2	0	0	0
Extradural abscess	0	3	0	0	0
Eye infection syphilitic	1	0	0	0	0
Focal peritonitis	0	1	0	0	0
Gastroenteritis	1	4	0	0	0
Gastroenteritis shigella	0	1	0	0	0
Gastroenteritis viral	0	1	0	0	0
Gastrointestinal infection	0	1	0	0	0
Giardiasis	0	1	0	0	0
HIV infection	1	0	0	0	0
Histoplasmosis	1	0	0	0	0
Infected skin ulcer	0	1	0	0	0
Infectious mononucleosis	1	0	0	0	0
Influenza	0	1	0	0	0
Intervertebral discitis	0	3	0	0	0
Kidney infection	0	2	0	0	0
Labyrinthitis	0	2	0	0	0
Large intestine infection	0	1	0	0	0
Liver abscess	1	0	0	0	0

Table 1 - Cumulative Summary Tabulations of Serious Adverse Events from Clinical Studies

System Organ Class Preferred Term	Total Up to 28-DEC-2022 Investigational Product	Blinded	Study Procedure	Active Comparator	Placebo / No Study Product
Localised infection	0	1	0	0	0
Malaria	0	2	0	0	0
Monkeypox	0	1	0	0	0
Orchitis	1	1	0	0	0
Oropharyngeal candidiasis	0	1	0	0	0
Osteomyelitis	0	6	0	0	0
Osteomyelitis bacterial	0	1	0	0	0
Otitis externa	2	1	0	0	0
Parainfluenzae virus infection	0	1	0	0	0
Pelvic abscess	0	1	0	0	0
Periorbital cellulitis	0	1	0	0	0
Perirectal abscess	0	2	0	0	0
Peritonitis	0	2	0	0	0
Peritonsillar abscess	1	1	0	0	0
Pharyngitis	0	1	0	0	0
Pharyngolaryngeal abscess	1	0	0	0	0
Pharyngotonsillitis	0	1	0	0	0
Pilonidal disease	1	0	0	0	0
Pneumonia	2	48	0	0	0
Pneumonia aspiration	0	3	0	0	0
Pneumonia bacterial	1	5	0	0	0

Table 1 - Cumulative Summary Tabulations of Serious Adverse Events from Clinical Studies

System Organ Class Preferred Term	Total Up to 28-DEC-2022 Investigational Product	Blinded	Study Procedure	Active Comparator	Placebo / No Study Product
Pneumonia klebsiella	0	1	0	0	0
Pneumonia legionella	0	2	0	0	0
Pneumonia streptococcal	1	2	0	0	0
Post-acute COVID-19 syndrome	1	2	0	0	0
Postoperative abscess	0	1	0	0	0
Postoperative wound infection	0	3	0	0	0
Psoas abscess	0	1	0	0	0
Pulmonary tuberculosis	2	0	0	0	0
Pyelitis	0	0	0	0	1
Pyelonephritis	3	6	0	0	0
Pyelonephritis acute	2	1	0	0	0
Renal cyst infection	0	1	0	0	0
Respiratory syncytial virus infection	0	1	0	0	0
Respiratory tract infection	1	0	0	0	0
SARS-CoV-2 sepsis	0	1	0	0	0
Salmonellosis	0	1	0	0	0
Scrotal cellulitis	0	1	0	0	0
Sepsis	1	14	0	0	0
Sepsis neonatal	1	0	0	0	0
Sepsis syndrome	0	3	0	0	0
Septic shock	1	6	0	0	0

Table 1 - Cumulative Summary Tabulations of Serious Adverse Events from Clinical Studies

System Organ Class Preferred Term	Total Up to 28-DEC-2022 Investigational Product	Blinded	Study Procedure	Active Comparator	Placebo / No Study Product
Sinusitis bacterial	0	1	0	0	0
Skin infection	0	1	0	0	0
Spontaneous bacterial peritonitis	0	0	0	0	1
Staphylococcal bacteraemia	1	3	0	0	0
Staphylococcal infection	0	6	0	0	0
Streptococcal bacteraemia	0	1	0	0	0
Stump appendicitis	0	1	0	0	0
Subcutaneous abscess	0	0	0	0	1
Tonsillitis	0	1	0	0	0
Tooth abscess	1	0	0	0	0
Toxic shock syndrome staphylococcal	0	1	0	0	0
Tubo-ovarian abscess	0	2	0	0	0
Urinary tract infection	4	13	0	0	0
Urinary tract infection bacterial	0	1	0	0	0
Urinary tract infection enterococcal	0	1	0	0	0
Urosepsis	3	3	0	0	0
Vascular device infection	0	1	0	0	0
Vestibular neuronitis	0	0	0	0	1
Viral infection	0	1	0	0	1
Viral pericarditis	0	1	0	0	0
West Nile viral infection	0	1	0	0	0

Table 1 - Cumulative Summary Tabulations of Serious Adverse Events from Clinical Studies

System Organ Class Preferred Term	Total Up to 28-DEC-2022 Investigational Product	Blinded	Study Procedure	Active Comparator	Placebo / No Study Product
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**43**	**332**	**0**	**0**	**2**
Acral lentiginous melanoma	0	2	0	0	0
Acute monocytic leukaemia	0	1	0	0	0
Acute myeloid leukaemia	0	3	0	0	0
Adenocarcinoma of colon	1	7	0	0	0
Adenocarcinoma pancreas	0	1	0	0	0
Angiosarcoma	0	1	0	0	0
Astrocytoma	0	3	0	0	0
B-cell lymphoma	0	2	0	0	0
Basal cell carcinoma	0	4	0	0	0
Benign neoplasm of bladder	0	1	0	0	0
Benign soft tissue neoplasm	1	0	0	0	0
Bladder cancer	1	4	0	0	0
Bladder neoplasm	0	1	0	0	0
Bladder transitional cell carcinoma	1	2	0	0	0
Borderline mucinous tumour of ovary	0	1	0	0	0
Brain neoplasm	0	1	0	0	0
Breast cancer	8	16	0	0	0
Breast cancer female	1	4	0	0	0
Breast cancer metastatic	1	3	0	0	0
Breast cancer stage 1	0	1	0	0	0

Table 1 - Cumulative Summary Tabulations of Serious Adverse Events from Clinical Studies

System Organ Class Preferred Term	Total Up to 28-DEC-2022 Investigational Product	Blinded	Study Procedure	Active Comparator	Placebo / No Study Product
Breast cancer stage II	0	1	0	0	0
Breast neoplasm	0	1	0	0	0
Central nervous system neoplasm	1	0	0	0	0
Cervix carcinoma	1	1	0	0	0
Cervix carcinoma stage IV	0	1	0	0	0
Cholangiocarcinoma	0	3	0	0	1
Choroid melanoma	0	1	0	0	0
Chronic lymphocytic leukaemia	0	2	0	0	0
Clear cell renal cell carcinoma	0	1	0	0	0
Colon cancer	0	4	0	0	0
Colon cancer metastatic	0	1	0	0	0
Colon cancer stage III	0	2	0	0	0
Colon cancer stage IV	0	3	0	0	0
Colorectal adenoma	0	4	0	0	0
Colorectal cancer	1	2	0	0	0
Colorectal cancer metastatic	0	1	0	0	0
Diffuse large B-cell lymphoma	0	1	0	0	0
Endometrial cancer	0	2	0	0	0
Ependymoma	0	1	0	0	0
Essential thrombocythaemia	1	0	0	0	0
Follicular lymphoma	1	1	0	0	0

Table 1 - Cumulative Summary Tabulations of Serious Adverse Events from Clinical Studies

System Organ Class Preferred Term	Total Up to 28-DEC-2022 Investigational Product	Blinded	Study Procedure	Active Comparator	Placebo / No Study Product
Follicular thyroid cancer	0	2	0	0	0
Gastric cancer	1	0	0	0	0
Gastrointestinal carcinoma	1	0	0	0	0
Gastrointestinal tract adenoma	0	1	0	0	0
Glioblastoma	0	2	0	0	0
Glioblastoma multiforme	0	1	0	0	0
Glioma	0	1	0	0	0
Haemangioma of bone	0	1	0	0	0
Hormone receptor positive breast cancer	0	1	0	0	0
Huerthle cell carcinoma	0	1	0	0	0
Intraductal papillary breast neoplasm	0	1	0	0	0
Intraductal proliferative breast lesion	0	9	0	0	0
Invasive breast carcinoma	0	1	0	0	0
Invasive ductal breast carcinoma	1	17	0	0	0
Invasive lobular breast carcinoma	1	3	0	0	0
Laryngeal squamous cell carcinoma	0	1	0	0	0
Lentigo maligna	0	1	0	0	0
Lip squamous cell carcinoma	0	1	0	0	0
Lipoma	0	1	0	0	0
Lung adenocarcinoma	0	3	0	0	1
Lung adenocarcinoma stage III	0	1	0	0	0

Table 1 - Cumulative Summary Tabulations of Serious Adverse Events from Clinical Studies

System Organ Class Preferred Term	Total Up to 28-DEC-2022 Investigational Product	Blinded	Study Procedure	Active Comparator	Placebo / No Study Product
Lung cancer metastatic	0	1	0	0	0
Lung carcinoma cell type unspecified stage IV	0	1	0	0	0
Lung neoplasm malignant	0	2	0	0	0
Lymphoma	0	1	0	0	0
Lymphoplasmacytoid lymphoma/immunocytoma	1	0	0	0	0
Malignant anorectal neoplasm	0	1	0	0	0
Malignant melanoma	1	12	0	0	0
Malignant neoplasm of ampulla of Vater	0	1	0	0	0
Malignant neoplasm of pleura	0	1	0	0	0
Malignant neoplasm of thymus	0	1	0	0	0
Malignant splenic neoplasm	0	1	0	0	0
Mantle cell lymphoma	0	1	0	0	0
Meningioma	0	2	0	0	0
Meningioma benign	0	1	0	0	0
Mesothelioma	2	0	0	0	0
Metastases to bone	0	1	0	0	0
Metastases to liver	0	1	0	0	0
Metastases to peritoneum	0	1	0	0	0
Metastatic malignant melanoma	1	0	0	0	0
Metastatic neoplasm	1	0	0	0	0
Metastatic squamous cell carcinoma	0	1	0	0	0

Table 1 - Cumulative Summary Tabulations of Serious Adverse Events from Clinical Studies

System Organ Class Preferred Term	Total Up to 28-DEC-2022 Investigational Product	Blinded	Study Procedure	Active Comparator	Placebo / No Study Product
Mucoepidermoid carcinoma	0	1	0	0	0
Myelodysplastic syndrome	0	2	0	0	0
Neoplasm malignant	0	1	0	0	0
Neuroendocrine carcinoma	0	2	0	0	0
Neuroendocrine carcinoma of the skin	0	1	0	0	0
Neuroendocrine tumour	0	1	0	0	0
Non-Hodgkin's lymphoma	0	6	0	0	0
Non-Hodgkin's lymphoma stage III	0	1	0	0	0
Non-small cell lung cancer	0	1	0	0	0
Oesophageal adenocarcinoma	0	1	0	0	0
Oesophageal adenocarcinoma stage III	0	1	0	0	0
Oesophageal cancer metastatic	0	1	0	0	0
Oesophageal carcinoma	0	1	0	0	0
Oesophageal squamous cell carcinoma stage II	0	1	0	0	0
Oligodendroglioma	0	1	0	0	0
Ovarian cancer	0	1	0	0	0
Ovarian cancer metastatic	0	1	0	0	0
Ovarian cancer recurrent	0	1	0	0	0
Ovarian cancer stage III	0	3	0	0	0
Ovarian epithelial cancer	1	1	0	0	0
Pancreatic carcinoma	1	2	0	0	0

Table 1 - Cumulative Summary Tabulations of Serious Adverse Events from Clinical Studies

System Organ Class Preferred Term	Total Up to 28-DEC-2022 Investigational Product	Blinded	Study Procedure	Active Comparator	Placebo / No Study Product
Pancreatic carcinoma metastatic	0	2	0	0	0
Pancreatic carcinoma stage IV	0	1	0	0	0
Pancreatic neuroendocrine tumour	1	0	0	0	0
Papillary thyroid cancer	1	7	0	0	0
Pituitary tumour benign	0	2	0	0	0
Plasma cell myeloma	0	4	0	0	0
Plasmacytoma	0	2	0	0	0
Pleomorphic adenoma	1	0	0	0	0
Polycythaemia vera	0	1	0	0	0
Prostate cancer	2	56	0	0	0
Prostate cancer metastatic	0	4	0	0	0
Prostate cancer recurrent	0	2	0	0	0
Prostate cancer stage I	0	2	0	0	0
Prostate cancer stage II	1	2	0	0	0
Prostate cancer stage III	0	3	0	0	0
Rectal adenocarcinoma	0	4	0	0	0
Rectal cancer	0	2	0	0	0
Renal cancer	0	1	0	0	0
Renal cell carcinoma	1	3	0	0	0
Renal cell carcinoma stage IV	0	1	0	0	0
Renal neoplasm	1	0	0	0	0

Table 1 - Cumulative Summary Tabulations of Serious Adverse Events from Clinical Studies

System Organ Class Preferred Term	Total Up to 28-DEC-2022 Investigational Product	Blinded	Study Procedure	Active Comparator	Placebo / No Study Product
Retinal melanocytoma	0	1	0	0	0
Sarcoma	1	1	0	0	0
Sarcoma uterus	0	1	0	0	0
Seminoma	0	1	0	0	0
Signet-ring cell carcinoma	0	1	0	0	0
Sinonasal papilloma	0	1	0	0	0
Small cell lung cancer	0	1	0	0	0
Small intestine carcinoma	0	1	0	0	0
Squamous cell carcinoma	0	3	0	0	0
Squamous cell carcinoma of skin	1	6	0	0	0
Squamous cell carcinoma of the oral cavity	0	2	0	0	0
T-cell lymphoma	0	1	0	0	0
Testicular seminoma (pure)	0	1	0	0	0
Testis cancer	0	1	0	0	0
Throat cancer	0	1	0	0	0
Tonsil cancer	0	1	0	0	0
Transitional cell carcinoma	1	5	0	0	0
Triple negative breast cancer	0	1	0	0	0
Tumour associated fever	0	1	0	0	0
Uterine leiomyoma	1	1	0	0	0
Blood and lymphatic system disorders	**9**	**19**	**0**	**0**	**2**

Table 1 - Cumulative Summary Tabulations of Serious Adverse Events from Clinical Studies

System Organ Class Preferred Term	Total Up to 28-DEC-2022 Investigational Product	Blinded	Study Procedure	Active Comparator	Placebo / No Study Product
Anaemia	1	5	0	0	1
Anaemia megaloblastic	0	1	0	0	0
Antiphospholipid syndrome	2	0	0	0	0
Blood loss anaemia	0	5	0	0	0
Eosinophilia	2	0	0	0	0
Hypercoagulation	0	1	0	0	0
Iron deficiency anaemia	1	1	0	0	0
Lymphadenopathy	1	1	0	0	1
Neutropenia	0	1	0	0	0
Splenic cyst	0	1	0	0	0
Splenic haematoma	0	1	0	0	0
Splenic infarction	1	1	0	0	0
Thrombocytopenia	1	1	0	0	0
Immune system disorders	**1**	**11**	**0**	**0**	**0**
Anaphylactic reaction	1	8	0	0	0
Hypersensitivity	0	2	0	0	0
Sarcoidosis	0	1	0	0	0
Endocrine disorders	**0**	**9**	**0**	**0**	**0**
Goitre	0	2	0	0	0
Hyperparathyroidism	0	1	0	0	0
Hypothyroidism	0	1	0	0	0
Secondary adrenocortical insufficiency	0	1	0	0	0

Table 1 - Cumulative Summary Tabulations of Serious Adverse Events from Clinical Studies

System Organ Class Preferred Term	Total Up to 28-DEC-2022 Investigational Product	Blinded	Study Procedure	Active Comparator	Placebo / No Study Product
Thyroid mass	0	1	0	0	0
Thyroiditis subacute	0	1	0	0	0
Thyrotoxic crisis	0	2	0	0	0
Metabolism and nutrition disorders	**1**	**47**	**0**	**0**	**1**
Decreased appetite	0	1	0	0	0
Dehydration	0	3	0	0	1
Diabetes mellitus	0	1	0	0	0
Diabetic ketoacidosis	0	11	0	0	0
Euglycaemic diabetic ketoacidosis	1	0	0	0	0
Failure to thrive	0	2	0	0	0
Gout	0	1	0	0	0
Hypercalcaemia	0	4	0	0	0
Hyperglycaemia	0	3	0	0	0
Hyperglycaemic hyperosmolar nonketotic syndrome	0	1	0	0	0
Hyperkalaemia	0	1	0	0	0
Hypoglycaemia	0	1	0	0	0
Hypokalaemia	0	4	0	0	0
Hypomagnesaemia	0	1	0	0	0
Hyponatraemia	0	7	0	0	0
Hypovolaemia	0	1	0	0	0
Obesity	0	1	0	0	0

Table 1 - Cumulative Summary Tabulations of Serious Adverse Events from Clinical Studies

System Organ Class Preferred Term	Total Up to 28-DEC-2022 Investigational Product	Blinded	Study Procedure	Active Comparator	Placebo / No Study Product
Type 2 diabetes mellitus	0	4	0	0	0
Psychiatric disorders	**8**	**63**	**0**	**0**	**2**
Acute psychosis	0	2	0	0	0
Adjustment disorder	1	0	0	0	0
Adjustment disorder with depressed mood	0	1	0	0	0
Affective disorder	0	1	0	0	0
Alcohol withdrawal syndrome	0	1	0	0	0
Alcoholism	0	1	0	0	0
Anxiety	0	2	0	0	0
Bipolar 1 disorder	0	1	0	0	0
Bipolar II disorder	0	1	0	0	0
Bipolar disorder	0	4	0	0	0
Completed suicide	0	2	0	0	1
Delirium	0	1	0	0	0
Delirium tremens	0	1	0	0	0
Depression	2	2	0	0	0
Depression suicidal	1	2	0	0	0
Major depression	0	1	0	0	0
Mania	0	1	0	0	0
Mental status changes	0	3	0	0	0
Post-traumatic stress disorder	0	3	0	0	0

Table 1 - Cumulative Summary Tabulations of Serious Adverse Events from Clinical Studies

System Organ Class Preferred Term	Total Up to 28-DEC-2022 Investigational Product	Blinded	Study Procedure	Active Comparator	Placebo / No Study Product
Schizoaffective disorder	0	4	0	0	0
Schizophrenia	0	3	0	0	0
Substance abuse	1	1	0	0	0
Substance-induced psychotic disorder	1	3	0	0	1
Suicidal ideation	0	11	0	0	0
Suicide attempt	2	11	0	0	0
Nervous system disorders	**55**	**160**	**1**	**2**	**2**
Alcoholic seizure	0	1	0	0	0
Amnesia	0	2	0	0	0
Amyloid related imaging abnormalities	0	1	0	0	0
Bell's palsy	0	1	0	0	0
Brain injury	1	1	0	0	0
Bulbar palsy	0	1	0	0	0
Carotid artery dissection	1	3	0	0	0
Carotid artery stenosis	0	4	0	0	0
Cauda equina syndrome	0	1	0	0	0
Cerebellar stroke	0	1	0	0	0
Cerebral artery occlusion	0	1	0	0	0
Cerebral haemorrhage	0	2	0	0	0
Cerebral infarction	0	3	0	0	0
Cerebral venous thrombosis	1	0	0	0	0

Table 1 - Cumulative Summary Tabulations of Serious Adverse Events from Clinical Studies

System Organ Class Preferred Term	Total Up to 28-DEC-2022 Investigational Product	Blinded	Study Procedure	Active Comparator	Placebo / No Study Product
Cerebrospinal fistula	1	0	0	0	0
Cerebrovascular accident	2	13	0	0	0
Chronic inflammatory demyelinating polyradiculoneuropathy	1	0	0	0	0
Corticobasal degeneration	0	1	0	0	0
Dementia	0	1	0	0	0
Dementia Alzheimer's type	1	0	0	0	0
Demyelinating polyneuropathy	1	1	0	0	0
Diabetic neuropathy	0	1	0	0	0
Dizziness	0	1	0	0	0
Dysarthria	0	1	0	0	0
Embolic stroke	0	1	0	0	0
Encephalopathy	1	0	0	0	0
Epilepsy	2	0	0	0	0
Facial spasm	1	0	0	0	0
Focal dyscognitive seizures	0	1	0	0	0
Generalised tonic-clonic seizure	0	1	0	0	0
Haemorrhage intracranial	1	5	0	0	0
Haemorrhagic transformation stroke	0	1	0	0	0
Headache	2	4	0	0	0
Hemianopia	0	1	0	0	0
Hemianopia homonymous	0	1	0	0	0

Table 1 - Cumulative Summary Tabulations of Serious Adverse Events from Clinical Studies

System Organ Class Preferred Term	Total Up to 28-DEC-2022 Investigational Product	Blinded	Study Procedure	Active Comparator	Placebo / No Study Product
Hemiparesis	0	3	0	0	0
Hydrocephalus	0	1	0	0	0
Hypoaesthesia	1	0	0	0	0
Hypoglossal nerve paralysis	0	1	0	0	0
Hypoxic-ischaemic encephalopathy	0	1	0	0	0
Internal capsule infarction	0	1	0	0	0
Intracranial aneurysm	1	1	0	0	0
Intracranial haematoma	0	1	0	0	0
Intraventricular haemorrhage	0	1	0	0	0
Ischaemic cerebral infarction	0	2	0	0	0
Ischaemic stroke	3	20	0	1	1
Loss of consciousness	1	1	0	0	0
Lumbar radiculopathy	0	2	0	0	0
Metabolic encephalopathy	0	1	0	0	0
Migraine	0	3	0	0	0
Migraine with aura	1	0	0	0	0
Motor neurone disease	0	1	0	0	0
Multiple sclerosis	4	1	0	1	0
Myasthenia gravis	1	1	0	0	0
Myelitis transverse	2	0	0	0	0
Myelomalacia	0	1	0	0	0

Table 1 - Cumulative Summary Tabulations of Serious Adverse Events from Clinical Studies

System Organ Class Preferred Term	Total Up to 28-DEC-2022 Investigational Product	Blinded	Study Procedure	Active Comparator	Placebo / No Study Product
Myelopathy	0	1	0	0	0
Myoclonic epilepsy	0	1	0	0	0
Neurodegenerative disorder	0	1	0	0	0
Neurological symptom	1	0	0	0	0
Normal pressure hydrocephalus	0	2	0	0	0
Optic neuritis	1	0	0	0	0
Paraesthesia	1	1	0	0	0
Parkinson's disease	0	2	0	0	0
Partial seizures	2	0	0	0	0
Peripheral sensory neuropathy	1	0	0	0	0
Post stroke seizure	0	1	0	0	0
Presyncope	1	2	0	0	0
Radiculopathy	0	2	0	0	0
SUNCT syndrome	1	0	0	0	0
Sciatica	2	2	0	0	0
Seizure	1	4	0	0	0
Sensory loss	0	1	0	0	0
Serotonin syndrome	1	0	0	0	0
Spinal cord compression	1	1	0	0	0
Status epilepticus	1	0	0	0	0
Subarachnoid haemorrhage	1	5	0	0	0

Table 1 - Cumulative Summary Tabulations of Serious Adverse Events from Clinical Studies

System Organ Class Preferred Term	Total Up to 28-DEC-2022 Investigational Product	Blinded	Study Procedure	Active Comparator	Placebo / No Study Product
Syncope	6	12	1	0	0
Thalamic infarction	0	1	0	0	0
Thrombotic stroke	0	1	0	0	0
Toxic encephalopathy	0	0	0	0	1
Transient global amnesia	0	2	0	0	0
Transient ischaemic attack	3	17	0	0	0
Ulnar neuritis	0	1	0	0	0
VIth nerve disorder	0	1	0	0	0
VIth nerve paralysis	1	0	0	0	0
Eye disorders	**6**	**7**	**0**	**0**	**1**
Amaurosis fugax	0	1	0	0	0
Cataract	0	1	0	0	0
Diplopia	1	0	0	0	0
Endocrine ophthalmopathy	0	1	0	0	0
Optic ischaemic neuropathy	0	0	0	0	1
Retinal artery occlusion	0	2	0	0	0
Retinal detachment	1	2	0	0	0
Retinal tear	1	0	0	0	0
Retinal vein occlusion	2	0	0	0	0
Vitreous haemorrhage	1	0	0	0	0
Ear and labyrinth disorders	**1**	**10**	**0**	**0**	**1**
Conductive deafness	0	1	0	0	0

Table 1 - Cumulative Summary Tabulations of Serious Adverse Events from Clinical Studies

System Organ Class Preferred Term	Total Up to 28-DEC-2022 Investigational Product	Blinded	Study Procedure	Active Comparator	Placebo / No Study Product
Deafness	0	2	0	0	0
Deafness unilateral	0	1	0	0	0
Neurosensory hypoacusis	0	0	0	0	1
Vertigo	1	3	0	0	0
Vertigo positional	0	3	0	0	0
Cardiac disorders	**32**	**234**	**0**	**0**	**4**
Acute coronary syndrome	1	4	0	0	0
Acute left ventricular failure	0	1	0	0	0
Acute myocardial infarction	6	33	0	0	1
Angina pectoris	4	3	0	0	0
Angina unstable	1	2	0	0	0
Aortic valve stenosis	0	1	0	0	0
Arrhythmia	1	4	0	0	0
Atrial fibrillation	1	35	0	0	0
Atrial flutter	1	3	0	0	0
Atrial tachycardia	0	2	0	0	0
Atrioventricular block	0	3	0	0	0
Atrioventricular block complete	3	3	0	0	0
Atrioventricular block first degree	0	1	0	0	0
Atrioventricular block second degree	0	3	0	0	0
Bradycardia	0	2	0	0	0

Table 1 - Cumulative Summary Tabulations of Serious Adverse Events from Clinical Studies

System Organ Class Preferred Term	Total Up to 28-DEC-2022 Investigational Product	Blinded	Study Procedure	Active Comparator	Placebo / No Study Product
Bundle branch block right	0	1	0	0	0
Cardiac arrest	1	7	0	0	0
Cardiac arrest neonatal	1	0	0	0	0
Cardiac disorder	0	1	0	0	0
Cardiac failure	1	5	0	0	0
Cardiac failure acute	0	3	0	0	0
Cardiac failure congestive	0	16	0	0	1
Cardiac tamponade	0	1	0	0	0
Cardio-respiratory arrest	0	2	0	0	0
Cardiomyopathy	0	1	0	0	0
Cardiopulmonary failure	0	1	0	0	0
Chronic left ventricular failure	0	1	0	0	0
Congestive cardiomyopathy	1	1	0	0	0
Coronary artery disease	2	28	0	0	0
Coronary artery dissection	0	2	0	0	0
Coronary artery occlusion	0	2	0	0	0
Coronary artery stenosis	0	2	0	0	0
Hypertensive heart disease	0	1	0	0	1
Ischaemic cardiomyopathy	0	1	0	0	0
Mitral valve incompetence	0	1	0	0	0
Mitral valve prolapse	0	1	0	0	0

Table 1 - Cumulative Summary Tabulations of Serious Adverse Events from Clinical Studies

System Organ Class Preferred Term	Total Up to 28-DEC-2022 Investigational Product	Blinded	Study Procedure	Active Comparator	Placebo / No Study Product
Myocardial infarction	2	24	0	0	1
Myocardial ischaemia	0	2	0	0	0
Myocarditis	1	0	0	0	0
Myopericarditis	0	1	0	0	0
Myxomatous mitral valve degeneration	0	1	0	0	0
Non-obstructive cardiomyopathy	0	1	0	0	0
Palpitations	0	1	0	0	0
Pericardial effusion	1	2	0	0	0
Pericarditis	2	1	0	0	0
Right ventricular failure	0	1	0	0	0
Sinus bradycardia	0	1	0	0	0
Sinus node dysfunction	0	3	0	0	0
Sinus tachycardia	0	3	0	0	0
Supraventricular tachycardia	1	7	0	0	0
Tachycardia	0	2	0	0	0
Tachycardia paroxysmal	1	0	0	0	0
Torsade de pointes	0	1	0	0	0
Ventricular fibrillation	0	3	0	0	0
Ventricular tachycardia	0	2	0	0	0
Vascular disorders	**6**	**48**	**0**	**0**	**0**
Aortic aneurysm	1	1	0	0	0

Table 1 - Cumulative Summary Tabulations of Serious Adverse Events from Clinical Studies

System Organ Class Preferred Term	Total Up to 28-DEC-2022 Investigational Product	Blinded	Study Procedure	Active Comparator	Placebo / No Study Product
Aortic aneurysm rupture	0	1	0	0	0
Aortic dilatation	0	1	0	0	0
Aortic dissection	0	2	0	0	0
Aortic stenosis	0	2	0	0	0
Arterial haemorrhage	0	1	0	0	0
Arterial occlusive disease	1	1	0	0	0
Arteriosclerosis	0	2	0	0	0
Deep vein thrombosis	1	13	0	0	0
Embolism	0	1	0	0	0
Granulomatosis with polyangiitis	1	0	0	0	0
Haematoma	0	1	0	0	0
Hypertension	0	2	0	0	0
Hypertensive crisis	0	2	0	0	0
Hypertensive emergency	0	2	0	0	0
Hypotension	1	7	0	0	0
Hypovolaemic shock	0	1	0	0	0
Orthostatic hypotension	1	0	0	0	0
Pelvic venous thrombosis	0	1	0	0	0
Peripheral artery occlusion	0	2	0	0	0
Shock haemorrhagic	0	1	0	0	0
Thrombosis	0	3	0	0	0

Table 1 - Cumulative Summary Tabulations of Serious Adverse Events from Clinical Studies

System Organ Class Preferred Term	Total Up to 28-DEC-2022 Investigational Product	Blinded	Study Procedure	Active Comparator	Placebo / No Study Product
Venous thrombosis limb	0	1	0	0	0
Respiratory, thoracic and mediastinal disorders	**23**	**101**	**0**	**0**	**5**
Acute pulmonary oedema	0	1	0	0	0
Acute respiratory distress syndrome	0	2	0	0	0
Acute respiratory failure	0	12	0	0	0
Adenoidal hypertrophy	0	0	0	0	1
Apnoeic attack	1	0	0	0	0
Asphyxia	0	1	0	0	0
Aspiration	0	1	0	0	0
Asthma	0	5	0	0	0
Asthmatic crisis	2	0	0	0	0
Bronchospasm	1	0	0	0	0
Chronic obstructive pulmonary disease	0	7	0	0	0
Chronic respiratory disease	0	1	0	0	0
Diaphragmatic paralysis	0	1	0	0	0
Dyspnoea	1	5	0	0	0
Dyspnoea exertional	0	1	0	0	0
Epistaxis	2	2	0	0	0
Haemoptysis	1	1	0	0	0
Haemothorax	0	1	0	0	0
Hypoxia	0	2	0	0	0

Table 1 - Cumulative Summary Tabulations of Serious Adverse Events from Clinical Studies

System Organ Class Preferred Term	Total Up to 28-DEC-2022 Investigational Product	Blinded	Study Procedure	Active Comparator	Placebo / No Study Product
Idiopathic pulmonary fibrosis	0	1	0	0	0
Laryngeal leukoplakia	0	1	0	0	0
Neonatal respiratory distress syndrome	1	0	0	0	0
Pleural effusion	1	3	0	0	1
Pneumothorax	2	3	0	0	0
Pulmonary embolism	9	34	0	0	2
Pulmonary fibrosis	0	2	0	0	0
Pulmonary haemorrhage	0	1	0	0	0
Pulmonary hypertension	0	1	0	0	1
Pulmonary infarction	0	1	0	0	0
Pulmonary mass	0	1	0	0	0
Pulmonary oedema	0	2	0	0	0
Respiratory arrest	0	1	0	0	0
Respiratory distress	1	0	0	0	0
Respiratory failure	0	5	0	0	0
Sleep apnoea syndrome	0	1	0	0	0
Tachypnoea	1	0	0	0	0
Vocal cord cyst	0	1	0	0	0
Gastrointestinal disorders	**35**	**120**	**0**	**0**	**3**
Abdominal hernia	1	4	0	0	0
Abdominal incarcerated hernia	0	1	0	0	0

Table 1 - Cumulative Summary Tabulations of Serious Adverse Events from Clinical Studies

System Organ Class Preferred Term	Total Up to 28-DEC-2022 Investigational Product	Blinded	Study Procedure	Active Comparator	Placebo / No Study Product
Abdominal mass	0	1	0	0	0
Abdominal pain	2	1	0	0	0
Abdominal pain lower	0	1	0	0	0
Abdominal pain upper	0	1	0	0	0
Abdominal wall haematoma	0	1	0	0	0
Ankyloglossia acquired	1	0	0	0	0
Aphthous ulcer	1	0	0	0	0
Chronic gastritis	0	1	0	0	0
Colitis	2	1	0	0	0
Colitis ischaemic	0	1	0	0	0
Colitis ulcerative	1	0	0	0	0
Constipation	1	2	0	0	0
Diarrhoea	1	2	0	0	0
Diverticular perforation	0	1	0	0	0
Diverticulum intestinal	0	1	0	0	0
Diverticulum intestinal haemorrhagic	0	2	0	0	0
Duodenal perforation	0	1	0	0	0
Duodenal ulcer haemorrhage	0	1	0	0	0
Dyspepsia	1	1	0	0	0
Erosive oesophagitis	0	2	0	0	0
Femoral hernia incarcerated	0	1	0	0	0

Table 1 - Cumulative Summary Tabulations of Serious Adverse Events from Clinical Studies

System Organ Class Preferred Term	Total Up to 28-DEC-2022 Investigational Product	Blinded	Study Procedure	Active Comparator	Placebo / No Study Product
Fistula of small intestine	1	0	0	0	0
Food poisoning	1	0	0	0	0
Gastric fistula	0	1	0	0	0
Gastric ulcer haemorrhage	0	2	0	0	0
Gastric ulcer perforation	0	1	0	0	0
Gastritis	2	1	0	0	0
Gastrointestinal haemorrhage	1	6	0	0	1
Gastrointestinal necrosis	0	1	0	0	0
Gastrooesophageal reflux disease	1	1	0	0	1
Haemorrhoids thrombosed	0	2	0	0	0
Hiatus hernia	0	4	0	0	0
Ileus	0	1	0	0	0
Incarcerated inguinal hernia	1	3	0	0	0
Incarcerated umbilical hernia	1	0	0	0	0
Inflammatory bowel disease	0	0	0	0	1
Inguinal hernia	1	4	0	0	0
Internal hernia	0	1	0	0	0
Intestinal ischaemia	0	1	0	0	0
Intestinal obstruction	1	11	0	0	0
Intussusception	1	0	0	0	0
Large intestine perforation	0	1	0	0	0

Table 1 - Cumulative Summary Tabulations of Serious Adverse Events from Clinical Studies

System Organ Class Preferred Term	Total Up to 28-DEC-2022 Investigational Product	Blinded	Study Procedure	Active Comparator	Placebo / No Study Product
Lower gastrointestinal haemorrhage	0	2	0	0	0
Mesenteric vein thrombosis	1	0	0	0	0
Nausea	1	0	0	0	0
Obstructive pancreatitis	0	2	0	0	0
Oesophageal achalasia	0	1	0	0	0
Oesophageal pain	1	0	0	0	0
Oesophageal ulcer haemorrhage	0	1	0	0	0
Oesophageal varices haemorrhage	0	1	0	0	0
Oesophagitis	0	1	0	0	0
Oesophagitis haemorrhagic	0	1	0	0	0
Pancreatic failure	0	1	0	0	0
Pancreatitis	2	5	0	0	0
Pancreatitis acute	3	2	0	0	0
Pancreatitis necrotising	0	1	0	0	0
Pancreatolithiasis	0	1	0	0	0
Peptic ulcer haemorrhage	0	2	0	0	0
Pharyngo-oesophageal diverticulum	0	1	0	0	0
Rectal haemorrhage	0	2	0	0	0
Small intestinal obstruction	1	17	0	0	0
Small intestinal perforation	0	2	0	0	0
Umbilical hernia	0	1	0	0	0

Table 1 - Cumulative Summary Tabulations of Serious Adverse Events from Clinical Studies

System Organ Class Preferred Term	Total Up to 28-DEC-2022 Investigational Product	Blinded	Study Procedure	Active Comparator	Placebo / No Study Product
Upper gastrointestinal haemorrhage	0	4	0	0	0
Volvulus	3	1	0	0	0
Vomiting	1	3	0	0	0
Hepatobiliary disorders	**10**	**50**	**0**	**2**	**2**
Bile duct stenosis	0	1	0	0	0
Bile duct stone	1	4	0	0	0
Cholangitis	0	1	0	0	0
Cholecystitis	1	9	0	0	1
Cholecystitis acute	0	13	0	0	0
Cholelithiasis	2	14	0	0	0
Cholestasis	0	0	0	1	0
Gallbladder polyp	0	1	0	0	0
Hepatic cirrhosis	0	1	0	0	0
Hepatic function abnormal	0	0	0	0	1
Hepatitis	1	0	0	1	0
Hepatitis alcoholic	0	1	0	0	0
Hyperbilirubinaemia neonatal	2	0	0	0	0
Ischaemic hepatitis	0	1	0	0	0
Jaundice	1	1	0	0	0
Jaundice cholestatic	0	3	0	0	0
Non-alcoholic fatty liver	1	0	0	0	0

Table 1 - Cumulative Summary Tabulations of Serious Adverse Events from Clinical Studies

System Organ Class Preferred Term	Total Up to 28-DEC-2022 Investigational Product	Blinded	Study Procedure	Active Comparator	Placebo / No Study Product
Portal vein thrombosis	1	0	0	0	0
Skin and subcutaneous tissue disorders	**0**	**4**	**0**	**0**	**0**
Angioedema	0	1	0	0	0
Diabetic foot	0	1	0	0	0
Petechiae	0	1	0	0	0
Rash	0	1	0	0	0
Musculoskeletal and connective tissue disorders	**14**	**95**	**0**	**1**	**1**
Arthralgia	0	3	0	0	0
Arthritis	0	3	0	0	0
Back pain	2	8	0	0	0
Cervical spinal stenosis	0	3	0	0	0
Costochondritis	0	2	0	0	0
Haematoma muscle	0	1	0	0	0
Intervertebral disc degeneration	1	4	0	0	0
Intervertebral disc protrusion	2	9	0	0	0
Limb mass	0	1	0	0	0
Lumbar spinal stenosis	0	8	0	0	0
Muscle spasms	0	1	0	0	0
Musculoskeletal chest pain	1	1	0	0	0
Neck pain	0	1	0	0	0
Osteoarthritis	1	25	0	0	0
Pain in extremity	0	1	0	0	0

Table 1 - Cumulative Summary Tabulations of Serious Adverse Events from Clinical Studies

System Organ Class Preferred Term	Total Up to 28-DEC-2022 Investigational Product	Blinded	Study Procedure	Active Comparator	Placebo / No Study Product
Pathological fracture	1	0	0	0	0
Periarthritis	0	1	0	0	0
Polymyalgia rheumatica	1	0	0	0	0
Rhabdomyolysis	0	6	0	0	1
Rheumatoid arthritis	0	1	0	0	0
Rotator cuff syndrome	2	2	0	0	0
Scoliosis	0	1	0	0	0
Spinal osteoarthritis	0	2	0	0	0
Spinal pain	1	1	0	0	0
Spinal stenosis	1	5	0	0	0
Spinal synovial cyst	0	1	0	0	0
Spondylolisthesis	0	2	0	0	0
Still's disease	0	0	0	1	0
Tendon discomfort	1	0	0	0	0
Vertebral foraminal stenosis	0	2	0	0	0
Renal and urinary disorders	**17**	**45**	**0**	**0**	**4**
Acute kidney injury	1	17	0	0	0
Bladder outlet obstruction	0	1	0	0	0
Bladder perforation	0	1	0	0	0
Calculus urinary	2	1	0	0	0
Chronic kidney disease	0	2	0	0	0

Table 1 - Cumulative Summary Tabulations of Serious Adverse Events from Clinical Studies

System Organ Class Preferred Term	Total Up to 28-DEC-2022 Investigational Product	Blinded	Study Procedure	Active Comparator	Placebo / No Study Product
Haematuria	0	1	0	0	1
Hydronephrosis	1	1	0	0	0
IgA nephropathy	1	0	0	0	0
Nephrolithiasis	4	9	0	0	1
Nephropathy toxic	0	1	0	0	0
Nephrotic syndrome	0	0	0	0	1
Pelvi-ureteric obstruction	0	1	0	0	0
Renal aneurysm	0	1	0	0	0
Renal colic	2	0	0	0	0
Renal failure	0	2	0	0	0
Renal mass	0	1	0	0	0
Renal tubular necrosis	0	1	0	0	0
Ureteric obstruction	0	0	0	0	1
Ureterolithiasis	2	0	0	0	0
Urethral caruncle	0	1	0	0	0
Urinary retention	0	3	0	0	0
Urinary tract obstruction	4	1	0	0	0
Pregnancy, puerperium and perinatal conditions	**39**	**34**	**0**	**0**	**5**
Abortion	1	1	0	0	0
Abortion spontaneous	21	24	0	0	3
Amniorrhexis	2	0	0	0	0

Table 1 - Cumulative Summary Tabulations of Serious Adverse Events from Clinical Studies

System Organ Class Preferred Term	Total Up to 28-DEC-2022 Investigational Product	Blinded	Study Procedure	Active Comparator	Placebo / No Study Product
Anembryonic gestation	0	0	0	0	1
Breech presentation	1	0	0	0	0
Cervical incompetence	0	1	0	0	0
Complication of pregnancy	0	1	0	0	0
Eclampsia	1	0	0	0	0
Ectopic pregnancy	1	2	0	0	0
Gestational hypertension	0	1	0	0	0
Hyperemesis gravidarum	1	0	0	0	0
Jaundice neonatal	1	0	0	0	0
Low birth weight baby	1	0	0	0	0
Oligohydramnios	1	0	0	0	0
Pre-eclampsia	1	1	0	0	0
Pregnancy	1	0	0	0	0
Premature baby	2	0	0	0	0
Premature delivery	2	0	0	0	1
Premature labour	0	1	0	0	0
Ruptured ectopic pregnancy	0	1	0	0	0
Stillbirth	1	1	0	0	0
Superimposed pre-eclampsia	1	0	0	0	0
Reproductive system and breast disorders	**12**	**24**	**0**	**0**	**2**
Abnormal uterine bleeding	2	0	0	0	0

Table 1 - Cumulative Summary Tabulations of Serious Adverse Events from Clinical Studies

System Organ Class Preferred Term	Total Up to 28-DEC-2022 Investigational Product	Blinded	Study Procedure	Active Comparator	Placebo / No Study Product
Adenomyosis	0	2	0	0	0
Adnexal torsion	2	0	0	0	0
Benign prostatic hyperplasia	0	6	0	0	0
Breast haematoma	0	1	0	0	0
Breast mass	1	0	0	0	0
Cervical dysplasia	0	2	0	0	1
Dysmenorrhoea	1	0	0	0	0
Endometriosis	2	1	0	0	0
Female genital tract fistula	0	1	0	0	0
Haemorrhagic ovarian cyst	1	0	0	0	0
Ovarian cyst	0	2	0	0	0
Ovarian cyst ruptured	0	1	0	0	0
Ovarian mass	0	1	0	0	0
Prostatitis	1	3	0	0	0
Rectocele	0	1	0	0	0
Testicular torsion	0	1	0	0	0
Uterine cervix stenosis	0	1	0	0	0
Uterine haemorrhage	1	0	0	0	1
Vaginal haemorrhage	1	1	0	0	0
Congenital, familial and genetic disorders	**4**	**11**	**0**	**0**	**0**
Anencephaly	0	1	0	0	0

Table 1 - Cumulative Summary Tabulations of Serious Adverse Events from Clinical Studies

System Organ Class Preferred Term	Total Up to 28-DEC-2022 Investigational Product	Blinded	Study Procedure	Active Comparator	Placebo / No Study Product
Atrial septal defect	0	1	0	0	0
Brugada syndrome	0	1	0	0	0
Cerebral cavernous malformation	0	1	0	0	0
Cerebral palsy	1	0	0	0	0
Haemorrhagic arteriovenous malformation	0	1	0	0	0
Hamartoma	0	1	0	0	0
Hypertrophic cardiomyopathy	0	2	0	0	0
Laryngomalacia	1	0	0	0	0
Multiple congenital abnormalities	0	1	0	0	0
Renal aplasia	0	1	0	0	0
Talipes	1	0	0	0	0
Thalassaemia minor	0	1	0	0	0
Ventricular septal defect	1	0	0	0	0
General disorders and administration site conditions	**15**	**41**	**0**	**0**	**1**
Asthenia	1	1	0	0	0
Catheter site haematoma	0	1	0	0	0
Catheter site haemorrhage	0	1	0	0	0
Chest discomfort	0	1	0	0	0
Chest pain	7	10	0	0	0
Death	2	11	0	0	1
Drowning	0	1	0	0	0

Table 1 - Cumulative Summary Tabulations of Serious Adverse Events from Clinical Studies

System Organ Class Preferred Term	Total Up to 28-DEC-2022 Investigational Product	Blinded	Study Procedure	Active Comparator	Placebo / No Study Product
Dysplasia	0	1	0	0	0
Hernia	0	1	0	0	0
Hypothermia	0	1	0	0	0
Incarcerated hernia	0	1	0	0	0
Mass	1	0	0	0	0
Non-cardiac chest pain	1	3	0	0	0
Oedema peripheral	0	3	0	0	0
Pelvic mass	0	1	0	0	0
Pyrexia	3	2	0	0	0
Sudden cardiac death	0	1	0	0	0
Swelling face	0	1	0	0	0
Investigations	**7**	**7**	**0**	**0**	**1**
Alanine aminotransferase increased	1	0	0	0	1
Anticoagulation drug level above therapeutic	0	2	0	0	0
C-reactive protein abnormal	2	0	0	0	0
C-reactive protein increased	4	0	0	0	0
Cardiac murmur	0	1	0	0	0
Catheterisation cardiac	0	1	0	0	0
Fibrin D dimer increased	0	1	0	0	0
Heart rate increased	0	1	0	0	0
Precancerous cells present	0	1	0	0	0
Injury, poisoning and procedural complications	**83**	**209**	**0**	**1**	**9**

Table 1 - Cumulative Summary Tabulations of Serious Adverse Events from Clinical Studies

System Organ Class Preferred Term	Total Up to 28-DEC-2022 Investigational Product	Blinded	Study Procedure	Active Comparator	Placebo / No Study Product
Abdominal injury	1	0	0	0	0
Accident	0	1	0	0	0
Accidental overdose	0	1	0	0	0
Acetabulum fracture	0	1	0	0	0
Acquired encephalocele	0	1	0	0	0
Alcohol poisoning	0	1	0	0	0
Animal bite	0	1	0	0	0
Ankle fracture	1	11	0	0	0
Aortic injury	0	1	0	0	0
Bladder injury	1	1	0	0	0
Burns second degree	1	2	0	0	0
Carbon monoxide poisoning	0	1	0	0	0
Cartilage injury	0	1	0	0	0
Cervical vertebral fracture	1	3	0	0	0
Chemical peritonitis	0	1	0	0	0
Clavicle fracture	1	2	0	0	0
Colon injury	0	1	0	0	0
Comminuted fracture	0	1	0	0	0
Compression fracture	0	1	0	0	0
Concussion	0	1	0	0	0
Contusion	0	1	0	0	0

Table 1 - Cumulative Summary Tabulations of Serious Adverse Events from Clinical Studies

System Organ Class Preferred Term	Total Up to 28-DEC-2022 Investigational Product	Blinded	Study Procedure	Active Comparator	Placebo / No Study Product
Craniocerebral injury	2	2	0	0	0
Exposure during pregnancy	29	27	0	0	5
Facial bones fracture	0	2	0	0	0
Fall	0	4	0	0	0
Femoral neck fracture	1	5	0	0	0
Femur fracture	1	9	0	0	0
Fibula fracture	3	3	0	0	0
Foot fracture	2	4	0	0	0
Forearm fracture	0	1	0	0	0
Fracture	0	1	0	0	0
Fracture displacement	0	1	0	0	0
[redacted]wound	2	1	0	0	0
Hand fracture	1	1	0	0	0
Head injury	0	2	0	0	1
Hip fracture	0	11	0	0	0
Humerus fracture	0	5	0	0	0
Hypobarism	0	1	0	0	0
Ilium fracture	0	2	0	0	0
Implantation complication	1	0	0	0	0
Incarcerated incisional hernia	0	1	0	0	0
Incision site haematoma	0	1	0	0	0

Table 1 - Cumulative Summary Tabulations of Serious Adverse Events from Clinical Studies

System Organ Class Preferred Term	Total Up to 28-DEC-2022 Investigational Product	Blinded	Study Procedure	Active Comparator	Placebo / No Study Product
Incisional hernia	0	1	0	0	0
Injury	0	1	0	0	0
Intentional overdose	0	1	0	0	0
Joint dislocation	1	6	0	0	0
Ligament rupture	0	1	0	0	0
Ligament sprain	0	1	0	0	0
Limb crushing injury	0	1	0	0	0
Limb injury	1	0	0	0	0
Lower limb fracture	0	1	0	0	0
Lumbar vertebral fracture	0	2	0	0	0
Meniscus injury	2	0	0	0	0
Multiple injuries	3	3	0	0	0
Osteochondral fracture	0	1	0	0	0
Overdose	0	5	0	0	0
Patella fracture	4	2	0	0	0
Pelvic fracture	0	1	0	0	0
Periprosthetic fracture	0	1	0	0	0
Pneumothorax traumatic	0	3	0	0	0
Post procedural complication	1	0	0	0	0
Post procedural haematuria	0	4	0	0	0
Post procedural swelling	0	1	0	0	0

Table 1 - Cumulative Summary Tabulations of Serious Adverse Events from Clinical Studies

System Organ Class Preferred Term	Total Up to 28-DEC-2022 Investigational Product	Blinded	Study Procedure	Active Comparator	Placebo / No Study Product
Postoperative ileus	0	1	0	0	0
Radius fracture	0	2	0	0	0
Reactive gastropathy	0	1	0	0	0
Rib fracture	1	6	0	0	0
Road traffic accident	1	5	0	0	0
Scapula fracture	1	0	0	0	0
Skin laceration	0	2	0	0	0
Skull fracture	0	1	0	0	0
Soft tissue injury	0	1	0	0	0
Spinal compression fracture	0	3	0	0	0
Spinal cord injury	0	1	0	0	0
Spinal fracture	1	0	0	0	0
Splenic rupture	0	1	0	0	0
[redacted]wound	0	1	0	0	0
Sternal fracture	0	2	0	0	0
Subdural haematoma	3	3	0	0	0
Subdural haemorrhage	0	1	0	0	0
Synovial rupture	1	0	0	0	0
Tendon injury	0	1	0	1	1
Tendon rupture	4	8	0	0	0
Thermal burn	1	1	0	0	0

Table 1 - Cumulative Summary Tabulations of Serious Adverse Events from Clinical Studies

System Organ Class Preferred Term	Total Up to 28-DEC-2022 Investigational Product	Blinded	Study Procedure	Active Comparator	Placebo / No Study Product
Tibia fracture	1	7	0	0	1
Toxicity to various agents	1	1	0	0	1
Traumatic haemothorax	2	1	0	0	0
Traumatic intracranial haematoma	0	1	0	0	0
Traumatic intracranial haemorrhage	0	1	0	0	0
Traumatic liver injury	0	1	0	0	0
Ulna fracture	2	0	0	0	0
Upper limb fracture	1	0	0	0	0
Wrist fracture	3	2	0	0	0
Surgical and medical procedures	**3**	**3**	**0**	**0**	**0**
Arthrolysis	1	0	0	0	0
Inguinal hernia repair	0	1	0	0	0
Knee arthroplasty	1	0	0	0	0
Pelvic floor repair	0	1	0	0	0
Spinal decompression	1	0	0	0	0
Umbilical hernia repair	0	1	0	0	0
Social circumstances	**1**	**0**	**0**	**0**	**1**
[redacted]	0	0	0	0	1
Physical assault	1	0	0	0	0
Product issues	**0**	**1**	**0**	**0**	**0**
Device breakage	0	1	0	0	0

Listing of MedDRA SOCs in the Internationally Agreed Order

MedDRA Version: 25.1

Infections and infestations
Neoplasms benign, malignant and unspecified (incl cysts and polyps)
Blood and lymphatic system disorders
Immune system disorders
Endocrine disorders
Metabolism and nutrition disorders
Psychiatric disorders
Nervous system disorders
Eye disorders
Ear and labyrinth disorders
Cardiac disorders
Vascular disorders
Respiratory, thoracic and mediastinal disorders
Gastrointestinal disorders
Hepatobiliary disorders
Skin and subcutaneous tissue disorders
Musculoskeletal and connective tissue disorders
Renal and urinary disorders
Pregnancy, puerperium and perinatal conditions
Reproductive system and breast disorders
Congenital, familial and genetic disorders
General disorders and administration site conditions
Investigations
Injury, poisoning and procedural complications
Surgical and medical procedures
Social circumstances
Product issues

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Infections and infestations	**3556**	**45002**	**2282**	**33236**	**78238**	**23**	**70**
AIDS related complex	0	1	0	1	2	0	0
Abdominal abscess	0	2	0	0	2	0	0
Abdominal infection	1	3	0	3	6	0	0
Abdominal sepsis	0	2	0	0	2	0	0
Abdominal wall infection	0	1	0	0	1	0	0
Abortion infected	0	1	0	0	1	0	0
Abscess	1	59	27	175	234	0	0
Abscess bacterial	0	1	1	1	2	0	0
Abscess jaw	0	0	0	1	1	0	0
Abscess limb	2	23	2	21	44	0	0
Abscess neck	0	0	0	1	1	0	0
Abscess of eyelid	0	0	0	1	1	0	0
Abscess oral	0	5	0	6	11	0	0
Abscess soft tissue	0	3	0	1	4	0	0
Acanthamoeba keratitis	0	1	0	0	1	0	0
Acarodermatitis	0	7	1	9	16	0	0
Acinetobacter infection	0	2	0	0	2	0	0
Acne pustular	0	0	0	2	2	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Acquired immunodeficiency syndrome	0	3	0	0	3	0	0
Acrodermatitis chronica atrophicans	0	0	0	1	1	0	0
Actinomycotic abdominal infection	0	0	0	2	2	0	0
Actinomycotic skin infection	0	0	0	1	1	0	0
Acute endocarditis	0	2	0	0	2	0	0
Acute haemorrhagic conjunctivitis	0	0	0	1	1	0	0
Acute hepatitis B	0	1	0	0	1	0	0
Acute sinusitis	0	7	1	12	19	0	0
Adenopathy syphilitic	0	1	0	1	2	0	0
Adenovirus infection	0	1	1	2	3	0	0
Administration site abscess	0	0	0	1	1	0	0
Administration site cellulitis	1	1	2	6	7	0	0
African trypanosomiasis	0	8	0	3	11	0	0
Amniotic cavity infection	0	0	0	0	0	0	1
Amoebiasis	1	1	0	0	1	0	0
Amoebic skin ulcer	0	0	0	1	1	0	0
Anal abscess	1	3	1	4	7	0	0
Anal candidiasis	0	2	0	0	2	0	0
Anthrax	0	0	0	1	1	0	0
Appendicitis	4	110	0	0	110	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Appendicitis perforated	0	10	0	0	10	0	0
Application site abscess	0	1	1	4	5	0	0
Application site cellulitis	0	0	0	1	1	0	0
Application site infection	0	0	0	2	2	0	0
Application site pustules	0	0	0	2	2	0	0
Arteriosclerotic gangrene	0	1	0	0	1	0	0
Arthritis bacterial	1	21	0	0	21	0	0
Arthritis infective	1	7	0	0	7	0	0
Arthritis viral	1	3	0	0	3	0	0
Aspergillus infection	1	2	0	0	2	0	0
Asymptomatic COVID-19	2	27	6	227	254	0	0
Asymptomatic bacteriuria	0	0	0	1	1	0	0
Atypical mycobacterial infection	0	0	0	1	1	0	0
Atypical pneumonia	3	15	0	2	17	0	0
Bacillus infection	0	1	0	0	1	0	0
Bacteraemia	1	7	0	3	10	0	0
Bacterial colitis	0	1	0	0	1	0	0
Bacterial diarrhoea	0	2	0	6	8	0	0
Bacterial infection	1	41	3	25	66	0	0
Bacterial parotitis	0	1	0	0	1	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Bacterial prostatitis	1	1	0	0	1	0	0
Bacterial sepsis	0	3	0	0	3	0	0
Bacterial toxaemia	0	1	0	0	1	0	0
Bacterial vaginosis	0	4	0	7	11	0	0
Bacterial vulvovaginitis	0	1	0	1	2	0	0
Balanitis candida	0	0	0	2	2	0	0
Beta haemolytic streptococcal infection	0	3	0	0	3	0	2
Biliary sepsis	0	6	0	0	6	0	0
Blackwater fever	0	1	0	2	3	0	0
Blister infected	0	1	2	8	9	0	0
Body tinea	0	5	1	8	13	0	0
Bone abscess	0	0	0	1	1	0	0
Borrelia infection	0	3	0	1	4	0	0
Boutonneuse fever	0	0	0	1	1	0	0
Brain abscess	0	6	0	0	6	0	0
Brain empyema	0	1	0	0	1	0	0
Breakthrough COVID-19	4	8	11	31	39	0	0
Breast abscess	0	6	1	2	8	0	0
Bronchiolitis	1	3	0	4	7	2	2
Bronchitis	6	58	8	106	164	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Bronchitis bacterial	0	1	0	0	1	0	0
Bronchitis viral	0	1	0	1	2	0	0
Bronchopulmonary aspergillosis	0	1	0	0	1	0	0
Brucellosis	0	1	0	0	1	0	0
Bursitis infective	0	3	0	1	4	0	0
CNS ventriculitis	1	1	0	0	1	0	0
COVID-19	2717	25482	325	3656	29138	2	30
COVID-19 pneumonia	21	387	0	0	387	0	1
Campylobacter colitis	0	0	0	1	1	0	0
Campylobacter gastroenteritis	0	1	0	1	2	0	0
Campylobacter infection	0	4	0	0	4	0	0
Candida infection	1	60	2	47	107	0	0
Candida sepsis	0	1	0	0	1	0	0
Capnocytophaga sepsis	0	1	0	0	1	0	0
Carbuncle	0	2	0	3	5	0	0
Cardiac infection	0	2	0	0	2	0	0
Cat scratch disease	0	0	1	1	1	0	0
Catheter site infection	0	1	0	0	1	0	0
Cavernous sinus thrombosis	1	20	0	1	21	0	0
Cellulitis	20	441	10	401	842	1	1

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Cellulitis orbital	0	4	0	0	4	0	0
Cellulitis staphylococcal	0	0	0	1	1	0	0
Cellulitis streptococcal	0	1	0	0	1	0	0
Central nervous system abscess	1	1	0	0	1	0	0
Central nervous system infection	0	2	0	0	2	0	0
Cervicitis	0	1	0	0	1	0	0
Chikungunya virus infection	1	2	0	4	6	0	0
Chlamydial infection	0	1	0	0	1	0	0
Cholecystitis infective	0	2	0	0	2	0	0
Chronic hepatitis B	0	1	0	0	1	0	0
Chronic sinusitis	0	17	1	11	28	0	0
Chronic tonsillitis	0	1	0	0	1	0	0
Clostridial infection	0	1	0	0	1	0	0
Clostridium difficile colitis	0	8	0	1	9	0	0
Clostridium difficile infection	0	3	0	1	4	0	0
Coinfection	0	0	0	1	1	0	0
Colitis herpes	0	0	0	1	1	0	0
Complicated appendicitis	0	1	0	0	1	0	0
Conjunctivitis	2	74	11	232	306	0	0
Conjunctivitis bacterial	0	1	0	0	1	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Conjunctivitis viral	0	5	0	3	8	0	0
Coronavirus infection	1	9	5	37	46	0	0
Coronavirus pneumonia	0	1	0	0	1	0	0
Cow pox	0	1	0	0	1	0	0
Coxsackie bronchitis	0	0	0	1	1	0	0
Coxsackie viral infection	0	0	0	1	1	0	0
Creutzfeldt-Jakob disease	1	14	0	1	15	0	0
Croup infectious	0	1	0	0	1	0	0
Cystitis	12	117	6	114	231	0	0
Cystitis bacterial	1	1	0	0	1	0	0
Cystitis escherichia	1	1	0	1	2	0	0
Cystitis klebsiella	0	1	0	0	1	0	0
Cystitis viral	0	1	0	0	1	0	0
Cytomegalovirus hepatitis	0	1	0	0	1	0	0
Cytomegalovirus infection	0	3	0	3	6	0	0
Cytomegalovirus infection reactivation	0	2	0	0	2	0	0
Dacryocystitis	0	1	0	0	1	0	0
Dengue fever	1	15	0	0	15	0	0
Dental fistula	0	0	1	1	1	0	0
Dermatitis infected	0	8	0	2	10	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Dermatophytosis	0	0	0	1	1	0	0
Dermo-hypodermitis	0	1	0	5	6	0	0
Device related infection	2	4	0	1	5	0	0
Diarrhoea infectious	1	5	0	3	8	0	0
Diphtheria	0	3	0	0	3	0	0
Disseminated Bacillus Calmette-Guerin infection	0	1	1	18	19	0	0
Diverticulitis	6	74	2	30	104	0	0
Diverticulitis intestinal perforated	0	1	0	0	1	0	0
Dysentery	0	55	1	69	124	0	0
Ear infection	12	160	7	90	250	0	0
Ear infection bacterial	0	3	0	0	3	0	0
Ear infection fungal	0	2	0	0	2	0	0
Ear infection viral	0	2	0	0	2	0	0
Ear lobe infection	0	0	0	1	1	0	0
Ear, nose and throat infection	0	0	0	1	1	0	0
Eczema herpeticum	0	6	0	2	8	0	0
Eczema infected	0	3	0	2	5	0	0
Embolic pneumonia	0	1	0	0	1	0	0
Empyema	0	3	0	0	3	0	0
Encephalitis	23	181	0	0	181	2	3

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Encephalitis Japanese B	1	1	0	0	1	0	0
Encephalitis brain stem	2	4	0	0	4	0	0
Encephalitis cytomegalovirus	0	1	0	0	1	0	0
Encephalitis lethargica	0	2	0	2	4	0	0
Encephalitis viral	3	11	0	2	13	0	0
Encephalomyelitis	5	23	0	3	26	0	0
Endocarditis	4	24	0	0	24	0	0
Endocarditis bacterial	0	5	0	0	5	0	0
Endocarditis meningococcal	0	0	0	1	1	0	0
Endometritis	0	2	0	2	4	0	0
Enteritis infectious	0	1	0	0	1	0	0
Enterobiasis	0	0	1	1	1	0	0
Enterococcal infection	1	2	0	1	3	0	0
Epididymitis	3	14	0	7	21	0	0
Epiglottitis	0	2	0	0	2	0	0
Epstein-Barr viraemia	0	1	0	0	1	0	0
Epstein-Barr virus infection	1	13	4	9	22	0	0
Epstein-Barr virus infection reactivation	3	15	1	5	20	0	0
Eruptive pseudoangiomatosis	0	0	4	10	10	0	0
Erysipelas	6	59	4	65	124	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Erysipeloid	0	0	0	3	3	0	0
Erythema induratum	0	2	0	4	6	1	1
Erythema infectiosum	0	0	1	2	2	0	0
Erythema migrans	1	4	0	2	6	0	0
Escherichia bacteraemia	0	3	0	0	3	0	0
Escherichia infection	0	3	0	3	6	0	0
Escherichia sepsis	0	3	0	0	3	0	0
Escherichia urinary tract infection	0	1	0	0	1	0	0
Exanthema subitum	0	1	1	12	13	0	0
External ear cellulitis	0	0	0	1	1	0	0
Extradural abscess	0	1	0	0	1	0	0
Eye abscess	0	2	0	3	5	0	0
Eye infection	2	42	5	45	87	0	0
Eye infection bacterial	0	0	0	2	2	0	0
Eye infection toxoplasmal	0	1	0	2	3	0	0
Eye infection viral	1	2	0	1	3	0	0
Eyelid boil	0	1	0	3	4	0	0
Eyelid infection	0	6	1	6	12	0	0
Fallopian tube abscess	0	1	0	0	1	0	0
Fascial infection	0	0	0	1	1	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Febrile infection	1	1	0	3	4	0	0
Filariasis	0	3	0	0	3	0	0
Folliculitis	0	11	2	24	35	0	0
Foot and mouth disease	0	0	0	4	4	0	0
Fungal foot infection	0	0	0	2	2	0	0
Fungal infection	6	30	5	37	67	0	0
Fungal rhinitis	1	1	0	0	1	0	0
Fungal sepsis	0	1	0	0	1	0	0
Fungal skin infection	0	5	0	11	16	0	0
Furuncle	2	40	5	61	101	0	0
Gangrene	2	12	0	0	12	0	0
Gardnerella infection	0	0	0	1	1	0	0
Gastric infection	1	2	0	1	3	0	0
Gastritis viral	0	1	0	0	1	0	0
Gastroenteritis	10	78	2	56	134	0	0
Gastroenteritis Escherichia coli	0	1	0	2	3	0	0
Gastroenteritis bacillus	0	1	0	0	1	0	0
Gastroenteritis bacterial	3	3	0	0	3	0	0
Gastroenteritis norovirus	0	1	0	0	1	0	0
Gastroenteritis rotavirus	0	1	0	0	1	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Gastroenteritis salmonella	0	0	0	1	1	0	0
Gastroenteritis staphylococcal	1	1	0	0	1	0	0
Gastroenteritis viral	2	65	3	29	94	0	0
Gastrointestinal bacterial infection	0	0	0	1	1	0	0
Gastrointestinal fungal infection	0	1	0	2	3	0	0
Gastrointestinal infection	2	8	3	12	20	0	0
Gastrointestinal viral infection	0	0	0	1	1	0	0
Genital abscess	1	2	0	4	6	0	0
Genital herpes	0	62	9	88	150	0	0
Genital herpes simplex	0	1	0	2	3	0	0
Genital herpes zoster	0	2	0	1	3	0	0
Genital infection	1	1	0	1	2	0	0
Genital infection female	0	1	0	1	2	0	0
Genital infection fungal	0	0	1	6	6	0	0
Genital ulcer syndrome	0	1	1	2	3	0	0
Genitourinary tract infection	0	2	0	0	2	0	0
Gingival abscess	0	5	2	8	13	0	0
Gingivitis	4	28	14	90	118	0	0
Gonorrhoea	0	0	0	1	1	0	0
Groin abscess	0	2	0	1	3	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Groin infection	0	1	0	2	3	0	0
H1N1 influenza	0	1	0	0	1	0	0
H2N2 influenza	0	4	0	1	5	0	0
HIV infection	0	3	0	1	4	0	0
HIV-associated neurocognitive disorder	0	0	0	1	1	0	0
Haematological infection	1	2	0	0	2	0	0
Haematoma infection	0	2	0	1	3	0	0
Haemophilus infection	1	1	0	0	1	0	0
Haemorrhagic fever	0	1	0	1	2	0	0
Haemorrhagic varicella syndrome	0	1	0	0	1	0	0
Hand-foot-and-mouth disease	0	1	0	1	2	0	0
Hantaviral infection	0	1	0	0	1	0	0
Helicobacter gastritis	1	2	1	1	3	0	0
Helicobacter infection	2	3	0	2	5	0	0
Hepatic amoebiasis	0	2	0	0	2	0	0
Hepatic infection	1	2	0	1	3	0	0
Hepatitis A	2	4	0	0	4	0	1
Hepatitis B reactivation	1	1	0	0	1	0	0
Hepatitis C	0	1	0	1	2	0	0
Hepatitis E	0	4	0	0	4	0	0

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	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Hepatitis infectious mononucleosis	0	1	0	1	2	0	0
Hepatitis viral	1	4	0	1	5	0	0
Herpangina	0	2	0	1	3	0	0
Herpes dermatitis	0	2	0	6	8	0	0
Herpes ophthalmic	4	40	2	18	58	1	2
Herpes pharyngitis	0	0	0	1	1	0	0
Herpes simplex	2	40	10	135	175	0	0
Herpes simplex encephalitis	0	2	0	0	2	0	0
Herpes simplex hepatitis	0	1	0	0	1	0	0
Herpes simplex meningitis	0	2	0	1	3	0	0
Herpes simplex reactivation	1	6	5	22	28	0	1
Herpes virus infection	5	34	29	200	234	0	0
Herpes zoster	40	1685	189	2597	4282	0	0
Herpes zoster cutaneous disseminated	1	4	0	5	9	0	0
Herpes zoster disseminated	1	4	0	4	8	0	0
Herpes zoster infection neurological	1	1	1	1	2	0	0
Herpes zoster meningitis	0	6	0	0	6	0	0
Herpes zoster meningoradiculitis	0	1	0	0	1	0	0
Herpes zoster oticus	1	28	0	12	40	0	0
Herpes zoster reactivation	1	8	2	21	29	0	0

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Herpetic radiculopathy	0	1	0	1	2	0	0
Hordeolum	1	26	5	55	81	0	0
Human herpesvirus 6 infection reactivation	0	0	0	1	1	0	0
Hypopyon	0	0	0	1	1	0	0
Impetigo	0	11	1	9	20	0	0
Implant site pustules	0	1	0	0	1	0	0
Inclusion conjunctivitis	1	1	0	0	1	0	0
Infected bite	0	4	0	3	7	0	0
Infected cyst	1	4	0	1	5	0	0
Infected dermal cyst	0	3	1	2	5	0	0
Infected lymphocele	0	1	0	0	1	0	0
Infected seroma	0	0	0	1	1	0	0
Infected varicose vein	0	1	0	0	1	0	0
Infection	22	478	17	231	709	2	3
Infection in an immunocompromised host	1	4	0	0	4	0	0
Infection parasitic	0	0	0	1	1	0	0
Infection reactivation	0	4	0	2	6	0	0
Infection susceptibility increased	2	7	9	18	25	0	0
Infectious mononucleosis	1	59	1	10	69	0	0
Infectious pleural effusion	0	6	0	0	6	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Infectious thyroiditis	0	1	0	1	2	0	0
Infective exacerbation of bronchiectasis	0	1	0	2	3	0	0
Infective myositis	1	1	0	0	1	0	0
Infective pulmonary exacerbation of cystic fibrosis	0	1	0	0	1	0	0
Infective spondylitis	0	1	0	0	1	0	0
Infective tenosynovitis	0	0	1	1	1	0	0
Infective thrombosis	0	1	0	0	1	0	0
Infestation	0	1	0	1	2	0	0
Influenza	55	6091	348	10767	16858	0	0
Injection site abscess	1	6	3	56	62	0	0
Injection site cellulitis	0	15	1	49	64	0	0
Injection site infection	1	14	0	56	70	0	0
Injection site pustule	0	3	0	5	8	0	0
Intervertebral discitis	0	8	0	0	8	0	0
Intestinal tuberculosis	1	1	0	0	1	0	0
Intrauterine infection	0	1	0	0	1	0	0
Janeway lesion	0	1	0	0	1	0	0
Joint abscess	0	1	0	0	1	0	0
Keratitis bacterial	0	0	0	1	1	0	0
Keratitis viral	0	0	0	1	1	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Keratouveitis	0	0	0	1	1	0	0
Kidney infection	3	75	0	6	81	0	0
Klebsiella infection	2	3	0	2	5	0	0
Klebsiella sepsis	0	1	0	0	1	0	0
Labyrinthitis	5	180	2	93	273	0	0
Large intestine infection	0	4	0	0	4	0	0
Laryngitis	3	44	2	48	92	0	0
Laryngitis viral	0	1	0	0	1	0	0
Laryngopharyngitis	0	1	0	0	1	0	0
Latent tuberculosis	0	1	0	0	1	0	0
Legionella infection	0	0	0	1	1	0	0
Lemierre syndrome	0	0	0	1	1	0	0
Leprosy	0	2	0	1	3	0	0
Leptospirosis	1	2	0	0	2	0	0
Lice infestation	0	0	0	2	2	0	0
Lip infection	0	0	0	3	3	0	0
Liver abscess	0	7	0	0	7	0	0
Localised infection	9	101	3	53	154	0	0
Lower respiratory tract infection	14	338	8	129	467	0	0
Lower respiratory tract infection viral	0	1	0	0	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Ludwig angina	0	0	0	1	1	0	0
Lung abscess	1	4	0	0	4	0	0
Lyme carditis	0	1	0	0	1	0	0
Lyme disease	4	26	2	16	42	0	0
Lymph gland infection	0	3	0	8	11	0	0
Lymph node abscess	0	3	0	12	15	0	0
Lymph node tuberculosis	0	2	0	1	3	0	0
Lymphadenitis bacterial	0	1	0	9	10	0	0
Lymphangitis	1	14	0	19	33	0	0
Malaria	0	7	1	6	13	0	0
Mastitis	0	50	0	27	77	0	0
Mastoiditis	1	10	0	5	15	0	0
Measles	0	3	0	4	7	0	0
Measles post vaccine	0	1	1	1	2	0	0
Medical device site joint infection	0	0	0	1	1	0	0
Meningitis	4	80	0	0	80	0	1
Meningitis aseptic	3	16	0	0	16	0	0
Meningitis bacterial	2	7	0	0	7	0	0
Meningitis borrelia	0	1	0	0	1	0	0
Meningitis coxsackie viral	0	2	0	0	2	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Meningitis cryptococcal	1	1	0	0	1	0	0
Meningitis meningococcal	0	1	0	0	1	0	0
Meningitis pneumococcal	0	2	0	0	2	0	0
Meningitis tuberculous	0	2	0	0	2	0	0
Meningitis viral	3	34	0	0	34	0	0
Meningococcal bacteraemia	1	1	0	0	1	0	0
Meningococcal sepsis	0	0	0	2	2	0	0
Meningoencephalitis bacterial	0	1	0	0	1	0	0
Meningoencephalitis herpes simplex neonatal	0	1	0	0	1	0	0
Meningoencephalitis herpetic	0	3	0	0	3	0	0
Meningoencephalitis viral	0	5	0	0	5	0	0
Molluscum contagiosum	0	1	0	0	1	0	0
Mononucleosis syndrome	0	1	0	0	1	0	0
Mucormycosis	0	1	0	0	1	0	0
Mumps	0	9	0	8	17	0	0
Muscle abscess	0	3	0	3	6	0	0
Mycoplasma infection	0	1	0	2	3	0	0
Myelitis	6	106	2	19	125	1	1
Myocarditis infectious	0	1	0	0	1	0	0
Myringitis	0	1	0	0	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Nail bed infection	1	1	1	3	4	0	0
Nasal abscess	0	1	0	1	2	0	0
Nasal herpes	1	14	3	36	50	0	0
Nasal vestibulitis	0	1	0	7	8	0	0
Nasopharyngitis	54	1604	514	5318	6922	0	0
Necrotising fasciitis	0	3	0	0	3	0	0
Necrotising soft tissue infection	0	1	0	0	1	0	0
Necrotising ulcerative periodontitis	0	0	0	1	1	0	0
Nematodiasis	0	0	0	1	1	0	0
Neonatal pneumonia	0	0	0	0	0	1	3
Neuroborreliosis	2	3	0	0	3	0	0
Neurological infection	0	3	1	1	4	0	0
Neurosyphilis	0	2	0	2	4	0	0
Neutropenic sepsis	1	13	0	0	13	0	0
Nipple infection	0	0	1	1	1	0	0
Norovirus infection	0	1	0	0	1	0	0
Nosocomial infection	0	3	0	0	3	0	0
Oesophageal infection	0	0	0	2	2	0	0
Omphalitis	0	1	0	1	2	0	1
Onychomycosis	0	0	1	3	3	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Ophthalmic herpes simplex	0	3	0	3	6	0	0
Ophthalmic herpes zoster	7	102	0	0	102	0	0
Oral bacterial infection	0	1	0	0	1	0	0
Oral candidiasis	2	58	2	31	89	0	0
Oral fungal infection	0	1	0	6	7	0	0
Oral herpes	9	490	55	878	1368	0	0
Oral infection	0	2	0	5	7	0	0
Oral pustule	0	3	0	4	7	0	0
Orchitis	1	8	1	6	14	0	0
Osteomyelitis	1	11	0	0	11	0	0
Osteomyelitis acute	0	0	0	1	1	0	0
Otitis externa	0	5	1	17	22	0	0
Otitis externa bacterial	0	1	0	0	1	0	0
Otitis media	0	13	0	16	29	0	0
Otitis media acute	0	1	0	1	2	0	0
Otitis media chronic	0	9	0	6	15	0	0
Otosalpingitis	0	0	0	2	2	0	0
Ovarian abscess	0	3	0	0	3	0	0
Overgrowth bacterial	1	1	0	0	1	0	0
Overgrowth fungal	0	0	0	1	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Pancreas infection	0	2	1	1	3	0	0
Papilloma viral infection	0	2	0	3	5	0	0
Paragonimiasis	0	1	0	0	1	0	0
Parainfluenzae viral laryngotracheobronchitis	0	0	0	1	1	0	0
Parainfluenzae virus infection	0	1	0	1	2	0	0
Paratyphoid fever	0	1	3	4	5	0	0
Paravaccinia	0	1	0	0	1	0	0
Paronychia	0	0	0	3	3	0	0
Parotitis	0	6	2	35	41	0	0
Parvovirus B19 infection	0	1	0	0	1	0	0
Pathogen resistance	0	2	0	1	3	0	0
Pelvic abscess	0	1	0	0	1	0	0
Pelvic infection	1	2	0	1	3	0	0
Pelvic inflammatory disease	0	6	0	2	8	0	0
Pelvic sepsis	0	1	0	0	1	0	0
Perichondritis	0	1	0	2	3	0	0
Pericoronitis	0	3	0	1	4	0	0
Periodontitis	0	2	2	5	7	0	0
Periorbital cellulitis	0	4	0	2	6	0	0
Periorbital infection	1	1	0	0	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Peritonitis	1	23	0	0	23	0	0
Peritonitis bacterial	0	1	0	0	1	0	0
Peritonsillar abscess	0	3	0	0	3	0	0
Peritonsillitis	0	1	0	0	1	0	0
Persistent generalised lymphadenopathy	0	1	0	1	2	0	0
Pertussis	1	3	0	5	8	0	0
Pharyngeal abscess	0	1	0	6	7	0	0
Pharyngitis	2	51	13	179	230	0	0
Pharyngitis bacterial	0	0	0	1	1	0	0
Pharyngitis streptococcal	2	9	0	3	12	0	0
Pharyngotonsillitis	0	0	0	1	1	0	0
Pilonidal disease	0	2	0	0	2	0	0
Pinta	0	1	0	1	2	0	0
Plasmodium vivax infection	1	2	0	0	2	0	0
Pleural infection	0	1	0	0	1	0	0
Pleurisy viral	0	2	0	1	3	0	0
Pneumococcal sepsis	0	1	0	0	1	0	0
Pneumocystis jirovecii infection	1	1	0	0	1	0	0
Pneumocystis jirovecii pneumonia	2	4	0	0	4	0	0
Pneumonia	86	776	9	190	966	5	6

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Pneumonia adenoviral	0	1	0	0	1	0	0
Pneumonia aspiration	6	69	0	0	69	0	0
Pneumonia bacterial	1	18	0	3	21	0	1
Pneumonia fungal	1	2	0	0	2	0	0
Pneumonia klebsiella	1	2	0	0	2	0	0
Pneumonia legionella	0	2	0	0	2	0	0
Pneumonia pneumococcal	0	1	0	0	1	0	0
Pneumonia pseudomonal	0	1	0	0	1	0	0
Pneumonia staphylococcal	0	2	0	1	3	0	0
Pneumonia viral	2	29	0	1	30	0	0
Poliomyelitis	1	1	0	0	1	0	0
Post procedural cellulitis	0	0	0	1	1	0	0
Post procedural infection	0	2	0	1	3	0	0
Post procedural sepsis	0	1	0	0	1	0	0
Post viral fatigue syndrome	17	174	8	54	228	0	0
Post-acute COVID-19 syndrome	19	41	12	34	75	0	0
Postoperative abscess	0	1	0	0	1	0	0
Postoperative wound infection	0	0	0	1	1	0	0
Prion disease	0	2	0	0	2	0	0
Progressive multifocal leukoencephalopathy	0	2	0	0	2	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Prostate infection	0	0	0	1	1	0	0
Prostatitis gonococcal	0	1	0	0	1	0	0
Pseudomembranous colitis	0	0	0	2	2	0	0
Pseudomonas infection	0	1	0	1	2	0	0
Pulmonary mucormycosis	0	1	0	0	1	0	0
Pulmonary sepsis	0	2	0	0	2	0	0
Pulmonary tuberculosis	1	6	0	2	8	0	0
Pulpitis dental	0	1	2	22	23	0	0
Puncture site infection	0	0	0	2	2	0	0
Purulence	0	0	0	2	2	0	0
Purulent discharge	1	3	2	5	8	0	0
Pustule	0	23	5	89	112	0	0
Pyelitis	0	2	0	0	2	0	0
Pyelonephritis	3	32	3	15	47	0	0
Pyelonephritis acute	2	7	0	3	10	0	0
Pyelonephritis chronic	0	1	0	1	2	0	0
Pyoderma	0	0	0	1	1	0	0
Pyometra	1	2	0	0	2	0	0
Pyonephrosis	1	1	0	0	1	0	0
Pyuria	0	1	0	1	2	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Q fever	0	102	0	45	147	0	0
Rash pustular	0	16	5	50	66	0	0
Rectal abscess	0	0	0	1	1	0	0
Relapsing fever	0	2	0	3	5	0	0
Renal abscess	2	4	0	0	4	0	0
Respiratory syncytial virus bronchitis	0	0	0	1	1	0	0
Respiratory syncytial virus infection	0	1	0	1	2	0	0
Respiratory tract infection	2	22	8	33	55	0	0
Retinitis	1	2	0	4	6	0	0
Retinitis viral	0	1	0	0	1	0	0
Rhinitis	7	108	309	3387	3495	0	0
Rhinovirus infection	0	1	0	2	3	0	0
Root canal infection	1	1	0	1	2	0	0
Roseola	0	1	0	0	1	0	0
Rotavirus infection	0	1	0	0	1	0	0
Rubella	0	0	0	1	1	0	0
SARS-CoV-2 carrier	0	2	0	1	3	0	0
SARS-CoV-2 sepsis	1	1	0	1	2	0	0
Salmonellosis	1	1	0	3	4	0	0
Scarlet fever	0	1	2	2	3	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Scrotal infection	0	0	0	1	1	0	0
Secondary transmission	0	8	0	10	18	0	0
Sepsis	23	289	0	0	289	3	4
Sepsis neonatal	0	0	0	0	0	1	2
Sepsis syndrome	0	4	0	0	4	0	0
Septic arthritis staphylococcal	1	1	0	0	1	0	0
Septic embolus	0	1	0	0	1	0	0
Septic encephalopathy	0	2	0	0	2	0	0
Septic pulmonary embolism	0	1	0	0	1	0	0
Septic rash	2	9	0	5	14	0	0
Septic shock	11	63	0	0	63	0	0
Severe acute respiratory syndrome	15	182	0	0	182	0	0
Severe asthma with fungal sensitisation	0	5	0	0	5	0	0
Severe fever with thrombocytopenia syndrome	0	9	0	1	10	0	0
Shigella infection	0	0	0	1	1	0	0
Sialoadenitis	0	8	0	1	9	0	0
Sinobronchitis	0	2	0	0	2	0	0
Sinusitis	16	374	40	353	727	0	0
Sinusitis bacterial	0	0	0	1	1	0	0
Skin bacterial infection	0	6	0	3	9	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Skin candida	0	3	0	1	4	0	0
Skin infection	1	46	0	47	93	0	0
Slow virus infection	0	0	0	1	1	0	0
Small intestine gangrene	0	1	0	0	1	0	0
Soft tissue infection	0	4	0	3	7	0	0
Spinal cord abscess	0	0	0	1	1	0	0
Spinal cord infection	2	5	0	1	6	0	0
Splenic abscess	0	1	0	0	1	0	0
Splenic infection	0	1	0	0	1	0	0
Spontaneous bacterial peritonitis	0	2	0	0	2	0	0
Sporotrichosis	1	1	0	0	1	0	0
Sputum purulent	0	2	1	3	5	0	0
Staphylococcal abscess	0	1	0	0	1	0	0
Staphylococcal bacteraemia	0	5	0	0	5	0	0
Staphylococcal infection	4	12	1	7	19	0	0
Staphylococcal scalded skin syndrome	0	1	0	1	2	0	0
Staphylococcal sepsis	0	10	0	0	10	0	0
Stenotrophomonas infection	0	1	0	0	1	0	0
Streptococcal abscess	0	1	0	0	1	0	0
Streptococcal bacteraemia	0	1	0	0	1	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Streptococcal infection	1	7	0	1	8	0	0
Streptococcal sepsis	0	3	0	0	3	0	0
Subcutaneous abscess	1	12	2	30	42	0	0
Superinfection	0	1	0	0	1	0	0
Superinfection bacterial	0	0	0	1	1	0	0
Suspected COVID-19	29	99	10	184	283	0	0
Sweating fever	2	636	6	158	794	0	0
Syphilis	0	4	1	4	8	0	0
Systemic candida	0	1	0	0	1	0	0
Systemic infection	1	3	0	0	3	0	0
Systemic mycosis	0	2	0	0	2	0	0
Tetanus	1	6	0	2	8	0	0
Tinea capitis	0	0	1	1	1	0	0
Tinea cruris	0	0	0	3	3	0	0
Tinea infection	0	1	1	5	6	0	0
Tinea pedis	0	3	1	9	12	0	0
Tinea versicolour	0	2	1	3	5	0	0
Tongue abscess	0	3	0	2	5	0	0
Tongue fungal infection	0	0	0	3	3	0	0
Tonsillitis	2	81	5	77	158	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Tonsillitis bacterial	0	4	0	0	4	0	0
Tonsillitis fungal	0	1	0	0	1	0	0
Tonsillitis streptococcal	0	0	1	2	2	0	0
Tooth abscess	1	13	2	17	30	0	0
Tooth infection	5	18	1	11	29	0	0
Toxic shock syndrome	1	3	0	0	3	0	0
Toxic shock syndrome staphylococcal	0	0	0	1	1	0	0
Toxoplasmosis	0	1	0	2	3	0	0
Tracheitis	0	3	0	12	15	0	0
Trombidiasis	0	3	0	0	3	0	0
Tuberculosis	0	4	3	21	25	0	0
Type 1 lepra reaction	0	0	4	4	4	0	0
Type 2 lepra reaction	1	4	2	3	7	0	0
Typhoid fever	0	4	0	16	20	0	0
Typhus	0	0	0	1	1	0	0
Upper respiratory tract infection	2	25	4	39	64	0	0
Ureteritis	0	0	0	1	1	0	0
Urethritis	0	1	0	1	2	0	0
Urinary tract infection	17	325	18	264	589	0	0
Urinary tract infection bacterial	0	5	0	3	8	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Urosepsis	1	25	0	0	25	0	0
Vaccination site abscess	1	11	18	51	62	0	0
Vaccination site cellulitis	0	14	2	30	44	0	0
Vaccination site infection	0	28	9	35	63	0	0
Vaccination site joint infection	0	1	0	0	1	0	0
Vaccination site pustule	0	4	0	4	8	0	0
Vaccine breakthrough infection	0	6	3	14	20	0	0
Vaccine derived SARS-CoV-2 infection	0	1	0	0	1	0	0
Vaccine virus shedding	0	0	0	1	1	0	0
Vaccinia virus infection	0	1	0	1	2	0	0
Vaginal abscess	1	5	0	1	6	0	0
Vaginal infection	1	4	2	14	18	0	0
Varicella	3	34	0	28	62	0	0
Varicella meningitis	1	1	0	0	1	0	0
Varicella zoster virus infection	0	12	2	11	23	0	0
Vestibular neuronitis	2	98	1	38	136	1	3
Vestibulitis	0	3	0	1	4	0	0
Viraemia	0	2	0	2	4	0	0
Viral diarrhoea	0	4	0	2	6	0	0
Viral infection	0	91	4	46	137	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Viral labyrinthitis	0	7	0	1	8	0	0
Viral myelitis	0	1	0	0	1	0	0
Viral myocarditis	1	8	0	0	8	0	0
Viral myositis	0	1	0	0	1	0	0
Viral pericarditis	1	6	0	0	6	0	0
Viral pharyngitis	0	24	2	16	40	0	0
Viral rash	0	50	2	46	96	0	0
Viral sepsis	0	1	0	0	1	0	0
Viral sinusitis	0	1	0	0	1	0	0
Viral tonsillitis	0	1	0	0	1	0	0
Viral upper respiratory tract infection	0	1	1	2	3	0	0
Viral uveitis	0	0	0	2	2	0	0
Vulval abscess	0	1	0	0	1	0	0
Vulvitis	0	0	0	1	1	0	0
Vulvovaginal candidiasis	2	36	1	43	79	0	0
Vulvovaginal mycotic infection	0	2	2	21	23	0	0
Vulvovaginitis	0	0	0	1	1	0	0
Vulvovaginitis staphylococcal	0	1	0	0	1	0	0
Wound abscess	0	0	0	1	1	0	0
Wound infection	2	5	4	6	11	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Wound infection staphylococcal	0	1	0	0	1	0	0
Wound sepsis	1	2	0	0	2	0	0
Yaws of skin	0	0	0	2	2	0	0
Yellow fever	0	0	0	2	2	0	0
Yellow fever vaccine-associated neurotropic disease	0	1	0	0	1	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**121**	**983**	**21**	**214**	**1197**	**4**	**4**
5q minus syndrome	1	7	0	0	7	0	0
Acoustic neuroma	2	9	1	2	11	0	0
Acral lentiginous melanoma stage III	0	1	0	0	1	0	0
Acrochordon	1	4	0	4	8	0	0
Acute leukaemia	3	11	0	0	11	0	0
Acute lymphocytic leukaemia	0	3	0	0	3	0	0
Acute lymphocytic leukaemia recurrent	0	1	0	0	1	0	0
Acute myeloid leukaemia	2	13	0	0	13	1	1
Acute myeloid leukaemia recurrent	0	1	0	0	1	0	0
Acute promyelocytic leukaemia	1	2	0	0	2	0	0
Adenocarcinoma	0	5	0	0	5	0	0
Adenocarcinoma of colon	1	1	0	0	1	0	0
Adenoma benign	0	1	0	1	2	0	0
Adrenal adenoma	0	1	0	0	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Adrenal gland cancer	1	2	0	0	2	0	0
Adrenal neoplasm	0	1	0	0	1	0	0
Anal cancer	0	2	0	0	2	0	0
Angiosarcoma	1	1	0	0	1	0	0
Anogenital warts	1	2	0	6	8	0	0
B-cell lymphoma	0	6	0	0	6	0	0
B-cell lymphoma stage II	0	1	0	0	1	0	0
B-cell lymphoma stage IV	0	1	0	0	1	0	0
Basal cell carcinoma	3	9	0	0	9	0	0
Benign breast neoplasm	0	4	0	2	6	0	0
Benign ear neoplasm	0	0	0	1	1	0	0
Benign hydatidiform mole	0	2	0	0	2	0	0
Benign lymph node neoplasm	0	0	0	1	1	0	0
Benign neoplasm of thyroid gland	1	2	0	0	2	0	0
Benign ovarian tumour	0	0	0	1	1	0	0
Benign soft tissue neoplasm	0	0	0	1	1	0	0
Benign spleen tumour	1	1	0	0	1	0	0
Bile duct cancer	0	1	0	0	1	0	0
Bladder cancer	1	8	0	0	8	0	0
Bladder cancer recurrent	0	1	0	0	1	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Bladder neoplasm	0	2	0	0	2	0	0
Bone cancer	0	2	0	0	2	0	0
Bowen's disease	0	1	0	0	1	0	0
Brain cancer metastatic	0	2	0	0	2	0	0
Brain neoplasm	4	23	0	0	23	0	0
Brain neoplasm malignant	0	3	0	0	3	0	0
Breast cancer	7	77	0	0	77	1	1
Breast cancer female	2	6	0	0	6	0	0
Breast cancer in situ	0	1	0	0	1	0	0
Breast cancer male	0	4	0	0	4	0	0
Breast cancer metastatic	1	5	0	0	5	0	0
Breast cancer stage I	0	1	0	0	1	0	0
Breast cancer stage III	0	3	0	0	3	0	0
Breast cancer stage IV	0	1	0	0	1	0	0
Breast neoplasm	0	2	0	0	2	0	0
Bronchial carcinoma	0	4	0	0	4	0	0
Burkitt's lymphoma stage II	0	1	0	0	1	0	0
Cancer fatigue	0	3	0	1	4	0	0
Cancer pain	0	2	0	0	2	0	0
Carcinoid tumour of the liver	1	1	0	0	1	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Cartilage neoplasm	0	0	1	1	1	0	0
Central nervous system lymphoma	0	2	0	0	2	0	0
Cerebellar haemangioma	0	1	0	0	1	0	0
Cerebral haemangioma	0	1	0	0	1	0	0
Cervix carcinoma	0	3	0	0	3	0	0
Cervix carcinoma stage 0	0	1	0	0	1	0	0
Cervix warts	0	1	0	0	1	0	0
Cholangiocarcinoma	1	3	0	0	3	0	0
Cholangiosarcoma	0	1	0	0	1	0	0
Cholesterol granuloma	0	1	0	0	1	0	0
Chronic leukaemia	0	1	0	0	1	0	0
Chronic lymphocytic leukaemia	0	13	0	0	13	0	0
Chronic myeloid leukaemia	2	6	0	0	6	0	0
Clear cell endometrial carcinoma	0	1	0	0	1	0	0
Clear cell renal cell carcinoma	0	5	0	0	5	0	0
Colon cancer	3	10	0	0	10	0	0
Colon cancer metastatic	1	1	0	0	1	0	0
Colon cancer stage I	1	1	0	0	1	0	0
Colon cancer stage III	0	1	0	0	1	0	0
Colon neoplasm	0	1	0	0	1	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Colorectal cancer	0	3	0	0	3	0	0
Cutaneous T-cell lymphoma	0	2	0	0	2	0	0
Cutaneous T-cell lymphoma recurrent	0	2	0	0	2	0	0
Cutaneous lymphoma	0	1	0	0	1	0	0
Dedifferentiated liposarcoma	0	1	0	0	1	0	0
Diffuse large B-cell lymphoma	0	3	0	0	3	0	0
Diffuse large B-cell lymphoma stage III	0	1	0	0	1	0	0
Diffuse large B-cell lymphoma stage IV	0	1	0	0	1	0	0
Endometrial adenocarcinoma	0	1	0	0	1	0	0
Endometrial cancer	0	4	0	0	4	0	0
Epstein Barr virus positive mucocutaneous ulcer	0	1	0	1	2	0	0
Essential thrombocythaemia	1	3	0	1	4	0	0
Extranodal marginal zone B-cell lymphoma (MALT type)	0	1	0	0	1	0	0
Eye naevus	0	4	0	0	4	0	0
Eyelid tumour	0	0	0	1	1	0	0
Fibroadenoma of breast	0	2	1	1	3	0	0
Fibroma	0	1	0	1	2	0	0
Focal nodular hyperplasia	0	1	0	0	1	0	0
Follicular lymphoma	0	5	0	0	5	0	0
Gammopathy	0	0	2	2	2	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Gastric cancer	0	4	0	0	4	0	0
Gastrointestinal carcinoma	1	11	0	0	11	0	0
Gastrointestinal lymphoma	1	1	0	0	1	0	0
Gastrointestinal stromal tumour	0	1	0	0	1	0	0
Gastrointestinal tract adenoma	0	1	0	0	1	0	0
Glioblastoma	0	9	0	0	9	0	0
Glioblastoma multiforme	0	1	0	0	1	0	0
Glioma	0	1	0	0	1	0	0
Glomus tumour	0	1	0	0	1	0	0
Good syndrome	0	0	0	4	4	0	0
Haemangioma	0	14	2	26	40	1	1
Haemangioma of liver	0	3	2	3	6	0	0
Haemangioma of skin	0	9	0	22	31	0	0
Haemangioma rupture	0	1	0	0	1	0	0
Haematological malignancy	0	4	0	0	4	0	0
Hairy cell leukaemia	0	1	0	0	1	0	0
Heavy chain disease	0	2	0	1	3	0	0
Hepatic cancer	0	2	0	0	2	0	0
Hepatic haemangioma rupture	0	1	0	0	1	0	0
Hepatic neoplasm	0	3	0	0	3	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Hepatoblastoma	0	2	0	0	2	0	0
Hepatocellular carcinoma	0	4	0	0	4	0	0
High-grade B-cell lymphoma	0	1	0	0	1	0	0
Histiocytic necrotising lymphadenitis	0	1	1	2	3	0	0
Hodgkin's disease	0	4	0	0	4	0	0
Hodgkin's disease mixed cellularity stage III	0	1	0	0	1	0	0
Huerthle cell carcinoma	0	1	0	0	1	0	0
Hypergammaglobulinaemia benign monoclonal	0	4	0	3	7	0	0
Inflammatory carcinoma of breast stage III	0	1	0	0	1	0	0
Inflammatory pseudotumour	0	1	0	0	1	0	0
Intracranial tumour haemorrhage	0	1	0	0	1	0	0
Intraductal proliferative breast lesion	0	2	0	0	2	0	0
Invasive ductal breast carcinoma	0	2	0	0	2	0	0
Kaposi's sarcoma	2	2	0	0	2	0	0
Keratinising squamous cell carcinoma of nasopharynx	0	1	0	0	1	0	0
Knuckle pads	0	0	0	1	1	0	0
Langerhans' cell histiocytosis	0	1	0	0	1	0	0
Leiomyoma	0	2	2	4	6	0	0
Leiomyosarcoma	1	1	0	0	1	0	0
Leukaemia	3	11	0	0	11	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Leukaemia recurrent	0	1	0	0	1	0	0
Lip and/or oral cavity cancer	0	1	0	0	1	0	0
Lip and/or oral cavity cancer stage I	0	1	0	0	1	0	0
Lip neoplasm malignant stage unspecified	0	1	0	0	1	0	0
Lip squamous cell carcinoma	0	2	0	0	2	0	0
Lipoma	2	14	0	12	26	0	0
Liposarcoma	1	4	0	0	4	0	0
Liposarcoma metastatic	1	1	0	0	1	0	0
Lung adenocarcinoma	1	3	0	0	3	0	0
Lung adenocarcinoma stage IV	0	1	0	0	1	0	0
Lung cancer metastatic	0	3	0	0	3	0	0
Lung neoplasm	0	4	0	0	4	0	0
Lung neoplasm malignant	0	34	0	0	34	0	0
Lymphoma	5	44	0	0	44	0	0
Lymphoplasmacytoid lymphoma/immunocytoma	0	1	0	0	1	0	0
Lymphoproliferative disorder	0	1	0	1	2	0	0
Lymphoproliferative disorder in remission	0	1	0	0	1	0	0
Malignant melanoma	2	13	0	0	13	0	0
Malignant melanoma in situ	0	3	0	0	3	0	0
Malignant neoplasm of spinal cord	0	1	0	0	1	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Malignant neoplasm progression	3	8	0	0	8	0	0
Maxillofacial sinus neoplasm	0	1	0	0	1	0	0
Melanocytic naevus	2	5	1	14	19	0	0
Melanoma recurrent	0	1	0	0	1	0	0
Meningeal neoplasm	0	1	0	0	1	0	0
Meningioma	1	9	0	1	10	0	0
Mesothelioma	0	0	0	1	1	0	0
Metastases to bone	0	3	0	0	3	0	0
Metastases to central nervous system	0	4	0	0	4	0	0
Metastases to liver	1	8	0	0	8	0	0
Metastases to lung	1	5	0	0	5	0	0
Metastases to lymph nodes	0	2	0	0	2	0	0
Metastases to meninges	0	1	0	0	1	0	0
Metastases to ovary	0	1	0	0	1	0	0
Metastases to spine	0	1	0	0	1	0	0
Metastasis	0	6	0	0	6	0	0
Metastatic malignant melanoma	0	1	0	0	1	0	0
Metastatic neoplasm	0	4	0	0	4	0	0
Metastatic renal cell carcinoma	0	1	0	0	1	0	0
Monoclonal gammopathy	0	2	1	3	5	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Multilocular cystic nephroma	0	0	1	1	1	0	0
Myelodysplastic syndrome	1	9	1	2	11	0	0
Myeloid leukaemia	1	2	0	0	2	0	0
Myeloproliferative neoplasm	1	5	0	0	5	0	0
Myxoma	0	0	1	1	1	0	0
Naevus haemorrhage	0	0	0	1	1	0	0
Nasal cavity cancer	1	3	0	0	3	0	0
Neoplasm	3	14	0	14	28	0	0
Neoplasm malignant	8	45	0	0	45	0	0
Neoplasm of appendix	0	1	0	0	1	0	0
Neoplasm progression	2	7	1	2	9	0	0
Neoplasm prostate	0	1	0	0	1	0	0
Neoplasm recurrence	0	9	0	0	9	0	0
Neoplasm skin	1	3	0	3	6	0	0
Neuroendocrine tumour	0	2	0	0	2	0	0
Neuroendocrine tumour of the lung metastatic	0	1	0	0	1	0	0
Neurogenic tumour	0	1	0	0	1	0	0
Neuroma	0	0	1	1	1	0	0
Non-Hodgkin's lymphoma	1	8	0	0	8	0	0
Oesophageal cancer metastatic	1	7	0	0	7	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Oesophageal carcinoma	0	4	0	0	4	0	0
Oesophageal neoplasm	0	1	0	0	1	0	0
Oesophageal squamous cell carcinoma	0	1	0	0	1	0	0
Oligodendroglioma	0	1	0	0	1	0	0
Oncologic complication	0	1	0	0	1	0	0
Oral haemangioma	0	0	0	1	1	0	0
Osteoma	1	3	0	0	3	0	0
Ovarian cancer	1	14	0	0	14	0	0
Ovarian cancer recurrent	0	2	0	0	2	0	0
Ovarian cancer stage IV	0	1	0	0	1	0	0
Paget's disease of nipple	0	1	0	0	1	0	0
Pancreatic carcinoma	2	12	0	0	12	0	0
Pancreatic carcinoma metastatic	0	2	0	0	2	0	0
Pancreatic carcinoma recurrent	0	1	0	0	1	0	0
Pancreatic neoplasm	1	2	0	0	2	0	0
Papillary cystadenoma lymphomatosum	0	1	0	0	1	0	0
Papillary thyroid cancer	1	1	0	0	1	0	0
Paraneoplastic syndrome	1	5	0	0	5	0	0
Paraproteinaemia	0	2	0	0	2	0	0
Parathyroid tumour	0	1	0	0	1	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Penile cancer	0	1	0	0	1	0	0
Pituitary tumour	0	1	0	1	2	0	0
Pituitary tumour benign	0	4	0	1	5	0	0
Plasma cell myeloma	3	12	0	0	12	0	0
Plasmacytoma	1	1	0	0	1	0	0
Pleomorphic leiomyosarcoma	0	1	0	0	1	0	0
Post transplant lymphoproliferative disorder	1	1	0	0	1	0	0
Primary mediastinal large B-cell lymphoma	0	1	0	0	1	0	0
Prolymphocytic leukaemia	0	1	0	0	1	0	0
Prostate cancer	2	16	0	0	16	1	1
Prostate cancer metastatic	0	1	0	0	1	0	0
Prostate cancer recurrent	1	2	0	0	2	0	0
Rectal adenocarcinoma	1	1	0	0	1	0	0
Rectal cancer	0	1	0	0	1	0	0
Rectosigmoid cancer metastatic	0	1	0	0	1	0	0
Recurrent cancer	1	4	0	0	4	0	0
Renal cancer	1	4	0	0	4	0	0
Renal cell carcinoma	0	1	0	0	1	0	0
Renal hamartoma	0	0	0	1	1	0	0
Renal lipoma	0	0	0	1	1	0	0

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	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Renal neoplasm	0	0	0	1	1	0	0
Retro-orbital neoplasm	0	0	0	1	1	0	0
Salivary gland cancer stage 0	0	1	0	0	1	0	0
Salivary gland cancer stage III	0	1	0	0	1	0	0
Salivary gland neoplasm	0	2	0	0	2	0	0
Sarcoma	1	1	0	0	1	0	0
Schwannoma	0	1	0	0	1	0	0
Seborrhoeic keratosis	1	2	0	2	4	0	0
Skin cancer	3	12	0	0	12	0	0
Skin papilloma	1	14	1	33	47	0	0
Small cell lung cancer	1	2	0	0	2	0	0
Small cell lung cancer metastatic	0	1	0	0	1	0	0
Spinal cord neoplasm	0	1	0	0	1	0	0
Spinal meningioma benign	0	1	0	0	1	0	0
Spindle cell sarcoma	0	2	0	0	2	0	0
Squamous cell carcinoma	1	9	0	0	9	0	0
Squamous cell carcinoma of skin	0	1	0	0	1	0	0
Squamous cell carcinoma of the oral cavity	0	2	0	0	2	0	0
Squamous cell carcinoma of the vulva	0	1	0	0	1	0	0
Synovial sarcoma	0	1	0	0	1	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Systemic mastocytosis	0	0	0	1	1	0	0
T-cell lymphoma	0	1	0	0	1	0	0
T-cell type acute leukaemia	1	1	0	0	1	0	0
Testicle adenoma	0	0	0	1	1	0	0
Throat cancer	0	3	0	0	3	0	0
Thyroid adenoma	0	0	0	1	1	0	0
Thyroid cancer	0	2	0	0	2	0	0
Thyroid neoplasm	0	0	0	2	2	0	0
Tongue neoplasm	0	1	0	0	1	0	0
Tongue neoplasm malignant stage unspecified	0	1	0	0	1	0	0
Tonsil cancer	0	5	0	0	5	0	0
Triple negative breast cancer	0	1	0	0	1	0	0
Tumour haemorrhage	0	5	0	0	5	0	0
Tumour inflammation	0	1	0	0	1	0	0
Tumour pain	0	1	1	3	4	0	0
Tumour perforation	0	1	0	0	1	0	0
Uterine cancer	1	6	0	0	6	0	0
Uterine leiomyoma	1	19	0	13	32	0	0
Vulval cancer	0	1	0	0	1	0	0
Waldenstrom's macroglobulinaemia	0	1	0	0	1	0	0

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	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Blood and lymphatic system disorders	**596**	**11309**	**1259**	**9083**	**20392**	**113**	**189**
Abdominal lymphadenopathy	0	1	0	3	4	0	0
Abnormal clotting factor	0	8	0	7	15	0	0
Acquired haemophilia	7	15	1	1	16	0	0
Agranulocytosis	1	15	0	0	15	0	0
Anaemia	30	321	12	99	420	0	3
Anaemia folate deficiency	0	3	1	1	4	0	0
Anaemia macrocytic	0	2	0	0	2	0	0
Anaemia of chronic disease	0	1	0	0	1	0	0
Anaemia vitamin B12 deficiency	1	12	0	3	15	0	0
Anisocytosis	0	4	0	3	7	0	0
Antiphospholipid syndrome	2	35	0	7	42	0	0
Aplasia pure red cell	0	1	0	0	1	0	0
Aplastic anaemia	6	22	0	0	22	0	0
Atypical haemolytic uraemic syndrome	4	11	0	1	12	0	0
Autoimmune anaemia	1	4	0	0	4	0	0
Autoimmune haemolytic anaemia	7	33	0	0	33	0	0
Autoimmune heparin-induced thrombocytopenia	0	1	0	0	1	0	0
Autoimmune neutropenia	0	3	0	0	3	0	0
B-cell aplasia	0	0	1	1	1	0	0

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	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Bicytopenia	0	2	0	2	4	0	0
Blood disorder	4	22	3	21	43	0	0
Blood loss anaemia	0	9	0	5	14	0	1
Bone marrow disorder	0	2	0	4	6	0	0
Bone marrow failure	0	1	0	0	1	0	0
Bone marrow ischaemia	0	1	0	0	1	0	0
Bone marrow oedema	1	5	1	4	9	0	0
Coagulopathy	12	259	10	134	393	0	0
Cold type haemolytic anaemia	0	3	0	0	3	0	0
Coombs negative haemolytic anaemia	0	2	0	0	2	0	0
Coombs positive haemolytic anaemia	0	2	0	0	2	0	0
Cytopenia	0	2	0	0	2	0	0
Deficiency anaemia	1	4	0	1	5	0	0
Dermatopathic lymphadenopathy	0	0	0	2	2	0	0
Disseminated intravascular coagulation	5	89	0	0	89	0	0
Eosinopenia	0	0	0	1	1	0	0
Eosinophilia	0	20	0	18	38	0	0
Eosinophilia myalgia syndrome	0	0	0	1	1	0	0
Evans syndrome	1	5	0	0	5	0	0
Febrile bone marrow aplasia	0	2	0	0	2	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Febrile neutropenia	0	3	0	0	3	0	0
Haemoconcentration	1	1	1	1	2	0	0
Haemoglobinaemia	0	0	0	2	2	0	0
Haemolysis	0	22	0	7	29	0	0
Haemolytic anaemia	0	33	0	0	33	0	0
Haemolytic uraemic syndrome	0	6	0	0	6	0	0
Haemorrhagic diathesis	5	19	1	17	36	0	0
Haemorrhagic disorder	0	3	0	11	14	0	0
Heparin-induced thrombocytopenia	1	38	0	3	41	0	0
Hilar lymphadenopathy	0	1	0	2	3	0	0
Hypercoagulation	2	45	0	15	60	0	3
Hypereosinophilic syndrome	0	1	0	0	1	0	0
Hyperfibrinogenaemia	0	3	0	0	3	0	0
Hyperfibrinolysis	0	1	0	0	1	0	0
Hypergammaglobulinaemia	0	0	1	1	1	0	0
Hyperleukocytosis	0	3	0	0	3	0	0
Hypochromic anaemia	0	4	0	0	4	0	0
Hypocoagulable state	0	3	0	0	3	0	0
Hypofibrinogenaemia	0	15	0	0	15	0	0
Immune thrombocytopenia	39	775	0	0	775	17	39

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Increased tendency to bruise	5	122	14	155	277	0	0
Iron deficiency anaemia	4	24	2	16	40	0	1
Leukocytosis	0	19	2	17	36	0	0
Leukopenia	6	60	2	32	92	0	0
Lymph node calcification	0	0	1	2	2	0	0
Lymph node fibrosis	0	1	0	0	1	0	0
Lymph node haemorrhage	0	1	0	0	1	0	0
Lymph node pain	29	498	314	898	1396	0	0
Lymphadenitis	3	61	46	259	320	0	0
Lymphadenopathy	89	4055	812	6939	10994	0	6
Lymphadenopathy mediastinal	1	4	2	3	7	0	0
Lymphatic disorder	0	3	2	5	8	0	0
Lymphatic insufficiency	0	1	0	0	1	0	0
Lymphatic obstruction	0	0	0	2	2	0	0
Lymphocytic infiltration	0	1	0	1	2	0	0
Lymphocytosis	0	11	1	8	19	0	0
Lymphoid tissue hyperplasia	0	2	0	0	2	0	0
Lymphopenia	2	33	2	25	58	0	0
Macrocytosis	0	3	0	2	5	0	0
Mast cell activation syndrome	16	37	2	3	40	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Mastocytosis	2	9	0	0	9	0	0
Methaemoglobinaemia	0	1	0	0	1	0	0
Microangiopathic haemolytic anaemia	1	5	0	0	5	0	0
Microcytic anaemia	0	5	0	1	6	0	0
Microcytosis	0	0	1	2	2	0	0
Monoclonal B-cell lymphocytosis	0	0	0	1	1	0	0
Monocytopenia	0	0	0	1	1	0	0
Monocytosis	0	2	1	3	5	0	0
Myeloid maturation arrest	0	0	0	1	1	0	0
Myelosuppression	0	5	0	0	5	0	0
Necrotic lymphadenopathy	0	2	0	2	4	0	0
Nephrogenic anaemia	0	0	0	1	1	0	0
Neutropenia	5	102	0	62	164	0	0
Neutrophilia	1	16	0	7	23	0	0
Normochromic anaemia	0	1	0	1	2	0	0
Normochromic normocytic anaemia	0	2	0	0	2	0	0
Normocytic anaemia	0	9	0	1	10	0	0
Pancytopenia	2	55	0	0	55	0	0
Paratracheal lymphadenopathy	0	0	0	2	2	0	0
Pernicious anaemia	0	7	0	0	7	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Platelet anisocytosis	1	6	0	0	6	0	0
Platelet destruction increased	0	0	0	1	1	0	0
Platelet disorder	1	22	2	22	44	0	0
Platelet production decreased	0	0	0	1	1	0	0
Poikilocytosis	0	0	0	2	2	0	0
Polychromasia	0	4	0	0	4	0	0
Polyclonal B-cell lymphocytosis	0	0	0	1	1	0	0
Polycythaemia	4	14	0	7	21	0	0
Pseudolymphoma	0	4	0	0	4	0	0
Purpura non-thrombocytopenic	1	7	0	3	10	0	0
Red blood cell abnormality	1	2	2	7	9	0	0
Red blood cell agglutination	0	1	0	0	1	0	0
Red cell fragmentation syndrome	0	1	0	0	1	0	0
Reticulocytosis	0	1	0	0	1	0	0
Rouleaux formation	0	1	1	1	2	0	0
Schistocytosis	0	1	0	0	1	0	0
Secondary thrombocytosis	0	0	0	1	1	0	0
Sickle cell anaemia with crisis	0	15	0	0	15	0	0
Spleen congestion	0	1	0	0	1	0	0
Spleen disorder	1	4	0	1	5	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Splenic artery thrombosis	1	14	0	2	16	0	0
Splenic cyst	0	1	1	1	2	0	0
Splenic embolism	0	2	0	0	2	0	0
Splenic haemorrhage	1	3	0	0	3	0	0
Splenic infarction	2	62	0	0	62	0	0
Splenic thrombosis	0	12	0	3	15	0	0
Splenic varices	0	1	0	1	2	0	0
Splenic vein occlusion	0	1	0	0	1	0	0
Splenic vein thrombosis	3	61	0	3	64	2	2
Splenitis	0	1	0	0	1	0	0
Splenomegaly	3	27	2	15	42	0	0
Splenorenal shunt	0	1	0	0	1	0	0
Spontaneous haematoma	0	37	8	122	159	0	0
Spontaneous haemorrhage	1	5	1	5	10	0	0
Spontaneous heparin-induced thrombocytopenia syndrome	0	4	0	1	5	0	0
Stress polycythaemia	0	2	0	1	3	1	1
Subcapsular splenic haematoma	0	1	0	0	1	0	0
Thrombasthenia	0	0	0	1	1	0	0
Thrombocytopenia	111	3368	0	0	3368	6	21
Thrombocytopenic purpura	2	36	1	8	44	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Thrombocytosis	3	38	5	28	66	0	0
Thrombosis with thrombocytopenia syndrome	159	427	0	0	427	85	109
Thrombotic microangiopathy	0	9	0	1	10	0	1
Thrombotic thrombocytopenic purpura	3	47	0	0	47	2	2
Thymus disorder	0	0	0	1	1	0	0
Warm autoimmune haemolytic anaemia	0	3	0	3	6	0	0
White blood cell disorder	1	7	0	10	17	0	0
Immune system disorders	**243**	**4715**	**712**	**5897**	**10612**	**16**	**26**
ASIA syndrome	1	2	0	0	2	0	0
Allergic oedema	0	20	0	10	30	0	0
Allergic reaction to excipient	0	2	0	3	5	0	0
Allergy to animal	1	3	0	0	3	0	0
Allergy to arthropod bite	1	3	5	7	10	0	0
Allergy to arthropod sting	0	4	0	8	12	0	0
Allergy to chemicals	1	8	0	5	13	0	0
Allergy to metals	0	0	0	2	2	0	0
Allergy to plants	0	0	0	2	2	0	0
Allergy to sting	0	0	0	1	1	0	0
Allergy to vaccine	2	58	8	80	138	1	1
Allergy to venom	0	1	0	0	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Amyloidosis	0	1	0	1	2	0	0
Anaphylactic reaction	48	1478	0	0	1478	6	9
Anaphylactic shock	12	302	0	0	302	1	1
Anaphylactoid reaction	2	88	0	0	88	0	0
Anaphylactoid shock	1	7	0	0	7	0	0
Anti-neutrophil cytoplasmic antibody positive vasculitis	2	15	0	0	15	0	0
Atopy	1	6	2	5	11	0	0
Autoimmune disorder	18	143	9	37	180	0	0
Autoinflammatory disease	1	6	0	0	6	0	0
Bacille Calmette-Guerin scar reactivation	1	12	1	51	63	0	0
Chronic allograft nephropathy	0	1	0	0	1	0	0
Contrast media reaction	1	3	0	3	6	0	0
Corneal graft rejection	0	9	1	4	13	0	1
Cross sensitivity reaction	0	1	0	0	1	0	0
Cytokine release syndrome	0	3	0	0	3	0	0
Cytokine storm	0	12	0	0	12	0	0
Decreased immune responsiveness	1	9	3	16	25	0	0
Drug hypersensitivity	13	71	4	48	119	0	1
Dust allergy	0	2	0	1	3	0	0
Eosinophilic granulomatosis with polyangiitis	0	6	0	0	6	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Food allergy	4	57	2	39	96	0	0
Graft versus host disease	0	1	0	0	1	0	0
Haemophagocytic lymphohistiocytosis	5	45	0	0	45	0	0
Hashitoxicosis	0	0	0	1	1	0	0
Humoral immune defect	0	0	0	3	3	0	0
Hypersensitivity	54	1684	275	2492	4176	2	2
Hypocomplementaemia	0	3	0	0	3	0	0
Hypogammaglobulinaemia	0	1	0	0	1	0	0
Immune reconstitution inflammatory syndrome	0	0	0	2	2	0	0
Immune system disorder	15	76	15	69	145	1	1
Immune-mediated adverse reaction	1	18	0	4	22	0	0
Immunisation reaction	16	171	342	2626	2797	0	0
Immunodeficiency	3	25	5	22	47	0	0
Immunosuppression	3	10	0	7	17	0	0
Infusion related hypersensitivity reaction	0	5	0	0	5	0	0
Iodine allergy	3	3	0	0	3	0	0
Kidney transplant rejection	0	2	0	0	2	0	0
Loefgren syndrome	1	3	0	0	3	0	0
Milk allergy	0	2	0	2	4	0	0
Mite allergy	0	0	0	2	2	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Multiple allergies	2	27	3	22	49	0	0
Multisystem inflammatory syndrome	4	12	0	0	12	0	0
Multisystem inflammatory syndrome in adults	4	6	0	0	6	0	0
Multisystem inflammatory syndrome in children	0	3	0	0	3	0	0
Mycotic allergy	0	0	1	1	1	0	0
Oral allergy syndrome	0	1	0	4	5	0	0
Perennial allergy	0	0	1	1	1	0	0
Perfume sensitivity	0	2	0	2	4	0	0
Polymers allergy	0	0	0	1	1	0	0
Pre-engraftment immune reaction	0	1	0	0	1	0	0
Reaction to colouring	0	2	0	0	2	0	0
Reaction to excipient	0	9	0	5	14	0	0
Reaction to flavouring	0	1	0	0	1	0	0
Reaction to preservatives	3	15	0	6	21	0	0
Rubber sensitivity	1	4	0	1	5	0	0
Sarcoidosis	5	51	1	9	60	0	2
Seasonal allergy	3	90	19	134	224	0	0
Secondary immunodeficiency	0	1	0	0	1	0	0
Selective IgA immunodeficiency	2	2	0	0	2	0	0
Sensitisation	0	27	3	108	135	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Serum sickness	0	16	0	0	16	0	0
Serum sickness-like reaction	0	13	0	4	17	0	0
Smoke sensitivity	0	1	0	2	3	0	0
Systemic immune activation	0	2	2	6	8	0	0
Transplant rejection	1	9	1	2	11	0	0
Type I hypersensitivity	0	9	0	0	9	4	6
Type II hypersensitivity	0	1	0	0	1	0	0
Type III immune complex mediated reaction	2	13	4	10	23	0	0
Type IV hypersensitivity reaction	2	9	5	24	33	1	2
Vaccine associated enhanced disease	0	3	0	2	5	0	0
Vaccine associated enhanced respiratory disease	2	3	0	0	3	0	0
Endocrine disorders	**74**	**757**	**45**	**378**	**1135**	**1**	**2**
Addison's disease	0	9	0	1	10	0	0
Adrenal disorder	1	4	0	1	5	0	0
Adrenal haematoma	0	5	0	0	5	0	0
Adrenal haemorrhage	4	24	0	0	24	0	0
Adrenal insufficiency	1	33	0	2	35	0	0
Adrenal mass	0	3	0	1	4	0	0
Adrenal thrombosis	1	3	0	0	3	0	0
Adrenocortical insufficiency acute	1	43	0	0	43	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Adrenomegaly	0	3	0	1	4	0	0
Anovulatory cycle	0	16	2	19	35	0	0
Autoimmune hypothyroidism	0	4	0	1	5	0	0
Autoimmune thyroid disorder	0	1	0	0	1	0	0
Autoimmune thyroiditis	7	40	1	16	56	0	0
Basedow's disease	9	72	6	27	99	0	0
Carcinoid syndrome	0	1	0	0	1	0	0
Cushing's syndrome	0	3	0	0	3	0	0
Cushingoid	0	5	0	0	5	0	0
Delayed menarche	0	0	0	2	2	0	0
Diabetes insipidus	0	11	0	0	11	0	0
Empty sella syndrome	0	1	0	0	1	0	0
Endocrine disorder	1	1	0	1	2	0	0
Euthyroid sick syndrome	0	0	0	2	2	0	0
Glucocorticoid deficiency	0	2	0	2	4	0	0
Goitre	2	32	1	25	57	0	0
Haemorrhagic adrenal infarction	0	9	0	0	9	1	1
Haemorrhagic thyroid cyst	0	0	0	2	2	0	0
Hyperadrenocorticism	0	1	0	0	1	0	0
Hyperaldosteronism	1	1	0	0	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Hyperparathyroidism	0	2	0	0	2	0	0
Hyperparathyroidism primary	0	1	0	0	1	0	0
Hyperplasia adrenal	0	1	0	0	1	0	0
Hyperprolactinaemia	0	2	0	2	4	0	0
Hyperthyroidism	9	103	4	47	150	0	0
Hypoparathyroidism	0	2	0	0	2	0	0
Hypophysitis	0	1	0	0	1	0	0
Hypopituitarism	0	4	0	0	4	0	0
Hypothalamo-pituitary disorder	2	7	0	1	8	0	0
Hypothyroidism	16	97	9	50	147	0	0
Immune-mediated hyperthyroidism	1	2	0	0	2	0	0
Immune-mediated hypothyroidism	0	1	0	0	1	0	0
Inappropriate antidiuretic hormone secretion	1	6	0	0	6	0	0
Luteal phase deficiency	0	0	0	2	2	0	0
Myxoedema	2	2	0	0	2	0	0
Oestrogenic effect	0	1	0	0	1	0	0
Ovarian dysfunction	0	1	0	0	1	0	0
Ovulation delayed	0	11	0	12	23	0	0
Pituitary apoplexy	2	5	0	0	5	0	0
Pituitary haemorrhage	0	3	0	0	3	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Pituitary infarction	0	1	0	0	1	0	0
Premature menarche	0	4	0	13	17	0	0
Primary adrenal insufficiency	0	2	0	0	2	0	0
Primary hyperaldosteronism	0	1	0	0	1	0	0
Primary hyperthyroidism	0	1	0	1	2	0	0
Primary hypoparathyroidism	0	1	0	0	1	0	0
Primary hypothyroidism	0	0	0	1	1	0	0
Secondary adrenocortical insufficiency	0	2	0	0	2	0	0
Secondary hyperthyroidism	0	2	0	1	3	0	0
Thyroid cyst	0	1	1	5	6	0	0
Thyroid disorder	1	24	5	43	67	0	0
Thyroid haemorrhage	0	1	0	0	1	0	0
Thyroid mass	2	21	2	11	32	0	0
Thyroid pain	0	16	3	23	39	0	0
Thyroiditis	2	41	5	22	63	0	0
Thyroiditis acute	2	20	0	3	23	0	0
Thyroiditis chronic	1	3	0	0	3	0	0
Thyroiditis subacute	4	27	6	38	65	0	1
Thyrotoxic crisis	0	7	0	0	7	0	0
Toxic nodular goitre	1	3	0	0	3	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Metabolism and nutrition disorders	**239**	**9143**	**1078**	**11558**	**20701**	**2**	**5**
Abnormal loss of weight	8	92	2	35	127	0	0
Abnormal weight gain	1	32	2	16	48	0	0
Acetonaemia	0	0	0	1	1	0	0
Acidosis	0	7	0	7	14	0	0
Adult failure to thrive	0	2	0	0	2	0	0
Alcohol intolerance	0	11	1	12	23	0	0
Alkalosis	0	2	0	0	2	0	0
Appetite disorder	0	39	39	107	146	0	0
Blood hyposmosis	0	2	0	0	2	0	0
Body fat disorder	0	1	0	0	1	0	0
Cachexia	1	5	1	5	10	0	0
Calcium deficiency	0	0	0	1	1	0	0
Calcium metabolism disorder	1	1	0	0	1	0	0
Cell death	0	0	0	1	1	0	0
Cholesterosis	0	0	0	1	1	0	0
Copper deficiency	0	0	0	1	1	0	0
Dairy intolerance	0	7	0	3	10	0	0
Decreased appetite	115	6338	859	9637	15975	0	0
Decreased insulin requirement	0	0	0	1	1	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Dehydration	15	651	22	376	1027	0	0
Diabetes mellitus	6	167	3	73	240	0	0
Diabetes mellitus inadequate control	4	55	2	34	89	0	0
Diabetic complication	1	3	0	0	3	0	0
Diabetic ketoacidosis	2	65	0	0	65	0	0
Diabetic ketosis	0	6	0	0	6	0	0
Diabetic metabolic decompensation	1	10	0	1	11	0	0
Diet refusal	0	3	0	2	5	0	0
Dyslipidaemia	1	6	0	0	6	0	0
Eating disorder symptom	0	1	1	3	4	0	0
Electrolyte imbalance	1	18	5	13	31	0	0
Euglycaemic diabetic ketoacidosis	0	2	0	0	2	0	0
Failure to thrive	0	3	0	0	3	0	1
Feeding disorder	3	230	17	122	352	1	1
Feeding intolerance	0	0	0	1	1	0	0
Fluid imbalance	0	1	0	0	1	0	0
Fluid intake reduced	0	11	1	11	22	0	0
Fluid retention	5	92	10	88	180	0	0
Folate deficiency	2	13	0	5	18	0	0
Food aversion	1	56	39	93	149	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Food craving	1	21	3	40	61	0	0
Food intolerance	5	35	4	24	59	0	0
Food refusal	0	38	1	18	56	0	0
Fulminant type 1 diabetes mellitus	1	1	0	0	1	0	0
Glucose tolerance impaired	0	9	0	4	13	0	0
Gluten sensitivity	1	6	0	4	10	0	0
Gout	5	162	6	97	259	0	0
Haemochromatosis	1	2	0	2	4	0	0
Histamine intolerance	0	3	3	11	14	0	0
Hypercalcaemia	3	6	0	1	7	0	0
Hypercholesterolaemia	1	6	0	2	8	0	0
Hypercreatininaemia	0	1	0	0	1	0	0
Hyperferritinaemia	0	3	0	4	7	0	0
Hyperglycaemia	4	172	5	140	312	0	0
Hyperglycaemic hyperosmolar nonketotic syndrome	0	3	0	0	3	0	0
Hyperhomocysteinaemia	0	1	0	0	1	0	0
Hyperinsulinaemic hypoglycaemia	0	2	0	0	2	0	0
Hyperkalaemia	2	23	0	3	26	0	0
Hyperlactacidaemia	0	3	0	0	3	0	0
Hyperlipasaemia	0	0	0	1	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Hyperlipidaemia	1	6	1	3	9	0	0
Hypermetabolism	0	2	0	2	4	0	0
Hypernatraemia	0	7	0	2	9	0	0
Hyperosmolar state	0	1	0	0	1	0	0
Hyperphagia	0	9	1	8	17	0	0
Hyperproteinaemia	0	0	0	2	2	0	0
Hypertriglyceridaemia	0	3	0	3	6	0	0
Hyperuricaemia	0	2	0	2	4	0	0
Hypervitaminosis A	0	0	0	1	1	0	0
Hypervolaemia	0	15	1	4	19	0	0
Hypoalbuminaemia	0	4	0	1	5	0	0
Hypocalcaemia	0	6	0	6	12	0	0
Hypoglycaemia	2	124	5	109	233	0	0
Hypoglycaemia unawareness	0	3	0	0	3	0	0
Hypokalaemia	4	36	2	12	48	1	1
Hypokalaemic syndrome	0	3	0	0	3	0	0
Hypomagnesaemia	0	3	0	2	5	0	0
Hypometabolism	1	2	0	1	3	0	0
Hyponatraemia	2	53	2	26	79	0	0
Hyponatraemic syndrome	0	5	0	0	5	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Hypoosmolar state	0	0	0	1	1	0	0
Hypophagia	3	48	4	39	87	0	0
Hypophosphataemia	0	3	0	0	3	0	0
Hypovitaminosis	0	3	2	7	10	0	0
Hypovolaemia	0	6	0	2	8	0	0
Impaired fasting glucose	0	1	0	0	1	0	0
Increased appetite	4	45	5	105	150	0	0
Increased insulin requirement	1	3	1	11	14	0	0
Insulin resistance	0	12	1	4	16	0	0
Insulin resistant diabetes	0	1	0	0	1	0	0
Iodine deficiency	0	0	0	1	1	0	0
Iron deficiency	2	24	1	22	46	0	0
Iron metabolism disorder	0	0	0	1	1	0	0
Iron overload	0	1	0	0	1	0	0
Ketoacidosis	1	6	0	0	6	0	0
Ketosis	0	8	0	0	8	0	0
Lack of satiety	0	1	0	0	1	0	0
Lactic acidosis	0	9	0	0	9	0	0
Lactose intolerance	1	9	1	6	15	0	0
Latent autoimmune diabetes in adults	0	1	0	0	1	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Latent tetany	0	1	0	0	1	0	0
Lipoedema	1	3	1	2	5	0	0
Lipomatosis	0	0	0	1	1	0	0
Malnutrition	1	5	2	3	8	0	0
Metabolic acidosis	1	24	0	0	24	0	0
Metabolic alkalosis	0	6	0	2	8	0	0
Metabolic disorder	0	3	2	8	11	0	0
Metabolic syndrome	0	2	0	0	2	0	0
Mineral deficiency	0	1	0	0	1	0	0
Mineral metabolism disorder	0	1	0	0	1	0	0
Mitochondrial cytopathy	2	4	0	0	4	0	0
Neonatal insufficient breast milk syndrome	0	4	0	0	4	0	0
New onset diabetes after transplantation	0	1	0	0	1	0	0
Obesity	1	4	1	9	13	0	0
Oligodipsia	0	2	0	4	6	0	0
Overfeeding of infant	0	0	0	1	1	0	0
Overweight	0	1	0	3	4	0	0
Polydipsia	1	22	4	60	82	0	0
Poor feeding infant	0	18	0	6	24	0	0
Postprandial hypoglycaemia	0	3	0	0	3	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Protein deficiency	0	1	0	0	1	0	0
Protein intolerance	1	1	0	0	1	0	0
Salt craving	0	2	0	4	6	0	0
Selenium deficiency	1	1	0	0	1	0	0
Starvation	0	1	0	1	2	0	0
Steroid diabetes	0	1	0	0	1	0	0
Tetany	1	15	7	22	37	0	0
Type 1 diabetes mellitus	6	45	2	12	57	0	0
Type 2 diabetes mellitus	5	28	2	9	37	0	2
Underweight	1	3	0	0	3	0	0
Vitamin B complex deficiency	0	0	0	3	3	0	0
Vitamin B12 deficiency	1	18	0	5	23	0	0
Vitamin C deficiency	0	0	1	1	1	0	0
Vitamin D deficiency	2	22	3	16	38	0	0
Vitamin K deficiency	0	0	0	1	1	0	0
Weight gain poor	0	1	0	0	1	0	0
Weight loss poor	0	4	0	1	5	0	0
Zinc deficiency	0	1	0	0	1	0	0
Psychiatric disorders	**564**	**18173**	**2098**	**18853**	**37026**	**2**	**2**
Abnormal behaviour	3	33	1	32	65	1	1

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Abnormal dreams	5	289	8	203	492	0	0
Abnormal sleep-related event	0	2	0	10	12	0	0
Abulia	0	1	0	2	3	0	0
Acrophobia	1	2	0	0	2	0	0
Acute psychosis	0	9	0	3	12	0	0
Acute stress disorder	0	5	1	111	116	0	0
Adjustment disorder	1	5	2	6	11	0	0
Adjustment disorder with depressed mood	1	7	2	9	16	0	0
Adjustment disorder with mixed anxiety and depressed mood	0	2	0	0	2	0	0
Affect lability	0	12	2	48	60	0	0
Affective disorder	1	4	2	12	16	0	0
Aggression	0	21	4	36	57	0	0
Agitated depression	0	3	0	1	4	0	0
Agitation	9	246	15	266	512	0	0
Agoraphobia	0	3	2	4	7	0	0
Alcohol abuse	0	0	0	2	2	0	0
Alcohol use disorder	0	1	0	4	5	0	0
Alcohol withdrawal syndrome	1	1	0	0	1	0	0
Alcoholic hangover	0	1	0	1	2	0	0
Alcoholism	0	2	0	1	3	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Alice in wonderland syndrome	1	3	0	1	4	0	0
Anger	0	73	3	40	113	0	0
Anhedonia	0	2	0	4	6	0	0
Anorexia nervosa	0	0	0	1	1	0	0
Anorgasmia	0	3	0	4	7	0	0
Anticipatory anxiety	1	1	0	1	2	0	0
Antisocial behaviour	0	1	0	1	2	0	0
Anxiety	61	1455	154	1389	2844	0	0
Anxiety disorder	3	11	3	19	30	0	0
Anxiety disorder due to a general medical condition	0	1	0	1	2	0	0
Apathy	2	97	44	331	428	0	0
Asocial behaviour	0	1	0	0	1	0	0
Astraphobia	0	0	1	1	1	0	0
Attention deficit hyperactivity disorder	0	20	1	8	28	0	0
Autism spectrum disorder	0	4	0	0	4	0	0
Autoscopy	1	26	0	16	42	0	0
Aversion	0	0	0	3	3	0	0
Behaviour disorder	2	9	0	2	11	0	0
Behavioural insomnia of childhood	0	1	0	1	2	0	0
Binge drinking	0	0	0	1	1	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Binge eating	0	1	0	3	4	0	0
Bipolar I disorder	0	7	0	1	8	0	0
Bipolar disorder	1	7	1	4	11	0	0
Blunted affect	0	0	0	1	1	0	0
Body dysmorphic disorder	0	2	0	1	3	0	0
Borderline personality disorder	0	0	0	3	3	0	0
Boredom	0	1	8	12	13	0	0
Bradyphrenia	1	101	12	96	197	0	0
Breath holding	0	5	0	0	5	0	0
Breathing-related sleep disorder	0	1	0	4	5	0	0
Bruxism	1	27	2	31	58	0	0
Burnout syndrome	1	20	1	4	24	0	0
Cardiovascular somatic symptom disorder	0	0	0	2	2	0	0
Catastrophic reaction	0	3	0	0	3	0	0
Catatonia	1	8	0	0	8	0	0
Change in sustained attention	0	1	0	0	1	0	0
Childhood depression	0	0	0	1	1	0	0
Chronic idiopathic pain syndrome	0	2	0	0	2	0	0
Claustrophobia	0	1	2	4	5	0	0
Clinomania	0	1	0	1	2	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Communication disorder	0	18	0	7	25	0	0
Completed suicide	2	13	0	0	13	0	0
Compulsive cheek biting	1	1	0	0	1	0	0
Compulsive shopping	0	2	0	1	3	0	0
Confabulation	0	1	0	0	1	0	0
Confusional arousal	0	2	0	2	4	0	0
Confusional state	36	2400	97	1464	3864	1	1
Constricted affect	0	13	0	5	18	0	0
Conversion disorder	12	69	2	21	90	0	0
Daydreaming	0	18	8	24	42	0	0
Decreased eye contact	0	2	0	0	2	0	0
Decreased interest	0	18	1	17	35	0	0
Deja vu	1	4	1	2	6	0	0
Delirium	10	518	9	192	710	0	0
Delirium febrile	1	17	0	25	42	0	0
Delusion	4	76	2	59	135	0	0
Delusion of parasitosis	0	2	0	0	2	0	0
Delusional disorder, erotomanic type	0	1	0	0	1	0	0
Delusional perception	0	2	0	2	4	0	0
Dependence	0	1	0	2	3	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Depersonalisation/derealisation disorder	0	21	0	15	36	0	0
Depressed mood	24	644	221	712	1356	0	0
Depression	37	724	60	410	1134	0	0
Depression suicidal	1	23	0	0	23	0	0
Depressive symptom	2	5	2	9	14	0	0
Derailment	0	1	0	2	3	0	0
Derealisation	2	18	10	34	52	0	0
Dermatillomania	0	1	0	1	2	0	0
Discouragement	0	1	5	23	24	0	0
Disinhibited social engagement disorder of childhood	0	1	0	0	1	0	0
Disinhibition	0	1	0	1	2	0	0
Disorganised speech	1	32	3	20	52	0	0
Disorientation	16	794	22	505	1299	0	0
Dissociation	0	66	2	49	115	0	0
Dissociative amnesia	0	1	0	0	1	0	0
Dissociative disorder	0	5	0	2	7	0	0
Distractibility	1	6	0	14	20	0	0
Disturbance in sexual arousal	1	6	0	3	9	0	0
Disturbance in social behaviour	0	2	0	1	3	0	0
Drug abuse	0	0	0	1	1	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Drug dependence	1	2	0	2	4	0	0
Drug use disorder	0	0	0	1	1	0	0
Dysphemia	3	40	1	17	57	0	0
Dysphoria	0	4	1	28	32	0	0
Dyssomnia	0	5	1	3	8	0	0
Eating disorder	3	20	5	38	58	0	0
Emotional disorder	2	84	1	54	138	0	0
Emotional disorder of childhood	0	1	0	0	1	0	0
Emotional distress	2	93	12	64	157	0	0
Emotional poverty	0	2	0	2	4	0	0
Enuresis	0	56	0	16	72	0	0
Euphoric mood	0	50	14	81	131	0	0
Excessive masturbation	0	1	0	0	1	0	0
Executive dysfunction	0	0	0	2	2	0	0
Exploding head syndrome	0	7	0	1	8	0	0
Factitious disorder	0	4	0	1	5	0	0
Fear	2	82	5	108	190	0	0
Fear of crowded places	0	0	0	1	1	0	0
Fear of death	4	27	5	28	55	0	0
Fear of disease	0	2	0	9	11	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Fear of eating	0	1	0	0	1	0	0
Fear of falling	0	4	0	4	8	0	0
Fear of injection	0	2	0	11	13	0	0
Fear of open spaces	0	1	0	0	1	0	0
Fear-related avoidance of activities	0	0	0	6	6	0	0
Feeling guilty	0	1	1	2	3	0	0
Feeling of despair	1	20	12	82	102	0	0
Feelings of worthlessness	0	0	1	2	2	0	0
Female orgasmic disorder	1	2	1	3	5	0	0
Fetishism	0	2	0	0	2	0	0
Flashback	1	4	0	0	4	0	0
Flat affect	0	12	0	4	16	0	0
Flight of ideas	0	0	0	1	1	0	0
Frustration tolerance decreased	2	16	2	14	30	0	0
Gender dysphoria	0	1	0	0	1	0	0
Generalised anxiety disorder	0	6	0	0	6	0	0
Genito-pelvic pain/penetration disorder	0	1	0	1	2	0	0
Grief reaction	1	1	0	2	3	0	0
Habit cough	0	25	1	17	42	0	0
Hallucination	20	927	16	426	1353	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Hallucination, auditory	1	51	0	26	77	0	0
Hallucination, olfactory	1	12	0	13	25	0	0
Hallucination, tactile	0	2	0	0	2	0	0
Hallucination, visual	3	72	1	40	112	0	0
Hallucinations, mixed	0	10	0	7	17	0	0
Head banging	1	46	1	34	80	0	0
Helplessness	1	6	1	16	22	0	0
Histrionic personality disorder	0	0	0	2	2	0	0
Homicidal ideation	0	1	0	0	1	0	0
Hydrophobia	1	1	0	1	2	0	0
Hyperarousal	0	1	0	4	5	0	0
Hypersexuality	0	2	0	1	3	0	0
Hypervigilance	0	7	1	7	14	0	0
Hypnagogic hallucination	0	4	1	3	7	0	0
Hypnopompic hallucination	0	0	0	1	1	0	0
Hypomania	0	1	1	3	4	0	0
Hyposomnia	0	0	0	2	2	0	0
Illness anxiety disorder	1	2	1	4	6	0	0
Illogical thinking	1	1	0	2	3	0	0
Illusion	0	14	2	27	41	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Immunisation stress-related response	0	5	2	8	13	0	0
Impaired reasoning	0	9	1	8	17	0	0
Impatience	0	4	1	6	10	0	0
Imperception	0	3	1	2	5	0	0
Impulse-control disorder	0	2	0	1	3	0	0
Impulsive behaviour	1	4	0	2	6	0	0
Inappropriate affect	0	14	0	17	31	0	0
Indifference	0	8	0	6	14	0	0
Inferiority complex	0	0	1	1	1	0	0
Initial insomnia	5	61	26	100	161	0	0
Insomnia	56	2940	492	4914	7854	0	0
Intentional self-injury	0	8	0	1	9	0	0
Intermittent explosive disorder	0	0	0	1	1	0	0
Intrusive thoughts	0	6	0	1	7	0	0
Irritability	3	300	76	1035	1335	0	0
Jamais vu	0	0	0	1	1	0	0
Lack of spontaneous speech	0	4	0	3	7	0	0
Laziness	0	0	1	31	31	0	0
Learning disability	0	0	0	1	1	0	0
Learning disorder	0	0	0	1	1	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Libido decreased	0	21	0	25	46	0	0
Libido disorder	0	1	0	1	2	0	0
Libido increased	0	4	4	15	19	0	0
Limited symptom panic attack	0	0	0	1	1	0	0
Listless	1	107	19	203	310	0	0
Logorrhoea	0	3	0	5	8	0	0
Loose associations	0	0	0	1	1	0	0
Loss of libido	0	48	4	21	69	0	0
Major depression	1	27	1	7	34	0	0
Mania	2	28	1	11	39	0	0
Menopausal depression	0	2	1	1	3	0	0
Mental disorder	5	57	14	90	147	0	0
Mental disorder due to a general medical condition	0	0	0	1	1	0	0
Mental fatigue	12	478	25	139	617	0	0
Mental status changes	1	5	1	9	14	0	0
Middle insomnia	7	70	22	100	170	0	0
Mixed anxiety and depressive disorder	1	6	1	4	10	0	0
Mixed delusion	0	1	0	2	3	0	0
Mood altered	2	82	51	187	269	0	0
Mood disorder due to a general medical condition	0	3	0	1	4	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Mood swings	4	121	8	102	223	0	0
Morbid thoughts	1	4	0	2	6	0	0
Morose	0	0	0	1	1	0	0
Mutism	0	6	0	3	9	0	0
Near death experience	1	6	0	3	9	0	0
Negative thoughts	0	8	0	11	19	0	0
Nervousness	10	556	16	326	882	0	0
Neuropsychiatric symptoms	0	3	0	0	3	0	0
Neuropsychiatric syndrome	0	1	0	0	1	0	0
Neurosis	0	3	0	3	6	0	0
Nicotine dependence	0	1	0	0	1	0	0
Nightmare	1	372	35	322	694	0	0
Nocturnal fear	0	1	0	0	1	0	0
Obsessive rumination	0	0	0	1	1	0	0
Obsessive thoughts	0	3	0	3	6	0	0
Obsessive-compulsive disorder	0	3	1	1	4	0	0
Obsessive-compulsive symptom	0	1	0	0	1	0	0
Onychophagia	0	0	0	1	1	0	0
Organic brain syndrome	0	2	0	1	3	0	0
Orgasm abnormal	0	1	0	1	2	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Orgasmic sensation decreased	0	3	0	1	4	0	0
Panic attack	16	342	24	245	587	0	0
Panic disorder	2	16	1	13	29	0	0
Panic reaction	0	43	7	41	84	0	0
Paradoxical insomnia	0	0	0	1	1	0	0
Paramnesia	0	9	0	3	12	0	0
Paranoia	0	35	1	16	51	0	0
Paranoid personality disorder	0	1	0	0	1	0	0
Parasomnia	0	0	0	4	4	0	0
Paruresis	0	1	0	0	1	0	0
Pedantic speech	0	1	0	0	1	0	0
Performance fear	0	3	0	0	3	0	0
Persecutory delusion	0	1	0	1	2	0	0
Persistent depressive disorder	0	2	0	0	2	0	0
Personality change	3	18	3	9	27	0	0
Personality disorder	0	1	1	2	3	0	0
Phantom vibration syndrome	0	0	0	1	1	0	0
Phobia	0	2	0	6	8	0	0
Phobia of driving	1	1	0	0	1	0	0
Phobic avoidance	0	0	0	1	1	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Phonophobia	1	17	2	18	35	0	0
Pica	0	0	0	1	1	0	0
Poor quality sleep	21	581	71	522	1103	0	0
Post stroke depression	0	1	0	0	1	0	0
Post-traumatic stress disorder	2	16	2	21	37	0	0
Poverty of speech	0	4	0	0	4	0	0
Premature ejaculation	2	5	0	1	6	0	0
Procedural anxiety	0	0	0	1	1	0	0
Pseudodementia	0	1	0	0	1	0	0
Pseudohallucination	0	3	0	3	6	0	0
Psychiatric decompensation	1	2	0	0	2	0	0
Psychiatric symptom	1	14	1	13	27	0	0
Psychogenic movement disorder	0	0	0	1	1	0	0
Psychogenic pseudosyncope	0	0	0	1	1	0	0
Psychogenic tremor	0	2	0	0	2	0	0
Psychogenic visual disorder	0	0	0	1	1	0	0
Psychological factor affecting medical condition	0	0	0	2	2	0	0
Psychological trauma	0	2	2	9	11	0	0
Psychomotor retardation	0	3	0	6	9	0	0
Psychotic behaviour	0	2	0	0	2	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Psychotic disorder	0	57	0	13	70	0	0
Psychotic disorder due to a general medical condition	0	1	0	0	1	0	0
Psychotic symptom	0	1	0	0	1	0	0
Pyromania	0	1	0	0	1	0	0
Rapid eye movements sleep abnormal	0	4	1	1	5	0	0
Reading disorder	0	7	1	8	15	0	0
Rebound psychosis	0	1	0	0	1	0	0
Restlessness	9	460	137	856	1316	0	0
Schizoaffective disorder	0	1	0	0	1	0	0
Schizophrenia	1	3	0	0	3	0	0
Secondary tic	0	2	0	0	2	0	0
Selective eating disorder	0	0	0	3	3	0	0
Self esteem decreased	0	1	3	5	6	0	0
Self-induced vomiting	0	1	0	0	1	0	0
Self-injurious ideation	0	4	0	3	7	0	0
Sense of a foreshortened future	1	4	0	0	4	0	0
Sexually inappropriate behaviour	0	1	0	0	1	0	0
Sleep attacks	1	4	1	9	13	0	0
Sleep disorder	41	520	169	1163	1683	0	0
Sleep disorder due to a general medical condition	0	0	1	2	2	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Sleep disorder due to general medical condition, insomnia type	0	1	0	3	4	0	0
Sleep inertia	0	1	0	0	1	0	0
Sleep talking	0	13	0	12	25	0	0
Sleep terror	3	52	0	17	69	0	0
Sleep-related eating disorder	0	1	0	3	4	0	0
Social anxiety disorder	0	1	0	2	3	0	0
Social avoidant behaviour	0	11	2	7	18	0	0
Social fear	0	1	0	1	2	0	0
Soliloquy	0	2	0	2	4	0	0
Somatic delusion	0	0	1	1	1	0	0
Somatic hallucination	0	0	0	1	1	0	0
Somatic symptom disorder	1	4	8	14	18	0	0
Somnambulism	0	6	1	12	18	0	0
Sopor	1	11	0	2	13	0	0
Speech sound disorder	0	2	0	1	3	0	0
Staring	0	15	0	6	21	0	0
Stress	17	150	23	151	301	0	0
Substance abuse	0	2	0	1	3	0	0
Substance-induced mood disorder	0	0	0	1	1	0	0
Suicidal behaviour	0	7	0	0	7	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Suicidal ideation	13	175	0	0	175	0	0
Suicide attempt	3	42	0	0	42	0	0
Suicide threat	0	1	0	0	1	0	0
Suspiciousness	0	0	0	1	1	0	0
Tachyphrenia	1	21	1	15	36	0	0
Taciturnity	0	1	0	0	1	0	0
Tearfulness	1	90	4	35	125	0	0
Tension	0	55	7	108	163	0	0
Terminal insomnia	0	14	2	20	34	0	0
Thanatophobia	0	0	0	1	1	0	0
Thinking abnormal	1	28	8	65	93	0	0
Thought blocking	1	9	1	2	11	0	0
Thought withdrawal	0	1	0	0	1	0	0
Tic	2	21	2	20	41	0	0
Time perception altered	0	8	0	1	9	0	0
Tobacco abuse	0	0	1	1	1	0	0
Trance	0	0	0	2	2	0	0
Verbigeration	0	2	0	0	2	0	0
Violence-related symptom	0	1	0	1	2	0	0
Waxy flexibility	0	2	0	0	2	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Nervous system disorders	**5747**	**188052**	**34205**	**349849**	**537901**	**95**	**239**
Acquired syringomyelia	0	1	0	0	1	0	0
Acrodynia	0	0	0	1	1	0	0
Action tremor	2	7	0	5	12	0	0
Acute disseminated encephalomyelitis	15	81	0	0	81	0	7
Acute encephalitis with refractory, repetitive partial seizures	0	1	0	0	1	0	0
Acute flaccid myelitis	1	2	0	0	2	0	0
Acute haemorrhagic leukoencephalitis	0	1	0	1	2	0	0
Acute motor axonal neuropathy	1	7	0	1	8	0	0
Acute motor-sensory axonal neuropathy	1	3	0	0	3	0	0
Acute painful neuropathy of rapid glycaemic control	0	0	0	1	1	0	0
Acute polyneuropathy	1	24	0	3	27	0	0
Acute post asthmatic amyotrophy	0	1	0	0	1	0	0
Adrenergic syndrome	0	1	0	0	1	0	0
Advanced sleep phase	0	1	0	0	1	0	0
Ageusia	21	981	154	1902	2883	0	0
Agitation neonatal	0	0	0	2	2	0	0
Agnosia	1	2	0	3	5	0	0
Agraphia	0	2	0	0	2	0	0
Akathisia	0	10	2	18	28	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Akinaesthesia	0	1	0	0	1	0	0
Akinesia	0	3	0	1	4	0	0
Alcoholic seizure	0	1	0	0	1	0	0
Alexia	0	6	0	1	7	0	0
Allodynia	0	50	6	68	118	0	0
Altered state of consciousness	12	114	5	56	170	0	0
Amnesia	37	604	33	342	946	0	0
Amnestic disorder	0	7	0	7	14	0	0
Amputation stump pain	0	0	0	2	2	0	0
Amyloid related imaging abnormalities	0	1	0	1	2	0	0
Amyotrophic lateral sclerosis	5	15	0	0	15	0	0
Anaesthesia	0	6	3	22	28	0	0
Anosmia	12	402	132	1452	1854	0	1
Anosognosia	0	1	0	0	1	0	0
Anterograde amnesia	0	4	0	0	4	0	0
Apallic syndrome	1	4	0	0	4	0	0
Aphasia	66	749	0	0	749	0	0
Apraxia	2	18	2	6	24	0	0
Arachnoid cyst	1	2	0	0	2	0	0
Arachnoiditis	0	5	0	2	7	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Areflexia	6	67	0	10	77	0	0
Ascending flaccid paralysis	0	6	0	0	6	0	0
Asterixis	0	1	0	1	2	0	0
Ataxia	10	123	8	49	172	0	0
Athetosis	0	0	0	1	1	0	0
Atonic seizures	2	14	0	1	15	1	1
Atypical benign partial epilepsy	0	0	0	1	1	0	0
Auditory nerve disorder	0	3	0	0	3	0	0
Aura	1	28	5	37	65	0	0
Autoimmune demyelinating disease	0	1	0	0	1	0	0
Autoimmune encephalopathy	2	11	0	0	11	0	0
Autoimmune neuropathy	0	7	0	1	8	0	0
Autonomic nervous system imbalance	11	50	6	16	66	0	0
Autonomic neuropathy	1	5	0	2	7	0	0
Autonomic seizure	0	1	0	0	1	0	0
Axonal and demyelinating polyneuropathy	1	8	0	1	9	0	0
Axonal neuropathy	1	7	0	2	9	0	0
Balance disorder	68	1256	126	1223	2479	0	0
Balint's syndrome	0	1	0	0	1	0	0
Ballismus	0	3	0	2	5	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Band sensation	2	11	1	7	18	0	0
Basal ganglia haemorrhage	1	15	0	0	15	0	0
Basal ganglia infarction	0	6	0	0	6	0	0
Basal ganglia stroke	0	3	0	0	3	0	0
Basilar artery aneurysm	0	1	0	1	2	0	0
Basilar artery occlusion	0	7	0	0	7	0	0
Basilar artery thrombosis	2	15	0	0	15	0	0
Basilar migraine	0	5	0	0	5	0	0
Bell's palsy	26	779	11	287	1066	1	1
Bickerstaff's encephalitis	0	5	0	0	5	0	0
Blood brain barrier defect	0	1	0	0	1	0	0
Brachial plexopathy	2	7	1	2	9	0	0
Bradykinesia	3	39	2	29	68	0	0
Brain compression	0	5	0	0	5	0	0
Brain hypoxia	1	2	0	0	2	0	0
Brain injury	12	81	0	0	81	0	0
Brain oedema	9	101	0	0	101	0	0
Brain stem embolism	0	1	0	0	1	0	0
Brain stem haematoma	0	1	0	0	1	0	0
Brain stem haemorrhage	1	13	0	0	13	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Brain stem infarction	1	41	0	0	41	1	1
Brain stem ischaemia	0	2	0	2	4	0	0
Brain stem microhaemorrhage	0	0	0	1	1	0	0
Brain stem stroke	1	15	0	0	15	0	0
Brain stem syndrome	0	8	0	0	8	0	0
Brain stem thrombosis	0	5	0	0	5	0	0
Brudzinski's sign	0	1	0	0	1	0	0
Bulbar palsy	0	7	0	1	8	0	0
Burning feet syndrome	0	26	1	12	38	0	0
Burning sensation	30	968	223	1719	2687	0	0
Burning sensation mucosal	1	5	1	12	17	0	0
Cardiac autonomic neuropathy	1	1	0	0	1	0	0
Carotid arterial embolus	0	1	0	0	1	0	0
Carotid arteriosclerosis	0	4	0	2	6	0	0
Carotid artery aneurysm	0	6	1	3	9	0	0
Carotid artery disease	1	2	0	0	2	0	0
Carotid artery dissection	0	14	0	0	14	0	0
Carotid artery occlusion	2	22	0	0	22	0	1
Carotid artery stenosis	0	11	0	3	14	0	0
Carotid artery thrombosis	2	53	0	0	53	1	2

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Carotid sinus syndrome	0	0	0	1	1	0	0
Carpal tunnel syndrome	6	50	7	30	80	0	0
Cataplexy	1	2	0	0	2	0	0
Cauda equina syndrome	0	9	0	0	9	0	0
Central nervous system immune reconstitution inflammatory response	0	2	0	0	2	0	0
Central nervous system inflammation	1	22	1	3	25	0	0
Central nervous system lesion	1	24	1	4	28	1	1
Central nervous system vasculitis	1	10	0	0	10	0	0
Central pain syndrome	1	5	0	4	9	0	0
Cerebellar artery thrombosis	0	2	0	1	3	0	0
Cerebellar ataxia	1	11	0	0	11	0	0
Cerebellar atrophy	0	1	0	0	1	0	0
Cerebellar embolism	0	1	0	0	1	0	0
Cerebellar haematoma	0	4	0	0	4	0	0
Cerebellar haemorrhage	0	13	0	0	13	0	0
Cerebellar infarction	2	41	0	0	41	1	1
Cerebellar ischaemia	1	9	0	0	9	0	0
Cerebellar stroke	5	36	0	0	36	0	0
Cerebellar syndrome	1	6	0	2	8	0	0
Cerebral amyloid angiopathy	0	7	0	1	8	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Cerebral arteriosclerosis	0	0	0	2	2	0	0
Cerebral arteritis	0	2	0	0	2	0	0
Cerebral artery embolism	1	35	0	0	35	0	0
Cerebral artery occlusion	2	24	0	0	24	0	2
Cerebral artery stenosis	0	3	0	1	4	0	0
Cerebral artery thrombosis	1	61	0	0	61	0	0
Cerebral atrophy	0	4	0	1	5	0	0
Cerebral circulatory failure	0	1	0	0	1	0	0
Cerebral congestion	0	4	0	2	6	0	0
Cerebral cyst	0	1	0	0	1	0	0
Cerebral disorder	4	17	2	12	29	0	0
Cerebral haematoma	2	47	0	0	47	0	0
Cerebral haemorrhage	51	664	0	0	664	5	13
Cerebral haemosiderin deposition	0	2	0	0	2	0	0
Cerebral infarction	22	493	0	0	493	0	1
Cerebral ischaemia	9	92	0	0	92	0	0
Cerebral mass effect	5	17	0	2	19	0	0
Cerebral microangiopathy	1	8	0	1	9	0	0
Cerebral microembolism	0	1	0	0	1	0	0
Cerebral microhaemorrhage	0	8	0	1	9	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Cerebral microinfarction	0	3	0	0	3	0	0
Cerebral small vessel ischaemic disease	3	10	0	1	11	0	0
Cerebral thrombosis	17	273	0	0	273	0	0
Cerebral vascular occlusion	1	6	0	0	6	0	0
Cerebral vasoconstriction	1	5	0	0	5	0	0
Cerebral venous sinus thrombosis	62	796	0	3	799	23	35
Cerebral venous thrombosis	24	290	0	0	290	2	10
Cerebrospinal fluid circulation disorder	0	5	0	2	7	0	0
Cerebrospinal fluid leakage	1	4	0	0	4	0	0
Cerebrovascular accident	145	2827	0	0	2827	2	4
Cerebrovascular disorder	3	31	1	7	38	0	0
Cerebrovascular insufficiency	0	2	0	0	2	0	0
Cerebrovascular stenosis	0	1	0	0	1	0	0
Cervical radiculopathy	0	8	0	8	16	0	0
Cervicobrachial syndrome	1	13	8	23	36	0	0
Cervicogenic headache	0	6	0	10	16	0	0
Change in seizure presentation	0	5	0	1	6	0	0
Cholinergic syndrome	0	0	0	1	1	0	0
Chorea	0	7	0	3	10	0	0
Choreoathetosis	0	0	0	2	2	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Chronic inflammatory demyelinating polyradiculoneuropathy	14	67	0	0	67	3	3
Chronic paroxysmal hemicrania	0	2	0	0	2	0	0
Circadian rhythm sleep disorder	0	2	1	11	13	0	0
Clinically isolated syndrome	2	6	0	1	7	0	0
Clonic convulsion	0	14	0	0	14	0	0
Clonus	0	2	1	4	6	0	0
Clumsiness	1	54	2	27	81	0	0
Cluster headache	4	689	10	382	1071	0	0
Cognitive disorder	29	290	36	182	472	0	0
Cognitive linguistic deficit	0	0	0	2	2	0	0
Cold dysaesthesia	0	1	0	0	1	0	0
Cold-stimulus headache	1	81	3	22	103	0	0
Colloid brain cyst	0	0	0	1	1	0	0
Coma	12	112	0	0	112	1	1
Complex regional pain syndrome	0	15	1	8	23	0	0
Consciousness fluctuating	0	4	0	6	10	0	0
Convulsions local	1	4	0	1	5	0	0
Convulsive threshold lowered	0	1	0	0	1	0	0
Coordination abnormal	8	172	14	170	342	0	0
Cramp-fasciculation syndrome	0	1	0	2	3	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Cranial nerve disorder	2	9	1	5	14	0	0
Cranial nerve paralysis	0	2	0	4	6	0	0
Crocodile tears syndrome	0	1	0	0	1	0	0
Cubital tunnel syndrome	0	2	2	3	5	0	0
Cytotoxic lesions of corpus callosum	0	1	0	0	1	0	0
Cytotoxic oedema	0	1	0	0	1	0	0
Decerebrate posture	0	1	0	0	1	0	0
Decorticate posture	0	1	0	0	1	0	0
Decreased vibratory sense	0	2	0	1	3	0	0
Delayed sleep phase	0	1	0	0	1	0	0
Dementia	4	72	4	16	88	0	0
Dementia Alzheimer's type	0	8	0	5	13	0	0
Dementia with Lewy bodies	0	2	0	1	3	0	0
Demyelinating polyneuropathy	5	37	1	2	39	0	0
Demyelination	10	77	2	21	98	3	4
Depressed level of consciousness	5	211	10	134	345	0	0
Diabetic coma	0	4	0	0	4	0	0
Diabetic mononeuropathy	0	0	0	1	1	0	0
Diabetic neuropathy	2	6	0	0	6	0	0
Diplegia	11	136	0	0	136	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Disturbance in attention	81	1022	245	1975	2997	0	0
Dizziness	412	21635	3867	39796	61431	2	5
Dizziness exertional	2	100	4	43	143	0	0
Dizziness postural	18	1837	13	628	2465	0	0
Dreamy state	0	16	0	9	25	0	0
Drooling	1	29	0	16	45	0	0
Drop attacks	0	3	0	3	6	0	0
Dropped head syndrome	0	0	0	1	1	0	0
Drug withdrawal convulsions	0	2	0	0	2	0	0
Drug withdrawal headache	0	12	0	11	23	0	0
Dural arteriovenous fistula	1	4	0	0	4	0	0
Dysaesthesia	5	93	12	201	294	0	0
Dysarthria	27	692	11	224	916	0	0
Dysdiadochokinesis	0	2	0	0	2	0	0
Dysgeusia	20	1316	171	2300	3616	0	0
Dysgraphia	0	15	0	9	24	0	0
Dyskinesia	4	151	17	169	320	0	0
Dyskinesia hyperpyrexia syndrome	0	0	0	15	15	0	0
Dyslalia	1	14	0	8	22	0	0
Dyslexia	0	4	0	3	7	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Dysmetria	0	3	0	2	5	0	0
Dyspraxia	0	13	0	4	17	0	0
Dysstasia	13	184	42	257	441	0	0
Dystonia	3	31	1	9	40	0	0
Dystonic tremor	0	3	0	1	4	0	0
Electric shock sensation	11	124	9	112	236	0	0
Embolic cerebellar infarction	0	1	0	1	2	0	0
Embolic cerebral infarction	0	8	0	0	8	0	1
Embolic stroke	2	52	0	0	52	0	0
Encephalitis autoimmune	6	36	0	0	36	1	1
Encephalitis post immunisation	1	3	0	0	3	0	0
Encephalitis post varicella	1	1	0	0	1	0	0
Encephalomalacia	0	2	0	1	3	0	0
Encephalopathy	7	41	0	3	44	0	0
Epilepsy	25	519	2	132	651	0	0
Epileptic aura	1	4	0	1	5	0	0
Epileptic encephalopathy	0	1	0	0	1	0	0
Essential tremor	2	6	3	16	22	0	0
Exaggerated startle response	0	3	1	6	9	0	0
Exertional headache	1	16	2	11	27	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Extensor plantar response	0	7	1	3	10	0	0
External compression headache	0	5	0	2	7	0	0
Extrapyramidal disorder	0	20	0	10	30	0	0
Facial nerve disorder	0	16	1	10	26	0	0
Facial paralysis	45	841	21	330	1171	0	3
Facial paresis	12	322	13	138	460	0	0
Facial spasm	3	39	3	38	77	0	1
Febrile convulsion	12	178	50	185	363	0	0
Femoral nerve palsy	0	0	0	1	1	0	0
Fine motor delay	0	2	0	1	3	0	0
Fine motor skill dysfunction	3	42	5	21	63	0	0
Focal dyscognitive seizures	0	9	0	0	9	0	0
Foetal movement disorder	0	1	0	1	2	0	0
Fontanelle bulging	0	3	0	1	4	0	0
Formication	7	93	49	267	360	0	0
Freezing phenomenon	0	138	1	46	184	0	0
Frontotemporal dementia	0	2	0	0	2	0	0
Fumbling	0	3	2	2	5	0	0
Gait apraxia	0	0	0	6	6	0	0
Gait spastic	0	1	0	1	2	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Gelastic seizure	1	1	0	0	1	0	0
Generalised tonic-clonic seizure	13	209	0	0	209	1	1
Glial scar	0	0	1	1	1	0	0
Gliosis	0	2	0	0	2	0	0
Glossopharyngeal nerve disorder	0	1	0	0	1	0	0
Glossopharyngeal neuralgia	0	0	0	3	3	0	0
Grimacing	0	1	0	1	2	0	0
Gross motor delay	1	1	0	1	2	0	0
Guillain-Barre syndrome	175	1662	0	0	1662	14	35
Haemorrhage intracranial	9	137	0	0	137	1	5
Haemorrhagic cerebellar infarction	0	1	0	0	1	0	0
Haemorrhagic cerebral infarction	1	18	0	0	18	0	0
Haemorrhagic stroke	15	146	0	0	146	6	6
Haemorrhagic transformation stroke	1	20	0	0	20	0	1
Hand-eye coordination impaired	0	4	0	3	7	0	0
Hashimoto's encephalopathy	0	1	0	0	1	0	0
Head discomfort	45	872	259	1697	2569	0	0
Head titubation	2	27	3	20	47	0	0
Headache	1280	75393	23418	229675	305068	2	18
Hemianaesthesia	2	11	0	5	16	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Hemianopia	1	29	0	8	37	0	0
Hemianopia homonymous	0	11	0	2	13	0	0
Hemiapraxia	0	1	0	0	1	0	0
Hemiataxia	0	4	0	0	4	0	0
Hemidysaesthesia	0	8	0	6	14	0	0
Hemihyperaesthesia	0	4	0	3	7	0	0
Hemihypoaesthesia	2	27	0	20	47	0	0
Hemiparaesthesia	3	77	2	41	118	0	0
Hemiparesis	33	524	0	0	524	1	3
Hemiplegia	13	231	0	0	231	0	0
Hemiplegic migraine	0	56	0	6	62	0	0
Hepatic encephalopathy	0	7	0	0	7	0	0
Hoffmann's sign	0	1	0	0	1	0	0
Horner's syndrome	1	4	0	2	6	0	0
Hydrocephalus	3	38	0	0	38	0	0
Hyperaesthesia	11	269	66	751	1020	0	0
Hypercapnic coma	0	1	0	0	1	0	0
Hypergeusia	0	0	0	2	2	0	0
Hyperintensity in brain deep nuclei	1	2	0	0	2	0	0
Hyperkinesia	0	22	0	6	28	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Hyperpathia	0	2	0	1	3	0	0
Hyperreflexia	1	17	2	6	23	0	0
Hyperresponsive to stimuli	0	1	0	1	2	0	0
Hypersomnia	15	223	76	375	598	0	0
Hypertensive cerebrovascular disease	0	3	0	0	3	0	0
Hypertensive encephalopathy	2	2	0	0	2	0	0
Hypertonia	0	11	2	19	30	0	0
Hypoaesthesia	198	5455	724	7964	13419	0	2
Hypogeusia	1	15	16	101	116	0	0
Hypoglossal nerve paralysis	2	6	0	0	6	0	0
Hypoglossal nerve paresis	0	0	0	1	1	0	0
Hypoglycaemic coma	0	2	0	0	2	0	0
Hypoglycaemic seizure	0	1	0	0	1	0	0
Hypoglycaemic unconsciousness	0	2	0	0	2	0	0
Hypokinesia	5	165	46	374	539	0	0
Hyporeflexia	3	42	1	10	52	0	0
Hyporesponsive to stimuli	1	8	0	6	14	0	0
Hyposmia	0	16	9	82	98	0	0
Hypotonia	9	171	43	841	1012	0	0
Hypotonic-hyporesponsive episode	11	49	45	50	99	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Hypoxic-ischaemic encephalopathy	1	8	0	0	8	0	0
IIIrd nerve disorder	0	2	0	0	2	0	0
IIIrd nerve paralysis	1	20	0	3	23	1	1
IIIrd nerve paresis	0	7	0	3	10	0	0
IVth nerve disorder	1	3	0	0	3	0	0
IVth nerve paralysis	0	3	0	2	5	0	0
IVth nerve paresis	1	3	0	1	4	0	0
Idiopathic generalised epilepsy	0	1	0	0	1	0	0
Idiopathic intracranial hypertension	2	14	0	1	15	0	0
Immune-mediated encephalitis	1	4	0	0	4	0	0
Immune-mediated encephalopathy	0	2	0	0	2	0	0
Immune-mediated neurological disorder	1	2	0	0	2	0	0
Immune-mediated neuropathy	1	4	0	0	4	0	0
Inability to crawl	0	3	0	0	3	0	0
Incoherent	1	30	1	19	49	0	0
Infant irritability	1	5	0	7	12	0	0
Intellectual disability	2	20	0	0	20	0	0
Intensive care unit acquired weakness	1	3	0	0	3	0	0
Intention tremor	0	2	0	2	4	0	0
Intercostal neuralgia	0	3	2	10	13	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Internal capsule infarction	0	2	0	1	3	0	0
Internal carotid artery deformity	0	1	1	1	2	0	0
Intracranial aneurysm	1	24	0	4	28	0	0
Intracranial haematoma	0	9	0	0	9	0	0
Intracranial hypotension	3	10	0	0	10	0	0
Intracranial mass	0	6	0	0	6	0	0
Intracranial pressure increased	12	94	0	0	94	0	1
Intraventricular haemorrhage	0	20	0	0	20	0	0
Irregular sleep phase	0	1	0	4	5	0	0
Irregular sleep wake rhythm disorder	0	2	0	2	4	0	0
Ischaemic cerebral infarction	1	61	0	0	61	0	3
Ischaemic neuropathy	0	2	0	1	3	0	0
Ischaemic stroke	40	756	0	0	756	2	5
Judgement impaired	0	4	0	3	7	0	0
Lacunar infarction	2	44	0	0	44	0	0
Lacunar stroke	1	38	0	2	40	0	0
Language disorder	10	58	11	72	130	0	0
Lateral medullary syndrome	1	7	0	0	7	0	0
Lateropulsion	0	2	0	0	2	0	0
Lethargy	33	4007	112	4974	8981	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Leukoencephalopathy	0	5	0	0	5	0	0
Lhermitte's sign	0	5	0	1	6	0	0
Limbic encephalitis	3	8	0	0	8	0	0
Locked-in syndrome	0	1	0	0	1	0	0
Long thoracic nerve palsy	0	2	0	0	2	0	0
Loss of consciousness	144	2042	26	770	2812	0	2
Loss of proprioception	2	14	1	3	17	0	0
Lower motor neurone lesion	0	2	0	0	2	0	0
Lumbar radiculopathy	0	6	1	1	7	0	0
Lumbosacral plexopathy	1	4	0	1	5	0	0
Lumbosacral plexus lesion	1	2	0	1	3	0	0
Lumbosacral radiculopathy	0	1	1	2	3	0	0
Medication overuse headache	0	15	0	47	62	0	0
Meige's syndrome	0	1	0	0	1	0	0
Memory impairment	49	550	115	662	1212	0	0
Meningeal disorder	0	1	0	1	2	0	0
Meningeal thickening	0	1	0	0	1	0	0
Meningism	3	12	4	39	51	0	0
Meningitis eosinophilic	1	1	0	0	1	0	0
Meningitis noninfective	0	1	0	0	1	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Meningoradiculitis	0	8	0	0	8	0	0
Meningorrhagia	0	2	0	0	2	0	0
Menstrual headache	0	9	1	9	18	0	0
Mental impairment	10	166	19	102	268	0	0
Meralgia paraesthetica	0	5	1	7	12	0	0
Metabolic encephalopathy	0	3	0	0	3	0	0
Microglial nodules	0	1	0	0	1	0	0
Micrographia	1	1	0	0	1	0	0
Microsleep	0	2	0	2	4	0	0
Microvascular cranial nerve palsy	0	3	0	1	4	0	0
Migraine	97	7299	443	4250	11549	0	1
Migraine with aura	12	391	23	212	603	0	0
Migraine without aura	0	43	3	21	64	0	0
Migraine-triggered seizure	0	3	0	0	3	0	0
Miller Fisher syndrome	8	57	0	8	65	1	2
Mixed dementia	0	1	0	0	1	0	0
Mononeuritis	1	9	0	4	13	0	0
Mononeuropathy	1	5	1	5	10	0	0
Mononeuropathy multiplex	0	0	0	1	1	0	0
Monoparesis	17	265	0	0	265	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Monoplegia	21	361	0	0	361	0	0
Morton's neuralgia	0	0	1	1	1	0	0
Motor dysfunction	9	89	4	79	168	0	1
Motor neurone disease	6	13	0	1	14	0	0
Movement disorder	30	221	44	457	678	0	0
Multifocal motor neuropathy	2	4	0	0	4	0	0
Multiple sclerosis	21	131	5	44	175	0	3
Multiple sclerosis pseudo relapse	1	4	1	2	6	0	0
Multiple sclerosis relapse	10	113	0	24	137	1	3
Muscle contractions involuntary	7	72	22	153	225	0	0
Muscle spasticity	7	45	7	31	76	0	0
Muscle tension dysphonia	0	1	0	1	2	0	0
Muscle tone disorder	0	1	0	4	5	0	0
Myasthenia gravis	5	60	4	22	82	4	4
Myasthenia gravis crisis	1	5	0	2	7	0	0
Myasthenic syndrome	0	2	0	0	2	0	0
Myelin oligodendrocyte glycoprotein antibody-associated disease	4	12	0	0	12	2	6
Myelitis transverse	25	234	2	20	254	0	1
Myelopathy	4	24	0	5	29	0	0
Myoclonic epilepsy	1	9	0	0	9	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Myoclonus	0	47	5	47	94	0	0
Myotonia	0	0	1	1	1	0	0
Narcolepsy	1	24	2	13	37	0	0
Neonatal seizure	1	1	0	0	1	1	1
Nerve compression	3	49	1	29	78	0	0
Nerve degeneration	0	1	1	1	2	0	0
Nervous system disorder	29	237	50	213	450	0	0
Neuralgia	51	1512	125	1298	2810	0	0
Neuralgic amyotrophy	8	55	7	25	80	0	0
Neuritis	4	45	6	50	95	0	0
Neuritis cranial	0	5	0	0	5	0	0
Neurodegenerative disorder	1	2	1	1	3	0	0
Neuroleptic malignant syndrome	0	1	0	0	1	0	0
Neurologic neglect syndrome	1	10	0	3	13	0	0
Neurological decompensation	1	10	1	3	13	0	0
Neurological symptom	17	185	9	87	272	0	0
Neuromuscular blockade	0	1	0	1	2	0	0
Neuromuscular pain	0	5	0	5	10	0	0
Neuromyelitis optica spectrum disorder	3	25	0	4	29	0	1
Neuromyopathy	1	8	1	2	10	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Neuromyotonia	1	2	1	2	4	0	0
Neuropathy peripheral	37	367	16	225	592	0	0
Neuropsychiatric lupus	0	0	0	1	1	0	0
Neurosarcoidosis	1	6	0	0	6	0	0
Neurotoxicity	0	5	0	0	5	0	0
Neurovascular conflict	0	3	1	1	4	0	0
New daily persistent headache	1	26	2	27	53	0	0
Non-24-hour sleep-wake disorder	0	2	0	2	4	0	0
Noninfectious myelitis	0	1	0	0	1	0	0
Noninfective encephalitis	10	33	0	0	33	0	0
Noninfective encephalomyelitis	1	3	0	0	3	0	0
Normal pressure hydrocephalus	0	2	0	0	2	0	0
Notalgia paraesthetica	0	0	0	1	1	0	0
Numb chin syndrome	0	5	0	2	7	0	0
Nystagmus	3	44	1	37	81	0	0
Occipital neuralgia	3	30	3	20	50	0	0
Oculofacial paralysis	0	2	0	0	2	0	0
Ophthalmic migraine	2	31	10	53	84	0	0
Ophthalmoplegic migraine	0	1	0	0	1	0	0
Opisthotonus	0	5	0	0	5	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Optic neuritis	15	155	2	34	189	0	4
Oromandibular dystonia	0	1	0	1	2	0	0
Orthostatic intolerance	1	13	0	8	21	0	0
Orthostatic tremor	2	2	0	0	2	0	0
Osmotic demyelination syndrome	0	1	0	0	1	0	0
Pachymeningitis	0	3	0	1	4	0	0
Paraesthesia	262	8381	1025	13309	21690	1	3
Paraesthesia mucosal	0	2	0	1	3	0	0
Paralysis	52	595	10	139	734	0	0
Paralysis recurrent laryngeal nerve	0	5	0	0	5	0	0
Paraparesis	5	55	0	0	55	0	0
Paraplegia	12	39	0	0	39	0	0
Paresis	20	116	10	81	197	0	0
Paresis cranial nerve	0	3	0	2	5	0	0
Parkinson's disease	2	34	3	9	43	0	0
Parkinsonian gait	0	3	0	0	3	0	0
Parkinsonism	2	15	0	6	21	0	0
Parosmia	8	265	78	655	920	0	0
Partial seizures	2	82	1	17	99	0	0
Partial seizures with secondary generalisation	1	2	0	0	2	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Patient elopement	0	3	0	3	6	0	0
Perinatal stroke	0	2	0	0	2	0	0
Periodic limb movement disorder	0	2	0	0	2	0	0
Peripheral motor neuropathy	2	10	0	3	13	0	0
Peripheral nerve lesion	3	7	0	5	12	0	0
Peripheral nerve palsy	0	2	0	0	2	0	0
Peripheral nerve paresis	0	2	0	0	2	0	0
Peripheral paralysis	1	10	0	1	11	0	0
Peripheral sensorimotor neuropathy	1	11	1	1	12	0	0
Peripheral sensory neuropathy	5	38	3	21	59	0	0
Peroneal nerve palsy	3	33	1	5	38	0	0
Persistent genital arousal disorder	0	2	0	1	3	0	0
Persistent postural-perceptual dizziness	1	41	1	9	50	0	0
Petit mal epilepsy	3	64	1	20	84	0	0
Phantom limb syndrome	0	16	1	15	31	0	0
Phrenic nerve irritation	0	0	0	1	1	0	0
Phrenic nerve paralysis	0	3	0	2	5	0	0
Pineal gland cyst	0	0	0	2	2	0	0
Piriformis syndrome	0	3	0	0	3	0	0
Pleocytosis	2	13	0	0	13	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Polyneuropathy	18	199	0	0	199	0	0
Polyneuropathy chronic	0	1	0	1	2	0	0
Polyneuropathy in malignant disease	0	0	0	1	1	0	0
Poor sucking reflex	0	4	0	0	4	0	0
Post cardiac arrest syndrome	0	1	0	0	1	0	0
Post herpetic neuralgia	1	20	4	26	46	0	0
Post polio syndrome	0	0	0	1	1	0	0
Post stroke epilepsy	0	1	0	0	1	0	0
Post-traumatic headache	0	4	0	2	6	0	0
Posterior reversible encephalopathy syndrome	4	10	0	0	10	0	0
Posthaemorrhagic hydrocephalus	0	2	0	0	2	0	0
Postictal paralysis	0	3	0	0	3	0	0
Postictal state	0	6	0	2	8	0	0
Postresuscitation encephalopathy	0	2	0	0	2	0	0
Postural tremor	0	1	0	3	4	0	0
Precerebral artery occlusion	0	1	0	0	1	0	0
Presyncope	23	704	117	1453	2157	0	0
Primary cough headache	0	2	0	1	3	0	0
Primary headache associated with sexual activity	0	12	0	2	14	0	0
Primary progressive aphasia	0	1	0	0	1	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Progressive multiple sclerosis	0	2	0	0	2	0	0
Prosopagnosia	1	2	0	2	4	0	0
Pseudoparalysis	0	0	0	2	2	0	0
Pseudostroke	0	6	0	0	6	0	0
Psychogenic seizure	1	9	0	10	19	0	0
Psychomotor disadaptation syndrome	0	0	0	1	1	0	0
Psychomotor hyperactivity	1	40	2	51	91	0	0
Psychomotor skills impaired	0	6	0	1	7	0	0
Quadrantanopia	2	3	0	1	4	0	0
Quadriparesis	5	49	0	0	49	0	0
Quadriplegia	7	27	0	0	27	0	0
Radial nerve compression	0	1	0	0	1	0	0
Radial nerve palsy	0	6	0	3	9	0	0
Radicular pain	1	5	0	1	6	0	0
Radiculitis brachial	1	32	1	12	44	0	0
Radiculopathy	5	40	3	20	60	0	0
Raymond-Cestan syndrome	1	1	0	0	1	0	0
Reduced facial expression	0	12	0	6	18	0	0
Reflexes abnormal	1	10	1	6	16	0	0
Relapsing multiple sclerosis	0	2	0	0	2	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Relapsing-remitting multiple sclerosis	0	4	0	0	4	2	7
Repetitive speech	0	5	0	1	6	0	0
Resting tremor	1	9	0	8	17	0	0
Restless arm syndrome	0	9	1	11	20	0	0
Restless legs syndrome	5	339	31	319	658	0	0
Retinal migraine	0	75	1	20	95	0	0
Retrograde amnesia	0	11	0	2	13	0	0
Reversed hot-cold sensation	0	3	0	18	21	0	0
Reversible cerebral vasoconstriction syndrome	1	7	0	1	8	0	0
Right hemisphere deficit syndrome	0	2	0	0	2	0	0
Ruptured cerebral aneurysm	1	11	0	0	11	0	0
SUNA syndrome	0	1	0	0	1	0	0
SUNCT syndrome	0	1	0	1	2	0	0
Sciatic nerve neuropathy	0	8	0	3	11	0	0
Sciatica	15	247	17	169	416	0	0
Secondary progressive multiple sclerosis	0	0	1	1	1	0	1
Sedation	0	23	2	46	69	0	0
Seizure	302	2970	0	0	2970	1	5
Seizure anoxic	1	3	0	1	4	0	0
Seizure cluster	0	8	0	1	9	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Seizure like phenomena	0	15	0	0	15	0	0
Senile dementia	0	3	0	0	3	0	0
Sensorimotor disorder	1	7	0	7	14	0	0
Sensory disturbance	40	372	75	781	1153	0	0
Sensory loss	14	271	45	255	526	0	1
Sensory overload	0	12	1	8	20	0	0
Sensory processing disorder	0	3	0	0	3	0	1
Serotonin deficiency	0	0	0	1	1	0	0
Serotonin syndrome	0	0	0	1	1	0	0
Sigmoid sinus thrombosis	5	5	1	1	6	1	1
Simple partial seizures	0	7	0	1	8	0	0
Sinus headache	8	775	11	294	1069	0	0
Sleep deficit	2	47	7	48	95	0	0
Sleep paralysis	0	21	0	16	37	0	0
Slow response to stimuli	0	10	1	16	26	0	0
Slow speech	3	50	0	19	69	0	0
Small fibre neuropathy	17	32	6	9	41	0	0
Somnolence	56	2171	553	7670	9841	1	1
Spasmodic dysphonia	0	0	0	1	1	0	0
Speech disorder	27	328	32	242	570	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Speech disorder developmental	2	8	1	3	11	0	0
Spinal artery thrombosis	0	1	0	1	2	0	0
Spinal cord compression	3	7	0	0	7	0	0
Spinal cord disorder	1	9	0	3	12	0	0
Spinal cord haematoma	0	3	0	0	3	0	0
Spinal cord haemorrhage	0	6	0	0	6	0	0
Spinal cord infarction	0	10	0	0	10	0	0
Spinal cord ischaemia	1	6	0	2	8	0	0
Spinal cord oedema	1	2	0	1	3	0	0
Spinal epidural haematoma	0	1	0	0	1	0	0
Spinal meningeal cyst	0	1	0	1	2	0	0
Spinal stroke	1	7	0	0	7	0	0
Spontaneous cerebrospinal fluid leak syndrome	0	2	0	0	2	0	0
Status epilepticus	2	105	0	0	105	1	1
Status migrainosus	0	10	0	6	16	0	0
Stiff leg syndrome	0	8	0	8	16	0	0
Stiff person syndrome	0	3	0	0	3	0	0
Stroke in evolution	0	1	0	0	1	0	0
Stupor	1	17	0	38	55	0	0
Subacute inflammatory demyelinating polyneuropathy	0	11	0	0	11	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Subarachnoid haemorrhage	18	234	0	0	234	0	0
Sudden onset of sleep	1	6	2	14	20	0	0
Superior sagittal sinus thrombosis	7	99	0	0	99	1	2
Sydenham's chorea	0	1	0	0	1	0	0
Sympathicotonia	0	0	0	1	1	0	0
Syncope	260	4001	105	3077	7078	2	2
Synkinesis	0	0	1	1	1	0	0
Tardive dyskinesia	0	1	0	0	1	0	0
Tarsal tunnel syndrome	0	0	0	2	2	0	0
Taste disorder	10	425	139	1109	1534	0	0
Temporal lobe epilepsy	1	10	0	2	12	0	0
Tension headache	11	1263	68	878	2141	0	0
Thalamic infarction	3	32	0	0	32	0	1
Thalamus haemorrhage	0	15	0	0	15	0	0
Thermohypoaesthesia	0	1	0	0	1	0	0
Thoracic outlet syndrome	2	5	0	1	6	0	0
Thrombotic cerebral infarction	0	5	0	0	5	0	0
Thrombotic stroke	3	36	0	0	36	0	0
Thunderclap headache	4	70	0	0	70	0	0
Tick paralysis	1	1	0	1	2	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Tongue biting	1	11	0	8	19	0	0
Tongue paralysis	1	10	0	2	12	0	0
Tonic clonic movements	0	12	0	11	23	0	0
Tonic convulsion	2	52	0	0	52	0	0
Tonic posturing	0	0	0	1	1	0	0
Transient aphasia	1	11	1	4	15	0	0
Transient global amnesia	0	48	0	27	75	0	0
Transient ischaemic attack	41	1107	0	0	1107	0	1
Transverse sinus stenosis	0	3	0	0	3	0	0
Transverse sinus thrombosis	2	60	0	3	63	0	0
Tremor	102	9183	624	6631	15814	0	1
Trigeminal nerve disorder	0	13	0	9	22	0	0
Trigeminal nerve paresis	0	2	0	0	2	0	0
Trigeminal neuralgia	4	182	12	124	306	0	0
Trigeminal neuritis	0	4	1	2	6	0	0
Trigeminal neuropathy	1	1	0	0	1	0	0
Trigeminal palsy	0	3	0	0	3	0	0
Tumefactive multiple sclerosis	0	1	0	0	1	0	1
Tunnel vision	2	27	1	15	42	0	0
Typical aura without headache	0	17	1	8	25	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Uhthoff's phenomenon	0	2	I	3	5	0	0
Ulnar nerve palsy	I	4	0	0	4	0	0
Ulnar neuritis	0	4	0	4	8	0	0
Ulnar tunnel syndrome	0	I	0	0	I	0	0
Unresponsive to stimuli	4	190	0	0	190	0	0
Upper motor neurone lesion	I	2	0	0	2	0	0
Uraemic encephalopathy	0	2	0	0	2	0	0
VIIIth nerve lesion	0	1	0	0	1	0	0
VIth nerve disorder	1	3	0	1	4	0	0
VIth nerve paralysis	2	31	2	20	51	0	0
VIth nerve paresis	0	6	0	1	7	0	0
Vagus nerve disorder	1	1	0	1	2	0	0
Vagus nerve paralysis	0	1	0	1	2	0	0
Vascular dementia	0	6	0	1	7	0	0
Vascular encephalopathy	0	0	0	1	1	0	0
Vascular headache	2	84	1	16	100	0	0
Vascular parkinsonism	0	1	0	0	1	0	0
Vasogenic cerebral oedema	0	2	0	1	3	0	0
Vertebral artery occlusion	0	5	0	1	6	0	0
Vertebral artery stenosis	0	0	0	1	I	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Vertebral artery thrombosis	1	10	0	0	10	0	0
Vertebrobasilar artery dissection	0	9	0	2	11	0	0
Vertebrobasilar insufficiency	1	4	0	0	4	0	0
Vertebrobasilar stroke	1	12	0	0	12	0	0
Vertigo CNS origin	1	4	0	0	4	0	0
Vestibular migraine	2	44	1	8	52	0	0
Vestibular nystagmus	0	1	0	1	2	0	0
Vibration syndrome	0	2	1	2	4	0	0
Vibratory sense increased	1	7	1	4	11	0	0
Visual pathway disorder	0	1	0	2	3	0	0
Visual perseveration	0	1	0	0	1	0	0
Visuospatial deficit	0	3	0	0	3	0	0
Vocal cord paralysis	1	15	0	5	20	0	0
Vocal cord paresis	1	2	0	0	2	0	0
Wernicke's encephalopathy	0	1	0	0	1	0	0
White matter lesion	1	11	2	5	16	0	0
Writer's cramp	0	1	0	0	1	0	0
Eye disorders	**600**	**16410**	**1607**	**18935**	**35345**	**31**	**64**
Abnormal sensation in eye	0	29	7	78	107	0	0
Accommodation disorder	0	5	0	34	39	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Acute macular neuroretinopathy	4	23	1	7	30	1	2
Altered visual depth perception	0	4	0	5	9	0	0
Amaurosis	1	21	0	4	25	0	0
Amaurosis fugax	2	41	0	0	41	4	4
Amblyopia	0	9	0	5	14	0	0
Angle closure glaucoma	0	10	0	2	12	4	4
Anisocoria	2	27	1	9	36	0	0
Anterior capsule contraction	0	2	1	1	3	0	0
Arcus lipoides	0	1	0	0	1	0	0
Arteriosclerotic retinopathy	0	0	0	0	0	0	1
Asthenopia	5	299	11	232	531	0	0
Astigmatism	0	1	1	4	5	0	0
Autoimmune eye disorder	0	1	0	0	1	0	0
Autoimmune uveitis	0	2	0	0	2	0	0
Bell's phenomenon	0	0	0	1	1	0	0
Binocular eye movement disorder	0	1	0	3	4	0	0
Birdshot chorioretinopathy	0	0	0	1	1	0	0
Blepharal pigmentation	0	0	0	1	1	0	0
Blepharitis	0	30	4	40	70	0	0
Blepharospasm	3	94	12	183	277	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Blindness	20	555	0	0	555	0	1
Blindness cortical	1	2	0	0	2	0	0
Blindness day	0	1	0	2	3	0	0
Blindness transient	13	117	0	0	117	0	0
Blindness unilateral	9	135	0	0	135	0	2
Cataract	9	41	4	20	61	0	0
Cataract cortical	0	2	0	0	2	0	0
Cataract nuclear	0	0	0	1	1	0	0
Cataract subcapsular	0	3	0	1	4	0	0
Central serous chorioretinopathy	2	9	0	1	10	0	0
Central vision loss	0	5	0	1	6	0	0
Chalazion	0	4	0	5	9	0	0
Charles Bonnet syndrome	0	1	0	0	1	0	0
Chloropsia	0	2	0	0	2	0	0
Chorioretinal disorder	1	2	0	0	2	0	0
Chorioretinopathy	0	5	2	3	8	1	1
Choroidal detachment	0	1	0	0	1	0	0
Choroidal effusion	0	2	1	4	6	0	0
Choroidal haemorrhage	0	1	0	0	1	0	0
Choroidal neovascularisation	0	1	0	1	2	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Choroiditis	0	1	0	1	2	0	0
Chromatopsia	0	3	0	4	7	0	0
Computer vision syndrome	0	0	0	1	1	0	0
Conjunctival bleb	0	1	0	0	1	0	0
Conjunctival disorder	0	1	0	0	1	0	0
Conjunctival haemorrhage	8	129	5	248	377	0	0
Conjunctival hyperaemia	0	8	2	31	39	0	0
Conjunctival irritation	0	0	1	9	9	0	0
Conjunctival oedema	1	2	5	19	21	0	0
Conjunctival opacity	0	0	0	2	2	0	0
Conjunctival pallor	0	0	1	1	1	0	0
Conjunctival suffusion	0	0	1	2	2	0	0
Conjunctivitis allergic	0	3	1	11	14	0	0
Corneal bleeding	0	3	0	4	7	0	0
Corneal cyst	0	1	0	0	1	0	0
Corneal defect	0	1	0	1	2	0	0
Corneal disorder	0	0	1	1	1	0	0
Corneal erosion	1	1	0	0	1	0	0
Corneal lesion	0	2	0	2	4	0	0
Corneal leukoma	0	1	0	0	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Corneal neovascularisation	0	1	0	0	1	0	0
Corneal oedema	0	3	3	10	13	0	0
Corneal opacity	0	4	0	1	5	0	0
Corneal perforation	0	2	0	0	2	0	0
Corneal scar	0	1	0	0	1	0	0
Cyanopsia	0	3	0	1	4	0	0
Cystoid macular oedema	1	7	2	3	10	0	0
Dacryostenosis acquired	0	1	0	2	3	0	0
Dark circles under eyes	0	10	4	17	27	0	0
Delayed dark adaptation	0	1	0	0	1	0	0
Deposit eye	0	1	0	0	1	0	0
Dermatochalasis	1	2	0	0	2	0	0
Detachment of macular retinal pigment epithelium	0	0	0	1	1	0	0
Diabetic retinopathy	1	5	0	1	6	0	0
Diplopia	17	527	23	362	889	0	0
Disorder of globe	0	1	0	1	2	0	0
Dry age-related macular degeneration	0	1	0	0	1	0	0
Dry eye	8	277	23	267	544	0	0
Dyschromatopsia	0	20	0	12	32	0	0
Dysmetropsia	0	1	0	0	1	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Ectropion	0	1	0	0	1	0	0
Eczema eyelids	0	8	1	6	14	0	0
Endocrine ophthalmopathy	1	7	3	4	11	0	0
Enophthalmos	0	0	0	1	1	0	0
Epiretinal membrane	0	3	1	3	6	0	0
Episcleral hyperaemia	0	0	0	1	1	0	0
Episcleritis	0	14	2	19	33	0	0
Erythema of eyelid	1	14	4	22	36	0	0
Erythropsia	0	3	0	4	7	0	0
Excessive eye blinking	0	5	4	10	15	0	0
Exophthalmos	0	14	0	13	27	0	0
Extraocular muscle disorder	0	0	0	2	2	0	0
Eye allergy	1	25	1	24	49	0	0
Eye colour change	0	7	1	6	13	0	0
Eye discharge	1	21	5	43	64	0	0
Eye disorder	9	61	13	116	177	0	0
Eye haematoma	0	13	2	35	48	0	0
Eye haemorrhage	24	181	20	233	414	0	0
Eye infarction	4	18	0	2	20	0	0
Eye inflammation	5	47	14	102	149	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Eye irritation	3	202	41	557	759	0	0
Eye movement disorder	0	64	4	49	113	0	0
Eye oedema	0	27	11	90	117	0	0
Eye opacity	0	3	0	0	3	0	0
Eye pain	39	3002	374	4509	7511	0	0
Eye paraesthesia	0	7	0	6	13	0	0
Eye pruritus	6	227	35	412	639	0	0
Eye swelling	12	488	49	730	1218	0	0
Eye symptom	0	15	0	6	21	0	0
Eye ulcer	0	7	1	7	14	0	0
Eyelash discolouration	0	0	0	1	1	0	0
Eyelid bleeding	0	6	3	11	17	0	0
Eyelid cyst	0	15	0	7	22	0	0
Eyelid disorder	1	16	0	15	31	0	0
Eyelid erosion	0	0	0	1	1	0	0
Eyelid exfoliation	0	1	1	4	5	0	0
Eyelid function disorder	0	2	0	4	6	0	0
Eyelid haematoma	1	4	1	28	32	0	0
Eyelid irritation	1	6	5	31	37	0	0
Eyelid margin crusting	0	1	0	1	2	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Eyelid myoclonus	0	1	1	3	4	0	0
Eyelid myokymia	0	3	1	4	7	0	0
Eyelid oedema	1	68	11	172	240	0	0
Eyelid pain	1	15	8	47	62	0	0
Eyelid ptosis	3	90	5	58	148	0	0
Eyelid rash	0	10	2	21	31	0	0
Eyelid sensory disorder	0	1	0	8	9	0	0
Eyelid skin dryness	0	3	1	4	7	0	0
Eyelid thickening	0	3	0	4	7	0	0
Eyelids pruritus	0	10	4	23	33	0	0
Floppy eyelid syndrome	0	0	0	1	1	0	0
Foreign body sensation in eyes	0	31	3	32	63	0	0
Gaze palsy	2	15	0	4	19	0	0
Glare	0	0	0	2	2	0	0
Glaucoma	10	33	3	10	43	0	0
Glaucomatocyclitic crises	0	1	0	0	1	0	0
Growth of eyelashes	0	8	0	2	10	0	0
Haemorrhagic occlusive retinal vasculitis	0	0	1	1	1	0	0
Halo vision	1	14	1	3	17	0	0
Heterophoria	0	0	0	2	2	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Hippus	0	0	0	1	1	0	0
Holmes-Adie pupil	0	3	0	2	5	0	0
Homonymous diplopia	0	1	0	0	1	0	0
Hyperaesthesia eye	0	0	0	6	6	0	0
Hypermetropia	0	3	0	6	9	0	0
Hypoaesthesia eye	1	22	1	13	35	0	0
Hypotony of eye	0	1	0	0	1	0	0
Idiopathic orbital inflammation	0	1	0	0	1	0	0
Inflammation of lacrimal passage	0	0	0	1	1	0	0
Iridocyclitis	5	40	1	16	56	1	1
Iris discolouration	0	0	0	2	2	0	0
Iris disorder	0	1	1	1	2	0	0
Iris haemorrhage	0	0	0	2	2	0	0
Iris neovascularisation	1	1	0	0	1	0	0
Iritis	0	15	2	15	30	0	0
Keratitis	0	18	0	0	18	0	0
Lacrimal disorder	0	1	0	6	7	0	0
Lacrimation decreased	0	3	0	1	4	0	0
Lacrimation disorder	0	3	0	5	8	0	0
Lacrimation increased	8	250	61	413	663	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Lagophthalmos	0	9	0	2	11	0	0
Lens dislocation	0	0	0	0	0	1	1
Lenticular opacities	0	0	0	2	2	0	0
Leukocoria	1	1	0	0	1	0	0
Lid sulcus deepened	0	3	0	2	5	0	0
Limbal swelling	0	6	0	4	10	0	0
Loss of visual contrast sensitivity	0	1	0	0	1	0	0
Macular cyst	0	1	0	0	1	0	0
Macular degeneration	6	18	1	5	23	0	0
Macular detachment	0	1	0	0	1	0	0
Macular hole	1	6	0	1	7	0	0
Macular oedema	5	34	1	11	45	0	2
Macular rupture	0	2	0	0	2	0	0
Maculopathy	0	11	1	4	15	0	0
Meibomian gland dysfunction	0	1	0	1	2	0	0
Meibomianitis	0	0	0	1	1	0	0
Metamorphopsia	0	46	0	21	67	0	0
Miosis	0	14	2	18	32	0	0
Mydriasis	0	42	2	29	71	0	0
Myopia	1	7	0	5	12	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Myopic chorioretinal degeneration	0	0	0	1	1	0	0
Myopic traction maculopathy	0	0	0	1	1	0	0
Neovascular age-related macular degeneration	1	15	0	5	20	0	0
Neurological eyelid disorder	0	1	0	0	1	0	0
Night blindness	0	4	1	4	8	0	0
Non-infectious endophthalmitis	0	0	0	2	2	0	0
Noninfective conjunctivitis	0	1	0	0	1	0	0
Normal tension glaucoma	0	0	0	1	1	0	0
Ocular discomfort	10	119	75	546	665	0	0
Ocular dysmetria	0	0	0	1	1	0	0
Ocular hyperaemia	12	327	58	778	1105	0	0
Ocular hypertension	1	13	2	11	24	0	0
Ocular ischaemic syndrome	1	3	0	0	3	0	0
Ocular myasthenia	3	10	0	2	12	0	0
Ocular retrobulbar haemorrhage	0	3	0	1	4	0	0
Ocular rosacea	0	0	0	3	3	0	0
Ocular sarcoidosis	0	1	0	0	1	0	0
Ocular vascular disorder	0	5	1	2	7	0	0
Ocular vasculitis	0	3	0	0	3	0	0
Ophthalmic artery thrombosis	0	6	0	0	6	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Ophthalmic vein thrombosis	5	72	0	3	75	0	0
Ophthalmoplegia	4	32	0	17	49	1	1
Opsoclonus myoclonus	0	0	0	2	2	0	0
Optic atrophy	0	5	2	3	8	0	0
Optic disc disorder	0	1	0	0	1	0	0
Optic disc drusen	1	1	0	0	1	0	0
Optic disc haemorrhage	0	3	0	1	4	0	0
Optic disc hyperaemia	0	1	0	0	1	0	0
Optic discs blurred	0	3	0	1	4	0	0
Optic ischaemic neuropathy	4	58	0	0	58	0	1
Optic nerve compression	0	2	0	0	2	0	0
Optic nerve disorder	0	10	0	5	15	0	1
Optic nerve infarction	1	6	0	0	6	0	0
Optic nerve sheath haemorrhage	0	3	0	0	3	0	0
Optic neuropathy	1	18	0	2	20	0	0
Orbital haematoma	0	2	0	2	4	0	0
Orbital haemorrhage	0	1	0	0	1	0	0
Orbital myositis	0	1	0	0	1	0	0
Orbital oedema	1	4	0	5	9	0	0
Orbital swelling	1	2	1	3	5	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Oscillopsia	0	1	0	2	3	0	0
Panophthalmitis	0	1	0	0	1	0	0
Papilloedema	3	44	3	11	55	0	0
Papillophlebitis	0	1	0	0	1	0	0
Paralytic lagophthalmos	0	2	0	1	3	0	0
Parinaud syndrome	0	0	0	1	1	0	0
Parophthalmia	1	3	0	2	5	0	0
Periorbital discomfort	0	3	0	4	7	0	0
Periorbital disorder	0	0	0	2	2	0	0
Periorbital inflammation	0	0	0	2	2	0	0
Periorbital irritation	0	0	1	1	1	0	0
Periorbital oedema	1	20	6	72	92	0	0
Periorbital pain	1	8	2	27	35	0	0
Periorbital swelling	3	108	10	163	271	0	0
Photophobia	26	1104	160	1407	2511	0	0
Photopsia	2	309	9	202	511	0	0
Pinguecula	0	0	0	1	1	0	0
Posterior capsule opacification	0	1	0	1	2	0	0
Presbyopia	2	3	0	3	6	0	0
Punctate keratitis	1	2	0	1	3	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Pupil fixed	1	18	0	3	21	0	0
Pupillary deformity	0	0	0	1	1	0	0
Pupillary disorder	0	2	0	3	5	0	0
Pupillary reflex impaired	0	7	0	2	9	0	0
Refraction disorder	0	1	0	1	2	0	0
Retinal aneurysm	0	3	0	0	3	0	0
Retinal artery embolism	0	13	0	2	15	0	0
Retinal artery occlusion	6	102	0	0	102	1	4
Retinal artery thrombosis	1	21	0	5	26	0	0
Retinal cyst	0	0	0	1	1	0	0
Retinal degeneration	0	3	0	0	3	0	0
Retinal detachment	5	114	0	0	114	0	0
Retinal disorder	0	4	0	1	5	0	0
Retinal drusen	0	1	1	1	2	0	0
Retinal exudates	1	14	1	5	19	0	0
Retinal fovea disorder	0	1	0	1	2	0	0
Retinal haemorrhage	3	57	2	15	72	0	2
Retinal infarction	0	2	0	2	4	0	0
Retinal ischaemia	0	8	0	1	9	0	0
Retinal microangiopathy	0	0	0	1	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Retinal neovascularisation	0	1	0	0	1	0	0
Retinal occlusive vasculitis	1	2	0	0	2	0	0
Retinal oedema	0	6	1	3	9	0	0
Retinal pigment epitheliopathy	2	4	0	0	4	0	0
Retinal scar	0	0	0	1	1	0	0
Retinal tear	0	38	0	8	46	0	0
Retinal telangiectasia	0	1	0	0	1	0	0
Retinal toxicity	0	6	0	0	6	0	0
Retinal vascular disorder	0	3	0	3	6	0	0
Retinal vascular occlusion	1	14	0	0	14	0	0
Retinal vascular thrombosis	1	45	0	0	45	0	1
Retinal vasculitis	0	1	0	0	1	0	0
Retinal vein occlusion	22	307	0	0	307	9	23
Retinal vein thrombosis	7	97	0	0	97	0	0
Retinal vein varices	0	1	0	0	1	0	0
Retinal vessel avulsion	0	1	0	0	1	0	0
Retinal white dots syndrome	0	3	0	0	3	0	0
Retinopathy	0	15	1	3	18	0	0
Retinopathy haemorrhagic	0	1	0	0	1	0	0
Retinopathy hypertensive	0	2	0	0	2	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Retinopathy of prematurity	0	1	0	0	1	0	0
Retinoschisis	0	0	1	1	1	0	0
Saccadic eye movement	0	1	0	2	3	0	0
Scintillating scotoma	0	13	0	16	29	0	0
Scleral discolouration	0	1	0	0	1	0	0
Scleral disorder	0	0	0	1	1	0	0
Scleral haemorrhage	0	4	0	2	6	0	0
Scleral hyperaemia	0	1	0	2	3	0	0
Scleral oedema	1	1	0	0	1	0	0
Scleritis	1	18	1	6	24	1	1
Serous retinopathy	0	1	0	0	1	0	0
Serpiginous choroiditis	0	1	0	0	1	0	0
Spontaneous hyphaema	0	1	0	0	1	0	0
Strabismus	0	15	1	19	34	1	1
Subconjunctival cyst	0	0	1	1	1	0	0
Subretinal fluid	0	0	0	0	0	0	2
Subretinal haematoma	0	1	0	0	1	0	0
Sudden visual loss	5	16	0	1	17	0	0
Swelling of eyelid	2	99	21	229	328	0	0
Tolosa-Hunt syndrome	0	2	0	0	2	1	1

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Ulcerative keratitis	1	6	0	4	10	0	0
Uveitis	5	66	2	30	96	3	3
Vision blurred	71	3129	186	3079	6208	0	1
Visual acuity reduced	8	101	13	91	192	0	0
Visual acuity reduced transiently	0	2	0	5	7	0	0
Visual brightness	0	8	0	3	11	0	0
Visual field defect	9	102	8	103	205	0	0
Visual impairment	76	1292	200	1992	3284	0	1
Visual snow syndrome	0	6	0	3	9	0	0
Vitreoretinal traction syndrome	0	1	0	0	1	0	0
Vitreous cyst	0	1	0	0	1	0	0
Vitreous degeneration	0	0	0	2	2	0	0
Vitreous detachment	6	89	1	43	132	0	0
Vitreous disorder	0	0	0	3	3	0	0
Vitreous floaters	7	198	6	127	325	0	0
Vitreous haematoma	0	1	0	0	1	0	0
Vitreous haemorrhage	4	31	0	5	36	2	2
Vitreous haze	0	0	0	1	1	0	0
Vitreous opacities	0	3	0	8	11	0	0
Vitritis	0	0	0	1	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Vogt-Koyanagi-Harada disease	1	2	2	3	5	0	0
Xanthopsia	0	8	0	4	12	0	0
Xerophthalmia	0	2	0	4	6	0	0
Ear and labyrinth disorders	**352**	**10521**	**888**	**12162**	**22683**	**5**	**13**
Acute vestibular syndrome	0	9	0	2	11	0	0
Auditory disorder	1	19	3	37	56	0	0
Aural polyp	0	0	0	1	1	0	0
Auricular swelling	0	2	0	11	13	0	0
Autoimmune inner ear disease	0	1	0	0	1	0	0
Cerumen impaction	0	0	1	1	1	0	0
Conductive deafness	0	0	0	2	2	0	0
Deafness	34	664	0	0	664	2	2
Deafness bilateral	2	40	0	0	40	0	0
Deafness neurosensory	8	69	0	12	81	2	6
Deafness transitory	2	10	1	12	22	0	0
Deafness unilateral	12	123	2	49	172	0	0
Diplacusis	0	0	1	2	2	0	0
Dysacusis	0	1	0	3	4	0	0
Ear canal erythema	0	1	1	1	2	0	0
Ear canal stenosis	0	1	0	0	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Ear congestion	0	31	4	43	74	0	0
Ear discomfort	11	147	60	450	597	0	0
Ear disorder	2	24	4	37	61	0	0
Ear haemorrhage	0	21	1	23	44	0	0
Ear inflammation	1	3	0	9	12	0	0
Ear pain	32	1870	169	1970	3840	0	0
Ear pruritus	0	10	3	17	27	0	0
Ear swelling	1	67	6	88	155	0	0
Endolymphatic hydrops	0	3	0	1	4	0	0
Eustachian tube disorder	0	3	0	6	9	0	0
Eustachian tube dysfunction	0	5	0	5	10	0	0
Eustachian tube obstruction	1	8	0	7	15	0	0
Excessive cerumen production	1	31	1	21	52	0	0
External ear disorder	0	1	0	0	1	0	0
External ear inflammation	0	1	0	11	12	0	0
External ear pain	1	12	3	13	25	0	0
Hyperacusis	11	193	41	290	483	0	0
Hypoacusis	16	310	26	305	615	0	0
Inner ear disorder	1	14	4	13	27	0	0
Inner ear infarction	0	3	0	1	4	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Inner ear inflammation	0	5	0	3	8	0	0
Juvenile spring eruption	0	0	0	1	1	0	0
Mastoid disorder	0	1	0	0	1	0	0
Mastoid effusion	0	0	0	1	1	0	0
Meniere's disease	6	44	1	15	59	0	0
Middle ear disorder	0	1	0	1	2	0	0
Middle ear effusion	1	7	0	4	11	0	0
Middle ear inflammation	0	1	1	2	3	0	0
Misophonia	0	0	1	1	1	0	0
Mixed deafness	0	4	0	1	5	0	0
Motion sickness	0	118	7	61	179	0	0
Neurosensory hypoacusis	0	8	0	1	9	0	0
Noninfective myringitis	0	0	0	1	1	0	0
Ossicle disorder	0	1	0	0	1	0	0
Otolithiasis	0	1	1	1	2	0	0
Otorrhoea	0	4	2	15	19	0	0
Paraesthesia ear	0	4	1	7	11	0	0
Phobic postural vertigo	1	7	0	3	10	0	0
Presbyacusis	0	1	0	1	2	0	0
Red ear syndrome	0	4	0	1	5	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Sudden hearing loss	8	205	8	86	291	0	0
Tinnitus	121	3493	291	4446	7939	1	5
Tympanic membrane disorder	0	1	0	2	3	0	0
Tympanic membrane perforation	0	8	1	4	12	0	0
Vertigo	65	2678	235	3912	6590	0	0
Vertigo labyrinthine	1	21	0	4	25	0	0
Vertigo positional	10	175	7	125	300	0	0
Vestibular ataxia	1	1	0	0	1	0	0
Vestibular disorder	1	31	1	20	51	0	0
Cardiac disorders	**1186**	**18349**	**1277**	**16130**	**34479**	**18**	**38**
Acute cardiac event	0	7	0	0	7	0	0
Acute coronary syndrome	15	183	0	0	183	0	0
Acute left ventricular failure	0	3	0	0	3	0	0
Acute myocardial infarction	36	526	0	0	526	3	4
Adams-Stokes syndrome	1	3	0	0	3	0	0
Agonal rhythm	0	1	0	0	1	0	0
Angina pectoris	37	495	18	283	778	0	1
Angina unstable	3	35	0	0	35	0	0
Aortic valve disease	0	0	0	1	1	0	0
Aortic valve incompetence	3	11	0	3	14	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Aortic valve sclerosis	0	2	0	0	2	0	0
Aortic valve stenosis	1	2	0	0	2	0	0
Arrhythmia	136	1044	46	863	1907	0	0
Arrhythmia neonatal	0	2	0	3	5	0	0
Arrhythmia supraventricular	2	22	1	5	27	0	0
Arrhythmic storm	0	1	0	0	1	0	0
Arteriosclerosis coronary artery	1	27	0	2	29	2	2
Arteriospasm coronary	0	11	1	1	12	0	0
Arteritis coronary	0	0	0	1	1	0	0
Atrial enlargement	0	0	0	1	1	0	0
Atrial fibrillation	60	780	9	235	1015	0	1
Atrial flutter	8	77	1	40	117	0	0
Atrial standstill	0	0	0	1	1	0	0
Atrial tachycardia	1	12	0	5	17	0	0
Atrial thrombosis	0	13	0	0	13	0	0
Atrioventricular block	1	47	0	9	56	0	0
Atrioventricular block complete	5	26	0	0	26	0	0
Atrioventricular block first degree	2	27	3	10	37	0	0
Atrioventricular block second degree	4	21	1	4	25	0	0
Atrioventricular dissociation	0	7	1	3	10	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Autoimmune myocarditis	0	3	0	0	3	0	0
Autoimmune pericarditis	0	1	0	0	1	0	0
Bifascicular block	0	1	1	1	2	0	0
Bradyarrhythmia	0	4	0	0	4	0	0
Bradycardia	21	201	1	159	360	0	0
Bradycardia foetal	0	0	0	1	1	0	0
Bundle branch block	2	6	1	1	7	0	0
Bundle branch block left	3	16	0	6	22	0	0
Bundle branch block right	2	13	0	2	15	0	0
Cardiac aneurysm	1	4	0	0	4	0	0
Cardiac arrest	17	469	0	0	469	0	1
Cardiac asthma	0	2	0	0	2	0	0
Cardiac discomfort	5	50	34	175	225	0	0
Cardiac disorder	21	184	27	146	330	0	0
Cardiac dysfunction	0	9	1	4	13	0	0
Cardiac failure	25	323	2	32	355	0	0
Cardiac failure acute	2	42	0	0	42	0	0
Cardiac failure chronic	1	7	0	0	7	0	1
Cardiac failure congestive	8	44	0	5	49	0	0
Cardiac fibrillation	7	46	0	13	59	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Cardiac flutter	16	255	4	124	379	0	0
Cardiac hypertrophy	0	4	0	1	5	0	0
Cardiac perfusion defect	0	1	0	0	1	0	0
Cardiac sarcoidosis	1	2	0	0	2	0	0
Cardiac septal hypertrophy	1	1	1	1	2	0	0
Cardiac tamponade	3	15	0	0	15	0	1
Cardiac valve disease	0	7	1	3	10	0	0
Cardiac ventricular scarring	1	1	0	0	1	0	0
Cardiac ventricular thrombosis	2	28	0	0	28	0	0
Cardio-respiratory arrest	7	114	0	0	114	0	0
Cardio-respiratory distress	0	2	0	0	2	0	0
Cardiogenic shock	4	52	0	0	52	0	0
Cardiomegaly	3	55	1	19	74	0	0
Cardiomyopathy	5	46	1	9	55	1	1
Cardiomyopathy acute	0	1	0	0	1	0	0
Cardiomyopathy alcoholic	0	1	0	0	1	0	0
Cardiomyopathy neonatal	1	1	0	0	1	0	0
Cardiopulmonary failure	3	14	0	0	14	0	0
Cardiorenal syndrome	1	1	0	0	1	0	0
Cardiotoxicity	0	1	0	0	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Cardiovascular deconditioning	1	1	0	1	2	0	0
Cardiovascular disorder	22	196	35	593	789	0	0
Cardiovascular insufficiency	3	27	1	10	37	0	0
Cardiovascular symptom	0	7	0	3	10	0	0
Carditis	3	8	0	5	13	0	0
Central bradycardia	0	1	0	0	1	0	0
Chronic myocarditis	0	1	0	0	1	0	0
Conduction disorder	1	3	0	0	3	0	0
Congestive cardiomyopathy	5	29	1	4	33	1	1
Cor pulmonale	0	5	0	0	5	0	0
Cor pulmonale acute	0	9	0	0	9	0	0
Coronary artery disease	13	76	3	7	83	0	0
Coronary artery dissection	0	15	0	0	15	0	0
Coronary artery embolism	0	4	0	0	4	0	0
Coronary artery insufficiency	0	1	0	0	1	0	0
Coronary artery occlusion	2	20	0	0	20	0	0
Coronary artery stenosis	1	8	0	1	9	0	0
Coronary artery thrombosis	8	80	0	0	80	1	1
Defect conduction intraventricular	1	2	0	0	2	0	0
Degenerative aortic valve disease	0	0	0	1	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Diastolic dysfunction	1	3	1	2	5	0	0
Dilatation ventricular	0	2	0	0	2	0	0
Extrasystoles	13	208	25	251	459	0	0
Foetal cardiac arrest	0	3	0	0	3	0	0
Giant cell myocarditis	0	2	0	0	2	0	0
Heart alternation	0	6	0	8	14	0	0
Heart valve incompetence	2	8	0	3	11	0	0
Heart valve stenosis	0	0	0	1	1	0	0
Hyperdynamic left ventricle	0	1	0	0	1	0	0
Hypertensive cardiomegaly	0	0	0	1	1	0	0
Hypertensive cardiomyopathy	0	2	0	0	2	0	0
Hypertensive heart disease	0	7	0	11	18	0	0
Immune-mediated myocarditis	0	1	0	0	1	0	0
Intracardiac thrombus	2	50	0	0	50	0	0
Ischaemic cardiomyopathy	0	5	0	0	5	0	0
Ischaemic mitral regurgitation	0	1	0	0	1	0	0
Kounis syndrome	1	3	0	0	3	0	0
Left atrial dilatation	0	1	0	0	1	0	0
Left ventricular dilatation	0	2	0	0	2	0	0
Left ventricular dysfunction	4	36	0	1	37	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Left ventricular enlargement	0	0	0	1	1	0	0
Left ventricular failure	2	19	0	0	19	0	0
Left ventricular hypertrophy	3	11	0	2	13	0	0
Long QT syndrome	0	2	0	0	2	0	0
Microvascular coronary artery disease	2	5	1	2	7	0	0
Mitral valve disease	1	2	0	1	3	0	0
Mitral valve incompetence	2	20	0	0	20	0	0
Mitral valve prolapse	3	12	1	2	14	0	0
Mitral valve stenosis	0	1	0	0	1	0	0
Mitral valve thickening	0	0	1	1	1	0	0
Myocardial depression	0	1	0	0	1	0	0
Myocardial fibrosis	0	5	0	1	6	0	0
Myocardial infarction	65	1170	0	0	1170	0	1
Myocardial injury	4	26	0	4	30	0	0
Myocardial ischaemia	3	70	0	8	78	0	0
Myocardial necrosis	0	2	0	0	2	0	0
Myocardial oedema	0	1	0	1	2	0	0
Myocardial rupture	2	6	0	0	6	0	0
Myocardial stunning	0	0	0	1	1	0	0
Myocarditis	74	734	0	0	734	2	4

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Myocarditis post infection	0	1	0	0	1	0	0
Myopericarditis	15	90	0	1	91	0	0
Neonatal bradyarrhythmia	0	0	0	0	0	0	1
Nodal arrhythmia	0	1	0	0	1	0	0
Palpitations	204	5805	711	6329	12134	1	3
Paroxysmal arrhythmia	0	3	0	0	3	0	0
Pericardial cyst	0	1	0	0	1	0	0
Pericardial disease	0	2	0	0	2	0	0
Pericardial effusion	12	162	2	26	188	0	2
Pericardial fibrosis	0	0	0	1	1	0	0
Pericardial haemorrhage	1	12	0	0	12	0	0
Pericardial rub	0	3	0	0	3	0	0
Pericarditis	42	581	17	163	744	4	6
Pleuropericarditis	0	10	0	0	10	0	0
Postural orthostatic tachycardia syndrome	18	61	6	19	80	0	0
Prinzmetal angina	0	4	1	2	6	0	0
Pulseless electrical activity	0	17	0	0	17	0	0
Restrictive cardiomyopathy	0	1	0	0	1	0	0
Rheumatic heart disease	0	2	0	0	2	0	0
Rhythm idioventricular	1	1	0	0	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Right atrial dilatation	0	1	0	1	2	0	0
Right atrial enlargement	0	0	0	1	1	0	0
Right ventricular dilatation	0	3	0	0	3	0	0
Right ventricular dysfunction	1	9	0	1	10	0	0
Right ventricular failure	1	14	1	2	16	0	0
Right ventricular hypertension	0	1	0	0	1	0	0
Right ventricular hypertrophy	0	1	0	0	1	0	0
Silent myocardial infarction	0	1	0	0	1	0	0
Sinoatrial block	1	2	0	0	2	0	0
Sinus arrest	0	1	0	0	1	0	0
Sinus arrhythmia	0	4	0	4	8	0	0
Sinus bradycardia	1	22	0	4	26	0	0
Sinus node dysfunction	1	8	0	3	11	0	0
Sinus tachycardia	6	114	5	60	174	0	0
Stress cardiomyopathy	1	21	0	2	23	0	0
Supraventricular extrasystoles	1	6	4	15	21	0	0
Supraventricular tachyarrhythmia	0	2	0	0	2	0	0
Supraventricular tachycardia	5	76	1	17	93	0	1
Systolic dysfunction	0	2	0	0	2	0	0
Tachyarrhythmia	4	29	1	19	48	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Tachycardia	131	2733	292	6306	9039	2	5
Tachycardia foetal	0	7	0	2	9	0	0
Tachycardia induced cardiomyopathy	0	1	0	0	1	0	0
Tachycardia paroxysmal	0	7	1	5	12	0	0
Torsade de pointes	0	1	0	0	1	0	0
Tricuspid valve incompetence	1	12	1	1	13	0	0
Trifascicular block	0	1	0	0	1	0	0
Ventricle rupture	0	1	0	0	1	0	0
Ventricular arrhythmia	2	12	0	0	12	0	0
Ventricular dysfunction	1	1	1	1	2	0	0
Ventricular dyskinesia	0	1	0	0	1	0	0
Ventricular extrasystoles	5	63	8	46	109	1	1
Ventricular failure	0	1	0	0	1	0	0
Ventricular fibrillation	0	34	0	0	34	0	0
Ventricular hyperkinesia	0	1	0	0	1	0	0
Ventricular hypertrophy	0	5	0	0	5	0	0
Ventricular hypokinesia	2	8	0	0	8	0	0
Ventricular tachycardia	5	52	0	0	52	0	0
Wolff-Parkinson-White syndrome	1	1	0	0	1	0	0
Vascular disorders	**947**	**23788**	**1534**	**19194**	**42982**	**35**	**62**

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Accelerated hypertension	0	18	0	0	18	0	0
Achenbach syndrome	0	7	1	12	19	0	0
Acute aortic syndrome	0	0	0	1	1	0	0
Air embolism	0	0	0	2	2	0	0
Aneurysm	1	26	0	5	31	0	0
Aneurysm ruptured	0	6	0	0	6	0	0
Angiodysplasia	0	1	0	1	2	0	0
Angiopathy	3	20	4	24	44	0	0
Aortic aneurysm	3	22	1	8	30	0	0
Aortic aneurysm rupture	0	6	0	0	6	0	0
Aortic arteriosclerosis	1	7	0	1	8	0	0
Aortic dilatation	0	3	0	0	3	0	0
Aortic dissection	2	29	0	0	29	0	0
Aortic dissection rupture	0	2	0	0	2	0	0
Aortic embolus	1	35	0	2	37	0	0
Aortic intramural haematoma	0	2	0	0	2	0	0
Aortic occlusion	0	5	0	0	5	0	0
Aortic rupture	0	2	0	0	2	0	0
Aortic stenosis	0	7	1	6	13	0	0
Aortic thrombosis	4	74	0	0	74	0	1

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Aortitis	1	7	0	1	8	0	0
Arterial disorder	0	2	0	3	5	0	0
Arterial haemorrhage	0	1	0	1	2	0	0
Arterial insufficiency	0	1	0	0	1	0	0
Arterial occlusive disease	3	40	1	8	48	0	0
Arterial rupture	1	4	0	1	5	0	0
Arterial spasm	0	2	0	0	2	0	0
Arterial stenosis	0	5	0	1	6	0	0
Arterial thrombosis	3	127	0	0	127	0	1
Arteriosclerosis	2	32	1	7	39	0	0
Arteriovenous fistula	0	2	0	0	2	0	0
Arteritis	1	11	1	8	19	0	0
Artery dissection	1	10	0	0	10	0	0
Atheroembolism	0	2	0	0	2	0	0
Axillary vein thrombosis	0	13	0	2	15	0	0
Behcet's syndrome	1	9	0	3	12	0	0
Bleeding varicose vein	0	2	0	4	6	0	0
Blood pressure fluctuation	15	119	30	268	387	1	1
Blood pressure inadequately controlled	0	3	0	8	11	0	0
Bloody discharge	0	13	2	30	43	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Blue toe syndrome	0	28	2	23	51	0	0
Brachiocephalic vein thrombosis	1	6	0	0	6	0	0
CT hypotension complex	1	1	0	0	1	0	0
Capillary disorder	0	6	0	17	23	0	0
Capillary fragility	1	10	1	42	52	0	0
Capillary leak syndrome	4	51	2	11	62	0	0
Carotidynia	0	0	0	1	1	0	0
Circulatory collapse	16	532	0	0	532	0	0
Claudication of jaw muscles	0	0	0	0	0	1	1
Coeliac artery occlusion	0	0	0	1	1	0	0
Collateral circulation	0	3	0	0	3	0	0
Cryoglobulinaemia	1	5	1	1	6	1	1
Cyanosis	17	285	43	477	762	0	0
Deep vein thrombosis	103	4492	0	0	4492	5	13
Dependent rubor	0	0	1	1	1	0	0
Diabetic vascular disorder	0	1	0	0	1	0	0
Diastolic hypertension	0	7	0	8	15	0	0
Diastolic hypotension	0	1	0	0	1	0	0
Diffuse vasculitis	0	4	0	0	4	0	0
Distributive shock	0	3	0	0	3	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Dry gangrene	1	4	0	1	5	0	0
Embolism	22	423	0	53	476	0	0
Embolism arterial	2	30	0	0	30	0	0
Embolism venous	4	47	0	4	51	0	0
Endocrine hypertension	0	0	1	1	1	0	0
Endothelial dysfunction	1	2	0	1	3	0	0
Erythrocyanosis	0	1	0	0	1	0	0
Erythromelalgia	2	11	1	9	20	1	1
Essential hypertension	1	14	1	3	17	0	0
Extravasation blood	0	5	4	13	18	0	0
Extremity necrosis	1	4	0	0	4	0	0
Femoral artery aneurysm	1	2	0	0	2	0	0
Femoral artery embolism	0	2	0	0	2	0	0
Fibromuscular dysplasia	0	1	0	0	1	0	0
Flushing	11	618	132	1483	2101	0	0
Giant cell arteritis	15	101	5	49	150	1	1
Granulomatosis with polyangiitis	2	12	0	0	12	0	0
Haematoma	11	418	164	1962	2380	0	0
Haemodynamic instability	0	22	0	1	23	0	0
Haemorrhage	44	1223	24	804	2027	2	2

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Haemorrhagic infarction	3	19	0	0	19	0	0
Haemorrhagic vasculitis	0	2	0	0	2	0	0
Hot flush	23	1751	203	2563	4314	0	0
Hyperaemia	1	17	62	410	427	0	0
Hypertension	122	2050	234	3069	5119	1	2
Hypertensive angiopathy	1	1	0	0	1	0	0
Hypertensive crisis	14	354	0	0	354	0	0
Hypertensive emergency	2	21	0	0	21	0	0
Hypertensive urgency	3	24	0	0	24	0	0
Hypoperfusion	0	4	0	4	8	0	0
Hypotension	41	930	94	1296	2226	0	0
Hypotensive crisis	0	3	0	3	6	0	0
Hypovolaemic shock	1	81	0	0	81	0	0
Iliac artery embolism	0	2	0	0	2	0	0
Iliac artery occlusion	0	3	0	0	3	0	0
Iliac artery stenosis	0	2	0	0	2	0	0
Infarction	7	94	1	9	103	0	0
Intermittent claudication	1	17	1	8	25	0	0
Internal haemorrhage	3	36	1	10	46	0	0
Ischaemia	0	61	2	16	77	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Ischaemic limb pain	0	6	1	17	23	0	0
Jugular vein distension	0	0	0	2	2	0	0
Jugular vein occlusion	0	4	0	0	4	0	0
Jugular vein thrombosis	7	98	0	0	98	1	2
Kawasaki's disease	0	1	0	0	1	0	1
Labile blood pressure	0	9	0	33	42	0	0
Labile hypertension	1	3	0	3	6	0	0
Leriche syndrome	0	1	0	0	1	1	1
Lower limb artery perforation	0	0	0	1	1	0	0
Lymphangiopathy	0	1	0	1	2	0	0
Lymphocele	0	2	0	1	3	0	0
Lymphoedema	7	73	9	85	158	0	0
Lymphorrhoea	0	0	1	2	2	0	0
Lymphostasis	1	1	0	1	2	0	0
MAGIC syndrome	0	10	0	6	16	0	0
Macroangiopathy	0	1	1	1	2	0	0
Malignant hypertension	0	11	0	0	11	0	0
May-Thurner syndrome	0	1	0	0	1	0	0
Microangiopathy	1	7	0	2	9	0	0
Microembolism	0	9	0	2	11	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Microscopic polyangiitis	0	4	0	0	4	0	0
Necrosis ischaemic	0	1	0	0	1	0	0
Neovascularisation	0	1	0	0	1	0	0
Neurogenic hypertension	0	1	0	0	1	0	0
Neurogenic shock	0	3	0	10	13	0	0
Non-dipping	0	0	0	1	1	0	0
Obstructive shock	0	3	0	0	3	0	0
Orthostatic hypertension	0	1	0	1	2	0	0
Orthostatic hypotension	2	62	8	71	133	1	1
Paget-Schroetter syndrome	0	2	0	0	2	0	0
Pallor	16	454	51	572	1026	0	0
Paradoxical embolism	0	1	0	0	1	0	0
Pelvic venous thrombosis	4	69	0	0	69	1	1
Penetrating aortic ulcer	0	1	0	0	1	0	0
Penetrating atherosclerotic ulcer	0	1	0	0	1	0	0
Peripheral arterial occlusive disease	2	15	0	0	15	0	0
Peripheral artery aneurysm	1	5	0	1	6	0	0
Peripheral artery occlusion	4	33	0	0	33	0	0
Peripheral artery stenosis	0	3	0	1	4	0	0
Peripheral artery thrombosis	5	171	0	0	171	2	3

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Peripheral circulatory failure	0	19	0	43	62	0	0
Peripheral coldness	20	1178	147	1532	2710	0	1
Peripheral embolism	1	42	0	7	49	0	0
Peripheral ischaemia	0	82	1	23	105	1	1
Peripheral vascular disorder	1	37	32	534	571	0	0
Peripheral vein occlusion	0	2	0	0	2	0	0
Peripheral vein thrombosis	0	0	1	1	1	2	2
Peripheral vein thrombus extension	2	7	0	3	10	0	0
Peripheral venous disease	1	26	8	64	90	0	0
Periphlebitis	0	1	0	4	5	0	0
Phlebitis	5	173	12	203	376	0	0
Phlebitis deep	1	4	0	2	6	0	0
Phlebitis superficial	1	38	2	47	85	0	0
Phlebosclerosis	0	1	0	0	1	0	0
Plethoric face	0	1	0	1	2	0	0
Polyarteritis nodosa	0	7	0	1	8	0	0
Poor peripheral circulation	3	62	9	89	151	0	0
Poor venous access	5	5	1	5	10	0	0
Post thrombotic syndrome	0	6	1	3	9	0	0
Postpartum thrombosis	0	0	0	1	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Raynaud's phenomenon	12	149	14	144	293	2	2
Rheumatoid vasculitis	0	1	0	0	1	0	0
Secondary hypertension	2	3	0	2	5	0	0
Shock	6	104	0	0	104	0	0
Shock haemorrhagic	1	6	0	0	6	0	0
Shock symptom	0	12	0	0	12	0	0
Spider vein	1	19	2	33	52	0	0
Subclavian artery embolism	0	4	0	0	4	0	0
Subclavian artery thrombosis	1	6	0	2	8	0	0
Subclavian steal syndrome	0	1	0	1	2	0	0
Subclavian vein thrombosis	1	35	0	0	35	0	0
Superficial vein prominence	0	12	6	23	35	0	0
Superficial vein thrombosis	16	442	17	403	845	0	1
Superior vena cava syndrome	0	2	0	0	2	0	0
Susac's syndrome	0	3	0	0	3	0	0
Systolic hypertension	0	2	0	6	8	0	0
Takayasu's arteritis	1	3	0	1	4	1	1
Thromboangiitis obliterans	0	2	0	0	2	0	0
Thrombophlebitis	16	416	21	296	712	0	0
Thrombophlebitis migrans	0	1	0	2	3	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Thrombosed varicose vein	0	4	0	4	8	0	0
Thrombosis	167	3623	40	923	4546	5	15
Tyramine reaction	0	1	0	0	1	0	0
Varicophlebitis	0	17	3	27	44	0	0
Varicose ulceration	0	0	0	2	2	0	0
Varicose vein	7	141	24	305	446	0	0
Varicose vein ruptured	0	3	2	5	8	0	0
Vascular calcification	0	0	1	1	1	0	0
Vascular compression	0	1	2	8	9	0	0
Vascular fragility	0	0	1	6	6	0	0
Vascular occlusion	1	13	1	5	18	0	0
Vascular pain	4	150	26	227	377	0	0
Vascular rupture	0	8	13	30	38	0	0
Vascular wall discolouration	0	0	0	1	1	0	0
Vasculitis	30	352	0	0	352	1	1
Vasculitis necrotising	1	3	0	0	3	0	0
Vasoconstriction	1	5	1	8	13	0	0
Vasodilatation	8	132	21	284	416	0	0
Vasospasm	1	13	3	15	28	0	0
Vein collapse	1	5	0	2	7	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Vein discolouration	1	8	4	23	31	0	0
Vein disorder	1	32	8	77	109	0	0
Vein rupture	3	24	1	23	47	0	0
Vena cava embolism	0	1	0	0	1	0	0
Vena cava thrombosis	3	41	0	0	41	0	0
Venous aneurysm	0	0	0	2	2	0	0
Venous haemorrhage	2	13	0	1	14	0	0
Venous hypertension	0	4	1	2	6	0	0
Venous occlusion	2	25	2	11	36	0	0
Venous recanalisation	1	1	0	0	1	0	0
Venous thrombosis	21	363	8	96	459	0	0
Venous thrombosis limb	17	283	3	49	332	4	5
Venous valve ruptured	0	1	1	2	3	0	0
Vessel perforation	0	3	1	2	5	0	0
White coat hypertension	0	11	0	2	13	0	0
Respiratory, thoracic and mediastinal disorders	**1525**	**38377**	**4979**	**56604**	**94981**	**24**	**49**
Acquired diaphragmatic eventration	1	1	0	0	1	0	0
Acute chest syndrome	0	1	0	0	1	0	0
Acute lung injury	0	3	0	0	3	0	0
Acute pulmonary oedema	0	31	0	0	31	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Acute respiratory distress syndrome	14	214	0	0	214	1	1
Acute respiratory failure	9	81	0	0	81	0	0
Adductor vocal cord weakness	0	1	0	5	6	0	0
Adenoidal disorder	0	0	0	4	4	0	0
Agonal respiration	0	7	0	0	7	0	0
Allergic bronchitis	0	1	0	1	2	0	0
Allergic cough	0	9	1	9	18	0	0
Allergic respiratory disease	0	2	0	2	4	0	0
Allergic respiratory symptom	0	10	0	6	16	0	0
Allergic sinusitis	0	2	0	3	5	0	0
Alveolar lung disease	0	1	0	0	1	0	0
Alveolar proteinosis	0	1	0	1	2	0	0
Alveolitis	0	3	0	0	3	0	0
Anoxia	0	0	0	1	1	0	0
Aphonia	11	129	15	170	299	0	0
Apnoea	4	58	0	0	58	0	0
Apnoeic attack	0	2	0	0	2	0	0
Asphyxia	2	37	0	0	37	0	0
Aspiration	0	16	2	18	34	0	0
Asthma	39	710	63	505	1215	1	2

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Asthma exercise induced	0	4	1	6	10	0	0
Asthma late onset	0	3	0	1	4	0	0
Asthma-chronic obstructive pulmonary disease overlap syndrome	0	2	0	0	2	0	0
Asthmatic crisis	10	77	0	0	77	0	1
Atelectasis	4	24	0	5	29	0	0
Autoimmune lung disease	0	1	0	0	1	0	0
Bradypnoea	0	3	0	0	3	0	0
Brief resolved unexplained event	0	3	0	0	3	0	0
Bronchial disorder	1	3	2	7	10	0	0
Bronchial haemorrhage	0	1	0	0	1	0	0
Bronchial hyperreactivity	1	4	3	8	12	0	0
Bronchial irritation	0	0	1	11	11	0	0
Bronchial obstruction	0	2	1	4	6	0	0
Bronchial oedema	0	2	0	0	2	0	0
Bronchial secretion retention	1	3	1	2	5	0	0
Bronchial wall thickening	0	3	1	2	5	0	0
Bronchiectasis	0	14	0	11	25	0	0
Bronchitis chronic	1	3	1	5	8	0	0
Bronchopleural fistula	1	1	0	0	1	0	0
Bronchopneumopathy	0	3	0	0	3	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Bronchospasm	1	60	3	110	170	0	0
Bronchostenosis	0	2	0	0	2	0	0
Catarrh	0	52	5	71	123	0	0
Cheyne-Stokes respiration	0	1	0	2	3	0	0
Choking	3	39	4	23	62	0	2
Choking sensation	2	30	3	39	69	0	0
Chronic obstructive pulmonary disease	13	105	2	37	142	0	0
Chronic respiratory disease	0	3	0	0	3	0	0
Chronic respiratory failure	0	2	0	0	2	0	0
Chylothorax	0	1	0	1	2	0	0
Cough	187	4531	1147	13634	18165	0	0
Cough decreased	0	0	0	3	3	0	0
Cough variant asthma	0	7	0	4	11	0	0
Cyanosis central	0	3	0	0	3	0	0
Cyanosis neonatal	0	1	0	0	1	0	0
Cystic lung disease	0	1	0	0	1	0	0
Dependence on respirator	3	12	0	0	12	0	0
Diaphragmalgia	1	20	3	23	43	0	0
Diaphragmatic disorder	1	1	1	1	2	0	0
Diaphragmatic paralysis	1	5	0	0	5	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Diaphragmatic spasm	0	2	1	8	10	0	0
Dry throat	3	204	22	371	575	0	0
Dysphonia	16	231	70	716	947	1	1
Dyspnoea	518	11233	1228	13178	24411	2	7
Dyspnoea at rest	2	32	2	27	59	0	0
Dyspnoea exertional	27	252	40	407	659	0	0
Dyspnoea paroxysmal nocturnal	0	3	0	1	4	0	0
Ear, nose and throat disorder	1	1	0	1	2	0	0
Emphysema	3	19	0	3	22	0	0
Eosinophilic pneumonia	1	3	0	1	4	0	0
Eosinophilic pneumonia chronic	0	1	0	0	1	0	0
Epiglottic oedema	0	4	0	2	6	0	0
Epistaxis	26	1714	381	3936	5650	0	1
Gasping syndrome	0	2	0	0	2	0	0
Grunting	0	4	0	1	5	0	0
Haemoptysis	11	210	10	152	362	1	2
Haemothorax	0	2	0	0	2	0	0
Hiccups	2	40	2	48	88	0	0
Hydrothorax	0	0	0	1	1	0	0
Hyperactive pharyngeal reflex	0	0	0	1	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Hypercapnia	0	6	0	1	7	0	0
Hypersensitivity pneumonitis	4	34	7	49	83	0	0
Hyperventilation	4	131	16	114	245	0	0
Hypocapnia	0	2	0	1	3	0	0
Hypopnoea	5	222	11	96	318	0	0
Hypoventilation	2	11	2	11	22	0	0
Hypoxia	12	160	3	44	204	0	0
Idiopathic pulmonary fibrosis	2	6	0	0	6	0	0
Increased bronchial secretion	0	4	2	12	16	0	0
Increased upper airway secretion	2	12	0	22	34	0	0
Increased viscosity of bronchial secretion	0	0	0	1	1	0	0
Increased viscosity of upper respiratory secretion	0	21	7	32	53	0	0
Infantile apnoea	0	0	0	0	0	0	1
Interstitial lung disease	6	59	0	0	59	0	0
Intranasal hypoaesthesia	0	1	0	2	3	0	0
Intranasal paraesthesia	0	1	0	0	1	0	0
Irregular breathing	1	31	1	11	42	1	1
Kussmaul respiration	0	1	0	3	4	0	0
Laryngeal discomfort	0	2	2	15	17	0	0
Laryngeal disorder	0	0	1	2	2	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Laryngeal erythema	0	1	0	0	1	0	0
Laryngeal haematoma	0	1	0	0	1	0	0
Laryngeal inflammation	0	0	1	4	4	0	0
Laryngeal obstruction	0	0	0	2	2	0	0
Laryngeal oedema	7	161	0	0	161	0	0
Laryngeal pain	0	2	2	12	14	0	0
Laryngeal stenosis	0	0	1	1	1	0	0
Laryngospasm	0	18	2	14	32	0	0
Laryngotracheal oedema	0	1	0	0	1	0	0
Larynx irritation	0	1	1	13	14	0	0
Lower respiratory tract congestion	2	4	0	3	7	0	0
Lower respiratory tract inflammation	0	0	0	1	1	0	0
Lung consolidation	0	17	0	2	19	0	0
Lung cyst	0	0	0	1	1	0	0
Lung diffusion disorder	0	0	0	1	1	0	0
Lung disorder	11	71	18	86	157	0	0
Lung hyperinflation	0	1	0	0	1	0	0
Lung induration	0	1	0	0	1	0	0
Lung infiltration	2	15	0	4	19	0	0
Lung opacity	1	16	0	7	23	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Lupus pleurisy	0	2	0	0	2	0	0
Mouth breathing	0	8	0	3	11	0	0
NSAID exacerbated respiratory disease	0	0	0	1	1	0	0
Nasal congestion	16	418	150	1943	2361	0	0
Nasal crusting	0	5	1	15	20	0	0
Nasal cyst	0	2	0	1	3	0	0
Nasal discharge discolouration	0	1	1	5	6	0	0
Nasal discomfort	0	35	7	101	136	0	0
Nasal disorder	1	6	2	13	19	0	0
Nasal dryness	2	45	9	110	155	0	0
Nasal flaring	0	1	0	0	1	0	0
Nasal inflammation	0	7	1	14	21	0	0
Nasal mucosa atrophy	0	0	0	1	1	0	0
Nasal mucosal blistering	0	0	0	2	2	0	0
Nasal mucosal discolouration	0	1	1	1	2	0	0
Nasal mucosal disorder	0	1	2	9	10	0	0
Nasal mucosal erosion	0	0	0	1	1	0	0
Nasal mucosal ulcer	0	1	0	1	2	0	0
Nasal obstruction	0	6	7	42	48	0	0
Nasal odour	0	1	1	3	4	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Nasal oedema	0	18	1	24	42	0	0
Nasal polyps	0	1	0	3	4	0	0
Nasal pruritus	0	8	0	27	35	0	0
Nasal septum deviation	0	2	0	0	2	0	0
Nasal septum disorder	1	1	0	1	2	0	0
Nasal septum perforation	0	1	0	0	1	0	0
Nasal turbinate hypertrophy	0	0	0	2	2	0	0
Nasal ulcer	1	5	3	8	13	0	0
Nasal valve collapse	0	0	0	1	1	0	0
Neonatal asphyxia	0	0	0	0	0	1	1
Neonatal dyspnoea	0	2	0	3	5	2	6
Neonatal respiratory distress	0	0	0	0	0	0	1
Neonatal respiratory failure	0	1	0	0	1	0	0
Nocturnal dyspnoea	0	4	4	8	12	0	0
Non-cardiogenic pulmonary oedema	0	1	0	0	1	0	0
Obstructive airways disorder	0	7	4	24	31	0	0
Obstructive sleep apnoea syndrome	1	2	2	2	4	0	0
Organising pneumonia	0	5	0	2	7	0	0
Oropharyngeal blistering	1	24	2	20	44	0	0
Oropharyngeal discolouration	0	1	0	0	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Oropharyngeal discomfort	6	65	56	354	419	0	0
Oropharyngeal oedema	0	3	0	2	5	0	0
Oropharyngeal pain	77	3687	762	9158	12845	0	0
Oropharyngeal plaque	0	2	2	6	8	0	0
Oropharyngeal swelling	0	4	0	11	15	0	0
Orthopnoea	1	18	0	12	30	0	0
Painful respiration	0	36	27	115	151	0	0
Paranasal cyst	0	0	0	1	1	0	0
Paranasal sinus discomfort	2	72	13	95	167	0	0
Paranasal sinus haemorrhage	0	3	0	6	9	0	0
Paranasal sinus hypersecretion	0	1	0	3	4	0	0
Paranasal sinus hyposecretion	0	1	0	2	3	0	0
Paranasal sinus inflammation	1	4	2	13	17	0	0
Pharyngeal disorder	0	0	0	26	26	0	0
Pharyngeal enanthema	0	0	0	1	1	0	0
Pharyngeal erythema	0	10	3	38	48	0	0
Pharyngeal haemorrhage	1	5	0	4	9	0	0
Pharyngeal hypoaesthesia	2	38	2	38	76	0	0
Pharyngeal inflammation	0	2	2	11	13	0	0
Pharyngeal oedema	1	30	4	55	85	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Pharyngeal paraesthesia	1	26	6	63	89	0	0
Pharyngeal swelling	7	316	41	386	702	0	0
Pharyngeal ulceration	0	12	1	9	21	0	0
Platypnoea	0	1	0	0	1	0	0
Pleural adhesion	0	1	0	0	1	0	0
Pleural disorder	0	2	0	1	3	0	0
Pleural effusion	13	160	3	31	191	0	1
Pleural rub	0	1	0	0	1	0	0
Pleural thickening	0	5	0	2	7	0	0
Pleurisy	4	78	2	25	103	0	0
Pleuritic pain	3	57	1	48	105	0	0
Pneumonitis	4	107	0	0	107	2	2
Pneumonitis aspiration	0	1	0	0	1	0	0
Pneumothorax	2	31	0	0	31	0	0
Pneumothorax spontaneous	0	6	0	0	6	0	0
Productive cough	11	226	35	436	662	0	0
Pulmonary alveolar haemorrhage	1	8	0	0	8	0	0
Pulmonary arterial hypertension	0	3	0	1	4	0	0
Pulmonary artery occlusion	1	3	0	0	3	0	0
Pulmonary artery thrombosis	2	24	0	0	24	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Pulmonary calcification	0	2	0	0	2	0	0
Pulmonary cavitation	0	5	0	0	5	0	0
Pulmonary congestion	3	34	1	21	55	0	0
Pulmonary embolism	160	5465	0	0	5465	6	9
Pulmonary fibrosis	4	35	0	0	35	0	0
Pulmonary haemorrhage	4	31	0	0	31	0	0
Pulmonary hilum mass	0	1	0	0	1	0	0
Pulmonary hypertension	1	27	0	0	27	0	0
Pulmonary hypoperfusion	0	1	0	0	1	0	0
Pulmonary infarction	3	93	0	0	93	0	0
Pulmonary mass	1	18	1	16	34	0	0
Pulmonary microemboli	1	9	0	0	9	0	0
Pulmonary oedema	10	124	0	0	124	0	0
Pulmonary pain	5	252	59	422	674	0	0
Pulmonary sarcoidosis	1	5	0	1	6	0	0
Pulmonary thrombosis	15	180	0	0	180	5	7
Pulmonary vascular disorder	0	2	0	2	4	0	0
Pulmonary vasculitis	0	1	0	0	1	0	0
Pulmonary venous thrombosis	0	7	0	1	8	0	0
Rales	3	13	1	10	23	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Rebound nasal congestion	0	0	1	1	1	0	0
Reflux laryngitis	0	3	0	2	5	0	0
Respiration abnormal	7	130	23	198	328	0	0
Respiratory acidosis	0	6	0	0	6	0	0
Respiratory alkalosis	0	0	0	1	1	0	0
Respiratory arrest	1	62	0	0	62	0	0
Respiratory depression	0	2	0	1	3	0	0
Respiratory depth decreased	0	1	5	13	14	0	0
Respiratory depth increased	0	0	1	1	1	0	0
Respiratory disorder	12	219	36	200	419	0	0
Respiratory distress	17	386	8	663	1049	0	0
Respiratory failure	19	204	0	0	204	1	1
Respiratory fatigue	0	15	0	18	33	0	0
Respiratory gas exchange disorder	0	1	0	1	2	0	0
Respiratory muscle weakness	2	8	1	1	9	0	0
Respiratory paralysis	0	2	0	0	2	0	0
Respiratory symptom	1	29	3	55	84	0	0
Respiratory tract congestion	3	13	1	7	20	0	0
Respiratory tract haemorrhage	0	4	0	3	7	0	0
Respiratory tract inflammation	0	1	0	3	4	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Respiratory tract irritation	1	16	4	27	43	0	0
Respiratory tract oedema	3	12	0	0	12	0	0
Restrictive pulmonary disease	0	1	0	0	1	0	0
Reversible airways obstruction	0	1	0	0	1	0	0
Rheumatoid arthritis-associated interstitial lung disease	0	1	0	0	1	0	0
Rhinalgia	4	92	12	106	198	0	0
Rhinitis allergic	3	21	8	72	93	0	0
Rhinitis atrophic	0	1	0	0	1	0	0
Rhinitis perennial	0	0	0	1	1	0	0
Rhinorrhoea	26	1324	271	3434	4758	0	1
Rhonchi	0	2	0	3	5	0	0
Sinonasal obstruction	0	11	2	23	34	0	0
Sinus congestion	5	86	7	75	161	0	0
Sinus disorder	3	17	5	39	56	0	0
Sinus pain	2	539	36	275	814	0	0
Sinus polyp	0	2	0	1	3	0	0
Sleep apnoea syndrome	5	38	4	19	57	0	0
Sneezing	3	380	77	1133	1513	0	0
Snoring	0	5	1	6	11	0	0
Sputum discoloured	5	16	1	17	33	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Sputum increased	0	3	1	10	13	0	0
Sputum retention	0	0	0	2	2	0	0
Stridor	0	37	1	18	55	0	1
Suffocation feeling	1	23	7	50	73	0	0
Tachypnoea	3	78	3	87	165	0	0
Thoracic haemorrhage	0	1	0	0	1	0	0
Throat clearing	4	11	3	36	47	0	0
Throat irritation	4	219	67	906	1125	0	0
Throat lesion	0	2	0	3	5	0	0
Throat tightness	6	263	24	476	739	0	0
Tonsillar atrophy	0	0	0	1	1	0	0
Tonsillar disorder	0	2	1	5	7	0	0
Tonsillar erythema	0	5	0	4	9	0	0
Tonsillar exudate	0	0	1	1	1	0	0
Tonsillar haemorrhage	0	1	0	0	1	0	0
Tonsillar hypertrophy	1	49	14	77	126	0	0
Tonsillar inflammation	0	5	0	15	20	0	0
Tonsillar ulcer	0	2	0	0	2	0	0
Tonsillolith	1	3	0	0	3	0	0
Tracheal disorder	1	1	0	0	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Tracheal fistula	0	1	0	0	1	0	0
Tracheal inflammation	1	1	0	3	4	0	0
Tracheal oedema	0	1	0	0	1	0	0
Tracheal pain	0	3	4	15	18	0	0
Tracheal stenosis	0	1	0	0	1	0	0
Tracheomalacia	0	1	0	0	1	0	0
Upper airway necrosis	0	0	1	1	1	0	0
Upper airway obstruction	0	7	0	0	7	0	0
Upper respiratory tract congestion	0	1	2	7	8	0	0
Upper respiratory tract inflammation	0	3	1	1	4	0	0
Upper respiratory tract irritation	0	0	1	5	5	0	0
Upper-airway cough syndrome	0	24	2	28	52	0	0
Use of accessory respiratory muscles	1	6	0	4	10	0	0
Ventilation perfusion mismatch	1	2	0	0	2	0	0
Vocal cord disorder	2	9	3	7	16	0	0
Vocal cord dysfunction	0	8	0	3	11	0	0
Vocal cord inflammation	0	1	1	3	4	0	0
Vocal cord thickening	0	1	0	1	2	0	0
Wheezing	20	593	16	401	994	0	0
Yawning	1	58	4	62	120	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Gastrointestinal disorders	**1828**	**78898**	**14056**	**149987**	**228885**	**12**	**37**
Abdominal adhesions	0	3	0	1	4	0	0
Abdominal compartment syndrome	0	2	0	0	2	0	0
Abdominal discomfort	43	1442	261	2061	3503	1	2
Abdominal distension	27	621	66	777	1398	0	0
Abdominal hernia	1	3	0	0	3	0	0
Abdominal mass	1	6	0	4	10	0	0
Abdominal migraine	0	3	0	2	5	0	0
Abdominal pain	129	4844	1064	10581	15425	1	2
Abdominal pain lower	10	298	35	514	812	0	0
Abdominal pain upper	69	4812	304	4366	9178	0	0
Abdominal rigidity	2	60	0	23	83	0	0
Abdominal symptom	0	10	1	10	20	0	0
Abdominal tenderness	3	35	1	38	73	0	0
Abdominal wall disorder	0	0	0	1	1	0	0
Abdominal wall haematoma	0	2	0	0	2	0	0
Abdominal wall oedema	0	2	0	1	3	0	0
Abnormal faeces	5	42	19	389	431	0	0
Acetonaemic vomiting	0	1	0	14	15	0	0
Achlorhydria	0	1	0	2	3	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Acid peptic disease	0	1	0	0	1	0	0
Acquired macroglossia	0	0	0	3	3	0	0
Acquired oesophageal web	0	1	0	0	1	0	0
Acute abdomen	1	28	0	0	28	0	0
Acute oesophageal mucosal lesion	0	0	0	1	1	0	0
Aerophagia	0	2	1	6	8	0	0
Allergic stomatitis	0	0	0	2	2	0	0
Amalgam tattoo	0	0	0	1	1	0	0
Anaesthesia oral	1	6	0	24	30	0	0
Anal blister	0	3	0	0	3	0	0
Anal erythema	0	0	0	1	1	0	0
Anal fissure	3	5	0	2	7	0	0
Anal fissure haemorrhage	0	0	0	1	1	0	0
Anal fistula	0	1	0	0	1	0	0
Anal haemorrhage	2	39	3	43	82	0	0
Anal hypoaesthesia	0	5	0	4	9	0	0
Anal incontinence	4	65	2	42	107	0	0
Anal inflammation	0	2	0	1	3	0	0
Anal paraesthesia	0	1	0	2	3	0	0
Anal pruritus	0	8	0	7	15	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Anal rash	0	1	0	1	2	0	0
Anal spasm	0	2	0	2	4	0	0
Anal sphincter atony	0	3	0	2	5	0	0
Anal ulcer	0	2	0	1	3	0	0
Angina bullosa haemorrhagica	0	0	0	5	5	0	0
Angular cheilitis	1	9	3	15	24	0	0
Ankyloglossia acquired	0	0	0	1	1	0	0
Anorectal discomfort	0	16	4	10	26	0	0
Anorectal disorder	1	3	1	1	4	0	0
Anorectal swelling	0	1	0	0	1	0	0
Anorectal varices	0	1	0	0	1	0	0
Aphthous ulcer	5	76	23	284	360	0	0
Apical granuloma	0	0	0	1	1	0	0
Appendiceal mucocoele	0	1	0	0	1	0	0
Appendicitis noninfective	0	2	0	0	2	0	0
Appendix disorder	0	7	0	0	7	0	1
Aptyalism	0	6	2	9	15	0	0
Ascites	3	38	1	3	41	0	0
Autoimmune colitis	0	4	0	1	5	0	0
Barrett's oesophagus	0	2	0	1	3	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Bile acid malabsorption	0	1	0	1	2	0	0
Bowel movement irregularity	2	11	2	25	36	0	0
Breath odour	2	19	7	27	46	0	0
Burning mouth syndrome	0	9	1	13	22	0	0
Cardiospasm	0	3	0	1	4	0	0
Change of bowel habit	1	26	2	10	36	0	0
Chapped lips	0	19	1	19	38	0	0
Cheilitis	1	29	6	55	84	0	0
Cheilosis	0	0	0	1	1	0	0
Chronic cheek biting	0	1	0	0	1	0	0
Chronic gastritis	0	6	1	7	13	0	0
Coating in mouth	0	2	0	5	7	0	0
Coeliac artery aneurysm	0	0	0	2	2	0	0
Coeliac disease	3	30	1	7	37	0	0
Colitis	7	90	2	42	132	0	0
Colitis erosive	0	1	0	0	1	0	0
Colitis ischaemic	0	54	0	0	54	0	0
Colitis microscopic	2	16	0	3	19	0	0
Colitis ulcerative	14	133	2	48	181	0	0
Constipation	26	464	41	523	987	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Crohn's disease	17	116	2	37	153	0	0
Cyclic vomiting syndrome	0	2	0	0	2	0	0
Defaecation disorder	1	1	0	7	8	0	0
Defaecation urgency	1	14	1	21	35	0	0
Dental caries	5	11	0	8	19	0	0
Dental discomfort	1	7	4	28	35	0	0
Dental dysaesthesia	0	0	0	3	3	0	0
Dental paraesthesia	0	12	1	9	21	0	0
Dental pulp disorder	0	0	1	3	3	0	0
Diarrhoea	189	8476	1742	19000	27476	2	6
Diarrhoea haemorrhagic	5	50	6	45	95	0	0
Diastema	0	1	0	0	1	0	0
Discoloured vomit	1	20	2	10	30	0	0
Distal intestinal obstruction syndrome	1	1	0	0	1	0	0
Diverticular perforation	1	4	0	0	4	0	0
Diverticulum	0	13	0	2	15	0	0
Diverticulum intestinal	0	3	1	1	4	0	0
Diverticulum intestinal haemorrhagic	0	1	0	0	1	0	0
Dry mouth	14	959	118	1331	2290	0	0
Duodenal perforation	0	2	0	0	2	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Duodenal ulcer	0	2	0	2	4	0	0
Duodenal ulcer haemorrhage	0	4	0	0	4	0	0
Duodenal ulcer perforation	0	1	0	0	1	0	0
Duodenitis	0	4	0	1	5	0	0
Duodenogastric reflux	2	7	2	3	10	0	0
Dysbiosis	1	3	1	4	7	0	0
Dyschezia	1	18	1	14	32	0	0
Dyspepsia	23	760	86	887	1647	0	0
Dysphagia	28	436	56	578	1014	0	0
Enlarged uvula	0	10	3	6	16	0	0
Enteritis	1	9	0	11	20	0	0
Enterocolitis	0	3	0	0	3	0	0
Enterocolitis haemorrhagic	0	2	0	0	2	0	0
Eosinophilic oesophagitis	1	4	0	3	7	0	0
Epigastric discomfort	0	20	2	45	65	0	0
Epiploic appendagitis	0	4	0	3	7	0	0
Epulis	0	1	0	0	1	0	0
Erosive duodenitis	0	2	0	0	2	0	0
Eructation	5	104	17	141	245	0	0
Excessive gingival display	0	1	0	0	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Faecal vomiting	0	3	0	0	3	0	0
Faecaloma	0	8	0	4	12	0	0
Faeces discoloured	9	63	5	85	148	0	0
Faeces hard	2	5	1	12	17	0	0
Faeces pale	1	10	0	12	22	0	0
Faeces soft	2	18	3	49	67	0	0
Flatulence	14	358	37	375	733	0	0
Food poisoning	0	9	1	10	19	0	0
Frequent bowel movements	4	47	8	92	139	0	0
Functional gastrointestinal disorder	6	36	3	18	54	0	0
Gastric antral vascular ectasia	0	10	0	2	12	0	0
Gastric dilatation	0	17	0	6	23	0	0
Gastric disorder	4	17	4	60	77	0	0
Gastric haemorrhage	2	25	0	3	28	0	0
Gastric hypertonia	0	0	0	1	1	0	0
Gastric polyps	2	2	0	0	2	0	0
Gastric ulcer	2	26	0	11	37	0	0
Gastric ulcer haemorrhage	0	5	0	0	5	0	0
Gastric ulcer perforation	0	1	0	0	1	0	0
Gastric varices haemorrhage	0	2	0	0	2	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Gastritis	7	146	13	111	257	0	0
Gastritis erosive	0	3	0	0	3	0	0
Gastritis haemorrhagic	1	1	0	0	1	0	0
Gastroduodenal haemorrhage	0	1	0	0	1	0	0
Gastroduodenal ulcer	0	1	0	0	1	0	0
Gastrointestinal disorder	9	106	27	318	424	0	0
Gastrointestinal haemorrhage	5	76	1	14	90	0	0
Gastrointestinal hypermotility	0	0	0	8	8	0	0
Gastrointestinal hypomotility	0	2	0	1	3	0	0
Gastrointestinal inflammation	1	13	3	21	34	0	0
Gastrointestinal motility disorder	1	10	0	15	25	0	0
Gastrointestinal mucosal disorder	0	1	0	0	1	0	0
Gastrointestinal necrosis	0	11	0	0	11	0	0
Gastrointestinal obstruction	0	2	0	0	2	0	0
Gastrointestinal oedema	0	4	0	0	4	0	0
Gastrointestinal pain	8	351	28	355	706	0	0
Gastrointestinal perforation	0	1	0	0	1	0	0
Gastrointestinal polyp haemorrhage	0	1	0	0	1	0	0
Gastrointestinal scarring	1	1	0	0	1	0	0
Gastrointestinal sounds abnormal	3	23	3	30	53	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Gastrointestinal tract irritation	0	4	0	6	10	0	0
Gastrointestinal tract mucosal discolouration	0	0	0	1	1	0	0
Gastrointestinal ulcer	0	1	0	1	2	0	0
Gastrointestinal vascular malformation haemorrhagic	0	1	0	0	1	0	0
Gastrointestinal wall thickening	0	2	0	0	2	0	0
Gastrooesophageal reflux disease	11	220	21	236	456	0	1
Gastroptosis	0	1	0	0	1	0	0
Gingival atrophy	0	0	0	1	1	0	0
Gingival bleeding	6	174	30	369	543	0	1
Gingival blister	0	17	1	14	31	0	0
Gingival discolouration	0	1	0	5	6	0	0
Gingival discomfort	1	9	0	14	23	0	0
Gingival disorder	2	14	3	20	34	0	0
Gingival erosion	0	0	0	2	2	0	0
Gingival erythema	2	2	2	10	12	0	0
Gingival hypertrophy	0	1	0	1	2	0	0
Gingival oedema	0	1	0	12	13	0	0
Gingival pain	4	190	20	234	424	0	0
Gingival pruritus	0	1	0	1	2	0	0
Gingival recession	0	2	1	5	7	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Gingival swelling	2	37	6	87	124	0	0
Gingival ulceration	0	2	0	10	12	0	0
Gingivitis ulcerative	0	1	0	1	2	0	0
Glossitis	1	21	3	41	62	0	0
Glossodynia	2	175	13	210	385	0	0
Haematemesis	9	199	0	0	199	0	0
Haematochezia	23	205	6	186	391	0	0
Haemoperitoneum	0	14	0	0	14	0	0
Haemorrhagic ascites	0	1	0	0	1	0	0
Haemorrhagic erosive gastritis	1	1	0	0	1	0	0
Haemorrhagic gastroenteritis	0	0	0	1	1	0	0
Haemorrhagic necrotic pancreatitis	0	1	0	0	1	0	0
Haemorrhoidal haemorrhage	0	9	2	25	34	0	0
Haemorrhoids	3	70	14	127	197	0	0
Haemorrhoids thrombosed	1	52	3	57	109	0	0
Hiatus hernia	2	21	2	13	34	0	0
Hyperaesthesia teeth	0	46	5	61	107	0	0
Hyperchlorhydria	0	2	1	70	72	0	0
Hypertrophy of tongue papillae	0	0	0	2	2	0	0
Hypoaesthesia oral	8	498	56	814	1312	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Hypoaesthesia teeth	0	1	0	2	3	0	0
Ileus	1	4	0	0	4	0	0
Ileus paralytic	2	6	0	0	6	0	0
Immune-mediated enterocolitis	1	1	0	0	1	0	0
Impaired gastric emptying	0	11	0	2	13	0	0
Incarcerated inguinal hernia	0	1	0	0	1	0	0
Increased intraperitoneal volume	0	1	0	0	1	0	0
Infantile spitting up	0	3	0	1	4	0	0
Infantile vomiting	0	3	0	4	7	0	0
Inflammatory bowel disease	0	20	0	7	27	0	0
Infrequent bowel movements	4	5	0	3	8	0	0
Inguinal hernia	1	11	0	6	17	0	0
Internal hernia	0	1	0	0	1	0	0
Intestinal angioedema	0	1	0	0	1	0	0
Intestinal atony	0	1	0	0	1	0	0
Intestinal congestion	0	1	0	2	3	0	0
Intestinal dilatation	0	5	0	0	5	0	0
Intestinal haemorrhage	2	30	0	13	43	0	0
Intestinal infarction	1	20	0	0	20	0	1
Intestinal ischaemia	4	97	0	0	97	0	1

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Intestinal mass	0	0	0	1	1	0	0
Intestinal obstruction	5	40	0	0	40	0	0
Intestinal perforation	0	10	0	0	10	0	0
Intestinal polyp	0	1	0	0	1	0	0
Intestinal stenosis	0	1	0	0	1	0	0
Intestinal ulcer	0	1	0	0	1	0	0
Intra-abdominal fluid collection	0	2	0	0	2	0	0
Intra-abdominal haematoma	1	16	0	0	16	0	0
Intra-abdominal haemorrhage	1	7	0	0	7	0	0
Intussusception	0	21	0	0	21	0	0
Irritable bowel syndrome	6	141	7	67	208	0	0
Ischaemic enteritis	0	1	0	0	1	0	0
Large intestinal haemorrhage	0	0	1	2	2	0	0
Large intestinal obstruction	0	1	0	0	1	0	0
Large intestinal stenosis	1	2	0	0	2	0	0
Large intestine perforation	0	5	0	0	5	0	0
Leukoplakia oral	0	2	0	0	2	0	0
Levator syndrome	0	0	0	1	1	0	0
Lip blister	0	14	3	54	68	0	0
Lip discolouration	1	5	1	14	19	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Lip disorder	0	7	0	13	20	0	0
Lip dry	2	59	1	69	128	0	0
Lip erythema	0	5	1	11	16	0	0
Lip exfoliation	0	8	0	3	11	0	0
Lip haematoma	0	1	0	7	8	0	0
Lip haemorrhage	0	5	3	9	14	0	0
Lip oedema	2	75	9	174	249	0	0
Lip pain	0	42	5	58	100	0	0
Lip pruritus	2	19	2	22	41	0	0
Lip swelling	13	735	84	1066	1801	0	0
Lip ulceration	1	18	0	10	28	0	0
Loose tooth	1	2	1	4	6	0	0
Lower gastrointestinal haemorrhage	0	3	0	1	4	0	0
Lumbar hernia	0	1	0	0	1	0	0
Malabsorption	0	0	1	3	3	0	0
Malignant dysphagia	0	0	0	1	1	0	0
Malocclusion	0	0	0	1	1	0	0
Malpositioned teeth	0	3	0	0	3	0	0
Megacolon	0	1	0	0	1	0	0
Melaena	5	55	1	19	74	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Mesenteric arterial occlusion	0	2	0	0	2	0	0
Mesenteric artery embolism	1	2	0	1	3	0	0
Mesenteric artery stenosis	0	3	0	0	3	0	0
Mesenteric artery thrombosis	1	27	0	0	27	0	2
Mesenteric haemorrhage	0	5	0	1	6	0	0
Mesenteric panniculitis	0	2	0	3	5	0	0
Mesenteric vascular occlusion	1	2	0	0	2	0	0
Mesenteric vein thrombosis	6	124	0	0	124	3	4
Mesenteric venous occlusion	0	2	0	1	3	0	0
Mouth cyst	0	9	1	9	18	0	0
Mouth haemorrhage	1	69	10	117	186	0	0
Mouth swelling	3	121	18	155	276	0	0
Mouth ulceration	5	463	20	501	964	0	0
Mucous stools	2	20	0	7	27	0	0
Nausea	559	32681	7132	74515	107196	1	6
Necrotising enterocolitis neonatal	0	0	0	0	0	1	1
Neurogenic bowel	0	1	0	1	2	0	0
Noninfective gingivitis	2	18	10	71	89	0	0
Noninfective sialoadenitis	0	2	3	13	15	0	0
Obstructive pancreatitis	1	5	0	0	5	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Odynophagia	2	64	122	789	853	0	0
Oedema mouth	0	13	2	30	43	0	0
Oedematous pancreatitis	0	1	0	1	2	0	0
Oesophageal achalasia	1	6	1	2	8	0	0
Oesophageal discomfort	1	2	2	3	5	0	0
Oesophageal disorder	0	1	0	1	2	0	0
Oesophageal haemorrhage	0	1	0	0	1	0	0
Oesophageal hypomotility	0	1	0	0	1	0	0
Oesophageal irritation	0	0	0	1	1	0	0
Oesophageal motility disorder	0	1	0	0	1	0	0
Oesophageal obstruction	0	1	0	0	1	0	0
Oesophageal oedema	0	2	0	0	2	0	0
Oesophageal pain	2	11	10	34	45	0	0
Oesophageal rupture	0	2	0	0	2	0	0
Oesophageal spasm	0	8	0	7	15	0	0
Oesophageal ulcer	0	1	0	0	1	0	0
Oesophageal varices haemorrhage	0	2	0	0	2	0	0
Oesophagitis	1	25	3	16	41	0	0
Oesophagitis ulcerative	0	1	0	0	1	0	0
Omental infarction	0	3	0	4	7	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Oral blood blister	1	33	3	38	71	0	0
Oral discharge	0	1	0	1	2	0	0
Oral discomfort	5	100	15	184	284	0	0
Oral disorder	2	22	5	41	63	0	0
Oral dysaesthesia	1	5	1	13	18	0	0
Oral lichen planus	2	17	0	12	29	0	0
Oral lichenoid reaction	0	1	0	1	2	0	0
Oral macule	0	0	0	1	1	0	0
Oral mucosa erosion	0	2	0	4	6	0	0
Oral mucosa haematoma	0	0	0	3	3	0	0
Oral mucosal blistering	2	31	26	136	167	0	0
Oral mucosal discolouration	0	1	0	3	4	0	0
Oral mucosal eruption	0	16	5	34	50	0	0
Oral mucosal erythema	0	5	2	27	32	0	0
Oral mucosal exfoliation	0	7	0	14	21	0	0
Oral mucosal roughening	0	1	1	5	6	0	0
Oral pain	3	263	25	302	565	0	0
Oral papule	0	1	0	2	3	0	0
Oral pruritus	0	16	2	44	60	0	0
Oral purpura	0	2	0	1	3	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Palatal disorder	0	2	0	14	16	0	0
Palatal oedema	0	17	0	8	25	0	0
Palatal swelling	0	15	2	15	30	0	0
Palatal ulcer	0	0	0	2	2	0	0
Pancreatic cyst	0	2	1	2	4	0	0
Pancreatic disorder	0	1	2	5	6	0	0
Pancreatic enlargement	0	2	0	0	2	0	0
Pancreatic failure	0	3	0	0	3	0	0
Pancreatic haemorrhage	0	2	0	0	2	0	0
Pancreatic infarction	0	1	0	0	1	0	0
Pancreatic mass	0	2	0	0	2	0	0
Pancreatic pseudocyst	0	1	0	0	1	0	0
Pancreatic steatosis	0	2	0	1	3	0	0
Pancreatitis	4	114	0	0	114	0	0
Pancreatitis acute	3	56	0	0	56	0	0
Pancreatitis chronic	1	2	0	0	2	0	0
Pancreatitis haemorrhagic	0	3	0	0	3	0	0
Pancreatitis necrotising	0	3	0	0	3	0	0
Pancreatitis relapsing	0	1	0	0	1	0	0
Paraesthesia oral	10	647	65	1269	1916	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Parotid duct obstruction	0	0	0	1	1	0	0
Parotid gland enlargement	1	10	2	24	34	0	0
Peptic ulcer	1	6	0	0	6	0	0
Peptic ulcer haemorrhage	1	10	0	0	10	0	0
Periodontal disease	0	0	0	1	1	0	0
Peristalsis visible	0	0	0	1	1	0	0
Peritoneal disorder	0	0	0	1	1	0	0
Pigmentation lip	0	0	0	3	3	0	0
Plicated tongue	0	1	0	9	10	0	0
Pneumatosis intestinalis	0	1	0	0	1	0	0
Pneumoperitoneum	0	1	0	0	1	0	0
Poor dental condition	1	1	0	0	1	0	0
Portal hypertensive gastropathy	2	2	0	1	3	0	0
Pouchitis	1	1	0	1	2	0	0
Proctalgia	0	30	0	25	55	0	0
Proctitis	0	6	0	1	7	0	0
Pulpless tooth	0	0	0	1	1	0	0
Rectal discharge	0	2	0	0	2	0	0
Rectal fissure	0	1	0	0	1	0	0
Rectal haemorrhage	9	184	5	123	307	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Rectal prolapse	0	0	0	1	1	0	0
Rectal spasm	0	2	0	2	4	0	0
Rectal tenesmus	0	4	0	6	10	0	0
Rectal ulcer	0	1	0	0	1	0	0
Reflux gastritis	1	20	2	18	38	0	0
Regurgitation	1	5	2	10	15	0	0
Retching	9	296	17	452	748	0	0
Retroperitoneal effusion	0	0	1	1	1	0	0
Retroperitoneal fibrosis	0	1	0	0	1	0	0
Retroperitoneal haematoma	0	8	0	0	8	0	0
Retroperitoneal haemorrhage	1	7	0	0	7	0	0
Saliva altered	0	8	2	17	25	0	0
Saliva discolouration	0	0	0	3	3	0	0
Salivary gland calculus	0	3	0	4	7	0	0
Salivary gland cyst	0	1	0	0	1	0	0
Salivary gland disorder	0	2	0	3	5	0	0
Salivary gland enlargement	2	9	1	11	20	0	0
Salivary gland mass	0	1	0	2	3	0	0
Salivary gland mucocoele	0	0	0	1	1	0	0
Salivary gland pain	1	14	3	13	27	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Salivary hypersecretion	3	84	10	97	181	0	0
Scalloped tongue	0	2	0	5	7	0	0
Short-bowel syndrome	0	0	0	1	1	0	0
Small intestinal haemorrhage	1	27	0	4	31	0	0
Small intestinal obstruction	0	4	0	0	4	0	0
Small intestinal stenosis	1	1	0	0	1	0	0
Splanchnic hypoperfusion	0	1	0	0	1	0	0
Steatorrhoea	0	2	0	2	4	0	0
Stiff tongue	0	6	0	3	9	0	0
Stomach mass	1	3	0	0	3	0	0
Stomatitis	3	79	15	200	279	0	0
Stomatitis necrotising	0	1	0	0	1	0	0
Strawberry tongue	0	0	0	1	1	0	0
Subileus	0	1	0	0	1	0	0
Submaxillary gland enlargement	0	1	1	3	4	0	0
Superior mesenteric artery syndrome	0	1	0	0	1	0	0
Swollen tongue	7	537	36	584	1121	0	0
Teeth brittle	0	0	0	4	4	0	0
Teething	0	18	0	16	34	0	0
Terminal ileitis	0	1	0	1	2	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Thrombosis mesenteric vessel	2	22	0	0	22	0	0
Tongue atrophy	0	0	0	1	1	0	0
Tongue blistering	0	18	5	39	57	0	0
Tongue coated	1	29	4	40	69	0	0
Tongue cyst	0	1	0	5	6	0	0
Tongue discolouration	1	27	3	53	80	0	0
Tongue discomfort	1	49	16	137	186	0	0
Tongue disorder	0	30	3	52	82	0	0
Tongue dry	0	16	6	26	42	0	0
Tongue eruption	0	7	4	24	31	0	0
Tongue erythema	0	7	2	20	27	0	0
Tongue exfoliation	0	3	0	4	7	0	0
Tongue geographic	0	3	0	9	12	0	0
Tongue haematoma	0	0	0	8	8	0	0
Tongue haemorrhage	0	4	1	7	11	0	0
Tongue induration	0	0	0	1	1	0	0
Tongue movement disturbance	1	10	1	10	20	0	0
Tongue oedema	7	132	0	0	132	0	0
Tongue polyp	0	0	0	2	2	0	0
Tongue pruritus	2	7	0	24	31	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Tongue rough	0	4	2	11	15	0	0
Tongue spasm	0	0	0	12	12	0	0
Tongue ulceration	0	19	4	39	58	0	0
Tooth deposit	0	0	0	2	2	0	0
Tooth discolouration	0	12	2	11	23	0	0
Tooth disorder	4	8	1	11	19	0	0
Tooth erosion	0	1	0	0	1	0	0
Tooth impacted	0	0	0	1	1	0	0
Tooth loss	1	13	6	15	28	0	0
Tooth malformation	0	0	1	1	1	0	0
Tooth socket haemorrhage	0	3	0	4	7	0	0
Toothache	9	303	75	592	895	0	0
Trichoglossia	0	2	0	6	8	0	0
Truncus coeliacus thrombosis	0	3	0	0	3	0	0
Umbilical hernia	1	1	0	0	1	0	0
Upper gastrointestinal haemorrhage	1	17	0	0	17	0	0
Uvulitis	0	3	0	5	8	0	0
Varices oesophageal	1	6	0	2	8	0	0
Vasculitis gastrointestinal	0	1	0	0	1	0	0
Visceral venous thrombosis	5	38	0	3	41	2	3

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Volvulus	0	3	0	0	3	0	0
Vomiting	235	11966	1977	20478	32444	1	6
Vomiting projectile	0	145	8	57	202	0	0
Hepatobiliary disorders	**100**	**1239**	**42**	**326**	**1565**	**26**	**34**
Acute hepatic failure	0	13	0	0	13	0	0
Acute on chronic liver failure	1	1	0	0	1	0	0
Acute yellow liver atrophy	0	1	0	0	1	0	0
Allergic hepatitis	0	0	0	1	1	0	0
Autoimmune hepatitis	13	60	2	8	68	1	1
Bile duct stenosis	0	1	0	0	1	0	0
Bile duct stone	0	0	0	1	1	0	0
Biliary cirrhosis	0	0	0	1	1	0	0
Biliary colic	3	36	3	18	54	0	0
Biliary cyst	0	0	0	1	1	0	0
Biliary dilatation	1	1	0	0	1	0	0
Biliary ischaemia	0	1	0	0	1	0	0
Biliary obstruction	0	2	0	0	2	0	0
Biliary tract disorder	0	1	1	2	3	0	0
Budd-Chiari syndrome	0	5	0	0	5	0	0
Cholangitis	0	8	0	0	8	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Cholangitis sclerosing	2	4	0	0	4	0	0
Cholecystitis	3	33	1	12	45	1	1
Cholecystitis acute	0	14	0	0	14	0	1
Cholelithiasis	7	32	2	14	46	0	0
Cholestasis	0	17	0	6	23	0	0
Cholestasis of pregnancy	1	2	0	0	2	0	1
Cholestatic liver injury	0	0	0	1	1	0	0
Cirrhosis alcoholic	1	1	0	0	1	0	0
Congestive hepatopathy	0	1	0	0	1	0	0
Diabetic hepatopathy	0	1	0	0	1	0	0
Dilatation intrahepatic duct acquired	1	1	0	0	1	0	0
Drug-induced liver injury	2	9	0	0	9	0	0
Flood syndrome	0	0	0	1	1	0	0
Gallbladder disorder	1	8	0	6	14	0	0
Gallbladder enlargement	0	0	0	1	1	0	0
Gallbladder haematoma	0	0	0	1	1	0	0
Gallbladder mass	0	2	0	0	2	0	0
Gallbladder necrosis	0	1	0	0	1	0	0
Gallbladder oedema	0	1	0	0	1	0	0
Gallbladder polyp	0	1	0	0	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Gallbladder rupture	0	1	0	0	1	0	0
Hepatic artery embolism	0	1	0	0	1	0	0
Hepatic artery occlusion	0	2	0	0	2	0	0
Hepatic artery thrombosis	0	5	0	0	5	0	0
Hepatic cirrhosis	3	21	1	4	25	1	1
Hepatic cyst	1	4	0	1	5	0	0
Hepatic cytolysis	2	21	0	11	32	0	0
Hepatic failure	3	38	0	0	38	0	0
Hepatic fibrosis	0	0	1	1	1	0	0
Hepatic function abnormal	1	19	3	14	33	0	0
Hepatic haematoma	0	2	0	0	2	0	0
Hepatic haemorrhage	0	3	0	0	3	0	0
Hepatic infarction	1	8	0	0	8	0	0
Hepatic ischaemia	0	1	0	0	1	0	0
Hepatic lesion	0	6	1	3	9	0	0
Hepatic mass	0	1	0	1	2	0	0
Hepatic necrosis	0	2	0	0	2	0	0
Hepatic pain	2	77	8	71	148	0	0
Hepatic perfusion disorder	0	2	0	1	3	0	0
Hepatic steatosis	6	24	3	15	39	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Hepatic vascular thrombosis	1	9	0	3	12	0	0
Hepatic vein embolism	0	0	0	1	1	0	0
Hepatic vein occlusion	0	1	0	0	1	0	0
Hepatic vein thrombosis	1	45	0	2	47	0	0
Hepatitis	1	74	0	0	74	0	0
Hepatitis acute	3	26	0	0	26	13	13
Hepatitis cholestatic	0	1	0	0	1	0	0
Hepatitis fulminant	2	2	0	0	2	0	0
Hepatocellular injury	0	2	0	2	4	0	0
Hepatomegaly	2	12	0	11	23	0	0
Hepatorenal failure	0	1	0	0	1	0	0
Hepatorenal syndrome	0	2	0	0	2	0	0
Hepatosplenomegaly	0	1	1	1	2	0	0
Hepatotoxicity	0	2	0	0	2	0	0
Hyperbilirubinaemia	0	3	0	3	6	0	0
Hypertransaminasaemia	0	14	0	9	23	0	0
Immune-mediated hepatitis	0	4	0	0	4	0	0
Ischaemic hepatitis	0	3	0	0	3	0	0
Jaundice	9	87	3	30	117	0	0
Jaundice cholestatic	0	7	0	6	13	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Liver disorder	2	36	9	30	66	0	0
Liver injury	0	39	1	8	47	0	0
Liver tenderness	0	6	1	8	14	0	0
Mixed liver injury	0	1	0	0	1	0	0
Non-alcoholic fatty liver	0	1	0	0	1	0	0
Non-alcoholic steatohepatitis	0	1	0	0	1	0	0
Ocular icterus	0	8	1	10	18	0	0
Peliosis hepatis	0	0	0	1	1	0	0
Perihepatic discomfort	0	2	0	1	3	0	0
Porcelain gallbladder	1	1	0	0	1	0	0
Portal hypertension	0	5	0	2	7	0	0
Portal shunt	0	1	0	0	1	0	0
Portal vein cavernous transformation	0	1	0	0	1	0	0
Portal vein embolism	1	2	0	0	2	0	0
Portal vein occlusion	0	3	0	0	3	0	0
Portal vein phlebitis	0	2	0	0	2	0	0
Portal vein thrombosis	20	304	0	0	304	10	16
Portosplenomesenteric venous thrombosis	2	26	0	2	28	0	0
Reye's syndrome	0	1	0	0	1	0	0
Sphincter of Oddi dysfunction	0	3	0	0	3	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Subacute hepatic failure	0	3	0	0	3	0	0
Venoocclusive liver disease	0	1	0	0	1	0	0
Skin and subcutaneous tissue disorders	**1082**	**40264**	**6906**	**75438**	**115702**	**20**	**29**
Acanthosis	0	1	0	0	1	0	0
Acne	3	106	17	210	316	0	0
Acne cystic	0	7	0	6	13	0	0
Acne varioliformis	0	0	0	1	1	0	0
Actinic keratosis	1	3	2	3	6	0	0
Acute cutaneous lupus erythematosus	0	1	0	0	1	0	0
Acute febrile neutrophilic dermatosis	0	10	3	6	16	0	0
Acute generalised exanthematous pustulosis	0	10	0	0	10	0	0
Alopecia	28	427	84	667	1094	0	0
Alopecia areata	4	45	7	66	111	0	0
Alopecia scarring	0	1	0	2	3	0	0
Alopecia totalis	1	5	1	2	7	0	0
Alopecia universalis	0	3	1	3	6	0	0
Androgenetic alopecia	0	0	0	3	3	0	0
Angiodermatitis	0	2	0	3	5	0	0
Angioedema	57	1004	0	0	1004	4	4
Angiokeratoma	0	0	0	1	1	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Anhidrosis	1	3	0	1	4	0	0
Annular elastolytic giant cell granuloma	0	0	1	1	1	0	0
Anonychia	0	0	0	1	1	0	0
Aquagenic pruritus	0	0	0	1	1	0	0
Autoimmune blistering disease	0	4	0	0	4	0	0
Autoimmune dermatitis	0	2	0	1	3	0	0
Blister	11	474	59	649	1123	0	0
Blister rupture	0	5	0	2	7	0	0
Blood blister	0	73	9	138	211	0	0
Brachioradial pruritus	0	0	1	1	1	0	0
Bromhidrosis	0	0	0	1	1	0	0
Bullous haemorrhagic dermatosis	0	3	0	1	4	0	0
Butterfly rash	1	11	1	10	21	0	0
Cafe au lait spots	0	0	0	1	1	0	0
Capillaritis	0	4	3	10	14	0	0
Cellulite	1	2	18	43	45	0	0
Chloasma	1	1	1	5	6	0	0
Chronic cutaneous lupus erythematosus	0	3	1	5	8	0	0
Chronic pigmented purpura	0	1	0	4	5	0	0
Chronic spontaneous urticaria	4	12	3	10	22	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Circumoral oedema	0	6	0	4	10	0	0
Circumoral swelling	0	2	0	7	9	0	0
Cold sweat	18	1520	179	1380	2900	0	0
Cold urticaria	1	7	5	23	30	0	0
Cullen's sign	0	0	0	1	1	0	0
Cutaneous lupus erythematosus	0	0	2	4	4	0	0
Cutaneous sarcoidosis	1	2	0	1	3	0	0
Cutaneous symptom	1	5	1	19	24	0	0
Cutaneous vasculitis	14	125	0	0	125	0	0
Dandruff	2	4	2	7	11	0	0
Decubitus ulcer	2	10	2	9	19	0	0
Dermal absorption impaired	0	0	0	1	1	0	0
Dermal cyst	0	19	1	15	34	0	0
Dermatitis	5	146	16	238	384	0	0
Dermatitis acneiform	0	11	2	40	51	0	0
Dermatitis allergic	3	244	38	442	686	0	0
Dermatitis atopic	0	35	7	50	85	0	0
Dermatitis bullous	8	120	0	0	120	0	0
Dermatitis contact	2	25	0	21	46	0	0
Dermatitis diaper	0	1	0	3	4	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Dermatitis exfoliative	0	4	0	0	4	0	0
Dermatitis exfoliative generalised	5	28	0	0	28	0	0
Dermatitis herpetiformis	0	3	0	1	4	0	0
Dermatitis papillaris capillitii	0	0	0	1	1	0	0
Dermatitis psoriasiform	0	6	1	9	15	0	0
Dermatomyositis	4	26	2	3	29	2	2
Dermatosis	1	6	2	12	18	0	0
Diabetic foot	1	8	1	2	10	0	0
Diabetic ulcer	0	1	0	1	2	0	0
Diffuse alopecia	1	6	3	14	20	0	0
Drug eruption	1	29	1	42	71	1	1
Drug reaction with eosinophilia and systemic symptoms	1	29	0	0	29	0	0
Dry skin	11	303	33	390	693	0	0
Dyshidrotic eczema	0	19	4	19	38	0	0
Ecchymosis	3	125	21	336	461	0	0
Eczema	16	287	68	501	788	0	0
Eczema asteatotic	0	13	1	12	25	0	0
Eczema nummular	0	4	1	14	18	0	0
Eczema vesicular	0	0	0	1	1	0	0
Eczema weeping	0	3	0	2	5	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Eosinophilic cellulitis	1	1	0	0	1	0	0
Ephelides	0	0	0	4	4	0	0
Epidermal necrosis	1	1	0	0	1	0	0
Erythema	57	2267	768	7770	10037	0	1
Erythema ab igne	0	0	0	2	2	0	0
Erythema annulare	0	1	0	6	7	0	0
Erythema dyschromicum perstans	0	1	0	0	1	0	0
Erythema elevatum diutinum	0	1	0	0	1	0	0
Erythema multiforme	15	122	0	0	122	1	1
Erythema nodosum	2	45	17	67	112	0	0
Erythematotelangiectatic rosacea	0	2	0	1	3	0	0
Erythrodermic atopic dermatitis	0	0	0	1	1	0	0
Erythrodermic psoriasis	0	7	0	1	8	0	0
Erythrosis	0	0	1	4	4	0	0
Excessive granulation tissue	0	0	1	1	1	0	0
Excessive skin	0	0	1	1	1	0	0
Exfoliative rash	0	15	2	16	31	0	0
Facial wasting	0	0	1	2	2	0	0
Fixed eruption	1	7	3	14	21	0	0
Generalised bullous fixed drug eruption	0	2	0	0	2	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Granuloma annulare	0	6	3	22	28	0	0
Granuloma skin	0	0	1	3	3	0	0
Granulomatous rosacea	0	0	0	1	1	0	0
Guttate psoriasis	2	20	1	25	45	0	0
Haemangioma-thrombocytopenia syndrome	0	4	0	0	4	0	0
Haemorrhage subcutaneous	6	35	6	63	98	0	0
Haemorrhage subepidermal	0	1	0	0	1	0	0
Haemorrhagic urticaria	0	0	0	1	1	0	0
Haemosiderin stain	1	1	0	2	3	0	0
Hair colour changes	0	9	2	17	26	0	0
Hair disorder	0	0	1	10	10	0	0
Hair growth abnormal	0	4	0	8	12	0	0
Hair growth rate abnormal	0	0	1	1	1	0	0
Hair texture abnormal	0	9	1	15	24	0	0
Hand dermatitis	0	3	1	17	20	0	0
Henoch-Schonlein purpura	4	27	4	20	47	0	0
Hidradenitis	1	5	2	10	15	0	0
Hirsutism	0	0	0	1	1	0	0
Hyperhidrosis	109	8449	1147	10141	18590	0	0
Hyperkeratosis	1	4	0	2	6	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Hypersensitivity vasculitis	3	19	0	0	19	0	0
Hypertrichosis	0	3	1	3	6	0	0
Hypertrophic scar	0	0	0	1	1	0	0
Hypohidrosis	0	3	0	8	11	0	0
Hypotrichosis	0	1	0	2	3	0	0
Ichthyosis acquired	0	0	0	1	1	0	0
Idiopathic angioedema	0	3	0	0	3	0	0
Idiopathic urticaria	0	8	1	6	14	0	0
Ingrowing nail	2	2	0	3	5	0	0
Ingrown hair	0	0	0	1	1	0	0
Intertrigo	0	2	0	2	4	0	0
Ischaemic skin ulcer	0	1	0	0	1	0	0
Itching scar	0	3	1	4	7	0	0
Keloid scar	0	1	0	3	4	0	0
Keratosis pilaris	0	0	0	3	3	0	0
Leukoplakia	0	1	0	0	1	0	0
Lichen planopilaris	0	2	2	3	5	0	0
Lichen planus	5	45	16	69	114	0	0
Lichen sclerosus	2	11	1	9	20	0	0
Lichen striatus	0	1	0	0	1	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Lichenoid keratosis	0	4	1	5	9	0	0
Linear IgA disease	0	2	0	2	4	0	0
Lipoatrophy	0	2	1	2	4	0	0
Lipodystrophy acquired	0	0	0	2	2	0	0
Lipohypertrophy	0	0	0	3	3	0	0
Livedo reticularis	3	74	9	93	167	0	0
Lividity	1	16	0	11	27	0	0
Lymphomatoid papulosis	0	1	0	2	3	0	0
Macule	0	9	4	56	65	0	0
Madarosis	0	4	1	14	18	0	0
Mechanical acne	0	1	0	0	1	0	0
Mechanical urticaria	0	10	0	24	34	0	0
Melanoderma	0	2	1	2	4	0	0
Miliaria	2	131	3	124	255	0	0
Mucocutaneous haemorrhage	0	3	0	1	4	0	0
Myxoid cyst	0	1	0	1	2	0	0
Nail bed bleeding	0	0	1	6	6	0	0
Nail bed disorder	0	2	0	0	2	0	0
Nail bed inflammation	0	0	0	4	4	0	0
Nail bed tenderness	0	1	1	3	4	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Nail cuticle fissure	0	0	0	1	1	0	0
Nail discolouration	0	17	1	44	61	0	0
Nail disorder	0	6	0	8	14	0	0
Nail dystrophy	0	0	0	1	1	0	0
Nail growth abnormal	0	3	1	3	6	0	0
Nail hypertrophy	0	1	0	0	1	0	0
Nail necrosis	0	1	0	0	1	0	0
Nail pigmentation	0	0	0	2	2	0	0
Nail pitting	0	1	0	1	2	0	0
Nail psoriasis	1	2	0	3	5	0	0
Nail ridging	0	4	0	9	13	0	0
Necrolytic acral erythema	1	1	0	0	1	0	0
Needle track marks	0	2	0	4	6	0	0
Neurodermatitis	2	9	8	39	48	0	0
Neuropathic pruritus	0	0	1	1	1	0	0
Neutrophilic dermatosis	0	2	0	2	4	0	0
Night sweats	30	1625	126	1343	2968	0	0
Nikolsky's sign	0	0	0	1	1	0	0
Nodular rash	0	1	1	5	6	0	0
Nodular vasculitis	1	2	0	0	2	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Oedema blister	0	1	0	0	1	0	0
Onychalgia	0	6	0	13	19	0	0
Onychoclasis	2	12	1	6	18	0	0
Onycholysis	0	3	0	2	5	0	0
Onychomadesis	0	4	1	6	10	0	0
PASH syndrome	0	0	0	1	1	0	0
Pain of skin	11	828	224	1205	2033	0	0
Palmar erythema	0	6	2	18	24	0	0
Palmar-plantar erythrodysaesthesia syndrome	1	3	2	9	12	0	0
Palmoplantar keratoderma	0	1	0	0	1	0	0
Palmoplantar pustulosis	0	6	3	4	10	0	0
Palpable purpura	0	4	0	5	9	0	0
Panniculitis	2	6	0	6	12	0	0
Panniculitis lobular	0	0	0	1	1	0	0
Papule	1	72	9	142	214	0	0
Papulopustular rosacea	0	1	0	1	2	0	0
Parakeratosis	0	1	1	1	2	0	0
Paraneoplastic dermatomyositis	1	1	0	0	1	0	0
Parapsoriasis	0	1	0	7	8	0	0
Pemphigoid	11	70	0	0	70	2	3

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Pemphigus	7	31	0	0	31	0	0
Perioral dermatitis	0	5	2	11	16	0	0
Pernio-like erythema	3	5	1	6	11	0	0
Petechiae	21	609	155	1496	2105	0	2
Photodermatosis	0	0	0	3	3	0	0
Photosensitivity reaction	1	156	28	268	424	0	0
Pigmentation disorder	0	18	9	71	89	0	0
Piloerection	3	92	14	85	177	0	0
Pityriasis	0	7	1	12	19	0	0
Pityriasis lichenoides et varioliformis acuta	0	1	0	2	3	0	0
Pityriasis rosea	1	35	5	93	128	0	0
Pityriasis rubra pilaris	0	4	6	10	14	0	0
Plantar erythema	0	2	0	4	6	0	0
Polymorphic eruption of pregnancy	0	1	0	0	1	0	0
Polymorphic light eruption	0	2	0	4	6	0	0
Progressive facial hemiatrophy	0	1	0	0	1	0	0
Prurigo	0	1	0	10	11	0	0
Pruritus	86	5132	941	12789	17921	0	0
Pruritus allergic	0	1	1	14	15	0	0
Pseudofolliculitis	0	0	0	4	4	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Psoriasis	28	269	51	300	569	0	1
Purpura	10	205	15	266	471	0	0
Pustular psoriasis	0	10	2	5	15	0	0
Pyoderma gangrenosum	1	5	0	2	7	0	0
Rash	129	5618	947	14604	20222	2	3
Rash erythematous	15	1107	113	2038	3145	1	1
Rash follicular	0	2	2	6	8	0	0
Rash macular	17	514	135	1509	2023	0	0
Rash maculo-papular	2	71	11	167	238	0	0
Rash maculovesicular	0	0	0	2	2	0	0
Rash morbilliform	3	39	7	54	93	0	0
Rash papular	4	293	15	545	838	0	0
Rash pruritic	20	1088	150	2289	3377	0	1
Rash rubelliform	1	4	1	4	8	0	0
Rash scarlatiniform	0	2	0	2	4	0	0
Rash vesicular	3	80	10	240	320	0	0
Rebound eczema	0	0	0	1	1	0	0
Rebound psoriasis	0	0	0	1	1	0	0
Rosacea	2	37	3	40	77	0	0
Scab	1	17	1	43	60	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Scar discomfort	0	0	1	4	4	0	0
Scar pain	0	15	1	18	33	0	0
Scleroedema	2	2	0	0	2	0	0
Sebaceous gland disorder	0	0	0	4	4	0	0
Sebaceous glands overactivity	0	1	0	0	1	0	0
Seborrhoea	1	11	0	10	21	0	0
Seborrhoeic dermatitis	3	16	2	13	29	0	0
Segmented hyalinising vasculitis	0	1	0	1	2	0	0
Senile pruritus	0	1	0	1	2	0	0
Sensitive skin	8	505	69	835	1340	0	0
Severe cutaneous adverse reaction	1	1	0	0	1	0	0
Skin adhesion	0	0	1	2	2	0	0
Skin atrophy	1	11	0	9	20	0	0
Skin burning sensation	17	529	72	693	1222	0	0
Skin depigmentation	1	5	2	19	24	0	0
Skin discharge	0	1	0	2	3	0	0
Skin discolouration	12	228	93	842	1070	0	1
Skin discomfort	0	9	13	66	75	0	0
Skin disorder	42	253	226	574	827	0	0
Skin erosion	0	52	0	20	72	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Skin exfoliation	7	142	25	255	397	0	0
Skin fissures	2	17	2	19	36	0	0
Skin fragility	1	3	1	3	6	0	0
Skin haemorrhage	4	78	54	254	332	0	1
Skin hyperpigmentation	0	2	2	29	31	0	0
Skin hypertrophy	0	3	2	14	17	0	0
Skin hypopigmentation	0	3	1	2	5	0	0
Skin indentation	0	9	1	13	22	0	0
Skin induration	0	14	12	168	182	1	1
Skin irritation	2	109	19	215	324	0	0
Skin laxity	0	1	0	0	1	0	0
Skin lesion	9	69	24	117	186	0	0
Skin lesion inflammation	0	1	0	0	1	0	0
Skin mass	2	38	12	148	186	0	0
Skin necrosis	0	7	0	4	11	0	0
Skin odour abnormal	0	37	2	68	105	0	0
Skin oedema	0	6	0	16	22	0	0
Skin plaque	1	7	8	51	58	1	1
Skin reaction	1	174	21	367	541	0	0
Skin sensitisation	1	86	11	116	202	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Skin striae	1	11	0	12	23	0	0
Skin swelling	1	61	9	100	161	0	0
Skin texture abnormal	0	3	2	8	11	0	0
Skin tightness	0	31	4	51	82	0	0
Skin ulcer	6	40	6	35	75	0	0
Skin ulcer haemorrhage	0	0	1	2	2	0	0
Skin warm	3	358	24	709	1067	0	0
Skin weeping	1	12	0	4	16	0	0
Skin wrinkling	0	3	2	9	12	0	0
Solar dermatitis	0	1	0	3	4	0	0
Solar lentigo	0	2	0	7	9	0	0
Solar urticaria	0	1	0	6	7	0	0
Spider naevus	0	4	0	5	9	0	0
Splinter haemorrhages	2	7	0	3	10	0	0
Stasis dermatitis	0	8	1	8	16	0	0
Stevens-Johnson syndrome	11	35	0	0	35	0	0
Sticky skin	0	8	0	6	14	0	0
Subacute cutaneous lupus erythematosus	0	2	2	3	5	0	0
Subcutaneous emphysema	0	0	0	1	1	0	0
Superficial inflammatory dermatosis	0	2	1	2	4	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Sweat discolouration	0	1	0	2	3	0	0
Sweat gland disorder	0	1	0	1	2	0	0
Symmetrical drug-related intertriginous and flexural exanthema	2	2	3	5	7	0	0
Systemic lupus erythematosus rash	0	7	0	4	11	0	0
Target skin lesion	0	3	0	2	5	0	0
Telangiectasia	2	10	4	29	39	0	0
Toxic epidermal necrolysis	1	5	0	0	5	0	0
Toxic skin eruption	1	3	0	8	11	0	0
Transient acantholytic dermatosis	0	2	1	3	5	0	0
Trichodynia	1	5	0	11	16	0	0
Trichorrhexis	0	6	1	5	11	0	0
Umbilical haemorrhage	0	2	0	0	2	0	0
Urticaria	57	2014	517	5095	7109	4	4
Urticaria cholinergic	0	1	0	1	2	0	0
Urticaria chronic	5	55	5	40	95	0	0
Urticaria contact	0	2	0	1	3	0	0
Urticaria papular	3	6	0	14	20	0	0
Urticaria physical	0	0	0	5	5	0	0
Urticaria pigmentosa	0	0	0	1	1	0	0
Urticaria pressure	0	0	0	2	2	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Urticaria thermal	0	3	0	4	7	0	0
Urticarial dermatitis	1	2	0	3	5	0	0
Urticarial vasculitis	5	12	0	0	12	1	1
Vancomycin infusion reaction	0	1	0	0	1	0	0
Vascular purpura	0	16	0	8	24	0	0
Vascular skin disorder	0	1	1	3	4	0	0
Vasculitic rash	0	17	2	29	46	0	0
Vasculitic ulcer	0	3	0	0	3	0	0
Venous ulcer pain	0	1	0	0	1	0	0
Vitiligo	4	30	19	75	105	0	0
Xanthelasma	0	0	0	1	1	0	0
Xeroderma	0	0	1	1	1	0	0
Yellow skin	2	27	3	40	67	0	0
Musculoskeletal and connective tissue disorders	**3074**	**100779**	**32210**	**294746**	**395525**	**16**	**59**
Acquired claw toe	0	1	0	0	1	0	0
Acral overgrowth	0	0	0	1	1	0	0
Acute aseptic arthritis	0	3	0	0	3	0	0
Amplified musculoskeletal pain syndrome	0	1	0	4	5	0	0
Amyotrophy	1	5	0	1	6	0	0
Ankle impingement	0	1	0	0	1	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Ankylosing spondylitis	4	41	3	25	66	0	0
Antisynthetase syndrome	2	4	0	0	4	0	0
Arthralgia	628	23200	8408	74591	97791	1	10
Arthritis	30	640	48	451	1091	0	0
Arthritis enteropathic	0	3	0	0	3	0	0
Arthritis reactive	6	78	2	26	104	0	0
Arthropathy	6	49	9	61	110	0	0
Articular disc disorder	0	0	0	1	1	0	0
Autoimmune arthritis	1	14	1	2	16	0	0
Autoimmune myositis	3	7	0	0	7	0	0
Axial spondyloarthritis	0	1	0	1	2	0	0
Axillary mass	0	54	16	111	165	0	0
Back disorder	1	6	2	14	20	0	0
Back pain	118	5596	834	9498	15094	0	0
Bone disorder	4	7	0	9	16	0	0
Bone erosion	0	1	0	0	1	0	0
Bone infarction	0	1	0	0	1	0	0
Bone lesion	0	0	0	1	1	0	0
Bone loss	0	2	0	1	3	0	0
Bone pain	20	1138	322	3110	4248	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Bone swelling	1	9	0	8	17	0	0
Bursa disorder	0	0	0	9	9	0	0
Bursal fluid accumulation	0	2	0	0	2	0	0
Bursitis	11	230	23	233	463	0	0
Camptocormia	0	1	0	1	2	0	0
Cartilage atrophy	0	0	0	1	1	0	0
Cervical spinal stenosis	0	0	1	1	1	0	0
Chest wall cyst	1	1	0	0	1	0	0
Chest wall haematoma	0	1	0	3	4	0	0
Chest wall mass	0	0	1	2	2	0	0
Chondritis	0	1	0	1	2	0	0
Chondrocalcinosis	1	7	0	1	8	0	0
Chondromalacia	1	1	0	0	1	0	0
Chondropathy	0	2	1	2	4	0	0
Chronic kidney disease-mineral and bone disorder	0	1	0	0	1	0	0
Clubbing	0	0	0	1	1	0	0
Coccydynia	1	13	4	18	31	0	0
Collagen disorder	1	3	0	3	6	0	0
Compartment syndrome	0	11	0	0	11	0	0
Connective tissue disorder	2	10	1	7	17	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Connective tissue inflammation	0	4	0	2	6	0	0
Costochondritis	3	93	4	48	141	0	0
Crystal arthropathy	0	1	2	2	3	0	0
Dactylitis	0	3	1	5	8	0	0
Dupuytren's contracture	0	6	0	1	7	0	0
Dwarfism	0	0	0	1	1	0	0
Dysponesis	0	0	0	2	2	0	0
Elbow deformity	1	2	0	0	2	0	0
Enthesopathy	1	6	1	4	10	0	0
Eosinophilic fasciitis	0	4	0	1	5	0	0
Epiphyses premature fusion	0	1	0	0	1	0	0
Exostosis	0	3	0	1	4	0	0
Extremity contracture	0	4	0	1	5	0	0
Facet joint syndrome	0	1	0	0	1	0	0
Facial asymmetry	1	36	1	16	52	0	0
Fasciitis	0	2	0	0	2	0	0
Felty's syndrome	0	0	0	1	1	0	0
Femoroacetabular impingement	0	2	0	1	3	0	0
Fibromyalgia	13	349	17	139	488	0	0
Finger deformity	1	5	3	7	12	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Fistula	2	6	1	4	10	0	0
Fistula discharge	1	1	0	0	1	0	0
Fistula inflammation	1	1	0	0	1	0	0
Flank pain	3	120	10	161	281	0	0
Fluctuance	0	1	0	1	2	0	0
Focal myositis	0	0	0	1	1	0	0
Foot deformity	0	15	1	11	26	0	0
Fracture pain	0	0	0	2	2	0	0
Gouty arthritis	1	2	0	2	4	0	0
Gouty tophus	0	1	0	0	1	0	0
Greater trochanteric pain syndrome	0	10	0	3	13	0	0
Groin pain	6	222	33	299	521	0	0
Growing pains	0	6	1	5	11	0	0
Growth retardation	0	1	0	0	1	1	1
Haemarthrosis	1	24	3	7	31	0	0
Haematoma muscle	0	17	7	37	54	0	0
Haemophilic arthropathy	0	0	0	1	1	0	0
Hand deformity	3	6	1	6	12	0	0
Head deformity	1	3	0	1	4	0	0
Immobilisation syndrome	0	0	0	1	1	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Immune-mediated myositis	0	4	0	0	4	0	0
Infantile back arching	0	0	0	1	1	0	0
Inguinal mass	0	1	0	0	1	0	0
Intervertebral disc degeneration	1	4	1	5	9	0	0
Intervertebral disc disorder	0	2	1	9	11	0	0
Intervertebral disc protrusion	4	24	6	20	44	0	0
Jaw clicking	0	6	1	5	11	0	0
Jaw cyst	0	1	0	2	3	0	0
Jaw disorder	0	4	2	9	13	0	0
Joint adhesion	0	0	0	1	1	0	0
Joint ankylosis	0	2	1	15	17	0	0
Joint contracture	0	2	0	6	8	0	0
Joint destruction	0	0	0	1	1	0	0
Joint effusion	1	16	2	34	50	0	0
Joint hyperextension	0	0	0	1	1	0	0
Joint instability	0	4	0	6	10	0	0
Joint laxity	0	5	0	3	8	0	0
Joint lock	3	64	3	17	81	0	0
Joint noise	5	42	1	30	72	0	0
Joint range of motion decreased	3	20	9	37	57	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Joint stiffness	8	438	43	372	810	0	0
Joint swelling	49	1000	97	1023	2023	0	0
Joint vibration	1	4	0	6	10	0	0
Joint warmth	0	31	2	28	59	0	0
Juvenile idiopathic arthritis	0	4	0	0	4	0	0
Knee deformity	1	3	3	5	8	0	0
Kyphosis	0	5	1	2	7	0	0
Ligament disorder	0	1	0	1	2	0	0
Ligament laxity	0	1	1	3	4	0	0
Ligament pain	0	7	0	7	14	0	0
Ligamentitis	0	0	0	2	2	0	0
Limb deformity	1	9	1	10	19	0	0
Limb discomfort	80	2295	518	11227	13522	0	0
Limb mass	2	27	3	55	82	0	0
Locomotive syndrome	1	8	0	21	29	0	0
Loose body in joint	0	1	0	1	2	0	0
Low turnover osteopathy	0	0	0	1	1	0	0
Lumbar spinal stenosis	0	1	0	0	1	0	0
Lupus-like syndrome	1	8	0	0	8	0	0
Mandibular mass	0	1	1	2	3	0	0

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	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Mastication disorder	2	22	0	20	42	0	0
Masticatory pain	0	0	0	5	5	0	0
Medial tibial stress syndrome	0	7	0	5	12	0	0
Metatarsalgia	0	0	2	3	3	0	0
Mixed connective tissue disease	1	5	0	1	6	0	0
Mobility decreased	41	391	223	832	1223	0	0
Morphoea	1	5	3	9	14	0	0
Muscle atrophy	9	65	10	47	112	0	0
Muscle contracture	1	17	7	54	71	0	0
Muscle discomfort	2	20	28	147	167	0	0
Muscle disorder	2	19	6	41	60	0	0
Muscle fatigue	13	917	50	457	1374	0	0
Muscle fibrosis	0	1	0	0	1	0	0
Muscle haemorrhage	0	8	1	4	12	0	0
Muscle hypertrophy	1	2	0	1	3	0	0
Muscle hypoxia	0	1	1	1	2	0	0
Muscle mass	3	13	0	9	22	0	0
Muscle necrosis	0	6	0	0	6	0	0
Muscle oedema	0	6	0	9	15	0	0
Muscle rigidity	1	83	10	104	187	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Muscle spasms	91	3247	346	3847	7094	0	2
Muscle swelling	1	32	5	37	69	0	0
Muscle tightness	16	228	74	418	646	0	0
Muscle twitching	32	504	83	750	1254	0	0
Muscular weakness	121	2725	306	2883	5608	0	1
Musculoskeletal chest pain	15	420	49	437	857	0	0
Musculoskeletal deformity	0	0	0	1	1	0	0
Musculoskeletal discomfort	16	153	72	458	611	0	0
Musculoskeletal disorder	6	24	11	37	61	0	0
Musculoskeletal pain	6	298	151	1717	2015	0	0
Musculoskeletal stiffness	77	2227	366	2441	4668	0	0
Myalgia	788	27877	14715	134754	162631	2	13
Myalgia intercostal	0	4	4	25	29	0	0
Myofascial pain syndrome	1	25	3	18	43	0	0
Myofascial spasm	0	0	0	1	1	0	0
Myokymia	0	3	0	8	11	0	0
Myopathy	1	20	1	13	33	0	0
Myopathy toxic	1	2	0	0	2	0	0
Myosclerosis	0	8	2	14	22	0	0
Myositis	11	100	9	86	186	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Neck deformity	0	1	1	2	3	0	0
Neck mass	3	29	4	42	71	0	0
Neck pain	76	2937	531	3998	6935	0	0
Necrotising myositis	0	1	0	0	1	0	0
Neurogenic fracture	0	1	0	0	1	0	0
Neuropathic arthropathy	0	1	0	0	1	0	0
Neuropathic muscular atrophy	1	2	0	2	4	0	0
Nodal osteoarthritis	0	2	1	1	3	0	0
Nose deformity	0	0	0	3	3	0	0
Nuchal rigidity	2	54	13	121	175	0	0
Oligoarthritis	2	4	2	5	9	0	0
Osteitis	0	12	0	13	25	0	0
Osteoarthritis	11	121	19	92	213	0	0
Osteoarthropathy	0	0	0	1	1	0	0
Osteochondrosis	1	3	1	2	5	0	0
Osteolysis	1	1	0	0	1	0	0
Osteonecrosis	0	11	1	3	14	0	0
Osteonecrosis of jaw	0	5	0	1	6	0	0
Osteopenia	1	3	1	2	5	0	0
Osteoporosis	6	19	0	5	24	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Osteoporotic fracture	0	5	0	0	5	0	0
Osteosclerosis	0	0	0	1	1	0	0
Pain in extremity	426	18860	4312	36197	55057	2	21
Pain in jaw	12	579	68	623	1202	0	0
Palindromic rheumatism	0	8	0	2	10	0	0
Patellofemoral pain syndrome	1	7	0	4	11	0	0
Pathological fracture	0	1	1	3	4	0	0
Pelvic misalignment	0	1	0	0	1	0	0
Periarthritis	17	531	8	152	683	0	0
Periostitis	0	1	0	5	6	0	0
Peripheral spondyloarthritis	0	0	2	2	2	1	1
Plantar fascial fibromatosis	0	1	1	1	2	0	0
Plantar fasciitis	1	16	3	15	31	0	0
Polyarthritis	4	59	2	28	87	0	0
Polychondritis	0	3	0	0	3	0	0
Polymyalgia rheumatica	33	218	8	95	313	4	4
Polymyositis	4	18	0	7	25	0	0
Posture abnormal	0	2	0	5	7	0	0
Psoriatic arthropathy	15	59	7	26	85	0	0
Pubic pain	0	4	0	2	6	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Reynold's syndrome	1	6	0	1	7	0	0
Rhabdomyolysis	4	56	0	0	56	0	0
Rheumatic disorder	6	55	10	66	121	0	0
Rheumatic fever	0	10	0	0	10	0	0
Rheumatoid arthritis	50	329	13	113	442	2	2
Rheumatoid nodule	0	1	1	1	2	0	0
Rotator cuff syndrome	7	124	5	52	176	0	0
Sacral pain	0	10	5	45	55	0	0
Sacroiliac joint dysfunction	0	0	3	4	4	0	0
Sacroiliitis	0	4	0	6	10	0	0
Sarcopenia	1	3	1	3	6	0	0
Scleroderma	3	9	0	2	11	0	0
Scoliosis	0	5	2	3	8	0	0
Seronegative arthritis	1	9	0	7	16	0	0
Shoulder girdle pain	0	0	1	1	1	0	0
Sjogren's syndrome	3	22	2	6	28	2	2
Snapping hip syndrome	0	0	1	1	1	0	0
Soft tissue atrophy	0	0	0	1	1	0	0
Soft tissue disorder	1	4	0	3	7	0	0
Soft tissue mass	0	2	0	6	8	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Soft tissue necrosis	0	2	0	0	2	0	0
Soft tissue swelling	0	2	1	17	19	0	0
Somatic dysfunction	1	2	0	0	2	0	0
Spinal deformity	1	2	0	2	4	0	0
Spinal disorder	2	9	2	9	18	0	0
Spinal osteoarthritis	2	17	2	9	26	0	0
Spinal pain	6	296	71	554	850	0	0
Spinal segmental dysfunction	0	0	1	1	1	0	0
Spinal stenosis	1	5	0	1	6	0	0
Spondylitis	1	9	0	10	19	0	0
Spondyloarthropathy	0	7	0	0	7	0	0
Still's disease	11	36	1	6	42	0	0
Sympathetic posterior cervical syndrome	0	1	0	0	1	0	0
Symphysiolysis	0	0	1	2	2	0	0
Synovial cyst	2	19	3	72	91	0	0
Synovial disorder	0	1	0	3	4	0	0
Synovitis	4	24	1	21	45	0	0
Systemic lupus erythematosus	7	67	4	28	95	1	2
Systemic scleroderma	2	6	1	1	7	0	0
Temporomandibular joint syndrome	3	29	3	21	50	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Tendinous contracture	0	0	2	4	4	0	0
Tendon calcification	1	1	0	0	1	0	0
Tendon discomfort	1	6	1	19	25	0	0
Tendon disorder	0	18	2	38	56	0	0
Tendon pain	2	56	12	77	133	0	0
Tendon sheath disorder	0	1	0	4	5	0	0
Tendonitis	7	127	17	126	253	0	0
Tenosynovitis	0	10	2	24	34	0	0
Tenosynovitis stenosans	0	5	0	1	6	0	0
Thoracic spinal stenosis	0	1	0	0	1	0	0
Torticollis	0	9	7	56	65	0	0
Trigger finger	1	32	2	18	50	0	0
Trigger points	0	0	1	4	4	0	0
Trismus	4	60	7	69	129	0	0
Undifferentiated connective tissue disease	0	1	0	0	1	0	0
Vertebral end plate impression	0	0	1	1	1	0	0
Vertebral foraminal stenosis	0	0	2	2	2	0	0
Vertebral lesion	0	0	1	1	1	0	0
Vertebral osteophyte	0	0	1	1	1	0	0
Weight bearing difficulty	18	51	33	125	176	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Winged scapula	0	3	1	1	4	0	0
Wrist deformity	0	1	0	1	2	0	0
Renal and urinary disorders	**241**	**3652**	**247**	**3200**	**6852**	**1**	**12**
Acquired cystic kidney disease	0	1	0	0	1	0	0
Acute kidney injury	26	246	0	0	246	0	2
Albuminuria	0	1	0	1	2	0	0
Anti-glomerular basement membrane disease	0	1	0	0	1	0	0
Anuria	3	33	0	0	33	0	0
Atonic urinary bladder	0	1	0	1	2	0	0
Automatic bladder	0	1	0	0	1	0	0
Azotaemia	0	1	0	1	2	0	0
Bence Jones proteinuria	1	1	0	0	1	0	0
Bilirubinuria	0	0	0	1	1	0	0
Bladder cyst	0	1	0	0	1	0	0
Bladder dilatation	0	2	0	0	2	0	0
Bladder discomfort	2	10	2	18	28	0	0
Bladder disorder	3	25	0	15	40	0	0
Bladder dysfunction	4	17	6	12	29	0	0
Bladder irritation	0	6	0	5	11	0	0
Bladder mass	0	1	0	0	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Bladder obstruction	0	1	0	0	1	0	0
Bladder pain	3	66	9	46	112	0	0
Bladder prolapse	0	1	0	0	1	0	0
Bladder spasm	0	1	0	1	2	0	0
Bladder sphincter atony	0	4	0	1	5	0	0
Bladder stenosis	0	0	1	1	1	0	0
C3 glomerulopathy	0	2	0	0	2	0	0
Calculus urinary	1	4	1	2	6	0	0
Choluria	0	0	0	5	5	0	0
Chromaturia	8	115	7	155	270	0	0
Chronic kidney disease	6	35	0	3	38	0	0
Costovertebral angle tenderness	0	3	0	11	14	0	0
Crush syndrome	0	1	0	0	1	0	0
Cystitis haemorrhagic	0	8	0	5	13	0	0
Cystitis interstitial	0	12	0	4	16	0	0
Cystitis noninfective	0	8	9	63	71	0	0
Cystitis-like symptom	0	1	1	7	8	0	0
Diabetic nephropathy	4	8	0	1	9	0	1
Dysuria	8	130	20	266	396	0	0
End stage renal disease	2	10	0	0	10	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Faecaluria	0	0	0	1	1	0	0
Focal segmental glomerulosclerosis	4	11	1	1	12	0	0
Genitourinary symptom	0	1	0	0	1	0	0
Glomerulonephritis	2	11	0	0	11	0	0
Glomerulonephritis acute	0	0	0	1	1	0	0
Glomerulonephritis chronic	0	1	0	0	1	0	0
Glomerulonephritis membranoproliferative	0	3	2	2	5	0	0
Glomerulonephritis membranous	0	4	0	1	5	0	0
Glomerulonephritis minimal lesion	3	13	2	4	17	0	3
Glomerulonephritis proliferative	0	1	0	0	1	0	0
Glomerulonephritis rapidly progressive	4	9	0	0	9	0	0
Glomerulonephropathy	0	1	0	1	2	0	0
Glycosuria	0	1	0	0	1	0	0
Goodpasture's syndrome	0	3	1	1	4	0	0
Haematinuria	0	1	0	0	1	0	0
Haematuria	3	122	9	185	307	0	1
Haemoglobinuria	0	1	0	0	1	0	0
Haemorrhage urinary tract	3	64	0	32	96	0	0
Henoch-Schonlein purpura nephritis	0	1	0	1	2	0	0
Hydronephrosis	1	4	1	1	5	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Hypertensive nephropathy	0	3	0	0	3	0	0
Hypertonic bladder	0	13	2	13	26	0	0
Hypotonic urinary bladder	0	0	0	1	1	0	0
IgA nephropathy	4	12	8	11	23	0	1
Incontinence	3	113	3	69	182	0	0
Ketonuria	0	0	0	1	1	0	0
Kidney congestion	0	1	0	8	9	0	0
Kidney enlargement	0	1	0	0	1	0	0
Kidney fibrosis	0	1	0	0	1	0	0
Leukocyturia	0	1	0	2	3	0	0
Loss of bladder sensation	0	13	0	3	16	0	0
Lower urinary tract symptoms	0	0	1	3	3	0	0
Lupus nephritis	3	6	1	2	8	0	0
Malnutrition-inflammation-atherosclerosis syndrome	0	1	0	0	1	0	0
Mesangioproliferative glomerulonephritis	0	1	0	0	1	0	0
Microalbuminuria	0	1	0	1	2	0	0
Micturition disorder	2	8	5	28	36	0	0
Micturition frequency decreased	0	0	0	3	3	0	0
Micturition urgency	1	81	11	165	246	0	0
Mixed incontinence	0	1	0	0	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Nephritis	1	13	0	1	14	0	0
Nephroangiosclerosis	0	1	0	0	1	0	0
Nephrolithiasis	5	46	1	16	62	0	0
Nephropathy	3	8	0	3	11	0	0
Nephropathy toxic	0	1	0	0	1	0	0
Nephrosclerosis	0	3	0	0	3	0	0
Nephrotic syndrome	6	40	0	9	49	0	0
Neurogenic bladder	4	12	1	2	14	0	0
Nocturia	0	23	4	56	79	0	0
Oedematous kidney	1	2	0	1	3	0	0
Oliguria	1	22	1	22	44	0	0
Paroxysmal nocturnal haemoglobinuria	0	1	0	0	1	0	0
Pneumaturia	0	0	0	1	1	0	0
Pollakiuria	14	258	35	468	726	0	0
Polyuria	0	39	10	168	207	0	0
Prerenal failure	0	3	0	0	3	0	0
Proteinuria	2	24	4	17	41	0	0
Pyelocaliectasis	0	1	0	0	1	0	0
Reflux nephropathy	0	0	0	1	1	0	0
Renal aneurysm	0	1	0	0	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Renal artery dissection	0	1	0	0	1	0	0
Renal artery occlusion	0	3	0	0	3	0	0
Renal artery stenosis	0	1	0	0	1	0	0
Renal artery thrombosis	3	15	0	0	15	0	1
Renal atrophy	2	5	0	0	5	0	0
Renal colic	0	23	1	30	53	0	0
Renal cortical necrosis	0	1	0	0	1	0	0
Renal cyst	4	4	1	4	8	0	0
Renal disorder	15	58	6	40	98	0	0
Renal embolism	0	2	0	0	2	0	0
Renal failure	15	164	0	0	164	0	0
Renal haemorrhage	1	7	0	0	7	0	0
Renal hypertension	0	0	0	1	1	0	0
Renal impairment	13	59	2	17	76	0	0
Renal infarct	2	56	0	0	56	0	1
Renal injury	0	12	0	0	12	0	0
Renal ischaemia	0	8	0	0	8	0	0
Renal pain	9	877	45	820	1697	0	0
Renal tubular acidosis	0	0	0	1	1	0	0
Renal tubular atrophy	0	1	0	0	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Renal tubular disorder	0	2	0	0	2	0	0
Renal tubular injury	0	2	0	0	2	0	0
Renal tubular necrosis	0	6	0	0	6	0	0
Renal vascular thrombosis	0	8	0	0	8	0	0
Renal vasculitis	0	2	0	0	2	0	0
Renal vein embolism	0	2	0	0	2	0	0
Renal vein occlusion	0	2	0	1	3	0	0
Renal vein thrombosis	1	35	0	0	35	0	0
Renal-limited thrombotic microangiopathy	0	2	0	0	2	0	0
Single functional kidney	0	2	0	0	2	0	0
Strangury	1	2	0	1	3	0	0
Stress urinary incontinence	1	3	0	1	4	0	0
Subcapsular renal haematoma	0	1	0	0	1	0	0
Tubulointerstitial nephritis	3	21	0	0	21	1	1
Urate nephropathy	1	1	0	0	1	0	0
Ureteral disorder	0	2	0	0	2	0	0
Ureteric obstruction	0	1	0	0	1	0	0
Urethral dilatation	0	0	0	1	1	0	0
Urethral discharge	0	0	0	1	1	0	0
Urethral disorder	0	0	0	1	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Urethral haemorrhage	1	1	0	1	2	0	0
Urethral intrinsic sphincter deficiency	0	0	0	1	1	0	0
Urethral pain	0	3	1	6	9	0	0
Urethral prolapse	0	0	0	1	1	0	0
Urethral spasm	0	0	0	2	2	0	0
Urethral stenosis	0	1	0	1	2	0	0
Urethritis noninfective	0	0	0	1	1	0	0
Urge incontinence	0	4	0	4	8	0	0
Urinary bladder haemorrhage	1	32	0	10	42	0	0
Urinary bladder rupture	0	1	0	0	1	0	0
Urinary hesitation	0	10	1	13	23	0	0
Urinary incontinence	12	191	17	156	347	0	0
Urinary retention	10	150	3	38	188	0	1
Urinary straining	0	0	0	3	3	0	0
Urinary tract discomfort	0	4	1	7	11	0	0
Urinary tract disorder	1	13	1	9	22	0	0
Urinary tract inflammation	0	3	2	8	11	0	0
Urinary tract obstruction	0	3	0	1	4	0	0
Urinary tract pain	0	15	0	6	21	0	0
Urine abnormality	2	17	6	33	50	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Urine flow decreased	1	23	0	6	29	0	0
Urine odour abnormal	1	24	1	43	67	0	0
Urogenital haemorrhage	0	1	0	0	1	0	0
Pregnancy, puerperium and perinatal conditions	**59**	**785**	**16**	**152**	**937**	**32**	**112**
Abortion	2	43	0	5	48	0	0
Abortion early	0	2	0	2	4	0	0
Abortion incomplete	2	2	0	0	2	0	0
Abortion missed	0	14	0	0	14	0	0
Abortion spontaneous	14	379	0	0	379	2	12
Abortion spontaneous complete	0	1	0	0	1	0	0
Abortion threatened	1	3	0	0	3	0	0
Amniorrhoea	0	2	0	0	2	0	0
Anaphylactoid syndrome of pregnancy	0	1	0	0	1	0	0
Anembryonic gestation	0	2	0	0	2	0	0
Arrested labour	0	2	0	0	2	0	0
Biochemical pregnancy	0	3	0	0	3	0	0
Breech presentation	1	1	0	0	1	1	11
Cephalo-pelvic disproportion	1	1	0	0	1	0	0
Chronic villitis of unknown etiology	0	1	0	0	1	0	0
Complication of pregnancy	0	1	0	0	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Decidual cast	0	3	0	0	3	0	0
Delivery	0	1	0	1	2	0	0
Eclampsia	0	2	0	0	2	0	2
Ectopic pregnancy	1	15	0	0	15	0	0
Ectopic pregnancy with contraceptive device	0	0	0	1	1	0	0
Face presentation	0	2	0	0	2	0	0
False labour	0	1	0	0	1	0	0
Foetal cardiac disorder	0	1	0	0	1	0	0
Foetal damage	0	1	0	0	1	0	0
Foetal death	5	19	0	0	19	0	1
Foetal disorder	1	2	0	2	4	1	1
Foetal distress syndrome	0	2	0	0	2	0	0
Foetal growth restriction	1	5	0	0	5	0	3
Foetal hypokinesia	0	1	0	0	1	0	4
Foetal vascular malperfusion	0	4	0	0	4	1	1
Gestational diabetes	2	9	0	2	11	10	22
Gestational hypertension	0	2	0	0	2	0	1
HELLP syndrome	2	3	0	0	3	0	0
Haemorrhage foetal	0	2	0	0	2	0	0
Haemorrhage in pregnancy	1	5	0	0	5	1	1

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Hyperemesis gravidarum	0	4	0	0	4	0	1
Hypoxic ischaemic encephalopathy neonatal	0	0	0	0	0	1	1
Imminent abortion	0	1	0	1	2	0	0
Labour pain	2	26	5	20	46	0	0
Large for dates baby	1	1	0	0	1	1	3
Live birth	0	7	1	4	11	0	0
Low birth weight baby	0	2	0	0	2	1	2
Morning sickness	2	45	3	42	87	0	1
Multiple pregnancy	1	1	0	0	1	0	0
Neonatal disorder	0	1	0	0	1	0	0
Normal newborn	1	1	3	5	6	0	0
Oligohydramnios	1	3	0	0	3	2	4
Pelvic girdle pain	0	1	0	3	4	0	1
Peripartum cardiomyopathy	0	1	0	0	1	0	0
Placenta accreta	0	0	0	1	1	0	0
Placenta praevia	0	1	0	0	1	1	4
Placental calcification	0	1	0	0	1	0	0
Placental disorder	0	1	0	0	1	0	0
Placental infarction	0	3	0	0	3	0	0
Placental insufficiency	0	1	0	0	1	1	1

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Placental lake	0	0	0	1	1	0	0
Polyhydramnios	0	0	0	0	0	1	2
Postmature baby	0	1	0	0	1	0	0
Postpartum disorder	0	0	0	1	1	0	0
Postpartum haemorrhage	1	3	0	0	3	0	2
Pre-eclampsia	3	11	0	0	11	1	4
Precipitate labour	0	1	0	0	1	0	0
Pregnancy	0	31	1	32	63	0	0
Pregnancy after post coital contraception	0	2	0	0	2	0	0
Pregnancy of unknown location	0	1	0	0	1	0	0
Pregnancy on contraceptive	0	3	0	1	4	0	0
Pregnancy on oral contraceptive	1	4	0	1	5	0	0
Pregnancy with contraceptive device	0	1	0	0	1	0	0
Pregnancy with contraceptive patch	0	1	0	0	1	0	0
Pregnancy with implant contraceptive	0	5	0	1	6	0	0
Premature baby	1	9	0	0	9	1	2
Premature delivery	1	7	0	3	10	0	0
Premature labour	1	8	0	0	8	0	1
Premature rupture of membranes	1	6	0	0	6	1	1
Premature separation of placenta	1	7	1	1	8	0	1

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Preterm premature rupture of membranes	0	3	0	0	3	0	0
Prolonged labour	3	4	0	1	5	3	14
Prolonged pregnancy	0	1	0	0	1	0	0
Risk of future pregnancy miscarriage	0	1	0	0	1	0	0
Small for dates baby	0	0	0	0	0	1	1
Somatic symptom disorder of pregnancy	0	2	0	0	2	0	0
Stillbirth	0	6	0	0	6	0	1
Subchorionic haematoma	0	1	0	0	1	0	0
Subchorionic haemorrhage	1	3	0	0	3	0	3
Term birth	1	1	1	2	3	0	0
Threatened labour	0	3	0	1	4	0	0
Traumatic delivery	0	1	0	0	1	0	0
Twin pregnancy	0	3	0	0	3	0	0
Umbilical cord around neck	0	1	0	0	1	1	2
Unintended pregnancy	0	4	0	1	5	0	0
Unwanted pregnancy	0	0	0	2	2	0	0
Uterine atony	0	0	0	1	1	0	0
Uterine contractions abnormal	0	4	1	4	8	0	0
Uterine contractions during pregnancy	1	2	0	1	3	0	0
Uterine hypertonus	1	5	0	7	12	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Uterine hypotonus	0	0	0	2	2	0	0
Weight decrease neonatal	0	0	0	0	0	0	1
Reproductive system and breast disorders	**248**	**12372**	**1110**	**20243**	**32615**	**1**	**3**
Abnormal uterine bleeding	2	11	1	14	25	0	0
Abnormal withdrawal bleeding	1	5	2	16	21	0	0
Adenomyosis	0	13	1	7	20	0	0
Adnexa uteri pain	0	46	3	66	112	0	0
Amenorrhoea	16	378	72	980	1358	0	0
Anisomastia	0	1	0	0	1	0	0
Artificial menopause	0	0	0	2	2	0	0
Aspermia	0	1	0	1	2	0	0
Atrophic vulvovaginitis	0	1	0	0	1	0	0
Balanoposthitis	1	4	0	3	7	0	0
Bartholin's cyst	0	5	0	1	6	0	0
Benign prostatic hyperplasia	1	7	1	1	8	0	0
Bleeding anovulatory	0	0	0	1	1	0	0
Breast calcifications	1	2	0	0	2	0	0
Breast cyst	0	11	2	16	27	0	0
Breast discharge	0	6	1	16	22	0	0
Breast discolouration	0	0	0	2	2	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Breast discomfort	1	11	5	36	47	0	0
Breast disorder	0	4	1	8	12	0	0
Breast disorder female	0	0	0	3	3	0	0
Breast engorgement	0	3	1	16	19	0	0
Breast enlargement	0	3	3	43	46	0	0
Breast haematoma	0	2	2	11	13	0	0
Breast haemorrhage	0	2	0	1	3	0	0
Breast hyperplasia	0	1	0	0	1	0	1
Breast induration	0	2	0	3	5	0	0
Breast inflammation	0	9	3	26	35	0	0
Breast mass	2	66	4	59	125	0	0
Breast milk discolouration	0	0	0	1	1	0	0
Breast oedema	0	7	0	8	15	0	0
Breast pain	9	379	46	627	1006	0	0
Breast swelling	2	56	4	81	137	0	0
Breast tenderness	0	46	6	68	114	0	0
Cervical friability	0	1	0	0	1	0	0
Cervical polyp	0	2	0	0	2	0	0
Cervix disorder	0	0	1	1	1	0	0
Cervix haemorrhage uterine	0	1	0	0	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Cervix oedema	0	0	0	1	1	0	0
Clitoral engorgement	0	1	0	0	1	0	0
Coital bleeding	0	5	0	8	13	0	0
Cystocele	0	1	0	0	1	0	0
Dysmenorrhoea	15	1102	59	996	2098	0	0
Dyspareunia	0	6	0	4	10	0	0
Ectropion of cervix	0	1	0	1	2	0	0
Ejaculation delayed	0	1	1	3	4	0	0
Ejaculation disorder	0	2	0	9	11	0	0
Ejaculation failure	0	3	0	7	10	0	0
Endometrial hyperplasia	0	2	0	1	3	0	0
Endometrial thickening	0	2	0	3	5	0	0
Endometriosis	1	75	2	36	111	0	0
Enlarged clitoris	0	0	0	2	2	0	0
Epididymal cyst	0	0	0	1	1	0	0
Erectile dysfunction	9	114	5	98	212	0	0
Erection increased	0	7	0	8	15	0	0
Fallopian tube spasm	0	1	0	0	1	0	0
Female genital tract fistula	0	1	0	0	1	0	0
Female reproductive tract disorder	0	0	0	2	2	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Female sexual arousal disorder	0	1	0	0	1	0	0
Female sexual dysfunction	0	1	0	0	1	0	0
Fibrocystic breast disease	0	0	0	2	2	0	0
Foreskin oedema	0	1	0	0	1	0	0
Galactorrhoea	1	4	0	8	12	0	0
Galactostasis	0	2	0	0	2	0	0
Genital blister	0	4	0	2	6	0	0
Genital burning sensation	0	6	0	6	12	0	0
Genital cyst	0	2	0	0	2	0	0
Genital discharge	1	2	0	3	5	0	0
Genital discomfort	0	5	0	7	12	0	0
Genital disorder	0	0	0	3	3	0	0
Genital dysaesthesia	0	1	0	1	2	0	0
Genital erythema	0	1	0	3	4	0	0
Genital haemorrhage	1	29	1	32	61	0	0
Genital hyperaesthesia	0	1	0	0	1	0	0
Genital hypoaesthesia	0	2	0	0	2	0	0
Genital lesion	0	3	0	2	5	0	0
Genital pain	1	9	3	24	33	0	0
Genital paraesthesia	0	2	1	6	8	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Genital rash	1	6	2	13	19	0	0
Genital swelling	0	2	0	5	7	0	0
Genital tract inflammation	0	2	2	6	8	0	0
Genital ulceration	0	8	0	14	22	0	0
Gynaecomastia	1	7	0	10	17	0	0
Haematospermia	0	16	0	19	35	0	0
Haemorrhagic ovarian cyst	0	2	0	0	2	0	0
Heavy menstrual bleeding	35	3140	198	3583	6723	0	0
Hydrosalpinx	0	2	0	0	2	0	0
Hypomenorrhoea	1	178	12	395	573	0	0
Hypospermia	0	1	0	0	1	0	0
Infertility	2	11	0	10	21	0	0
Infertility female	0	6	0	1	7	0	0
Infertility male	0	3	1	1	4	0	0
Intermenstrual bleeding	8	408	69	1208	1616	0	0
Labia enlarged	0	3	0	1	4	0	0
Lactation disorder	0	2	2	8	10	0	0
Lactation puerperal increased	0	4	0	5	9	0	0
Male reproductive tract disorder	0	0	0	1	1	0	0
Male sexual dysfunction	0	1	0	2	3	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Mammary duct ectasia	0	1	0	0	1	0	0
Menometrorrhagia	2	21	16	67	88	0	0
Menopausal disorder	0	3	0	0	3	0	0
Menopausal symptoms	2	34	3	78	112	0	0
Menopause delayed	0	0	0	6	6	0	0
Menstrual discomfort	0	13	5	79	92	0	0
Menstrual disorder	26	894	153	2489	3383	0	0
Menstruation delayed	5	1258	60	2631	3889	0	0
Menstruation irregular	22	1113	120	2396	3509	0	0
Metrorrhoea	0	1	0	0	1	0	0
Nipple disorder	0	2	0	3	5	0	0
Nipple enlargement	0	1	0	0	1	0	0
Nipple exudate bloody	0	1	0	2	3	0	0
Nipple inflammation	0	1	1	3	4	0	0
Nipple pain	0	23	3	38	61	0	0
Nipple swelling	0	4	0	2	6	0	0
Nocturnal emission	0	0	0	2	2	0	0
Noninfective oophoritis	0	1	0	2	3	0	0
Oedema genital	1	1	0	2	3	0	0
Oligomenorrhoea	1	72	27	343	415	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Orchitis noninfective	0	2	2	5	7	0	0
Organic erectile dysfunction	0	16	0	3	19	0	0
Ovarian adhesion	0	1	0	0	1	0	0
Ovarian cyst	0	32	7	29	61	0	0
Ovarian cyst ruptured	1	11	0	3	14	0	0
Ovarian disorder	0	0	0	1	1	0	0
Ovarian enlargement	0	3	0	1	4	0	0
Ovarian failure	0	3	0	1	4	0	0
Ovarian haemorrhage	1	5	1	1	6	0	0
Ovarian hyperstimulation syndrome	0	0	0	2	2	0	0
Ovarian mass	1	2	0	0	2	0	0
Ovarian necrosis	1	1	0	0	1	0	0
Ovarian oedema	0	1	0	0	1	0	0
Ovarian vein thrombosis	1	8	0	0	8	0	0
Ovulation disorder	0	2	0	3	5	0	0
Ovulation pain	1	40	3	41	81	0	0
Painful ejaculation	0	2	0	0	2	0	0
Painful erection	0	2	0	2	4	0	0
Pelvic congestion	0	1	0	0	1	0	0
Pelvic discomfort	0	5	1	10	15	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Pelvic floor muscle weakness	1	1	0	0	1	0	0
Pelvic fluid collection	1	1	1	1	2	0	0
Pelvic haematoma	0	1	0	0	1	0	0
Pelvic haemorrhage	4	22	0	10	32	0	0
Pelvic organ prolapse	0	1	0	0	1	0	0
Pelvic pain	9	196	28	201	397	0	0
Penile blister	0	2	0	4	6	0	0
Penile burning sensation	0	1	0	1	2	0	0
Penile curvature	0	4	0	0	4	0	0
Penile dermatitis	0	0	0	2	2	0	0
Penile discharge	0	4	0	1	5	0	0
Penile discomfort	0	1	0	1	2	0	0
Penile erosion	0	1	0	0	1	0	0
Penile erythema	0	0	0	1	1	0	0
Penile exfoliation	0	1	0	1	2	0	0
Penile haematoma	0	0	0	2	2	0	0
Penile haemorrhage	1	8	0	1	9	0	0
Penile oedema	0	1	0	4	5	0	0
Penile pain	0	2	0	5	7	0	0
Penile size reduced	0	1	0	2	3	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Penile swelling	0	0	0	1	1	0	0
Penile vascular disorder	0	0	0	1	1	0	0
Penile vein thrombosis	0	9	0	1	10	0	0
Penis disorder	0	7	0	9	16	0	0
Perineal disorder	0	1	0	1	2	0	0
Perineal erythema	0	0	0	1	1	0	0
Perineal pain	0	2	1	4	6	0	0
Peyronie's disease	1	6	0	0	6	0	0
Polycystic ovaries	0	22	2	29	51	0	0
Polymenorrhagia	0	0	0	2	2	0	0
Polymenorrhoea	5	349	60	908	1257	0	0
Postmenopausal haemorrhage	10	271	18	299	570	0	0
Premature menopause	4	36	0	25	61	0	0
Premature ovulation	0	8	0	1	9	0	0
Premenstrual dysphoric disorder	0	5	0	5	10	0	0
Premenstrual pain	0	65	4	51	116	0	0
Premenstrual syndrome	0	52	3	62	114	0	0
Priapism	0	15	0	0	15	0	0
Prostate tenderness	0	0	0	1	1	0	0
Prostatic haemorrhage	0	2	0	1	3	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Prostatic pain	0	2	0	3	5	0	0
Prostatism	0	1	0	0	1	0	0
Prostatitis	0	11	2	18	29	0	0
Prostatomegaly	1	6	1	3	9	0	0
Pruritus genital	0	9	4	33	42	0	0
Reproductive tract disorder	0	0	1	1	1	0	0
Retrograde ejaculation	0	1	0	5	6	0	0
Retrograde menstruation	0	1	0	4	5	0	0
Scrotal cyst	1	1	0	0	1	0	0
Scrotal dermatitis	0	0	0	1	1	0	0
Scrotal discomfort	0	0	0	2	2	0	0
Scrotal oedema	0	1	2	3	4	0	0
Scrotal pain	0	13	1	8	21	0	0
Scrotal swelling	0	6	0	7	13	0	0
Semen discolouration	0	1	1	2	3	0	0
Sexual dysfunction	2	13	1	13	26	0	0
Spontaneous penile erection	0	3	2	5	8	0	0
Suppressed lactation	2	18	5	26	44	0	0
Testicular atrophy	0	1	0	1	2	0	0
Testicular cyst	0	1	0	1	2	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Testicular disorder	0	6	0	4	10	0	0
Testicular haemorrhage	0	0	0	1	1	0	0
Testicular mass	0	1	0	1	2	0	0
Testicular oedema	0	2	0	5	7	0	0
Testicular pain	0	74	5	102	176	0	0
Testicular retraction	0	1	0	4	5	0	0
Testicular swelling	0	21	1	20	41	0	0
Testicular torsion	0	1	0	0	1	0	0
Testis discomfort	0	4	0	9	13	0	0
Uterine cyst	0	1	0	2	3	0	0
Uterine disorder	0	1	0	1	2	0	0
Uterine enlargement	0	2	0	1	3	0	0
Uterine haemorrhage	2	62	0	42	104	0	1
Uterine inflammation	0	0	0	1	1	0	0
Uterine mass	2	2	0	0	2	0	0
Uterine pain	0	16	3	20	36	0	0
Uterine polyp	0	3	0	3	6	0	0
Uterine prolapse	0	1	0	0	1	0	0
Uterine spasm	0	19	5	23	42	0	0
Vaginal cyst	0	12	1	6	18	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Vaginal discharge	0	58	5	85	143	0	0
Vaginal disorder	0	1	1	3	4	0	0
Vaginal erosion	0	0	0	1	1	0	0
Vaginal haematoma	0	0	0	1	1	0	0
Vaginal haemorrhage	21	880	26	1034	1914	1	1
Vaginal lesion	0	4	0	5	9	0	0
Vaginal mucosal blistering	0	1	0	0	1	0	0
Vaginal odour	0	4	0	6	10	0	0
Vaginal prolapse	0	2	0	2	4	0	0
Vaginal ulceration	0	6	1	8	14	0	0
Varicocele	0	2	0	1	3	0	0
Varicose veins pelvic	0	2	0	0	2	0	0
Vulva cyst	0	1	0	0	1	0	0
Vulval disorder	0	0	0	6	6	0	0
Vulval haematoma	0	0	0	1	1	0	0
Vulval haemorrhage	0	17	0	17	34	0	0
Vulval oedema	0	1	0	1	2	0	0
Vulval ulceration	1	9	0	14	23	0	0
Vulvovaginal burning sensation	0	8	0	13	21	0	0
Vulvovaginal discomfort	0	9	2	17	26	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Vulvovaginal disorder	0	0	1	2	2	0	0
Vulvovaginal dryness	1	12	1	16	28	0	0
Vulvovaginal erythema	0	1	0	2	3	0	0
Vulvovaginal inflammation	0	4	0	1	5	0	0
Vulvovaginal pain	0	34	0	26	60	0	0
Vulvovaginal pruritus	0	11	1	15	26	0	0
Vulvovaginal rash	0	2	0	2	4	0	0
Vulvovaginal swelling	1	7	0	5	12	0	0
Vulvovaginal ulceration	0	3	1	3	6	0	0
Withdrawal bleed	0	8	0	12	20	0	0
Congenital, familial and genetic disorders	**48**	**347**	**0**	**0**	**347**	**17**	**21**
11-beta-hydroxylase deficiency	2	5	0	0	5	0	0
17,20-desmolase deficiency	0	1	0	0	1	0	0
17-alpha-hydroxylase deficiency	0	3	0	0	3	0	0
1p36 deletion syndrome	0	1	0	0	1	0	0
20,22-desmolase deficiency	1	2	0	0	2	0	0
21-hydroxylase deficiency	0	1	0	0	1	0	0
Accessory spleen	0	1	0	0	1	0	0
Acquired gene mutation	1	1	0	0	1	0	0
Alagille syndrome	0	1	0	0	1	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Alport's syndrome	0	1	0	0	1	0	0
Amegakaryocytic thrombocytopenia	0	1	0	0	1	0	0
Anencephaly	0	3	0	0	3	0	0
Ankyloglossia congenital	0	1	0	0	1	2	2
Aplasia	0	1	0	0	1	0	0
Arnold-Chiari malformation	0	2	0	0	2	0	0
Arrhythmogenic right ventricular dysplasia	1	1	0	0	1	0	0
Arteriovenous malformation	2	11	0	0	11	0	0
Ataxia telangiectasia	1	1	0	0	1	0	0
Atrial septal defect	2	7	0	0	7	0	1
BRAF gene mutation	1	1	0	0	1	0	0
Benign familial pemphigus	0	2	0	0	2	0	0
Bicuspid aortic valve	0	1	0	0	1	0	0
Brachyolmia	0	1	0	0	1	0	0
Brain malformation	1	2	0	0	2	0	0
Branchial cyst	0	2	0	0	2	0	0
Brugada syndrome	0	1	0	0	1	0	0
CANDLE syndrome	0	2	0	0	2	0	0
Cancer gene carrier	0	1	0	0	1	0	0
Cerebral arteriovenous malformation haemorrhagic	0	1	0	0	1	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Cerebral cavernous malformation	2	2	0	0	2	0	0
Cerebral palsy	0	5	0	0	5	0	0
Chronic granulomatous disease	0	1	0	0	1	0	0
Cleft lip and palate	0	1	0	0	1	0	0
Coarctation of the aorta	0	2	0	0	2	0	0
Colour blindness	0	13	0	0	13	0	0
Combined immunodeficiency	0	2	0	0	2	0	0
Congenital anomaly	0	5	0	0	5	0	0
Congenital arterial malformation	0	2	0	0	2	0	0
Congenital cerebrovascular anomaly	1	1	0	0	1	0	0
Congenital cystic kidney disease	0	1	0	0	1	1	1
Congenital diaphragmatic hernia	0	2	0	0	2	0	0
Congenital hearing disorder	0	1	0	0	1	0	0
Congenital hydrocephalus	0	0	0	0	0	1	1
Congenital hydronephrosis	0	0	0	0	0	1	1
Congenital hyperthyroidism	1	2	0	0	2	0	0
Congenital knee deformity	0	1	0	0	1	0	0
Congenital midline defect	0	1	0	0	1	0	0
Congenital multiplex arthrogryposis	0	1	0	0	1	0	0
Congenital musculoskeletal disorder of limbs	1	1	0	0	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Congenital musculoskeletal disorder of skull	0	3	0	0	3	0	0
Congenital musculoskeletal disorder of spine	0	2	0	0	2	0	0
Congenital ureterocele	0	0	0	0	0	1	1
Cryptorchism	0	0	0	0	0	1	1
Cystic fibrosis	1	3	0	0	3	0	0
Cystic lymphangioma	0	1	0	0	1	0	0
Cytogenetic abnormality	0	0	0	0	0	0	1
Dacryostenosis congenital	0	1	0	0	1	0	0
Deafness congenital	0	1	0	0	1	0	0
Deficiency of the interleukin-36 receptor antagonist	0	1	0	0	1	0	0
Dermoid cyst	0	0	0	0	0	1	1
Developmental hip dysplasia	0	0	0	0	0	1	1
Double outlet right ventricle	1	1	0	0	1	0	0
Dysmorphism	0	3	0	0	3	0	0
Eagle Barrett syndrome	0	1	0	0	1	0	0
Ectrodactyly	0	1	0	0	1	0	0
Ehlers-Danlos syndrome	0	8	0	0	8	0	0
Endocardial fibroelastosis	1	1	0	0	1	0	0
Epilepsy with myoclonic-atonic seizures	0	2	0	0	2	0	0
Factor II mutation	1	1	0	0	1	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Factor V Leiden mutation	1	4	0	0	4	0	0
Factor VII deficiency	0	1	0	0	1	0	0
Factor VIII deficiency	0	2	0	0	2	0	0
Factor XI deficiency	0	1	0	0	1	0	0
Factor XIII deficiency	1	4	0	0	4	0	0
Fallot's tetralogy	0	0	0	0	0	0	1
Familial hemiplegic migraine	0	1	0	0	1	0	0
Foetal chromosome abnormality	0	1	0	0	1	0	0
Foetal malformation	0	7	0	0	7	0	0
Gastrointestinal malformation	0	2	0	0	2	0	0
Gastroschisis	1	2	0	0	2	0	0
Gilbert's syndrome	2	5	0	0	5	0	0
Glucose-6-phosphate dehydrogenase deficiency	0	0	0	0	0	2	2
Glycogen storage disease type I	0	1	0	0	1	0	0
Grey matter heterotopia	0	1	0	0	1	0	0
Haemangioma of retina	0	1	0	0	1	0	0
Haemophilia	0	2	0	0	2	0	0
Haemorrhagic arteriovenous malformation	1	3	0	0	3	0	0
Heart disease congenital	5	22	0	0	22	0	0
Hereditary disorder	0	1	0	0	1	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Hereditary pancreatitis	0	1	0	0	1	0	0
Heterotaxia	0	3	0	0	3	0	0
Holoprosencephaly	0	1	0	0	1	0	0
Huntington's disease	0	2	0	0	2	0	0
Hydrocele	0	6	0	0	6	1	1
Hyper IgD syndrome	1	2	0	0	2	0	0
Hyperglycinaemia	0	1	0	0	1	0	0
Hypermobility syndrome	0	3	0	0	3	0	0
Hypertrophic cardiomyopathy	1	10	0	0	10	0	0
Hypoplastic left heart syndrome	0	1	0	0	1	0	0
Hypoplastic right heart syndrome	0	1	0	0	1	0	0
Hypospadias	0	0	0	0	0	0	1
Ichthyosis	0	1	0	0	1	0	0
Intestinal atresia	0	1	0	0	1	0	0
Intracranial lipoma	0	1	0	0	1	0	0
Keratosis follicular	0	1	0	0	1	0	0
Kidney duplex	0	0	0	0	0	1	1
Klinefelter's syndrome	0	1	0	0	1	0	0
Klippel-Trenaunay syndrome	0	1	0	0	1	0	0
Larsen syndrome	0	1	0	0	1	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Left ventricle outflow tract obstruction	0	1	0	0	1	0	0
Limb reduction defect	3	5	0	0	5	0	0
Macroglossia	0	4	0	0	4	0	0
Malformation venous	1	1	0	0	1	0	0
Melkersson-Rosenthal syndrome	1	1	0	0	1	0	0
Meningomyelocele	0	1	0	0	1	0	0
Micropenis	0	2	0	0	2	0	0
Mitral valve atresia	0	1	0	0	1	0	0
Monolid eyes	0	1	0	0	1	0	0
Mucolipidosis	0	1	0	0	1	0	0
Multiple cardiac defects	0	1	0	0	1	0	0
Multiple congenital abnormalities	0	3	0	0	3	0	0
Myoclonic dystonia	0	1	0	0	1	0	0
Myotonic dystrophy	0	1	0	0	1	0	0
Naevus flammeus	0	2	0	0	2	0	0
Neonatal alloimmune thrombocytopenia	0	2	0	0	2	0	0
Neural tube defect	0	1	0	0	1	0	0
Neurofibromatosis	1	2	0	0	2	0	0
Opitz-G/BBB syndrome	1	1	0	0	1	0	0
Os trigonum	0	1	0	0	1	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Otocephaly	0	1	0	0	1	0	0
Paroxysmal extreme pain disorder	1	20	0	0	20	0	0
Pelizaeus-Merzbacher disease	0	2	0	0	2	0	0
Penoscrotal fusion	0	3	0	0	3	0	0
Plagiocephaly	0	1	0	0	1	0	0
Polycystic liver disease	0	1	0	0	1	0	0
Porphyria acute	1	2	0	0	2	0	0
Porphyria non-acute	0	1	0	0	1	0	0
Preauricular cyst	0	0	0	0	0	1	1
Protein C deficiency	0	1	0	0	1	0	0
Pseudotruncus arteriosus	0	1	0	0	1	0	0
Pyloric stenosis	0	0	0	0	0	1	1
Retinitis pigmentosa	0	1	0	0	1	0	0
Rippling muscle disease	0	1	0	0	1	0	0
SADDAN syndrome	0	2	0	0	2	0	0
Sickle cell anaemia	1	1	0	0	1	0	0
Sickle cell disease	0	1	0	0	1	0	0
Spina bifida	0	4	0	0	4	0	0
Spinal muscular atrophy	0	1	0	0	1	0	0
Spinal vessel congenital anomaly	0	1	0	0	1	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Syndactyly	0	1	0	0	1	0	0
Syringomyelia	2	3	0	0	3	0	0
Talipes	0	1	0	0	1	2	2
Thalassaemia	0	1	0	0	1	0	0
Thalassaemia beta	0	1	0	0	1	0	0
Thyroglossal cyst	0	2	0	0	2	0	0
Tourette's disorder	0	3	0	0	3	0	0
Transposition of the great vessels	0	3	0	0	3	0	0
Trisomy 18	0	2	0	0	2	0	0
Trisomy 21	0	1	0	0	1	0	0
Tuberous sclerosis complex	0	1	0	0	1	0	0
Turner's syndrome	0	1	0	0	1	0	0
Type IIa hyperlipidaemia	1	2	0	0	2	0	0
Vascular malformation	1	6	0	0	6	0	0
Vein of Galen aneurysmal malformation	0	1	0	0	1	0	0
Venous angioma of brain	0	1	0	0	1	0	0
Ventricular hypoplasia	0	1	0	0	1	0	0
Ventricular septal defect	0	1	0	0	1	0	0
Vertebral artery hypoplasia	0	2	0	0	2	0	0
Vestibulocerebellar syndrome	0	1	0	0	1	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Von Willebrand's disease	0	1	0	0	1	0	0
Young's syndrome	0	1	0	0	1	0	0
General disorders and administration site conditions	**9072**	**278480**	**92552**	**884235**	**1162715**	**21**	**101**
Abscess sterile	0	1	0	1	2	0	0
Absence of immediate treatment response	0	0	0	1	1	0	0
Acute phase reaction	0	0	0	2	2	0	0
Adhesion	1	3	0	3	6	0	0
Administration site anaesthesia	0	0	0	1	1	0	0
Administration site bruise	0	6	1	40	46	0	0
Administration site coldness	0	1	0	2	3	0	0
Administration site dermatitis	0	0	0	1	1	0	0
Administration site discolouration	0	0	0	2	2	0	0
Administration site discomfort	0	0	2	5	5	0	0
Administration site dysaesthesia	0	0	0	1	1	0	0
Administration site erythema	1	6	42	182	188	0	0
Administration site extravasation	0	0	0	2	2	0	0
Administration site haematoma	0	2	3	12	14	0	0
Administration site haemorrhage	0	1	0	0	1	0	0
Administration site hyperaesthesia	0	0	0	1	1	0	0
Administration site hypersensitivity	0	0	0	10	10	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Administration site indentation	0	0	1	5	5	0	0
Administration site induration	0	1	8	83	84	0	0
Administration site inflammation	0	1	0	7	8	0	0
Administration site injury	0	1	0	0	1	0	0
Administration site irritation	0	0	0	1	1	0	0
Administration site joint erythema	0	0	0	2	2	0	0
Administration site joint inflammation	0	0	0	1	1	0	0
Administration site joint movement impairment	1	1	0	1	2	0	0
Administration site joint pain	0	1	0	17	18	0	0
Administration site joint warmth	0	0	0	1	1	0	0
Administration site lymphadenopathy	0	1	0	2	3	0	0
Administration site macule	0	0	0	1	1	0	0
Administration site mass	0	1	0	0	1	0	0
Administration site movement impairment	0	1	1	7	8	0	0
Administration site nodule	0	1	0	1	2	0	0
Administration site odour	0	0	0	1	1	0	0
Administration site oedema	1	2	36	169	171	0	0
Administration site pain	2	77	228	1281	1358	0	0
Administration site pallor	0	0	0	1	1	0	0
Administration site papule	0	0	0	1	1	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Administration site paraesthesia	0	0	0	3	3	0	0
Administration site pruritus	0	1	0	15	16	0	0
Administration site rash	0	2	1	19	21	0	0
Administration site reaction	0	11	14	99	110	0	0
Administration site scar	0	0	0	1	1	0	0
Administration site swelling	0	1	2	25	26	0	0
Administration site urticaria	0	4	1	4	8	0	0
Administration site warmth	0	3	2	18	21	0	0
Administration site wound	0	0	0	1	1	0	0
Adverse drug reaction	73	358	34	304	662	0	0
Adverse event	7	21	22	2117	2138	0	0
Adverse food reaction	0	3	0	3	6	0	0
Adverse reaction	4	25	11	121	146	0	0
Agonal death struggle	0	2	0	0	2	0	0
Alcohol interaction	0	1	0	3	4	0	0
Antidepressant discontinuation syndrome	0	0	0	1	1	0	0
Apparent death	1	2	0	0	2	0	0
Application site acne	0	0	1	5	5	0	0
Application site anaesthesia	0	0	0	2	2	0	0
Application site atrophy	0	0	0	4	4	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Application site bruise	1	19	2	45	64	0	0
Application site burn	0	3	0	2	5	0	0
Application site coldness	0	2	1	9	11	0	0
Application site cyst	0	0	0	1	1	0	0
Application site dermatitis	0	0	3	17	17	0	0
Application site discharge	0	1	1	1	2	0	0
Application site discolouration	0	3	1	23	26	0	0
Application site discomfort	0	2	3	76	78	0	0
Application site dryness	0	0	0	1	1	0	0
Application site dysaesthesia	0	0	0	1	1	0	0
Application site eczema	0	0	0	2	2	0	0
Application site erosion	0	0	0	1	1	0	0
Application site erythema	0	22	54	1075	1097	0	0
Application site exfoliation	0	1	2	4	5	0	0
Application site extravasation	0	0	0	1	1	0	0
Application site fibrosis	0	0	0	1	1	0	0
Application site granuloma	0	1	0	0	1	0	0
Application site haematoma	0	2	6	76	78	0	0
Application site haemorrhage	0	0	1	23	23	0	0
Application site hyperaesthesia	0	0	0	1	1	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Application site hypersensitivity	0	2	4	136	138	0	0
Application site hypoaesthesia	0	6	2	50	56	0	0
Application site induration	0	1	9	306	307	0	0
Application site inflammation	0	1	0	15	16	0	0
Application site injury	0	2	0	3	5	0	0
Application site irritation	0	1	0	6	7	0	0
Application site ischaemia	0	0	0	1	1	0	0
Application site joint erythema	0	0	0	2	2	0	0
Application site joint inflammation	0	0	0	1	1	0	0
Application site joint movement impairment	0	0	0	1	1	0	0
Application site joint pain	0	1	0	58	59	0	0
Application site joint swelling	0	1	1	8	9	0	0
Application site joint warmth	0	0	0	1	1	0	0
Application site laceration	0	1	0	0	1	0	0
Application site lymphadenopathy	0	0	0	12	12	0	0
Application site macule	0	0	0	1	1	0	0
Application site mass	0	0	2	11	11	0	0
Application site movement impairment	0	0	0	13	13	0	0
Application site necrosis	0	1	0	0	1	0	0
Application site nodule	0	0	5	33	33	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Application site odour	0	1	2	122	123	0	0
Application site oedema	1	11	97	2414	2425	0	0
Application site pain	3	115	631	13174	13289	0	1
Application site pallor	0	0	0	1	1	0	0
Application site paraesthesia	0	1	0	15	16	0	0
Application site perspiration	0	0	0	1	1	0	0
Application site plaque	0	0	0	1	1	0	0
Application site pruritus	1	20	47	797	817	0	0
Application site purpura	0	0	0	1	1	0	0
Application site rash	0	2	1	16	18	0	0
Application site reaction	0	6	4	639	645	0	0
Application site scar	0	1	0	1	2	0	0
Application site streaking	0	0	0	1	1	0	0
Application site swelling	0	8	28	1173	1181	0	0
Application site ulcer	0	0	0	1	1	0	0
Application site urticaria	0	0	1	2	2	0	0
Application site vesicles	0	7	0	14	21	0	0
Application site warmth	0	5	71	334	339	0	0
Application site wound	0	1	0	6	7	0	0
Asthenia	314	7033	2521	27681	34714	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Atrophy	0	3	2	17	20	0	0
Axillary pain	13	577	124	927	1504	0	0
Brain death	2	28	0	0	28	0	0
Breakthrough pain	0	1	2	3	4	0	0
Calcinosis	0	2	0	1	3	0	0
Capsular contracture associated with breast implant	0	2	0	0	2	0	0
Cardiac death	0	18	0	0	18	0	0
Catheter site haemorrhage	1	3	0	0	3	0	0
Catheter site pain	1	1	0	0	1	0	0
Catheter site swelling	1	1	0	0	1	0	0
Catheter site thrombosis	0	1	0	0	1	0	0
Catheter site urticaria	0	0	0	1	1	0	0
Chest discomfort	80	2313	386	3583	5896	1	2
Chest pain	244	6841	566	7105	13946	0	0
Chills	675	41286	14331	136084	177370	0	20
Chronic disease	0	3	0	0	3	0	0
Chronic fatigue syndrome	25	210	22	76	286	0	0
Chronic inflammatory response syndrome	0	0	2	2	2	0	0
Clinical death	0	2	0	0	2	0	0
Complication associated with device	1	2	0	0	2	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Complication of device removal	0	1	0	0	1	0	0
Concomitant disease aggravated	0	49	17	392	441	0	0
Concomitant disease progression	0	28	0	10	38	0	0
Condition aggravated	54	644	75	597	1241	0	0
Crepitations	1	11	2	9	20	0	0
Critical illness	1	4	0	0	4	0	0
Crying	3	271	13	255	526	0	0
Cyst	2	38	5	44	82	0	0
Cyst rupture	1	3	0	2	5	0	0
Death	168	1598	0	0	1598	4	4
Death neonatal	0	1	0	0	1	0	0
Decreased activity	0	15	5	40	55	0	0
Decreased gait velocity	0	5	0	1	6	0	0
Deformity	0	1	0	1	2	0	0
Developmental delay	0	3	0	1	4	0	0
Device related thrombosis	0	3	0	0	3	0	0
Diet failure	0	1	0	0	1	0	0
Discharge	0	16	1	27	43	0	0
Discomfort	22	593	278	1704	2297	0	0
Disease complication	0	0	0	1	1	0	0

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	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Disease prodromal stage	0	1	0	0	1	0	0
Disease progression	2	8	1	6	14	0	0
Disease recurrence	12	57	2	31	88	0	0
Disease susceptibility	0	0	0	4	4	0	0
Drowning	1	4	0	0	4	0	0
Drug effect less than expected	0	0	0	4	4	0	0
Drug ineffective	155	482	70	738	1220	3	8
Drug ineffective for unapproved indication	1	1	0	0	1	0	0
Drug interaction	9	54	7	53	107	0	0
Drug intolerance	3	12	3	13	25	0	0
Drug resistance	1	1	0	0	1	0	0
Drug tolerance	0	0	0	4	4	0	0
Drug withdrawal syndrome	0	9	0	0	9	0	0
Drug withdrawal syndrome neonatal	0	0	0	0	0	0	1
Drug-device interaction	0	1	0	1	2	0	0
Drug-disease interaction	0	1	0	0	1	0	0
Dysplasia	0	2	1	3	5	0	0
Early satiety	0	2	1	2	4	0	0
Effusion	0	9	3	16	25	0	0
Electrocution	0	1	0	0	1	0	0

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	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Enanthema	0	0	0	7	7	0	0
Encapsulation reaction	0	1	0	0	1	0	0
Energy increased	1	15	2	40	55	0	0
Exercise tolerance decreased	23	141	68	330	471	0	0
Extensive swelling of vaccinated limb	31	285	145	1084	1369	0	0
Extravasation	0	3	1	6	9	0	0
Face oedema	5	145	28	436	581	0	0
Facial discomfort	2	24	11	80	104	0	0
Facial pain	11	301	39	368	669	0	0
Fat necrosis	0	4	2	11	15	0	0
Fat tissue decreased	0	0	1	3	3	0	0
Fatigue	1144	48673	12777	121108	169781	0	17
Feeling abnormal	81	2886	404	3309	6195	0	0
Feeling cold	56	4533	741	6557	11090	0	0
Feeling drunk	3	108	11	134	242	0	0
Feeling hot	39	2037	463	5478	7515	0	0
Feeling jittery	1	46	0	55	101	0	0
Feeling of body temperature change	17	866	100	1081	1947	0	0
Feeling of relaxation	0	3	0	15	18	0	0
Fibrosis	0	8	1	5	13	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Foaming at mouth	3	8	0	5	13	0	0
Food interaction	0	3	0	0	3	0	0
Foreign body reaction	0	0	0	2	2	0	0
Gait deviation	0	2	0	1	3	0	0
Gait disturbance	99	1001	138	1172	2173	0	2
Gait inability	18	332	10	226	558	0	0
General physical health deterioration	24	181	75	571	752	0	0
General symptom	3	15	3	32	47	0	0
Generalised oedema	5	30	7	51	81	0	0
Glassy eyes	0	9	0	15	24	0	0
Granuloma	1	4	3	13	17	0	0
Gravitational oedema	1	5	0	6	11	0	0
Haemorrhagic cyst	0	0	0	2	2	0	0
Hanging	0	1	0	1	2	0	0
Hangover	1	159	15	148	307	0	0
Hernia	2	12	1	7	19	0	0
Hernia pain	0	3	1	7	10	0	0
Heteroplasia	0	1	0	0	1	0	0
High-pitched crying	0	6	0	2	8	0	0
Humidity intolerance	0	1	0	0	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Hunger	3	57	10	124	181	0	0
Hyperplasia	0	3	0	0	3	0	0
Hyperpyrexia	4	841	12	851	1692	0	0
Hyperthermia	3	47	22	329	376	0	0
Hyperthermia malignant	0	6	0	0	6	0	0
Hypertrophy	0	0	0	1	1	0	0
Hypothermia	10	142	8	187	329	0	0
Idiopathic environmental intolerance	0	2	0	2	4	0	0
Idiosyncratic drug reaction	0	1	0	0	1	0	0
Ill-defined disorder	7	23	16	1134	1157	0	0
Illness	41	4322	131	1803	6125	0	0
Immediate post-injection reaction	0	1	0	3	4	0	0
Impaired healing	1	10	3	35	45	0	0
Impaired self-care	0	5	0	1	6	0	0
Implant site coldness	0	1	0	0	1	0	0
Implant site dermatitis	0	0	1	1	1	0	0
Implant site discharge	0	1	0	0	1	0	0
Implant site discolouration	0	2	0	2	4	0	0
Implant site extravasation	0	0	1	2	2	0	0
Implant site haemorrhage	0	0	0	1	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Implant site hypoaesthesia	1	2	0	0	2	0	0
Implant site induration	0	0	1	1	1	0	0
Implant site inflammation	0	0	0	1	1	0	0
Implant site mass	0	0	1	1	1	0	0
Implant site pain	0	3	1	7	10	0	0
Implant site pruritus	0	0	0	1	1	0	0
Implant site rash	0	0	0	2	2	0	0
Implant site scar	0	0	0	1	1	0	0
Implant site swelling	0	1	0	3	4	0	0
Implant site urticaria	0	1	0	3	4	0	0
Implant site vesicles	0	0	0	1	1	0	0
Implant site warmth	0	4	0	4	8	0	0
Inadequate analgesia	0	30	0	23	53	0	0
Induration	2	30	24	940	970	0	0
Inflammation	39	862	82	1398	2260	0	0
Inflammatory pain	5	39	1	15	54	0	0
Influenza like illness	145	10253	1337	27450	37703	0	0
Infusion site bruising	2	4	0	2	6	0	0
Infusion site discolouration	1	1	0	0	1	0	0
Infusion site discomfort	0	0	0	1	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Infusion site erythema	1	4	0	5	9	0	0
Infusion site extravasation	1	2	0	2	4	0	0
Infusion site haematoma	0	0	0	6	6	0	0
Infusion site haemorrhage	1	3	0	0	3	0	0
Infusion site hypoaesthesia	0	0	0	1	1	0	0
Infusion site joint pain	0	1	0	0	1	0	0
Infusion site joint swelling	0	0	0	2	2	0	0
Infusion site mass	0	3	0	3	6	0	0
Infusion site mobility decreased	0	2	0	6	8	0	0
Infusion site nodule	0	0	0	2	2	0	0
Infusion site pain	4	19	1	13	32	0	0
Infusion site pruritus	1	1	0	3	4	0	0
Infusion site rash	0	0	0	1	1	0	0
Infusion site reaction	0	0	0	1	1	0	0
Infusion site swelling	1	3	0	0	3	0	0
Infusion site urticaria	0	1	0	1	2	0	0
Infusion site warmth	0	2	0	4	6	0	0
Inhibitory drug interaction	0	10	0	3	13	0	0
Injected limb mobility decreased	8	147	61	392	539	0	0
Injection site abscess sterile	0	1	0	4	5	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Injection site anaesthesia	0	0	0	2	2	0	0
Injection site atrophy	0	6	2	15	21	0	0
Injection site bruising	2	102	21	310	412	0	0
Injection site coldness	0	6	0	9	15	0	0
Injection site cyst	0	2	1	8	10	0	0
Injection site deformation	2	2	0	15	17	0	0
Injection site dermatitis	0	0	0	3	3	0	0
Injection site discharge	1	3	0	7	10	0	0
Injection site discolouration	0	2	10	79	81	0	0
Injection site discomfort	0	20	22	756	776	0	0
Injection site dryness	0	1	0	2	3	0	0
Injection site dysaesthesia	0	0	0	11	11	0	0
Injection site eczema	0	0	0	1	1	0	0
Injection site erosion	0	0	0	4	4	0	0
Injection site erythema	13	514	335	6633	7147	0	0
Injection site exfoliation	0	0	1	5	5	0	0
Injection site extravasation	0	0	3	12	12	0	0
Injection site fibrosis	0	0	0	1	1	0	0
Injection site granuloma	0	0	0	2	2	0	0
Injection site haematoma	0	13	37	1582	1595	1	1

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Injection site haemorrhage	2	23	12	116	139	0	0
Injection site hyperaesthesia	0	0	0	8	8	0	0
Injection site hypersensitivity	0	7	11	190	197	0	0
Injection site hypertrophy	0	0	0	4	4	0	0
Injection site hypoaesthesia	0	16	13	170	186	0	0
Injection site indentation	0	12	1	22	34	0	0
Injection site induration	4	65	95	3756	3821	0	0
Injection site inflammation	1	49	124	8513	8562	0	0
Injection site injury	0	7	0	26	33	0	0
Injection site irritation	1	3	3	26	29	0	0
Injection site joint discomfort	0	0	0	4	4	0	0
Injection site joint erythema	0	3	0	14	17	0	0
Injection site joint inflammation	0	0	0	6	6	0	0
Injection site joint movement impairment	0	7	1	30	37	0	0
Injection site joint pain	0	39	7	96	135	0	0
Injection site joint swelling	0	2	2	32	34	0	0
Injection site joint warmth	0	0	0	8	8	0	0
Injection site lymphadenopathy	0	0	1	20	20	0	0
Injection site macule	0	0	3	4	4	0	0
Injection site mass	3	891	15	843	1734	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Injection site movement impairment	3	15	14	96	111	0	0
Injection site muscle atrophy	1	2	0	2	4	0	0
Injection site muscle weakness	1	8	5	24	32	0	0
Injection site necrosis	1	8	0	6	14	0	0
Injection site nerve damage	0	2	0	0	2	0	0
Injection site nodule	0	3	1	86	89	0	0
Injection site oedema	0	44	13	366	410	0	0
Injection site pain	112	4397	3516	54306	58703	0	0
Injection site papule	0	2	0	10	12	0	0
Injection site paraesthesia	2	30	15	140	170	0	0
Injection site phlebitis	0	0	0	5	5	0	0
Injection site plaque	0	2	3	10	12	0	0
Injection site pruritus	3	212	122	2235	2447	0	0
Injection site rash	2	176	14	444	620	0	0
Injection site reaction	210	1671	499	5679	7350	0	0
Injection site scab	0	3	0	6	9	0	0
Injection site scar	0	4	2	11	15	0	0
Injection site streaking	0	0	0	1	1	0	0
Injection site swelling	33	371	999	9696	10067	0	4
Injection site telangiectasia	0	0	0	1	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Injection site thrombosis	2	8	0	5	13	0	0
Injection site ulcer	0	1	0	2	3	0	0
Injection site urticaria	1	26	7	73	99	0	0
Injection site vasculitis	0	1	0	0	1	0	0
Injection site vesicles	2	11	5	50	61	0	0
Injection site warmth	8	284	132	5298	5582	0	0
Injury associated with device	1	9	0	9	18	0	0
Instillation site bruise	0	0	0	1	1	0	0
Instillation site discomfort	0	0	0	2	2	0	0
Instillation site erythema	0	0	0	1	1	0	0
Instillation site pain	0	1	2	6	7	0	0
Instillation site pruritus	0	1	0	1	2	0	0
Instillation site vesicles	0	0	0	1	1	0	0
Instillation site warmth	0	8	0	7	15	0	0
Irritability postvaccinal	0	3	0	8	11	0	0
Lithiasis	0	2	0	0	2	0	0
Local reaction	3	84	30	1119	1203	0	0
Localised oedema	5	52	14	276	328	0	0
Loss of control of legs	1	66	0	26	92	0	0
Macrosomia	0	0	0	0	0	1	1

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Malaise	606	14127	5850	71852	85979	1	14
Masked fever	0	1	0	0	1	0	0
Mass	5	61	12	135	196	0	0
Maxillofacial pain	0	0	1	1	1	0	0
Medical device pain	0	0	0	3	3	0	0
Medical device site dysaesthesia	0	0	0	1	1	0	0
Medical device site hypersensitivity	0	0	0	1	1	0	0
Medical device site hypoaesthesia	0	0	0	1	1	0	0
Medical device site joint discomfort	0	1	0	0	1	0	0
Medical device site joint pain	0	1	0	1	2	0	0
Medical device site pain	0	0	0	1	1	0	0
Medical device site papule	0	0	0	1	1	0	0
Medical device site reaction	0	0	0	1	1	0	0
Meteoropathy	0	0	1	1	1	0	0
Moaning	0	9	0	8	17	0	0
Mucosa vesicle	0	0	0	6	6	0	0
Mucosal atrophy	0	0	0	1	1	0	0
Mucosal discolouration	0	0	0	2	2	0	0
Mucosal disorder	2	3	5	16	19	0	0
Mucosal dryness	1	4	5	26	30	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Mucosal erosion	1	2	0	0	2	0	0
Mucosal haemorrhage	0	17	5	18	35	0	0
Mucosal hyperaemia	0	1	0	0	1	0	0
Mucosal hypertrophy	0	0	0	2	2	0	0
Mucosal inflammation	1	13	3	20	33	0	0
Mucosal necrosis	0	1	0	0	1	0	0
Mucosal pain	0	2	1	9	11	0	0
Mucosal roughness	0	0	0	1	1	0	0
Mucosal ulceration	0	5	0	0	5	0	0
Multi-organ disorder	0	2	0	0	2	0	0
Multiple organ dysfunction syndrome	5	96	0	0	96	1	1
Necrosis	2	14	1	11	25	0	0
Neurological complication associated with device	0	1	0	1	2	0	0
No adverse event	0	3	22	90	93	0	0
No reaction on previous exposure to drug	0	4	0	76	80	0	0
Nodule	4	43	33	811	854	0	0
Non-cardiac chest pain	3	49	6	64	113	0	0
Non-pitting oedema	0	0	0	1	1	0	0
Nonspecific reaction	2	6	0	3	9	0	0
Obstruction	1	3	0	2	5	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Oedema	30	268	291	2785	3053	0	0
Oedema mucosal	1	10	3	20	30	0	0
Oedema peripheral	38	533	105	1187	1720	0	0
Organ failure	1	15	0	0	15	0	0
PFAPA syndrome	0	1	0	1	2	0	0
Pain	255	15606	5128	39130	54736	1	2
Papillitis	1	4	0	0	4	0	0
Paradoxical drug reaction	0	1	0	1	2	0	0
Pelvic mass	0	1	1	1	2	0	0
Perforation	0	1	0	1	2	0	0
Performance status decreased	8	17	10	78	95	0	0
Peripheral swelling	98	4724	492	5227	9951	0	1
Phantom shocks	0	3	0	2	5	0	0
Physical deconditioning	0	8	4	11	19	0	0
Polyp	3	9	0	3	12	0	0
Polyserositis	2	11	0	0	11	0	0
Pre-existing condition improved	0	5	2	38	43	0	0
Pre-existing disease	0	2	0	6	8	0	0
Premature ageing	0	1	0	2	3	0	0
Procedural failure	0	0	0	1	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Product intolerance	0	0	1	2	2	0	0
Prolapse	1	2	0	2	4	0	0
Prosthetic cardiac valve thrombosis	1	4	0	0	4	0	0
Pseudocyst	0	0	0	1	1	0	0
Puncture site bruise	0	39	3	32	71	0	0
Puncture site erythema	0	2	0	8	10	0	0
Puncture site haematoma	0	0	0	3	3	0	0
Puncture site haemorrhage	0	1	0	1	2	0	0
Puncture site induration	0	1	0	6	7	0	0
Puncture site oedema	0	7	1	21	28	0	0
Puncture site pain	0	26	7	194	220	0	0
Puncture site pruritus	0	0	0	4	4	0	0
Puncture site reaction	0	1	0	15	16	0	0
Puncture site swelling	0	1	0	6	7	0	0
Pyrexia	1122	56480	26059	216505	272985	4	16
Rebound effect	0	0	0	2	2	0	0
Remission not achieved	0	0	0	1	1	0	0
Scar inflammation	0	0	1	6	6	0	0
Screaming	0	28	1	8	36	0	0
Secretion discharge	3	29	10	74	103	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Sensation of blood flow	1	13	3	34	47	0	0
Sensation of foreign body	5	93	16	165	258	0	0
Sense of oppression	3	44	8	78	122	0	0
Sensitivity to weather change	0	2	0	10	12	0	0
Serositis	0	3	0	0	3	0	0
Shoulder injury related to vaccine administration	4	125	7	62	187	0	0
Sick building syndrome	0	1	0	6	7	0	0
Similar reaction on previous exposure to drug	0	1	0	3	4	0	0
Sluggishness	0	38	49	472	510	0	0
Soft tissue inflammation	1	1	0	3	4	0	0
Stenosis	0	5	0	5	10	0	0
Stent-graft endoleak	0	0	0	1	1	0	0
Steroid dependence	0	0	0	2	2	0	0
Strangulated hernia	0	2	0	0	2	0	0
Sudden cardiac death	30	180	0	0	180	0	0
Sudden death	8	218	0	0	218	4	4
Sudden infant death syndrome	0	7	0	0	7	0	0
Sudden unexplained death in epilepsy	0	1	0	0	1	0	0
Supraclavicular fossa pain	0	0	0	3	3	0	0
Suprapubic pain	0	3	0	6	9	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Swelling	42	1940	346	3669	5609	0	0
Swelling face	32	992	123	1512	2504	0	0
Symptom masked	0	3	0	8	11	0	0
Symptom recurrence	1	7	0	16	23	0	0
Systemic inflammatory response syndrome	1	18	0	0	18	0	0
Temperature intolerance	4	88	11	64	152	0	0
Temperature regulation disorder	3	45	10	153	198	0	0
Tenderness	12	1306	524	7862	9168	0	0
Terminal state	2	4	0	0	4	0	0
Therapeutic product effect decreased	11	17	10	19	36	0	0
Therapeutic product effect delayed	1	1	0	2	3	0	0
Therapeutic product effect incomplete	4	6	5	11	17	0	0
Therapeutic product effect prolonged	0	1	0	2	3	0	0
Therapeutic product ineffective	1	10	0	25	35	0	0
Therapeutic reaction time decreased	0	1	0	1	2	0	0
Therapeutic response changed	0	1	0	0	1	0	0
Therapeutic response decreased	5	6	0	3	9	0	0
Therapeutic response delayed	0	0	0	1	1	0	0
Therapeutic response increased	0	0	0	1	1	0	0
Therapeutic response shortened	3	4	6	7	11	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Therapeutic response unexpected	5	72	17	316	388	0	0
Therapy non-responder	1	6	0	2	8	0	0
Therapy partial responder	0	0	1	69	69	0	0
Therapy responder	0	0	0	1	1	0	0
Thirst	10	1101	107	1284	2385	0	0
Thirst decreased	0	11	5	23	34	0	0
Tissue discolouration	0	2	0	1	3	0	0
Tissue infiltration	0	1	0	3	4	0	0
Tissue rupture	0	0	0	1	1	0	0
Treatment failure	0	18	0	2	20	0	0
Treatment noncompliance	2	2	0	2	4	0	0
Ulcer	0	39	6	52	91	0	0
Ulcer haemorrhage	0	1	1	7	8	0	0
Unevaluable event	7	19	13	128	147	0	0
Unmasking of previously unidentified disease	0	1	0	0	1	0	0
Vaccination failure	2304	23120	76	660	23780	0	2
Vaccination site abscess sterile	0	1	0	2	3	0	0
Vaccination site anaesthesia	0	1	1	7	8	0	0
Vaccination site atrophy	0	6	4	14	20	0	0
Vaccination site bruising	2	90	116	341	431	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Vaccination site coldness	0	2	3	14	16	0	0
Vaccination site cyst	0	3	0	5	8	0	0
Vaccination site dermatitis	0	0	1	8	8	0	0
Vaccination site discharge	1	3	0	4	7	0	0
Vaccination site discolouration	2	19	13	59	78	0	0
Vaccination site discomfort	1	29	41	1159	1188	0	0
Vaccination site dryness	0	1	0	3	4	0	0
Vaccination site dysaesthesia	0	1	3	14	15	0	0
Vaccination site eczema	0	0	1	16	16	0	0
Vaccination site erosion	0	2	1	1	3	0	0
Vaccination site erythema	20	519	914	3626	4145	0	0
Vaccination site exfoliation	0	2	1	6	8	0	0
Vaccination site extravasation	0	1	0	5	6	0	0
Vaccination site granuloma	0	1	2	14	15	0	0
Vaccination site haematoma	3	43	42	312	355	0	0
Vaccination site haemorrhage	4	17	11	35	52	0	0
Vaccination site hyperaesthesia	0	5	3	22	27	0	0
Vaccination site hypersensitivity	0	5	8	64	69	0	0
Vaccination site hypoaesthesia	0	27	5	47	74	0	0
Vaccination site induration	0	72	152	461	533	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Vaccination site inflammation	0	79	53	534	613	0	0
Vaccination site injury	1	5	2	14	19	0	0
Vaccination site irritation	1	8	8	39	47	0	0
Vaccination site joint discomfort	0	1	0	7	8	0	0
Vaccination site joint effusion	0	1	0	1	2	0	0
Vaccination site joint erythema	0	10	5	56	66	0	0
Vaccination site joint inflammation	1	2	1	9	11	0	0
Vaccination site joint movement impairment	1	34	1	45	79	0	0
Vaccination site joint pain	1	50	12	149	199	0	0
Vaccination site joint swelling	1	8	2	43	51	0	0
Vaccination site joint warmth	0	1	0	4	5	0	0
Vaccination site lymphadenopathy	1	20	16	119	139	0	0
Vaccination site macule	0	0	1	11	11	0	0
Vaccination site mass	0	298	68	509	807	0	0
Vaccination site movement impairment	8	165	29	375	540	0	0
Vaccination site necrosis	0	1	0	1	2	0	0
Vaccination site nerve damage	0	1	0	1	2	0	0
Vaccination site nodule	0	6	9	38	44	0	0
Vaccination site oedema	3	83	129	544	627	0	0
Vaccination site pain	78	2534	5733	26001	28535	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Vaccination site pallor	0	0	0	3	3	0	0
Vaccination site papule	0	1	0	12	13	0	0
Vaccination site paraesthesia	0	27	19	107	134	0	0
Vaccination site phlebitis	0	2	0	3	5	0	0
Vaccination site plaque	0	0	0	9	9	0	0
Vaccination site pruritus	7	129	276	744	873	0	0
Vaccination site rash	1	107	59	346	453	0	0
Vaccination site reaction	49	216	820	2791	3007	0	0
Vaccination site recall reaction	0	0	1	5	5	0	0
Vaccination site scab	0	1	0	1	2	0	0
Vaccination site scar	1	5	0	11	16	0	0
Vaccination site swelling	17	451	1498	3719	4170	0	0
Vaccination site thrombosis	0	2	0	3	5	0	0
Vaccination site ulcer	0	0	3	6	6	0	0
Vaccination site urticaria	0	9	11	41	50	0	0
Vaccination site vasculitis	0	1	0	0	1	0	0
Vaccination site vesicles	1	10	8	31	41	0	0
Vaccination site warmth	0	278	354	1032	1310	0	0
Vaccine positive rechallenge	0	1	0	0	1	0	0
Vascular stent occlusion	0	5	0	0	5	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Vascular stent stenosis	0	4	0	0	4	0	0
Vascular stent thrombosis	2	19	0	0	19	0	0
Vessel puncture site bruise	1	2	0	1	3	0	0
Vessel puncture site haematoma	0	0	0	1	1	0	0
Vessel puncture site haemorrhage	0	0	1	2	2	0	0
Visceral pain	1	5	0	8	13	0	0
Withdrawal syndrome	1	61	1	43	104	0	0
Xerosis	0	0	0	4	4	0	0
Investigations	**811**	**14817**	**3131**	**36513**	**51330**	**6**	**20**
17 ketosteroids urine	0	0	0	1	1	0	0
17 ketosteroids urine decreased	0	0	0	1	1	0	0
5'nucleotidase increased	0	0	0	2	2	0	0
5-hydroxyindolacetic acid increased	0	0	0	1	1	0	0
ADAMTS13 activity abnormal	0	1	0	0	1	0	0
ADAMTS13 activity decreased	0	1	0	0	1	0	0
APACHE II score	0	0	0	1	1	0	0
Abdominal bruit	0	1	0	0	1	0	0
Acid base balance abnormal	0	1	0	0	1	0	0
Acoustic stimulation tests	0	6	0	2	8	0	0
Acoustic stimulation tests abnormal	0	0	0	1	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Activated partial thromboplastin time	0	0	0	3	3	0	0
Activated partial thromboplastin time abnormal	0	0	0	1	1	0	0
Activated partial thromboplastin time normal	0	0	1	1	1	0	0
Activated partial thromboplastin time prolonged	1	141	0	21	162	0	0
Activated partial thromboplastin time shortened	0	4	0	1	5	0	0
Adenovirus test positive	0	0	0	1	1	0	0
Alanine aminotransferase abnormal	0	1	0	0	1	0	0
Alanine aminotransferase decreased	1	1	0	1	2	0	0
Alanine aminotransferase increased	3	37	1	29	66	0	1
Alanine aminotransferase normal	0	0	1	1	1	0	0
Albumin globulin ratio	0	6	8	46	52	0	0
Albumin globulin ratio normal	0	3	13	45	48	0	0
Albumin urine present	0	0	1	1	1	0	0
Allergy alert test	0	3	0	2	5	0	0
Allergy test negative	0	0	0	1	1	0	0
Allergy test positive	0	0	0	2	2	0	0
Alpha 1 foetoprotein abnormal	0	1	0	0	1	0	0
Amniotic fluid volume	0	1	0	0	1	0	0
Amylase	0	0	0	1	1	0	0
Amylase abnormal	0	1	0	0	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Amylase increased	0	3	0	1	4	0	0
Analgesic drug level	0	14	0	5	19	0	0
Analgesic drug level decreased	0	0	0	1	1	0	0
Analgesic drug level increased	0	2	0	0	2	0	0
Analgesic drug level therapeutic	0	1	0	1	2	0	0
Angiocardiogram	0	3	0	1	4	0	0
Angiogram	1	2	0	1	3	0	0
Angiogram abnormal	0	2	0	0	2	0	0
Angiogram peripheral abnormal	0	1	0	0	1	0	0
Anion gap abnormal	0	1	0	0	1	0	0
Anion gap decreased	2	2	0	0	2	0	0
Anion gap increased	0	1	0	0	1	0	0
Anti factor VIII antibody increased	0	0	0	1	1	0	0
Anti factor VIII antibody positive	0	1	0	0	1	0	0
Anti-Muellerian hormone level decreased	0	4	0	1	5	0	0
Anti-ganglioside antibody negative	0	1	0	0	1	0	0
Anti-myelin-associated glycoprotein antibodies positive	1	3	0	0	3	0	0
Anti-platelet antibody	0	4	0	2	6	0	0
Anti-platelet antibody negative	0	1	0	0	1	0	0
Anti-platelet antibody positive	0	6	0	0	6	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Anti-platelet factor 4 antibody positive	0	10	0	1	11	0	0
Anti-sperm antibody	0	0	0	1	1	0	0
Anti-thyroid antibody	0	2	0	0	2	0	0
Anti-thyroid antibody increased	0	1	0	2	3	0	0
Anti-thyroid antibody positive	0	0	0	2	2	0	0
Antiacetylcholine receptor antibody positive	0	1	0	0	1	0	0
Antibody test	0	3	0	25	28	0	0
Antibody test abnormal	3	3	2	95	98	0	0
Antibody test negative	0	3	2	70	73	0	0
Antibody test normal	0	0	0	2	2	0	0
Antibody test positive	1	2	3	13	15	0	0
Anticoagulation drug level above therapeutic	0	1	0	2	3	0	0
Anticoagulation drug level below therapeutic	0	2	0	4	6	0	0
Anticoagulation drug level increased	0	1	0	0	1	0	0
Anticoagulation drug level therapeutic	0	0	0	1	1	0	0
Antidepressant drug level decreased	0	1	0	0	1	0	0
Antimitochondrial antibody positive	0	0	0	2	2	0	0
Antineutrophil cytoplasmic antibody increased	0	0	2	4	4	0	0
Antineutrophil cytoplasmic antibody negative	0	1	0	0	1	0	0
Antineutrophil cytoplasmic antibody positive	1	3	1	1	4	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Antinuclear antibody	0	4	0	3	7	0	0
Antinuclear antibody increased	0	2	0	5	7	0	0
Antinuclear antibody positive	0	6	3	11	17	0	0
Antiphospholipid antibodies	0	3	1	2	5	0	0
Antiphospholipid antibodies positive	1	9	0	1	10	0	0
Antithrombin III abnormal	0	2	0	3	5	0	0
Antithrombin III decreased	0	2	0	0	2	0	0
Antithrombin III increased	1	3	0	1	4	0	0
Aortic bruit	0	1	0	0	1	0	0
Apolipoprotein	0	1	0	0	1	0	0
Arteriogram carotid	0	1	0	0	1	0	0
Arteriogram coronary abnormal	0	1	0	0	1	0	0
Arteriogram coronary normal	0	1	0	0	1	0	0
Arthroscopy	1	1	0	0	1	0	0
Aspartate aminotransferase	0	1	0	1	2	0	0
Aspartate aminotransferase abnormal	0	0	0	1	1	0	0
Aspartate aminotransferase decreased	1	1	0	0	1	0	0
Aspartate aminotransferase increased	1	11	0	11	22	0	0
Aspiration joint	0	1	0	1	2	0	0
Atrial pressure increased	0	0	0	1	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Audiogram	0	1	0	0	1	0	0
Audiogram abnormal	0	0	0	1	1	0	0
Auscultation	0	0	1	1	1	0	0
Autoantibody positive	7	10	5	7	17	0	0
Autoantibody test	1	1	0	0	1	0	0
B-lymphocyte count decreased	0	0	0	1	1	0	0
Babinski reflex test	0	2	0	0	2	0	0
Bacterial test	0	0	0	1	1	0	0
Bacterial test positive	1	1	0	0	1	0	0
Balance test	1	1	0	0	1	0	0
Barium swallow	0	1	0	1	2	0	0
Base excess	0	1	0	0	1	0	0
Basophil count increased	0	2	0	0	2	0	0
Basophil percentage increased	0	1	0	0	1	0	0
Beta 2 microglobulin increased	0	0	0	1	1	0	0
Beta-2 glycoprotein antibody	0	2	0	0	2	0	0
Bile duct pressure	0	0	1	1	1	0	0
Bile output	0	4	0	0	4	0	0
Bile output increased	0	0	0	1	1	0	0
Bilirubin conjugated increased	0	2	0	1	3	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Biopsy	0	1	0	0	1	0	0
Biopsy brain	0	1	0	0	1	0	0
Biopsy breast	0	1	0	0	1	0	0
Biopsy endometrium	1	1	0	0	1	0	0
Biopsy kidney	0	1	0	0	1	0	0
Biopsy lymph gland	0	1	0	3	4	0	0
Biopsy pharynx normal	0	0	0	1	1	0	0
Biopsy skin	0	1	0	1	2	0	0
Biopsy vagina	0	1	0	0	1	0	0
Bladder scan	1	1	0	0	1	0	0
Bleeding time	0	5	0	5	10	0	0
Bleeding time abnormal	0	1	0	4	5	0	0
Bleeding time prolonged	0	9	4	25	34	0	0
Bleeding time shortened	0	0	0	3	3	0	0
Blood HIV RNA increased	0	2	0	1	3	0	0
Blood albumin abnormal	0	1	0	0	1	0	0
Blood albumin decreased	0	3	0	0	3	0	0
Blood alkaline phosphatase	0	1	1	1	2	0	0
Blood alkaline phosphatase abnormal	0	1	0	0	1	0	0
Blood alkaline phosphatase decreased	0	0	0	1	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Blood alkaline phosphatase increased	0	8	0	9	17	0	0
Blood aluminium	0	1	0	0	1	0	0
Blood arsenic normal	0	0	0	1	1	0	0
Blood bicarbonate abnormal	0	1	0	0	1	0	0
Blood bilirubin	0	0	0	1	1	0	0
Blood bilirubin abnormal	0	1	0	0	1	0	0
Blood bilirubin increased	0	14	1	10	24	0	1
Blood bilirubin unconjugated increased	0	0	0	2	2	0	0
Blood caffeine decreased	0	0	0	1	1	0	0
Blood calcitonin increased	0	0	0	1	1	0	0
Blood calcium	0	2	0	0	2	0	0
Blood calcium decreased	2	2	0	2	4	0	0
Blood calcium increased	1	3	0	4	7	0	0
Blood cannabinoids	0	1	0	0	1	0	0
Blood carbon monoxide decreased	0	0	0	1	1	0	0
Blood carbon monoxide increased	0	2	0	1	3	0	0
Blood cholesterol	0	1	0	0	1	0	0
Blood cholesterol abnormal	0	0	0	2	2	0	0
Blood cholesterol decreased	0	1	0	1	2	0	0
Blood cholesterol increased	4	23	1	28	51	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Blood corticotrophin	1	2	0	0	2	0	0
Blood corticotrophin abnormal	1	1	0	0	1	0	0
Blood cortisol	0	1	0	0	1	0	0
Blood creatine abnormal	0	0	1	3	3	0	0
Blood creatine increased	0	3	1	6	9	0	0
Blood creatine normal	0	0	0	1	1	0	0
Blood creatine phosphokinase	0	1	0	0	1	0	0
Blood creatine phosphokinase MB abnormal	0	0	0	1	1	0	0
Blood creatine phosphokinase MB increased	0	0	0	3	3	0	0
Blood creatine phosphokinase abnormal	0	0	0	3	3	0	0
Blood creatine phosphokinase increased	4	25	3	25	50	0	0
Blood creatine phosphokinase normal	0	0	0	1	1	0	0
Blood creatinine	0	0	0	1	1	0	0
Blood creatinine abnormal	1	1	0	2	3	0	0
Blood creatinine decreased	1	3	1	3	6	0	0
Blood creatinine increased	2	21	1	17	38	0	0
Blood culture	1	3	0	0	3	0	0
Blood culture negative	0	0	0	2	2	0	0
Blood cyanide	0	1	0	0	1	0	0
Blood electrolytes abnormal	0	1	0	1	2	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Blood electrolytes decreased	0	2	0	1	3	0	0
Blood fibrinogen	0	1	0	4	5	0	0
Blood fibrinogen abnormal	0	1	0	7	8	0	0
Blood fibrinogen decreased	1	22	1	10	32	0	0
Blood fibrinogen increased	0	53	2	53	106	0	0
Blood folate	0	2	0	1	3	0	0
Blood folate abnormal	0	1	0	0	1	0	0
Blood folate decreased	4	15	2	8	23	0	0
Blood folate increased	0	0	1	1	1	0	0
Blood follicle stimulating hormone increased	0	1	0	3	4	0	0
Blood gases	0	1	0	0	1	0	0
Blood gases abnormal	0	1	1	1	2	0	0
Blood gastrin	0	0	0	1	1	0	0
Blood gastrin normal	0	1	0	0	1	0	0
Blood glucagon increased	0	0	0	4	4	0	0
Blood glucose	0	16	0	7	23	0	0
Blood glucose abnormal	3	27	7	44	71	0	0
Blood glucose decreased	0	41	3	71	112	1	1
Blood glucose false positive	0	0	0	1	1	0	0
Blood glucose fluctuation	1	39	0	56	95	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Blood glucose increased	13	200	27	360	560	0	0
Blood group O	0	1	0	1	2	0	0
Blood grouping	0	0	0	1	1	0	0
Blood growth hormone increased	0	1	0	0	1	0	0
Blood homocysteine	0	0	0	1	1	0	0
Blood homocysteine increased	0	0	1	9	9	0	0
Blood immunoglobulin A decreased	0	0	1	1	1	0	0
Blood immunoglobulin A increased	0	1	0	2	3	0	0
Blood immunoglobulin E	0	1	0	0	1	0	0
Blood immunoglobulin E abnormal	0	1	0	1	2	0	0
Blood immunoglobulin E increased	0	1	1	11	12	0	0
Blood immunoglobulin G	0	1	0	7	8	0	0
Blood immunoglobulin G decreased	2	2	1	6	8	0	0
Blood immunoglobulin G increased	0	0	0	5	5	0	0
Blood immunoglobulin M	0	1	0	5	6	0	0
Blood immunoglobulin M abnormal	0	0	0	1	1	0	0
Blood immunoglobulin M decreased	0	0	0	1	1	0	0
Blood immunoglobulin M increased	0	1	0	2	3	0	0
Blood insulin	0	4	0	1	5	0	0
Blood insulin abnormal	0	0	1	2	2	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Blood insulin decreased	0	1	0	2	3	0	0
Blood insulin increased	0	3	1	4	7	0	0
Blood iron	0	12	0	2	14	0	0
Blood iron abnormal	0	0	0	2	2	0	0
Blood iron decreased	8	45	4	21	66	0	0
Blood iron increased	0	2	0	7	9	0	0
Blood ketone body	0	9	0	1	10	0	0
Blood ketone body increased	0	1	1	2	3	0	0
Blood ketone body present	0	2	0	0	2	0	0
Blood lactate dehydrogenase	0	1	0	0	1	0	0
Blood lactate dehydrogenase abnormal	0	0	0	2	2	0	0
Blood lactate dehydrogenase increased	0	4	2	9	13	0	0
Blood lactic acid	0	2	2	4	6	0	0
Blood lactic acid abnormal	0	1	0	0	1	0	0
Blood lactic acid increased	0	10	0	3	13	0	0
Blood lead	0	1	0	0	1	0	0
Blood luteinising hormone decreased	0	1	0	0	1	0	0
Blood magnesium	0	0	0	1	1	0	0
Blood magnesium decreased	0	3	0	3	6	0	0
Blood oestrogen	0	1	0	1	2	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Blood oestrogen abnormal	1	1	0	1	2	0	0
Blood oestrogen decreased	0	0	0	1	1	0	0
Blood oestrogen increased	0	0	0	3	3	0	0
Blood osmolarity	0	1	0	0	1	0	0
Blood osmolarity increased	0	0	0	1	1	0	0
Blood pH	0	15	0	5	20	0	0
Blood pH decreased	0	2	0	0	2	0	0
Blood pH increased	0	13	0	2	15	0	0
Blood parathyroid hormone decreased	0	1	0	0	1	0	0
Blood phosphorus abnormal	0	1	0	0	1	0	0
Blood phosphorus decreased	1	7	0	3	10	0	0
Blood phosphorus increased	0	3	0	1	4	0	0
Blood potassium abnormal	0	2	0	1	3	0	0
Blood potassium decreased	0	24	0	8	32	0	0
Blood potassium increased	1	10	1	4	14	0	0
Blood pregnenolone increased	0	0	0	1	1	0	0
Blood pressure abnormal	7	63	46	280	343	0	0
Blood pressure ambulatory decreased	0	0	0	3	3	0	0
Blood pressure ambulatory increased	0	0	0	11	11	0	0
Blood pressure decreased	21	270	93	789	1059	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Blood pressure diastolic	0	2	0	0	2	0	0
Blood pressure diastolic abnormal	6	7	0	1	8	0	0
Blood pressure diastolic decreased	1	5	0	11	16	0	0
Blood pressure diastolic increased	7	20	3	34	54	0	0
Blood pressure difference of extremities	0	3	0	0	3	0	0
Blood pressure immeasurable	0	3	0	0	3	0	0
Blood pressure increased	63	932	341	7399	8331	2	5
Blood pressure measurement	5	114	1	109	223	0	0
Blood pressure normal	0	6	1	8	14	0	0
Blood pressure orthostatic decreased	1	1	1	3	4	0	0
Blood pressure systolic	0	2	1	6	8	0	0
Blood pressure systolic abnormal	3	4	1	2	6	0	0
Blood pressure systolic decreased	0	2	3	8	10	0	0
Blood pressure systolic increased	11	25	2	37	62	0	0
Blood prolactin abnormal	0	0	0	1	1	0	0
Blood prolactin increased	0	1	0	1	2	0	0
Blood pyruvic acid increased	0	0	0	1	1	0	0
Blood sodium	0	1	0	1	2	0	0
Blood sodium decreased	3	15	1	9	24	0	0
Blood test	0	45	0	13	58	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Blood test abnormal	5	103	4	37	140	0	0
Blood test normal	0	1	0	1	2	0	0
Blood testosterone decreased	1	3	0	0	3	0	0
Blood testosterone increased	0	1	0	0	1	0	0
Blood thrombin	0	0	0	1	1	0	0
Blood thrombin abnormal	0	1	0	0	1	0	0
Blood thromboplastin	0	1	0	1	2	0	0
Blood thromboplastin increased	0	0	1	3	3	0	0
Blood thyroid stimulating hormone	0	2	0	2	4	0	0
Blood thyroid stimulating hormone abnormal	1	2	0	3	5	0	0
Blood thyroid stimulating hormone decreased	1	7	1	7	14	0	0
Blood thyroid stimulating hormone increased	1	9	0	25	34	0	0
Blood triglycerides	0	1	0	0	1	0	0
Blood triglycerides abnormal	0	0	0	2	2	0	0
Blood triglycerides increased	2	8	1	6	14	0	0
Blood urea	0	4	0	3	7	0	0
Blood urea abnormal	0	0	1	3	3	0	0
Blood urea decreased	0	0	0	1	1	0	0
Blood urea increased	0	1	0	5	6	0	0
Blood uric acid abnormal	0	0	1	1	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Blood uric acid increased	0	2	1	11	13	0	0
Blood urine	1	40	1	19	59	0	0
Blood urine present	7	105	13	123	228	0	0
Blood viscosity abnormal	0	1	0	0	1	0	0
Blood viscosity decreased	0	0	0	1	1	0	0
Blood viscosity increased	1	6	0	4	10	0	0
Blood zinc decreased	0	1	0	0	1	0	0
Blood zinc increased	0	0	0	1	1	0	0
Body height	0	0	0	1	1	0	0
Body height decreased	0	0	0	1	1	0	0
Body mass index decreased	0	0	1	2	2	0	0
Body mass index increased	0	0	0	1	1	0	0
Body surface area	0	2	0	2	4	0	0
Body surface area decreased	0	0	0	1	1	0	0
Body surface area increased	0	0	0	1	1	0	0
Body temperature	2	810	15	617	1427	0	0
Body temperature abnormal	4	70	121	936	1006	0	0
Body temperature decreased	6	151	17	377	528	0	0
Body temperature fluctuation	6	173	22	189	362	0	0
Body temperature increased	17	1079	1171	12057	13136	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Body temperature normal	0	5	2	30	35	0	0
Bone densitometry	0	0	0	1	1	0	0
Bone density decreased	0	0	1	1	1	0	0
Bone marrow myelogram abnormal	0	0	0	1	1	0	0
Borrelia test	0	0	0	1	1	0	0
Borrelia test positive	1	3	1	4	7	0	0
Brachial pulse abnormal	0	1	0	0	1	0	0
Brachial pulse decreased	0	0	0	2	2	0	0
Brachial pulse increased	0	2	0	3	5	0	0
Brain natriuretic peptide increased	0	4	0	2	6	0	0
Brain scan abnormal	0	2	0	1	3	0	0
Brain stem auditory evoked response abnormal	0	1	0	0	1	0	0
Breath sounds	0	3	1	5	8	0	0
Breath sounds abnormal	6	14	1	6	20	0	0
Breath sounds absent	0	1	0	0	1	0	0
Breath sounds normal	0	0	0	1	1	0	0
C-reactive protein	0	2	0	1	3	0	0
C-reactive protein abnormal	0	6	1	4	10	0	0
C-reactive protein decreased	0	1	0	2	3	0	0
C-reactive protein increased	10	175	14	144	319	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
CD4 lymphocytes abnormal	0	0	0	1	1	0	0
CD4 lymphocytes decreased	0	0	0	2	2	0	0
CD4 lymphocytes increased	0	0	0	1	1	0	0
CD8 lymphocytes decreased	0	0	0	1	1	0	0
CSF cell count abnormal	0	1	0	0	1	0	0
CSF cell count increased	0	1	1	1	2	0	0
CSF glucose decreased	0	1	0	0	1	0	0
CSF glucose increased	0	1	0	0	1	0	0
CSF lactate dehydrogenase increased	0	1	0	0	1	0	0
CSF lymphocyte count abnormal	0	1	0	0	1	0	0
CSF oligoclonal band present	0	2	0	0	2	0	0
CSF pressure	1	5	0	0	5	0	0
CSF pressure increased	0	2	0	1	3	0	0
CSF protein	0	1	0	0	1	0	0
CSF protein increased	1	11	0	1	12	0	0
CSF test abnormal	0	3	0	2	5	0	0
CSF white blood cell count increased	1	1	0	1	2	0	0
CSF white blood cell count positive	1	1	0	0	1	0	0
Capillary fragility abnormal	0	0	0	3	3	0	0
Capillary nail refill test	0	1	0	0	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Capillary nail refill test abnormal	0	1	0	1	2	0	0
Capillary permeability increased	0	2	0	0	2	0	0
Carbohydrate antigen 125 increased	0	0	1	2	2	0	0
Carbohydrate antigen 15-3	0	0	0	1	1	0	0
Carbohydrate antigen 15-3 increased	0	0	0	1	1	0	0
Carbon dioxide abnormal	0	1	0	0	1	0	0
Carbon dioxide increased	0	1	0	1	2	0	0
Carcinoembryonic antigen decreased	1	1	0	0	1	0	0
Carcinoembryonic antigen increased	0	2	0	0	2	0	0
Cardiac imaging procedure	0	1	0	0	1	0	0
Cardiac monitoring	0	1	0	3	4	0	0
Cardiac murmur	4	39	1	24	63	0	0
Cardiac murmur functional	0	1	0	3	4	0	0
Cardiac output decreased	0	0	0	1	1	0	0
Cardiac stress test abnormal	0	2	0	0	2	0	0
Cardiac telemetry	0	0	0	1	1	0	0
Cardiolipin antibody	0	1	0	1	2	0	0
Cardiolipin antibody positive	0	1	0	0	1	0	0
Cardiovascular examination abnormal	0	1	0	0	1	0	0
Carotid bruit	0	2	0	0	2	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Carotid pulse	0	1	0	0	1	0	0
Carotid pulse abnormal	0	0	0	2	2	0	0
Carotid pulse increased	0	0	0	2	2	0	0
Catheterisation cardiac	0	1	0	0	1	0	0
Cells in urine	0	1	0	1	2	0	0
Central nervous system function test abnormal	0	0	0	1	1	0	0
Central venous pressure	0	1	0	0	1	0	0
Ceruloplasmin increased	0	0	0	1	1	0	0
Chest X-ray	0	17	0	5	22	0	0
Chest X-ray abnormal	0	3	1	5	8	0	0
Chest expansion decreased	0	0	0	1	1	0	0
Cholangiogram	0	0	0	1	1	0	0
Cholesterol absorption efficiency decreased	0	0	0	1	1	0	0
Clostridium test positive	0	2	0	0	2	0	0
Clot retraction	0	1	0	0	1	0	0
Clot retraction abnormal	0	0	0	1	1	0	0
Clot retraction time prolonged	0	1	0	0	1	0	0
Coagulation factor	0	1	0	1	2	0	0
Coagulation factor VIII level abnormal	0	1	0	0	1	0	0
Coagulation factor VIII level decreased	0	5	0	1	6	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Coagulation factor decreased	0	0	0	1	1	0	0
Coagulation factor increased	0	4	0	2	6	0	0
Coagulation test abnormal	0	8	1	8	16	0	0
Coagulation time	0	8	0	2	10	0	0
Coagulation time abnormal	0	0	0	1	1	0	0
Coagulation time prolonged	0	15	4	13	28	0	0
Coagulation time shortened	0	4	0	6	10	0	0
Cold agglutinins	0	1	0	0	1	0	0
Cold agglutinins positive	0	1	0	1	2	0	0
Colonoscopy	0	0	0	1	1	0	0
Colour vision tests abnormal	0	0	0	1	1	0	0
Coma scale	0	1	0	1	2	0	0
Coma scale abnormal	2	34	0	8	42	0	0
Coma scale normal	0	1	0	1	2	0	0
Complement factor C3 decreased	0	0	0	1	1	0	0
Complement factor decreased	0	0	0	1	1	0	0
Computerised tomogram	0	7	0	1	8	0	0
Computerised tomogram abdomen	0	2	0	1	3	0	0
Computerised tomogram abnormal	0	2	0	2	4	0	0
Computerised tomogram head	1	31	0	4	35	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Computerised tomogram head abnormal	0	0	0	1	1	0	0
Computerised tomogram normal	0	1	0	1	2	0	0
Computerised tomogram thorax	0	5	0	2	7	0	0
Coombs test positive	0	1	1	1	2	0	0
Corneal reflex decreased	0	2	0	2	4	0	0
Coronavirus test	0	35	0	6	41	0	0
Coronavirus test negative	0	0	1	2	2	0	0
Coronavirus test positive	0	1	2	12	13	0	0
Cortisol decreased	0	4	0	0	4	0	0
Cortisol increased	0	1	0	1	2	0	0
Creatine urine abnormal	0	0	0	1	1	0	0
Creatinine renal clearance decreased	0	0	0	1	1	0	0
Cryoglobulins present	0	0	0	1	1	0	0
Crystal urine	0	2	0	2	4	0	0
Culture urine negative	0	0	0	1	1	0	0
Culture urine positive	1	1	0	0	1	0	0
Cystoscopy	0	2	0	1	3	0	0
Cytokine abnormal	1	1	0	0	1	0	0
Cytokine increased	0	0	3	3	3	0	0
Cytomegalovirus test	0	1	0	0	1	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Cytomegalovirus test positive	0	0	0	2	2	0	0
DNA antibody negative	0	0	0	1	1	0	0
DNA antibody positive	0	1	0	0	1	0	0
Dengue virus test positive	1	1	0	1	2	0	0
Dermatologic examination	0	0	0	1	1	0	0
Dermatologic examination abnormal	0	1	0	0	1	0	0
Dihydrotestosterone decreased	0	1	0	0	1	0	0
Disability assessment scale	0	1	0	0	1	0	0
Disability assessment scale score increased	1	1	0	0	1	0	0
Discogram abnormal	0	1	0	0	1	0	0
Double stranded DNA antibody positive	0	1	0	0	1	0	0
Drug level abnormal	1	1	0	0	1	0	0
Drug level decreased	1	1	0	1	2	0	0
Drug level increased	0	2	0	1	3	0	0
Drug screen positive	0	4	0	1	5	0	0
Drug specific antibody	0	0	1	4	4	0	0
Ear, nose and throat examination	0	0	0	1	1	0	0
Eastern Cooperative Oncology Group performance status improved	0	0	1	1	1	0	0
Eastern Cooperative Oncology Group performance status worsened	0	0	0	1	1	0	0
Echocardiogram	0	4	0	6	10	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Echocardiogram abnormal	0	1	1	3	4	0	0
Echocardiogram normal	0	1	0	0	1	0	0
Effective peritoneal surface area increased	0	0	0	1	1	0	0
Ejection fraction abnormal	1	1	0	0	1	0	0
Ejection fraction decreased	4	15	1	6	21	0	0
Electrocardiogram	0	8	1	11	19	0	0
Electrocardiogram P wave abnormal	0	1	0	0	1	0	0
Electrocardiogram PR prolongation	0	1	0	0	1	0	0
Electrocardiogram PR segment depression	0	0	0	1	1	0	0
Electrocardiogram QRS complex shortened	0	1	0	0	1	0	0
Electrocardiogram QT prolonged	1	11	0	0	11	0	0
Electrocardiogram QT shortened	0	1	0	0	1	0	0
Electrocardiogram ST segment abnormal	0	2	0	1	3	0	0
Electrocardiogram ST segment depression	2	7	0	1	8	0	0
Electrocardiogram ST segment elevation	0	14	0	6	20	0	0
Electrocardiogram ST-T segment abnormal	0	8	0	0	8	0	0
Electrocardiogram T wave abnormal	0	2	0	0	2	0	0
Electrocardiogram T wave inversion	0	10	0	1	11	0	0
Electrocardiogram abnormal	3	41	2	27	68	0	0
Electrocardiogram ambulatory	0	0	1	1	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Electrocardiogram change	1	4	0	0	4	0	0
Electrocardiogram normal	0	1	0	3	4	0	0
Electrocardiogram pacemaker spike	0	1	0	0	1	0	0
Electrocardiogram repolarisation abnormality	0	1	0	0	1	0	0
Electroencephalogram	0	1	0	1	2	0	0
Electroencephalogram abnormal	1	3	0	3	6	0	0
Electroencephalogram normal	0	2	0	0	2	0	0
Electromyogram abnormal	1	5	0	4	9	0	0
Electroneuromyography	0	1	0	0	1	0	0
Electronystagmogram abnormal	0	0	0	1	1	0	0
Emergency care examination	0	1	0	2	3	0	0
Endoscopy upper gastrointestinal tract	0	0	0	1	1	0	0
Enterococcus test positive	0	0	0	1	1	0	0
Eosinophil count	0	1	0	0	1	0	0
Eosinophil count abnormal	0	0	0	3	3	0	0
Eosinophil count decreased	0	1	1	3	4	0	0
Eosinophil count increased	1	9	0	8	17	0	0
Epinephrine abnormal	0	0	0	1	1	0	0
Epinephrine increased	0	1	0	2	3	0	0
Episcleral venous pressure increased	0	0	0	1	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Epstein-Barr virus antibody positive	0	2	0	1	3	0	0
Epstein-Barr virus antigen positive	0	0	1	1	1	0	0
Epstein-Barr virus test positive	1	2	0	1	3	0	0
Exercise electrocardiogram	0	1	1	1	2	0	0
Exercise electrocardiogram abnormal	0	1	0	0	1	0	0
Exocrine pancreatic function test abnormal	0	0	0	1	1	0	0
Face and mouth X-ray	0	1	0	0	1	0	0
Faecal calprotectin	1	2	0	0	2	0	0
Faecal calprotectin increased	1	7	1	5	12	0	0
Faecal elastase concentration decreased	0	0	0	1	1	0	0
Faecal volume decreased	1	1	0	0	1	0	0
Faecal volume increased	0	1	0	1	2	0	0
False negative pregnancy test	0	1	0	2	3	0	0
False positive investigation result	0	0	1	3	3	0	0
Female sex hormone level	0	1	0	0	1	0	0
Femoral pulse	0	1	0	0	1	0	0
Femoral pulse abnormal	0	0	0	1	1	0	0
Femoral pulse increased	0	0	0	1	1	0	0
Fibrin D dimer	0	11	1	24	35	0	0
Fibrin D dimer decreased	1	3	0	13	16	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Fibrin D dimer increased	15	789	39	959	1748	0	0
Fibrin D dimer normal	0	0	0	9	9	0	0
Fibrinolysis abnormal	0	0	0	1	1	0	0
Foetal heart rate	0	1	0	0	1	0	0
Foetal heart rate abnormal	2	3	0	0	3	0	1
Foetal heart rate decreased	1	3	0	0	3	2	4
Foetal heart rate increased	0	0	0	1	1	0	0
Forced expiratory volume	0	2	1	1	3	0	0
Forced expiratory volume decreased	0	2	0	1	3	0	0
Forced expiratory volume increased	0	13	0	1	14	0	0
Forced expiratory volume normal	0	1	0	0	1	0	0
Forced vital capacity decreased	0	2	0	0	2	0	0
Fractional exhaled nitric oxide normal	0	0	0	1	1	0	0
Full blood count	0	15	0	11	26	0	0
Full blood count abnormal	5	27	4	31	58	0	0
Full blood count decreased	1	3	0	3	6	0	0
Full blood count increased	0	1	0	0	1	0	0
Full blood count normal	0	0	0	4	4	0	0
Functional residual capacity	0	0	1	1	1	0	0
Fungal test	0	0	0	1	1	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Gamma-glutamyltransferase abnormal	0	1	0	1	2	0	0
Gamma-glutamyltransferase increased	1	10	1	17	27	0	0
Gastric pH	0	2	0	0	2	0	0
Gastric pH decreased	1	4	1	10	14	0	0
Gastric pH increased	0	0	0	2	2	0	0
Gastrointestinal stoma output increased	0	2	0	1	3	0	0
General physical condition abnormal	0	8	1	27	35	0	0
General physical condition normal	0	0	0	3	3	0	0
Glomerular filtration rate abnormal	0	1	0	0	1	0	0
Glomerular filtration rate decreased	1	7	1	10	17	0	0
Glomerular filtration rate increased	1	1	0	0	1	0	0
Glucose urine	0	1	0	1	2	0	0
Glycosylated haemoglobin increased	0	4	1	6	10	0	0
Granulocyte count increased	0	0	0	1	1	0	0
Granulocyte-colony stimulating factor level increased	0	0	0	1	1	0	0
Grip strength	0	12	0	5	17	0	0
Grip strength decreased	1	40	5	32	72	0	0
Gynaecological examination	0	0	0	1	1	0	0
HIV antibody negative	0	2	0	0	2	0	0
HIV test false positive	0	0	0	2	2	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
HIV test positive	0	2	0	0	2	0	1
HLA-B*27 positive	1	1	0	0	1	0	0
HTLV test positive	0	0	0	1	1	0	0
Haematocrit	0	9	1	3	12	0	0
Haematocrit abnormal	0	2	0	1	3	0	0
Haematocrit decreased	2	12	1	8	20	0	0
Haematocrit increased	1	7	0	9	16	0	0
Haematology test abnormal	0	1	0	3	4	0	0
Haematology test normal	0	0	0	1	1	0	0
Haemoglobin	0	6	1	5	11	0	0
Haemoglobin abnormal	2	5	0	2	7	0	0
Haemoglobin decreased	7	63	6	43	106	0	0
Haemoglobin increased	2	10	0	2	12	0	0
Haemoglobin urine	0	2	0	0	2	0	0
Haptoglobin decreased	0	0	0	1	1	0	0
Haptoglobin increased	0	0	0	1	1	0	0
Head lag	0	15	0	5	20	0	0
Head lag abnormal	0	0	0	2	2	0	0
Heart rate	9	960	6	266	1226	0	0
Heart rate abnormal	4	86	31	160	246	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Heart rate decreased	13	159	22	164	323	0	0
Heart rate increased	86	2226	447	3755	5981	0	2
Heart rate irregular	16	288	48	323	611	0	0
Heart rate normal	0	2	1	7	9	0	0
Heart rate variability decreased	0	1	0	1	2	0	0
Heart rate variability increased	0	3	0	4	7	0	0
Heart sounds	1	11	0	9	20	0	0
Heart sounds abnormal	0	7	0	6	13	0	0
Heart sounds normal	0	0	0	1	1	0	0
Heavy metal abnormal	0	0	1	1	1	0	0
Heavy metal test	0	1	0	0	1	0	0
Heel-knee-shin test abnormal	0	1	0	0	1	0	0
Helicobacter test positive	1	2	0	0	2	0	0
Heparin-induced thrombocytopenia test	0	5	0	1	6	0	0
Heparin-induced thrombocytopenia test positive	1	48	2	7	55	0	0
Hepatic enzyme abnormal	1	3	0	4	7	0	0
Hepatic enzyme increased	4	31	8	47	78	0	0
Hepatitis A virus test positive	0	0	0	1	1	0	0
Hepatitis B core antibody positive	0	1	0	0	1	0	0
Hepatitis B surface antibody positive	0	0	0	2	2	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Hepatitis B surface antigen positive	0	1	0	0	1	0	0
Hepatitis C antibody positive	0	0	0	1	1	0	0
Herpes virus test	0	1	0	0	1	0	0
High density lipoprotein decreased	0	1	0	2	3	0	0
Histamine abnormal	1	3	0	3	6	0	0
Histamine level	0	4	0	0	4	0	0
Histamine level increased	0	1	0	0	1	0	0
Homans' sign negative	0	0	0	1	1	0	0
Homans' sign positive	0	3	0	0	3	0	0
Hoover's sign of leg paresis	0	1	0	0	1	0	0
Hormone level abnormal	1	49	6	73	122	0	0
Human chorionic gonadotropin decreased	0	0	0	1	1	0	0
Human papilloma virus test negative	0	1	0	0	1	0	0
Human papilloma virus test positive	0	1	0	0	1	0	0
Hydroxycorticosteroids urine increased	0	0	1	2	2	0	0
Hypophonesis	1	2	0	0	2	0	0
Immunoglobulins abnormal	0	1	0	0	1	0	0
Immunoglobulins decreased	0	1	0	2	3	0	0
Immunology test	1	14	1	6	20	0	0
Immunology test abnormal	0	2	0	0	2	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Immunology test normal	0	0	0	1	1	0	0
Increased steroid activity	0	0	0	5	5	0	0
Infertility tests	0	1	0	0	1	0	0
Inflammation scan	1	1	0	0	1	0	0
Inflammatory marker decreased	0	0	0	1	1	0	0
Inflammatory marker increased	5	36	1	25	61	0	0
Influenza A virus test negative	0	1	0	0	1	0	0
Influenza virus test	0	0	0	1	1	0	0
Inhibiting antibodies positive	0	0	0	1	1	0	0
Inspiratory capacity decreased	0	1	0	2	3	0	0
Interferon alpha level	0	0	0	1	1	0	0
Interferon gamma release assay positive	0	3	0	1	4	0	0
Interleukin level increased	0	3	1	3	6	0	0
International normalised ratio	0	1	0	3	4	0	0
International normalised ratio abnormal	0	7	0	10	17	0	0
International normalised ratio decreased	1	36	0	40	76	0	0
International normalised ratio fluctuation	0	4	0	7	11	0	0
International normalised ratio increased	1	73	3	75	148	0	0
Intestinal transit time	0	1	0	0	1	0	0
Intestinal transit time abnormal	0	1	0	3	4	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Intestinal transit time decreased	0	1	0	1	2	0	0
Intestinal transit time increased	0	1	0	1	2	0	0
Intraocular pressure increased	2	16	2	23	39	0	0
Intraocular pressure test	0	6	2	10	16	0	0
Intraocular pressure test abnormal	0	0	0	3	3	0	0
Investigation	0	0	0	2	2	0	0
Investigation abnormal	1	1	0	0	1	0	0
Investigation normal	0	0	0	1	1	0	0
Iron binding capacity total decreased	0	1	0	0	1	0	0
Joint position sense decreased	0	2	0	0	2	0	0
Laboratory test	0	1	0	2	3	0	0
Laboratory test abnormal	3	7	3	13	20	0	0
Laboratory test normal	0	0	0	2	2	0	0
Lactate dehydrogenase urine increased	0	1	0	0	1	0	0
Laparoscopy	0	1	0	0	1	0	0
Laryngoscopy	0	1	0	0	1	0	0
Legionella test positive	0	1	0	0	1	0	0
Lipase increased	0	1	0	3	4	0	0
Lipids increased	0	0	0	1	1	0	0
Lipoprotein (a) increased	0	0	1	2	2	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Lipoprotein abnormal	0	0	0	1	1	0	0
Lipoprotein increased	0	0	0	1	1	0	0
Liver function test	0	2	0	4	6	0	0
Liver function test abnormal	3	69	0	57	126	0	0
Liver function test decreased	0	2	0	0	2	0	0
Liver function test increased	1	19	3	23	42	0	0
Liver palpable	1	1	0	0	1	0	0
Low density lipoprotein	0	0	0	1	1	0	0
Low density lipoprotein increased	1	1	1	5	6	0	0
Lumbar puncture	1	24	0	0	24	0	0
Lumbar puncture abnormal	1	1	0	0	1	0	0
Lung diffusion test abnormal	0	1	0	0	1	0	0
Lymph node palpable	0	6	3	37	43	0	0
Lymph nodes scan abnormal	0	1	0	1	2	0	0
Lymphocyte count	0	3	0	3	6	0	0
Lymphocyte count abnormal	1	2	0	2	4	0	0
Lymphocyte count decreased	4	10	2	12	22	0	0
Lymphocyte count increased	1	10	1	8	18	0	0
Lymphocyte morphology abnormal	0	0	0	1	1	0	0
Lymphocyte percentage decreased	0	0	0	1	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Magnetic resonance imaging	0	4	0	1	5	0	0
Magnetic resonance imaging abdominal	0	1	0	0	1	0	0
Magnetic resonance imaging abnormal	0	2	0	2	4	0	0
Magnetic resonance imaging head	0	38	0	15	53	0	0
Magnetic resonance imaging head abnormal	0	2	2	2	4	0	0
Magnetic resonance imaging head normal	0	1	0	0	1	0	0
Magnetic resonance imaging heart	0	2	0	0	2	0	0
Magnetic resonance imaging neck	0	1	0	0	1	0	0
Magnetic resonance imaging normal	0	0	0	1	1	0	0
Magnetic resonance imaging whole body	0	1	0	0	1	0	0
Male genital examination abnormal	0	1	0	1	2	0	0
Mammogram	0	0	0	1	1	0	0
Mast cell degranulation present	0	1	0	0	1	0	0
Maximal voluntary ventilation	0	1	0	1	2	0	0
Maximum heart rate	0	9	0	0	9	0	0
Maximum heart rate decreased	0	1	0	0	1	0	0
Maximum heart rate increased	0	2	0	1	3	0	0
Mean arterial pressure decreased	0	1	0	3	4	0	0
Mean arterial pressure increased	0	0	0	1	1	0	0
Mean cell haemoglobin concentration	0	1	0	0	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Mean cell haemoglobin concentration increased	1	1	0	0	1	0	0
Mean cell haemoglobin decreased	2	2	0	1	3	0	0
Mean cell haemoglobin increased	1	1	0	1	2	0	0
Mean cell volume abnormal	1	4	0	0	4	0	0
Mean cell volume decreased	2	2	0	2	4	0	0
Mean cell volume increased	2	2	0	0	2	0	0
Mean platelet volume decreased	0	2	1	1	3	0	0
Mean platelet volume increased	0	0	0	2	2	0	0
Measles antibody positive	0	1	0	0	1	0	0
Medical observation	0	0	0	2	2	0	0
Medication crystals in urine present	0	0	0	1	1	0	0
Megakaryocytes abnormal	0	0	0	1	1	0	0
Menstruation normal	0	3	0	15	18	0	0
Mini mental status examination	0	0	0	1	1	0	0
Modified Rankin score decreased	0	1	0	0	1	0	0
Modified Rankin score increased	0	2	0	0	2	0	0
Monoclonal immunoglobulin increased	0	1	0	1	2	0	0
Monoclonal immunoglobulin present	1	1	0	1	2	0	0
Monocyte count abnormal	1	1	0	1	2	0	0
Monocyte count decreased	0	0	0	1	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Monocyte count increased	0	4	0	6	10	0	0
Mononuclear cell count abnormal	0	0	0	1	1	0	0
Muscle enzyme increased	2	3	0	1	4	0	0
Muscle mass percentage	0	1	0	0	1	0	0
Muscle strength abnormal	3	20	7	51	71	0	0
Muscle strength normal	1	1	0	0	1	0	0
Mycoplasma test positive	0	0	0	1	1	0	0
Myocardial necrosis marker	1	2	0	0	2	0	0
Myocardial necrosis marker increased	2	5	0	0	5	0	0
Myocardial strain imaging	1	34	0	8	42	0	0
Myocardial strain imaging abnormal	0	1	0	1	2	0	0
Myoglobin blood increased	0	1	0	0	1	0	0
Myoglobin urine	0	1	0	0	1	0	0
N-terminal prohormone brain natriuretic peptide increased	0	7	1	3	10	0	0
NIH stroke scale score decreased	0	1	0	0	1	0	0
NIH stroke scale score increased	0	1	0	0	1	0	0
Natural killer cell count decreased	0	1	0	0	1	0	0
Natural killer cell count increased	0	0	0	1	1	0	0
Nerve conduction studies	0	3	0	0	3	0	0
Nerve conduction studies abnormal	0	1	0	2	3	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Nerve stimulation test abnormal	0	2	0	1	3	0	0
Neuro-ophthalmological test abnormal	1	1	0	0	1	0	0
Neurological examination	0	2	0	2	4	0	0
Neurological examination abnormal	0	4	0	4	8	0	0
Neurological examination normal	0	0	0	2	2	0	0
Neuropsychological test	0	0	0	2	2	0	0
Neurotransmitter level altered	0	1	0	0	1	0	0
Neutralising antibodies	0	0	0	2	2	0	0
Neutralising antibodies negative	0	0	0	7	7	0	0
Neutrophil count	0	3	0	3	6	0	0
Neutrophil count abnormal	1	2	0	2	4	0	0
Neutrophil count decreased	2	24	2	19	43	0	0
Neutrophil count increased	2	8	0	5	13	0	0
Neutrophil toxic granulation present	0	2	0	0	2	0	0
Nitrite urine present	1	1	0	0	1	0	0
Non-neutralising antibodies	0	0	0	1	1	0	0
Norepinephrine increased	0	2	0	2	4	0	0
Nutritional condition abnormal	0	0	1	1	1	0	0
Occult blood	0	0	0	1	1	0	0
Occult blood positive	1	1	0	0	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Oculomotor study abnormal	0	0	0	1	1	0	0
Oestradiol	0	2	0	0	2	0	0
Oestradiol decreased	0	0	0	1	1	0	0
Oestradiol increased	0	0	0	2	2	0	0
Oestriol	0	1	0	0	1	0	0
Olfactory test	0	1	0	0	1	0	0
Olfactory test abnormal	0	0	0	1	1	0	0
Ophthalmological examination	0	5	0	0	5	0	0
Ophthalmological examination abnormal	0	1	0	0	1	0	0
Ophthalmological examination normal	0	0	0	1	1	0	0
Opiates	0	0	1	1	1	0	0
Orthostatic heart rate response increased	0	1	0	0	1	0	0
Osteocalcin	0	1	0	0	1	0	0
Oxycorticosteroids increased	0	0	0	16	16	0	0
Oxygen consumption	0	1	0	2	3	0	0
Oxygen consumption decreased	0	0	0	2	2	0	0
Oxygen consumption increased	0	2	0	1	3	0	0
Oxygen saturation	2	66	3	25	91	0	0
Oxygen saturation abnormal	3	9	4	34	43	0	0
Oxygen saturation decreased	25	459	19	284	743	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Oxygen saturation increased	0	0	0	1	1	0	0
Oxygen saturation normal	1	2	0	7	9	0	0
Oxygenation index	0	0	1	3	3	0	0
PCO2 abnormal	0	2	0	0	2	0	0
PO2 abnormal	0	1	0	1	2	0	0
PO2 decreased	0	0	0	1	1	0	0
Pain assessment	0	0	0	1	1	0	0
Pain threshold decreased	0	2	0	2	4	0	0
Palpatory finding abnormal	0	1	0	1	2	0	0
Pancreatic enzymes increased	0	1	0	1	2	0	0
Paracentesis	0	0	0	1	1	0	0
Paracentesis eye	0	1	0	0	1	0	0
Paranasal biopsy	0	0	0	1	1	0	0
Pathology test	0	0	0	1	1	0	0
Peak expiratory flow rate	0	0	0	1	1	0	0
Peak expiratory flow rate abnormal	0	0	0	1	1	0	0
Peak expiratory flow rate decreased	1	7	0	4	11	0	0
Pedal pulse abnormal	0	0	0	1	1	0	0
Pedal pulse decreased	0	0	0	1	1	0	0
Plasma viscosity abnormal	0	1	0	0	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Platelet aggregation abnormal	0	1	0	5	6	0	0
Platelet aggregation test	0	1	0	0	1	0	0
Platelet count	0	8	0	9	17	0	0
Platelet count abnormal	2	10	0	12	22	0	0
Platelet count decreased	29	543	15	321	864	0	0
Platelet count increased	2	35	4	76	111	0	0
Platelet count normal	0	1	1	5	6	0	0
Platelet distribution width decreased	0	0	0	1	1	0	0
Platelet distribution width increased	0	1	0	0	1	0	0
Platelet factor 4	0	2	0	0	2	0	0
Platelet factor 4 decreased	0	1	0	0	1	0	0
Platelet factor 4 increased	0	0	0	1	1	0	0
Platelet function test abnormal	0	0	0	2	2	0	0
Platelet morphology abnormal	0	3	0	1	4	0	0
Plateletcrit	0	1	0	0	1	0	0
Plateletcrit abnormal	0	1	0	0	1	0	0
Plateletcrit decreased	0	3	1	3	6	0	0
Polymerase chain reaction	0	4	0	6	10	0	0
Polymerase chain reaction positive	1	9	0	19	28	0	0
Popliteal pulse	0	1	0	2	3	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Positron emission tomogram	0	3	0	0	3	0	0
Positron emission tomogram abnormal	0	1	0	0	1	0	0
Pregnancy test	0	4	0	12	16	0	0
Pregnancy test false positive	0	1	0	1	2	0	0
Pregnancy test negative	0	2	0	3	5	0	0
Pregnancy test positive	0	0	0	1	1	0	0
Prenatal screening test abnormal	0	0	0	0	0	0	1
Procalcitonin increased	0	4	0	0	4	0	0
Procalcitonin normal	0	0	0	1	1	0	0
Product residue present	0	2	1	2	4	0	0
Progesterone decreased	0	1	0	3	4	0	0
Prostate examination abnormal	0	0	0	1	1	0	0
Prostatic specific antigen abnormal	0	0	0	2	2	0	0
Prostatic specific antigen decreased	0	1	1	2	3	0	0
Prostatic specific antigen increased	0	8	1	12	20	0	0
Protein C decreased	0	0	0	1	1	0	0
Protein C increased	0	4	2	5	9	0	0
Protein S abnormal	0	1	0	0	1	0	0
Protein total	0	2	0	0	2	0	0
Protein total abnormal	0	2	0	3	5	0	1

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Protein total decreased	1	1	0	2	3	0	0
Protein total increased	0	2	0	3	5	0	0
Protein urine	0	6	0	3	9	0	0
Protein urine present	2	5	0	1	6	0	0
Prothrombin level	0	0	0	1	1	0	0
Prothrombin level abnormal	0	1	1	1	2	0	0
Prothrombin level decreased	0	0	0	2	2	0	0
Prothrombin level increased	0	3	0	4	7	0	0
Prothrombin level normal	0	0	1	1	1	0	0
Prothrombin time	0	3	0	1	4	0	0
Prothrombin time abnormal	0	1	0	0	1	0	0
Prothrombin time prolonged	0	4	0	2	6	0	0
Prothrombin time ratio abnormal	0	0	0	1	1	0	0
Prothrombin time ratio increased	0	0	0	1	1	0	0
Prothrombin time shortened	0	4	1	4	8	0	0
Psoriasis area severity index decreased	0	0	0	1	1	0	0
Psoriasis area severity index increased	0	1	0	0	1	0	0
Psychiatric evaluation abnormal	0	0	0	1	1	0	0
Pulmonary arterial pressure abnormal	0	1	0	2	3	0	0
Pulmonary arterial pressure increased	0	2	0	0	2	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Pulmonary function test	0	5	0	1	6	0	0
Pulmonary function test abnormal	0	1	0	1	2	0	0
Pulmonary function test decreased	2	13	4	18	31	0	0
Pulmonary imaging procedure abnormal	0	1	0	0	1	0	0
Pulse abnormal	4	45	29	141	186	0	0
Pulse absent	0	15	0	0	15	0	0
Pulse pressure abnormal	0	0	0	2	2	0	0
Pulse pressure decreased	0	2	0	0	2	0	0
Pulse pressure increased	0	3	1	10	13	0	0
Pulse waveform abnormal	0	0	0	1	1	0	0
Pupillary light reflex tests abnormal	0	6	0	2	8	0	0
Pupillary light reflex tests normal	0	1	0	0	1	0	0
Pus in stool	0	1	0	0	1	0	0
QRS axis abnormal	2	4	0	0	4	0	0
Quality of life decreased	6	13	3	23	36	0	0
Quantitative sensory testing	0	0	0	1	1	0	0
Radial pulse	0	0	0	1	1	0	0
Red blood cell Heinz bodies present	0	2	0	3	5	0	0
Red blood cell count	0	1	1	5	6	0	0
Red blood cell count abnormal	1	1	1	1	2	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Red blood cell count decreased	3	14	1	9	23	0	1
Red blood cell count increased	1	5	1	9	14	0	0
Red blood cell elliptocytes present	0	1	0	0	1	0	0
Red blood cell morphology abnormal	0	2	0	0	2	0	0
Red blood cell sedimentation rate	0	1	0	0	1	0	0
Red blood cell sedimentation rate abnormal	0	2	0	8	10	0	0
Red blood cell sedimentation rate increased	4	34	4	37	71	0	0
Red blood cell target cells present	0	1	0	0	1	0	0
Red blood cells urine	0	1	0	0	1	0	0
Red blood cells urine positive	1	2	0	2	4	0	0
Red cell distribution width decreased	1	1	0	0	1	0	0
Red cell distribution width increased	1	2	0	1	3	0	0
Renal function test abnormal	0	1	1	5	6	0	0
Renin decreased	1	1	0	0	1	0	0
Reproductive hormone	0	1	0	0	1	0	0
Respiratory rate	1	10	0	5	15	0	0
Respiratory rate decreased	0	29	3	25	54	0	0
Respiratory rate increased	9	104	17	129	233	0	0
Respiratory sinus arrhythmia magnitude increased	0	1	0	0	1	0	0
Retinal function test abnormal	0	1	0	0	1	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Rhesus antigen negative	0	1	0	0	1	0	0
Rheumatoid factor	0	3	0	1	4	0	0
Rheumatoid factor increased	0	3	1	11	14	0	0
Rheumatoid factor negative	0	0	0	1	1	0	0
Rheumatoid factor positive	0	1	0	2	3	0	0
Romberg test positive	0	4	0	4	8	0	0
SARS-CoV-1 test negative	0	0	0	3	3	0	0
SARS-CoV-1 test positive	0	0	0	6	6	0	0
SARS-CoV-2 RNA	0	0	0	1	1	0	0
SARS-CoV-2 antibody test	0	10	1	34	44	0	0
SARS-CoV-2 antibody test negative	0	19	29	674	693	0	0
SARS-CoV-2 antibody test positive	0	5	2	46	51	0	0
SARS-CoV-2 test	0	28	3	33	61	0	0
SARS-CoV-2 test false negative	0	5	0	3	8	0	0
SARS-CoV-2 test false positive	1	3	0	3	6	0	0
SARS-CoV-2 test negative	2	54	1	191	245	0	0
SARS-CoV-2 test positive	9	229	126	1115	1344	0	0
Scan	0	2	0	0	2	0	0
Scan brain	1	2	0	0	2	0	0
Scan lymph nodes	0	2	0	0	2	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Scan myocardial perfusion abnormal	0	1	0	0	1	0	0
Semen analysis abnormal	0	1	0	1	2	0	0
Semen viscosity increased	0	0	1	1	1	0	0
Semen volume decreased	0	2	2	3	5	0	0
Semen volume increased	0	0	0	1	1	0	0
Sensory level	0	1	0	0	1	0	0
Sensory level abnormal	1	20	3	63	83	0	0
Septic screen	0	1	0	0	1	0	0
Seroconversion test negative	0	0	0	1	1	0	0
Serology positive	0	0	0	1	1	0	0
Serology test	0	1	0	2	3	0	0
Serum ferritin	0	1	0	0	1	0	0
Serum ferritin abnormal	0	0	0	1	1	0	0
Serum ferritin decreased	0	7	2	11	18	0	0
Serum ferritin increased	0	15	0	14	29	0	0
Serum serotonin increased	0	0	0	1	1	0	0
Sinus rhythm	3	8	0	4	12	0	0
Skin temperature	0	146	0	35	181	0	0
Skin test	0	0	1	1	1	0	0
Skin test positive	0	3	0	9	12	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Skin turgor decreased	0	2	0	2	4	0	0
Skull X-ray	0	10	0	0	10	0	0
Sleep study normal	0	1	0	0	1	0	0
Slow vital capacity	0	1	0	1	2	0	0
Smear cervix	0	0	0	2	2	0	0
Smear cervix abnormal	0	1	0	0	1	0	0
Smear test	0	2	1	1	3	0	0
Smooth muscle antibody	0	1	0	0	1	0	0
Specific gravity urine abnormal	0	0	0	1	1	0	0
Specific gravity urine decreased	1	1	0	0	1	0	0
Sperm analysis abnormal	0	0	0	1	1	0	0
Sperm concentration	0	1	0	0	1	0	0
Spermatozoa abnormal	0	1	0	2	3	0	0
Spinal myelogram	0	0	0	1	1	0	0
Spleen palpable	0	1	0	0	1	0	0
Sputum abnormal	0	2	0	3	5	0	0
Sputum culture positive	0	0	1	1	1	0	0
Staphylococcus test positive	0	2	0	0	2	0	0
Steroid activity	0	0	0	1	1	0	0
Stomach scan	0	1	0	0	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Stool analysis abnormal	0	2	0	0	2	0	0
Streptococcus test positive	0	3	0	0	3	0	0
Stroke volume decreased	0	1	0	1	2	0	0
Stroke volume increased	0	3	0	0	3	0	0
Sulphur dioxide test	0	0	0	1	1	0	0
Swallow study	0	0	0	3	3	0	0
Sweat test	0	1	0	3	4	0	0
Swollen joint count	0	2	0	1	3	0	0
Swollen joint count increased	0	4	0	1	5	0	0
T-lymphocyte count increased	0	1	0	0	1	0	0
Tartrate-resistant acid phosphatase decreased	0	1	0	0	1	0	0
Temperature difference of extremities	1	6	1	13	19	0	0
Temperature perception test abnormal	0	0	0	3	3	0	0
Temperature perception test decreased	0	0	0	1	1	0	0
Temperature perception test increased	0	1	0	8	9	0	0
Tender joint count	0	3	0	1	4	0	0
Tender joint count decreased	0	0	0	1	1	0	0
Thrombin time	0	1	0	0	1	0	0
Thrombin time abnormal	0	0	0	2	2	0	0
Thyroid function test	0	1	0	0	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Thyroid function test abnormal	1	7	0	5	12	0	0
Thyroid hormones increased	2	2	1	4	6	0	0
Thyroxine	0	2	0	0	2	0	0
Thyroxine abnormal	0	1	0	0	1	0	0
Thyroxine free decreased	0	1	0	2	3	0	0
Thyroxine free increased	0	1	0	3	4	0	0
Thyroxine increased	0	1	0	4	5	0	0
Total lung capacity abnormal	1	1	0	0	1	0	0
Total lung capacity decreased	0	6	3	16	22	0	0
Transaminases	0	0	0	2	2	0	0
Transaminases abnormal	1	3	0	1	4	0	0
Transaminases increased	2	22	1	19	41	0	0
Transferrin decreased	0	1	0	1	2	0	0
Transferrin saturation decreased	0	1	0	0	1	0	0
Treponema test positive	0	0	0	1	1	0	0
Tri-iodothyronine	0	0	0	1	1	0	0
Tri-iodothyronine decreased	0	8	0	4	12	0	0
Tri-iodothyronine increased	0	0	1	1	1	0	0
Troponin	0	6	0	3	9	0	0
Troponin I	0	1	0	0	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Troponin I abnormal	0	1	0	0	1	0	0
Troponin I increased	0	9	1	6	15	0	0
Troponin I normal	0	1	0	0	1	0	0
Troponin T	0	1	0	1	2	0	0
Troponin T increased	2	7	0	2	9	0	0
Troponin abnormal	0	4	0	8	12	0	0
Troponin decreased	0	1	0	0	1	0	0
Troponin increased	2	94	4	64	158	0	0
Troponin normal	0	0	0	2	2	0	0
Tryptase	0	0	0	1	1	0	0
Tryptase increased	1	2	0	1	3	0	0
Tumour marker increased	1	3	0	1	4	0	0
Ubiquinone	0	0	0	4	4	0	0
Ubiquinone decreased	0	0	0	2	2	0	0
Ultrasound Doppler	0	1	0	2	3	0	0
Ultrasound Doppler abnormal	0	0	0	3	3	1	1
Ultrasound kidney	0	1	0	0	1	0	0
Ultrasound liver abnormal	0	0	0	1	1	0	0
Ultrasound scan	0	1	0	1	2	0	0
Ultrasound scan abnormal	0	0	1	2	2	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Ultrasound scan vagina abnormal	0	1	0	0	1	0	0
Ultrasound scan vagina normal	0	0	0	1	1	0	0
Unevaluable investigation	0	1	0	0	1	0	0
Urea urine increased	0	1	0	0	1	0	0
Urinary casts	0	1	0	0	1	0	0
Urinary occult blood	0	0	0	1	1	0	0
Urinary sediment	0	0	0	1	1	0	0
Urine analysis	0	1	0	0	1	0	0
Urine analysis abnormal	1	15	0	22	37	0	0
Urine analysis normal	0	2	0	2	4	0	0
Urine bilirubin increased	0	1	0	0	1	0	0
Urine copper	0	2	0	0	2	0	0
Urine ketone body present	1	3	0	1	4	0	0
Urine output	1	39	0	15	54	0	0
Urine output decreased	2	20	0	13	33	0	0
Urine output increased	0	12	2	30	42	0	0
Urine uric acid increased	0	0	0	1	1	0	0
Urobilinogen urine increased	1	1	0	0	1	0	0
Urological examination	0	1	0	0	1	0	0
Vaccine induced antibody absent	2	2	1	1	3	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Varicella virus test positive	0	2	0	0	2	0	0
Vascular resistance systemic decreased	0	0	0	1	1	0	0
Venogram	0	1	0	2	3	0	0
Venous oxygen saturation	0	1	0	0	1	0	0
Venous oxygen saturation decreased	0	1	1	2	3	0	0
Venous pressure	1	1	1	2	3	0	0
Venous pressure increased	0	1	0	0	1	0	0
Venous pressure jugular	0	0	0	1	1	0	0
Venous pressure jugular increased	0	1	0	0	1	0	0
Ventilation/perfusion scan	0	1	0	0	1	0	0
Ventilation/perfusion scan abnormal	0	3	0	0	3	0	0
Very low density lipoprotein decreased	0	1	0	0	1	0	0
Vibration test abnormal	0	0	1	1	1	0	0
Viral load	0	1	0	1	2	0	0
Viral load decreased	0	0	1	1	1	0	0
Viral test	1	5	0	0	5	0	0
Viral test negative	0	0	0	1	1	0	0
Viral test positive	0	3	0	2	5	0	0
Visual acuity tests abnormal	1	2	0	0	2	0	0
Visual analogue scale	0	1	0	0	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Visual field tests abnormal	0	1	0	0	1	0	0
Visual field tests normal	0	1	0	0	1	0	0
Visual tracking test	0	1	0	0	1	0	0
Vital capacity decreased	0	1	0	1	2	0	0
Vital functions abnormal	0	1	0	1	2	0	0
Vital signs measurement	0	2	0	1	3	0	0
Vitamin B12	0	2	0	1	3	0	0
Vitamin B12 abnormal	0	3	0	1	4	0	0
Vitamin B12 decreased	2	9	1	5	14	0	0
Vitamin B12 increased	0	1	0	0	1	0	0
Vitamin B6 increased	0	0	0	1	1	0	0
Vitamin D	0	4	0	1	5	0	0
Vitamin D abnormal	0	0	0	1	1	0	0
Vitamin D decreased	2	9	1	10	19	0	0
Vitamin D increased	0	0	0	1	1	0	0
Vitamin E decreased	0	0	0	1	1	0	0
Volume blood	0	5	0	2	7	0	0
Volume blood increased	0	0	0	1	1	0	0
Weight	0	1	0	0	1	0	0
Weight abnormal	1	1	0	3	4	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Weight decreased	59	421	68	433	854	0	0
Weight increased	28	106	28	132	238	0	0
White blood cell analysis abnormal	0	1	0	0	1	0	0
White blood cell count	0	15	0	11	26	0	0
White blood cell count abnormal	1	2	0	5	7	0	0
White blood cell count decreased	0	34	4	52	86	0	0
White blood cell count increased	3	35	1	34	69	0	0
White blood cell count normal	0	0	0	2	2	0	0
White blood cells urine positive	2	4	0	2	6	0	0
X-ray	0	1	0	1	2	0	0
X-ray abnormal	0	2	0	0	2	0	0
X-ray limb	0	2	0	0	2	0	0
X-ray limb abnormal	0	1	0	0	1	0	0
X-ray of pelvis and hip	0	2	0	0	2	0	0
Xanthochromia	0	1	0	0	1	0	0
Zinc sulphate turbidity increased	0	1	0	0	1	0	0
pH urine	1	6	0	7	13	0	0
pH urine decreased	0	2	0	0	2	0	0
pH urine increased	0	2	0	1	3	0	0
Injury, poisoning and procedural complications	**594**	**8528**	**1335**	**14574**	**23102**	**44**	**109**

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Abdomen crushing	1	4	0	0	4	0	0
Abdominal injury	0	1	0	0	1	0	0
Accident	0	3	0	4	7	0	0
Accident at home	0	0	0	1	1	0	0
Accident at work	1	2	1	2	4	0	0
Accidental exposure to product	0	20	4	35	55	0	0
Accidental exposure to product packaging	0	0	0	1	1	0	0
Accidental overdose	1	4	0	13	17	0	0
Accidental underdose	0	1	0	4	5	0	0
Administration related reaction	0	0	0	5	5	0	0
Adverse event following immunisation	6	124	10	126	250	1	1
Airway burns	0	1	0	1	2	0	0
Airway complication of anaesthesia	0	1	0	0	1	0	0
Alcohol poisoning	0	2	0	4	6	0	0
Anaesthetic complication	0	2	0	1	3	0	0
Anaesthetic complication neurological	0	2	0	0	2	0	0
Anastomotic ulcer	0	1	0	0	1	0	0
Animal bite	2	3	1	9	12	0	0
Animal scratch	0	0	0	1	1	0	0
Ankle fracture	2	9	1	9	18	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Aortic injury	0	1	0	0	1	0	0
Aortic pseudoaneurysm	0	0	0	1	1	0	0
Arterial injury	0	2	0	1	3	0	0
Arteriovenous fistula thrombosis	0	3	0	0	3	0	0
Arteriovenous graft thrombosis	0	0	0	0	0	1	1
Arthropod bite	1	4	1	12	16	0	0
Arthropod sting	3	17	2	11	28	0	0
Asbestosis	0	1	0	0	1	0	0
Atypical femur fracture	0	1	0	0	1	0	0
Auricular haematoma	0	1	0	2	3	0	0
Autonomic dysreflexia	0	1	0	1	2	0	0
Axillary nerve injury	0	1	0	2	3	0	0
Axillary web syndrome	0	2	0	3	5	0	0
Back injury	3	8	1	6	14	0	0
Barotitis media	0	0	0	1	1	0	0
Barotrauma	0	1	0	1	2	0	0
Bite	0	0	2	11	11	0	0
Bladder injury	0	2	0	0	2	0	0
Bone contusion	2	4	1	3	7	0	0
Bone fragmentation	0	0	0	1	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Booster dose missed	0	0	0	9	9	0	0
Brachial plexus injury	0	3	0	0	3	0	0
Brain contusion	0	20	0	0	20	0	0
Brain herniation	4	23	0	0	23	0	1
Breast injury	0	0	0	1	1	0	0
Burn oesophageal	0	3	0	4	7	0	0
Burn of internal organs	0	4	0	1	5	0	0
Burn oral cavity	0	6	0	8	14	0	0
Burns first degree	0	0	0	2	2	0	0
Burns second degree	0	4	0	6	10	0	0
Bursa injury	1	3	0	0	3	0	0
Cardiac procedure complication	0	1	0	0	1	0	0
Cartilage injury	1	4	0	0	4	1	1
Cataract traumatic	0	1	0	0	1	0	0
Central cord syndrome	0	2	0	0	2	0	0
Central nervous system injury	0	1	0	0	1	0	0
Cerebral ventricle collapse	0	1	0	0	1	0	0
Cervical vertebral fracture	0	2	0	0	2	0	0
Cervix injury	0	1	0	0	1	0	0
Chemical burn	0	2	0	0	2	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Chemical burn of oral cavity	0	1	0	1	2	0	0
Chemical burn of skin	0	4	0	2	6	0	0
Chemical phlebitis	0	0	0	2	2	0	0
Chemical poisoning	0	1	0	1	2	0	0
Chest crushing	0	17	0	2	19	0	0
Chest injury	0	6	0	1	7	0	0
Child maltreatment syndrome	0	0	0	1	1	0	0
Chillblains	2	41	3	98	139	0	0
Circumstance or information capable of leading to medication error	0	4	1	91	95	0	0
Clavicle fracture	0	23	0	6	29	0	0
Cold burn	0	3	0	0	3	0	0
Cold exposure injury	0	0	0	2	2	0	0
Colon injury	0	2	0	0	2	0	0
Compensatory sweating	0	0	0	2	2	0	0
Complications of transplant surgery	0	0	0	1	1	0	0
Complications of transplanted kidney	0	1	0	0	1	0	0
Complications of transplanted pancreas	0	1	0	0	1	0	0
Compression fracture	1	1	1	1	2	0	0
Concussion	4	21	0	9	30	0	0
Contraindicated product administered	0	3	0	3	6	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Contraindicated product prescribed	0	8	0	2	10	0	0
Contusion	75	2281	609	4047	6328	0	1
Corneal abrasion	0	1	0	0	1	0	0
Coronary artery restenosis	0	1	0	0	1	0	0
Coronary bypass thrombosis	0	1	0	0	1	0	0
Counterfeit product administered	0	0	0	1	1	0	0
Cranial nerve injury	0	0	0	2	2	0	0
Craniocerebral injury	2	21	0	0	21	0	0
Deafness traumatic	0	0	0	1	1	0	0
Decerebration	0	1	0	0	1	0	0
Decompression sickness	0	1	0	1	2	0	0
Deep vein thrombosis postoperative	0	1	0	0	1	0	0
Delayed effects of radiation	0	0	1	1	1	0	0
Delayed recovery from anaesthesia	0	4	0	1	5	0	0
Dental restoration failure	0	0	0	2	2	0	0
Dermal filler overcorrection	0	1	0	0	1	0	0
Dermal filler reaction	0	0	3	4	4	0	0
Device dispensing error	0	0	0	1	1	0	0
Device use confusion	0	0	0	1	1	0	0
Device use error	0	0	0	2	2	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Device use issue	0	1	1	2	3	0	0
Diffuse axonal injury	0	1	0	0	1	0	0
Dislocation of vertebra	0	1	0	0	1	0	0
Documented hypersensitivity to administered product	0	0	0	1	1	0	0
Dose calculation error	0	1	0	7	8	0	0
Drug administered in wrong device	0	1	0	0	1	0	0
Drug exposure before pregnancy	1	2	0	2	4	0	0
Drug monitoring procedure not performed	0	0	0	1	1	0	0
Drug titration error	2	2	0	1	3	0	0
Duplicate therapy error	0	0	0	1	1	0	0
Dysphotopsia	0	0	0	1	1	0	0
Ear canal injury	2	2	0	1	3	0	0
Electric shock	3	30	1	14	44	0	0
Electrical burn	0	1	0	0	1	0	0
Environmental exposure	0	0	0	1	1	0	0
Epicondylitis	2	26	2	27	53	0	0
Epidural haemorrhage	0	1	0	0	1	0	0
Eschar	0	0	1	2	2	0	0
Expired product administered	0	23	15	168	191	0	0
Exposure during pregnancy	7	154	26	461	615	4	9

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Exposure to SARS-CoV-2	0	6	0	19	25	0	0
Exposure to chemical pollution	0	0	0	2	2	0	0
Exposure to communicable disease	1	2	1	5	7	0	0
Exposure to contaminated device	0	1	0	0	1	0	0
Exposure to extreme temperature	0	6	0	4	10	0	0
Exposure to household chemicals	0	0	0	1	1	0	0
Exposure to noise	0	2	0	0	2	0	0
Exposure to toxic agent	0	0	0	1	1	0	0
Exposure to vaccinated person	0	3	0	1	4	0	0
Exposure to violent event	0	1	0	0	1	0	0
Exposure via body fluid	0	1	0	0	1	0	0
Exposure via breast milk	1	65	6	128	193	0	0
Exposure via direct contact	0	0	0	1	1	0	0
Exposure via partner	0	1	0	0	1	0	0
Exposure via unknown route	0	0	0	1	1	0	0
Extra dose administered	0	3	1	28	31	0	0
Extradural haematoma	1	5	0	0	5	0	0
Extraskeletal ossification	0	1	0	1	2	0	0
Eye contusion	0	30	4	55	85	0	0
Eye injury	2	60	2	49	109	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Eye laser scar	0	0	0	1	1	0	0
Eye luxation	0	3	0	0	3	0	0
Eyeball avulsion	0	0	0	2	2	0	0
Eyelid abrasion	0	0	1	1	1	0	0
Eyelid contusion	0	4	1	6	10	0	0
Eyelid injury	0	0	0	1	1	0	0
Face crushing	0	1	0	0	1	0	0
Face injury	1	8	2	7	15	0	0
Facial bones fracture	1	1	0	0	1	0	0
Fall	41	545	41	422	967	0	0
Fat adherence syndrome	0	0	0	1	1	0	0
Femoral neck fracture	1	4	0	0	4	0	0
Femur fracture	1	11	0	0	11	0	0
Flail chest	0	1	0	0	1	0	0
Foetal exposure during pregnancy	2	55	1	16	71	9	30
Foot fracture	0	7	0	9	16	0	0
Foreign body	0	2	0	3	5	0	0
Foreign body in eye	0	2	0	0	2	0	0
Foreign body in respiratory tract	0	1	0	0	1	0	0
Foreign body in throat	0	3	0	4	7	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Fracture	1	11	7	31	42	0	0
Fracture displacement	0	0	0	1	1	0	0
Frostbite	0	1	1	17	18	0	0
Gastrointestinal injury	0	0	0	1	1	0	0
Gastrointestinal stoma complication	1	2	0	0	2	0	0
Genital injury	0	0	0	1	1	0	0
Gingival injury	0	0	0	3	3	0	0
Graft thrombosis	0	1	0	0	1	0	0
Hair injury	0	2	0	2	4	0	0
Hand fracture	0	2	0	0	2	0	0
Head and neck procedural complication	0	1	0	0	1	0	0
Head injury	5	85	5	40	125	0	0
Heat cramps	0	2	0	1	3	0	0
Heat exhaustion	0	3	0	6	9	0	0
Heat illness	0	4	1	10	14	0	0
Heat oedema	0	8	0	10	18	0	0
Heat stroke	0	11	7	35	46	0	0
Heavy exposure to ultraviolet light	0	1	0	0	1	0	0
Hip fracture	2	5	0	0	5	0	0
Humerus fracture	0	4	0	1	5	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Hyphaema	0	0	0	4	4	0	0
Hypobarism	0	2	0	1	3	0	0
Inadequate aseptic technique in use of product	0	1	0	1	2	0	0
Inappropriate schedule of product administration	35	51	23	754	805	0	0
Incision site discharge	1	1	0	0	1	0	0
Incision site erythema	0	0	0	1	1	0	0
Incision site haemorrhage	0	0	0	2	2	0	0
Incision site oedema	0	0	0	1	1	0	0
Incision site pain	0	4	0	9	13	0	0
Incision site pruritus	0	0	0	2	2	0	0
Incision site swelling	0	0	1	3	3	0	0
Incisional hernia	0	1	0	0	1	0	0
Incomplete course of vaccination	0	11	7	230	241	0	0
Incorrect dosage administered	0	0	0	12	12	0	0
Incorrect dose administered	2	19	7	242	261	0	0
Incorrect dose administered by device	0	0	1	2	2	0	0
Incorrect dose administered by product	0	0	0	2	2	0	0
Incorrect product administration duration	1	1	0	6	7	0	0
Incorrect product dosage form administered	0	1	0	1	2	0	0
Incorrect product formulation administered	0	0	0	2	2	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Incorrect route of product administration	5	51	9	607	658	0	0
Inflammation of wound	0	6	0	4	10	0	0
Infusion related reaction	16	31	1	16	47	0	0
Injection related reaction	4	513	11	186	699	0	0
Injury	7	49	7	67	116	0	0
Injury corneal	1	2	0	0	2	0	0
Injury to brachial plexus due to birth trauma	1	1	0	0	1	0	0
Intentional device misuse	0	0	0	1	1	0	0
Intentional dose omission	3	4	3	145	149	0	0
Intentional overdose	0	15	0	1	16	0	0
Intentional product misuse	1	2	3	92	94	0	0
Intentional product use issue	3	3	1	11	14	0	0
Intentional underdose	1	1	0	2	3	0	0
Intercepted medication error	0	1	0	37	38	0	0
Intercepted product administration error	0	1	0	2	3	0	0
Intercepted product storage error	0	0	0	20	20	0	0
Internal injury	0	0	0	1	1	0	0
Intoxication by breast feeding	0	0	0	1	1	0	0
Ischaemic contracture of the left ventricle	0	1	0	0	1	0	0
Jaw fracture	0	1	0	1	2	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Joint dislocation	5	38	0	0	38	0	0
Joint injury	1	19	3	37	56	0	0
Kidney rupture	0	3	0	0	3	0	0
Labelled drug-drug interaction issue	1	1	0	1	2	0	0
Labelled drug-drug interaction medication error	1	2	0	0	2	0	0
Lack of vaccination site rotation	0	1	0	0	1	0	0
Lacrimal structure injury	0	1	0	0	1	0	0
Ligament injury	1	5	1	1	6	1	1
Ligament rupture	0	2	1	2	4	0	0
Ligament sprain	3	30	4	29	59	0	0
Limb crushing injury	0	12	0	0	12	0	0
Limb injury	13	339	11	135	474	0	0
Lip injury	1	5	1	5	10	0	0
Liver contusion	0	1	0	1	2	0	0
Lower limb fracture	1	7	0	6	13	0	0
Lumbar vertebral fracture	2	5	0	0	5	0	0
Lymphatic duct injury	0	0	0	1	1	0	0
Maternal exposure before pregnancy	0	14	3	17	31	1	1
Maternal exposure during breast feeding	7	974	15	779	1753	0	1
Maternal exposure during pregnancy	19	428	15	249	677	25	60

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Maternal exposure timing unspecified	3	7	0	6	13	0	0
Maternal exposure via partner during pregnancy	0	0	1	1	1	0	0
Median nerve injury	0	2	0	0	2	0	0
Medication error	41	128	10	456	584	0	0
Meniscus injury	1	2	1	3	5	1	1
Metal fume fever	0	0	0	1	1	0	0
Metal poisoning	0	2	0	0	2	0	0
Metallosis of globe	0	0	0	1	1	0	0
Mouth injury	0	3	2	16	19	0	0
Multiple fractures	2	9	0	6	15	0	0
Multiple injuries	1	5	1	8	13	0	0
Muscle contusion	0	0	0	1	1	0	0
Muscle injury	3	63	0	23	86	0	0
Muscle rupture	2	31	0	15	46	0	0
Muscle strain	4	59	9	124	183	0	0
Musculoskeletal injury	0	1	0	2	3	0	0
Nail avulsion	0	0	0	1	1	0	0
Nail injury	0	0	0	3	3	0	0
Nasal injury	0	3	0	8	11	0	0
Neck crushing	0	1	0	0	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Neck injury	1	4	0	1	5	0	0
Needle fatigue	0	1	0	1	2	0	0
Nerve injury	12	225	4	69	294	0	0
Nerve root injury	1	1	0	0	1	0	0
Nervous system injury	0	7	0	0	7	0	0
Occupational exposure to product	0	3	0	6	9	0	0
Ocular procedural complication	0	0	0	3	3	0	0
Off label use	46	120	221	1611	1731	0	0
Open fracture	0	1	0	0	1	0	0
Optic nerve injury	1	23	0	0	23	0	0
Oral contusion	0	7	6	34	41	0	0
Osteochondral fracture	0	0	1	1	1	0	0
Ovarian injury	0	1	0	0	1	0	0
Overdose	0	41	0	88	129	0	0
Palate injury	0	1	0	7	8	0	0
Parasympathetic nerve injury	0	0	0	1	1	0	0
Patella fracture	0	2	0	0	2	0	0
Paternal exposure before pregnancy	0	1	0	2	3	0	0
Paternal exposure during pregnancy	0	5	0	3	8	0	0
Pelvic bone injury	0	1	0	0	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Pelvic fracture	2	3	0	0	3	0	0
Penile contusion	0	1	0	2	3	0	0
Penis injury	0	1	0	1	2	0	0
Periorbital haematoma	0	1	1	15	16	0	0
Periorbital haemorrhage	1	4	3	17	21	0	0
Peripancreatic fluid collection	0	1	0	0	1	0	0
Peripheral nerve injury	0	2	0	2	4	0	0
Peroneal nerve injury	0	0	0	1	1	0	0
Persistent corneal epithelial defect	0	1	0	0	1	0	0
Pharyngeal contusion	0	3	0	1	4	0	0
Pharyngeal injury	0	0	0	9	9	0	0
Poisoning	2	10	1	12	22	0	0
Poor quality product administered	0	3	1	7	10	0	0
Post concussion syndrome	0	2	0	1	3	0	0
Post lumbar puncture syndrome	1	12	0	6	18	0	0
Post procedural complication	2	29	3	18	47	0	0
Post procedural contusion	1	2	0	1	3	0	0
Post procedural diarrhoea	0	0	0	2	2	0	0
Post procedural discomfort	0	0	0	2	2	0	0
Post procedural fever	0	0	0	2	2	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Post procedural fistula	0	0	0	1	1	0	0
Post procedural haematoma	0	0	0	1	1	0	0
Post procedural haemorrhage	0	4	1	4	8	0	0
Post procedural hypothyroidism	1	1	0	0	1	0	0
Post procedural stroke	0	7	0	1	8	0	0
Post vaccination syndrome	20	29	11	23	52	0	0
Post-traumatic neck syndrome	0	4	1	3	7	0	0
Post-traumatic pain	0	0	1	5	5	0	0
Post-traumatic punctate intraepidermal haemorrhage	0	0	0	1	1	0	0
Posterior fossa syndrome	0	1	0	0	1	0	0
Postmastectomy lymphoedema syndrome	0	1	0	0	1	0	0
Postoperative thrombosis	0	1	0	0	1	0	0
Postoperative wound complication	0	2	0	0	2	0	0
Prescribed overdose	0	0	0	1	1	0	0
Prescribed underdose	2	3	0	3	6	0	0
Prescription drug used without a prescription	0	2	0	0	2	0	0
Prevertebral soft tissue swelling of cervical space	0	1	0	1	2	0	0
Procedural complication	0	0	0	1	1	0	0
Procedural dizziness	0	29	0	12	41	0	0
Procedural haemorrhage	1	3	0	1	4	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Procedural headache	0	0	0	18	18	0	0
Procedural hypertension	0	1	0	0	1	0	0
Procedural intestinal perforation	0	1	0	0	1	0	0
Procedural nausea	0	26	2	14	40	0	0
Procedural pain	1	10	1	25	35	0	0
Procedural pneumothorax	0	1	0	0	1	0	0
Procedural site reaction	0	1	0	2	3	0	0
Procedural vomiting	0	4	0	10	14	0	0
Product administered at inappropriate site	1	43	2	75	118	0	0
Product administered to patient of inappropriate age	3	9	21	173	182	0	0
Product administration error	1	17	12	211	228	0	0
Product administration interrupted	0	0	0	1	1	0	0
Product communication issue	0	0	0	3	3	0	0
Product confusion	0	0	0	2	2	0	0
Product dispensing error	0	11	0	7	18	0	0
Product dose omission in error	0	0	1	15	15	0	0
Product dose omission issue	17	22	10	278	300	0	0
Product label confusion	0	0	0	1	1	0	0
Product monitoring error	0	1	0	3	4	0	0
Product name confusion	0	1	0	1	2	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Product packaging confusion	0	0	0	2	2	0	0
Product preparation error	0	0	0	4	4	0	0
Product preparation issue	2	2	0	6	8	0	0
Product prescribing error	1	2	0	10	12	0	0
Product prescribing issue	0	0	0	1	1	0	0
Product selection error	0	0	0	2	2	0	0
Product storage error	2	2	0	76	78	0	0
Product substitution error	0	0	0	1	1	0	0
Product use complaint	0	0	1	1	1	0	0
Product use in unapproved indication	1	3	0	5	8	0	0
Product use issue	6	15	2	54	69	0	0
Pulmonary oil microembolism	0	2	0	0	2	0	0
Radial nerve injury	0	5	0	1	6	0	0
Radiation associated pain	0	0	0	1	1	0	0
Radiation injury affecting foetus	0	0	0	1	1	0	0
Radius fracture	0	3	0	2	5	0	0
Reaction to previous exposure to any vaccine	0	1	0	1	2	0	0
Reactive gastropathy	0	1	0	1	2	0	0
Recall phenomenon	0	2	1	3	5	0	0
Rectal injury	0	0	0	1	1	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Recurrence of neuromuscular blockade	0	2	0	0	2	0	0
Repetitive strain injury	0	3	0	0	3	0	0
Restenosis	0	1	0	0	1	0	0
Retinal injury	0	9	0	3	12	0	0
Rib fracture	3	17	3	11	28	0	0
Road traffic accident	6	24	0	4	28	0	0
Scar	2	41	6	36	77	0	0
Sciatic nerve injury	0	1	1	2	3	0	0
Scratch	2	3	1	21	24	0	0
Scrotal injury	0	1	0	0	1	0	0
Sedation complication	0	4	0	1	5	0	0
Seroma	0	0	1	4	4	0	0
Shunt thrombosis	0	1	0	0	1	0	0
Skeletal injury	1	5	0	7	12	0	0
Skin abrasion	0	5	5	26	31	0	0
Skin injury	2	25	2	20	45	0	0
Skin laceration	0	11	2	9	20	0	0
Skin pressure mark	0	0	0	3	3	0	0
Skin procedural complication	0	1	0	0	1	0	0
Skin wound	2	9	3	15	24	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Skull fracture	1	7	0	0	7	0	0
Skull fractured base	0	2	0	0	2	0	0
Snake bite	0	0	0	1	1	0	0
Soft tissue foreign body	0	0	0	1	1	0	0
Soft tissue injury	0	6	0	2	8	0	0
Spinal column injury	3	6	0	0	6	0	0
Spinal compression fracture	0	6	0	4	10	0	0
Spinal cord injury	1	11	0	0	11	0	0
Spinal cord injury sacral	0	1	0	0	1	0	0
Spinal cord injury thoracic	0	3	0	0	3	0	0
Spinal fracture	3	23	1	2	25	0	0
Spinal shock	0	1	0	0	1	0	0
Splenic injury	0	2	0	0	2	0	0
Splenic rupture	1	11	0	0	11	0	0
Splinter	0	0	0	2	2	0	0
Sports injury	0	1	0	0	1	0	0
[redacted]wound	0	0	0	3	3	0	0
Sternal fracture	0	2	0	0	2	0	0
Stoma obstruction	0	1	0	0	1	0	0
Stoma site haemorrhage	0	2	0	0	2	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Stoma site pain	0	2	0	1	3	0	0
Stoma site rash	0	0	0	1	1	0	0
Stress fracture	1	6	1	2	8	0	0
Stroke-like migraine attacks after radiation therapy	0	1	0	1	2	0	0
Struck by lightning	0	1	0	0	1	0	0
Subarachnoid haematoma	0	2	0	0	2	0	0
Subcutaneous haematoma	0	7	4	30	37	0	0
Subdural haematoma	6	69	0	0	69	0	0
Subdural haemorrhage	1	22	0	0	22	0	0
Sunburn	1	35	3	32	67	0	0
Superficial injury of eye	0	1	0	1	2	0	0
Suture related complication	0	0	0	1	1	0	0
Synovial rupture	0	5	0	0	5	0	0
Systemic toxicity	0	3	0	0	3	0	0
Tendon injury	1	10	0	10	20	0	0
Tendon rupture	2	39	3	12	51	0	0
Thermal burn	1	52	6	47	99	0	0
Thermal burns of eye	1	35	0	30	65	0	0
Tibia fracture	0	4	0	0	4	0	0
Tissue injury	0	6	0	3	9	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Tongue injury	0	1	0	9	10	0	0
Tooth fracture	0	1	1	5	6	0	0
Tooth injury	0	5	4	7	12	0	0
Toxicity to various agents	1	20	0	0	20	0	0
Transcription medication error	0	0	0	2	2	0	0
Transfusion-related acute lung injury	0	1	0	0	1	0	0
Transplant dysfunction	0	2	0	0	2	0	0
Transplant failure	0	1	0	1	2	0	0
Traumatic fracture	0	2	0	0	2	0	0
Traumatic haematoma	0	7	0	8	15	0	0
Traumatic haemorrhage	1	2	0	0	2	0	0
Traumatic haemothorax	0	1	0	0	1	0	0
Traumatic intracranial haemorrhage	1	4	0	0	4	0	0
Traumatic iritis	0	1	0	0	1	0	0
Traumatic liver injury	1	1	0	0	1	0	0
Traumatic lung injury	0	2	0	4	6	0	0
Traumatic shock	0	0	0	1	1	0	0
Ulnar nerve injury	0	4	0	3	7	0	0
Underdose	1	3	2	53	56	0	0
Unintentional use for unapproved indication	0	0	0	1	1	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Unknown vaccine product administered	0	0	1	1	1	0	0
Unwanted awareness during anaesthesia	1	1	0	0	1	0	0
Upper limb fracture	5	12	0	7	19	0	0
Urinary tract stoma complication	0	0	0	1	1	0	0
Uterine rupture	0	2	0	0	2	0	1
VIIIth nerve injury	0	3	0	1	4	0	0
VIIth nerve injury	0	2	0	0	2	0	0
VIth nerve injury	0	1	0	0	1	0	0
Vaccination complication	8	19	3	19	38	0	0
Vaccination error	0	8	4	81	89	0	0
Vascular access site bruising	0	1	0	1	2	0	0
Vascular access site haemorrhage	0	1	0	0	1	0	0
Vascular graft occlusion	0	4	0	0	4	0	0
Vascular graft stenosis	0	1	0	0	1	0	0
Vascular graft thrombosis	0	8	0	0	8	0	0
Vascular injury	0	17	4	15	32	0	0
Vascular pseudoaneurysm	0	2	0	3	5	0	0
Vasoplegia syndrome	0	4	0	0	4	0	0
Venous injury	1	3	1	4	7	0	0
Vth nerve injury	0	1	0	0	1	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Vulvovaginal injury	0	2	0	1	3	0	0
Weaning failure	0	0	0	1	1	0	0
Wound	8	29	24	92	121	0	0
Wound complication	2	11	0	13	24	0	0
Wound decomposition	0	0	0	2	2	0	0
Wound haematoma	0	0	0	1	1	0	0
Wound haemorrhage	5	9	2	26	35	0	0
Wound necrosis	0	0	0	1	1	0	0
Wound secretion	1	5	0	3	8	0	0
Wrist fracture	1	3	1	6	9	0	0
Wrong device used	0	0	0	1	1	0	0
Wrong dosage form	0	0	0	1	1	0	0
Wrong dose	0	0	0	2	2	0	0
Wrong drug	0	0	0	4	4	0	0
Wrong patient received product	0	0	0	1	1	0	0
Wrong product administered	3	9	15	194	203	0	0
Wrong route	0	0	0	2	2	0	0
Wrong schedule	0	0	0	8	8	0	0
Wrong technique in device usage process	0	0	1	2	2	0	0
Wrong technique in product usage process	1	10	1	25	35	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Surgical and medical procedures	**192**	**1357**	**569**	**3006**	**4363**	**1**	**1**
Abdominal cavity drainage	0	1	0	0	1	0	0
Abortion induced	1	4	0	1	5	0	0
Abscess drainage	1	5	1	9	14	0	0
Abscess management	0	1	1	8	9	0	0
Adrenalectomy	0	0	0	1	1	0	0
Adrenocortical steroid therapy	0	1	0	2	3	0	0
Airway secretion clearance therapy	0	1	0	0	1	0	0
Amputation	0	4	0	1	5	0	0
Analgesic therapy	0	0	0	12	12	0	0
Anaphylaxis prophylaxis	0	2	0	0	2	0	0
Anaphylaxis treatment	0	4	0	2	6	0	0
Angioplasty	0	3	0	1	4	0	0
Anorectal operation	1	1	0	0	1	0	0
Antacid therapy	0	0	0	1	1	0	0
Antiallergic therapy	0	2	0	1	3	0	0
Antibiotic prophylaxis	0	0	0	1	1	0	0
Antibiotic therapy	0	1	0	4	5	0	0
Anticoagulant therapy	0	0	0	3	3	0	0
Antidepressant therapy	0	0	0	1	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Antiinflammatory therapy	0	0	0	1	1	0	0
Antitussive therapy	0	1	0	1	2	0	0
Aortic valve replacement	0	0	0	1	1	0	0
Apicectomy	0	0	0	1	1	0	0
Appendicectomy	1	15	0	1	16	0	0
Arm amputation	0	1	0	2	3	0	0
Arterial stent insertion	0	1	0	1	2	0	0
Arteriovenous fistula operation	1	1	0	0	1	0	0
Arthrodesis	0	1	0	0	1	0	0
Asthma prophylaxis	0	1	0	0	1	0	0
Astringent therapy	0	0	0	1	1	0	0
Axillary lymphadenectomy	0	2	0	1	3	0	0
Bed rest	6	34	13	69	103	0	0
Bilateral orchidectomy	0	1	0	0	1	0	0
Bladder catheter permanent	0	1	0	0	1	0	0
Bladder catheterisation	0	2	0	1	3	0	0
Bladder fistula repair	1	1	0	0	1	0	0
Bladder neoplasm surgery	0	1	0	0	1	0	0
Bladder training	0	1	0	0	1	0	0
Blood donation	0	0	0	2	2	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Blood pressure management	0	1	0	0	1	0	0
Brachytherapy to breast	0	0	0	1	1	0	0
Brain operation	0	1	0	0	1	0	0
Breast conserving surgery	0	2	0	2	4	0	0
Breast cyst drainage	0	0	1	1	1	0	0
Breast operation	0	1	0	0	1	0	0
Bursa removal	0	1	0	0	1	0	0
COVID-19 immunisation	40	316	227	626	942	0	0
COVID-19 prophylaxis	0	2	0	3	5	0	0
COVID-19 treatment	0	4	0	4	8	0	0
Caesarean section	5	11	0	1	12	0	0
Cardiac ablation	1	3	0	1	4	0	0
Cardiac operation	0	3	0	0	3	0	0
Cardiac pacemaker insertion	2	7	0	2	9	0	0
Cardiac pacemaker replacement	0	1	0	0	1	0	0
Cardioversion	0	4	0	2	6	0	0
Carpal tunnel decompression	0	1	0	0	1	0	0
Catheter management	0	2	0	2	4	0	0
Catheter placement	1	3	0	0	3	0	0
Central nervous system stimulation	0	2	0	5	7	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Cerebral revascularisation	0	1	0	0	1	0	0
Cerumen removal	0	2	0	0	2	0	0
Chemotherapy	1	1	0	2	3	0	0
Chemotherapy toxicity attenuation	0	0	0	1	1	0	0
Chest tube removal	0	1	0	0	1	0	0
Cholecystectomy	3	5	0	0	5	0	0
Cholelithotomy	0	1	0	0	1	0	0
Ciliary body operation	0	1	0	0	1	0	0
Clamping of blood vessel	0	0	0	2	2	0	0
Colectomy	0	2	0	0	2	0	0
Colectomy total	0	0	0	1	1	0	0
Colon operation	0	1	0	0	1	0	0
Compression garment application	0	0	0	2	2	0	0
Continuous passive motion machine therapy	0	1	0	0	1	0	0
Contraception	0	1	0	2	3	0	0
Contraceptive diaphragm	0	3	0	0	3	0	0
Cooling therapy	0	4	0	9	13	0	0
Corneal transplant	0	2	0	0	2	0	0
Coronary angioplasty	0	3	0	0	3	0	0
Coronary arterial stent insertion	2	4	0	0	4	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Coronary artery bypass	0	5	0	0	5	0	0
Craniectomy	0	1	0	0	1	0	0
Cranioplasty	0	1	0	0	1	0	0
Craniotomy	1	3	0	0	3	0	0
Decompressive craniectomy	0	4	0	0	4	0	0
Dental care	0	2	0	1	3	0	0
Dental local anaesthesia	0	0	0	1	1	0	0
Dental operation	0	0	0	1	1	0	0
Dermabrasion	0	1	0	0	1	0	0
Dermal filler injection	0	0	0	1	1	0	0
Diabetes mellitus management	0	0	0	2	2	0	0
Dialysis	1	5	0	2	7	0	0
Distraction osteogenesis	0	1	0	2	3	0	0
Drug toxicity prophylaxis	0	0	0	2	2	0	0
Dry skin prophylaxis	0	0	1	1	1	0	0
Electroconvulsive therapy	0	0	0	1	1	0	0
Emergency care	3	7	0	4	11	0	0
Endodontic procedure	2	2	0	0	2	0	0
Endometrial ablation	0	4	0	3	7	0	0
Endometrial scratching	0	4	0	4	8	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Endometriosis ablation	1	1	0	0	1	0	0
Endotracheal intubation	1	13	0	1	14	0	0
Endovenous ablation	0	0	0	1	1	0	0
Enteral nutrition	0	1	0	0	1	0	0
Epidural anaesthesia	0	1	0	0	1	0	0
Epidural injection	1	1	0	0	1	0	0
Explorative laparotomy	0	1	0	0	1	0	0
External counterpulsation	0	0	0	1	1	0	0
Extradural haematoma evacuation	0	1	0	0	1	0	0
Eye irrigation	0	3	0	1	4	0	0
Eye laser surgery	0	2	0	0	2	0	0
Eye muscle operation	0	0	0	1	1	0	0
Eye operation	0	0	0	1	1	0	0
Eyelid operation	0	0	0	1	1	0	0
Face lift	0	1	0	2	3	0	0
Fallopian tube operation	0	0	0	1	1	0	0
Fasciotomy	0	2	0	1	3	0	0
Fatigue management	0	1	0	2	3	0	0
Finger amputation	0	0	0	1	1	0	0
Fluid replacement	0	2	0	0	2	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Foot amputation	0	2	0	1	3	0	0
Fraction of inspired oxygen	0	2	0	1	3	0	0
Fracture reduction	0	0	0	1	1	0	0
Gallbladder operation	0	1	0	1	2	0	0
Gastrooesophageal variceal haemorrhage prophylaxis	0	1	0	0	1	0	0
General anaesthesia	0	1	0	0	1	0	0
Genital labial operation	0	1	0	0	1	0	0
Gluten free diet	1	2	0	0	2	0	0
Gynaecological disorder prophylaxis	0	1	0	0	1	0	0
Haematoma evacuation	0	1	0	1	2	0	0
Haemodialysis	0	2	0	0	2	0	0
Haemofiltration	0	1	0	0	1	0	0
Haemorrhoid operation	0	0	0	1	1	0	0
Hand amputation	0	0	0	1	1	0	0
Heart valve replacement	0	1	0	0	1	0	0
Heat therapy	0	1	0	9	10	0	0
Heparin neutralisation therapy	0	0	0	1	1	0	0
High frequency ablation	0	1	0	0	1	0	0
High intensity focused ultrasound	0	2	0	0	2	0	0
Hip arthroplasty	1	1	0	1	2	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Hip surgery	1	1	0	1	2	0	0
Home care	0	0	0	1	1	0	0
Hormone replacement therapy	0	3	0	3	6	0	0
Hormone therapy	0	6	0	3	9	0	0
Hospitalisation	7	98	0	9	107	0	0
Hyperthermia therapy	0	0	0	1	1	0	0
Hysterectomy	0	4	0	0	4	0	0
Ileocolostomy	0	1	0	0	1	0	0
Ileostomy	0	4	0	0	4	0	0
Immobilisation bandage	0	2	0	0	2	0	0
Immunisation	4	97	4	74	171	0	0
Immunoadsorption therapy	0	1	0	0	1	0	0
Immunoglobulin therapy	0	2	0	0	2	0	0
Influenza immunisation	0	0	0	4	4	0	0
Infusion	0	0	0	2	2	0	0
Inguinal hernia repair	0	1	0	0	1	0	0
Inhalation therapy	0	1	0	0	1	0	0
Injection	0	28	0	33	61	0	0
Intensive care	0	6	0	1	7	0	0
Interchange of vaccine products	61	128	299	1780	1908	1	1

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Intestinal resection	4	6	0	0	6	0	0
Intra-uterine contraceptive device insertion	0	0	0	1	1	0	0
Intracerebral haematoma evacuation	0	2	0	0	2	0	0
Intrauterine contraception	0	1	0	2	3	0	0
Intravesical immunotherapy	0	1	0	0	1	0	0
Involuntary commitment	0	9	0	0	9	0	0
Joint injection	0	6	0	1	7	0	0
Joint stabilisation	1	5	0	1	6	0	0
Knee operation	1	5	1	2	7	0	0
Laparotomy	0	2	0	1	3	0	0
Laryngeal prosthesis placement	0	1	0	0	1	0	0
Leg amputation	0	17	1	1	18	0	0
Lesion excision	0	1	0	0	1	0	0
Light anaesthesia	0	0	0	1	1	0	0
Limb amputation	1	3	0	0	3	0	0
Limb immobilisation	2	31	1	13	44	0	0
Limb operation	0	12	0	5	17	0	0
Limb reattachment surgery	0	1	0	0	1	0	0
Limb reconstructive surgery	0	1	0	0	1	0	0
Liposuction	0	0	0	1	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Liver transplant	1	1	0	0	1	0	0
Local anaesthesia	0	2	0	5	7	0	0
Localised alternating hot and cold therapy	0	3	0	5	8	0	0
Lung operation	0	1	0	0	1	0	0
Lung transplant	1	1	0	0	1	0	0
Lymphadenectomy	0	0	0	3	3	0	0
Magnetic therapy	0	0	0	1	1	0	0
Manipulation	0	0	0	1	1	0	0
Manual lymphatic drainage	0	0	0	1	1	0	0
Mass excision	1	9	0	11	20	0	0
Mastectomy	0	1	0	0	1	0	0
Maxillary antrum operation	0	0	0	1	1	0	0
Measles immunisation	0	0	0	1	1	0	0
Mechanical ventilation	0	5	0	0	5	0	0
Medical counselling	0	0	0	1	1	0	0
Medical device removal	0	0	0	1	1	0	0
Medical diet	0	4	0	3	7	0	0
Medical induction of coma	0	3	0	0	3	0	0
Medication dilution	0	3	0	0	3	0	0
Menstrual cycle management	0	4	5	43	47	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Mesenteric artery stent insertion	0	1	0	0	1	0	0
Mineral supplementation	0	1	0	0	1	0	0
Mitral valve repair	0	1	0	0	1	0	0
Multiple sclerosis relapse prophylaxis	0	2	0	0	2	0	0
Muscle relaxant therapy	0	3	0	1	4	0	0
Muscle suture	0	0	0	1	1	0	0
Nail operation	0	1	0	1	2	0	0
Nasal cavity packing	0	0	0	3	3	0	0
Nasal irrigation	0	1	0	0	1	0	0
Neck lift	0	1	0	0	1	0	0
Neonatal warming therapy	0	0	0	1	1	0	0
Nephrectomy	0	3	0	0	3	0	0
Nerve block	0	6	0	2	8	0	0
Neurological rehabilitation	0	1	0	0	1	0	0
Nothing by mouth order	0	1	1	9	10	0	0
Nutritional supplementation	0	0	0	1	1	0	0
Occupational therapy	0	1	0	0	1	0	0
Oesophageal tamponade	0	0	0	1	1	0	0
Oophorectomy	0	2	0	0	2	0	0
Oral contraception	0	0	0	7	7	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Orthodontic procedure	0	1	0	0	1	0	0
Ovulation induction	0	0	0	2	2	0	0
Oxygen therapy	2	4	0	1	5	0	0
Pacemaker generated rhythm	0	1	0	0	1	0	0
Parathyroidectomy	0	1	0	0	1	0	0
Parenteral nutrition	0	0	0	1	1	0	0
Patient isolation	0	0	0	1	1	0	0
Percutaneous coronary intervention	0	4	0	0	4	0	0
Pericardial drainage	0	2	0	0	2	0	0
Pericardial excision	0	2	0	0	2	0	0
Phlebotomy	2	3	1	3	6	0	0
Photopheresis	0	1	0	0	1	0	0
Physical fitness training	0	2	0	3	5	0	0
Physiotherapy	0	1	0	0	1	0	0
Plastic surgery to the face	0	0	0	1	1	0	0
Platelet transfusion	0	1	0	0	1	0	0
Positive airway pressure therapy	0	0	0	2	2	0	0
Post coital contraception	0	0	0	1	1	0	0
Posterior lens capsulotomy	0	0	1	1	1	0	0
Postoperative care	0	0	0	1	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Product substitution	0	1	0	2	3	0	0
Product used for unknown indication	0	1	0	2	3	0	0
Promotion of wound healing	0	1	0	0	1	0	0
Prone position	0	2	0	1	3	0	0
Prophylaxis	0	0	0	1	1	0	0
Prophylaxis against gastrointestinal ulcer	0	1	0	0	1	0	0
Prophylaxis of nausea and vomiting	0	23	1	11	34	0	0
Prostate ablation	1	1	0	0	1	0	0
Prosthetic vessel removal	0	0	0	1	1	0	0
Psychotherapy	0	1	0	1	2	0	0
Pterygium operation	0	1	0	0	1	0	0
Pupil constriction procedure	0	0	0	1	1	0	0
Quarantine	0	0	0	3	3	0	0
Radiotherapy	0	0	0	1	1	0	0
Red blood cell transfusion	0	1	0	0	1	0	0
Rehabilitation therapy	0	1	0	2	3	0	0
Renal transplant	0	1	0	0	1	0	0
Renal tumour excision	0	1	0	0	1	0	0
Reproductive system disorder prophylaxis	0	1	0	0	1	0	0
Respiratory therapy	0	1	0	0	1	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Resuscitation	2	18	0	3	21	0	0
Retained placenta operation	0	1	0	0	1	0	0
Retinal laser coagulation	0	1	0	0	1	0	0
Rubella immunisation	0	0	0	1	1	0	0
Salpingectomy	0	1	0	0	1	0	0
Self-medication	0	1	0	0	1	0	0
Shoulder operation	0	3	0	0	3	0	0
Sinus antrostomy	0	1	0	0	1	0	0
Skin graft	1	1	0	0	1	0	0
Skin neoplasm excision	1	2	0	0	2	0	0
Skin operation	0	1	0	0	1	0	0
Smoking cessation therapy	0	0	0	1	1	0	0
Specialist consultation	0	1	1	4	5	0	0
Spinal decompression	0	0	0	1	1	0	0
Spinal fusion surgery	1	1	0	0	1	0	0
Spinal operation	0	1	0	0	1	0	0
Spinal rod insertion	0	0	1	1	1	0	0
Splenectomy	1	4	0	0	4	0	0
Splenic artery embolisation	0	1	0	0	1	0	0
Stent placement	0	5	0	1	6	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Steroid therapy	0	1	0	1	2	0	0
Stoma care	0	1	0	0	1	0	0
Subdural haematoma evacuation	0	2	0	0	2	0	0
Supine position	0	1	0	0	1	0	0
Surgery	1	13	0	7	20	0	0
Suture insertion	2	3	0	2	5	0	0
Tattoo excision	0	0	0	1	1	0	0
Tenodesis	0	1	0	0	1	0	0
Testes exploration	0	1	0	0	1	0	0
Tetanus immunisation	0	0	0	1	1	0	0
Therapeutic hypothermia	0	2	0	1	3	0	0
Therapeutic procedure	0	1	0	0	1	0	0
Therapy change	0	3	0	4	7	0	0
Therapy interrupted	3	5	0	1	6	0	0
Thoracic cavity drainage	1	2	0	0	2	0	0
Thrombectomy	0	11	0	0	11	0	0
Thromboembolectomy	0	4	0	0	4	0	0
Thrombolysis	1	12	1	2	14	0	0
Thrombosis prophylaxis	0	3	0	1	4	0	0
Thyroidectomy	0	1	0	0	1	0	0

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	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Toe amputation	0	6	0	1	7	0	0
Tonsillectomy	0	2	0	0	2	0	0
Tooth extraction	5	8	2	6	14	0	0
Tooth restoration	0	2	0	2	4	0	0
Tracheostomy	0	4	0	1	5	0	0
Transfusion	1	6	1	1	7	0	0
Transgender operation	0	1	0	0	1	0	0
Transurethral bladder resection	0	1	0	0	1	0	0
Treatment delayed	0	0	0	1	1	0	0
Trigeminal nerve ablation	0	1	0	0	1	0	0
Tuberculosis immunisation	0	1	0	0	1	0	0
Tumour excision	0	1	0	0	1	0	0
Tumour vaccine therapy	0	0	0	1	1	0	0
UV light therapy	0	1	0	0	1	0	0
Unrelated donor bone marrow transplantation therapy	0	0	0	1	1	0	0
Uterine dilation and curettage	0	3	1	1	4	0	0
Uterine dilation and evacuation	0	0	0	1	1	0	0
Vaccine coadministration	0	0	0	1	1	0	0
Vagotomy	0	1	0	2	3	0	0
Vascular anastomosis	0	0	1	1	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Vascular compression therapy	0	0	0	1	1	0	0
Vascular graft	0	2	0	0	2	0	0
Vascular operation	0	2	0	1	3	0	0
Vena cava filter insertion	0	1	1	1	2	0	0
Venipuncture	0	0	1	1	1	0	0
Ventricular drainage	1	2	0	0	2	0	0
Ventriculo-peritoneal shunt	0	0	0	1	1	0	0
Vessel harvesting	0	0	0	2	2	0	0
Vitamin supplementation	0	1	0	1	2	0	0
Vitrectomy	0	1	0	0	1	0	0
Weight loss diet	0	1	0	1	2	0	0
Wisdom teeth removal	1	1	0	0	1	0	0
Wound closure	0	1	0	0	1	0	0
Wound drainage	0	1	0	0	1	0	0
Wound treatment	1	2	0	0	2	0	0
X-ray therapy to lung	0	1	0	0	1	0	0
Social circumstances	**104**	**1150**	**203**	**1901**	**3051**	**0**	**0**
Abstains from alcohol	0	0	0	2	2	0	0
Alcohol use	0	0	0	1	1	0	0
Alcoholic	0	4	0	1	5	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Anal sex	0	1	0	0	1	0	0
Bedridden	11	194	22	393	587	0	0
Bereavement	0	1	0	0	1	0	0
Blood donor	0	2	0	0	2	0	0
Blood product transfusion dependent	0	1	0	0	1	0	0
Breast feeding	0	8	0	9	17	0	0
Breast prosthesis user	0	1	0	0	1	0	0
Cardiac assistance device user	0	1	0	0	1	0	0
Chemical submission	0	0	0	1	1	0	0
Childhood	0	0	0	1	1	0	0
Contraindication to medical treatment	0	0	0	1	1	0	0
Contraindication to vaccination	0	7	5	48	55	0	0
Convalescent	0	1	0	2	3	0	0
Corrective lens user	0	1	1	1	2	0	0
Death of pet	0	1	0	0	1	0	0
Death of relative	0	2	0	0	2	0	0
Dependence on oxygen therapy	0	3	0	2	5	0	0
Disability	9	33	1	9	42	0	0
Disease risk factor	0	2	0	3	5	0	0
Economic problem	0	2	0	3	5	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Educational problem	0	0	0	1	1	0	0
Ex-tobacco user	0	0	0	1	1	0	0
Excessive exercise	0	0	0	2	2	0	0
Exercise lack of	0	0	0	1	1	0	0
Food contamination	0	0	0	1	1	0	0
Hair dye user	0	0	0	1	1	0	0
Hearing aid user	0	3	0	1	4	0	0
Hearing disability	1	5	0	5	10	0	0
Homosexual parent	0	1	0	0	1	0	0
Homosexuality	0	0	0	1	1	0	0
Housebound	4	10	2	5	15	0	0
Illiteracy	0	4	0	0	4	0	0
Immobile	5	76	0	26	102	0	0
Immobilisation prolonged	0	8	0	0	8	0	0
Impaired driving ability	3	37	0	30	67	0	0
Impaired quality of life	6	37	8	30	67	0	0
Impaired work ability	28	337	75	725	1062	0	0
Inability to afford medication	0	1	0	0	1	0	0
Inadequate diet	0	1	0	0	1	0	0
Infant	0	0	0	1	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Job dissatisfaction	0	3	0	5	8	0	0
Kosher diet	0	0	0	1	1	0	0
Life expectancy shortened	0	1	0	1	2	0	0
Loss of personal independence in daily activities	18	166	72	404	570	0	0
Menarche	0	0	0	3	3	0	0
Menopause	5	57	1	38	95	0	0
Mental disability	0	3	0	2	5	0	0
Non-tobacco user	0	5	0	2	7	0	0
Occupational problem environmental	0	1	0	0	1	0	0
Orthosis user	0	1	0	1	2	0	0
Paralytic disability	0	1	0	0	1	0	0
Partner stress	0	0	0	1	1	0	0
Patient dissatisfaction with treatment	0	1	0	3	4	0	0
Patient uncooperative	0	1	0	0	1	0	0
Personal relationship issue	0	2	0	0	2	0	0
Physical assault	0	1	0	0	1	0	0
Physical disability	0	7	3	14	21	0	0
Planning to become pregnant	0	1	0	0	1	0	0
Pollution	0	0	0	1	1	0	0
Postmenopause	0	11	0	8	19	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Refusal of treatment by patient	0	0	0	2	2	0	0
Refusal of vaccination	0	0	0	8	8	0	0
Retirement	0	3	0	5	8	0	0
Sexual activity increased	0	0	0	2	2	0	0
Sexually active	0	0	0	1	1	0	0
Sick leave	6	11	11	37	48	0	0
Sick relative	0	3	0	1	4	0	0
Sight disability	1	28	0	8	36	0	0
Sitting disability	0	7	0	12	19	0	0
Social problem	0	0	0	1	1	0	0
Stress at work	0	2	0	1	3	0	0
Tanning	0	0	0	2	2	0	0
Tattoo	0	1	0	0	1	0	0
Tobacco user	0	1	0	1	2	0	0
Unemployment	0	0	0	1	1	0	0
Unhealthy lifestyle	0	1	0	1	2	0	0
Verbal abuse	0	1	0	1	2	0	0
Victim [redacted]	0	1	0	0	1	0	0
Walking aid user	3	9	1	4	13	0	0
Walking disability	3	24	0	19	43	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Water pollution	0	5	0	0	5	0	0
Wheelchair user	1	6	1	2	8	0	0
Product issues	**9**	**160**	**8**	**211**	**371**	**0**	**0**
Device breakage	1	1	0	1	2	0	0
Device delivery system issue	0	0	1	2	2	0	0
Device dislocation	1	3	0	0	3	0	0
Device electrical impedance issue	0	1	0	0	1	0	0
Device end of service	0	0	0	1	1	0	0
Device expulsion	0	2	0	2	4	0	0
Device inappropriate shock delivery	0	1	0	0	1	0	0
Device issue	0	1	2	4	5	0	0
Device leakage	0	0	0	3	3	0	0
Device occlusion	0	3	0	1	4	0	0
Device physical property issue	0	0	0	3	3	0	0
Device power source issue	1	1	0	0	1	0	0
Drug delivery system issue	0	0	0	1	1	0	0
Electromagnetic interference	0	2	0	8	10	0	0
Liquid product physical issue	0	1	0	4	5	0	0
Manufacturing equipment issue	0	0	0	1	1	0	0
Needle issue	1	3	0	11	14	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Oversensing	0	33	1	18	51	0	0
Patient-device incompatibility	0	1	0	1	2	0	0
Physical product label issue	1	1	0	0	1	0	0
Product after taste	0	3	0	6	9	0	0
Product availability issue	0	0	3	17	17	0	0
Product barcode issue	0	1	0	0	1	0	0
Product colour issue	0	0	0	4	4	0	0
Product complaint	1	3	0	2	5	0	0
Product container issue	0	1	0	6	7	0	0
Product contamination	0	1	0	4	5	0	0
Product contamination microbial	0	0	0	1	1	0	0
Product contamination physical	0	0	0	2	2	0	0
Product counterfeit	0	0	0	2	2	0	0
Product deposit	0	0	0	1	1	0	0
Product formulation issue	0	1	0	0	1	0	0
Product identification number issue	0	0	0	1	1	0	0
Product impurity	0	0	0	2	2	0	0
Product label issue	0	0	0	2	2	0	0
Product leakage	0	0	0	1	1	0	0
Product lot number issue	0	0	0	1	1	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous	Non-interventional post-marketing study	
	Serious		Non-serious			Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative all	Interval	Cumulative
Product odour abnormal	0	1	0	2	3	0	0
Product origin unknown	0	1	0	3	4	0	0
Product physical consistency issue	0	0	0	1	1	0	0
Product physical issue	0	1	0	1	2	0	0
Product quality issue	1	2	0	8	10	0	0
Product reconstitution quality issue	0	0	0	2	2	0	0
Product substitution issue	0	0	0	1	1	0	0
Product supply issue	0	0	0	2	2	0	0
Product taste abnormal	0	9	0	5	14	0	0
Product temperature excursion issue	1	1	0	49	50	0	0
Stent malfunction	0	2	0	0	2	0	0
Suspected counterfeit product	0	0	0	8	8	0	0
Suspected product contamination	0	0	0	2	2	0	0
Suspected product quality issue	0	0	0	2	2	0	0
Suspected product tampering	0	0	0	1	1	0	0
Syringe issue	0	0	0	5	5	0	0
Thrombosis in device	1	75	0	0	75	0	0
Undersensing	0	4	1	6	10	0	0

Table 2 - Number of Adverse Reactions by Term from Post Marketing Sources

Listing of MedDRA SOCs in the Internationally Agreed Order

MedDRA Version: 25.1

Infections and infestations
Neoplasms benign, malignant and unspecified (incl cysts and polyps)
Blood and lymphatic system disorders
Immune system disorders
Endocrine disorders
Metabolism and nutrition disorders
Psychiatric disorders
Nervous system disorders
Eye disorders
Ear and labyrinth disorders
Cardiac disorders
Vascular disorders
Respiratory, thoracic and mediastinal disorders
Gastrointestinal disorders
Hepatobiliary disorders
Skin and subcutaneous tissue disorders
Musculoskeletal and connective tissue disorders
Renal and urinary disorders
Pregnancy, puerperium and perinatal conditions
Reproductive system and breast disorders
Congenital, familial and genetic disorders
General disorders and administration site conditions
Investigations
Injury, poisoning and procedural complications
Surgical and medical procedures
Social circumstances
Product issues

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Infections and infestations	**3556**	**0**	**44995**	**7**	**2282**	**0**	**33206**	**30**	**78201**	**37**	**23**	**70**
AIDS related complex	0	0	1	0	0	0	1	0	2	0	0	0
Abdominal abscess	0	0	2	0	0	0	0	0	2	0	0	0
Abdominal infection	1	0	3	0	0	0	3	0	6	0	0	0
Abdominal sepsis	0	0	2	0	0	0	0	0	2	0	0	0
Abdominal wall infection	0	0	1	0	0	0	0	0	1	0	0	0
Abortion infected	0	0	1	0	0	0	0	0	1	0	0	0
Abscess	1	0	59	0	27	0	175	0	234	0	0	0
Abscess bacterial	0	0	1	0	1	0	1	0	2	0	0	0
Abscess jaw	0	0	0	0	0	0	1	0	1	0	0	0
Abscess limb	2	0	23	0	2	0	21	0	44	0	0	0
Abscess neck	0	0	0	0	0	0	1	0	1	0	0	0
Abscess of eyelid	0	0	0	0	0	0	1	0	1	0	0	0
Abscess oral	0	0	5	0	0	0	6	0	11	0	0	0
Abscess soft tissue	0	0	3	0	0	0	1	0	4	0	0	0
Acanthamoeba keratitis	0	0	1	0	0	0	0	0	1	0	0	0
Acarodermatitis	0	0	7	0	1	0	9	0	16	0	0	0
Acinetobacter infection	0	0	2	0	0	0	0	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Acne pustular	0	0	0	0	0	0	2	0	2	0	0	0
Acquired immunodeficiency syndrome	0	0	3	0	0	0	0	0	3	0	0	0
Acrodermatitis chronica atrophicans	0	0	0	0	0	0	1	0	1	0	0	0
Actinomycotic abdominal infection	0	0	0	0	0	0	2	0	2	0	0	0
Actinomycotic skin infection	0	0	0	0	0	0	1	0	1	0	0	0
Acute endocarditis	0	0	2	0	0	0	0	0	2	0	0	0
Acute haemorrhagic conjunctivitis	0	0	0	0	0	0	1	0	1	0	0	0
Acute hepatitis B	0	0	1	0	0	0	0	0	1	0	0	0
Acute sinusitis	0	0	7	0	1	0	12	0	19	0	0	0
Adenopathy syphilitic	0	0	1	0	0	0	1	0	2	0	0	0
Adenovirus infection	0	0	1	0	1	0	2	0	3	0	0	0
Administration site abscess	0	0	0	0	0	0	1	0	1	0	0	0
Administration site cellulitis	1	0	1	0	2	0	6	0	7	0	0	0
African trypanosomiasis	0	0	8	0	0	0	3	0	11	0	0	0
Amniotic cavity infection	0	0	0	0	0	0	0	0	0	0	0	1
Amoebiasis	1	0	1	0	0	0	0	0	1	0	0	0
Amoebic skin ulcer	0	0	0	0	0	0	1	0	1	0	0	0
Anal abscess	1	0	2	1	1	0	4	0	6	1	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Anal candidiasis	0	0	2	0	0	0	0	0	2	0	0	0
Anthrax	0	0	0	0	0	0	1	0	1	0	0	0
Appendicitis	4	0	110	0	0	0	0	0	110	0	0	0
Appendicitis perforated	0	0	10	0	0	0	0	0	10	0	0	0
Application site abscess	0	0	1	0	1	0	4	0	5	0	0	0
Application site cellulitis	0	0	0	0	0	0	1	0	1	0	0	0
Application site infection	0	0	0	0	0	0	2	0	2	0	0	0
Application site pustules	0	0	0	0	0	0	2	0	2	0	0	0
Arteriosclerotic gangrene	0	0	1	0	0	0	0	0	1	0	0	0
Arthritis bacterial	1	0	21	0	0	0	0	0	21	0	0	0
Arthritis infective	1	0	7	0	0	0	0	0	7	0	0	0
Arthritis viral	1	0	3	0	0	0	0	0	3	0	0	0
Aspergillus infection	1	0	2	0	0	0	0	0	2	0	0	0
Asymptomatic COVID-19	2	0	27	0	6	0	227	0	254	0	0	0
Asymptomatic bacteriuria	0	0	0	0	0	0	1	0	1	0	0	0
Atypical mycobacterial infection	0	0	0	0	0	0	1	0	1	0	0	0
Atypical pneumonia	3	0	15	0	0	0	2	0	17	0	0	0
Bacillus infection	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Bacteraemia	1	0	7	0	0	0	3	0	10	0	0	0
Bacterial colitis	0	0	1	0	0	0	0	0	1	0	0	0
Bacterial diarrhoea	0	0	2	0	0	0	6	0	8	0	0	0
Bacterial infection	1	0	41	0	3	0	25	0	66	0	0	0
Bacterial parotitis	0	0	1	0	0	0	0	0	1	0	0	0
Bacterial prostatitis	1	0	1	0	0	0	0	0	1	0	0	0
Bacterial sepsis	0	0	3	0	0	0	0	0	3	0	0	0
Bacterial toxaemia	0	0	1	0	0	0	0	0	1	0	0	0
Bacterial vaginosis	0	0	4	0	0	0	7	0	11	0	0	0
Bacterial vulvovaginitis	0	0	1	0	0	0	1	0	2	0	0	0
Balanitis candida	0	0	0	0	0	0	2	0	2	0	0	0
Beta haemolytic streptococcal infection	0	0	3	0	0	0	0	0	3	0	0	2
Biliary sepsis	0	0	6	0	0	0	0	0	6	0	0	0
Blackwater fever	0	0	1	0	0	0	2	0	3	0	0	0
Blister infected	0	0	1	0	2	0	8	0	9	0	0	0
Body tinea	0	0	5	0	1	0	8	0	13	0	0	0
Bone abscess	0	0	0	0	0	0	1	0	1	0	0	0
Borrelia infection	0	0	3	0	0	0	1	0	4	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Boutonneuse fever	0	0	0	0	0	0	1	0	1	0	0	0
Brain abscess	0	0	6	0	0	0	0	0	6	0	0	0
Brain empyema	0	0	1	0	0	0	0	0	1	0	0	0
Breakthrough COVID-19	4	0	8	0	11	0	31	0	39	0	0	0
Breast abscess	0	0	6	0	1	0	2	0	8	0	0	0
Bronchiolitis	1	0	3	0	0	0	4	0	7	0	2	2
Bronchitis	6	0	58	0	8	0	104	2	162	2	0	0
Bronchitis bacterial	0	0	1	0	0	0	0	0	1	0	0	0
Bronchitis viral	0	0	1	0	0	0	1	0	2	0	0	0
Bronchopulmonary aspergillosis	0	0	1	0	0	0	0	0	1	0	0	0
Brucellosis	0	0	1	0	0	0	0	0	1	0	0	0
Bursitis infective	0	0	3	0	0	0	1	0	4	0	0	0
CNS ventriculitis	1	0	1	0	0	0	0	0	1	0	0	0
COVID-19	2717	0	25482	0	325	0	3645	11	29127	11	2	30
COVID-19 pneumonia	21	0	386	1	0	0	0	0	386	1	0	1
Campylobacter colitis	0	0	0	0	0	0	1	0	1	0	0	0
Campylobacter gastroenteritis	0	0	1	0	0	0	1	0	2	0	0	0
Campylobacter infection	0	0	4	0	0	0	0	0	4	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Candida infection	1	0	60	0	2	0	47	0	107	0	0	0
Candida sepsis	0	0	1	0	0	0	0	0	1	0	0	0
Capnocytophaga sepsis	0	0	1	0	0	0	0	0	1	0	0	0
Carbuncle	0	0	2	0	0	0	3	0	5	0	0	0
Cardiac infection	0	0	2	0	0	0	0	0	2	0	0	0
Cat scratch disease	0	0	0	0	1	0	1	0	1	0	0	0
Catheter site infection	0	0	1	0	0	0	0	0	1	0	0	0
Cavernous sinus thrombosis	1	0	20	0	0	0	1	0	21	0	0	0
Cellulitis	20	0	441	0	10	0	401	0	842	0	1	1
Cellulitis orbital	0	0	4	0	0	0	0	0	4	0	0	0
Cellulitis staphylococcal	0	0	0	0	0	0	1	0	1	0	0	0
Cellulitis streptococcal	0	0	1	0	0	0	0	0	1	0	0	0
Central nervous system abscess	1	0	1	0	0	0	0	0	1	0	0	0
Central nervous system infection	0	0	2	0	0	0	0	0	2	0	0	0
Cervicitis	0	0	1	0	0	0	0	0	1	0	0	0
Chikungunya virus infection	1	0	2	0	0	0	4	0	6	0	0	0
Chlamydial infection	0	0	1	0	0	0	0	0	1	0	0	0
Cholecystitis infective	0	0	2	0	0	0	0	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Chronic hepatitis B	0	0	1	0	0	0	0	0	1	0	0	0
Chronic sinusitis	0	0	17	0	1	0	11	0	28	0	0	0
Chronic tonsillitis	0	0	1	0	0	0	0	0	1	0	0	0
Clostridial infection	0	0	1	0	0	0	0	0	1	0	0	0
Clostridium difficile colitis	0	0	8	0	0	0	1	0	9	0	0	0
Clostridium difficile infection	0	0	3	0	0	0	1	0	4	0	0	0
Coinfection	0	0	0	0	0	0	1	0	1	0	0	0
Colitis herpes	0	0	0	0	0	0	1	0	1	0	0	0
Complicated appendicitis	0	0	1	0	0	0	0	0	1	0	0	0
Conjunctivitis	2	0	74	0	11	0	232	0	306	0	0	0
Conjunctivitis bacterial	0	0	1	0	0	0	0	0	1	0	0	0
Conjunctivitis viral	0	0	5	0	0	0	3	0	8	0	0	0
Coronavirus infection	1	0	9	0	5	0	36	1	45	1	0	0
Coronavirus pneumonia	0	0	1	0	0	0	0	0	1	0	0	0
Cow pox	0	0	1	0	0	0	0	0	1	0	0	0
Coxsackie bronchitis	0	0	0	0	0	0	1	0	1	0	0	0
Coxsackie viral infection	0	0	0	0	0	0	1	0	1	0	0	0
Creutzfeldt-Jakob disease	1	0	14	0	0	0	1	0	15	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Croup infectious	0	0	1	0	0	0	0	0	1	0	0	0
Cystitis	12	0	117	0	6	0	113	1	230	1	0	0
Cystitis bacterial	1	0	1	0	0	0	0	0	1	0	0	0
Cystitis escherichia	1	0	1	0	0	0	1	0	2	0	0	0
Cystitis klebsiella	0	0	1	0	0	0	0	0	1	0	0	0
Cystitis viral	0	0	1	0	0	0	0	0	1	0	0	0
Cytomegalovirus hepatitis	0	0	1	0	0	0	0	0	1	0	0	0
Cytomegalovirus infection	0	0	3	0	0	0	3	0	6	0	0	0
Cytomegalovirus infection reactivation	0	0	2	0	0	0	0	0	2	0	0	0
Dacryocystitis	0	0	1	0	0	0	0	0	1	0	0	0
Dengue fever	1	0	15	0	0	0	0	0	15	0	0	0
Dental fistula	0	0	0	0	1	0	1	0	1	0	0	0
Dermatitis infected	0	0	8	0	0	0	2	0	10	0	0	0
Dermatophytosis	0	0	0	0	0	0	1	0	1	0	0	0
Dermo-hypodermitis	0	0	1	0	0	0	5	0	6	0	0	0
Device related infection	2	0	4	0	0	0	1	0	5	0	0	0
Diarrhoea infectious	1	0	5	0	0	0	3	0	8	0	0	0
Diphtheria	0	0	3	0	0	0	0	0	3	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Disseminated Bacillus Calmette-Guerin infection	0	0	1	0	1	0	18	0	19	0	0	0
Diverticulitis	6	0	74	0	2	0	30	0	104	0	0	0
Diverticulitis intestinal perforated	0	0	1	0	0	0	0	0	1	0	0	0
Dysentery	0	0	55	0	1	0	69	0	124	0	0	0
Ear infection	12	0	160	0	7	0	89	1	249	1	0	0
Ear infection bacterial	0	0	3	0	0	0	0	0	3	0	0	0
Ear infection fungal	0	0	2	0	0	0	0	0	2	0	0	0
Ear infection viral	0	0	2	0	0	0	0	0	2	0	0	0
Ear lobe infection	0	0	0	0	0	0	0	1	0	1	0	0
Ear, nose and throat infection	0	0	0	0	0	0	1	0	1	0	0	0
Eczema herpeticum	0	0	6	0	0	0	2	0	8	0	0	0
Eczema infected	0	0	3	0	0	0	2	0	5	0	0	0
Embolic pneumonia	0	0	1	0	0	0	0	0	1	0	0	0
Empyema	0	0	3	0	0	0	0	0	3	0	0	0
Encephalitis	23	0	181	0	0	0	0	0	181	0	2	3
Encephalitis Japanese B	1	0	1	0	0	0	0	0	1	0	0	0
Encephalitis brain stem	2	0	4	0	0	0	0	0	4	0	0	0
Encephalitis cytomegalovirus	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Encephalitis lethargica	0	0	2	0	0	0	2	0	4	0	0	0
Encephalitis viral	3	0	11	0	0	0	2	0	13	0	0	0
Encephalomyelitis	5	0	23	0	0	0	3	0	26	0	0	0
Endocarditis	4	0	24	0	0	0	0	0	24	0	0	0
Endocarditis bacterial	0	0	5	0	0	0	0	0	5	0	0	0
Endocarditis meningococcal	0	0	0	0	0	0	1	0	1	0	0	0
Endometritis	0	0	2	0	0	0	2	0	4	0	0	0
Enteritis infectious	0	0	1	0	0	0	0	0	1	0	0	0
Enterobiasis	0	0	0	0	1	0	1	0	1	0	0	0
Enterococcal infection	1	0	2	0	0	0	1	0	3	0	0	0
Epididymitis	3	0	14	0	0	0	7	0	21	0	0	0
Epiglottitis	0	0	2	0	0	0	0	0	2	0	0	0
Epstein-Barr viraemia	0	0	1	0	0	0	0	0	1	0	0	0
Epstein-Barr virus infection	1	0	13	0	4	0	9	0	22	0	0	0
Epstein-Barr virus infection reactivation	3	0	15	0	1	0	5	0	20	0	0	0
Eruptive pseudoangiomatosis	0	0	0	0	4	0	10	0	10	0	0	0
Erysipelas	6	0	59	0	4	0	65	0	124	0	0	0
Erysipeloid	0	0	0	0	0	0	3	0	3	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Erythema induratum	0	0	2	0	0	0	4	0	6	0	1	1
Erythema infectiosum	0	0	0	0	1	0	2	0	2	0	0	0
Erythema migrans	1	0	4	0	0	0	2	0	6	0	0	0
Escherichia bacteraemia	0	0	3	0	0	0	0	0	3	0	0	0
Escherichia infection	0	0	3	0	0	0	3	0	6	0	0	0
Escherichia sepsis	0	0	3	0	0	0	0	0	3	0	0	0
Escherichia urinary tract infection	0	0	1	0	0	0	0	0	1	0	0	0
Exanthema subitum	0	0	1	0	1	0	12	0	13	0	0	0
External ear cellulitis	0	0	0	0	0	0	1	0	1	0	0	0
Extradural abscess	0	0	1	0	0	0	0	0	1	0	0	0
Eye abscess	0	0	2	0	0	0	3	0	5	0	0	0
Eye infection	2	0	42	0	5	0	45	0	87	0	0	0
Eye infection bacterial	0	0	0	0	0	0	2	0	2	0	0	0
Eye infection toxoplasmal	0	0	1	0	0	0	2	0	3	0	0	0
Eye infection viral	1	0	2	0	0	0	1	0	3	0	0	0
Eyelid boil	0	0	1	0	0	0	3	0	4	0	0	0
Eyelid infection	0	0	6	0	1	0	6	0	12	0	0	0
Fallopian tube abscess	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Fascial infection	0	0	0	0	0	0	1	0	1	0	0	0
Febrile infection	1	0	1	0	0	0	3	0	4	0	0	0
Filariasis	0	0	3	0	0	0	0	0	3	0	0	0
Folliculitis	0	0	11	0	2	0	24	0	35	0	0	0
Foot and mouth disease	0	0	0	0	0	0	4	0	4	0	0	0
Fungal foot infection	0	0	0	0	0	0	2	0	2	0	0	0
Fungal infection	6	0	30	0	5	0	37	0	67	0	0	0
Fungal rhinitis	1	0	1	0	0	0	0	0	1	0	0	0
Fungal sepsis	0	0	1	0	0	0	0	0	1	0	0	0
Fungal skin infection	0	0	5	0	0	0	11	0	16	0	0	0
Furuncle	2	0	40	0	5	0	61	0	101	0	0	0
Gangrene	2	0	12	0	0	0	0	0	12	0	0	0
Gardnerella infection	0	0	0	0	0	0	1	0	1	0	0	0
Gastric infection	1	0	2	0	0	0	1	0	3	0	0	0
Gastritis viral	0	0	1	0	0	0	0	0	1	0	0	0
Gastroenteritis	10	0	78	0	2	0	56	0	134	0	0	0
Gastroenteritis Escherichia coli	0	0	1	0	0	0	2	0	3	0	0	0
Gastroenteritis bacillus	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Gastroenteritis bacterial	3	0	3	0	0	0	0	0	3	0	0	0
Gastroenteritis norovirus	0	0	1	0	0	0	0	0	1	0	0	0
Gastroenteritis rotavirus	0	0	1	0	0	0	0	0	1	0	0	0
Gastroenteritis salmonella	0	0	0	0	0	0	1	0	1	0	0	0
Gastroenteritis staphylococcal	1	0	1	0	0	0	0	0	1	0	0	0
Gastroenteritis viral	2	0	65	0	3	0	29	0	94	0	0	0
Gastrointestinal bacterial infection	0	0	0	0	0	0	1	0	1	0	0	0
Gastrointestinal fungal infection	0	0	1	0	0	0	2	0	3	0	0	0
Gastrointestinal infection	2	0	8	0	3	0	12	0	20	0	0	0
Gastrointestinal viral infection	0	0	0	0	0	0	1	0	1	0	0	0
Genital abscess	1	0	2	0	0	0	4	0	6	0	0	0
Genital herpes	0	0	62	0	9	0	88	0	150	0	0	0
Genital herpes simplex	0	0	1	0	0	0	2	0	3	0	0	0
Genital herpes zoster	0	0	2	0	0	0	1	0	3	0	0	0
Genital infection	1	0	1	0	0	0	1	0	2	0	0	0
Genital infection female	0	0	1	0	0	0	1	0	2	0	0	0
Genital infection fungal	0	0	0	0	1	0	6	0	6	0	0	0
Genital ulcer syndrome	0	0	1	0	1	0	2	0	3	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Genitourinary tract infection	0	0	2	0	0	0	0	0	2	0	0	0
Gingival abscess	0	0	5	0	2	0	8	0	13	0	0	0
Gingivitis	4	0	28	0	14	0	90	0	118	0	0	0
Gonorrhoea	0	0	0	0	0	0	1	0	1	0	0	0
Groin abscess	0	0	2	0	0	0	1	0	3	0	0	0
Groin infection	0	0	1	0	0	0	2	0	3	0	0	0
H1N1 influenza	0	0	1	0	0	0	0	0	1	0	0	0
H2N2 influenza	0	0	4	0	0	0	1	0	5	0	0	0
HIV infection	0	0	3	0	0	0	1	0	4	0	0	0
HIV-associated neurocognitive disorder	0	0	0	0	0	0	1	0	1	0	0	0
Haematological infection	1	0	2	0	0	0	0	0	2	0	0	0
Haematoma infection	0	0	2	0	0	0	1	0	3	0	0	0
Haemophilus infection	1	0	1	0	0	0	0	0	1	0	0	0
Haemorrhagic fever	0	0	1	0	0	0	1	0	2	0	0	0
Haemorrhagic varicella syndrome	0	0	1	0	0	0	0	0	1	0	0	0
Hand-foot-and-mouth disease	0	0	1	0	0	0	1	0	2	0	0	0
Hantaviral infection	0	0	1	0	0	0	0	0	1	0	0	0
Helicobacter gastritis	1	0	2	0	1	0	1	0	3	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Helicobacter infection	2	0	3	0	0	0	2	0	5	0	0	0
Hepatic amoebiasis	0	0	2	0	0	0	0	0	2	0	0	0
Hepatic infection	1	0	2	0	0	0	1	0	3	0	0	0
Hepatitis A	2	0	4	0	0	0	0	0	4	0	0	1
Hepatitis B reactivation	1	0	1	0	0	0	0	0	1	0	0	0
Hepatitis C	0	0	1	0	0	0	1	0	2	0	0	0
Hepatitis E	0	0	4	0	0	0	0	0	4	0	0	0
Hepatitis infectious mononucleosis	0	0	1	0	0	0	1	0	2	0	0	0
Hepatitis viral	1	0	4	0	0	0	1	0	5	0	0	0
Herpangina	0	0	2	0	0	0	1	0	3	0	0	0
Herpes dermatitis	0	0	2	0	0	0	6	0	8	0	0	0
Herpes ophthalmic	4	0	40	0	2	0	18	0	58	0	1	2
Herpes pharyngitis	0	0	0	0	0	0	1	0	1	0	0	0
Herpes simplex	2	0	40	0	10	0	135	0	175	0	0	0
Herpes simplex encephalitis	0	0	2	0	0	0	0	0	2	0	0	0
Herpes simplex hepatitis	0	0	1	0	0	0	0	0	1	0	0	0
Herpes simplex meningitis	0	0	2	0	0	0	1	0	3	0	0	0
Herpes simplex reactivation	1	0	6	0	5	0	22	0	28	0	0	1

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Herpes virus infection	5	0	34	0	29	0	200	0	234	0	0	0
Herpes zoster	40	0	1685	0	189	0	2594	3	4279	3	0	0
Herpes zoster cutaneous disseminated	1	0	4	0	0	0	5	0	9	0	0	0
Herpes zoster disseminated	1	0	4	0	0	0	4	0	8	0	0	0
Herpes zoster infection neurological	1	0	1	0	1	0	1	0	2	0	0	0
Herpes zoster meningitis	0	0	6	0	0	0	0	0	6	0	0	0
Herpes zoster meningoradiculitis	0	0	1	0	0	0	0	0	1	0	0	0
Herpes zoster oticus	1	0	28	0	0	0	12	0	40	0	0	0
Herpes zoster reactivation	1	0	8	0	2	0	21	0	29	0	0	0
Herpetic radiculopathy	0	0	1	0	0	0	1	0	2	0	0	0
Hordeolum	1	0	26	0	5	0	55	0	81	0	0	0
Human herpesvirus 6 infection reactivation	0	0	0	0	0	0	1	0	1	0	0	0
Hypopyon	0	0	0	0	0	0	1	0	1	0	0	0
Impetigo	0	0	11	0	1	0	9	0	20	0	0	0
Implant site pustules	0	0	1	0	0	0	0	0	1	0	0	0
Inclusion conjunctivitis	1	0	1	0	0	0	0	0	1	0	0	0
Infected bite	0	0	4	0	0	0	3	0	7	0	0	0
Infected cyst	1	0	4	0	0	0	1	0	5	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Infected dermal cyst	0	0	3	0	1	0	2	0	5	0	0	0
Infected lymphocele	0	0	1	0	0	0	0	0	1	0	0	0
Infected seroma	0	0	0	0	0	0	1	0	1	0	0	0
Infected varicose vein	0	0	1	0	0	0	0	0	1	0	0	0
Infection	22	0	478	0	17	0	230	1	708	1	2	3
Infection in an immunocompromised host	1	0	4	0	0	0	0	0	4	0	0	0
Infection parasitic	0	0	0	0	0	0	1	0	1	0	0	0
Infection reactivation	0	0	4	0	0	0	2	0	6	0	0	0
Infection susceptibility increased	2	0	7	0	9	0	18	0	25	0	0	0
Infectious mononucleosis	1	0	59	0	1	0	10	0	69	0	0	0
Infectious pleural effusion	0	0	6	0	0	0	0	0	6	0	0	0
Infectious thyroiditis	0	0	1	0	0	0	1	0	2	0	0	0
Infective exacerbation of bronchiectasis	0	0	1	0	0	0	2	0	3	0	0	0
Infective myositis	1	0	1	0	0	0	0	0	1	0	0	0
Infective pulmonary exacerbation of cystic fibrosis	0	0	1	0	0	0	0	0	1	0	0	0
Infective spondylitis	0	0	1	0	0	0	0	0	1	0	0	0
Infective tenosynovitis	0	0	0	0	1	0	1	0	1	0	0	0
Infective thrombosis	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Infestation	0	0	1	0	0	0	1	0	2	0	0	0
Influenza	55	0	6091	0	348	0	10765	2	16856	2	0	0
Injection site abscess	1	0	6	0	3	0	56	0	62	0	0	0
Injection site cellulitis	0	0	15	0	1	0	49	0	64	0	0	0
Injection site infection	1	0	14	0	0	0	56	0	70	0	0	0
Injection site pustule	0	0	3	0	0	0	5	0	8	0	0	0
Intervertebral discitis	0	0	8	0	0	0	0	0	8	0	0	0
Intestinal tuberculosis	1	0	1	0	0	0	0	0	1	0	0	0
Intrauterine infection	0	0	1	0	0	0	0	0	1	0	0	0
Janeway lesion	0	0	1	0	0	0	0	0	1	0	0	0
Joint abscess	0	0	1	0	0	0	0	0	1	0	0	0
Keratitis bacterial	0	0	0	0	0	0	1	0	1	0	0	0
Keratitis viral	0	0	0	0	0	0	1	0	1	0	0	0
Keratouveitis	0	0	0	0	0	0	1	0	1	0	0	0
Kidney infection	3	0	75	0	0	0	6	0	81	0	0	0
Klebsiella infection	2	0	3	0	0	0	2	0	5	0	0	0
Klebsiella sepsis	0	0	1	0	0	0	0	0	1	0	0	0
Labyrinthitis	5	0	180	0	2	0	93	0	273	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Large intestine infection	0	0	4	0	0	0	0	0	4	0	0	0
Laryngitis	3	0	44	0	2	0	48	0	92	0	0	0
Laryngitis viral	0	0	1	0	0	0	0	0	1	0	0	0
Laryngopharyngitis	0	0	1	0	0	0	0	0	1	0	0	0
Latent tuberculosis	0	0	1	0	0	0	0	0	1	0	0	0
Legionella infection	0	0	0	0	0	0	1	0	1	0	0	0
Lemierre syndrome	0	0	0	0	0	0	1	0	1	0	0	0
Leprosy	0	0	2	0	0	0	1	0	3	0	0	0
Leptospirosis	1	0	2	0	0	0	0	0	2	0	0	0
Lice infestation	0	0	0	0	0	0	2	0	2	0	0	0
Lip infection	0	0	0	0	0	0	3	0	3	0	0	0
Liver abscess	0	0	7	0	0	0	0	0	7	0	0	0
Localised infection	9	0	100	1	3	0	53	0	153	1	0	0
Lower respiratory tract infection	14	0	338	0	8	0	129	0	467	0	0	0
Lower respiratory tract infection viral	0	0	1	0	0	0	0	0	1	0	0	0
Ludwig angina	0	0	0	0	0	0	1	0	1	0	0	0
Lung abscess	1	0	4	0	0	0	0	0	4	0	0	0
Lyme carditis	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Lyme disease	4	0	26	0	2	0	15	1	41	1	0	0
Lymph gland infection	0	0	3	0	0	0	8	0	11	0	0	0
Lymph node abscess	0	0	3	0	0	0	12	0	15	0	0	0
Lymph node tuberculosis	0	0	2	0	0	0	1	0	3	0	0	0
Lymphadenitis bacterial	0	0	1	0	0	0	9	0	10	0	0	0
Lymphangitis	1	0	14	0	0	0	19	0	33	0	0	0
Malaria	0	0	7	0	1	0	6	0	13	0	0	0
Mastitis	0	0	50	0	0	0	27	0	77	0	0	0
Mastoiditis	1	0	10	0	0	0	5	0	15	0	0	0
Measles	0	0	3	0	0	0	4	0	7	0	0	0
Measles post vaccine	0	0	1	0	1	0	1	0	2	0	0	0
Medical device site joint infection	0	0	0	0	0	0	1	0	1	0	0	0
Meningitis	4	0	80	0	0	0	0	0	80	0	0	1
Meningitis aseptic	3	0	16	0	0	0	0	0	16	0	0	0
Meningitis bacterial	2	0	7	0	0	0	0	0	7	0	0	0
Meningitis borrelia	0	0	1	0	0	0	0	0	1	0	0	0
Meningitis coxsackie viral	0	0	2	0	0	0	0	0	2	0	0	0
Meningitis cryptococcal	1	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Meningitis meningococcal	0	0	1	0	0	0	0	0	1	0	0	0
Meningitis pneumococcal	0	0	2	0	0	0	0	0	2	0	0	0
Meningitis tuberculous	0	0	2	0	0	0	0	0	2	0	0	0
Meningitis viral	3	0	34	0	0	0	0	0	34	0	0	0
Meningococcal bacteraemia	1	0	1	0	0	0	0	0	1	0	0	0
Meningococcal sepsis	0	0	0	0	0	0	2	0	2	0	0	0
Meningoencephalitis bacterial	0	0	1	0	0	0	0	0	1	0	0	0
Meningoencephalitis herpes simplex neonatal	0	0	1	0	0	0	0	0	1	0	0	0
Meningoencephalitis herpetic	0	0	3	0	0	0	0	0	3	0	0	0
Meningoencephalitis viral	0	0	5	0	0	0	0	0	5	0	0	0
Molluscum contagiosum	0	0	1	0	0	0	0	0	1	0	0	0
Mononucleosis syndrome	0	0	1	0	0	0	0	0	1	0	0	0
Mucormycosis	0	0	1	0	0	0	0	0	1	0	0	0
Mumps	0	0	9	0	0	0	8	0	17	0	0	0
Muscle abscess	0	0	3	0	0	0	3	0	6	0	0	0
Mycoplasma infection	0	0	1	0	0	0	2	0	3	0	0	0
Myelitis	6	0	106	0	2	0	19	0	125	0	1	1
Myocarditis infectious	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Myringitis	0	0	1	0	0	0	0	0	1	0	0	0
Nail bed infection	1	0	1	0	1	0	3	0	4	0	0	0
Nasal abscess	0	0	1	0	0	0	1	0	2	0	0	0
Nasal herpes	1	0	14	0	3	0	36	0	50	0	0	0
Nasal vestibulitis	0	0	1	0	0	0	7	0	8	0	0	0
Nasopharyngitis	54	0	1604	0	514	0	5314	4	6918	4	0	0
Necrotising fasciitis	0	0	3	0	0	0	0	0	3	0	0	0
Necrotising soft tissue infection	0	0	1	0	0	0	0	0	1	0	0	0
Necrotising ulcerative periodontitis	0	0	0	0	0	0	1	0	1	0	0	0
Nematodiasis	0	0	0	0	0	0	1	0	1	0	0	0
Neonatal pneumonia	0	0	0	0	0	0	0	0	0	0	1	3
Neuroborreliosis	2	0	3	0	0	0	0	0	3	0	0	0
Neurological infection	0	0	3	0	1	0	1	0	4	0	0	0
Neurosyphilis	0	0	2	0	0	0	2	0	4	0	0	0
Neutropenic sepsis	1	0	13	0	0	0	0	0	13	0	0	0
Nipple infection	0	0	0	0	1	0	1	0	1	0	0	0
Norovirus infection	0	0	1	0	0	0	0	0	1	0	0	0
Nosocomial infection	0	0	3	0	0	0	0	0	3	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Oesophageal infection	0	0	0	0	0	0	2	0	2	0	0	0
Omphalitis	0	0	1	0	0	0	1	0	2	0	0	1
Onychomycosis	0	0	0	0	1	0	3	0	3	0	0	0
Ophthalmic herpes simplex	0	0	3	0	0	0	3	0	6	0	0	0
Ophthalmic herpes zoster	7	0	102	0	0	0	0	0	102	0	0	0
Oral bacterial infection	0	0	1	0	0	0	0	0	1	0	0	0
Oral candidiasis	2	0	58	0	2	0	31	0	89	0	0	0
Oral fungal infection	0	0	1	0	0	0	6	0	7	0	0	0
Oral herpes	9	0	490	0	55	0	878	0	1368	0	0	0
Oral infection	0	0	2	0	0	0	5	0	7	0	0	0
Oral pustule	0	0	3	0	0	0	4	0	7	0	0	0
Orchitis	1	0	8	0	1	0	6	0	14	0	0	0
Osteomyelitis	1	0	11	0	0	0	0	0	11	0	0	0
Osteomyelitis acute	0	0	0	0	0	0	1	0	1	0	0	0
Otitis externa	0	0	5	0	1	0	17	0	22	0	0	0
Otitis externa bacterial	0	0	1	0	0	0	0	0	1	0	0	0
Otitis media	0	0	13	0	0	0	16	0	29	0	0	0
Otitis media acute	0	0	1	0	0	0	1	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Otitis media chronic	0	0	9	0	0	0	6	0	15	0	0	0
Otosalpingitis	0	0	0	0	0	0	2	0	2	0	0	0
Ovarian abscess	0	0	3	0	0	0	0	0	3	0	0	0
Overgrowth bacterial	1	0	1	0	0	0	0	0	1	0	0	0
Overgrowth fungal	0	0	0	0	0	0	1	0	1	0	0	0
Pancreas infection	0	0	2	0	1	0	1	0	3	0	0	0
Papilloma viral infection	0	0	2	0	0	0	3	0	5	0	0	0
Paragonimiasis	0	0	1	0	0	0	0	0	1	0	0	0
Parainfluenzae viral laryngotracheobronchitis	0	0	0	0	0	0	1	0	1	0	0	0
Parainfluenzae virus infection	0	0	1	0	0	0	1	0	2	0	0	0
Paratyphoid fever	0	0	1	0	3	0	4	0	5	0	0	0
Paravaccinia	0	0	1	0	0	0	0	0	1	0	0	0
Paronychia	0	0	0	0	0	0	3	0	3	0	0	0
Parotitis	0	0	6	0	2	0	35	0	41	0	0	0
Parvovirus B19 infection	0	0	1	0	0	0	0	0	1	0	0	0
Pathogen resistance	0	0	2	0	0	0	1	0	3	0	0	0
Pelvic abscess	0	0	1	0	0	0	0	0	1	0	0	0
Pelvic infection	1	0	2	0	0	0	1	0	3	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Pelvic inflammatory disease	0	0	6	0	0	0	2	0	8	0	0	0
Pelvic sepsis	0	0	1	0	0	0	0	0	1	0	0	0
Perichondritis	0	0	1	0	0	0	2	0	3	0	0	0
Pericoronitis	0	0	3	0	0	0	1	0	4	0	0	0
Periodontitis	0	0	2	0	2	0	5	0	7	0	0	0
Periorbital cellulitis	0	0	4	0	0	0	2	0	6	0	0	0
Periorbital infection	1	0	1	0	0	0	0	0	1	0	0	0
Peritonitis	1	0	23	0	0	0	0	0	23	0	0	0
Peritonitis bacterial	0	0	1	0	0	0	0	0	1	0	0	0
Peritonsillar abscess	0	0	3	0	0	0	0	0	3	0	0	0
Peritonsillitis	0	0	1	0	0	0	0	0	1	0	0	0
Persistent generalised lymphadenopathy	0	0	1	0	0	0	1	0	2	0	0	0
Pertussis	1	0	3	0	0	0	5	0	8	0	0	0
Pharyngeal abscess	0	0	1	0	0	0	6	0	7	0	0	0
Pharyngitis	2	0	51	0	13	0	178	1	229	1	0	0
Pharyngitis bacterial	0	0	0	0	0	0	1	0	1	0	0	0
Pharyngitis streptococcal	2	0	9	0	0	0	3	0	12	0	0	0
Pharyngotonsillitis	0	0	0	0	0	0	1	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Pilonidal disease	0	0	2	0	0	0	0	0	2	0	0	0
Pinta	0	0	1	0	0	0	1	0	2	0	0	0
Plasmodium vivax infection	1	0	2	0	0	0	0	0	2	0	0	0
Pleural infection	0	0	1	0	0	0	0	0	1	0	0	0
Pleurisy viral	0	0	2	0	0	0	1	0	3	0	0	0
Pneumococcal sepsis	0	0	1	0	0	0	0	0	1	0	0	0
Pneumocystis jirovecii infection	1	0	1	0	0	0	0	0	1	0	0	0
Pneumocystis jirovecii pneumonia	2	0	4	0	0	0	0	0	4	0	0	0
Pneumonia	86	0	775	1	9	0	189	1	964	2	5	6
Pneumonia adenoviral	0	0	1	0	0	0	0	0	1	0	0	0
Pneumonia aspiration	6	0	69	0	0	0	0	0	69	0	0	0
Pneumonia bacterial	1	0	18	0	0	0	3	0	21	0	0	1
Pneumonia fungal	1	0	2	0	0	0	0	0	2	0	0	0
Pneumonia klebsiella	1	0	2	0	0	0	0	0	2	0	0	0
Pneumonia legionella	0	0	2	0	0	0	0	0	2	0	0	0
Pneumonia pneumococcal	0	0	1	0	0	0	0	0	1	0	0	0
Pneumonia pseudomonal	0	0	1	0	0	0	0	0	1	0	0	0
Pneumonia staphylococcal	0	0	2	0	0	0	1	0	3	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Pneumonia viral	2	0	29	0	0	0	1	0	30	0	0	0
Poliomyelitis	1	0	1	0	0	0	0	0	1	0	0	0
Post procedural cellulitis	0	0	0	0	0	0	1	0	1	0	0	0
Post procedural infection	0	0	2	0	0	0	1	0	3	0	0	0
Post procedural sepsis	0	0	1	0	0	0	0	0	1	0	0	0
Post viral fatigue syndrome	17	0	174	0	8	0	54	0	228	0	0	0
Post-acute COVID-19 syndrome	19	0	41	0	12	0	34	0	75	0	0	0
Postoperative abscess	0	0	1	0	0	0	0	0	1	0	0	0
Postoperative wound infection	0	0	0	0	0	0	1	0	1	0	0	0
Prion disease	0	0	2	0	0	0	0	0	2	0	0	0
Progressive multifocal leukoencephalopathy	0	0	2	0	0	0	0	0	2	0	0	0
Prostate infection	0	0	0	0	0	0	1	0	1	0	0	0
Prostatitis gonococcal	0	0	1	0	0	0	0	0	1	0	0	0
Pseudomembranous colitis	0	0	0	0	0	0	2	0	2	0	0	0
Pseudomonas infection	0	0	1	0	0	0	1	0	2	0	0	0
Pulmonary mucormycosis	0	0	1	0	0	0	0	0	1	0	0	0
Pulmonary sepsis	0	0	2	0	0	0	0	0	2	0	0	0
Pulmonary tuberculosis	1	0	6	0	0	0	2	0	8	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Pulpitis dental	0	0	1	0	2	0	22	0	23	0	0	0
Puncture site infection	0	0	0	0	0	0	2	0	2	0	0	0
Purulence	0	0	0	0	0	0	2	0	2	0	0	0
Purulent discharge	1	0	3	0	2	0	5	0	8	0	0	0
Pustule	0	0	23	0	5	0	89	0	112	0	0	0
Pyelitis	0	0	2	0	0	0	0	0	2	0	0	0
Pyelonephritis	3	0	32	0	3	0	15	0	47	0	0	0
Pyelonephritis acute	2	0	7	0	0	0	3	0	10	0	0	0
Pyelonephritis chronic	0	0	1	0	0	0	1	0	2	0	0	0
Pyoderma	0	0	0	0	0	0	1	0	1	0	0	0
Pyometra	1	0	2	0	0	0	0	0	2	0	0	0
Pyonephrosis	1	0	1	0	0	0	0	0	1	0	0	0
Pyuria	0	0	1	0	0	0	1	0	2	0	0	0
Q fever	0	0	102	0	0	0	45	0	147	0	0	0
Rash pustular	0	0	16	0	5	0	50	0	66	0	0	0
Rectal abscess	0	0	0	0	0	0	1	0	1	0	0	0
Relapsing fever	0	0	2	0	0	0	3	0	5	0	0	0
Renal abscess	2	0	4	0	0	0	0	0	4	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Respiratory syncytial virus bronchitis	0	0	0	0	0	0	1	0	1	0	0	0
Respiratory syncytial virus infection	0	0	1	0	0	0	1	0	2	0	0	0
Respiratory tract infection	2	0	22	0	8	0	33	0	55	0	0	0
Retinitis	1	0	2	0	0	0	4	0	6	0	0	0
Retinitis viral	0	0	1	0	0	0	0	0	1	0	0	0
Rhinitis	7	0	108	0	309	0	3387	0	3495	0	0	0
Rhinovirus infection	0	0	1	0	0	0	2	0	3	0	0	0
Root canal infection	1	0	1	0	0	0	1	0	2	0	0	0
Roseola	0	0	1	0	0	0	0	0	1	0	0	0
Rotavirus infection	0	0	1	0	0	0	0	0	1	0	0	0
Rubella	0	0	0	0	0	0	1	0	1	0	0	0
SARS-CoV-2 carrier	0	0	2	0	0	0	1	0	3	0	0	0
SARS-CoV-2 sepsis	1	0	1	0	0	0	1	0	2	0	0	0
Salmonellosis	1	0	1	0	0	0	3	0	4	0	0	0
Scarlet fever	0	0	1	0	2	0	2	0	3	0	0	0
Scrotal infection	0	0	0	0	0	0	1	0	1	0	0	0
Secondary transmission	0	0	8	0	0	0	10	0	18	0	0	0
Sepsis	23	0	289	0	0	0	0	0	289	0	3	4

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Sepsis neonatal	0	0	0	0	0	0	0	0	0	0	1	2
Sepsis syndrome	0	0	4	0	0	0	0	0	4	0	0	0
Septic arthritis staphylococcal	1	0	1	0	0	0	0	0	1	0	0	0
Septic embolus	0	0	1	0	0	0	0	0	1	0	0	0
Septic encephalopathy	0	0	2	0	0	0	0	0	2	0	0	0
Septic pulmonary embolism	0	0	1	0	0	0	0	0	1	0	0	0
Septic rash	2	0	9	0	0	0	5	0	14	0	0	0
Septic shock	11	0	63	0	0	0	0	0	63	0	0	0
Severe acute respiratory syndrome	15	0	182	0	0	0	0	0	182	0	0	0
Severe asthma with fungal sensitisation	0	0	5	0	0	0	0	0	5	0	0	0
Severe fever with thrombocytopenia syndrome	0	0	9	0	0	0	1	0	10	0	0	0
Shigella infection	0	0	0	0	0	0	1	0	1	0	0	0
Sialoadenitis	0	0	8	0	0	0	1	0	9	0	0	0
Sinobronchitis	0	0	2	0	0	0	0	0	2	0	0	0
Sinusitis	16	0	374	0	40	0	353	0	727	0	0	0
Sinusitis bacterial	0	0	0	0	0	0	1	0	1	0	0	0
Skin bacterial infection	0	0	6	0	0	0	3	0	9	0	0	0
Skin candida	0	0	3	0	0	0	1	0	4	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Skin infection	1	0	46	0	0	0	47	0	93	0	0	0
Slow virus infection	0	0	0	0	0	0	1	0	1	0	0	0
Small intestine gangrene	0	0	1	0	0	0	0	0	1	0	0	0
Soft tissue infection	0	0	4	0	0	0	3	0	7	0	0	0
Spinal cord abscess	0	0	0	0	0	0	1	0	1	0	0	0
Spinal cord infection	2	0	5	0	0	0	1	0	6	0	0	0
Splenic abscess	0	0	1	0	0	0	0	0	1	0	0	0
Splenic infection	0	0	1	0	0	0	0	0	1	0	0	0
Spontaneous bacterial peritonitis	0	0	2	0	0	0	0	0	2	0	0	0
Sporotrichosis	1	0	1	0	0	0	0	0	1	0	0	0
Sputum purulent	0	0	2	0	1	0	3	0	5	0	0	0
Staphylococcal abscess	0	0	1	0	0	0	0	0	1	0	0	0
Staphylococcal bacteraemia	0	0	5	0	0	0	0	0	5	0	0	0
Staphylococcal infection	4	0	12	0	1	0	7	0	19	0	0	0
Staphylococcal scalded skin syndrome	0	0	1	0	0	0	1	0	2	0	0	0
Staphylococcal sepsis	0	0	10	0	0	0	0	0	10	0	0	0
Stenotrophomonas infection	0	0	1	0	0	0	0	0	1	0	0	0
Streptococcal abscess	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Streptococcal bacteraemia	0	0	1	0	0	0	0	0	1	0	0	0
Streptococcal infection	1	0	7	0	0	0	1	0	8	0	0	0
Streptococcal sepsis	0	0	3	0	0	0	0	0	3	0	0	0
Subcutaneous abscess	1	0	12	0	2	0	30	0	42	0	0	0
Superinfection	0	0	1	0	0	0	0	0	1	0	0	0
Superinfection bacterial	0	0	0	0	0	0	1	0	1	0	0	0
Suspected COVID-19	29	0	99	0	10	0	184	0	283	0	0	0
Sweating fever	2	0	636	0	6	0	158	0	794	0	0	0
Syphilis	0	0	4	0	1	0	4	0	8	0	0	0
Systemic candida	0	0	1	0	0	0	0	0	1	0	0	0
Systemic infection	1	0	3	0	0	0	0	0	3	0	0	0
Systemic mycosis	0	0	1	1	0	0	0	0	1	1	0	0
Tetanus	1	0	6	0	0	0	2	0	8	0	0	0
Tinea capitis	0	0	0	0	1	0	1	0	1	0	0	0
Tinea cruris	0	0	0	0	0	0	3	0	3	0	0	0
Tinea infection	0	0	1	0	1	0	5	0	6	0	0	0
Tinea pedis	0	0	3	0	1	0	9	0	12	0	0	0
Tinea versicolour	0	0	2	0	1	0	3	0	5	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Tongue abscess	0	0	3	0	0	0	2	0	5	0	0	0
Tongue fungal infection	0	0	0	0	0	0	3	0	3	0	0	0
Tonsillitis	2	0	81	0	5	0	77	0	158	0	0	0
Tonsillitis bacterial	0	0	4	0	0	0	0	0	4	0	0	0
Tonsillitis fungal	0	0	1	0	0	0	0	0	1	0	0	0
Tonsillitis streptococcal	0	0	0	0	1	0	2	0	2	0	0	0
Tooth abscess	1	0	13	0	2	0	17	0	30	0	0	0
Tooth infection	5	0	18	0	1	0	11	0	29	0	0	0
Toxic shock syndrome	1	0	3	0	0	0	0	0	3	0	0	0
Toxic shock syndrome staphylococcal	0	0	0	0	0	0	1	0	1	0	0	0
Toxoplasmosis	0	0	1	0	0	0	2	0	3	0	0	0
Tracheitis	0	0	3	0	0	0	12	0	15	0	0	0
Trombidiasis	0	0	3	0	0	0	0	0	3	0	0	0
Tuberculosis	0	0	4	0	3	0	21	0	25	0	0	0
Type 1 lepra reaction	0	0	0	0	4	0	4	0	4	0	0	0
Type 2 lepra reaction	1	0	4	0	2	0	3	0	7	0	0	0
Typhoid fever	0	0	4	0	0	0	16	0	20	0	0	0
Typhus	0	0	0	0	0	0	1	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Upper respiratory tract infection	2	0	25	0	4	0	39	0	64	0	0	0
Ureteritis	0	0	0	0	0	0	1	0	1	0	0	0
Urethritis	0	0	1	0	0	0	1	0	2	0	0	0
Urinary tract infection	17	0	323	2	18	0	264	0	587	2	0	0
Urinary tract infection bacterial	0	0	5	0	0	0	3	0	8	0	0	0
Urosepsis	1	0	25	0	0	0	0	0	25	0	0	0
Vaccination site abscess	1	0	11	0	18	0	51	0	62	0	0	0
Vaccination site cellulitis	0	0	14	0	2	0	30	0	44	0	0	0
Vaccination site infection	0	0	28	0	9	0	35	0	63	0	0	0
Vaccination site joint infection	0	0	1	0	0	0	0	0	1	0	0	0
Vaccination site pustule	0	0	4	0	0	0	4	0	8	0	0	0
Vaccine breakthrough infection	0	0	6	0	3	0	14	0	20	0	0	0
Vaccine derived SARS-CoV-2 infection	0	0	1	0	0	0	0	0	1	0	0	0
Vaccine virus shedding	0	0	0	0	0	0	1	0	1	0	0	0
Vaccinia virus infection	0	0	1	0	0	0	1	0	2	0	0	0
Vaginal abscess	1	0	5	0	0	0	1	0	6	0	0	0
Vaginal infection	1	0	4	0	2	0	14	0	18	0	0	0
Varicella	3	0	34	0	0	0	28	0	62	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Varicella meningitis	1	0	1	0	0	0	0	0	1	0	0	0
Varicella zoster virus infection	0	0	12	0	2	0	11	0	23	0	0	0
Vestibular neuronitis	2	0	98	0	1	0	38	0	136	0	1	3
Vestibulitis	0	0	3	0	0	0	1	0	4	0	0	0
Viraemia	0	0	2	0	0	0	2	0	4	0	0	0
Viral diarrhoea	0	0	4	0	0	0	2	0	6	0	0	0
Viral infection	0	0	91	0	4	0	46	0	137	0	0	0
Viral labyrinthitis	0	0	7	0	0	0	1	0	8	0	0	0
Viral myelitis	0	0	1	0	0	0	0	0	1	0	0	0
Viral myocarditis	1	0	8	0	0	0	0	0	8	0	0	0
Viral myositis	0	0	1	0	0	0	0	0	1	0	0	0
Viral pericarditis	1	0	6	0	0	0	0	0	6	0	0	0
Viral pharyngitis	0	0	24	0	2	0	16	0	40	0	0	0
Viral rash	0	0	50	0	2	0	46	0	96	0	0	0
Viral sepsis	0	0	1	0	0	0	0	0	1	0	0	0
Viral sinusitis	0	0	1	0	0	0	0	0	1	0	0	0
Viral tonsillitis	0	0	1	0	0	0	0	0	1	0	0	0
Viral upper respiratory tract infection	0	0	1	0	1	0	2	0	3	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Viral uveitis	0	0	0	0	0	0	2	0	2	0	0	0
Vulval abscess	0	0	1	0	0	0	0	0	1	0	0	0
Vulvitis	0	0	0	0	0	0	1	0	1	0	0	0
Vulvovaginal candidiasis	2	0	36	0	1	0	43	0	79	0	0	0
Vulvovaginal mycotic infection	0	0	2	0	2	0	21	0	23	0	0	0
Vulvovaginitis	0	0	0	0	0	0	1	0	1	0	0	0
Vulvovaginitis staphylococcal	0	0	1	0	0	0	0	0	1	0	0	0
Wound abscess	0	0	0	0	0	0	1	0	1	0	0	0
Wound infection	2	0	5	0	4	0	6	0	11	0	0	0
Wound infection staphylococcal	0	0	1	0	0	0	0	0	1	0	0	0
Wound sepsis	1	0	2	0	0	0	0	0	2	0	0	0
Yaws of skin	0	0	0	0	0	0	2	0	2	0	0	0
Yellow fever	0	0	0	0	0	0	2	0	2	0	0	0
Yellow fever vaccine-associated neurotropic disease	0	0	1	0	0	0	0	0	1	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**121**	**0**	**982**	**1**	**21**	**0**	**214**	**0**	**1196**	**1**	**4**	**4**
5q minus syndrome	1	0	7	0	0	0	0	0	7	0	0	0
Acoustic neuroma	2	0	9	0	1	0	2	0	11	0	0	0
Acral lentiginous melanoma stage III	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Acrochordon	1	0	4	0	0	0	4	0	8	0	0	0
Acute leukaemia	3	0	11	0	0	0	0	0	11	0	0	0
Acute lymphocytic leukaemia	0	0	3	0	0	0	0	0	3	0	0	0
Acute lymphocytic leukaemia recurrent	0	0	1	0	0	0	0	0	1	0	0	0
Acute myeloid leukaemia	2	0	13	0	0	0	0	0	13	0	1	1
Acute myeloid leukaemia recurrent	0	0	1	0	0	0	0	0	1	0	0	0
Acute promyelocytic leukaemia	1	0	2	0	0	0	0	0	2	0	0	0
Adenocarcinoma	0	0	5	0	0	0	0	0	5	0	0	0
Adenocarcinoma of colon	1	0	1	0	0	0	0	0	1	0	0	0
Adenoma benign	0	0	1	0	0	0	1	0	2	0	0	0
Adrenal adenoma	0	0	1	0	0	0	0	0	1	0	0	0
Adrenal gland cancer	1	0	2	0	0	0	0	0	2	0	0	0
Adrenal neoplasm	0	0	1	0	0	0	0	0	1	0	0	0
Anal cancer	0	0	2	0	0	0	0	0	2	0	0	0
Angiosarcoma	1	0	1	0	0	0	0	0	1	0	0	0
Anogenital warts	1	0	2	0	0	0	6	0	8	0	0	0
B-cell lymphoma	0	0	6	0	0	0	0	0	6	0	0	0
B-cell lymphoma stage II	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
B-cell lymphoma stage IV	0	0	1	0	0	0	0	0	1	0	0	0
Basal cell carcinoma	3	0	9	0	0	0	0	0	9	0	0	0
Benign breast neoplasm	0	0	4	0	0	0	2	0	6	0	0	0
Benign ear neoplasm	0	0	0	0	0	0	1	0	1	0	0	0
Benign hydatidiform mole	0	0	2	0	0	0	0	0	2	0	0	0
Benign lymph node neoplasm	0	0	0	0	0	0	1	0	1	0	0	0
Benign neoplasm of thyroid gland	1	0	2	0	0	0	0	0	2	0	0	0
Benign ovarian tumour	0	0	0	0	0	0	1	0	1	0	0	0
Benign soft tissue neoplasm	0	0	0	0	0	0	1	0	1	0	0	0
Benign spleen tumour	1	0	1	0	0	0	0	0	1	0	0	0
Bile duct cancer	0	0	1	0	0	0	0	0	1	0	0	0
Bladder cancer	1	0	8	0	0	0	0	0	8	0	0	0
Bladder cancer recurrent	0	0	1	0	0	0	0	0	1	0	0	0
Bladder neoplasm	0	0	2	0	0	0	0	0	2	0	0	0
Bone cancer	0	0	2	0	0	0	0	0	2	0	0	0
Bowen's disease	0	0	1	0	0	0	0	0	1	0	0	0
Brain cancer metastatic	0	0	2	0	0	0	0	0	2	0	0	0
Brain neoplasm	4	0	23	0	0	0	0	0	23	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Brain neoplasm malignant	0	0	3	0	0	0	0	0	3	0	0	0
Breast cancer	7	0	77	0	0	0	0	0	77	0	1	1
Breast cancer female	2	0	6	0	0	0	0	0	6	0	0	0
Breast cancer in situ	0	0	1	0	0	0	0	0	1	0	0	0
Breast cancer male	0	0	4	0	0	0	0	0	4	0	0	0
Breast cancer metastatic	1	0	5	0	0	0	0	0	5	0	0	0
Breast cancer stage I	0	0	1	0	0	0	0	0	1	0	0	0
Breast cancer stage III	0	0	3	0	0	0	0	0	3	0	0	0
Breast cancer stage IV	0	0	1	0	0	0	0	0	1	0	0	0
Breast neoplasm	0	0	2	0	0	0	0	0	2	0	0	0
Bronchial carcinoma	0	0	4	0	0	0	0	0	4	0	0	0
Burkitt's lymphoma stage II	0	0	1	0	0	0	0	0	1	0	0	0
Cancer fatigue	0	0	3	0	0	0	1	0	4	0	0	0
Cancer pain	0	0	2	0	0	0	0	0	2	0	0	0
Carcinoid tumour of the liver	1	0	1	0	0	0	0	0	1	0	0	0
Cartilage neoplasm	0	0	0	0	1	0	1	0	1	0	0	0
Central nervous system lymphoma	0	0	2	0	0	0	0	0	2	0	0	0
Cerebellar haemangioma	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Cerebral haemangioma	0	0	1	0	0	0	0	0	1	0	0	0
Cervix carcinoma	0	0	3	0	0	0	0	0	3	0	0	0
Cervix carcinoma stage 0	0	0	1	0	0	0	0	0	1	0	0	0
Cervix warts	0	0	1	0	0	0	0	0	1	0	0	0
Cholangiocarcinoma	1	0	3	0	0	0	0	0	3	0	0	0
Cholangiosarcoma	0	0	1	0	0	0	0	0	1	0	0	0
Cholesterol granuloma	0	0	1	0	0	0	0	0	1	0	0	0
Chronic leukaemia	0	0	1	0	0	0	0	0	1	0	0	0
Chronic lymphocytic leukaemia	0	0	13	0	0	0	0	0	13	0	0	0
Chronic myeloid leukaemia	2	0	6	0	0	0	0	0	6	0	0	0
Clear cell endometrial carcinoma	0	0	1	0	0	0	0	0	1	0	0	0
Clear cell renal cell carcinoma	0	0	5	0	0	0	0	0	5	0	0	0
Colon cancer	3	0	10	0	0	0	0	0	10	0	0	0
Colon cancer metastatic	1	0	1	0	0	0	0	0	1	0	0	0
Colon cancer stage I	1	0	1	0	0	0	0	0	1	0	0	0
Colon cancer stage III	0	0	1	0	0	0	0	0	1	0	0	0
Colon neoplasm	0	0	1	0	0	0	0	0	1	0	0	0
Colorectal cancer	0	0	3	0	0	0	0	0	3	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Cutaneous T-cell lymphoma	0	0	2	0	0	0	0	0	2	0	0	0
Cutaneous T-cell lymphoma recurrent	0	0	2	0	0	0	0	0	2	0	0	0
Cutaneous lymphoma	0	0	1	0	0	0	0	0	1	0	0	0
Dedifferentiated liposarcoma	0	0	1	0	0	0	0	0	1	0	0	0
Diffuse large B-cell lymphoma	0	0	3	0	0	0	0	0	3	0	0	0
Diffuse large B-cell lymphoma stage III	0	0	1	0	0	0	0	0	1	0	0	0
Diffuse large B-cell lymphoma stage IV	0	0	1	0	0	0	0	0	1	0	0	0
Endometrial adenocarcinoma	0	0	1	0	0	0	0	0	1	0	0	0
Endometrial cancer	0	0	4	0	0	0	0	0	4	0	0	0
Epstein Barr virus positive mucocutaneous ulcer	0	0	1	0	0	0	1	0	2	0	0	0
Essential thrombocythaemia	1	0	3	0	0	0	1	0	4	0	0	0
Extranodal marginal zone B-cell lymphoma (MALT type)	0	0	1	0	0	0	0	0	1	0	0	0
Eye naevus	0	0	4	0	0	0	0	0	4	0	0	0
Eyelid tumour	0	0	0	0	0	0	1	0	1	0	0	0
Fibroadenoma of breast	0	0	2	0	1	0	1	0	3	0	0	0
Fibroma	0	0	1	0	0	0	1	0	2	0	0	0
Focal nodular hyperplasia	0	0	1	0	0	0	0	0	1	0	0	0
Follicular lymphoma	0	0	5	0	0	0	0	0	5	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Gammopathy	0	0	0	0	2	0	2	0	2	0	0	0
Gastric cancer	0	0	4	0	0	0	0	0	4	0	0	0
Gastrointestinal carcinoma	1	0	11	0	0	0	0	0	11	0	0	0
Gastrointestinal lymphoma	1	0	1	0	0	0	0	0	1	0	0	0
Gastrointestinal stromal tumour	0	0	1	0	0	0	0	0	1	0	0	0
Gastrointestinal tract adenoma	0	0	1	0	0	0	0	0	1	0	0	0
Glioblastoma	0	0	9	0	0	0	0	0	9	0	0	0
Glioblastoma multiforme	0	0	1	0	0	0	0	0	1	0	0	0
Glioma	0	0	1	0	0	0	0	0	1	0	0	0
Glomus tumour	0	0	1	0	0	0	0	0	1	0	0	0
Good syndrome	0	0	0	0	0	0	4	0	4	0	0	0
Haemangioma	0	0	14	0	2	0	26	0	40	0	1	1
Haemangioma of liver	0	0	3	0	2	0	3	0	6	0	0	0
Haemangioma of skin	0	0	9	0	0	0	22	0	31	0	0	0
Haemangioma rupture	0	0	1	0	0	0	0	0	1	0	0	0
Haematological malignancy	0	0	4	0	0	0	0	0	4	0	0	0
Hairy cell leukaemia	0	0	1	0	0	0	0	0	1	0	0	0
Heavy chain disease	0	0	2	0	0	0	1	0	3	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Hepatic cancer	0	0	2	0	0	0	0	0	2	0	0	0
Hepatic haemangioma rupture	0	0	1	0	0	0	0	0	1	0	0	0
Hepatic neoplasm	0	0	3	0	0	0	0	0	3	0	0	0
Hepatoblastoma	0	0	2	0	0	0	0	0	2	0	0	0
Hepatocellular carcinoma	0	0	4	0	0	0	0	0	4	0	0	0
High-grade B-cell lymphoma	0	0	1	0	0	0	0	0	1	0	0	0
Histiocytic necrotising lymphadenitis	0	0	1	0	1	0	2	0	3	0	0	0
Hodgkin's disease	0	0	4	0	0	0	0	0	4	0	0	0
Hodgkin's disease mixed cellularity stage III	0	0	1	0	0	0	0	0	1	0	0	0
Huerthle cell carcinoma	0	0	1	0	0	0	0	0	1	0	0	0
Hypergammaglobulinaemia benign monoclonal	0	0	4	0	0	0	3	0	7	0	0	0
Inflammatory carcinoma of breast stage III	0	0	1	0	0	0	0	0	1	0	0	0
Inflammatory pseudotumour	0	0	1	0	0	0	0	0	1	0	0	0
Intracranial tumour haemorrhage	0	0	1	0	0	0	0	0	1	0	0	0
Intraductal proliferative breast lesion	0	0	2	0	0	0	0	0	2	0	0	0
Invasive ductal breast carcinoma	0	0	2	0	0	0	0	0	2	0	0	0
Kaposi's sarcoma	2	0	2	0	0	0	0	0	2	0	0	0
Keratinising squamous cell carcinoma of nasopharynx	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Knuckle pads	0	0	0	0	0	0	1	0	1	0	0	0
Langerhans' cell histiocytosis	0	0	1	0	0	0	0	0	1	0	0	0
Leiomyoma	0	0	2	0	2	0	4	0	6	0	0	0
Leiomyosarcoma	1	0	1	0	0	0	0	0	1	0	0	0
Leukaemia	3	0	11	0	0	0	0	0	11	0	0	0
Leukaemia recurrent	0	0	1	0	0	0	0	0	1	0	0	0
Lip and/or oral cavity cancer	0	0	1	0	0	0	0	0	1	0	0	0
Lip and/or oral cavity cancer stage I	0	0	1	0	0	0	0	0	1	0	0	0
Lip neoplasm malignant stage unspecified	0	0	1	0	0	0	0	0	1	0	0	0
Lip squamous cell carcinoma	0	0	2	0	0	0	0	0	2	0	0	0
Lipoma	2	0	14	0	0	0	12	0	26	0	0	0
Liposarcoma	1	0	4	0	0	0	0	0	4	0	0	0
Liposarcoma metastatic	1	0	1	0	0	0	0	0	1	0	0	0
Lung adenocarcinoma	1	0	3	0	0	0	0	0	3	0	0	0
Lung adenocarcinoma stage IV	0	0	1	0	0	0	0	0	1	0	0	0
Lung cancer metastatic	0	0	3	0	0	0	0	0	3	0	0	0
Lung neoplasm	0	0	4	0	0	0	0	0	4	0	0	0
Lung neoplasm malignant	0	0	34	0	0	0	0	0	34	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Lymphoma	5	0	43	1	0	0	0	0	43	1	0	0
Lymphoplasmacytoid lymphoma/immunocytoma	0	0	1	0	0	0	0	0	1	0	0	0
Lymphoproliferative disorder	0	0	1	0	0	0	1	0	2	0	0	0
Lymphoproliferative disorder in remission	0	0	1	0	0	0	0	0	1	0	0	0
Malignant melanoma	2	0	13	0	0	0	0	0	13	0	0	0
Malignant melanoma in situ	0	0	3	0	0	0	0	0	3	0	0	0
Malignant neoplasm of spinal cord	0	0	1	0	0	0	0	0	1	0	0	0
Malignant neoplasm progression	3	0	8	0	0	0	0	0	8	0	0	0
Maxillofacial sinus neoplasm	0	0	1	0	0	0	0	0	1	0	0	0
Melanocytic naevus	2	0	5	0	1	0	14	0	19	0	0	0
Melanoma recurrent	0	0	1	0	0	0	0	0	1	0	0	0
Meningeal neoplasm	0	0	1	0	0	0	0	0	1	0	0	0
Meningioma	1	0	9	0	0	0	1	0	10	0	0	0
Mesothelioma	0	0	0	0	0	0	1	0	1	0	0	0
Metastases to bone	0	0	3	0	0	0	0	0	3	0	0	0
Metastases to central nervous system	0	0	4	0	0	0	0	0	4	0	0	0
Metastases to liver	1	0	8	0	0	0	0	0	8	0	0	0
Metastases to lung	1	0	5	0	0	0	0	0	5	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Metastases to lymph nodes	0	0	2	0	0	0	0	0	2	0	0	0
Metastases to meninges	0	0	1	0	0	0	0	0	1	0	0	0
Metastases to ovary	0	0	1	0	0	0	0	0	1	0	0	0
Metastases to spine	0	0	1	0	0	0	0	0	1	0	0	0
Metastasis	0	0	6	0	0	0	0	0	6	0	0	0
Metastatic malignant melanoma	0	0	1	0	0	0	0	0	1	0	0	0
Metastatic neoplasm	0	0	4	0	0	0	0	0	4	0	0	0
Metastatic renal cell carcinoma	0	0	1	0	0	0	0	0	1	0	0	0
Monoclonal gammopathy	0	0	2	0	1	0	3	0	5	0	0	0
Multilocular cystic nephroma	0	0	0	0	1	0	1	0	1	0	0	0
Myelodysplastic syndrome	1	0	9	0	1	0	2	0	11	0	0	0
Myeloid leukaemia	1	0	2	0	0	0	0	0	2	0	0	0
Myeloproliferative neoplasm	1	0	5	0	0	0	0	0	5	0	0	0
Myxoma	0	0	0	0	1	0	1	0	1	0	0	0
Naevus haemorrhage	0	0	0	0	0	0	1	0	1	0	0	0
Nasal cavity cancer	1	0	3	0	0	0	0	0	3	0	0	0
Neoplasm	3	0	14	0	0	0	14	0	28	0	0	0
Neoplasm malignant	8	0	45	0	0	0	0	0	45	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Neoplasm of appendix	0	0	1	0	0	0	0	0	1	0	0	0
Neoplasm progression	2	0	7	0	1	0	2	0	9	0	0	0
Neoplasm prostate	0	0	1	0	0	0	0	0	1	0	0	0
Neoplasm recurrence	0	0	9	0	0	0	0	0	9	0	0	0
Neoplasm skin	1	0	3	0	0	0	3	0	6	0	0	0
Neuroendocrine tumour	0	0	2	0	0	0	0	0	2	0	0	0
Neuroendocrine tumour of the lung metastatic	0	0	1	0	0	0	0	0	1	0	0	0
Neurogenic tumour	0	0	1	0	0	0	0	0	1	0	0	0
Neuroma	0	0	0	0	1	0	1	0	1	0	0	0
Non-Hodgkin's lymphoma	1	0	8	0	0	0	0	0	8	0	0	0
Oesophageal cancer metastatic	1	0	7	0	0	0	0	0	7	0	0	0
Oesophageal carcinoma	0	0	4	0	0	0	0	0	4	0	0	0
Oesophageal neoplasm	0	0	1	0	0	0	0	0	1	0	0	0
Oesophageal squamous cell carcinoma	0	0	1	0	0	0	0	0	1	0	0	0
Oligodendroglioma	0	0	1	0	0	0	0	0	1	0	0	0
Oncologic complication	0	0	1	0	0	0	0	0	1	0	0	0
Oral haemangioma	0	0	0	0	0	0	1	0	1	0	0	0
Osteoma	1	0	3	0	0	0	0	0	3	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Ovarian cancer	1	0	14	0	0	0	0	0	14	0	0	0
Ovarian cancer recurrent	0	0	2	0	0	0	0	0	2	0	0	0
Ovarian cancer stage IV	0	0	1	0	0	0	0	0	1	0	0	0
Paget's disease of nipple	0	0	1	0	0	0	0	0	1	0	0	0
Pancreatic carcinoma	2	0	12	0	0	0	0	0	12	0	0	0
Pancreatic carcinoma metastatic	0	0	2	0	0	0	0	0	2	0	0	0
Pancreatic carcinoma recurrent	0	0	1	0	0	0	0	0	1	0	0	0
Pancreatic neoplasm	1	0	2	0	0	0	0	0	2	0	0	0
Papillary cystadenoma lymphomatosum	0	0	1	0	0	0	0	0	1	0	0	0
Papillary thyroid cancer	1	0	1	0	0	0	0	0	1	0	0	0
Paraneoplastic syndrome	1	0	5	0	0	0	0	0	5	0	0	0
Paraproteinaemia	0	0	2	0	0	0	0	0	2	0	0	0
Parathyroid tumour	0	0	1	0	0	0	0	0	1	0	0	0
Penile cancer	0	0	1	0	0	0	0	0	1	0	0	0
Pituitary tumour	0	0	1	0	0	0	1	0	2	0	0	0
Pituitary tumour benign	0	0	4	0	0	0	1	0	5	0	0	0
Plasma cell myeloma	3	0	12	0	0	0	0	0	12	0	0	0
Plasmacytoma	1	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Pleomorphic leiomyosarcoma	0	0	1	0	0	0	0	0	1	0	0	0
Post transplant lymphoproliferative disorder	1	0	1	0	0	0	0	0	1	0	0	0
Primary mediastinal large B-cell lymphoma	0	0	1	0	0	0	0	0	1	0	0	0
Prolymphocytic leukaemia	0	0	1	0	0	0	0	0	1	0	0	0
Prostate cancer	2	0	16	0	0	0	0	0	16	0	1	1
Prostate cancer metastatic	0	0	1	0	0	0	0	0	1	0	0	0
Prostate cancer recurrent	1	0	2	0	0	0	0	0	2	0	0	0
Rectal adenocarcinoma	1	0	1	0	0	0	0	0	1	0	0	0
Rectal cancer	0	0	1	0	0	0	0	0	1	0	0	0
Rectosigmoid cancer metastatic	0	0	1	0	0	0	0	0	1	0	0	0
Recurrent cancer	1	0	4	0	0	0	0	0	4	0	0	0
Renal cancer	1	0	4	0	0	0	0	0	4	0	0	0
Renal cell carcinoma	0	0	1	0	0	0	0	0	1	0	0	0
Renal hamartoma	0	0	0	0	0	0	1	0	1	0	0	0
Renal lipoma	0	0	0	0	0	0	1	0	1	0	0	0
Renal neoplasm	0	0	0	0	0	0	1	0	1	0	0	0
Retro-orbital neoplasm	0	0	0	0	0	0	1	0	1	0	0	0
Salivary gland cancer stage 0	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Salivary gland cancer stage III	0	0	1	0	0	0	0	0	1	0	0	0
Salivary gland neoplasm	0	0	2	0	0	0	0	0	2	0	0	0
Sarcoma	1	0	1	0	0	0	0	0	1	0	0	0
Schwannoma	0	0	1	0	0	0	0	0	1	0	0	0
Seborrhoeic keratosis	1	0	2	0	0	0	2	0	4	0	0	0
Skin cancer	3	0	12	0	0	0	0	0	12	0	0	0
Skin papilloma	1	0	14	0	1	0	33	0	47	0	0	0
Small cell lung cancer	1	0	2	0	0	0	0	0	2	0	0	0
Small cell lung cancer metastatic	0	0	1	0	0	0	0	0	1	0	0	0
Spinal cord neoplasm	0	0	1	0	0	0	0	0	1	0	0	0
Spinal meningioma benign	0	0	1	0	0	0	0	0	1	0	0	0
Spindle cell sarcoma	0	0	2	0	0	0	0	0	2	0	0	0
Squamous cell carcinoma	1	0	9	0	0	0	0	0	9	0	0	0
Squamous cell carcinoma of skin	0	0	1	0	0	0	0	0	1	0	0	0
Squamous cell carcinoma of the oral cavity	0	0	2	0	0	0	0	0	2	0	0	0
Squamous cell carcinoma of the vulva	0	0	1	0	0	0	0	0	1	0	0	0
Synovial sarcoma	0	0	1	0	0	0	0	0	1	0	0	0
Systemic mastocytosis	0	0	0	0	0	0	1	0	1	0	0	0

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System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
T-cell lymphoma	0	0	1	0	0	0	0	0	1	0	0	0
T-cell type acute leukaemia	1	0	1	0	0	0	0	0	1	0	0	0
Testicle adenoma	0	0	0	0	0	0	1	0	1	0	0	0
Throat cancer	0	0	3	0	0	0	0	0	3	0	0	0
Thyroid adenoma	0	0	0	0	0	0	1	0	1	0	0	0
Thyroid cancer	0	0	2	0	0	0	0	0	2	0	0	0
Thyroid neoplasm	0	0	0	0	0	0	2	0	2	0	0	0
Tongue neoplasm	0	0	1	0	0	0	0	0	1	0	0	0
Tongue neoplasm malignant stage unspecified	0	0	1	0	0	0	0	0	1	0	0	0
Tonsil cancer	0	0	5	0	0	0	0	0	5	0	0	0
Triple negative breast cancer	0	0	1	0	0	0	0	0	1	0	0	0
Tumour haemorrhage	0	0	5	0	0	0	0	0	5	0	0	0
Tumour inflammation	0	0	1	0	0	0	0	0	1	0	0	0
Tumour pain	0	0	1	0	1	0	3	0	4	0	0	0
Tumour perforation	0	0	1	0	0	0	0	0	1	0	0	0
Uterine cancer	1	0	6	0	0	0	0	0	6	0	0	0
Uterine leiomyoma	1	0	19	0	0	0	13	0	32	0	0	0
Vulval cancer	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Waldenstrom's macroglobulinaemia	0	0	1	0	0	0	0	0	1	0	0	0
Blood and lymphatic system disorders	**596**	**0**	**11305**	**4**	**1259**	**0**	**9083**	**0**	**20388**	**4**	**113**	**189**
Abdominal lymphadenopathy	0	0	1	0	0	0	3	0	4	0	0	0
Abnormal clotting factor	0	0	8	0	0	0	7	0	15	0	0	0
Acquired haemophilia	7	0	15	0	1	0	1	0	16	0	0	0
Agranulocytosis	1	0	15	0	0	0	0	0	15	0	0	0
Anaemia	30	0	321	0	12	0	99	0	420	0	0	3
Anaemia folate deficiency	0	0	3	0	1	0	1	0	4	0	0	0
Anaemia macrocytic	0	0	2	0	0	0	0	0	2	0	0	0
Anaemia of chronic disease	0	0	1	0	0	0	0	0	1	0	0	0
Anaemia vitamin B12 deficiency	1	0	12	0	0	0	3	0	15	0	0	0
Anisocytosis	0	0	4	0	0	0	3	0	7	0	0	0
Antiphospholipid syndrome	2	0	35	0	0	0	7	0	42	0	0	0
Aplasia pure red cell	0	0	1	0	0	0	0	0	1	0	0	0
Aplastic anaemia	6	0	22	0	0	0	0	0	22	0	0	0
Atypical haemolytic uraemic syndrome	4	0	11	0	0	0	1	0	12	0	0	0
Autoimmune anaemia	1	0	4	0	0	0	0	0	4	0	0	0
Autoimmune haemolytic anaemia	7	0	33	0	0	0	0	0	33	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Autoimmune heparin-induced thrombocytopenia	0	0	1	0	0	0	0	0	1	0	0	0
Autoimmune neutropenia	0	0	3	0	0	0	0	0	3	0	0	0
B-cell aplasia	0	0	0	0	1	0	1	0	1	0	0	0
Bicytopenia	0	0	2	0	0	0	2	0	4	0	0	0
Blood disorder	4	0	22	0	3	0	21	0	43	0	0	0
Blood loss anaemia	0	0	9	0	0	0	5	0	14	0	0	1
Bone marrow disorder	0	0	2	0	0	0	4	0	6	0	0	0
Bone marrow failure	0	0	1	0	0	0	0	0	1	0	0	0
Bone marrow ischaemia	0	0	1	0	0	0	0	0	1	0	0	0
Bone marrow oedema	1	0	5	0	1	0	4	0	9	0	0	0
Coagulopathy	12	0	259	0	10	0	134	0	393	0	0	0
Cold type haemolytic anaemia	0	0	3	0	0	0	0	0	3	0	0	0
Coombs negative haemolytic anaemia	0	0	2	0	0	0	0	0	2	0	0	0
Coombs positive haemolytic anaemia	0	0	2	0	0	0	0	0	2	0	0	0
Cytopenia	0	0	2	0	0	0	0	0	2	0	0	0
Deficiency anaemia	1	0	4	0	0	0	1	0	5	0	0	0
Dermatopathic lymphadenopathy	0	0	0	0	0	0	2	0	2	0	0	0
Disseminated intravascular coagulation	5	0	89	0	0	0	0	0	89	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Eosinopenia	0	0	0	0	0	0	1	0	1	0	0	0
Eosinophilia	0	0	20	0	0	0	18	0	38	0	0	0
Eosinophilia myalgia syndrome	0	0	0	0	0	0	1	0	1	0	0	0
Evans syndrome	1	0	5	0	0	0	0	0	5	0	0	0
Febrile bone marrow aplasia	0	0	2	0	0	0	0	0	2	0	0	0
Febrile neutropenia	0	0	3	0	0	0	0	0	3	0	0	0
Haemoconcentration	1	0	1	0	1	0	1	0	2	0	0	0
Haemoglobinaemia	0	0	0	0	0	0	2	0	2	0	0	0
Haemolysis	0	0	22	0	0	0	7	0	29	0	0	0
Haemolytic anaemia	0	0	33	0	0	0	0	0	33	0	0	0
Haemolytic uraemic syndrome	0	0	6	0	0	0	0	0	6	0	0	0
Haemorrhagic diathesis	5	0	19	0	1	0	17	0	36	0	0	0
Haemorrhagic disorder	0	0	3	0	0	0	11	0	14	0	0	0
Heparin-induced thrombocytopenia	1	0	38	0	0	0	3	0	41	0	0	0
Hilar lymphadenopathy	0	0	1	0	0	0	2	0	3	0	0	0
Hypercoagulation	2	0	45	0	0	0	15	0	60	0	0	3
Hypereosinophilic syndrome	0	0	1	0	0	0	0	0	1	0	0	0
Hyperfibrinogenaemia	0	0	3	0	0	0	0	0	3	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Hyperfibrinolysis	0	0	1	0	0	0	0	0	1	0	0	0
Hypergammaglobulinaemia	0	0	0	0	1	0	1	0	1	0	0	0
Hyperleukocytosis	0	0	3	0	0	0	0	0	3	0	0	0
Hypochromic anaemia	0	0	4	0	0	0	0	0	4	0	0	0
Hypocoagulable state	0	0	3	0	0	0	0	0	3	0	0	0
Hypofibrinogenaemia	0	0	15	0	0	0	0	0	15	0	0	0
Immune thrombocytopenia	39	0	774	1	0	0	0	0	774	1	17	39
Increased tendency to bruise	5	0	122	0	14	0	155	0	277	0	0	0
Iron deficiency anaemia	4	0	24	0	2	0	16	0	40	0	0	1
Leukocytosis	0	0	19	0	2	0	17	0	36	0	0	0
Leukopenia	6	0	60	0	2	0	32	0	92	0	0	0
Lymph node calcification	0	0	0	0	1	0	2	0	2	0	0	0
Lymph node fibrosis	0	0	1	0	0	0	0	0	1	0	0	0
Lymph node haemorrhage	0	0	1	0	0	0	0	0	1	0	0	0
Lymph node pain	29	0	498	0	314	0	898	0	1396	0	0	0
Lymphadenitis	3	0	61	0	46	0	259	0	320	0	0	0
Lymphadenopathy	89	0	4055	0	812	0	6939	0	10994	0	0	6
Lymphadenopathy mediastinal	1	0	4	0	2	0	3	0	7	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Lymphatic disorder	0	0	3	0	2	0	5	0	8	0	0	0
Lymphatic insufficiency	0	0	1	0	0	0	0	0	1	0	0	0
Lymphatic obstruction	0	0	0	0	0	0	2	0	2	0	0	0
Lymphocytic infiltration	0	0	1	0	0	0	1	0	2	0	0	0
Lymphocytosis	0	0	11	0	1	0	8	0	19	0	0	0
Lymphoid tissue hyperplasia	0	0	2	0	0	0	0	0	2	0	0	0
Lymphopenia	2	0	33	0	2	0	25	0	58	0	0	0
Macrocytosis	0	0	3	0	0	0	2	0	5	0	0	0
Mast cell activation syndrome	16	0	37	0	2	0	3	0	40	0	0	0
Mastocytosis	2	0	9	0	0	0	0	0	9	0	0	0
Methaemoglobinaemia	0	0	1	0	0	0	0	0	1	0	0	0
Microangiopathic haemolytic anaemia	1	0	5	0	0	0	0	0	5	0	0	0
Microcytic anaemia	0	0	5	0	0	0	1	0	6	0	0	0
Microcytosis	0	0	0	0	1	0	2	0	2	0	0	0
Monoclonal B-cell lymphocytosis	0	0	0	0	0	0	1	0	1	0	0	0
Monocytopenia	0	0	0	0	0	0	1	0	1	0	0	0
Monocytosis	0	0	2	0	1	0	3	0	5	0	0	0
Myeloid maturation arrest	0	0	0	0	0	0	1	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Myelosuppression	0	0	5	0	0	0	0	0	5	0	0	0
Necrotic lymphadenopathy	0	0	2	0	0	0	2	0	4	0	0	0
Nephrogenic anaemia	0	0	0	0	0	0	1	0	1	0	0	0
Neutropenia	5	0	102	0	0	0	62	0	164	0	0	0
Neutrophilia	1	0	16	0	0	0	7	0	23	0	0	0
Normochromic anaemia	0	0	1	0	0	0	1	0	2	0	0	0
Normochromic normocytic anaemia	0	0	2	0	0	0	0	0	2	0	0	0
Normocytic anaemia	0	0	9	0	0	0	1	0	10	0	0	0
Pancytopenia	2	0	55	0	0	0	0	0	55	0	0	0
Paratracheal lymphadenopathy	0	0	0	0	0	0	2	0	2	0	0	0
Pernicious anaemia	0	0	7	0	0	0	0	0	7	0	0	0
Platelet anisocytosis	1	0	6	0	0	0	0	0	6	0	0	0
Platelet destruction increased	0	0	0	0	0	0	1	0	1	0	0	0
Platelet disorder	1	0	21	1	2	0	22	0	43	1	0	0
Platelet production decreased	0	0	0	0	0	0	1	0	1	0	0	0
Poikilocytosis	0	0	0	0	0	0	2	0	2	0	0	0
Polychromasia	0	0	4	0	0	0	0	0	4	0	0	0
Polyclonal B-cell lymphocytosis	0	0	0	0	0	0	1	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Polycythaemia	4	0	14	0	0	0	7	0	21	0	0	0
Pseudolymphoma	0	0	4	0	0	0	0	0	4	0	0	0
Purpura non-thrombocytopenic	1	0	7	0	0	0	3	0	10	0	0	0
Red blood cell abnormality	1	0	2	0	2	0	7	0	9	0	0	0
Red blood cell agglutination	0	0	1	0	0	0	0	0	1	0	0	0
Red cell fragmentation syndrome	0	0	1	0	0	0	0	0	1	0	0	0
Reticulocytosis	0	0	1	0	0	0	0	0	1	0	0	0
Rouleaux formation	0	0	1	0	1	0	1	0	2	0	0	0
Schistocytosis	0	0	1	0	0	0	0	0	1	0	0	0
Secondary thrombocytosis	0	0	0	0	0	0	1	0	1	0	0	0
Sickle cell anaemia with crisis	0	0	15	0	0	0	0	0	15	0	0	0
Spleen congestion	0	0	1	0	0	0	0	0	1	0	0	0
Spleen disorder	1	0	4	0	0	0	1	0	5	0	0	0
Splenic artery thrombosis	1	0	14	0	0	0	2	0	16	0	0	0
Splenic cyst	0	0	1	0	1	0	1	0	2	0	0	0
Splenic embolism	0	0	2	0	0	0	0	0	2	0	0	0
Splenic haemorrhage	1	0	3	0	0	0	0	0	3	0	0	0
Splenic infarction	2	0	62	0	0	0	0	0	62	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Splenic thrombosis	0	0	12	0	0	0	3	0	15	0	0	0
Splenic varices	0	0	1	0	0	0	1	0	2	0	0	0
Splenic vein occlusion	0	0	1	0	0	0	0	0	1	0	0	0
Splenic vein thrombosis	3	0	61	0	0	0	3	0	64	0	2	2
Splenitis	0	0	1	0	0	0	0	0	1	0	0	0
Splenomegaly	3	0	27	0	2	0	15	0	42	0	0	0
Splenorenal shunt	0	0	1	0	0	0	0	0	1	0	0	0
Spontaneous haematoma	0	0	37	0	8	0	122	0	159	0	0	0
Spontaneous haemorrhage	1	0	5	0	1	0	5	0	10	0	0	0
Spontaneous heparin-induced thrombocytopenia syndrome	0	0	4	0	0	0	1	0	5	0	0	0
Stress polycythaemia	0	0	2	0	0	0	1	0	3	0	1	1
Subcapsular splenic haematoma	0	0	1	0	0	0	0	0	1	0	0	0
Thrombasthenia	0	0	0	0	0	0	1	0	1	0	0	0
Thrombocytopenia	111	0	3367	1	0	0	0	0	3367	1	6	21
Thrombocytopenic purpura	2	0	36	0	1	0	8	0	44	0	0	0
Thrombocytosis	3	0	38	0	5	0	28	0	66	0	0	0
Thrombosis with thrombocytopenia syndrome	159	0	427	0	0	0	0	0	427	0	85	109
Thrombotic microangiopathy	0	0	9	0	0	0	1	0	10	0	0	1

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Thrombotic thrombocytopenic purpura	3	0	47	0	0	0	0	0	47	0	2	2
Thymus disorder	0	0	0	0	0	0	1	0	1	0	0	0
Warm autoimmune haemolytic anaemia	0	0	3	0	0	0	3	0	6	0	0	0
White blood cell disorder	1	0	6	1	0	0	10	0	16	1	0	0
Immune system disorders	**243**	**0**	**4714**	**1**	**712**	**0**	**5896**	**1**	**10610**	**2**	**16**	**26**
AS1A syndrome	1	0	2	0	0	0	0	0	2	0	0	0
Allergic oedema	0	0	20	0	0	0	10	0	30	0	0	0
Allergic reaction to excipient	0	0	2	0	0	0	3	0	5	0	0	0
Allergy to animal	1	0	3	0	0	0	0	0	3	0	0	0
Allergy to arthropod bite	1	0	3	0	5	0	7	0	10	0	0	0
Allergy to arthropod sting	0	0	4	0	0	0	8	0	12	0	0	0
Allergy to chemicals	1	0	8	0	0	0	5	0	13	0	0	0
Allergy to metals	0	0	0	0	0	0	2	0	2	0	0	0
Allergy to plants	0	0	0	0	0	0	2	0	2	0	0	0
Allergy to sting	0	0	0	0	0	0	1	0	1	0	0	0
Allergy to vaccine	2	0	58	0	8	0	80	0	138	0	1	1
Allergy to venom	0	0	1	0	0	0	0	0	1	0	0	0
Amyloidosis	0	0	1	0	0	0	1	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Anaphylactic reaction	48	0	1478	0	0	0	0	0	1478	0	6	9
Anaphylactic shock	12	0	302	0	0	0	0	0	302	0	1	1
Anaphylactoid reaction	2	0	88	0	0	0	0	0	88	0	0	0
Anaphylactoid shock	1	0	7	0	0	0	0	0	7	0	0	0
Anti-neutrophil cytoplasmic antibody positive vasculitis	2	0	15	0	0	0	0	0	15	0	0	0
Atopy	1	0	6	0	2	0	5	0	11	0	0	0
Autoimmune disorder	18	0	143	0	9	0	37	0	180	0	0	0
Autoinflammatory disease	1	0	6	0	0	0	0	0	6	0	0	0
Bacille Calmette-Guerin scar reactivation	1	0	12	0	1	0	51	0	63	0	0	0
Chronic allograft nephropathy	0	0	1	0	0	0	0	0	1	0	0	0
Contrast media reaction	1	0	3	0	0	0	3	0	6	0	0	0
Corneal graft rejection	0	0	9	0	1	0	4	0	13	0	0	1
Cross sensitivity reaction	0	0	1	0	0	0	0	0	1	0	0	0
Cytokine release syndrome	0	0	3	0	0	0	0	0	3	0	0	0
Cytokine storm	0	0	12	0	0	0	0	0	12	0	0	0
Decreased immune responsiveness	1	0	9	0	3	0	16	0	25	0	0	0
Drug hypersensitivity	13	0	71	0	4	0	48	0	119	0	0	1
Dust allergy	0	0	2	0	0	0	1	0	3	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Eosinophilic granulomatosis with polyangiitis	0	0	6	0	0	0	0	0	6	0	0	0
Food allergy	4	0	57	0	2	0	39	0	96	0	0	0
Graft versus host disease	0	0	1	0	0	0	0	0	1	0	0	0
Haemophagocytic lymphohistiocytosis	5	0	45	0	0	0	0	0	45	0	0	0
Hashitoxicosis	0	0	0	0	0	0	1	0	1	0	0	0
Humoral immune defect	0	0	0	0	0	0	3	0	3	0	0	0
Hypersensitivity	54	0	1684	0	275	0	2491	1	4175	1	2	2
Hypocomplementaemia	0	0	3	0	0	0	0	0	3	0	0	0
Hypogammaglobulinaemia	0	0	1	0	0	0	0	0	1	0	0	0
Immune reconstitution inflammatory syndrome	0	0	0	0	0	0	2	0	2	0	0	0
Immune system disorder	15	0	75	1	15	0	69	0	144	1	1	1
Immune-mediated adverse reaction	1	0	18	0	0	0	4	0	22	0	0	0
Immunisation reaction	16	0	171	0	342	0	2626	0	2797	0	0	0
Immunodeficiency	3	0	25	0	5	0	22	0	47	0	0	0
Immunosuppression	3	0	10	0	0	0	7	0	17	0	0	0
Infusion related hypersensitivity reaction	0	0	5	0	0	0	0	0	5	0	0	0
Iodine allergy	3	0	3	0	0	0	0	0	3	0	0	0
Kidney transplant rejection	0	0	2	0	0	0	0	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Loefgren syndrome	1	0	3	0	0	0	0	0	3	0	0	0
Milk allergy	0	0	2	0	0	0	2	0	4	0	0	0
Mite allergy	0	0	0	0	0	0	2	0	2	0	0	0
Multiple allergies	2	0	27	0	3	0	22	0	49	0	0	0
Multisystem inflammatory syndrome	4	0	12	0	0	0	0	0	12	0	0	0
Multisystem inflammatory syndrome in adults	4	0	6	0	0	0	0	0	6	0	0	0
Multisystem inflammatory syndrome in children	0	0	3	0	0	0	0	0	3	0	0	0
Mycotic allergy	0	0	0	0	1	0	1	0	1	0	0	0
Oral allergy syndrome	0	0	1	0	0	0	4	0	5	0	0	0
Perennial allergy	0	0	0	0	1	0	1	0	1	0	0	0
Perfume sensitivity	0	0	2	0	0	0	2	0	4	0	0	0
Polymers allergy	0	0	0	0	0	0	1	0	1	0	0	0
Pre-engraftment immune reaction	0	0	1	0	0	0	0	0	1	0	0	0
Reaction to colouring	0	0	2	0	0	0	0	0	2	0	0	0
Reaction to excipient	0	0	9	0	0	0	5	0	14	0	0	0
Reaction to flavouring	0	0	1	0	0	0	0	0	1	0	0	0
Reaction to preservatives	3	0	15	0	0	0	6	0	21	0	0	0
Rubber sensitivity	1	0	4	0	0	0	1	0	5	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Sarcoidosis	5	0	51	0	1	0	9	0	60	0	0	2
Seasonal allergy	3	0	90	0	19	0	134	0	224	0	0	0
Secondary immunodeficiency	0	0	1	0	0	0	0	0	1	0	0	0
Selective IgA immunodeficiency	2	0	2	0	0	0	0	0	2	0	0	0
Sensitisation	0	0	27	0	3	0	108	0	135	0	0	0
Serum sickness	0	0	16	0	0	0	0	0	16	0	0	0
Serum sickness-like reaction	0	0	13	0	0	0	4	0	17	0	0	0
Smoke sensitivity	0	0	1	0	0	0	2	0	3	0	0	0
Systemic immune activation	0	0	2	0	2	0	6	0	8	0	0	0
Transplant rejection	1	0	9	0	1	0	2	0	11	0	0	0
Type I hypersensitivity	0	0	9	0	0	0	0	0	9	0	4	6
Type II hypersensitivity	0	0	1	0	0	0	0	0	1	0	0	0
Type III immune complex mediated reaction	2	0	13	0	4	0	10	0	23	0	0	0
Type IV hypersensitivity reaction	2	0	9	0	5	0	24	0	33	0	1	2
Vaccine associated enhanced disease	0	0	3	0	0	0	2	0	5	0	0	0
Vaccine associated enhanced respiratory disease	2	0	3	0	0	0	0	0	3	0	0	0
Endocrine disorders	**74**	**0**	**757**	**0**	**45**	**0**	**378**	**0**	**1135**	**0**	**1**	**2**
Addison's disease	0	0	9	0	0	0	1	0	10	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Adrenal disorder	1	0	4	0	0	0	1	0	5	0	0	0
Adrenal haematoma	0	0	5	0	0	0	0	0	5	0	0	0
Adrenal haemorrhage	4	0	24	0	0	0	0	0	24	0	0	0
Adrenal insufficiency	1	0	33	0	0	0	2	0	35	0	0	0
Adrenal mass	0	0	3	0	0	0	1	0	4	0	0	0
Adrenal thrombosis	1	0	3	0	0	0	0	0	3	0	0	0
Adrenocortical insufficiency acute	1	0	43	0	0	0	0	0	43	0	0	0
Adrenomegaly	0	0	3	0	0	0	1	0	4	0	0	0
Anovulatory cycle	0	0	16	0	2	0	19	0	35	0	0	0
Autoimmune hypothyroidism	0	0	4	0	0	0	1	0	5	0	0	0
Autoimmune thyroid disorder	0	0	1	0	0	0	0	0	1	0	0	0
Autoimmune thyroiditis	7	0	40	0	1	0	16	0	56	0	0	0
Basedow's disease	9	0	72	0	6	0	27	0	99	0	0	0
Carcinoid syndrome	0	0	1	0	0	0	0	0	1	0	0	0
Cushing's syndrome	0	0	3	0	0	0	0	0	3	0	0	0
Cushingoid	0	0	5	0	0	0	0	0	5	0	0	0
Delayed menarche	0	0	0	0	0	0	2	0	2	0	0	0
Diabetes insipidus	0	0	11	0	0	0	0	0	11	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Empty sella syndrome	0	0	1	0	0	0	0	0	1	0	0	0
Endocrine disorder	1	0	1	0	0	0	1	0	2	0	0	0
Euthyroid sick syndrome	0	0	0	0	0	0	2	0	2	0	0	0
Glucocorticoid deficiency	0	0	2	0	0	0	2	0	4	0	0	0
Goitre	2	0	32	0	1	0	25	0	57	0	0	0
Haemorrhagic adrenal infarction	0	0	9	0	0	0	0	0	9	0	1	1
Haemorrhagic thyroid cyst	0	0	0	0	0	0	2	0	2	0	0	0
Hyperadrenocorticism	0	0	1	0	0	0	0	0	1	0	0	0
Hyperaldosteronism	1	0	1	0	0	0	0	0	1	0	0	0
Hyperparathyroidism	0	0	2	0	0	0	0	0	2	0	0	0
Hyperparathyroidism primary	0	0	1	0	0	0	0	0	1	0	0	0
Hyperplasia adrenal	0	0	1	0	0	0	0	0	1	0	0	0
Hyperprolactinaemia	0	0	2	0	0	0	2	0	4	0	0	0
Hyperthyroidism	9	0	103	0	4	0	47	0	150	0	0	0
Hypoparathyroidism	0	0	2	0	0	0	0	0	2	0	0	0
Hypophysitis	0	0	1	0	0	0	0	0	1	0	0	0
Hypopituitarism	0	0	4	0	0	0	0	0	4	0	0	0
Hypothalamo-pituitary disorder	2	0	7	0	0	0	1	0	8	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Hypothyroidism	16	0	97	0	9	0	50	0	147	0	0	0
Immune-mediated hyperthyroidism	1	0	2	0	0	0	0	0	2	0	0	0
Immune-mediated hypothyroidism	0	0	1	0	0	0	0	0	1	0	0	0
Inappropriate antidiuretic hormone secretion	1	0	6	0	0	0	0	0	6	0	0	0
Luteal phase deficiency	0	0	0	0	0	0	2	0	2	0	0	0
Myxoedema	2	0	2	0	0	0	0	0	2	0	0	0
Oestrogenic effect	0	0	1	0	0	0	0	0	1	0	0	0
Ovarian dysfunction	0	0	1	0	0	0	0	0	1	0	0	0
Ovulation delayed	0	0	11	0	0	0	12	0	23	0	0	0
Pituitary apoplexy	2	0	5	0	0	0	0	0	5	0	0	0
Pituitary haemorrhage	0	0	3	0	0	0	0	0	3	0	0	0
Pituitary infarction	0	0	1	0	0	0	0	0	1	0	0	0
Premature menarche	0	0	4	0	0	0	13	0	17	0	0	0
Primary adrenal insufficiency	0	0	2	0	0	0	0	0	2	0	0	0
Primary hyperaldosteronism	0	0	1	0	0	0	0	0	1	0	0	0
Primary hyperthyroidism	0	0	1	0	0	0	1	0	2	0	0	0
Primary hypoparathyroidism	0	0	1	0	0	0	0	0	1	0	0	0
Primary hypothyroidism	0	0	0	0	0	0	1	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Secondary adrenocortical insufficiency	0	0	2	0	0	0	0	0	2	0	0	0
Secondary hyperthyroidism	0	0	2	0	0	0	1	0	3	0	0	0
Thyroid cyst	0	0	1	0	1	0	5	0	6	0	0	0
Thyroid disorder	1	0	24	0	5	0	43	0	67	0	0	0
Thyroid haemorrhage	0	0	1	0	0	0	0	0	1	0	0	0
Thyroid mass	2	0	21	0	2	0	11	0	32	0	0	0
Thyroid pain	0	0	16	0	3	0	23	0	39	0	0	0
Thyroiditis	2	0	41	0	5	0	22	0	63	0	0	0
Thyroiditis acute	2	0	20	0	0	0	3	0	23	0	0	0
Thyroiditis chronic	1	0	3	0	0	0	0	0	3	0	0	0
Thyroiditis subacute	4	0	27	0	6	0	38	0	65	0	0	1
Thyrotoxic crisis	0	0	7	0	0	0	0	0	7	0	0	0
Toxic nodular goitre	1	0	3	0	0	0	0	0	3	0	0	0
Metabolism and nutrition disorders	**239**	**0**	**9143**	**0**	**1078**	**0**	**11556**	**3**	**20699**	**3**	**2**	**5**
Abnormal loss of weight	8	0	92	0	2	0	35	0	127	0	0	0
Abnormal weight gain	1	0	32	0	2	0	16	0	48	0	0	0
Acetonaemia	0	0	0	0	0	0	1	0	1	0	0	0
Acidosis	0	0	7	0	0	0	7	0	14	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Adult failure to thrive	0	0	2	0	0	0	0	0	2	0	0	0
Alcohol intolerance	0	0	11	0	1	0	12	0	23	0	0	0
Alkalosis	0	0	2	0	0	0	0	0	2	0	0	0
Appetite disorder	0	0	39	0	39	0	107	0	146	0	0	0
Blood hyposmosis	0	0	2	0	0	0	0	0	2	0	0	0
Body fat disorder	0	0	1	0	0	0	0	0	1	0	0	0
Cachexia	1	0	5	0	1	0	5	0	10	0	0	0
Calcium deficiency	0	0	0	0	0	0	1	0	1	0	0	0
Calcium metabolism disorder	1	0	1	0	0	0	0	0	1	0	0	0
Cell death	0	0	0	0	0	0	1	0	1	0	0	0
Cholesterosis	0	0	0	0	0	0	1	0	1	0	0	0
Copper deficiency	0	0	0	0	0	0	1	0	1	0	0	0
Dairy intolerance	0	0	7	0	0	0	3	0	10	0	0	0
Decreased appetite	115	0	6338	0	859	0	9636	1	15974	1	0	0
Decreased insulin requirement	0	0	0	0	0	0	1	0	1	0	0	0
Dehydration	15	0	651	0	22	0	376	0	1027	0	0	0
Diabetes mellitus	6	0	167	0	3	0	73	0	240	0	0	0
Diabetes mellitus inadequate control	4	0	55	0	2	0	34	0	89	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Diabetic complication	1	0	3	0	0	0	0	0	3	0	0	0
Diabetic ketoacidosis	2	0	65	0	0	0	0	0	65	0	0	0
Diabetic ketosis	0	0	6	0	0	0	0	0	6	0	0	0
Diabetic metabolic decompensation	1	0	10	0	0	0	1	0	11	0	0	0
Diet refusal	0	0	3	0	0	0	2	0	5	0	0	0
Dyslipidaemia	1	0	6	0	0	0	0	0	6	0	0	0
Eating disorder symptom	0	0	1	0	1	0	3	0	4	0	0	0
Electrolyte imbalance	1	0	18	0	5	0	13	0	31	0	0	0
Euglycaemic diabetic ketoacidosis	0	0	2	0	0	0	0	0	2	0	0	0
Failure to thrive	0	0	3	0	0	0	0	0	3	0	0	1
Feeding disorder	3	0	230	0	17	0	122	0	352	0	1	1
Feeding intolerance	0	0	0	0	0	0	1	0	1	0	0	0
Fluid imbalance	0	0	1	0	0	0	0	0	1	0	0	0
Fluid intake reduced	0	0	11	0	1	0	11	0	22	0	0	0
Fluid retention	5	0	92	0	10	0	88	0	180	0	0	0
Folate deficiency	2	0	13	0	0	0	5	0	18	0	0	0
Food aversion	1	0	56	0	39	0	93	0	149	0	0	0
Food craving	1	0	21	0	3	0	40	0	61	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Food intolerance	5	0	35	0	4	0	24	0	59	0	0	0
Food refusal	0	0	38	0	1	0	18	0	56	0	0	0
Fulminant type 1 diabetes mellitus	1	0	1	0	0	0	0	0	1	0	0	0
Glucose tolerance impaired	0	0	9	0	0	0	4	0	13	0	0	0
Gluten sensitivity	1	0	6	0	0	0	4	0	10	0	0	0
Gout	5	0	162	0	6	0	97	0	259	0	0	0
Haemochromatosis	1	0	2	0	0	0	2	0	4	0	0	0
Histamine intolerance	0	0	3	0	3	0	11	0	14	0	0	0
Hypercalcaemia	3	0	6	0	0	0	1	0	7	0	0	0
Hypercholesterolaemia	1	0	6	0	0	0	2	0	8	0	0	0
Hypercreatininaemia	0	0	1	0	0	0	0	0	1	0	0	0
Hyperferritinaemia	0	0	3	0	0	0	4	0	7	0	0	0
Hyperglycaemia	4	0	172	0	5	0	140	0	312	0	0	0
Hyperglycaemic hyperosmolar nonketotic syndrome	0	0	3	0	0	0	0	0	3	0	0	0
Hyperhomocysteinaemia	0	0	1	0	0	0	0	0	1	0	0	0
Hyperinsulinaemic hypoglycaemia	0	0	2	0	0	0	0	0	2	0	0	0
Hyperkalaemia	2	0	23	0	0	0	3	0	26	0	0	0
Hyperlactacidaemia	0	0	3	0	0	0	0	0	3	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Hyperlipasaemia	0	0	0	0	0	0	1	0	1	0	0	0
Hyperlipidaemia	1	0	6	0	1	0	3	0	9	0	0	0
Hypermetabolism	0	0	2	0	0	0	2	0	4	0	0	0
Hypernatraemia	0	0	7	0	0	0	2	0	9	0	0	0
Hyperosmolar state	0	0	1	0	0	0	0	0	1	0	0	0
Hyperphagia	0	0	9	0	1	0	8	0	17	0	0	0
Hyperproteinaemia	0	0	0	0	0	0	2	0	2	0	0	0
Hypertriglyceridaemia	0	0	3	0	0	0	3	0	6	0	0	0
Hyperuricaemia	0	0	2	0	0	0	2	0	4	0	0	0
Hypervitaminosis A	0	0	0	0	0	0	1	0	1	0	0	0
Hypervolaemia	0	0	15	0	1	0	4	0	19	0	0	0
Hypoalbuminaemia	0	0	4	0	0	0	1	0	5	0	0	0
Hypocalcaemia	0	0	6	0	0	0	6	0	12	0	0	0
Hypoglycaemia	2	0	124	0	5	0	109	0	233	0	0	0
Hypoglycaemia unawareness	0	0	3	0	0	0	0	0	3	0	0	0
Hypokalaemia	4	0	36	0	2	0	12	0	48	0	1	1
Hypokalaemic syndrome	0	0	3	0	0	0	0	0	3	0	0	0
Hypomagnesaemia	0	0	3	0	0	0	2	0	5	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Hypometabolism	1	0	2	0	0	0	1	0	3	0	0	0
Hyponatraemia	2	0	53	0	2	0	26	0	79	0	0	0
Hyponatraemic syndrome	0	0	5	0	0	0	0	0	5	0	0	0
Hypoosmolar state	0	0	0	0	0	0	1	0	1	0	0	0
Hypophagia	3	0	48	0	4	0	39	0	87	0	0	0
Hypophosphataemia	0	0	3	0	0	0	0	0	3	0	0	0
Hypovitaminosis	0	0	3	0	2	0	7	0	10	0	0	0
Hypovolaemia	0	0	6	0	0	0	2	0	8	0	0	0
Impaired fasting glucose	0	0	1	0	0	0	0	0	1	0	0	0
Increased appetite	4	0	45	0	5	0	105	0	150	0	0	0
Increased insulin requirement	1	0	3	0	1	0	11	0	14	0	0	0
Insulin resistance	0	0	12	0	1	0	4	0	16	0	0	0
Insulin resistant diabetes	0	0	1	0	0	0	0	0	1	0	0	0
Iodine deficiency	0	0	0	0	0	0	1	0	1	0	0	0
Iron deficiency	2	0	24	0	1	0	22	0	46	0	0	0
Iron metabolism disorder	0	0	0	0	0	0	1	0	1	0	0	0
Iron overload	0	0	1	0	0	0	0	0	1	0	0	0
Ketoacidosis	1	0	6	0	0	0	0	0	6	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Ketosis	0	0	8	0	0	0	0	0	8	0	0	0
Lack of satiety	0	0	1	0	0	0	0	0	1	0	0	0
Lactic acidosis	0	0	9	0	0	0	0	0	9	0	0	0
Lactose intolerance	1	0	9	0	1	0	6	0	15	0	0	0
Latent autoimmune diabetes in adults	0	0	1	0	0	0	0	0	1	0	0	0
Latent tetany	0	0	1	0	0	0	0	0	1	0	0	0
Lipoedema	1	0	3	0	1	0	2	0	5	0	0	0
Lipomatosis	0	0	0	0	0	0	1	0	1	0	0	0
Malnutrition	1	0	5	0	2	0	3	0	8	0	0	0
Metabolic acidosis	1	0	24	0	0	0	0	0	24	0	0	0
Metabolic alkalosis	0	0	6	0	0	0	2	0	8	0	0	0
Metabolic disorder	0	0	3	0	2	0	8	0	11	0	0	0
Metabolic syndrome	0	0	2	0	0	0	0	0	2	0	0	0
Mineral deficiency	0	0	1	0	0	0	0	0	1	0	0	0
Mineral metabolism disorder	0	0	1	0	0	0	0	0	1	0	0	0
Mitochondrial cytopathy	2	0	4	0	0	0	0	0	4	0	0	0
Neonatal insufficient breast milk syndrome	0	0	4	0	0	0	0	0	4	0	0	0
New onset diabetes after transplantation	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Obesity	1	0	4	0	1	0	9	0	13	0	0	0
Oligodipsia	0	0	2	0	0	0	4	0	6	0	0	0
Overfeeding of infant	0	0	0	0	0	0	1	0	1	0	0	0
Overweight	0	0	1	0	0	0	3	0	4	0	0	0
Polydipsia	1	0	22	0	4	0	60	1	82	1	0	0
Poor feeding infant	0	0	18	0	0	0	6	0	24	0	0	0
Postprandial hypoglycaemia	0	0	3	0	0	0	0	0	3	0	0	0
Protein deficiency	0	0	1	0	0	0	0	0	1	0	0	0
Protein intolerance	1	0	1	0	0	0	0	0	1	0	0	0
Salt craving	0	0	2	0	0	0	4	0	6	0	0	0
Selenium deficiency	1	0	1	0	0	0	0	0	1	0	0	0
Starvation	0	0	1	0	0	0	1	0	2	0	0	0
Steroid diabetes	0	0	1	0	0	0	0	0	1	0	0	0
Tetany	1	0	15	0	7	0	22	0	37	0	0	0
Type 1 diabetes mellitus	6	0	45	0	2	0	12	0	57	0	0	0
Type 2 diabetes mellitus	5	0	28	0	2	0	9	0	37	0	0	2
Underweight	1	0	3	0	0	0	0	0	3	0	0	0
Vitamin B complex deficiency	0	0	0	0	0	0	2	1	2	1	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Vitamin B12 deficiency	1	0	18	0	0	0	5	0	23	0	0	0
Vitamin C deficiency	0	0	0	0	1	0	1	0	1	0	0	0
Vitamin D deficiency	2	0	22	0	3	0	16	0	38	0	0	0
Vitamin K deficiency	0	0	0	0	0	0	1	0	1	0	0	0
Weight gain poor	0	0	1	0	0	0	0	0	1	0	0	0
Weight loss poor	0	0	4	0	0	0	1	0	5	0	0	0
Zinc deficiency	0	0	1	0	0	0	0	0	1	0	0	0
Psychiatric disorders	**564**	**0**	**18173**	**0**	**2097**	**1**	**18847**	**6**	**37020**	**6**	**2**	**2**
Abnormal behaviour	3	0	33	0	1	0	32	0	65	0	1	1
Abnormal dreams	5	0	289	0	8	0	203	0	492	0	0	0
Abnormal sleep-related event	0	0	2	0	0	0	10	0	12	0	0	0
Abulia	0	0	1	0	0	0	2	0	3	0	0	0
Acrophobia	1	0	2	0	0	0	0	0	2	0	0	0
Acute psychosis	0	0	9	0	0	0	3	0	12	0	0	0
Acute stress disorder	0	0	5	0	1	0	111	0	116	0	0	0
Adjustment disorder	1	0	5	0	2	0	6	0	11	0	0	0
Adjustment disorder with depressed mood	1	0	7	0	2	0	9	0	16	0	0	0
Adjustment disorder with mixed anxiety and depressed mood	0	0	2	0	0	0	0	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Affect lability	0	0	12	0	2	0	48	0	60	0	0	0
Affective disorder	1	0	4	0	2	0	12	0	16	0	0	0
Aggression	0	0	21	0	4	0	36	0	57	0	0	0
Agitated depression	0	0	3	0	0	0	1	0	4	0	0	0
Agitation	9	0	246	0	15	0	266	0	512	0	0	0
Agoraphobia	0	0	3	0	2	0	4	0	7	0	0	0
Alcohol abuse	0	0	0	0	0	0	2	0	2	0	0	0
Alcohol use disorder	0	0	1	0	0	0	4	0	5	0	0	0
Alcohol withdrawal syndrome	1	0	1	0	0	0	0	0	1	0	0	0
Alcoholic hangover	0	0	1	0	0	0	1	0	2	0	0	0
Alcoholism	0	0	2	0	0	0	1	0	3	0	0	0
Alice in wonderland syndrome	1	0	3	0	0	0	1	0	4	0	0	0
Anger	0	0	73	0	3	0	40	0	113	0	0	0
Anhedonia	0	0	2	0	0	0	4	0	6	0	0	0
Anorexia nervosa	0	0	0	0	0	0	1	0	1	0	0	0
Anorgasmia	0	0	3	0	0	0	4	0	7	0	0	0
Anticipatory anxiety	1	0	1	0	0	0	1	0	2	0	0	0
Antisocial behaviour	0	0	1	0	0	0	1	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Anxiety	61	0	1455	0	154	0	1389	0	2844	0	0	0
Anxiety disorder	3	0	11	0	3	0	19	0	30	0	0	0
Anxiety disorder due to a general medical condition	0	0	1	0	0	0	1	0	2	0	0	0
Apathy	2	0	97	0	44	0	331	0	428	0	0	0
Asocial behaviour	0	0	1	0	0	0	0	0	1	0	0	0
Astraphobia	0	0	0	0	1	0	1	0	1	0	0	0
Attention deficit hyperactivity disorder	0	0	20	0	1	0	8	0	28	0	0	0
Autism spectrum disorder	0	0	4	0	0	0	0	0	4	0	0	0
Autoscopy	1	0	26	0	0	0	16	0	42	0	0	0
Aversion	0	0	0	0	0	0	3	0	3	0	0	0
Behaviour disorder	2	0	9	0	0	0	2	0	11	0	0	0
Behavioural insomnia of childhood	0	0	1	0	0	0	1	0	2	0	0	0
Binge drinking	0	0	0	0	0	0	1	0	1	0	0	0
Binge eating	0	0	1	0	0	0	3	0	4	0	0	0
Bipolar I disorder	0	0	7	0	0	0	1	0	8	0	0	0
Bipolar disorder	1	0	7	0	1	0	4	0	11	0	0	0
Blunted affect	0	0	0	0	0	0	1	0	1	0	0	0
Body dysmorphic disorder	0	0	2	0	0	0	1	0	3	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Borderline personality disorder	0	0	0	0	0	0	3	0	3	0	0	0
Boredom	0	0	1	0	8	0	12	0	13	0	0	0
Bradyphrenia	1	0	101	0	12	0	96	0	197	0	0	0
Breath holding	0	0	5	0	0	0	0	0	5	0	0	0
Breathing-related sleep disorder	0	0	1	0	0	0	4	0	5	0	0	0
Bruxism	1	0	27	0	2	0	31	0	58	0	0	0
Burnout syndrome	1	0	20	0	1	0	4	0	24	0	0	0
Cardiovascular somatic symptom disorder	0	0	0	0	0	0	2	0	2	0	0	0
Catastrophic reaction	0	0	3	0	0	0	0	0	3	0	0	0
Catatonia	1	0	8	0	0	0	0	0	8	0	0	0
Change in sustained attention	0	0	1	0	0	0	0	0	1	0	0	0
Childhood depression	0	0	0	0	0	0	1	0	1	0	0	0
Chronic idiopathic pain syndrome	0	0	2	0	0	0	0	0	2	0	0	0
Claustrophobia	0	0	1	0	2	0	4	0	5	0	0	0
Clinomania	0	0	1	0	0	0	1	0	2	0	0	0
Communication disorder	0	0	18	0	0	0	7	0	25	0	0	0
Completed suicide	2	0	13	0	0	0	0	0	13	0	0	0
Compulsive cheek biting	1	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Compulsive shopping	0	0	2	0	0	0	1	0	3	0	0	0
Confabulation	0	0	1	0	0	0	0	0	1	0	0	0
Confusional arousal	0	0	2	0	0	0	2	0	4	0	0	0
Confusional state	36	0	2400	0	97	0	1464	0	3864	0	1	1
Constricted affect	0	0	13	0	0	0	5	0	18	0	0	0
Conversion disorder	12	0	69	0	2	0	21	0	90	0	0	0
Daydreaming	0	0	18	0	8	0	24	0	42	0	0	0
Decreased eye contact	0	0	2	0	0	0	0	0	2	0	0	0
Decreased interest	0	0	18	0	1	0	17	0	35	0	0	0
Deja vu	1	0	4	0	1	0	2	0	6	0	0	0
Delirium	10	0	518	0	9	0	192	0	710	0	0	0
Delirium febrile	1	0	17	0	0	0	25	0	42	0	0	0
Delusion	4	0	76	0	2	0	59	0	135	0	0	0
Delusion of parasitosis	0	0	2	0	0	0	0	0	2	0	0	0
Delusional disorder, erotomanic type	0	0	1	0	0	0	0	0	1	0	0	0
Delusional perception	0	0	2	0	0	0	2	0	4	0	0	0
Dependence	0	0	1	0	0	0	2	0	3	0	0	0
Depersonalisation/derealisation disorder	0	0	21	0	0	0	15	0	36	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Depressed mood	24	0	644	0	221	0	711	1	1355	1	0	0
Depression	37	0	724	0	60	0	410	0	1134	0	0	0
Depression suicidal	1	0	23	0	0	0	0	0	23	0	0	0
Depressive symptom	2	0	5	0	2	0	9	0	14	0	0	0
Derailment	0	0	1	0	0	0	2	0	3	0	0	0
Derealisation	2	0	18	0	10	0	34	0	52	0	0	0
Dermatillomania	0	0	1	0	0	0	1	0	2	0	0	0
Discouragement	0	0	1	0	5	0	23	0	24	0	0	0
Disinhibited social engagement disorder of childhood	0	0	1	0	0	0	0	0	1	0	0	0
Disinhibition	0	0	1	0	0	0	1	0	2	0	0	0
Disorganised speech	1	0	32	0	3	0	20	0	52	0	0	0
Disorientation	16	0	794	0	22	0	505	0	1299	0	0	0
Dissociation	0	0	66	0	2	0	49	0	115	0	0	0
Dissociative amnesia	0	0	1	0	0	0	0	0	1	0	0	0
Dissociative disorder	0	0	5	0	0	0	2	0	7	0	0	0
Distractibility	1	0	6	0	0	0	14	0	20	0	0	0
Disturbance in sexual arousal	1	0	6	0	0	0	3	0	9	0	0	0
Disturbance in social behaviour	0	0	2	0	0	0	1	0	3	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Drug abuse	0	0	0	0	0	0	1	0	1	0	0	0
Drug dependence	1	0	2	0	0	0	2	0	4	0	0	0
Drug use disorder	0	0	0	0	0	0	1	0	1	0	0	0
Dysphemia	3	0	40	0	1	0	17	0	57	0	0	0
Dysphoria	0	0	4	0	1	0	28	0	32	0	0	0
Dyssomnia	0	0	5	0	1	0	3	0	8	0	0	0
Eating disorder	3	0	20	0	5	0	38	0	58	0	0	0
Emotional disorder	2	0	84	0	1	0	54	0	138	0	0	0
Emotional disorder of childhood	0	0	1	0	0	0	0	0	1	0	0	0
Emotional distress	2	0	93	0	12	0	64	0	157	0	0	0
Emotional poverty	0	0	2	0	0	0	2	0	4	0	0	0
Enuresis	0	0	56	0	0	0	16	0	72	0	0	0
Euphoric mood	0	0	50	0	14	0	81	0	131	0	0	0
Excessive masturbation	0	0	1	0	0	0	0	0	1	0	0	0
Executive dysfunction	0	0	0	0	0	0	2	0	2	0	0	0
Exploding head syndrome	0	0	7	0	0	0	1	0	8	0	0	0
Factitious disorder	0	0	4	0	0	0	1	0	5	0	0	0
Fear	2	0	82	0	5	0	108	0	190	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Fear of crowded places	0	0	0	0	0	0	1	0	1	0	0	0
Fear of death	4	0	27	0	5	0	28	0	55	0	0	0
Fear of disease	0	0	2	0	0	0	9	0	11	0	0	0
Fear of eating	0	0	1	0	0	0	0	0	1	0	0	0
Fear of falling	0	0	4	0	0	0	4	0	8	0	0	0
Fear of injection	0	0	2	0	0	0	11	0	13	0	0	0
Fear of open spaces	0	0	1	0	0	0	0	0	1	0	0	0
Fear-related avoidance of activities	0	0	0	0	0	0	6	0	6	0	0	0
Feeling guilty	0	0	1	0	1	0	2	0	3	0	0	0
Feeling of despair	1	0	20	0	12	0	82	0	102	0	0	0
Feelings of worthlessness	0	0	0	0	1	0	2	0	2	0	0	0
Female orgasmic disorder	1	0	2	0	1	0	3	0	5	0	0	0
Fetishism	0	0	2	0	0	0	0	0	2	0	0	0
Flashback	1	0	4	0	0	0	0	0	4	0	0	0
Flat affect	0	0	12	0	0	0	4	0	16	0	0	0
Flight of ideas	0	0	0	0	0	0	1	0	1	0	0	0
Frustration tolerance decreased	2	0	16	0	2	0	14	0	30	0	0	0
Gender dysphoria	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Generalised anxiety disorder	0	0	6	0	0	0	0	0	6	0	0	0
Genito-pelvic pain/penetration disorder	0	0	1	0	0	0	1	0	2	0	0	0
Grief reaction	1	0	1	0	0	0	2	0	3	0	0	0
Habit cough	0	0	25	0	1	0	17	0	42	0	0	0
Hallucination	20	0	927	0	16	0	426	0	1353	0	0	0
Hallucination, auditory	1	0	51	0	0	0	26	0	77	0	0	0
Hallucination, olfactory	1	0	12	0	0	0	13	0	25	0	0	0
Hallucination, tactile	0	0	2	0	0	0	0	0	2	0	0	0
Hallucination, visual	3	0	72	0	1	0	39	1	111	1	0	0
Hallucinations, mixed	0	0	10	0	0	0	7	0	17	0	0	0
Head banging	1	0	46	0	1	0	34	0	80	0	0	0
Helplessness	1	0	6	0	1	0	16	0	22	0	0	0
Histrionic personality disorder	0	0	0	0	0	0	2	0	2	0	0	0
Homicidal ideation	0	0	1	0	0	0	0	0	1	0	0	0
Hydrophobia	1	0	1	0	0	0	1	0	2	0	0	0
Hyperarousal	0	0	1	0	0	0	4	0	5	0	0	0
Hypersexuality	0	0	2	0	0	0	1	0	3	0	0	0
Hypervigilance	0	0	7	0	1	0	7	0	14	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Hypnagogic hallucination	0	0	4	0	1	0	3	0	7	0	0	0
Hypnopompic hallucination	0	0	0	0	0	0	1	0	1	0	0	0
Hypomania	0	0	1	0	1	0	3	0	4	0	0	0
Hyposomnia	0	0	0	0	0	0	2	0	2	0	0	0
Illness anxiety disorder	1	0	2	0	1	0	4	0	6	0	0	0
Illogical thinking	1	0	1	0	0	0	2	0	3	0	0	0
Illusion	0	0	14	0	2	0	27	0	41	0	0	0
Immunisation stress-related response	0	0	5	0	2	0	8	0	13	0	0	0
Impaired reasoning	0	0	9	0	1	0	8	0	17	0	0	0
Impatience	0	0	4	0	1	0	6	0	10	0	0	0
Imperception	0	0	3	0	1	0	2	0	5	0	0	0
Impulse-control disorder	0	0	2	0	0	0	1	0	3	0	0	0
Impulsive behaviour	1	0	4	0	0	0	2	0	6	0	0	0
Inappropriate affect	0	0	14	0	0	0	17	0	31	0	0	0
Indifference	0	0	8	0	0	0	6	0	14	0	0	0
Inferiority complex	0	0	0	0	1	0	1	0	1	0	0	0
Initial insomnia	5	0	61	0	26	0	100	0	161	0	0	0
Insomnia	56	0	2940	0	492	0	4912	2	7852	2	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Intentional self-injury	0	0	8	0	0	0	1	0	9	0	0	0
Intermittent explosive disorder	0	0	0	0	0	0	1	0	1	0	0	0
Intrusive thoughts	0	0	6	0	0	0	1	0	7	0	0	0
Irritability	3	0	300	0	76	0	1035	0	1335	0	0	0
Jamais vu	0	0	0	0	0	0	1	0	1	0	0	0
Lack of spontaneous speech	0	0	4	0	0	0	3	0	7	0	0	0
Laziness	0	0	0	0	1	0	31	0	31	0	0	0
Learning disability	0	0	0	0	0	0	1	0	1	0	0	0
Learning disorder	0	0	0	0	0	0	1	0	1	0	0	0
Libido decreased	0	0	21	0	0	0	25	0	46	0	0	0
Libido disorder	0	0	1	0	0	0	1	0	2	0	0	0
Libido increased	0	0	4	0	4	0	15	0	19	0	0	0
Limited symptom panic attack	0	0	0	0	0	0	1	0	1	0	0	0
Listless	1	0	107	0	19	0	203	0	310	0	0	0
Logorrhoea	0	0	3	0	0	0	5	0	8	0	0	0
Loose associations	0	0	0	0	0	0	1	0	1	0	0	0
Loss of libido	0	0	48	0	4	0	21	0	69	0	0	0
Major depression	1	0	27	0	1	0	7	0	34	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Mania	2	0	28	0	1	0	11	0	39	0	0	0
Menopausal depression	0	0	2	0	1	0	1	0	3	0	0	0
Mental disorder	5	0	57	0	13	1	89	1	146	1	0	0
Mental disorder due to a general medical condition	0	0	0	0	0	0	1	0	1	0	0	0
Mental fatigue	12	0	478	0	25	0	139	0	617	0	0	0
Mental status changes	1	0	5	0	1	0	9	0	14	0	0	0
Middle insomnia	7	0	70	0	22	0	100	0	170	0	0	0
Mixed anxiety and depressive disorder	1	0	6	0	1	0	4	0	10	0	0	0
Mixed delusion	0	0	1	0	0	0	2	0	3	0	0	0
Mood altered	2	0	82	0	51	0	187	0	269	0	0	0
Mood disorder due to a general medical condition	0	0	3	0	0	0	1	0	4	0	0	0
Mood swings	4	0	121	0	8	0	102	0	223	0	0	0
Morbid thoughts	1	0	4	0	0	0	2	0	6	0	0	0
Morose	0	0	0	0	0	0	1	0	1	0	0	0
Mutism	0	0	6	0	0	0	3	0	9	0	0	0
Near death experience	1	0	6	0	0	0	3	0	9	0	0	0
Negative thoughts	0	0	8	0	0	0	11	0	19	0	0	0
Nervousness	10	0	556	0	16	0	326	0	882	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Neuropsychiatric symptoms	0	0	3	0	0	0	0	0	3	0	0	0
Neuropsychiatric syndrome	0	0	1	0	0	0	0	0	1	0	0	0
Neurosis	0	0	3	0	0	0	3	0	6	0	0	0
Nicotine dependence	0	0	1	0	0	0	0	0	1	0	0	0
Nightmare	1	0	372	0	35	0	322	0	694	0	0	0
Nocturnal fear	0	0	1	0	0	0	0	0	1	0	0	0
Obsessive rumination	0	0	0	0	0	0	1	0	1	0	0	0
Obsessive thoughts	0	0	3	0	0	0	3	0	6	0	0	0
Obsessive-compulsive disorder	0	0	3	0	1	0	1	0	4	0	0	0
Obsessive-compulsive symptom	0	0	1	0	0	0	0	0	1	0	0	0
Onychophagia	0	0	0	0	0	0	1	0	1	0	0	0
Organic brain syndrome	0	0	2	0	0	0	1	0	3	0	0	0
Orgasm abnormal	0	0	1	0	0	0	1	0	2	0	0	0
Orgasmic sensation decreased	0	0	3	0	0	0	1	0	4	0	0	0
Panic attack	16	0	342	0	24	0	245	0	587	0	0	0
Panic disorder	2	0	16	0	1	0	13	0	29	0	0	0
Panic reaction	0	0	43	0	7	0	41	0	84	0	0	0
Paradoxical insomnia	0	0	0	0	0	0	1	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Paramnesia	0	0	9	0	0	0	3	0	12	0	0	0
Paranoia	0	0	35	0	1	0	16	0	51	0	0	0
Paranoid personality disorder	0	0	1	0	0	0	0	0	1	0	0	0
Parasomnia	0	0	0	0	0	0	4	0	4	0	0	0
Paruresis	0	0	1	0	0	0	0	0	1	0	0	0
Pedantic speech	0	0	1	0	0	0	0	0	1	0	0	0
Performance fear	0	0	3	0	0	0	0	0	3	0	0	0
Persecutory delusion	0	0	1	0	0	0	1	0	2	0	0	0
Persistent depressive disorder	0	0	2	0	0	0	0	0	2	0	0	0
Personality change	3	0	18	0	3	0	9	0	27	0	0	0
Personality disorder	0	0	1	0	1	0	2	0	3	0	0	0
Phantom vibration syndrome	0	0	0	0	0	0	1	0	1	0	0	0
Phobia	0	0	2	0	0	0	6	0	8	0	0	0
Phobia of driving	1	0	1	0	0	0	0	0	1	0	0	0
Phobic avoidance	0	0	0	0	0	0	1	0	1	0	0	0
Phonophobia	1	0	17	0	2	0	18	0	35	0	0	0
Pica	0	0	0	0	0	0	1	0	1	0	0	0
Poor quality sleep	21	0	581	0	71	0	522	0	1103	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Post stroke depression	0	0	1	0	0	0	0	0	1	0	0	0
Post-traumatic stress disorder	2	0	16	0	2	0	21	0	37	0	0	0
Poverty of speech	0	0	4	0	0	0	0	0	4	0	0	0
Premature ejaculation	2	0	5	0	0	0	1	0	6	0	0	0
Procedural anxiety	0	0	0	0	0	0	1	0	1	0	0	0
Pseudodementia	0	0	1	0	0	0	0	0	1	0	0	0
Pseudohallucination	0	0	3	0	0	0	3	0	6	0	0	0
Psychiatric decompensation	1	0	2	0	0	0	0	0	2	0	0	0
Psychiatric symptom	1	0	14	0	1	0	13	0	27	0	0	0
Psychogenic movement disorder	0	0	0	0	0	0	1	0	1	0	0	0
Psychogenic pseudosyncope	0	0	0	0	0	0	1	0	1	0	0	0
Psychogenic tremor	0	0	2	0	0	0	0	0	2	0	0	0
Psychogenic visual disorder	0	0	0	0	0	0	1	0	1	0	0	0
Psychological factor affecting medical condition	0	0	0	0	0	0	2	0	2	0	0	0
Psychological trauma	0	0	2	0	2	0	9	0	11	0	0	0
Psychomotor retardation	0	0	3	0	0	0	6	0	9	0	0	0
Psychotic behaviour	0	0	2	0	0	0	0	0	2	0	0	0
Psychotic disorder	0	0	57	0	0	0	13	0	70	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Psychotic disorder due to a general medical condition	0	0	1	0	0	0	0	0	1	0	0	0
Psychotic symptom	0	0	1	0	0	0	0	0	1	0	0	0
Pyromania	0	0	1	0	0	0	0	0	1	0	0	0
Rapid eye movements sleep abnormal	0	0	4	0	1	0	1	0	5	0	0	0
Reading disorder	0	0	7	0	1	0	8	0	15	0	0	0
Rebound psychosis	0	0	1	0	0	0	0	0	1	0	0	0
Restlessness	9	0	460	0	137	0	856	0	1316	0	0	0
Schizoaffective disorder	0	0	1	0	0	0	0	0	1	0	0	0
Schizophrenia	1	0	3	0	0	0	0	0	3	0	0	0
Secondary tic	0	0	2	0	0	0	0	0	2	0	0	0
Selective eating disorder	0	0	0	0	0	0	3	0	3	0	0	0
Self esteem decreased	0	0	1	0	3	0	5	0	6	0	0	0
Self-induced vomiting	0	0	1	0	0	0	0	0	1	0	0	0
Self-injurious ideation	0	0	4	0	0	0	3	0	7	0	0	0
Sense of a foreshortened future	1	0	4	0	0	0	0	0	4	0	0	0
Sexually inappropriate behaviour	0	0	1	0	0	0	0	0	1	0	0	0
Sleep attacks	1	0	4	0	1	0	9	0	13	0	0	0
Sleep disorder	41	0	520	0	169	0	1163	0	1683	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Sleep disorder due to a general medical condition	0	0	0	0	1	0	2	0	2	0	0	0
Sleep disorder due to general medical condition, insomnia type	0	0	1	0	0	0	3	0	4	0	0	0
Sleep inertia	0	0	1	0	0	0	0	0	1	0	0	0
Sleep talking	0	0	13	0	0	0	12	0	25	0	0	0
Sleep terror	3	0	52	0	0	0	17	0	69	0	0	0
Sleep-related eating disorder	0	0	1	0	0	0	3	0	4	0	0	0
Social anxiety disorder	0	0	1	0	0	0	2	0	3	0	0	0
Social avoidant behaviour	0	0	11	0	2	0	7	0	18	0	0	0
Social fear	0	0	1	0	0	0	1	0	2	0	0	0
Soliloquy	0	0	2	0	0	0	2	0	4	0	0	0
Somatic delusion	0	0	0	0	1	0	1	0	1	0	0	0
Somatic hallucination	0	0	0	0	0	0	1	0	1	0	0	0
Somatic symptom disorder	1	0	4	0	8	0	14	0	18	0	0	0
Somnambulism	0	0	6	0	1	0	12	0	18	0	0	0
Sopor	1	0	11	0	0	0	2	0	13	0	0	0
Speech sound disorder	0	0	2	0	0	0	1	0	3	0	0	0
Staring	0	0	15	0	0	0	6	0	21	0	0	0
Stress	17	0	150	0	23	0	151	0	301	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Substance abuse	0	0	2	0	0	0	1	0	3	0	0	0
Substance-induced mood disorder	0	0	0	0	0	0	1	0	1	0	0	0
Suicidal behaviour	0	0	7	0	0	0	0	0	7	0	0	0
Suicidal ideation	13	0	175	0	0	0	0	0	175	0	0	0
Suicide attempt	3	0	42	0	0	0	0	0	42	0	0	0
Suicide threat	0	0	1	0	0	0	0	0	1	0	0	0
Suspiciousness	0	0	0	0	0	0	1	0	1	0	0	0
Tachyphrenia	1	0	21	0	1	0	15	0	36	0	0	0
Taciturnity	0	0	1	0	0	0	0	0	1	0	0	0
Tearfulness	1	0	90	0	4	0	34	1	124	1	0	0
Tension	0	0	55	0	7	0	108	0	163	0	0	0
Terminal insomnia	0	0	14	0	2	0	20	0	34	0	0	0
Thanatophobia	0	0	0	0	0	0	1	0	1	0	0	0
Thinking abnormal	1	0	28	0	8	0	65	0	93	0	0	0
Thought blocking	1	0	9	0	1	0	2	0	11	0	0	0
Thought withdrawal	0	0	1	0	0	0	0	0	1	0	0	0
Tic	2	0	21	0	2	0	20	0	41	0	0	0
Time perception altered	0	0	8	0	0	0	1	0	9	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Tobacco abuse	0	0	0	0	1	0	1	0	1	0	0	0
Trance	0	0	0	0	0	0	2	0	2	0	0	0
Verbigeration	0	0	2	0	0	0	0	0	2	0	0	0
Violence-related symptom	0	0	1	0	0	0	1	0	2	0	0	0
Waxy flexibility	0	0	2	0	0	0	0	0	2	0	0	0
Nervous system disorders	**5747**	**0**	**188044**	**9**	**34198**	**7**	**349809**	**43**	**537853**	**52**	**95**	**239**
Acquired syringomyelia	0	0	1	0	0	0	0	0	1	0	0	0
Acrodynia	0	0	0	0	0	0	1	0	1	0	0	0
Action tremor	2	0	7	0	0	0	5	0	12	0	0	0
Acute disseminated encephalomyelitis	15	0	81	0	0	0	0	0	81	0	0	7
Acute encephalitis with refractory, repetitive partial seizures	0	0	1	0	0	0	0	0	1	0	0	0
Acute flaccid myelitis	1	0	2	0	0	0	0	0	2	0	0	0
Acute haemorrhagic leukoencephalitis	0	0	1	0	0	0	1	0	2	0	0	0
Acute motor axonal neuropathy	1	0	7	0	0	0	1	0	8	0	0	0
Acute motor-sensory axonal neuropathy	1	0	3	0	0	0	0	0	3	0	0	0
Acute painful neuropathy of rapid glycaemic control	0	0	0	0	0	0	1	0	1	0	0	0
Acute polyneuropathy	1	0	24	0	0	0	3	0	27	0	0	0
Acute post asthmatic amyotrophy	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Adrenergic syndrome	0	0	1	0	0	0	0	0	1	0	0	0
Advanced sleep phase	0	0	1	0	0	0	0	0	1	0	0	0
Ageusia	21	0	981	0	154	0	1900	2	2881	2	0	0
Agitation neonatal	0	0	0	0	0	0	2	0	2	0	0	0
Agnosia	1	0	2	0	0	0	3	0	5	0	0	0
Agraphia	0	0	2	0	0	0	0	0	2	0	0	0
Akathisia	0	0	10	0	2	0	18	0	28	0	0	0
Akinaesthesia	0	0	1	0	0	0	0	0	1	0	0	0
Akinesia	0	0	3	0	0	0	1	0	4	0	0	0
Alcoholic seizure	0	0	1	0	0	0	0	0	1	0	0	0
Alexia	0	0	6	0	0	0	1	0	7	0	0	0
Allodynia	0	0	50	0	6	0	68	0	118	0	0	0
Altered state of consciousness	12	0	114	0	5	0	56	0	170	0	0	0
Amnesia	37	0	604	0	33	0	342	0	946	0	0	0
Amnestic disorder	0	0	7	0	0	0	7	0	14	0	0	0
Amputation stump pain	0	0	0	0	0	0	2	0	2	0	0	0
Amyloid related imaging abnormalities	0	0	1	0	0	0	1	0	2	0	0	0
Amyotrophic lateral sclerosis	5	0	15	0	0	0	0	0	15	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Anaesthesia	0	0	6	0	3	0	22	0	28	0	0	0
Anosmia	12	0	402	0	132	0	1448	4	1850	4	0	1
Anosognosia	0	0	1	0	0	0	0	0	1	0	0	0
Anterograde amnesia	0	0	4	0	0	0	0	0	4	0	0	0
Apallic syndrome	1	0	4	0	0	0	0	0	4	0	0	0
Aphasia	66	0	749	0	0	0	0	0	749	0	0	0
Apraxia	2	0	18	0	2	0	6	0	24	0	0	0
Arachnoid cyst	1	0	2	0	0	0	0	0	2	0	0	0
Arachnoiditis	0	0	5	0	0	0	2	0	7	0	0	0
Areflexia	6	0	67	0	0	0	10	0	77	0	0	0
Ascending flaccid paralysis	0	0	6	0	0	0	0	0	6	0	0	0
Asterixis	0	0	1	0	0	0	1	0	2	0	0	0
Ataxia	10	0	123	0	8	0	49	0	172	0	0	0
Athetosis	0	0	0	0	0	0	1	0	1	0	0	0
Atonic seizures	2	0	14	0	0	0	1	0	15	0	1	1
Atypical benign partial epilepsy	0	0	0	0	0	0	1	0	1	0	0	0
Auditory nerve disorder	0	0	3	0	0	0	0	0	3	0	0	0
Aura	1	0	28	0	5	0	37	0	65	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Autoimmune demyelinating disease	0	0	1	0	0	0	0	0	1	0	0	0
Autoimmune encephalopathy	2	0	11	0	0	0	0	0	11	0	0	0
Autoimmune neuropathy	0	0	7	0	0	0	1	0	8	0	0	0
Autonomic nervous system imbalance	11	0	50	0	6	0	16	0	66	0	0	0
Autonomic neuropathy	1	0	5	0	0	0	2	0	7	0	0	0
Autonomic seizure	0	0	1	0	0	0	0	0	1	0	0	0
Axonal and demyelinating polyneuropathy	1	0	8	0	0	0	1	0	9	0	0	0
Axonal neuropathy	1	0	7	0	0	0	2	0	9	0	0	0
Balance disorder	68	0	1256	0	126	0	1223	0	2479	0	0	0
Balint's syndrome	0	0	1	0	0	0	0	0	1	0	0	0
Ballismus	0	0	3	0	0	0	2	0	5	0	0	0
Band sensation	2	0	11	0	1	0	7	0	18	0	0	0
Basal ganglia haemorrhage	1	0	15	0	0	0	0	0	15	0	0	0
Basal ganglia infarction	0	0	6	0	0	0	0	0	6	0	0	0
Basal ganglia stroke	0	0	3	0	0	0	0	0	3	0	0	0
Basilar artery aneurysm	0	0	1	0	0	0	1	0	2	0	0	0
Basilar artery occlusion	0	0	7	0	0	0	0	0	7	0	0	0
Basilar artery thrombosis	2	0	15	0	0	0	0	0	15	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Basilar migraine	0	0	5	0	0	0	0	0	5	0	0	0
Bell's palsy	26	0	779	0	11	0	287	0	1066	0	1	1
Bickerstaff's encephalitis	0	0	5	0	0	0	0	0	5	0	0	0
Blood brain barrier defect	0	0	1	0	0	0	0	0	1	0	0	0
Brachial plexopathy	2	0	7	0	1	0	2	0	9	0	0	0
Bradykinesia	3	0	39	0	2	0	29	0	68	0	0	0
Brain compression	0	0	5	0	0	0	0	0	5	0	0	0
Brain hypoxia	1	0	2	0	0	0	0	0	2	0	0	0
Brain injury	12	0	81	0	0	0	0	0	81	0	0	0
Brain oedema	9	0	101	0	0	0	0	0	101	0	0	0
Brain stem embolism	0	0	1	0	0	0	0	0	1	0	0	0
Brain stem haematoma	0	0	1	0	0	0	0	0	1	0	0	0
Brain stem haemorrhage	1	0	13	0	0	0	0	0	13	0	0	0
Brain stem infarction	1	0	41	0	0	0	0	0	41	0	1	1
Brain stem ischaemia	0	0	2	0	0	0	2	0	4	0	0	0
Brain stem microhaemorrhage	0	0	0	0	0	0	1	0	1	0	0	0
Brain stem stroke	1	0	15	0	0	0	0	0	15	0	0	0
Brain stem syndrome	0	0	8	0	0	0	0	0	8	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Brain stem thrombosis	0	0	5	0	0	0	0	0	5	0	0	0
Brudzinski's sign	0	0	1	0	0	0	0	0	1	0	0	0
Bulbar palsy	0	0	7	0	0	0	1	0	8	0	0	0
Burning feet syndrome	0	0	26	0	1	0	12	0	38	0	0	0
Burning sensation	30	0	968	0	223	0	1719	0	2687	0	0	0
Burning sensation mucosal	1	0	5	0	1	0	12	0	17	0	0	0
Cardiac autonomic neuropathy	1	0	1	0	0	0	0	0	1	0	0	0
Carotid arterial embolus	0	0	1	0	0	0	0	0	1	0	0	0
Carotid arteriosclerosis	0	0	4	0	0	0	2	0	6	0	0	0
Carotid artery aneurysm	0	0	6	0	1	0	3	0	9	0	0	0
Carotid artery disease	1	0	2	0	0	0	0	0	2	0	0	0
Carotid artery dissection	0	0	14	0	0	0	0	0	14	0	0	0
Carotid artery occlusion	2	0	22	0	0	0	0	0	22	0	0	1
Carotid artery stenosis	0	0	11	0	0	0	3	0	14	0	0	0
Carotid artery thrombosis	2	0	53	0	0	0	0	0	53	0	1	2
Carotid sinus syndrome	0	0	0	0	0	0	1	0	1	0	0	0
Carpal tunnel syndrome	6	0	50	1	7	0	30	0	80	1	0	0
Cataplexy	1	0	2	0	0	0	0	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Cauda equina syndrome	0	0	9	0	0	0	0	0	9	0	0	0
Central nervous system immune reconstitution inflammatory response	0	0	2	0	0	0	0	0	2	0	0	0
Central nervous system inflammation	1	0	22	0	1	0	3	0	25	0	0	0
Central nervous system lesion	1	0	24	0	1	0	4	0	28	0	1	1
Central nervous system vasculitis	1	0	10	0	0	0	0	0	10	0	0	0
Central pain syndrome	1	0	5	0	0	0	4	0	9	0	0	0
Cerebellar artery thrombosis	0	0	2	0	0	0	1	0	3	0	0	0
Cerebellar ataxia	1	0	11	0	0	0	0	0	11	0	0	0
Cerebellar atrophy	0	0	1	0	0	0	0	0	1	0	0	0
Cerebellar embolism	0	0	1	0	0	0	0	0	1	0	0	0
Cerebellar haematoma	0	0	4	0	0	0	0	0	4	0	0	0
Cerebellar haemorrhage	0	0	13	0	0	0	0	0	13	0	0	0
Cerebellar infarction	2	0	41	0	0	0	0	0	41	0	1	1
Cerebellar ischaemia	1	0	9	0	0	0	0	0	9	0	0	0
Cerebellar stroke	5	0	36	0	0	0	0	0	36	0	0	0
Cerebellar syndrome	1	0	6	0	0	0	2	0	8	0	0	0
Cerebral amyloid angiopathy	0	0	7	0	0	0	1	0	8	0	0	0
Cerebral arteriosclerosis	0	0	0	0	0	0	2	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Cerebral arteritis	0	0	2	0	0	0	0	0	2	0	0	0
Cerebral artery embolism	1	0	35	0	0	0	0	0	35	0	0	0
Cerebral artery occlusion	2	0	24	0	0	0	0	0	24	0	0	2
Cerebral artery stenosis	0	0	3	0	0	0	1	0	4	0	0	0
Cerebral artery thrombosis	1	0	60	1	0	0	0	0	60	1	0	0
Cerebral atrophy	0	0	4	0	0	0	1	0	5	0	0	0
Cerebral circulatory failure	0	0	1	0	0	0	0	0	1	0	0	0
Cerebral congestion	0	0	4	0	0	0	2	0	6	0	0	0
Cerebral cyst	0	0	1	0	0	0	0	0	1	0	0	0
Cerebral disorder	4	0	17	0	2	0	12	0	29	0	0	0
Cerebral haematoma	2	0	47	0	0	0	0	0	47	0	0	0
Cerebral haemorrhage	51	0	663	1	0	0	0	0	663	1	5	13
Cerebral haemosiderin deposition	0	0	2	0	0	0	0	0	2	0	0	0
Cerebral infarction	22	0	492	1	0	0	0	0	492	1	0	1
Cerebral ischaemia	9	0	92	0	0	0	0	0	92	0	0	0
Cerebral mass effect	5	0	17	0	0	0	2	0	19	0	0	0
Cerebral microangiopathy	1	0	8	0	0	0	1	0	9	0	0	0
Cerebral microembolism	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Cerebral microhaemorrhage	0	0	8	0	0	0	1	0	9	0	0	0
Cerebral microinfarction	0	0	3	0	0	0	0	0	3	0	0	0
Cerebral small vessel ischaemic disease	3	0	10	0	0	0	1	0	11	0	0	0
Cerebral thrombosis	17	0	273	0	0	0	0	0	273	0	0	0
Cerebral vascular occlusion	1	0	6	0	0	0	0	0	6	0	0	0
Cerebral vasoconstriction	1	0	5	0	0	0	0	0	5	0	0	0
Cerebral venous sinus thrombosis	62	0	796	0	0	0	3	0	799	0	23	35
Cerebral venous thrombosis	24	0	290	0	0	0	0	0	290	0	2	10
Cerebrospinal fluid circulation disorder	0	0	5	0	0	0	2	0	7	0	0	0
Cerebrospinal fluid leakage	1	0	4	0	0	0	0	0	4	0	0	0
Cerebrovascular accident	145	0	2826	1	0	0	0	0	2826	1	2	4
Cerebrovascular disorder	3	0	31	0	1	0	7	0	38	0	0	0
Cerebrovascular insufficiency	0	0	2	0	0	0	0	0	2	0	0	0
Cerebrovascular stenosis	0	0	1	0	0	0	0	0	1	0	0	0
Cervical radiculopathy	0	0	8	0	0	0	8	0	16	0	0	0
Cervicobrachial syndrome	1	0	13	0	8	0	23	0	36	0	0	0
Cervicogenic headache	0	0	6	0	0	0	10	0	16	0	0	0
Change in seizure presentation	0	0	5	0	0	0	1	0	6	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Cholinergic syndrome	0	0	0	0	0	0	1	0	1	0	0	0
Chorea	0	0	7	0	0	0	3	0	10	0	0	0
Choreoathetosis	0	0	0	0	0	0	2	0	2	0	0	0
Chronic inflammatory demyelinating polyradiculoneuropathy	14	0	67	0	0	0	0	0	67	0	3	3
Chronic paroxysmal hemicrania	0	0	2	0	0	0	0	0	2	0	0	0
Circadian rhythm sleep disorder	0	0	2	0	1	0	11	0	13	0	0	0
Clinically isolated syndrome	2	0	6	0	0	0	1	0	7	0	0	0
Clonic convulsion	0	0	14	0	0	0	0	0	14	0	0	0
Clonus	0	0	2	0	1	0	4	0	6	0	0	0
Clumsiness	1	0	54	0	2	0	27	0	81	0	0	0
Cluster headache	4	0	689	0	10	0	382	0	1071	0	0	0
Cognitive disorder	29	0	290	0	36	0	182	0	472	0	0	0
Cognitive linguistic deficit	0	0	0	0	0	0	2	0	2	0	0	0
Cold dysaesthesia	0	0	1	0	0	0	0	0	1	0	0	0
Cold-stimulus headache	1	0	81	0	3	0	22	0	103	0	0	0
Colloid brain cyst	0	0	0	0	0	0	1	0	1	0	0	0
Coma	12	0	112	0	0	0	0	0	112	0	1	1
Complex regional pain syndrome	0	0	15	0	1	0	8	0	23	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Consciousness fluctuating	0	0	4	0	0	0	6	0	10	0	0	0
Convulsions local	1	0	4	0	0	0	1	0	5	0	0	0
Convulsive threshold lowered	0	0	1	0	0	0	0	0	1	0	0	0
Coordination abnormal	8	0	172	0	14	0	170	0	342	0	0	0
Cramp-fasciculation syndrome	0	0	1	0	0	0	2	0	3	0	0	0
Cranial nerve disorder	2	0	9	0	1	0	5	0	14	0	0	0
Cranial nerve paralysis	0	0	2	0	0	0	4	0	6	0	0	0
Crocodile tears syndrome	0	0	1	0	0	0	0	0	1	0	0	0
Cubital tunnel syndrome	0	0	2	0	2	0	3	0	5	0	0	0
Cytotoxic lesions of corpus callosum	0	0	1	0	0	0	0	0	1	0	0	0
Cytotoxic oedema	0	0	1	0	0	0	0	0	1	0	0	0
Decerebrate posture	0	0	1	0	0	0	0	0	1	0	0	0
Decorticate posture	0	0	1	0	0	0	0	0	1	0	0	0
Decreased vibratory sense	0	0	2	0	0	0	1	0	3	0	0	0
Delayed sleep phase	0	0	1	0	0	0	0	0	1	0	0	0
Dementia	4	0	72	0	4	0	16	0	88	0	0	0
Dementia Alzheimer's type	0	0	8	0	0	0	5	0	13	0	0	0
Dementia with Lewy bodies	0	0	2	0	0	0	1	0	3	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Demyelinating polyneuropathy	5	0	37	0	1	0	2	0	39	0	0	0
Demyelination	10	0	77	0	2	0	21	0	98	0	3	4
Depressed level of consciousness	5	0	211	0	10	0	134	0	345	0	0	0
Diabetic coma	0	0	4	0	0	0	0	0	4	0	0	0
Diabetic mononeuropathy	0	0	0	0	0	0	1	0	1	0	0	0
Diabetic neuropathy	2	0	6	0	0	0	0	0	6	0	0	0
Diplegia	11	0	136	0	0	0	0	0	136	0	0	0
Disturbance in attention	81	0	1022	0	245	0	1973	2	2995	2	0	0
Dizziness	412	0	21635	0	3866	1	39788	9	61423	9	2	5
Dizziness exertional	2	0	100	0	4	0	43	0	143	0	0	0
Dizziness postural	18	0	1837	0	13	0	628	0	2465	0	0	0
Dreamy state	0	0	16	0	0	0	9	0	25	0	0	0
Drooling	1	0	29	0	0	0	16	0	45	0	0	0
Drop attacks	0	0	3	0	0	0	3	0	6	0	0	0
Dropped head syndrome	0	0	0	0	0	0	1	0	1	0	0	0
Drug withdrawal convulsions	0	0	2	0	0	0	0	0	2	0	0	0
Drug withdrawal headache	0	0	12	0	0	0	11	0	23	0	0	0
Dural arteriovenous fistula	1	0	4	0	0	0	0	0	4	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Dysaesthesia	5	0	93	0	12	0	201	0	294	0	0	0
Dysarthria	27	0	692	0	11	0	224	0	916	0	0	0
Dysdiadochokinesis	0	0	2	0	0	0	0	0	2	0	0	0
Dysgeusia	20	0	1316	0	171	0	2300	0	3616	0	0	0
Dysgraphia	0	0	15	0	0	0	9	0	24	0	0	0
Dyskinesia	4	0	151	0	17	0	169	0	320	0	0	0
Dyskinesia hyperpyrexia syndrome	0	0	0	0	0	0	15	0	15	0	0	0
Dyslalia	1	0	14	0	0	0	8	0	22	0	0	0
Dyslexia	0	0	4	0	0	0	3	0	7	0	0	0
Dysmetria	0	0	3	0	0	0	2	0	5	0	0	0
Dyspraxia	0	0	13	0	0	0	4	0	17	0	0	0
Dysstasia	13	0	184	0	42	0	257	0	441	0	0	0
Dystonia	3	0	31	0	1	0	9	0	40	0	0	0
Dystonic tremor	0	0	3	0	0	0	1	0	4	0	0	0
Electric shock sensation	11	0	124	0	9	0	112	0	236	0	0	0
Embolic cerebellar infarction	0	0	1	0	0	0	1	0	2	0	0	0
Embolic cerebral infarction	0	0	8	0	0	0	0	0	8	0	0	1
Embolic stroke	2	0	52	0	0	0	0	0	52	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Encephalitis autoimmune	6	0	36	0	0	0	0	0	36	0	1	1
Encephalitis post immunisation	1	0	3	0	0	0	0	0	3	0	0	0
Encephalitis post varicella	1	0	1	0	0	0	0	0	1	0	0	0
Encephalomalacia	0	0	2	0	0	0	1	0	3	0	0	0
Encephalopathy	7	0	41	0	0	0	3	0	44	0	0	0
Epilepsy	25	0	519	0	2	0	132	0	651	0	0	0
Epileptic aura	1	0	4	0	0	0	1	0	5	0	0	0
Epileptic encephalopathy	0	0	1	0	0	0	0	0	1	0	0	0
Essential tremor	2	0	6	0	3	0	16	0	22	0	0	0
Exaggerated startle response	0	0	3	0	1	0	6	0	9	0	0	0
Exertional headache	1	0	16	0	2	0	11	0	27	0	0	0
Extensor plantar response	0	0	7	0	1	0	3	0	10	0	0	0
External compression headache	0	0	5	0	0	0	2	0	7	0	0	0
Extrapyramidal disorder	0	0	20	0	0	0	10	0	30	0	0	0
Facial nerve disorder	0	0	16	0	1	0	10	0	26	0	0	0
Facial paralysis	45	0	841	0	21	0	330	0	1171	0	0	3
Facial paresis	12	0	322	0	13	0	138	0	460	0	0	0
Facial spasm	3	0	39	0	3	0	38	0	77	0	0	1

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Febrile convulsion	12	0	178	0	50	0	185	0	363	0	0	0
Femoral nerve palsy	0	0	0	0	0	0	1	0	1	0	0	0
Fine motor delay	0	0	2	0	0	0	1	0	3	0	0	0
Fine motor skill dysfunction	3	0	42	0	5	0	21	0	63	0	0	0
Focal dyscognitive seizures	0	0	9	0	0	0	0	0	9	0	0	0
Foetal movement disorder	0	0	1	0	0	0	1	0	2	0	0	0
Fontanelle bulging	0	0	3	0	0	0	1	0	4	0	0	0
Formication	7	0	93	0	49	0	267	0	360	0	0	0
Freezing phenomenon	0	0	138	0	1	0	46	0	184	0	0	0
Frontotemporal dementia	0	0	2	0	0	0	0	0	2	0	0	0
Fumbling	0	0	3	0	2	0	2	0	5	0	0	0
Gait apraxia	0	0	0	0	0	0	6	0	6	0	0	0
Gait spastic	0	0	1	0	0	0	1	0	2	0	0	0
Gelastic seizure	1	0	1	0	0	0	0	0	1	0	0	0
Generalised tonic-clonic seizure	13	0	209	0	0	0	0	0	209	0	1	1
Glial scar	0	0	0	0	1	0	1	0	1	0	0	0
Gliosis	0	0	2	0	0	0	0	0	2	0	0	0
Glossopharyngeal nerve disorder	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Glossopharyngeal neuralgia	0	0	0	0	0	0	3	0	3	0	0	0
Grimacing	0	0	1	0	0	0	1	0	2	0	0	0
Gross motor delay	1	0	1	0	0	0	1	0	2	0	0	0
Guillain-Barre syndrome	175	0	1662	0	0	0	0	0	1662	0	14	35
Haemorrhage intracranial	9	0	137	0	0	0	0	0	137	0	1	5
Haemorrhagic cerebellar infarction	0	0	1	0	0	0	0	0	1	0	0	0
Haemorrhagic cerebral infarction	1	0	18	0	0	0	0	0	18	0	0	0
Haemorrhagic stroke	15	0	146	0	0	0	0	0	146	0	6	6
Haemorrhagic transformation stroke	1	0	20	0	0	0	0	0	20	0	0	1
Hand-eye coordination impaired	0	0	4	0	0	0	3	0	7	0	0	0
Hashimoto's encephalopathy	0	0	1	0	0	0	0	0	1	0	0	0
Head discomfort	45	0	872	0	259	0	1697	0	2569	0	0	0
Head titubation	2	0	27	0	3	0	20	0	47	0	0	0
Headache	1280	0	75392	1	23416	2	229664	13	305056	14	2	18
Hemianaesthesia	2	0	11	0	0	0	5	0	16	0	0	0
Hemianopia	1	0	29	0	0	0	8	0	37	0	0	0
Hemianopia homonymous	0	0	11	0	0	0	2	0	13	0	0	0
Hemiapraxia	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Hemiataxia	0	0	4	0	0	0	0	0	4	0	0	0
Hemidysaesthesia	0	0	8	0	0	0	6	0	14	0	0	0
Hemihyperaesthesia	0	0	4	0	0	0	3	0	7	0	0	0
Hemihypoaesthesia	2	0	27	0	0	0	20	0	47	0	0	0
Hemiparaesthesia	3	0	77	0	2	0	41	0	118	0	0	0
Hemiparesis	33	0	524	0	0	0	0	0	524	0	1	3
Hemiplegia	13	0	231	0	0	0	0	0	231	0	0	0
Hemiplegic migraine	0	0	56	0	0	0	6	0	62	0	0	0
Hepatic encephalopathy	0	0	7	0	0	0	0	0	7	0	0	0
Hoffmann's sign	0	0	1	0	0	0	0	0	1	0	0	0
Horner's syndrome	1	0	4	0	0	0	2	0	6	0	0	0
Hydrocephalus	3	0	38	0	0	0	0	0	38	0	0	0
Hyperaesthesia	11	0	269	0	66	0	751	0	1020	0	0	0
Hypercapnic coma	0	0	1	0	0	0	0	0	1	0	0	0
Hypergeusia	0	0	0	0	0	0	2	0	2	0	0	0
Hyperintensity in brain deep nuclei	1	0	2	0	0	0	0	0	2	0	0	0
Hyperkinesia	0	0	22	0	0	0	6	0	28	0	0	0
Hyperpathia	0	0	2	0	0	0	1	0	3	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Hyperreflexia	1	0	17	0	2	0	6	0	23	0	0	0
Hyperresponsive to stimuli	0	0	1	0	0	0	1	0	2	0	0	0
Hypersomnia	15	0	223	0	76	0	375	0	598	0	0	0
Hypertensive cerebrovascular disease	0	0	3	0	0	0	0	0	3	0	0	0
Hypertensive encephalopathy	2	0	2	0	0	0	0	0	2	0	0	0
Hypertonia	0	0	11	0	2	0	19	0	30	0	0	0
Hypoaesthesia	198	0	5455	0	724	0	7962	2	13417	2	0	2
Hypogeusia	1	0	15	0	16	0	101	0	116	0	0	0
Hypoglossal nerve paralysis	2	0	6	0	0	0	0	0	6	0	0	0
Hypoglossal nerve paresis	0	0	0	0	0	0	1	0	1	0	0	0
Hypoglycaemic coma	0	0	2	0	0	0	0	0	2	0	0	0
Hypoglycaemic seizure	0	0	1	0	0	0	0	0	1	0	0	0
Hypoglycaemic unconsciousness	0	0	2	0	0	0	0	0	2	0	0	0
Hypokinesia	5	0	165	0	46	0	374	0	539	0	0	0
Hyporeflexia	3	0	42	0	1	0	10	0	52	0	0	0
Hyporesponsive to stimuli	1	0	8	0	0	0	6	0	14	0	0	0
Hyposmia	0	0	16	0	9	0	82	0	98	0	0	0
Hypotonia	9	0	171	0	43	0	841	0	1012	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Hypotonic-hyporesponsive episode	11	0	49	0	45	0	50	0	99	0	0	0
Hypoxic-ischaemic encephalopathy	1	0	8	0	0	0	0	0	8	0	0	0
IIIrd nerve disorder	0	0	2	0	0	0	0	0	2	0	0	0
IIIrd nerve paralysis	1	0	20	0	0	0	3	0	23	0	1	1
IIIrd nerve paresis	0	0	7	0	0	0	3	0	10	0	0	0
IVth nerve disorder	1	0	3	0	0	0	0	0	3	0	0	0
IVth nerve paralysis	0	0	3	0	0	0	2	0	5	0	0	0
IVth nerve paresis	1	0	3	0	0	0	1	0	4	0	0	0
Idiopathic generalised epilepsy	0	0	1	0	0	0	0	0	1	0	0	0
Idiopathic intracranial hypertension	2	0	14	0	0	0	1	0	15	0	0	0
Immune-mediated encephalitis	1	0	4	0	0	0	0	0	4	0	0	0
Immune-mediated encephalopathy	0	0	2	0	0	0	0	0	2	0	0	0
Immune-mediated neurological disorder	1	0	2	0	0	0	0	0	2	0	0	0
Immune-mediated neuropathy	1	0	4	0	0	0	0	0	4	0	0	0
Inability to crawl	0	0	3	0	0	0	0	0	3	0	0	0
Incoherent	1	0	30	0	1	0	19	0	49	0	0	0
Infant irritability	1	0	5	0	0	0	7	0	12	0	0	0
Intellectual disability	2	0	20	0	0	0	0	0	20	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Intensive care unit acquired weakness	1	0	3	0	0	0	0	0	3	0	0	0
Intention tremor	0	0	2	0	0	0	2	0	4	0	0	0
Intercostal neuralgia	0	0	3	0	2	0	10	0	13	0	0	0
Internal capsule infarction	0	0	2	0	0	0	1	0	3	0	0	0
Internal carotid artery deformity	0	0	1	0	1	0	1	0	2	0	0	0
Intracranial aneurysm	1	0	24	0	0	0	4	0	28	0	0	0
Intracranial haematoma	0	0	9	0	0	0	0	0	9	0	0	0
Intracranial hypotension	3	0	10	0	0	0	0	0	10	0	0	0
Intracranial mass	0	0	6	0	0	0	0	0	6	0	0	0
Intracranial pressure increased	12	0	94	0	0	0	0	0	94	0	0	1
Intraventricular haemorrhage	0	0	20	0	0	0	0	0	20	0	0	0
Irregular sleep phase	0	0	1	0	0	0	4	0	5	0	0	0
Irregular sleep wake rhythm disorder	0	0	2	0	0	0	2	0	4	0	0	0
Ischaemic cerebral infarction	1	0	61	0	0	0	0	0	61	0	0	3
Ischaemic neuropathy	0	0	2	0	0	0	1	0	3	0	0	0
Ischaemic stroke	40	0	756	0	0	0	0	0	756	0	2	5
Judgement impaired	0	0	4	0	0	0	3	0	7	0	0	0
Lacunar infarction	2	0	44	0	0	0	0	0	44	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Lacunar stroke	1	0	38	0	0	0	2	0	40	0	0	0
Language disorder	10	0	58	0	11	0	72	0	130	0	0	0
Lateral medullary syndrome	1	0	7	0	0	0	0	0	7	0	0	0
Lateropulsion	0	0	2	0	0	0	0	0	2	0	0	0
Lethargy	33	0	4007	0	112	0	4974	0	8981	0	0	0
Leukoencephalopathy	0	0	5	0	0	0	0	0	5	0	0	0
Lhermitte's sign	0	0	5	0	0	0	1	0	6	0	0	0
Limbic encephalitis	3	0	8	0	0	0	0	0	8	0	0	0
Locked-in syndrome	0	0	1	0	0	0	0	0	1	0	0	0
Long thoracic nerve palsy	0	0	2	0	0	0	0	0	2	0	0	0
Loss of consciousness	144	0	2042	0	26	0	770	0	2812	0	0	2
Loss of proprioception	2	0	14	0	1	0	3	0	17	0	0	0
Lower motor neurone lesion	0	0	2	0	0	0	0	0	2	0	0	0
Lumbar radiculopathy	0	0	6	0	1	0	1	0	7	0	0	0
Lumbosacral plexopathy	1	0	4	0	0	0	1	0	5	0	0	0
Lumbosacral plexus lesion	1	0	2	0	0	0	1	0	3	0	0	0
Lumbosacral radiculopathy	0	0	1	0	1	0	2	0	3	0	0	0
Medication overuse headache	0	0	15	0	0	0	47	0	62	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Meige's syndrome	0	0	1	0	0	0	0	0	1	0	0	0
Memory impairment	49	0	550	0	115	0	661	1	1211	1	0	0
Meningeal disorder	0	0	1	0	0	0	1	0	2	0	0	0
Meningeal thickening	0	0	1	0	0	0	0	0	1	0	0	0
Meningism	3	0	12	0	4	0	39	0	51	0	0	0
Meningitis eosinophilic	1	0	1	0	0	0	0	0	1	0	0	0
Meningitis noninfective	0	0	1	0	0	0	0	0	1	0	0	0
Meningoradiculitis	0	0	8	0	0	0	0	0	8	0	0	0
Meningorrhagia	0	0	2	0	0	0	0	0	2	0	0	0
Menstrual headache	0	0	9	0	1	0	9	0	18	0	0	0
Mental impairment	10	0	166	0	19	0	102	0	268	0	0	0
Meralgia paraesthetica	0	0	5	0	1	0	7	0	12	0	0	0
Metabolic encephalopathy	0	0	3	0	0	0	0	0	3	0	0	0
Microglial nodules	0	0	1	0	0	0	0	0	1	0	0	0
Micrographia	1	0	1	0	0	0	0	0	1	0	0	0
Microsleep	0	0	2	0	0	0	2	0	4	0	0	0
Microvascular cranial nerve palsy	0	0	3	0	0	0	1	0	4	0	0	0
Migraine	97	0	7299	0	443	0	4249	1	11548	1	0	1

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Migraine with aura	12	0	391	0	23	0	212	0	603	0	0	0
Migraine without aura	0	0	43	0	3	0	21	0	64	0	0	0
Migraine-triggered seizure	0	0	3	0	0	0	0	0	3	0	0	0
Miller Fisher syndrome	8	0	57	0	0	0	8	0	65	0	1	2
Mixed dementia	0	0	1	0	0	0	0	0	1	0	0	0
Mononeuritis	1	0	9	0	0	0	4	0	13	0	0	0
Mononeuropathy	1	0	5	0	1	0	5	0	10	0	0	0
Mononeuropathy multiplex	0	0	0	0	0	0	1	0	1	0	0	0
Monoparesis	17	0	265	0	0	0	0	0	265	0	0	0
Monoplegia	21	0	361	0	0	0	0	0	361	0	0	0
Morton's neuralgia	0	0	0	0	1	0	1	0	1	0	0	0
Motor dysfunction	9	0	89	0	4	0	79	0	168	0	0	1
Motor neurone disease	6	0	13	0	0	0	1	0	14	0	0	0
Movement disorder	30	0	220	1	44	0	457	0	677	1	0	0
Multifocal motor neuropathy	2	0	4	0	0	0	0	0	4	0	0	0
Multiple sclerosis	21	0	131	0	5	0	44	0	175	0	0	3
Multiple sclerosis pseudo relapse	1	0	4	0	1	0	2	0	6	0	0	0
Multiple sclerosis relapse	10	0	113	0	0	0	24	0	137	0	1	3

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Muscle contractions involuntary	7	0	72	0	22	0	153	0	225	0	0	0
Muscle spasticity	7	0	45	0	7	0	31	0	76	0	0	0
Muscle tension dysphonia	0	0	1	0	0	0	1	0	2	0	0	0
Muscle tone disorder	0	0	1	0	0	0	4	0	5	0	0	0
Myasthenia gravis	5	0	60	0	4	0	22	0	82	0	4	4
Myasthenia gravis crisis	1	0	5	0	0	0	2	0	7	0	0	0
Myasthenic syndrome	0	0	2	0	0	0	0	0	2	0	0	0
Myelin oligodendrocyte glycoprotein antibody-associated disease	4	0	12	0	0	0	0	0	12	0	2	6
Myelitis transverse	25	0	234	0	2	0	20	0	254	0	0	1
Myelopathy	4	0	24	0	0	0	5	0	29	0	0	0
Myoclonic epilepsy	1	0	9	0	0	0	0	0	9	0	0	0
Myoclonus	0	0	47	0	5	0	47	0	94	0	0	0
Myotonia	0	0	0	0	1	0	1	0	1	0	0	0
Narcolepsy	1	0	24	0	2	0	13	0	37	0	0	0
Neonatal seizure	1	0	1	0	0	0	0	0	1	0	1	1
Nerve compression	3	0	49	0	1	0	29	0	78	0	0	0
Nerve degeneration	0	0	1	0	1	0	1	0	2	0	0	0
Nervous system disorder	29	0	237	0	50	0	213	0	450	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Neuralgia	51	0	1512	0	125	0	1298	0	2810	0	0	0
Neuralgic amyotrophy	8	0	55	0	7	0	25	0	80	0	0	0
Neuritis	4	0	45	0	6	0	50	0	95	0	0	0
Neuritis cranial	0	0	5	0	0	0	0	0	5	0	0	0
Neurodegenerative disorder	1	0	2	0	1	0	1	0	3	0	0	0
Neuroleptic malignant syndrome	0	0	1	0	0	0	0	0	1	0	0	0
Neurologic neglect syndrome	1	0	10	0	0	0	3	0	13	0	0	0
Neurological decompensation	1	0	10	0	1	0	3	0	13	0	0	0
Neurological symptom	17	0	185	0	9	0	87	0	272	0	0	0
Neuromuscular blockade	0	0	1	0	0	0	1	0	2	0	0	0
Neuromuscular pain	0	0	5	0	0	0	5	0	10	0	0	0
Neuromyelitis optica spectrum disorder	3	0	25	0	0	0	4	0	29	0	0	1
Neuromyopathy	1	0	8	0	1	0	2	0	10	0	0	0
Neuromyotonia	1	0	2	0	1	0	2	0	4	0	0	0
Neuropathy peripheral	37	0	367	0	16	0	225	0	592	0	0	0
Neuropsychiatric lupus	0	0	0	0	0	0	1	0	1	0	0	0
Neurosarcoidosis	1	0	6	0	0	0	0	0	6	0	0	0
Neurotoxicity	0	0	5	0	0	0	0	0	5	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Neurovascular conflict	0	0	3	0	1	0	1	0	4	0	0	0
New daily persistent headache	1	0	26	0	2	0	27	0	53	0	0	0
Non-24-hour sleep-wake disorder	0	0	2	0	0	0	2	0	4	0	0	0
Noninfectious myelitis	0	0	1	0	0	0	0	0	1	0	0	0
Noninfective encephalitis	10	0	33	0	0	0	0	0	33	0	0	0
Noninfective encephalomyelitis	1	0	3	0	0	0	0	0	3	0	0	0
Normal pressure hydrocephalus	0	0	2	0	0	0	0	0	2	0	0	0
Notalgia paraesthetica	0	0	0	0	0	0	1	0	1	0	0	0
Numb chin syndrome	0	0	5	0	0	0	2	0	7	0	0	0
Nystagmus	3	0	44	0	1	0	37	0	81	0	0	0
Occipital neuralgia	3	0	30	0	3	0	20	0	50	0	0	0
Oculofacial paralysis	0	0	2	0	0	0	0	0	2	0	0	0
Ophthalmic migraine	2	0	31	0	10	0	53	0	84	0	0	0
Ophthalmoplegic migraine	0	0	1	0	0	0	0	0	1	0	0	0
Opisthotonus	0	0	5	0	0	0	0	0	5	0	0	0
Optic neuritis	15	0	155	0	2	0	34	0	189	0	0	4
Oromandibular dystonia	0	0	1	0	0	0	1	0	2	0	0	0
Orthostatic intolerance	1	0	13	0	0	0	8	0	21	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Orthostatic tremor	2	0	2	0	0	0	0	0	2	0	0	0
Osmotic demyelination syndrome	0	0	1	0	0	0	0	0	1	0	0	0
Pachymeningitis	0	0	3	0	0	0	1	0	4	0	0	0
Paraesthesia	262	0	8381	0	1023	2	13306	3	21687	3	1	3
Paraesthesia mucosal	0	0	2	0	0	0	1	0	3	0	0	0
Paralysis	52	0	595	0	10	0	138	1	733	1	0	0
Paralysis recurrent laryngeal nerve	0	0	5	0	0	0	0	0	5	0	0	0
Paraparesis	5	0	54	1	0	0	0	0	54	1	0	0
Paraplegia	12	0	39	0	0	0	0	0	39	0	0	0
Paresis	20	0	116	0	10	0	81	0	197	0	0	0
Paresis cranial nerve	0	0	3	0	0	0	2	0	5	0	0	0
Parkinson's disease	2	0	34	0	3	0	9	0	43	0	0	0
Parkinsonian gait	0	0	3	0	0	0	0	0	3	0	0	0
Parkinsonism	2	0	15	0	0	0	6	0	21	0	0	0
Parosmia	8	0	265	0	78	0	655	0	920	0	0	0
Partial seizures	2	0	82	0	1	0	17	0	99	0	0	0
Partial seizures with secondary generalisation	1	0	2	0	0	0	0	0	2	0	0	0
Patient elopement	0	0	3	0	0	0	3	0	6	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Perinatal stroke	0	0	2	0	0	0	0	0	2	0	0	0
Periodic limb movement disorder	0	0	2	0	0	0	0	0	2	0	0	0
Peripheral motor neuropathy	2	0	10	0	0	0	3	0	13	0	0	0
Peripheral nerve lesion	3	0	7	0	0	0	5	0	12	0	0	0
Peripheral nerve palsy	0	0	2	0	0	0	0	0	2	0	0	0
Peripheral nerve paresis	0	0	2	0	0	0	0	0	2	0	0	0
Peripheral paralysis	1	0	10	0	0	0	1	0	11	0	0	0
Peripheral sensorimotor neuropathy	1	0	11	0	1	0	1	0	12	0	0	0
Peripheral sensory neuropathy	5	0	38	0	3	0	21	0	59	0	0	0
Peroneal nerve palsy	3	0	33	0	1	0	5	0	38	0	0	0
Persistent genital arousal disorder	0	0	2	0	0	0	1	0	3	0	0	0
Persistent postural-perceptual dizziness	1	0	41	0	1	0	9	0	50	0	0	0
Petit mal epilepsy	3	0	64	0	1	0	20	0	84	0	0	0
Phantom limb syndrome	0	0	16	0	1	0	15	0	31	0	0	0
Phrenic nerve irritation	0	0	0	0	0	0	1	0	1	0	0	0
Phrenic nerve paralysis	0	0	3	0	0	0	2	0	5	0	0	0
Pineal gland cyst	0	0	0	0	0	0	2	0	2	0	0	0
Piriformis syndrome	0	0	3	0	0	0	0	0	3	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Pleocytosis	2	0	13	0	0	0	0	0	13	0	0	0
Polyneuropathy	18	0	198	1	0	0	0	0	198	1	0	0
Polyneuropathy chronic	0	0	1	0	0	0	1	0	2	0	0	0
Polyneuropathy in malignant disease	0	0	0	0	0	0	1	0	1	0	0	0
Poor sucking reflex	0	0	4	0	0	0	0	0	4	0	0	0
Post cardiac arrest syndrome	0	0	1	0	0	0	0	0	1	0	0	0
Post herpetic neuralgia	1	0	20	0	4	0	26	0	46	0	0	0
Post polio syndrome	0	0	0	0	0	0	1	0	1	0	0	0
Post stroke epilepsy	0	0	1	0	0	0	0	0	1	0	0	0
Post-traumatic headache	0	0	4	0	0	0	2	0	6	0	0	0
Posterior reversible encephalopathy syndrome	4	0	10	0	0	0	0	0	10	0	0	0
Posthaemorrhagic hydrocephalus	0	0	2	0	0	0	0	0	2	0	0	0
Postictal paralysis	0	0	3	0	0	0	0	0	3	0	0	0
Postictal state	0	0	6	0	0	0	2	0	8	0	0	0
Postresuscitation encephalopathy	0	0	2	0	0	0	0	0	2	0	0	0
Postural tremor	0	0	1	0	0	0	3	0	4	0	0	0
Precerebral artery occlusion	0	0	1	0	0	0	0	0	1	0	0	0
Presyncope	23	0	704	0	117	0	1453	0	2157	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Primary cough headache	0	0	2	0	0	0	1	0	3	0	0	0
Primary headache associated with sexual activity	0	0	12	0	0	0	2	0	14	0	0	0
Primary progressive aphasia	0	0	1	0	0	0	0	0	1	0	0	0
Progressive multiple sclerosis	0	0	2	0	0	0	0	0	2	0	0	0
Prosopagnosia	1	0	2	0	0	0	2	0	4	0	0	0
Pseudoparalysis	0	0	0	0	0	0	2	0	2	0	0	0
Pseudostroke	0	0	6	0	0	0	0	0	6	0	0	0
Psychogenic seizure	1	0	9	0	0	0	10	0	19	0	0	0
Psychomotor disadaptation syndrome	0	0	0	0	0	0	1	0	1	0	0	0
Psychomotor hyperactivity	1	0	40	0	2	0	51	0	91	0	0	0
Psychomotor skills impaired	0	0	6	0	0	0	1	0	7	0	0	0
Quadrantanopia	2	0	3	0	0	0	1	0	4	0	0	0
Quadriparesis	5	0	49	0	0	0	0	0	49	0	0	0
Quadriplegia	7	0	27	0	0	0	0	0	27	0	0	0
Radial nerve compression	0	0	1	0	0	0	0	0	1	0	0	0
Radial nerve palsy	0	0	6	0	0	0	3	0	9	0	0	0
Radicular pain	1	0	5	0	0	0	1	0	6	0	0	0
Radiculitis brachial	1	0	32	0	1	0	12	0	44	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Radiculopathy	5	0	40	0	3	0	20	0	60	0	0	0
Raymond-Cestan syndrome	1	0	1	0	0	0	0	0	1	0	0	0
Reduced facial expression	0	0	12	0	0	0	6	0	18	0	0	0
Reflexes abnormal	1	0	10	0	1	0	6	0	16	0	0	0
Relapsing multiple sclerosis	0	0	2	0	0	0	0	0	2	0	0	0
Relapsing-remitting multiple sclerosis	0	0	4	0	0	0	0	0	4	0	2	7
Repetitive speech	0	0	5	0	0	0	1	0	6	0	0	0
Resting tremor	1	0	9	0	0	0	8	0	17	0	0	0
Restless arm syndrome	0	0	9	0	1	0	11	0	20	0	0	0
Restless legs syndrome	5	0	339	0	31	0	319	0	658	0	0	0
Retinal migraine	0	0	75	0	1	0	20	0	95	0	0	0
Retrograde amnesia	0	0	11	0	0	0	2	0	13	0	0	0
Reversed hot-cold sensation	0	0	3	0	0	0	18	0	21	0	0	0
Reversible cerebral vasoconstriction syndrome	1	0	7	0	0	0	1	0	8	0	0	0
Right hemisphere deficit syndrome	0	0	2	0	0	0	0	0	2	0	0	0
Ruptured cerebral aneurysm	1	0	11	0	0	0	0	0	11	0	0	0
SUNA syndrome	0	0	1	0	0	0	0	0	1	0	0	0
SUNCT syndrome	0	0	1	0	0	0	1	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Sciatic nerve neuropathy	0	0	8	0	0	0	3	0	11	0	0	0
Sciatica	15	0	247	0	16	1	168	1	415	1	0	0
Secondary progressive multiple sclerosis	0	0	0	0	1	0	1	0	1	0	0	1
Sedation	0	0	23	0	2	0	46	0	69	0	0	0
Seizure	302	0	2970	0	0	0	0	0	2970	0	1	5
Seizure anoxic	1	0	3	0	0	0	1	0	4	0	0	0
Seizure cluster	0	0	8	0	0	0	1	0	9	0	0	0
Seizure like phenomena	0	0	15	0	0	0	0	0	15	0	0	0
Senile dementia	0	0	3	0	0	0	0	0	3	0	0	0
Sensorimotor disorder	1	0	7	0	0	0	7	0	14	0	0	0
Sensory disturbance	40	0	372	0	75	0	781	0	1153	0	0	0
Sensory loss	14	0	271	0	45	0	255	0	526	0	0	1
Sensory overload	0	0	12	0	1	0	8	0	20	0	0	0
Sensory processing disorder	0	0	3	0	0	0	0	0	3	0	0	1
Serotonin deficiency	0	0	0	0	0	0	1	0	1	0	0	0
Serotonin syndrome	0	0	0	0	0	0	1	0	1	0	0	0
Sigmoid sinus thrombosis	5	0	5	0	1	0	1	0	6	0	1	1
Simple partial seizures	0	0	7	0	0	0	1	0	8	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Sinus headache	8	0	775	0	11	0	294	0	1069	0	0	0
Sleep deficit	2	0	47	0	7	0	48	0	95	0	0	0
Sleep paralysis	0	0	21	0	0	0	16	0	37	0	0	0
Slow response to stimuli	0	0	10	0	1	0	16	0	26	0	0	0
Slow speech	3	0	50	0	0	0	19	0	69	0	0	0
Small fibre neuropathy	17	0	32	0	6	0	9	0	41	0	0	0
Somnolence	56	0	2171	0	553	0	7668	2	9839	2	1	1
Spasmodic dysphonia	0	0	0	0	0	0	1	0	1	0	0	0
Speech disorder	27	0	328	0	32	0	242	0	570	0	0	0
Speech disorder developmental	2	0	8	0	1	0	3	0	11	0	0	0
Spinal artery thrombosis	0	0	1	0	0	0	1	0	2	0	0	0
Spinal cord compression	3	0	7	0	0	0	0	0	7	0	0	0
Spinal cord disorder	1	0	9	0	0	0	3	0	12	0	0	0
Spinal cord haematoma	0	0	3	0	0	0	0	0	3	0	0	0
Spinal cord haemorrhage	0	0	6	0	0	0	0	0	6	0	0	0
Spinal cord infarction	0	0	10	0	0	0	0	0	10	0	0	0
Spinal cord ischaemia	1	0	6	0	0	0	2	0	8	0	0	0
Spinal cord oedema	1	0	2	0	0	0	1	0	3	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Spinal epidural haematoma	0	0	1	0	0	0	0	0	1	0	0	0
Spinal meningeal cyst	0	0	1	0	0	0	1	0	2	0	0	0
Spinal stroke	1	0	7	0	0	0	0	0	7	0	0	0
Spontaneous cerebrospinal fluid leak syndrome	0	0	2	0	0	0	0	0	2	0	0	0
Status epilepticus	2	0	105	0	0	0	0	0	105	0	1	1
Status migrainosus	0	0	10	0	0	0	6	0	16	0	0	0
Stiff leg syndrome	0	0	8	0	0	0	8	0	16	0	0	0
Stiff person syndrome	0	0	3	0	0	0	0	0	3	0	0	0
Stroke in evolution	0	0	1	0	0	0	0	0	1	0	0	0
Stupor	1	0	17	0	0	0	38	0	55	0	0	0
Subacute inflammatory demyelinating polyneuropathy	0	0	11	0	0	0	0	0	11	0	0	0
Subarachnoid haemorrhage	18	0	234	0	0	0	0	0	234	0	0	0
Sudden onset of sleep	1	0	6	0	2	0	14	0	20	0	0	0
Superior sagittal sinus thrombosis	7	0	99	0	0	0	0	0	99	0	1	2
Sydenham's chorea	0	0	1	0	0	0	0	0	1	0	0	0
Sympathicotonia	0	0	0	0	0	0	1	0	1	0	0	0
Syncope	260	0	4001	0	104	1	3075	2	7076	2	2	2
Synkinesis	0	0	0	0	1	0	1	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Tardive dyskinesia	0	0	1	0	0	0	0	0	1	0	0	0
Tarsal tunnel syndrome	0	0	0	0	0	0	2	0	2	0	0	0
Taste disorder	10	0	425	0	139	0	1109	0	1534	0	0	0
Temporal lobe epilepsy	1	0	10	0	0	0	2	0	12	0	0	0
Tension headache	11	0	1263	0	68	0	878	0	2141	0	0	0
Thalamic infarction	3	0	32	0	0	0	0	0	32	0	0	1
Thalamus haemorrhage	0	0	15	0	0	0	0	0	15	0	0	0
Thermohypoaesthesia	0	0	1	0	0	0	0	0	1	0	0	0
Thoracic outlet syndrome	2	0	5	0	0	0	1	0	6	0	0	0
Thrombotic cerebral infarction	0	0	5	0	0	0	0	0	5	0	0	0
Thrombotic stroke	3	0	36	0	0	0	0	0	36	0	0	0
Thunderclap headache	4	0	70	0	0	0	0	0	70	0	0	0
Tick paralysis	1	0	1	0	0	0	1	0	2	0	0	0
Tongue biting	1	0	11	0	0	0	8	0	19	0	0	0
Tongue paralysis	1	0	10	0	0	0	2	0	12	0	0	0
Tonic clonic movements	0	0	12	0	0	0	11	0	23	0	0	0
Tonic convulsion	2	0	52	0	0	0	0	0	52	0	0	0
Tonic posturing	0	0	0	0	0	0	1	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Transient aphasia	1	0	11	0	1	0	4	0	15	0	0	0
Transient global amnesia	0	0	48	0	0	0	27	0	75	0	0	0
Transient ischaemic attack	41	0	1107	0	0	0	0	0	1107	0	0	1
Transverse sinus stenosis	0	0	3	0	0	0	0	0	3	0	0	0
Transverse sinus thrombosis	2	0	60	0	0	0	3	0	63	0	0	0
Tremor	102	0	9183	0	624	0	6631	0	15814	0	0	1
Trigeminal nerve disorder	0	0	13	0	0	0	9	0	22	0	0	0
Trigeminal nerve paresis	0	0	2	0	0	0	0	0	2	0	0	0
Trigeminal neuralgia	4	0	182	0	12	0	124	0	306	0	0	0
Trigeminal neuritis	0	0	4	0	1	0	2	0	6	0	0	0
Trigeminal neuropathy	1	0	1	0	0	0	0	0	1	0	0	0
Trigeminal palsy	0	0	3	0	0	0	0	0	3	0	0	0
Tumefactive multiple sclerosis	0	0	1	0	0	0	0	0	1	0	0	1
Tunnel vision	2	0	27	0	1	0	15	0	42	0	0	0
Typical aura without headache	0	0	17	0	1	0	8	0	25	0	0	0
Uhthoff's phenomenon	0	0	2	0	1	0	3	0	5	0	0	0
Ulnar nerve palsy	1	0	4	0	0	0	0	0	4	0	0	0
Ulnar neuritis	0	0	4	0	0	0	4	0	8	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Ulnar tunnel syndrome	0	0	1	0	0	0	0	0	1	0	0	0
Unresponsive to stimuli	4	0	190	0	0	0	0	0	190	0	0	0
Upper motor neurone lesion	1	0	2	0	0	0	0	0	2	0	0	0
Uraemic encephalopathy	0	0	2	0	0	0	0	0	2	0	0	0
VIIIth nerve lesion	0	0	1	0	0	0	0	0	1	0	0	0
VIth nerve disorder	1	0	3	0	0	0	1	0	4	0	0	0
VIth nerve paralysis	2	0	31	0	2	0	20	0	51	0	0	0
VIth nerve paresis	0	0	6	0	0	0	1	0	7	0	0	0
Vagus nerve disorder	1	0	1	0	0	0	1	0	2	0	0	0
Vagus nerve paralysis	0	0	1	0	0	0	1	0	2	0	0	0
Vascular dementia	0	0	6	0	0	0	1	0	7	0	0	0
Vascular encephalopathy	0	0	0	0	0	0	1	0	1	0	0	0
Vascular headache	2	0	84	0	1	0	16	0	100	0	0	0
Vascular parkinsonism	0	0	1	0	0	0	0	0	1	0	0	0
Vasogenic cerebral oedema	0	0	2	0	0	0	1	0	3	0	0	0
Vertebral artery occlusion	0	0	5	0	0	0	1	0	6	0	0	0
Vertebral artery stenosis	0	0	0	0	0	0	1	0	1	0	0	0
Vertebral artery thrombosis	1	0	10	0	0	0	0	0	10	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Vertebrobasilar artery dissection	0	0	9	0	0	0	2	0	11	0	0	0
Vertebrobasilar insufficiency	1	0	4	0	0	0	0	0	4	0	0	0
Vertebrobasilar stroke	1	0	12	0	0	0	0	0	12	0	0	0
Vertigo CNS origin	1	0	4	0	0	0	0	0	4	0	0	0
Vestibular migraine	2	0	44	0	1	0	8	0	52	0	0	0
Vestibular nystagmus	0	0	1	0	0	0	1	0	2	0	0	0
Vibration syndrome	0	0	2	0	1	0	2	0	4	0	0	0
Vibratory sense increased	1	0	7	0	1	0	4	0	11	0	0	0
Visual pathway disorder	0	0	1	0	0	0	2	0	3	0	0	0
Visual perseveration	0	0	1	0	0	0	0	0	1	0	0	0
Visuospatial deficit	0	0	3	0	0	0	0	0	3	0	0	0
Vocal cord paralysis	1	0	15	0	0	0	5	0	20	0	0	0
Vocal cord paresis	1	0	2	0	0	0	0	0	2	0	0	0
Wernicke's encephalopathy	0	0	1	0	0	0	0	0	1	0	0	0
White matter lesion	1	0	11	0	2	0	5	0	16	0	0	0
Writer's cramp	0	0	1	0	0	0	0	0	1	0	0	0
Eye disorders	**600**	**0**	**16409**	**1**	**1607**	**0**	**18930**	**5**	**35339**	**6**	**31**	**64**
Abnormal sensation in eye	0	0	29	0	7	0	78	0	107	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Accommodation disorder	0	0	5	0	0	0	34	0	39	0	0	0
Acute macular neuroretinopathy	4	0	23	0	1	0	7	0	30	0	1	2
Altered visual depth perception	0	0	4	0	0	0	5	0	9	0	0	0
Amaurosis	1	0	21	0	0	0	4	0	25	0	0	0
Amaurosis fugax	2	0	41	0	0	0	0	0	41	0	4	4
Amblyopia	0	0	9	0	0	0	5	0	14	0	0	0
Angle closure glaucoma	0	0	10	0	0	0	2	0	12	0	4	4
Anisocoria	2	0	27	0	1	0	9	0	36	0	0	0
Anterior capsule contraction	0	0	2	0	1	0	1	0	3	0	0	0
Arcus lipoides	0	0	1	0	0	0	0	0	1	0	0	0
Arteriosclerotic retinopathy	0	0	0	0	0	0	0	0	0	0	0	1
Asthenopia	5	0	299	0	11	0	232	0	531	0	0	0
Astigmatism	0	0	1	0	1	0	4	0	5	0	0	0
Autoimmune eye disorder	0	0	1	0	0	0	0	0	1	0	0	0
Autoimmune uveitis	0	0	2	0	0	0	0	0	2	0	0	0
Bell's phenomenon	0	0	0	0	0	0	1	0	1	0	0	0
Binocular eye movement disorder	0	0	1	0	0	0	3	0	4	0	0	0
Birdshot chorioretinopathy	0	0	0	0	0	0	1	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Blepharal pigmentation	0	0	0	0	0	0	1	0	1	0	0	0
Blepharitis	0	0	30	0	4	0	40	0	70	0	0	0
Blepharospasm	3	0	94	0	12	0	183	0	277	0	0	0
Blindness	20	0	555	0	0	0	0	0	555	0	0	1
Blindness cortical	1	0	2	0	0	0	0	0	2	0	0	0
Blindness day	0	0	1	0	0	0	2	0	3	0	0	0
Blindness transient	13	0	117	0	0	0	0	0	117	0	0	0
Blindness unilateral	9	0	135	0	0	0	0	0	135	0	0	2
Cataract	9	0	41	0	4	0	20	0	61	0	0	0
Cataract cortical	0	0	2	0	0	0	0	0	2	0	0	0
Cataract nuclear	0	0	0	0	0	0	1	0	1	0	0	0
Cataract subcapsular	0	0	3	0	0	0	1	0	4	0	0	0
Central serous chorioretinopathy	2	0	9	0	0	0	1	0	10	0	0	0
Central vision loss	0	0	5	0	0	0	1	0	6	0	0	0
Chalazion	0	0	4	0	0	0	5	0	9	0	0	0
Charles Bonnet syndrome	0	0	1	0	0	0	0	0	1	0	0	0
Chloropsia	0	0	2	0	0	0	0	0	2	0	0	0
Chorioretinal disorder	1	0	2	0	0	0	0	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Chorioretinopathy	0	0	5	0	2	0	3	0	8	0	1	1
Choroidal detachment	0	0	1	0	0	0	0	0	1	0	0	0
Choroidal effusion	0	0	2	0	1	0	4	0	6	0	0	0
Choroidal haemorrhage	0	0	1	0	0	0	0	0	1	0	0	0
Choroidal neovascularisation	0	0	1	0	0	0	1	0	2	0	0	0
Choroiditis	0	0	1	0	0	0	1	0	2	0	0	0
Chromatopsia	0	0	3	0	0	0	4	0	7	0	0	0
Computer vision syndrome	0	0	0	0	0	0	1	0	1	0	0	0
Conjunctival bleb	0	0	1	0	0	0	0	0	1	0	0	0
Conjunctival disorder	0	0	1	0	0	0	0	0	1	0	0	0
Conjunctival haemorrhage	8	0	129	0	5	0	248	0	377	0	0	0
Conjunctival hyperaemia	0	0	8	0	2	0	31	0	39	0	0	0
Conjunctival irritation	0	0	0	0	1	0	9	0	9	0	0	0
Conjunctival oedema	1	0	2	0	5	0	19	0	21	0	0	0
Conjunctival opacity	0	0	0	0	0	0	2	0	2	0	0	0
Conjunctival pallor	0	0	0	0	1	0	1	0	1	0	0	0
Conjunctival suffusion	0	0	0	0	1	0	2	0	2	0	0	0
Conjunctivitis allergic	0	0	3	0	1	0	11	0	14	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Corneal bleeding	0	0	3	0	0	0	4	0	7	0	0	0
Corneal cyst	0	0	1	0	0	0	0	0	1	0	0	0
Corneal defect	0	0	1	0	0	0	1	0	2	0	0	0
Corneal disorder	0	0	0	0	1	0	1	0	1	0	0	0
Corneal erosion	1	0	1	0	0	0	0	0	1	0	0	0
Corneal lesion	0	0	2	0	0	0	2	0	4	0	0	0
Corneal leukoma	0	0	1	0	0	0	0	0	1	0	0	0
Corneal neovascularisation	0	0	1	0	0	0	0	0	1	0	0	0
Corneal oedema	0	0	3	0	3	0	10	0	13	0	0	0
Corneal opacity	0	0	4	0	0	0	1	0	5	0	0	0
Corneal perforation	0	0	2	0	0	0	0	0	2	0	0	0
Corneal scar	0	0	1	0	0	0	0	0	1	0	0	0
Cyanopsia	0	0	3	0	0	0	1	0	4	0	0	0
Cystoid macular oedema	1	0	7	0	2	0	3	0	10	0	0	0
Dacryostenosis acquired	0	0	1	0	0	0	2	0	3	0	0	0
Dark circles under eyes	0	0	10	0	4	0	17	0	27	0	0	0
Delayed dark adaptation	0	0	1	0	0	0	0	0	1	0	0	0
Deposit eye	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Dermatochalasis	1	0	2	0	0	0	0	0	2	0	0	0
Detachment of macular retinal pigment epithelium	0	0	0	0	0	0	1	0	1	0	0	0
Diabetic retinopathy	1	0	5	0	0	0	1	0	6	0	0	0
Diplopia	17	0	527	0	23	0	362	0	889	0	0	0
Disorder of globe	0	0	1	0	0	0	1	0	2	0	0	0
Dry age-related macular degeneration	0	0	1	0	0	0	0	0	1	0	0	0
Dry eye	8	0	277	0	23	0	267	0	544	0	0	0
Dyschromatopsia	0	0	20	0	0	0	12	0	32	0	0	0
Dysmetropsia	0	0	1	0	0	0	0	0	1	0	0	0
Ectropion	0	0	1	0	0	0	0	0	1	0	0	0
Eczema eyelids	0	0	8	0	1	0	6	0	14	0	0	0
Endocrine ophthalmopathy	1	0	7	0	3	0	4	0	11	0	0	0
Enophthalmos	0	0	0	0	0	0	1	0	1	0	0	0
Epiretinal membrane	0	0	3	0	1	0	3	0	6	0	0	0
Episcleral hyperaemia	0	0	0	0	0	0	1	0	1	0	0	0
Episcleritis	0	0	14	0	2	0	19	0	33	0	0	0
Erythema of eyelid	1	0	14	0	4	0	22	0	36	0	0	0
Erythropsia	0	0	3	0	0	0	4	0	7	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Excessive eye blinking	0	0	5	0	4	0	10	0	15	0	0	0
Exophthalmos	0	0	14	0	0	0	13	0	27	0	0	0
Extraocular muscle disorder	0	0	0	0	0	0	2	0	2	0	0	0
Eye allergy	1	0	25	0	1	0	24	0	49	0	0	0
Eye colour change	0	0	7	0	1	0	6	0	13	0	0	0
Eye discharge	1	0	21	0	5	0	43	0	64	0	0	0
Eye disorder	9	0	61	0	13	0	116	0	177	0	0	0
Eye haematoma	0	0	13	0	2	0	35	0	48	0	0	0
Eye haemorrhage	24	0	181	0	20	0	233	0	414	0	0	0
Eye infarction	4	0	18	0	0	0	2	0	20	0	0	0
Eye inflammation	5	0	47	0	14	0	102	0	149	0	0	0
Eye irritation	3	0	202	0	41	0	556	1	758	1	0	0
Eye movement disorder	0	0	64	0	4	0	49	0	113	0	0	0
Eye oedema	0	0	27	0	11	0	90	0	117	0	0	0
Eye opacity	0	0	3	0	0	0	0	0	3	0	0	0
Eye pain	39	0	3002	0	374	0	4508	1	7510	1	0	0
Eye paraesthesia	0	0	7	0	0	0	6	0	13	0	0	0
Eye pruritus	6	0	227	0	35	0	412	0	639	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Eye swelling	12	0	488	0	49	0	730	0	1218	0	0	0
Eye symptom	0	0	15	0	0	0	6	0	21	0	0	0
Eye ulcer	0	0	7	0	1	0	7	0	14	0	0	0
Eyelash discolouration	0	0	0	0	0	0	1	0	1	0	0	0
Eyelid bleeding	0	0	6	0	3	0	11	0	17	0	0	0
Eyelid cyst	0	0	15	0	0	0	7	0	22	0	0	0
Eyelid disorder	1	0	16	0	0	0	15	0	31	0	0	0
Eyelid erosion	0	0	0	0	0	0	1	0	1	0	0	0
Eyelid exfoliation	0	0	1	0	1	0	4	0	5	0	0	0
Eyelid function disorder	0	0	2	0	0	0	4	0	6	0	0	0
Eyelid haematoma	1	0	4	0	1	0	28	0	32	0	0	0
Eyelid irritation	1	0	6	0	5	0	31	0	37	0	0	0
Eyelid margin crusting	0	0	1	0	0	0	1	0	2	0	0	0
Eyelid myoclonus	0	0	1	0	1	0	3	0	4	0	0	0
Eyelid myokymia	0	0	3	0	1	0	4	0	7	0	0	0
Eyelid oedema	1	0	68	0	11	0	172	0	240	0	0	0
Eyelid pain	1	0	15	0	8	0	47	0	62	0	0	0
Eyelid ptosis	3	0	90	0	5	0	58	0	148	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Eyelid rash	0	0	10	0	2	0	21	0	31	0	0	0
Eyelid sensory disorder	0	0	1	0	0	0	8	0	9	0	0	0
Eyelid skin dryness	0	0	3	0	1	0	4	0	7	0	0	0
Eyelid thickening	0	0	3	0	0	0	4	0	7	0	0	0
Eyelids pruritus	0	0	10	0	4	0	23	0	33	0	0	0
Floppy eyelid syndrome	0	0	0	0	0	0	1	0	1	0	0	0
Foreign body sensation in eyes	0	0	31	0	3	0	32	0	63	0	0	0
Gaze palsy	2	0	15	0	0	0	4	0	19	0	0	0
Glare	0	0	0	0	0	0	2	0	2	0	0	0
Glaucoma	10	0	33	0	3	0	10	0	43	0	0	0
Glaucomatocyclitic crises	0	0	1	0	0	0	0	0	1	0	0	0
Growth of eyelashes	0	0	8	0	0	0	2	0	10	0	0	0
Haemorrhagic occlusive retinal vasculitis	0	0	0	0	1	0	1	0	1	0	0	0
Halo vision	1	0	14	0	1	0	3	0	17	0	0	0
Heterophoria	0	0	0	0	0	0	2	0	2	0	0	0
Hippus	0	0	0	0	0	0	1	0	1	0	0	0
Holmes-Adie pupil	0	0	3	0	0	0	2	0	5	0	0	0
Homonymous diplopia	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Hyperaesthesia eye	0	0	0	0	0	0	6	0	6	0	0	0
Hypermetropia	0	0	3	0	0	0	6	0	9	0	0	0
Hypoaesthesia eye	1	0	22	0	1	0	13	0	35	0	0	0
Hypotony of eye	0	0	1	0	0	0	0	0	1	0	0	0
Idiopathic orbital inflammation	0	0	1	0	0	0	0	0	1	0	0	0
Inflammation of lacrimal passage	0	0	0	0	0	0	1	0	1	0	0	0
Iridocyclitis	5	0	40	0	1	0	16	0	56	0	1	1
Iris discolouration	0	0	0	0	0	0	2	0	2	0	0	0
Iris disorder	0	0	1	0	1	0	1	0	2	0	0	0
Iris haemorrhage	0	0	0	0	0	0	2	0	2	0	0	0
Iris neovascularisation	1	0	1	0	0	0	0	0	1	0	0	0
Iritis	0	0	15	0	2	0	15	0	30	0	0	0
Keratitis	0	0	18	0	0	0	0	0	18	0	0	0
Lacrimal disorder	0	0	1	0	0	0	6	0	7	0	0	0
Lacrimation decreased	0	0	3	0	0	0	1	0	4	0	0	0
Lacrimation disorder	0	0	3	0	0	0	5	0	8	0	0	0
Lacrimation increased	8	0	250	0	61	0	413	0	663	0	0	0
Lagophthalmos	0	0	9	0	0	0	2	0	11	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Lens dislocation	0	0	0	0	0	0	0	0	0	0	1	1
Lenticular opacities	0	0	0	0	0	0	2	0	2	0	0	0
Leukocoria	1	0	1	0	0	0	0	0	1	0	0	0
Lid sulcus deepened	0	0	3	0	0	0	2	0	5	0	0	0
Limbal swelling	0	0	6	0	0	0	4	0	10	0	0	0
Loss of visual contrast sensitivity	0	0	1	0	0	0	0	0	1	0	0	0
Macular cyst	0	0	1	0	0	0	0	0	1	0	0	0
Macular degeneration	6	0	18	0	1	0	5	0	23	0	0	0
Macular detachment	0	0	1	0	0	0	0	0	1	0	0	0
Macular hole	1	0	6	0	0	0	1	0	7	0	0	0
Macular oedema	5	0	34	0	1	0	11	0	45	0	0	2
Macular rupture	0	0	2	0	0	0	0	0	2	0	0	0
Maculopathy	0	0	11	0	1	0	4	0	15	0	0	0
Meibomian gland dysfunction	0	0	1	0	0	0	1	0	2	0	0	0
Meibomianitis	0	0	0	0	0	0	1	0	1	0	0	0
Metamorphopsia	0	0	46	0	0	0	21	0	67	0	0	0
Miosis	0	0	14	0	2	0	18	0	32	0	0	0
Mydriasis	0	0	42	0	2	0	29	0	71	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Myopia	1	0	7	0	0	0	5	0	12	0	0	0
Myopic chorioretinal degeneration	0	0	0	0	0	0	1	0	1	0	0	0
Myopic traction maculopathy	0	0	0	0	0	0	1	0	1	0	0	0
Neovascular age-related macular degeneration	1	0	15	0	0	0	5	0	20	0	0	0
Neurological eyelid disorder	0	0	1	0	0	0	0	0	1	0	0	0
Night blindness	0	0	4	0	1	0	4	0	8	0	0	0
Non-infectious endophthalmitis	0	0	0	0	0	0	2	0	2	0	0	0
Noninfective conjunctivitis	0	0	1	0	0	0	0	0	1	0	0	0
Normal tension glaucoma	0	0	0	0	0	0	1	0	1	0	0	0
Ocular discomfort	10	0	119	0	75	0	546	0	665	0	0	0
Ocular dysmetria	0	0	0	0	0	0	1	0	1	0	0	0
Ocular hyperaemia	12	0	327	0	58	0	778	0	1105	0	0	0
Ocular hypertension	1	0	13	0	2	0	11	0	24	0	0	0
Ocular ischaemic syndrome	1	0	3	0	0	0	0	0	3	0	0	0
Ocular myasthenia	3	0	10	0	0	0	2	0	12	0	0	0
Ocular retrobulbar haemorrhage	0	0	3	0	0	0	1	0	4	0	0	0
Ocular rosacea	0	0	0	0	0	0	3	0	3	0	0	0
Ocular sarcoidosis	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Ocular vascular disorder	0	0	5	0	1	0	2	0	7	0	0	0
Ocular vasculitis	0	0	3	0	0	0	0	0	3	0	0	0
Ophthalmic artery thrombosis	0	0	6	0	0	0	0	0	6	0	0	0
Ophthalmic vein thrombosis	5	0	72	0	0	0	3	0	75	0	0	0
Ophthalmoplegia	4	0	32	0	0	0	17	0	49	0	1	1
Opsoclonus myoclonus	0	0	0	0	0	0	2	0	2	0	0	0
Optic atrophy	0	0	5	0	2	0	3	0	8	0	0	0
Optic disc disorder	0	0	1	0	0	0	0	0	1	0	0	0
Optic disc drusen	1	0	1	0	0	0	0	0	1	0	0	0
Optic disc haemorrhage	0	0	3	0	0	0	1	0	4	0	0	0
Optic disc hyperaemia	0	0	1	0	0	0	0	0	1	0	0	0
Optic discs blurred	0	0	3	0	0	0	1	0	4	0	0	0
Optic ischaemic neuropathy	4	0	58	0	0	0	0	0	58	0	0	1
Optic nerve compression	0	0	2	0	0	0	0	0	2	0	0	0
Optic nerve disorder	0	0	10	0	0	0	5	0	15	0	0	1
Optic nerve infarction	1	0	6	0	0	0	0	0	6	0	0	0
Optic nerve sheath haemorrhage	0	0	3	0	0	0	0	0	3	0	0	0
Optic neuropathy	1	0	18	0	0	0	2	0	20	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Orbital haematoma	0	0	2	0	0	0	2	0	4	0	0	0
Orbital haemorrhage	0	0	1	0	0	0	0	0	1	0	0	0
Orbital myositis	0	0	1	0	0	0	0	0	1	0	0	0
Orbital oedema	1	0	4	0	0	0	5	0	9	0	0	0
Orbital swelling	1	0	2	0	1	0	3	0	5	0	0	0
Oscillopsia	0	0	1	0	0	0	2	0	3	0	0	0
Panophthalmitis	0	0	1	0	0	0	0	0	1	0	0	0
Papilloedema	3	0	44	0	3	0	11	0	55	0	0	0
Papillophlebitis	0	0	1	0	0	0	0	0	1	0	0	0
Paralytic lagophthalmos	0	0	2	0	0	0	1	0	3	0	0	0
Parinaud syndrome	0	0	0	0	0	0	1	0	1	0	0	0
Parophthalmia	1	0	3	0	0	0	2	0	5	0	0	0
Periorbital discomfort	0	0	3	0	0	0	4	0	7	0	0	0
Periorbital disorder	0	0	0	0	0	0	2	0	2	0	0	0
Periorbital inflammation	0	0	0	0	0	0	2	0	2	0	0	0
Periorbital irritation	0	0	0	0	1	0	1	0	1	0	0	0
Periorbital oedema	1	0	20	0	6	0	72	0	92	0	0	0
Periorbital pain	1	0	8	0	2	0	27	0	35	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Periorbital swelling	3	0	108	0	10	0	163	0	271	0	0	0
Photophobia	26	0	1104	0	160	0	1407	0	2511	0	0	0
Photopsia	2	0	309	0	9	0	202	0	511	0	0	0
Pinguecula	0	0	0	0	0	0	1	0	1	0	0	0
Posterior capsule opacification	0	0	1	0	0	0	1	0	2	0	0	0
Presbyopia	2	0	3	0	0	0	3	0	6	0	0	0
Punctate keratitis	1	0	2	0	0	0	1	0	3	0	0	0
Pupil fixed	1	0	18	0	0	0	3	0	21	0	0	0
Pupillary deformity	0	0	0	0	0	0	1	0	1	0	0	0
Pupillary disorder	0	0	2	0	0	0	3	0	5	0	0	0
Pupillary reflex impaired	0	0	7	0	0	0	2	0	9	0	0	0
Refraction disorder	0	0	1	0	0	0	1	0	2	0	0	0
Retinal aneurysm	0	0	3	0	0	0	0	0	3	0	0	0
Retinal artery embolism	0	0	13	0	0	0	2	0	15	0	0	0
Retinal artery occlusion	6	0	102	0	0	0	0	0	102	0	1	4
Retinal artery thrombosis	1	0	21	0	0	0	5	0	26	0	0	0
Retinal cyst	0	0	0	0	0	0	1	0	1	0	0	0
Retinal degeneration	0	0	3	0	0	0	0	0	3	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Retinal detachment	5	0	114	0	0	0	0	0	114	0	0	0
Retinal disorder	0	0	4	0	0	0	1	0	5	0	0	0
Retinal drusen	0	0	1	0	1	0	1	0	2	0	0	0
Retinal exudates	1	0	14	0	1	0	5	0	19	0	0	0
Retinal fovea disorder	0	0	1	0	0	0	1	0	2	0	0	0
Retinal haemorrhage	3	0	57	0	2	0	15	0	72	0	0	2
Retinal infarction	0	0	2	0	0	0	2	0	4	0	0	0
Retinal ischaemia	0	0	8	0	0	0	1	0	9	0	0	0
Retinal microangiopathy	0	0	0	0	0	0	1	0	1	0	0	0
Retinal neovascularisation	0	0	1	0	0	0	0	0	1	0	0	0
Retinal occlusive vasculitis	1	0	2	0	0	0	0	0	2	0	0	0
Retinal oedema	0	0	6	0	1	0	3	0	9	0	0	0
Retinal pigment epitheliopathy	2	0	4	0	0	0	0	0	4	0	0	0
Retinal scar	0	0	0	0	0	0	1	0	1	0	0	0
Retinal tear	0	0	38	0	0	0	8	0	46	0	0	0
Retinal telangiectasia	0	0	1	0	0	0	0	0	1	0	0	0
Retinal toxicity	0	0	6	0	0	0	0	0	6	0	0	0
Retinal vascular disorder	0	0	3	0	0	0	3	0	6	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Retinal vascular occlusion	1	0	14	0	0	0	0	0	14	0	0	0
Retinal vascular thrombosis	1	0	45	0	0	0	0	0	45	0	0	1
Retinal vasculitis	0	0	1	0	0	0	0	0	1	0	0	0
Retinal vein occlusion	22	0	307	0	0	0	0	0	307	0	9	23
Retinal vein thrombosis	7	0	96	1	0	0	0	0	96	1	0	0
Retinal vein varices	0	0	1	0	0	0	0	0	1	0	0	0
Retinal vessel avulsion	0	0	1	0	0	0	0	0	1	0	0	0
Retinal white dots syndrome	0	0	3	0	0	0	0	0	3	0	0	0
Retinopathy	0	0	15	0	1	0	3	0	18	0	0	0
Retinopathy haemorrhagic	0	0	1	0	0	0	0	0	1	0	0	0
Retinopathy hypertensive	0	0	2	0	0	0	0	0	2	0	0	0
Retinopathy of prematurity	0	0	1	0	0	0	0	0	1	0	0	0
Retinoschisis	0	0	0	0	1	0	1	0	1	0	0	0
Saccadic eye movement	0	0	1	0	0	0	2	0	3	0	0	0
Scintillating scotoma	0	0	13	0	0	0	16	0	29	0	0	0
Scleral discolouration	0	0	1	0	0	0	0	0	1	0	0	0
Scleral disorder	0	0	0	0	0	0	1	0	1	0	0	0
Scleral haemorrhage	0	0	4	0	0	0	2	0	6	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Scleral hyperaemia	0	0	1	0	0	0	2	0	3	0	0	0
Scleral oedema	1	0	1	0	0	0	0	0	1	0	0	0
Scleritis	1	0	18	0	1	0	6	0	24	0	1	1
Serous retinopathy	0	0	1	0	0	0	0	0	1	0	0	0
Serpiginous choroiditis	0	0	1	0	0	0	0	0	1	0	0	0
Spontaneous hyphaema	0	0	1	0	0	0	0	0	1	0	0	0
Strabismus	0	0	15	0	1	0	19	0	34	0	1	1
Subconjunctival cyst	0	0	0	0	1	0	1	0	1	0	0	0
Subretinal fluid	0	0	0	0	0	0	0	0	0	0	0	2
Subretinal haematoma	0	0	1	0	0	0	0	0	1	0	0	0
Sudden visual loss	5	0	16	0	0	0	1	0	17	0	0	0
Swelling of eyelid	2	0	99	0	21	0	229	0	328	0	0	0
Tolosa-Hunt syndrome	0	0	2	0	0	0	0	0	2	0	1	1
Ulcerative keratitis	1	0	6	0	0	0	4	0	10	0	0	0
Uveitis	5	0	66	0	2	0	29	1	95	1	3	3
Vision blurred	71	0	3129	0	186	0	3079	0	6208	0	0	1
Visual acuity reduced	8	0	101	0	13	0	91	0	192	0	0	0
Visual acuity reduced transiently	0	0	2	0	0	0	5	0	7	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Visual brightness	0	0	8	0	0	0	3	0	11	0	0	0
Visual field defect	9	0	102	0	8	0	102	1	204	1	0	0
Visual impairment	76	0	1292	0	200	0	1991	1	3283	1	0	1
Visual snow syndrome	0	0	6	0	0	0	3	0	9	0	0	0
Vitreoretinal traction syndrome	0	0	1	0	0	0	0	0	1	0	0	0
Vitreous cyst	0	0	1	0	0	0	0	0	1	0	0	0
Vitreous degeneration	0	0	0	0	0	0	2	0	2	0	0	0
Vitreous detachment	6	0	89	0	1	0	43	0	132	0	0	0
Vitreous disorder	0	0	0	0	0	0	3	0	3	0	0	0
Vitreous floaters	7	0	198	0	6	0	127	0	325	0	0	0
Vitreous haematoma	0	0	1	0	0	0	0	0	1	0	0	0
Vitreous haemorrhage	4	0	31	0	0	0	5	0	36	0	2	2
Vitreous haze	0	0	0	0	0	0	1	0	1	0	0	0
Vitreous opacities	0	0	3	0	0	0	8	0	11	0	0	0
Vitritis	0	0	0	0	0	0	1	0	1	0	0	0
Vogt-Koyanagi-Harada disease	1	0	2	0	2	0	3	0	5	0	0	0
Xanthopsia	0	0	8	0	0	0	4	0	12	0	0	0
Xerophthalmia	0	0	2	0	0	0	4	0	6	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Ear and labyrinth disorders	**352**	**0**	**10520**	**1**	**884**	**4**	**12156**	**6**	**22676**	**7**	**5**	**13**
Acute vestibular syndrome	0	0	9	0	0	0	2	0	11	0	0	0
Auditory disorder	1	0	19	0	3	0	37	0	56	0	0	0
Aural polyp	0	0	0	0	0	0	1	0	1	0	0	0
Auricular swelling	0	0	2	0	0	0	11	0	13	0	0	0
Autoimmune inner ear disease	0	0	1	0	0	0	0	0	1	0	0	0
Cerumen impaction	0	0	0	0	1	0	1	0	1	0	0	0
Conductive deafness	0	0	0	0	0	0	2	0	2	0	0	0
Deafness	34	0	664	0	0	0	0	0	664	0	2	2
Deafness bilateral	2	0	40	0	0	0	0	0	40	0	0	0
Deafness neurosensory	8	0	69	0	0	0	12	0	81	0	2	6
Deafness transitory	2	0	10	0	1	0	12	0	22	0	0	0
Deafness unilateral	12	0	122	1	2	0	49	0	171	1	0	0
Diplacusis	0	0	0	0	1	0	2	0	2	0	0	0
Dysacusis	0	0	1	0	0	0	3	0	4	0	0	0
Ear canal erythema	0	0	1	0	1	0	1	0	2	0	0	0
Ear canal stenosis	0	0	1	0	0	0	0	0	1	0	0	0
Ear congestion	0	0	31	0	4	0	43	0	74	0	0	0
Ear discomfort	11	0	147	0	60	0	450	0	597	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Ear disorder	2	0	24	0	4	0	37	0	61	0	0	0
Ear haemorrhage	0	0	21	0	1	0	23	0	44	0	0	0
Ear inflammation	1	0	3	0	0	0	9	0	12	0	0	0
Ear pain	32	0	1870	0	169	0	1970	0	3840	0	0	0
Ear pruritus	0	0	10	0	3	0	17	0	27	0	0	0
Ear swelling	1	0	67	0	6	0	88	0	155	0	0	0
Endolymphatic hydrops	0	0	3	0	0	0	1	0	4	0	0	0
Eustachian tube disorder	0	0	3	0	0	0	6	0	9	0	0	0
Eustachian tube dysfunction	0	0	5	0	0	0	5	0	10	0	0	0
Eustachian tube obstruction	1	0	8	0	0	0	7	0	15	0	0	0
Excessive cerumen production	1	0	31	0	1	0	21	0	52	0	0	0
External ear disorder	0	0	1	0	0	0	0	0	1	0	0	0
External ear inflammation	0	0	1	0	0	0	11	0	12	0	0	0
External ear pain	1	0	12	0	3	0	13	0	25	0	0	0
Hyperacusis	11	0	193	0	40	1	289	1	482	1	0	0
Hypoacusis	16	0	310	0	26	0	305	0	615	0	0	0
Inner ear disorder	1	0	14	0	4	0	13	0	27	0	0	0
Inner ear infarction	0	0	3	0	0	0	1	0	4	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Inner ear inflammation	0	0	5	0	0	0	3	0	8	0	0	0
Juvenile spring eruption	0	0	0	0	0	0	1	0	1	0	0	0
Mastoid disorder	0	0	1	0	0	0	0	0	1	0	0	0
Mastoid effusion	0	0	0	0	0	0	1	0	1	0	0	0
Meniere's disease	6	0	44	0	1	0	15	0	59	0	0	0
Middle ear disorder	0	0	1	0	0	0	1	0	2	0	0	0
Middle ear effusion	1	0	7	0	0	0	4	0	11	0	0	0
Middle ear inflammation	0	0	1	0	1	0	2	0	3	0	0	0
Misophonia	0	0	0	0	1	0	1	0	1	0	0	0
Mixed deafness	0	0	4	0	0	0	1	0	5	0	0	0
Motion sickness	0	0	118	0	7	0	61	0	179	0	0	0
Neurosensory hypoacusis	0	0	8	0	0	0	1	0	9	0	0	0
Noninfective myringitis	0	0	0	0	0	0	1	0	1	0	0	0
Ossicle disorder	0	0	1	0	0	0	0	0	1	0	0	0
Otolithiasis	0	0	1	0	1	0	1	0	2	0	0	0
Otorrhoea	0	0	4	0	2	0	15	0	19	0	0	0
Paraesthesia ear	0	0	4	0	1	0	7	0	11	0	0	0
Phobic postural vertigo	1	0	7	0	0	0	3	0	10	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Presbyacusis	0	0	1	0	0	0	1	0	2	0	0	0
Red ear syndrome	0	0	4	0	0	0	1	0	5	0	0	0
Sudden hearing loss	8	0	205	0	8	0	86	0	291	0	0	0
Tinnitus	121	0	3493	0	288	3	4441	5	7934	5	1	5
Tympanic membrane disorder	0	0	1	0	0	0	2	0	3	0	0	0
Tympanic membrane perforation	0	0	8	0	1	0	4	0	12	0	0	0
Vertigo	65	0	2678	0	235	0	3912	0	6590	0	0	0
Vertigo labyrinthine	1	0	21	0	0	0	4	0	25	0	0	0
Vertigo positional	10	0	175	0	7	0	125	0	300	0	0	0
Vestibular ataxia	1	0	1	0	0	0	0	0	1	0	0	0
Vestibular disorder	1	0	31	0	1	0	20	0	51	0	0	0
Cardiac disorders	**1182**	**4**	**18339**	**13**	**1276**	**1**	**16128**	**2**	**34467**	**15**	**18**	**38**
Acute cardiac event	0	0	7	0	0	0	0	0	7	0	0	0
Acute coronary syndrome	15	0	183	0	0	0	0	0	183	0	0	0
Acute left ventricular failure	0	0	3	0	0	0	0	0	3	0	0	0
Acute myocardial infarction	36	0	526	0	0	0	0	0	526	0	3	4
Adams-Stokes syndrome	1	0	3	0	0	0	0	0	3	0	0	0
Agonal rhythm	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Angina pectoris	37	0	495	0	18	0	283	0	778	0	0	1
Angina unstable	3	0	35	1	0	0	0	0	35	1	0	0
Aortic valve disease	0	0	0	0	0	0	1	0	1	0	0	0
Aortic valve incompetence	3	0	11	0	0	0	3	0	14	0	0	0
Aortic valve sclerosis	0	0	2	0	0	0	0	0	2	0	0	0
Aortic valve stenosis	1	0	2	0	0	0	0	0	2	0	0	0
Arrhythmia	136	0	1044	1	46	0	863	0	1907	1	0	0
Arrhythmia neonatal	0	0	2	0	0	0	3	0	5	0	0	0
Arrhythmia supraventricular	2	0	22	0	1	0	5	0	27	0	0	0
Arrhythmic storm	0	0	1	0	0	0	0	0	1	0	0	0
Arteriosclerosis coronary artery	1	0	27	0	0	0	2	0	29	0	2	2
Arteriospasm coronary	0	0	11	0	1	0	1	0	12	0	0	0
Arteritis coronary	0	0	0	0	0	0	1	0	1	0	0	0
Atrial enlargement	0	0	0	0	0	0	1	0	1	0	0	0
Atrial fibrillation	60	0	780	0	9	0	235	0	1015	0	0	1
Atrial flutter	8	0	77	0	1	0	40	0	117	0	0	0
Atrial standstill	0	0	0	0	0	0	1	0	1	0	0	0
Atrial tachycardia	1	0	12	0	0	0	5	0	17	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Atrial thrombosis	0	0	13	0	0	0	0	0	13	0	0	0
Atrioventricular block	1	0	47	0	0	0	9	0	56	0	0	0
Atrioventricular block complete	5	0	26	0	0	0	0	0	26	0	0	0
Atrioventricular block first degree	2	0	27	0	3	0	10	0	37	0	0	0
Atrioventricular block second degree	4	0	21	0	1	0	4	0	25	0	0	0
Atrioventricular dissociation	0	0	7	0	1	0	3	0	10	0	0	0
Autoimmune myocarditis	0	0	3	0	0	0	0	0	3	0	0	0
Autoimmune pericarditis	0	0	1	0	0	0	0	0	1	0	0	0
Bifascicular block	0	0	1	0	1	0	1	0	2	0	0	0
Bradyarrhythmia	0	0	4	0	0	0	0	0	4	0	0	0
Bradycardia	21	0	201	0	1	0	159	0	360	0	0	0
Bradycardia foetal	0	0	0	0	0	0	1	0	1	0	0	0
Bundle branch block	2	0	6	0	1	0	1	0	7	0	0	0
Bundle branch block left	3	0	16	0	0	0	6	0	22	0	0	0
Bundle branch block right	2	0	13	0	0	0	2	0	15	0	0	0
Cardiac aneurysm	1	0	4	0	0	0	0	0	4	0	0	0
Cardiac arrest	17	0	469	0	0	0	0	0	469	0	0	1
Cardiac asthma	0	0	2	0	0	0	0	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Cardiac discomfort	5	0	50	0	34	0	175	0	225	0	0	0
Cardiac disorder	21	0	184	0	27	0	146	0	330	0	0	0
Cardiac dysfunction	0	0	9	0	1	0	4	0	13	0	0	0
Cardiac failure	25	0	323	0	2	0	32	0	355	0	0	0
Cardiac failure acute	2	0	41	1	0	0	0	0	41	1	0	0
Cardiac failure chronic	1	0	7	0	0	0	0	0	7	0	0	1
Cardiac failure congestive	8	0	44	0	0	0	5	0	49	0	0	0
Cardiac fibrillation	7	0	46	0	0	0	13	0	59	0	0	0
Cardiac flutter	16	0	255	0	4	0	124	0	379	0	0	0
Cardiac hypertrophy	0	0	4	0	0	0	1	0	5	0	0	0
Cardiac perfusion defect	0	0	1	0	0	0	0	0	1	0	0	0
Cardiac sarcoidosis	1	0	2	0	0	0	0	0	2	0	0	0
Cardiac septal hypertrophy	1	0	1	0	1	0	1	0	2	0	0	0
Cardiac tamponade	3	0	15	0	0	0	0	0	15	0	0	1
Cardiac valve disease	0	0	7	0	1	0	3	0	10	0	0	0
Cardiac ventricular scarring	1	0	1	0	0	0	0	0	1	0	0	0
Cardiac ventricular thrombosis	2	0	28	0	0	0	0	0	28	0	0	0
Cardio-respiratory arrest	7	0	113	1	0	0	0	0	113	1	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Cardio-respiratory distress	0	0	2	0	0	0	0	0	2	0	0	0
Cardiogenic shock	4	0	52	0	0	0	0	0	52	0	0	0
Cardiomegaly	3	0	55	0	1	0	19	0	74	0	0	0
Cardiomyopathy	5	0	46	0	1	0	9	0	55	0	1	1
Cardiomyopathy acute	0	0	1	0	0	0	0	0	1	0	0	0
Cardiomyopathy alcoholic	0	0	1	0	0	0	0	0	1	0	0	0
Cardiomyopathy neonatal	1	0	1	0	0	0	0	0	1	0	0	0
Cardiopulmonary failure	3	0	14	0	0	0	0	0	14	0	0	0
Cardiorenal syndrome	1	0	1	0	0	0	0	0	1	0	0	0
Cardiotoxicity	0	0	1	0	0	0	0	0	1	0	0	0
Cardiovascular deconditioning	1	0	1	0	0	0	1	0	2	0	0	0
Cardiovascular disorder	22	0	196	0	35	0	592	1	788	1	0	0
Cardiovascular insufficiency	3	0	27	0	1	0	10	0	37	0	0	0
Cardiovascular symptom	0	0	7	0	0	0	3	0	10	0	0	0
Carditis	3	0	8	0	0	0	5	0	13	0	0	0
Central bradycardia	0	0	1	0	0	0	0	0	1	0	0	0
Chronic myocarditis	0	0	1	0	0	0	0	0	1	0	0	0
Conduction disorder	0	1	2	1	0	0	0	0	2	1	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Congestive cardiomyopathy	5	0	29	0	1	0	4	0	33	0	1	1
Cor pulmonale	0	0	5	0	0	0	0	0	5	0	0	0
Cor pulmonale acute	0	0	9	0	0	0	0	0	9	0	0	0
Coronary artery disease	13	0	76	0	3	0	7	0	83	0	0	0
Coronary artery dissection	0	0	15	0	0	0	0	0	15	0	0	0
Coronary artery embolism	0	0	4	0	0	0	0	0	4	0	0	0
Coronary artery insufficiency	0	0	1	0	0	0	0	0	1	0	0	0
Coronary artery occlusion	2	0	20	0	0	0	0	0	20	0	0	0
Coronary artery stenosis	1	0	8	0	0	0	1	0	9	0	0	0
Coronary artery thrombosis	8	0	80	0	0	0	0	0	80	0	1	1
Defect conduction intraventricular	1	0	2	0	0	0	0	0	2	0	0	0
Degenerative aortic valve disease	0	0	0	0	0	0	1	0	1	0	0	0
Diastolic dysfunction	1	0	3	0	1	0	2	0	5	0	0	0
Dilatation ventricular	0	0	2	0	0	0	0	0	2	0	0	0
Extrasystoles	13	0	208	0	25	0	251	0	459	0	0	0
Foetal cardiac arrest	0	0	3	0	0	0	0	0	3	0	0	0
Giant cell myocarditis	0	0	2	0	0	0	0	0	2	0	0	0
Heart alternation	0	0	6	0	0	0	8	0	14	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Heart valve incompetence	2	0	8	0	0	0	3	0	11	0	0	0
Heart valve stenosis	0	0	0	0	0	0	1	0	1	0	0	0
Hyperdynamic left ventricle	0	0	1	0	0	0	0	0	1	0	0	0
Hypertensive cardiomegaly	0	0	0	0	0	0	1	0	1	0	0	0
Hypertensive cardiomyopathy	0	0	2	0	0	0	0	0	2	0	0	0
Hypertensive heart disease	0	0	7	0	0	0	11	0	18	0	0	0
Immune-mediated myocarditis	0	0	1	0	0	0	0	0	1	0	0	0
Intracardiac thrombus	2	0	50	0	0	0	0	0	50	0	0	0
Ischaemic cardiomyopathy	0	0	5	0	0	0	0	0	5	0	0	0
Ischaemic mitral regurgitation	0	0	1	0	0	0	0	0	1	0	0	0
Kounis syndrome	1	0	3	0	0	0	0	0	3	0	0	0
Left atrial dilatation	0	0	1	0	0	0	0	0	1	0	0	0
Left ventricular dilatation	0	0	2	0	0	0	0	0	2	0	0	0
Left ventricular dysfunction	4	0	36	0	0	0	1	0	37	0	0	0
Left ventricular enlargement	0	0	0	0	0	0	1	0	1	0	0	0
Left ventricular failure	2	0	19	0	0	0	0	0	19	0	0	0
Left ventricular hypertrophy	3	0	11	0	0	0	2	0	13	0	0	0
Long QT syndrome	0	0	2	0	0	0	0	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Microvascular coronary artery disease	2	0	5	0	1	0	2	0	7	0	0	0
Mitral valve disease	1	0	2	0	0	0	1	0	3	0	0	0
Mitral valve incompetence	2	0	20	0	0	0	0	0	20	0	0	0
Mitral valve prolapse	3	0	12	0	1	0	2	0	14	0	0	0
Mitral valve stenosis	0	0	1	0	0	0	0	0	1	0	0	0
Mitral valve thickening	0	0	0	0	1	0	1	0	1	0	0	0
Myocardial depression	0	0	1	0	0	0	0	0	1	0	0	0
Myocardial fibrosis	0	0	5	0	0	0	1	0	6	0	0	0
Myocardial infarction	63	2	1165	5	0	0	0	0	1165	5	0	1
Myocardial injury	4	0	26	0	0	0	4	0	30	0	0	0
Myocardial ischaemia	3	0	70	0	0	0	8	0	78	0	0	0
Myocardial necrosis	0	0	2	0	0	0	0	0	2	0	0	0
Myocardial oedema	0	0	1	0	0	0	1	0	2	0	0	0
Myocardial rupture	2	0	6	0	0	0	0	0	6	0	0	0
Myocardial stunning	0	0	0	0	0	0	1	0	1	0	0	0
Myocarditis	73	1	732	2	0	0	0	0	732	2	2	4
Myocarditis post infection	0	0	1	0	0	0	0	0	1	0	0	0
Myopericarditis	15	0	90	0	0	0	1	0	91	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Neonatal bradyarrhythmia	0	0	0	0	0	0	0	0	0	0	0	1
Nodal arrhythmia	0	0	1	0	0	0	0	0	1	0	0	0
Palpitations	204	0	5805	0	711	0	6329	0	12134	0	1	3
Paroxysmal arrhythmia	0	0	3	0	0	0	0	0	3	0	0	0
Pericardial cyst	0	0	1	0	0	0	0	0	1	0	0	0
Pericardial disease	0	0	2	0	0	0	0	0	2	0	0	0
Pericardial effusion	12	0	162	0	2	0	26	0	188	0	0	2
Pericardial fibrosis	0	0	0	0	0	0	1	0	1	0	0	0
Pericardial haemorrhage	1	0	12	0	0	0	0	0	12	0	0	0
Pericardial rub	0	0	3	0	0	0	0	0	3	0	0	0
Pericarditis	42	0	581	0	16	1	162	1	743	1	4	6
Pleuropericarditis	0	0	10	0	0	0	0	0	10	0	0	0
Postural orthostatic tachycardia syndrome	18	0	61	0	6	0	19	0	80	0	0	0
Prinzmetal angina	0	0	4	0	1	0	2	0	6	0	0	0
Pulseless electrical activity	0	0	17	0	0	0	0	0	17	0	0	0
Restrictive cardiomyopathy	0	0	1	0	0	0	0	0	1	0	0	0
Rheumatic heart disease	0	0	2	0	0	0	0	0	2	0	0	0
Rhythm idioventricular	1	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Right atrial dilatation	0	0	1	0	0	0	1	0	2	0	0	0
Right atrial enlargement	0	0	0	0	0	0	1	0	1	0	0	0
Right ventricular dilatation	0	0	3	0	0	0	0	0	3	0	0	0
Right ventricular dysfunction	1	0	9	0	0	0	1	0	10	0	0	0
Right ventricular failure	1	0	14	0	1	0	2	0	16	0	0	0
Right ventricular hypertension	0	0	1	0	0	0	0	0	1	0	0	0
Right ventricular hypertrophy	0	0	1	0	0	0	0	0	1	0	0	0
Silent myocardial infarction	0	0	1	0	0	0	0	0	1	0	0	0
Sinoatrial block	1	0	2	0	0	0	0	0	2	0	0	0
Sinus arrest	0	0	1	0	0	0	0	0	1	0	0	0
Sinus arrhythmia	0	0	4	0	0	0	4	0	8	0	0	0
Sinus bradycardia	1	0	22	0	0	0	4	0	26	0	0	0
Sinus node dysfunction	1	0	8	0	0	0	3	0	11	0	0	0
Sinus tachycardia	6	0	114	0	5	0	60	0	174	0	0	0
Stress cardiomyopathy	1	0	21	0	0	0	2	0	23	0	0	0
Supraventricular extrasystoles	1	0	6	0	4	0	15	0	21	0	0	0
Supraventricular tachyarrhythmia	0	0	2	0	0	0	0	0	2	0	0	0
Supraventricular tachycardia	5	0	76	0	1	0	17	0	93	0	0	1

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Systolic dysfunction	0	0	2	0	0	0	0	0	2	0	0	0
Tachyarrhythmia	4	0	29	0	1	0	19	0	48	0	0	0
Tachycardia	131	0	2733	1	292	0	6306	0	9039	1	2	5
Tachycardia foetal	0	0	7	0	0	0	2	0	9	0	0	0
Tachycardia induced cardiomyopathy	0	0	1	0	0	0	0	0	1	0	0	0
Tachycardia paroxysmal	0	0	7	0	1	0	5	0	12	0	0	0
Torsade de pointes	0	0	1	0	0	0	0	0	1	0	0	0
Tricuspid valve incompetence	1	0	12	0	1	0	1	0	13	0	0	0
Trifascicular block	0	0	1	0	0	0	0	0	1	0	0	0
Ventricle rupture	0	0	1	0	0	0	0	0	1	0	0	0
Ventricular arrhythmia	2	0	12	0	0	0	0	0	12	0	0	0
Ventricular dysfunction	1	0	1	0	1	0	1	0	2	0	0	0
Ventricular dyskinesia	0	0	1	0	0	0	0	0	1	0	0	0
Ventricular extrasystoles	5	0	63	0	8	0	46	0	109	0	1	1
Ventricular failure	0	0	1	0	0	0	0	0	1	0	0	0
Ventricular fibrillation	0	0	34	0	0	0	0	0	34	0	0	0
Ventricular hyperkinesia	0	0	1	0	0	0	0	0	1	0	0	0
Ventricular hypertrophy	0	0	5	0	0	0	0	0	5	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Ventricular hypokinesia	2	0	8	0	0	0	0	0	8	0	0	0
Ventricular tachycardia	5	0	52	0	0	0	0	0	52	0	0	0
Wolff-Parkinson-White syndrome	1	0	1	0	0	0	0	0	1	0	0	0
Vascular disorders	**947**	**0**	**23782**	**7**	**1533**	**1**	**19191**	**3**	**42973**	**10**	**35**	**62**
Accelerated hypertension	0	0	18	0	0	0	0	0	18	0	0	0
Achenbach syndrome	0	0	7	0	1	0	12	0	19	0	0	0
Acute aortic syndrome	0	0	0	0	0	0	1	0	1	0	0	0
Air embolism	0	0	0	0	0	0	2	0	2	0	0	0
Aneurysm	1	0	26	0	0	0	5	0	31	0	0	0
Aneurysm ruptured	0	0	6	0	0	0	0	0	6	0	0	0
Angiodysplasia	0	0	1	0	0	0	1	0	2	0	0	0
Angiopathy	3	0	20	0	4	0	24	0	44	0	0	0
Aortic aneurysm	3	0	22	0	1	0	8	0	30	0	0	0
Aortic aneurysm rupture	0	0	6	0	0	0	0	0	6	0	0	0
Aortic arteriosclerosis	1	0	7	0	0	0	1	0	8	0	0	0
Aortic dilatation	0	0	3	0	0	0	0	0	3	0	0	0
Aortic dissection	2	0	29	0	0	0	0	0	29	0	0	0
Aortic dissection rupture	0	0	2	0	0	0	0	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Aortic embolus	1	0	35	0	0	0	2	0	37	0	0	0
Aortic intramural haematoma	0	0	2	0	0	0	0	0	2	0	0	0
Aortic occlusion	0	0	5	0	0	0	0	0	5	0	0	0
Aortic rupture	0	0	2	0	0	0	0	0	2	0	0	0
Aortic stenosis	0	0	7	0	1	0	6	0	13	0	0	0
Aortic thrombosis	4	0	74	0	0	0	0	0	74	0	0	1
Aortitis	1	0	7	0	0	0	1	0	8	0	0	0
Arterial disorder	0	0	2	0	0	0	3	0	5	0	0	0
Arterial haemorrhage	0	0	1	0	0	0	1	0	2	0	0	0
Arterial insufficiency	0	0	1	0	0	0	0	0	1	0	0	0
Arterial occlusive disease	3	0	40	0	1	0	8	0	48	0	0	0
Arterial rupture	1	0	4	0	0	0	1	0	5	0	0	0
Arterial spasm	0	0	2	0	0	0	0	0	2	0	0	0
Arterial stenosis	0	0	5	0	0	0	1	0	6	0	0	0
Arterial thrombosis	3	0	126	1	0	0	0	0	126	1	0	1
Arteriosclerosis	2	0	31	1	1	0	7	0	38	1	0	0
Arteriovenous fistula	0	0	2	0	0	0	0	0	2	0	0	0
Arteritis	1	0	11	0	1	0	8	0	19	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Artery dissection	1	0	10	0	0	0	0	0	10	0	0	0
Atheroembolism	0	0	2	0	0	0	0	0	2	0	0	0
Axillary vein thrombosis	0	0	13	0	0	0	2	0	15	0	0	0
Behcet's syndrome	1	0	9	0	0	0	3	0	12	0	0	0
Bleeding varicose vein	0	0	2	0	0	0	4	0	6	0	0	0
Blood pressure fluctuation	15	0	119	0	30	0	268	0	387	0	1	1
Blood pressure inadequately controlled	0	0	3	0	0	0	8	0	11	0	0	0
Bloody discharge	0	0	13	0	2	0	30	0	43	0	0	0
Blue toe syndrome	0	0	28	0	2	0	23	0	51	0	0	0
Brachiocephalic vein thrombosis	1	0	6	0	0	0	0	0	6	0	0	0
CT hypotension complex	1	0	1	0	0	0	0	0	1	0	0	0
Capillary disorder	0	0	6	0	0	0	17	0	23	0	0	0
Capillary fragility	1	0	10	0	1	0	42	0	52	0	0	0
Capillary leak syndrome	4	0	51	0	2	0	11	0	62	0	0	0
Carotidynia	0	0	0	0	0	0	1	0	1	0	0	0
Circulatory collapse	16	0	531	1	0	0	0	0	531	1	0	0
Claudication of jaw muscles	0	0	0	0	0	0	0	0	0	0	1	1
Coeliac artery occlusion	0	0	0	0	0	0	1	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Collateral circulation	0	0	3	0	0	0	0	0	3	0	0	0
Cryoglobulinaemia	1	0	5	0	1	0	1	0	6	0	1	1
Cyanosis	17	0	285	0	43	0	477	0	762	0	0	0
Deep vein thrombosis	103	0	4490	2	0	0	0	0	4490	2	5	13
Dependent rubor	0	0	0	0	1	0	1	0	1	0	0	0
Diabetic vascular disorder	0	0	1	0	0	0	0	0	1	0	0	0
Diastolic hypertension	0	0	7	0	0	0	8	0	15	0	0	0
Diastolic hypotension	0	0	1	0	0	0	0	0	1	0	0	0
Diffuse vasculitis	0	0	4	0	0	0	0	0	4	0	0	0
Distributive shock	0	0	3	0	0	0	0	0	3	0	0	0
Dry gangrene	1	0	4	0	0	0	1	0	5	0	0	0
Embolism	22	0	423	0	0	0	53	0	476	0	0	0
Embolism arterial	2	0	30	0	0	0	0	0	30	0	0	0
Embolism venous	4	0	47	0	0	0	4	0	51	0	0	0
Endocrine hypertension	0	0	0	0	1	0	1	0	1	0	0	0
Endothelial dysfunction	1	0	2	0	0	0	1	0	3	0	0	0
Erythrocyanosis	0	0	1	0	0	0	0	0	1	0	0	0
Erythromelalgia	2	0	11	0	1	0	9	0	20	0	1	1

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Essential hypertension	1	0	14	0	0	1	2	1	16	1	0	0
Extravasation blood	0	0	5	0	4	0	13	0	18	0	0	0
Extremity necrosis	1	0	4	0	0	0	0	0	4	0	0	0
Femoral artery aneurysm	1	0	2	0	0	0	0	0	2	0	0	0
Femoral artery embolism	0	0	2	0	0	0	0	0	2	0	0	0
Fibromuscular dysplasia	0	0	1	0	0	0	0	0	1	0	0	0
Flushing	11	0	618	0	132	0	1483	0	2101	0	0	0
Giant cell arteritis	15	0	101	0	5	0	49	0	150	0	1	1
Granulomatosis with polyangiitis	2	0	12	0	0	0	0	0	12	0	0	0
Haematoma	11	0	418	0	164	0	1962	0	2380	0	0	0
Haemodynamic instability	0	0	22	0	0	0	1	0	23	0	0	0
Haemorrhage	44	0	1223	0	24	0	804	0	2027	0	2	2
Haemorrhagic infarction	3	0	19	0	0	0	0	0	19	0	0	0
Haemorrhagic vasculitis	0	0	2	0	0	0	0	0	2	0	0	0
Hot flush	23	0	1751	0	203	0	2563	0	4314	0	0	0
Hyperaemia	1	0	17	0	62	0	410	0	427	0	0	0
Hypertension	122	0	2050	1	234	0	3067	2	5117	3	1	2
Hypertensive angiopathy	1	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Hypertensive crisis	14	0	354	0	0	0	0	0	354	0	0	0
Hypertensive emergency	2	0	21	0	0	0	0	0	21	0	0	0
Hypertensive urgency	3	0	24	0	0	0	0	0	24	0	0	0
Hypoperfusion	0	0	4	0	0	0	4	0	8	0	0	0
Hypotension	41	0	930	0	94	0	1296	0	2226	0	0	0
Hypotensive crisis	0	0	3	0	0	0	3	0	6	0	0	0
Hypovolaemic shock	1	0	81	0	0	0	0	0	81	0	0	0
Iliac artery embolism	0	0	2	0	0	0	0	0	2	0	0	0
Iliac artery occlusion	0	0	3	0	0	0	0	0	3	0	0	0
Iliac artery stenosis	0	0	2	0	0	0	0	0	2	0	0	0
Infarction	7	0	94	0	1	0	9	0	103	0	0	0
Intermittent claudication	1	0	17	0	1	0	8	0	25	0	0	0
Internal haemorrhage	3	0	36	0	1	0	10	0	46	0	0	0
Ischaemia	0	0	61	0	2	0	16	0	77	0	0	0
Ischaemic limb pain	0	0	6	0	1	0	17	0	23	0	0	0
Jugular vein distension	0	0	0	0	0	0	2	0	2	0	0	0
Jugular vein occlusion	0	0	4	0	0	0	0	0	4	0	0	0
Jugular vein thrombosis	7	0	98	0	0	0	0	0	98	0	1	2

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Kawasaki's disease	0	0	1	0	0	0	0	0	1	0	0	1
Labile blood pressure	0	0	9	0	0	0	33	0	42	0	0	0
Labile hypertension	1	0	3	0	0	0	3	0	6	0	0	0
Leriche syndrome	0	0	1	0	0	0	0	0	1	0	1	1
Lower limb artery perforation	0	0	0	0	0	0	1	0	1	0	0	0
Lymphangiopathy	0	0	1	0	0	0	1	0	2	0	0	0
Lymphocele	0	0	2	0	0	0	1	0	3	0	0	0
Lymphoedema	7	0	73	0	9	0	85	0	158	0	0	0
Lymphorrhoea	0	0	0	0	1	0	2	0	2	0	0	0
Lymphostasis	1	0	1	0	0	0	1	0	2	0	0	0
MAGIC syndrome	0	0	10	0	0	0	6	0	16	0	0	0
Macroangiopathy	0	0	1	0	1	0	1	0	2	0	0	0
Malignant hypertension	0	0	11	0	0	0	0	0	11	0	0	0
May-Thurner syndrome	0	0	1	0	0	0	0	0	1	0	0	0
Microangiopathy	1	0	7	0	0	0	2	0	9	0	0	0
Microembolism	0	0	9	0	0	0	2	0	11	0	0	0
Microscopic polyangiitis	0	0	4	0	0	0	0	0	4	0	0	0
Necrosis ischaemic	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Neovascularisation	0	0	1	0	0	0	0	0	1	0	0	0
Neurogenic hypertension	0	0	1	0	0	0	0	0	1	0	0	0
Neurogenic shock	0	0	3	0	0	0	10	0	13	0	0	0
Non-dipping	0	0	0	0	0	0	1	0	1	0	0	0
Obstructive shock	0	0	3	0	0	0	0	0	3	0	0	0
Orthostatic hypertension	0	0	1	0	0	0	1	0	2	0	0	0
Orthostatic hypotension	2	0	62	0	8	0	71	0	133	0	1	1
Paget-Schroetter syndrome	0	0	2	0	0	0	0	0	2	0	0	0
Pallor	16	0	454	0	51	0	572	0	1026	0	0	0
Paradoxical embolism	0	0	1	0	0	0	0	0	1	0	0	0
Pelvic venous thrombosis	4	0	69	0	0	0	0	0	69	0	1	1
Penetrating aortic ulcer	0	0	1	0	0	0	0	0	1	0	0	0
Penetrating atherosclerotic ulcer	0	0	1	0	0	0	0	0	1	0	0	0
Peripheral arterial occlusive disease	2	0	15	0	0	0	0	0	15	0	0	0
Peripheral artery aneurysm	1	0	5	0	0	0	1	0	6	0	0	0
Peripheral artery occlusion	4	0	33	0	0	0	0	0	33	0	0	0
Peripheral artery stenosis	0	0	3	0	0	0	1	0	4	0	0	0
Peripheral artery thrombosis	5	0	171	0	0	0	0	0	171	0	2	3

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Peripheral circulatory failure	0	0	19	0	0	0	43	0	62	0	0	0
Peripheral coldness	20	0	1178	0	147	0	1532	0	2710	0	0	1
Peripheral embolism	1	0	42	0	0	0	7	0	49	0	0	0
Peripheral ischaemia	0	0	82	0	1	0	23	0	105	0	1	1
Peripheral vascular disorder	1	0	37	0	32	0	534	0	571	0	0	0
Peripheral vein occlusion	0	0	2	0	0	0	0	0	2	0	0	0
Peripheral vein thrombosis	0	0	0	0	1	0	1	0	1	0	2	2
Peripheral vein thrombus extension	2	0	7	0	0	0	3	0	10	0	0	0
Peripheral venous disease	1	0	26	0	8	0	64	0	90	0	0	0
Periphlebitis	0	0	1	0	0	0	4	0	5	0	0	0
Phlebitis	5	0	173	0	12	0	203	0	376	0	0	0
Phlebitis deep	1	0	4	0	0	0	2	0	6	0	0	0
Phlebitis superficial	1	0	38	0	2	0	47	0	85	0	0	0
Phlebosclerosis	0	0	1	0	0	0	0	0	1	0	0	0
Plethoric face	0	0	1	0	0	0	1	0	2	0	0	0
Polyarteritis nodosa	0	0	7	0	0	0	1	0	8	0	0	0
Poor peripheral circulation	3	0	62	0	9	0	89	0	151	0	0	0
Poor venous access	5	0	5	0	1	0	5	0	10	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Post thrombotic syndrome	0	0	6	0	1	0	3	0	9	0	0	0
Postpartum thrombosis	0	0	0	0	0	0	1	0	1	0	0	0
Raynaud's phenomenon	12	0	149	0	14	0	144	0	293	0	2	2
Rheumatoid vasculitis	0	0	1	0	0	0	0	0	1	0	0	0
Secondary hypertension	2	0	3	0	0	0	2	0	5	0	0	0
Shock	6	0	104	0	0	0	0	0	104	0	0	0
Shock haemorrhagic	1	0	6	0	0	0	0	0	6	0	0	0
Shock symptom	0	0	12	0	0	0	0	0	12	0	0	0
Spider vein	1	0	19	0	2	0	33	0	52	0	0	0
Subclavian artery embolism	0	0	4	0	0	0	0	0	4	0	0	0
Subclavian artery thrombosis	1	0	6	0	0	0	2	0	8	0	0	0
Subclavian steal syndrome	0	0	1	0	0	0	1	0	2	0	0	0
Subclavian vein thrombosis	1	0	35	0	0	0	0	0	35	0	0	0
Superficial vein prominence	0	0	12	0	6	0	23	0	35	0	0	0
Superficial vein thrombosis	16	0	442	0	17	0	403	0	845	0	0	1
Superior vena cava syndrome	0	0	2	0	0	0	0	0	2	0	0	0
Susac's syndrome	0	0	3	0	0	0	0	0	3	0	0	0
Systolic hypertension	0	0	2	0	0	0	6	0	8	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Takayasu's arteritis	1	0	3	0	0	0	1	0	4	0	1	1
Thromboangiitis obliterans	0	0	2	0	0	0	0	0	2	0	0	0
Thrombophlebitis	16	0	416	0	21	0	296	0	712	0	0	0
Thrombophlebitis migrans	0	0	1	0	0	0	2	0	3	0	0	0
Thrombosed varicose vein	0	0	4	0	0	0	4	0	8	0	0	0
Thrombosis	167	0	3623	0	40	0	923	0	4546	0	5	15
Tyramine reaction	0	0	1	0	0	0	0	0	1	0	0	0
Varicophlebitis	0	0	17	0	3	0	27	0	44	0	0	0
Varicose ulceration	0	0	0	0	0	0	2	0	2	0	0	0
Varicose vein	7	0	141	0	24	0	305	0	446	0	0	0
Varicose vein ruptured	0	0	3	0	2	0	5	0	8	0	0	0
Vascular calcification	0	0	0	0	1	0	1	0	1	0	0	0
Vascular compression	0	0	1	0	2	0	8	0	9	0	0	0
Vascular fragility	0	0	0	0	1	0	6	0	6	0	0	0
Vascular occlusion	1	0	13	0	1	0	5	0	18	0	0	0
Vascular pain	4	0	150	0	26	0	227	0	377	0	0	0
Vascular rupture	0	0	8	0	13	0	30	0	38	0	0	0
Vascular wall discolouration	0	0	0	0	0	0	1	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Vasculitis	30	0	352	0	0	0	0	0	352	0	1	1
Vasculitis necrotising	1	0	3	0	0	0	0	0	3	0	0	0
Vasoconstriction	1	0	5	0	1	0	8	0	13	0	0	0
Vasodilatation	8	0	132	0	21	0	284	0	416	0	0	0
Vasospasm	1	0	13	0	3	0	15	0	28	0	0	0
Vein collapse	1	0	5	0	0	0	2	0	7	0	0	0
Vein discolouration	1	0	8	0	4	0	23	0	31	0	0	0
Vein disorder	1	0	32	0	8	0	77	0	109	0	0	0
Vein rupture	3	0	24	0	1	0	23	0	47	0	0	0
Vena cava embolism	0	0	1	0	0	0	0	0	1	0	0	0
Vena cava thrombosis	3	0	41	0	0	0	0	0	41	0	0	0
Venous aneurysm	0	0	0	0	0	0	2	0	2	0	0	0
Venous haemorrhage	2	0	13	0	0	0	1	0	14	0	0	0
Venous hypertension	0	0	4	0	1	0	2	0	6	0	0	0
Venous occlusion	2	0	25	0	2	0	11	0	36	0	0	0
Venous recanalisation	1	0	1	0	0	0	0	0	1	0	0	0
Venous thrombosis	21	0	363	0	8	0	96	0	459	0	0	0
Venous thrombosis limb	17	0	282	1	3	0	49	0	331	1	4	5

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Venous valve ruptured	0	0	1	0	1	0	2	0	3	0	0	0
Vessel perforation	0	0	3	0	1	0	2	0	5	0	0	0
White coat hypertension	0	0	11	0	0	0	2	0	13	0	0	0
Respiratory, thoracic and mediastinal disorders	**1523**	**2**	**38371**	**6**	**4977**	**2**	**56585**	**19**	**94956**	**25**	**24**	**49**
Acquired diaphragmatic eventration	1	0	1	0	0	0	0	0	1	0	0	0
Acute chest syndrome	0	0	1	0	0	0	0	0	1	0	0	0
Acute lung injury	0	0	3	0	0	0	0	0	3	0	0	0
Acute pulmonary oedema	0	0	31	0	0	0	0	0	31	0	0	0
Acute respiratory distress syndrome	14	0	213	1	0	0	0	0	213	1	1	1
Acute respiratory failure	9	0	81	0	0	0	0	0	81	0	0	0
Adductor vocal cord weakness	0	0	1	0	0	0	5	0	6	0	0	0
Adenoidal disorder	0	0	0	0	0	0	4	0	4	0	0	0
Agonal respiration	0	0	7	0	0	0	0	0	7	0	0	0
Allergic bronchitis	0	0	1	0	0	0	1	0	2	0	0	0
Allergic cough	0	0	9	0	1	0	9	0	18	0	0	0
Allergic respiratory disease	0	0	2	0	0	0	2	0	4	0	0	0
Allergic respiratory symptom	0	0	10	0	0	0	6	0	16	0	0	0
Allergic sinusitis	0	0	2	0	0	0	3	0	5	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Alveolar lung disease	0	0	1	0	0	0	0	0	1	0	0	0
Alveolar proteinosis	0	0	1	0	0	0	1	0	2	0	0	0
Alveolitis	0	0	3	0	0	0	0	0	3	0	0	0
Anoxia	0	0	0	0	0	0	1	0	1	0	0	0
Aphonia	11	0	129	0	15	0	170	0	299	0	0	0
Apnoea	4	0	58	0	0	0	0	0	58	0	0	0
Apnoeic attack	0	0	2	0	0	0	0	0	2	0	0	0
Asphyxia	2	0	37	0	0	0	0	0	37	0	0	0
Aspiration	0	0	16	0	2	0	18	0	34	0	0	0
Asthma	38	1	709	1	63	0	505	0	1214	1	1	2
Asthma exercise induced	0	0	4	0	1	0	6	0	10	0	0	0
Asthma late onset	0	0	3	0	0	0	1	0	4	0	0	0
Asthma-chronic obstructive pulmonary disease overlap syndrome	0	0	2	0	0	0	0	0	2	0	0	0
Asthmatic crisis	10	0	77	0	0	0	0	0	77	0	0	1
Atelectasis	4	0	24	0	0	0	5	0	29	0	0	0
Autoimmune lung disease	0	0	1	0	0	0	0	0	1	0	0	0
Bradypnoea	0	0	3	0	0	0	0	0	3	0	0	0
Brief resolved unexplained event	0	0	3	0	0	0	0	0	3	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Bronchial disorder	1	0	3	0	2	0	7	0	10	0	0	0
Bronchial haemorrhage	0	0	1	0	0	0	0	0	1	0	0	0
Bronchial hyperreactivity	1	0	4	0	3	0	8	0	12	0	0	0
Bronchial irritation	0	0	0	0	1	0	11	0	11	0	0	0
Bronchial obstruction	0	0	2	0	1	0	4	0	6	0	0	0
Bronchial oedema	0	0	2	0	0	0	0	0	2	0	0	0
Bronchial secretion retention	1	0	3	0	1	0	2	0	5	0	0	0
Bronchial wall thickening	0	0	3	0	1	0	2	0	5	0	0	0
Bronchiectasis	0	0	14	0	0	0	11	0	25	0	0	0
Bronchitis chronic	1	0	3	0	1	0	5	0	8	0	0	0
Bronchopleural fistula	1	0	1	0	0	0	0	0	1	0	0	0
Bronchopneumopathy	0	0	3	0	0	0	0	0	3	0	0	0
Bronchospasm	1	0	60	0	3	0	110	0	170	0	0	0
Bronchostenosis	0	0	2	0	0	0	0	0	2	0	0	0
Catarrh	0	0	52	0	5	0	71	0	123	0	0	0
Cheyne-Stokes respiration	0	0	1	0	0	0	2	0	3	0	0	0
Choking	3	0	39	0	4	0	23	0	62	0	0	2
Choking sensation	2	0	30	0	3	0	39	0	69	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Chronic obstructive pulmonary disease	13	0	105	0	2	0	36	1	141	1	0	0
Chronic respiratory disease	0	0	3	0	0	0	0	0	3	0	0	0
Chronic respiratory failure	0	0	2	0	0	0	0	0	2	0	0	0
Chylothorax	0	0	1	0	0	0	1	0	2	0	0	0
Cough	187	0	4531	0	1147	0	13630	4	18161	4	0	0
Cough decreased	0	0	0	0	0	0	3	0	3	0	0	0
Cough variant asthma	0	0	7	0	0	0	4	0	11	0	0	0
Cyanosis central	0	0	3	0	0	0	0	0	3	0	0	0
Cyanosis neonatal	0	0	1	0	0	0	0	0	1	0	0	0
Cystic lung disease	0	0	1	0	0	0	0	0	1	0	0	0
Dependence on respirator	3	0	12	0	0	0	0	0	12	0	0	0
Diaphragmalgia	1	0	20	0	3	0	23	0	43	0	0	0
Diaphragmatic disorder	1	0	1	0	1	0	1	0	2	0	0	0
Diaphragmatic paralysis	1	0	5	0	0	0	0	0	5	0	0	0
Diaphragmatic spasm	0	0	2	0	1	0	8	0	10	0	0	0
Dry throat	3	0	204	0	22	0	371	0	575	0	0	0
Dysphonia	16	0	231	0	69	1	715	1	946	1	1	1
Dyspnoea	518	0	11233	0	1228	0	13178	0	24411	0	2	7

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Dyspnoea at rest	2	0	32	0	2	0	27	0	59	0	0	0
Dyspnoea exertional	27	0	252	0	40	0	407	0	659	0	0	0
Dyspnoea paroxysmal nocturnal	0	0	3	0	0	0	1	0	4	0	0	0
Ear, nose and throat disorder	1	0	1	0	0	0	1	0	2	0	0	0
Emphysema	3	0	19	0	0	0	2	1	21	1	0	0
Eosinophilic pneumonia	1	0	3	0	0	0	1	0	4	0	0	0
Eosinophilic pneumonia chronic	0	0	1	0	0	0	0	0	1	0	0	0
Epiglottic oedema	0	0	4	0	0	0	2	0	6	0	0	0
Epistaxis	26	0	1714	0	380	1	3935	1	5649	1	0	1
Gasping syndrome	0	0	2	0	0	0	0	0	2	0	0	0
Grunting	0	0	4	0	0	0	1	0	5	0	0	0
Haemoptysis	11	0	210	0	10	0	152	0	362	0	1	2
Haemothorax	0	0	2	0	0	0	0	0	2	0	0	0
Hiccups	2	0	40	0	2	0	48	0	88	0	0	0
Hydrothorax	0	0	0	0	0	0	1	0	1	0	0	0
Hyperactive pharyngeal reflex	0	0	0	0	0	0	1	0	1	0	0	0
Hypercapnia	0	0	6	0	0	0	1	0	7	0	0	0
Hypersensitivity pneumonitis	4	0	34	0	7	0	49	0	83	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Hyperventilation	4	0	131	0	16	0	114	0	245	0	0	0
Hypocapnia	0	0	2	0	0	0	1	0	3	0	0	0
Hypopnoea	5	0	222	0	11	0	96	0	318	0	0	0
Hypoventilation	2	0	11	0	2	0	11	0	22	0	0	0
Hypoxia	12	0	160	0	3	0	44	0	204	0	0	0
Idiopathic pulmonary fibrosis	2	0	6	0	0	0	0	0	6	0	0	0
Increased bronchial secretion	0	0	4	0	2	0	12	0	16	0	0	0
Increased upper airway secretion	2	0	12	0	0	0	22	0	34	0	0	0
Increased viscosity of bronchial secretion	0	0	0	0	0	0	1	0	1	0	0	0
Increased viscosity of upper respiratory secretion	0	0	21	0	7	0	32	0	53	0	0	0
Infantile apnoea	0	0	0	0	0	0	0	0	0	0	0	1
Interstitial lung disease	6	0	59	0	0	0	0	0	59	0	0	0
Intranasal hypoaesthesia	0	0	1	0	0	0	2	0	3	0	0	0
Intranasal paraesthesia	0	0	1	0	0	0	0	0	1	0	0	0
Irregular breathing	1	0	31	0	1	0	11	0	42	0	1	1
Kussmaul respiration	0	0	1	0	0	0	3	0	4	0	0	0
Laryngeal discomfort	0	0	2	0	2	0	15	0	17	0	0	0
Laryngeal disorder	0	0	0	0	1	0	2	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Laryngeal erythema	0	0	1	0	0	0	0	0	1	0	0	0
Laryngeal haematoma	0	0	1	0	0	0	0	0	1	0	0	0
Laryngeal inflammation	0	0	0	0	1	0	4	0	4	0	0	0
Laryngeal obstruction	0	0	0	0	0	0	2	0	2	0	0	0
Laryngeal oedema	7	0	161	0	0	0	0	0	161	0	0	0
Laryngeal pain	0	0	2	0	2	0	12	0	14	0	0	0
Laryngeal stenosis	0	0	0	0	1	0	1	0	1	0	0	0
Laryngospasm	0	0	18	0	2	0	14	0	32	0	0	0
Laryngotracheal oedema	0	0	1	0	0	0	0	0	1	0	0	0
Larynx irritation	0	0	1	0	1	0	13	0	14	0	0	0
Lower respiratory tract congestion	2	0	4	0	0	0	3	0	7	0	0	0
Lower respiratory tract inflammation	0	0	0	0	0	0	1	0	1	0	0	0
Lung consolidation	0	0	17	0	0	0	2	0	19	0	0	0
Lung cyst	0	0	0	0	0	0	1	0	1	0	0	0
Lung diffusion disorder	0	0	0	0	0	0	1	0	1	0	0	0
Lung disorder	11	0	71	0	18	0	86	0	157	0	0	0
Lung hyperinflation	0	0	1	0	0	0	0	0	1	0	0	0
Lung induration	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Lung infiltration	2	0	15	0	0	0	4	0	19	0	0	0
Lung opacity	1	0	16	0	0	0	7	0	23	0	0	0
Lupus pleurisy	0	0	2	0	0	0	0	0	2	0	0	0
Mouth breathing	0	0	8	0	0	0	3	0	11	0	0	0
NSAID exacerbated respiratory disease	0	0	0	0	0	0	1	0	1	0	0	0
Nasal congestion	16	0	418	0	150	0	1943	0	2361	0	0	0
Nasal crusting	0	0	5	0	1	0	15	0	20	0	0	0
Nasal cyst	0	0	2	0	0	0	1	0	3	0	0	0
Nasal discharge discolouration	0	0	1	0	1	0	5	0	6	0	0	0
Nasal discomfort	0	0	35	0	7	0	101	0	136	0	0	0
Nasal disorder	1	0	6	0	2	0	13	0	19	0	0	0
Nasal dryness	2	0	45	0	9	0	110	0	155	0	0	0
Nasal flaring	0	0	1	0	0	0	0	0	1	0	0	0
Nasal inflammation	0	0	7	0	1	0	14	0	21	0	0	0
Nasal mucosa atrophy	0	0	0	0	0	0	1	0	1	0	0	0
Nasal mucosal blistering	0	0	0	0	0	0	2	0	2	0	0	0
Nasal mucosal discolouration	0	0	1	0	1	0	1	0	2	0	0	0
Nasal mucosal disorder	0	0	1	0	2	0	9	0	10	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Nasal mucosal erosion	0	0	0	0	0	0	1	0	1	0	0	0
Nasal mucosal ulcer	0	0	1	0	0	0	1	0	2	0	0	0
Nasal obstruction	0	0	6	0	7	0	42	0	48	0	0	0
Nasal odour	0	0	1	0	1	0	3	0	4	0	0	0
Nasal oedema	0	0	18	0	1	0	24	0	42	0	0	0
Nasal polyps	0	0	1	0	0	0	3	0	4	0	0	0
Nasal pruritus	0	0	8	0	0	0	27	0	35	0	0	0
Nasal septum deviation	0	0	2	0	0	0	0	0	2	0	0	0
Nasal septum disorder	1	0	1	0	0	0	1	0	2	0	0	0
Nasal septum perforation	0	0	1	0	0	0	0	0	1	0	0	0
Nasal turbinate hypertrophy	0	0	0	0	0	0	2	0	2	0	0	0
Nasal ulcer	1	0	5	0	3	0	8	0	13	0	0	0
Nasal valve collapse	0	0	0	0	0	0	1	0	1	0	0	0
Neonatal asphyxia	0	0	0	0	0	0	0	0	0	0	1	1
Neonatal dyspnoea	0	0	2	0	0	0	3	0	5	0	2	6
Neonatal respiratory distress	0	0	0	0	0	0	0	0	0	0	0	1
Neonatal respiratory failure	0	0	1	0	0	0	0	0	1	0	0	0
Nocturnal dyspnoea	0	0	4	0	4	0	8	0	12	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Non-cardiogenic pulmonary oedema	0	0	1	0	0	0	0	0	1	0	0	0
Obstructive airways disorder	0	0	7	0	4	0	24	0	31	0	0	0
Obstructive sleep apnoea syndrome	1	0	2	0	2	0	2	0	4	0	0	0
Organising pneumonia	0	0	5	0	0	0	2	0	7	0	0	0
Oropharyngeal blistering	1	0	24	0	2	0	20	0	44	0	0	0
Oropharyngeal discolouration	0	0	1	0	0	0	0	0	1	0	0	0
Oropharyngeal discomfort	6	0	65	0	56	0	352	2	417	2	0	0
Oropharyngeal oedema	0	0	3	0	0	0	2	0	5	0	0	0
Oropharyngeal pain	77	0	3687	0	762	0	9151	7	12838	7	0	0
Oropharyngeal plaque	0	0	2	0	2	0	6	0	8	0	0	0
Oropharyngeal swelling	0	0	4	0	0	0	11	0	15	0	0	0
Orthopnoea	1	0	18	0	0	0	12	0	30	0	0	0
Painful respiration	0	0	36	0	27	0	115	0	151	0	0	0
Paranasal cyst	0	0	0	0	0	0	1	0	1	0	0	0
Paranasal sinus discomfort	2	0	72	0	13	0	95	0	167	0	0	0
Paranasal sinus haemorrhage	0	0	3	0	0	0	6	0	9	0	0	0
Paranasal sinus hypersecretion	0	0	1	0	0	0	3	0	4	0	0	0
Paranasal sinus hyposecretion	0	0	1	0	0	0	2	0	3	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Paranasal sinus inflammation	1	0	4	0	2	0	13	0	17	0	0	0
Pharyngeal disorder	0	0	0	0	0	0	26	0	26	0	0	0
Pharyngeal enanthema	0	0	0	0	0	0	1	0	1	0	0	0
Pharyngeal erythema	0	0	10	0	3	0	38	0	48	0	0	0
Pharyngeal haemorrhage	1	0	5	0	0	0	4	0	9	0	0	0
Pharyngeal hypoaesthesia	2	0	38	0	2	0	38	0	76	0	0	0
Pharyngeal inflammation	0	0	2	0	2	0	11	0	13	0	0	0
Pharyngeal oedema	1	0	30	0	4	0	55	0	85	0	0	0
Pharyngeal paraesthesia	1	0	26	0	6	0	63	0	89	0	0	0
Pharyngeal swelling	7	0	316	0	41	0	386	0	702	0	0	0
Pharyngeal ulceration	0	0	12	0	1	0	9	0	21	0	0	0
Platypnoea	0	0	1	0	0	0	0	0	1	0	0	0
Pleural adhesion	0	0	1	0	0	0	0	0	1	0	0	0
Pleural disorder	0	0	2	0	0	0	1	0	3	0	0	0
Pleural effusion	13	0	160	0	3	0	31	0	191	0	0	1
Pleural rub	0	0	1	0	0	0	0	0	1	0	0	0
Pleural thickening	0	0	5	0	0	0	2	0	7	0	0	0
Pleurisy	4	0	78	0	2	0	25	0	103	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Pleuritic pain	3	0	57	0	1	0	48	0	105	0	0	0
Pneumonitis	4	0	107	0	0	0	0	0	107	0	2	2
Pneumonitis aspiration	0	0	1	0	0	0	0	0	1	0	0	0
Pneumothorax	2	0	31	0	0	0	0	0	31	0	0	0
Pneumothorax spontaneous	0	0	6	0	0	0	0	0	6	0	0	0
Productive cough	11	0	226	0	35	0	436	0	662	0	0	0
Pulmonary alveolar haemorrhage	1	0	8	0	0	0	0	0	8	0	0	0
Pulmonary arterial hypertension	0	0	3	0	0	0	1	0	4	0	0	0
Pulmonary artery occlusion	1	0	3	0	0	0	0	0	3	0	0	0
Pulmonary artery thrombosis	2	0	24	0	0	0	0	0	24	0	0	0
Pulmonary calcification	0	0	2	0	0	0	0	0	2	0	0	0
Pulmonary cavitation	0	0	5	0	0	0	0	0	5	0	0	0
Pulmonary congestion	3	0	34	0	1	0	21	0	55	0	0	0
Pulmonary embolism	159	1	5461	4	0	0	0	0	5461	4	6	9
Pulmonary fibrosis	4	0	35	0	0	0	0	0	35	0	0	0
Pulmonary haemorrhage	4	0	31	0	0	0	0	0	31	0	0	0
Pulmonary hilum mass	0	0	1	0	0	0	0	0	1	0	0	0
Pulmonary hypertension	1	0	27	0	0	0	0	0	27	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Pulmonary hypoperfusion	0	0	1	0	0	0	0	0	1	0	0	0
Pulmonary infarction	3	0	93	0	0	0	0	0	93	0	0	0
Pulmonary mass	1	0	18	0	1	0	16	0	34	0	0	0
Pulmonary microemboli	1	0	9	0	0	0	0	0	9	0	0	0
Pulmonary oedema	10	0	124	0	0	0	0	0	124	0	0	0
Pulmonary pain	5	0	252	0	59	0	422	0	674	0	0	0
Pulmonary sarcoidosis	1	0	5	0	0	0	1	0	6	0	0	0
Pulmonary thrombosis	15	0	180	0	0	0	0	0	180	0	5	7
Pulmonary vascular disorder	0	0	2	0	0	0	2	0	4	0	0	0
Pulmonary vasculitis	0	0	1	0	0	0	0	0	1	0	0	0
Pulmonary venous thrombosis	0	0	7	0	0	0	1	0	8	0	0	0
Rales	3	0	13	0	1	0	10	0	23	0	0	0
Rebound nasal congestion	0	0	0	0	1	0	1	0	1	0	0	0
Reflux laryngitis	0	0	3	0	0	0	2	0	5	0	0	0
Respiration abnormal	7	0	130	0	23	0	198	0	328	0	0	0
Respiratory acidosis	0	0	6	0	0	0	0	0	6	0	0	0
Respiratory alkalosis	0	0	0	0	0	0	1	0	1	0	0	0
Respiratory arrest	1	0	62	0	0	0	0	0	62	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Respiratory depression	0	0	2	0	0	0	1	0	3	0	0	0
Respiratory depth decreased	0	0	1	0	5	0	13	0	14	0	0	0
Respiratory depth increased	0	0	0	0	1	0	1	0	1	0	0	0
Respiratory disorder	12	0	219	0	36	0	200	0	419	0	0	0
Respiratory distress	17	0	386	0	8	0	663	0	1049	0	0	0
Respiratory failure	19	0	204	0	0	0	0	0	204	0	1	1
Respiratory fatigue	0	0	15	0	0	0	18	0	33	0	0	0
Respiratory gas exchange disorder	0	0	1	0	0	0	1	0	2	0	0	0
Respiratory muscle weakness	2	0	8	0	1	0	1	0	9	0	0	0
Respiratory paralysis	0	0	2	0	0	0	0	0	2	0	0	0
Respiratory symptom	1	0	29	0	3	0	55	0	84	0	0	0
Respiratory tract congestion	3	0	13	0	1	0	7	0	20	0	0	0
Respiratory tract haemorrhage	0	0	4	0	0	0	3	0	7	0	0	0
Respiratory tract inflammation	0	0	1	0	0	0	3	0	4	0	0	0
Respiratory tract irritation	1	0	16	0	4	0	27	0	43	0	0	0
Respiratory tract oedema	3	0	12	0	0	0	0	0	12	0	0	0
Restrictive pulmonary disease	0	0	1	0	0	0	0	0	1	0	0	0
Reversible airways obstruction	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Rheumatoid arthritis-associated interstitial lung disease	0	0	1	0	0	0	0	0	1	0	0	0
Rhinalgia	4	0	92	0	12	0	106	0	198	0	0	0
Rhinitis allergic	3	0	21	0	8	0	72	0	93	0	0	0
Rhinitis atrophic	0	0	1	0	0	0	0	0	1	0	0	0
Rhinitis perennial	0	0	0	0	0	0	1	0	1	0	0	0
Rhinorrhoea	26	0	1324	0	271	0	3433	1	4757	1	0	1
Rhonchi	0	0	2	0	0	0	3	0	5	0	0	0
Sinonasal obstruction	0	0	11	0	2	0	23	0	34	0	0	0
Sinus congestion	5	0	86	0	7	0	75	0	161	0	0	0
Sinus disorder	3	0	17	0	5	0	39	0	56	0	0	0
Sinus pain	2	0	539	0	36	0	275	0	814	0	0	0
Sinus polyp	0	0	2	0	0	0	1	0	3	0	0	0
Sleep apnoea syndrome	5	0	38	0	4	0	19	0	57	0	0	0
Sneezing	3	0	380	0	77	0	1133	0	1513	0	0	0
Snoring	0	0	5	0	1	0	6	0	11	0	0	0
Sputum discoloured	5	0	16	0	1	0	17	0	33	0	0	0
Sputum increased	0	0	3	0	1	0	10	0	13	0	0	0
Sputum retention	0	0	0	0	0	0	2	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Stridor	0	0	37	0	1	0	18	0	55	0	0	1
Suffocation feeling	1	0	23	0	7	0	50	0	73	0	0	0
Tachypnoea	3	0	78	0	3	0	87	0	165	0	0	0
Thoracic haemorrhage	0	0	1	0	0	0	0	0	1	0	0	0
Throat clearing	4	0	11	0	3	0	36	0	47	0	0	0
Throat irritation	4	0	219	0	67	0	905	1	1124	1	0	0
Throat lesion	0	0	2	0	0	0	3	0	5	0	0	0
Throat tightness	6	0	263	0	24	0	476	0	739	0	0	0
Tonsillar atrophy	0	0	0	0	0	0	1	0	1	0	0	0
Tonsillar disorder	0	0	2	0	1	0	5	0	7	0	0	0
Tonsillar erythema	0	0	5	0	0	0	4	0	9	0	0	0
Tonsillar exudate	0	0	0	0	1	0	1	0	1	0	0	0
Tonsillar haemorrhage	0	0	1	0	0	0	0	0	1	0	0	0
Tonsillar hypertrophy	1	0	49	0	14	0	77	0	126	0	0	0
Tonsillar inflammation	0	0	5	0	0	0	15	0	20	0	0	0
Tonsillar ulcer	0	0	2	0	0	0	0	0	2	0	0	0
Tonsillolith	1	0	3	0	0	0	0	0	3	0	0	0
Tracheal disorder	1	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Tracheal fistula	0	0	1	0	0	0	0	0	1	0	0	0
Tracheal inflammation	1	0	1	0	0	0	3	0	4	0	0	0
Tracheal oedema	0	0	1	0	0	0	0	0	1	0	0	0
Tracheal pain	0	0	3	0	4	0	15	0	18	0	0	0
Tracheal stenosis	0	0	1	0	0	0	0	0	1	0	0	0
Tracheomalacia	0	0	1	0	0	0	0	0	1	0	0	0
Upper airway necrosis	0	0	0	0	1	0	1	0	1	0	0	0
Upper airway obstruction	0	0	7	0	0	0	0	0	7	0	0	0
Upper respiratory tract congestion	0	0	1	0	2	0	7	0	8	0	0	0
Upper respiratory tract inflammation	0	0	3	0	1	0	1	0	4	0	0	0
Upper respiratory tract irritation	0	0	0	0	1	0	5	0	5	0	0	0
Upper-airway cough syndrome	0	0	24	0	2	0	28	0	52	0	0	0
Use of accessory respiratory muscles	1	0	6	0	0	0	4	0	10	0	0	0
Ventilation perfusion mismatch	1	0	2	0	0	0	0	0	2	0	0	0
Vocal cord disorder	2	0	9	0	3	0	7	0	16	0	0	0
Vocal cord dysfunction	0	0	8	0	0	0	3	0	11	0	0	0
Vocal cord inflammation	0	0	1	0	1	0	3	0	4	0	0	0
Vocal cord thickening	0	0	1	0	0	0	1	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Wheezing	20	0	593	0	16	0	401	0	994	0	0	0
Yawning	1	0	58	0	4	0	62	0	120	0	0	0
Gastrointestinal disorders	**1828**	**0**	**78896**	**2**	**14054**	**2**	**149973**	**18**	**228869**	**20**	**12**	**37**
Abdominal adhesions	0	0	3	0	0	0	1	0	4	0	0	0
Abdominal compartment syndrome	0	0	2	0	0	0	0	0	2	0	0	0
Abdominal discomfort	43	0	1442	0	261	0	2060	1	3502	1	1	2
Abdominal distension	27	0	621	0	66	0	777	0	1398	0	0	0
Abdominal hernia	1	0	3	0	0	0	0	0	3	0	0	0
Abdominal mass	1	0	6	0	0	0	4	0	10	0	0	0
Abdominal migraine	0	0	3	0	0	0	2	0	5	0	0	0
Abdominal pain	129	0	4844	0	1064	0	10579	2	15423	2	1	2
Abdominal pain lower	10	0	298	0	35	0	514	0	812	0	0	0
Abdominal pain upper	69	0	4812	0	304	0	4366	0	9178	0	0	0
Abdominal rigidity	2	0	60	0	0	0	23	0	83	0	0	0
Abdominal symptom	0	0	10	0	1	0	10	0	20	0	0	0
Abdominal tenderness	3	0	35	0	1	0	38	0	73	0	0	0
Abdominal wall disorder	0	0	0	0	0	0	1	0	1	0	0	0
Abdominal wall haematoma	0	0	2	0	0	0	0	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Abdominal wall oedema	0	0	2	0	0	0	1	0	3	0	0	0
Abnormal faeces	5	0	42	0	19	0	389	0	431	0	0	0
Acetonaemic vomiting	0	0	1	0	0	0	14	0	15	0	0	0
Achlorhydria	0	0	1	0	0	0	2	0	3	0	0	0
Acid peptic disease	0	0	1	0	0	0	0	0	1	0	0	0
Acquired macroglossia	0	0	0	0	0	0	3	0	3	0	0	0
Acquired oesophageal web	0	0	1	0	0	0	0	0	1	0	0	0
Acute abdomen	1	0	28	0	0	0	0	0	28	0	0	0
Acute oesophageal mucosal lesion	0	0	0	0	0	0	1	0	1	0	0	0
Aerophagia	0	0	2	0	1	0	6	0	8	0	0	0
Allergic stomatitis	0	0	0	0	0	0	2	0	2	0	0	0
Amalgam tattoo	0	0	0	0	0	0	1	0	1	0	0	0
Anaesthesia oral	1	0	6	0	0	0	24	0	30	0	0	0
Anal blister	0	0	3	0	0	0	0	0	3	0	0	0
Anal erythema	0	0	0	0	0	0	1	0	1	0	0	0
Anal fissure	3	0	5	0	0	0	2	0	7	0	0	0
Anal fissure haemorrhage	0	0	0	0	0	0	1	0	1	0	0	0
Anal fistula	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Anal haemorrhage	2	0	39	0	3	0	43	0	82	0	0	0
Anal hypoaesthesia	0	0	5	0	0	0	4	0	9	0	0	0
Anal incontinence	4	0	65	0	2	0	42	0	107	0	0	0
Anal inflammation	0	0	2	0	0	0	1	0	3	0	0	0
Anal paraesthesia	0	0	1	0	0	0	2	0	3	0	0	0
Anal pruritus	0	0	8	0	0	0	7	0	15	0	0	0
Anal rash	0	0	1	0	0	0	1	0	2	0	0	0
Anal spasm	0	0	2	0	0	0	2	0	4	0	0	0
Anal sphincter atony	0	0	3	0	0	0	2	0	5	0	0	0
Anal ulcer	0	0	2	0	0	0	1	0	3	0	0	0
Angina bullosa haemorrhagica	0	0	0	0	0	0	5	0	5	0	0	0
Angular cheilitis	1	0	9	0	3	0	15	0	24	0	0	0
Ankyloglossia acquired	0	0	0	0	0	0	1	0	1	0	0	0
Anorectal discomfort	0	0	16	0	4	0	10	0	26	0	0	0
Anorectal disorder	1	0	3	0	1	0	1	0	4	0	0	0
Anorectal swelling	0	0	1	0	0	0	0	0	1	0	0	0
Anorectal varices	0	0	1	0	0	0	0	0	1	0	0	0
Aphthous ulcer	5	0	76	0	23	0	283	1	359	1	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Apical granuloma	0	0	0	0	0	0	1	0	1	0	0	0
Appendiceal mucocoele	0	0	1	0	0	0	0	0	1	0	0	0
Appendicitis noninfective	0	0	2	0	0	0	0	0	2	0	0	0
Appendix disorder	0	0	7	0	0	0	0	0	7	0	0	1
Aptyalism	0	0	6	0	2	0	9	0	15	0	0	0
Ascites	3	0	38	0	1	0	3	0	41	0	0	0
Autoimmune colitis	0	0	4	0	0	0	1	0	5	0	0	0
Barrett's oesophagus	0	0	2	0	0	0	1	0	3	0	0	0
Bile acid malabsorption	0	0	1	0	0	0	1	0	2	0	0	0
Bowel movement irregularity	2	0	11	0	2	0	25	0	36	0	0	0
Breath odour	2	0	19	0	7	0	27	0	46	0	0	0
Burning mouth syndrome	0	0	9	0	1	0	13	0	22	0	0	0
Cardiospasm	0	0	3	0	0	0	1	0	4	0	0	0
Change of bowel habit	1	0	26	0	2	0	10	0	36	0	0	0
Chapped lips	0	0	19	0	1	0	19	0	38	0	0	0
Cheilitis	1	0	29	0	6	0	55	0	84	0	0	0
Cheilosis	0	0	0	0	0	0	1	0	1	0	0	0
Chronic cheek biting	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Chronic gastritis	0	0	6	0	1	0	7	0	13	0	0	0
Coating in mouth	0	0	2	0	0	0	5	0	7	0	0	0
Coeliac artery aneurysm	0	0	0	0	0	0	2	0	2	0	0	0
Coeliac disease	3	0	30	0	1	0	7	0	37	0	0	0
Colitis	7	0	90	0	2	0	42	0	132	0	0	0
Colitis erosive	0	0	1	0	0	0	0	0	1	0	0	0
Colitis ischaemic	0	0	54	0	0	0	0	0	54	0	0	0
Colitis microscopic	2	0	16	0	0	0	3	0	19	0	0	0
Colitis ulcerative	14	0	133	0	2	0	48	0	181	0	0	0
Constipation	26	0	464	0	41	0	523	0	987	0	0	0
Crohn's disease	17	0	116	0	2	0	37	0	153	0	0	0
Cyclic vomiting syndrome	0	0	2	0	0	0	0	0	2	0	0	0
Defaecation disorder	1	0	1	0	0	0	7	0	8	0	0	0
Defaecation urgency	1	0	14	0	1	0	21	0	35	0	0	0
Dental caries	5	0	11	0	0	0	8	0	19	0	0	0
Dental discomfort	1	0	7	0	4	0	28	1	35	1	0	0
Dental dysaesthesia	0	0	0	0	0	0	3	0	3	0	0	0
Dental paraesthesia	0	0	12	0	1	0	9	0	21	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Dental pulp disorder	0	0	0	0	1	0	3	0	3	0	0	0
Diarrhoea	189	0	8476	0	1742	0	18996	5	27472	5	2	6
Diarrhoea haemorrhagic	5	0	50	0	6	0	45	0	95	0	0	0
Diastema	0	0	1	0	0	0	0	0	1	0	0	0
Discoloured vomit	1	0	20	0	2	0	10	0	30	0	0	0
Distal intestinal obstruction syndrome	1	0	1	0	0	0	0	0	1	0	0	0
Diverticular perforation	1	0	4	0	0	0	0	0	4	0	0	0
Diverticulum	0	0	13	0	0	0	2	0	15	0	0	0
Diverticulum intestinal	0	0	3	0	1	0	1	0	4	0	0	0
Diverticulum intestinal haemorrhagic	0	0	1	0	0	0	0	0	1	0	0	0
Dry mouth	14	0	959	0	118	0	1331	0	2290	0	0	0
Duodenal perforation	0	0	2	0	0	0	0	0	2	0	0	0
Duodenal ulcer	0	0	2	0	0	0	2	0	4	0	0	0
Duodenal ulcer haemorrhage	0	0	4	0	0	0	0	0	4	0	0	0
Duodenal ulcer perforation	0	0	1	0	0	0	0	0	1	0	0	0
Duodenitis	0	0	4	0	0	0	1	0	5	0	0	0
Duodenogastric reflux	2	0	7	0	2	0	3	0	10	0	0	0
Dysbiosis	1	0	3	0	1	0	4	0	7	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Dyschezia	1	0	18	0	1	0	14	0	32	0	0	0
Dyspepsia	23	0	760	0	86	0	887	0	1647	0	0	0
Dysphagia	28	0	436	0	56	0	578	0	1014	0	0	0
Enlarged uvula	0	0	10	0	3	0	6	0	16	0	0	0
Enteritis	1	0	9	0	0	0	11	0	20	0	0	0
Enterocolitis	0	0	3	0	0	0	0	0	3	0	0	0
Enterocolitis haemorrhagic	0	0	2	0	0	0	0	0	2	0	0	0
Eosinophilic oesophagitis	1	0	4	0	0	0	3	0	7	0	0	0
Epigastric discomfort	0	0	20	0	2	0	45	0	65	0	0	0
Epiploic appendagitis	0	0	4	0	0	0	3	0	7	0	0	0
Epulis	0	0	1	0	0	0	0	0	1	0	0	0
Erosive duodenitis	0	0	2	0	0	0	0	0	2	0	0	0
Eructation	5	0	104	0	17	0	141	0	245	0	0	0
Excessive gingival display	0	0	1	0	0	0	0	0	1	0	0	0
Faecal vomiting	0	0	3	0	0	0	0	0	3	0	0	0
Faecaloma	0	0	8	0	0	0	4	0	12	0	0	0
Faeces discoloured	9	0	63	0	4	1	84	1	147	1	0	0
Faeces hard	2	0	5	0	1	0	12	0	17	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Faeces pale	1	0	10	0	0	0	12	0	22	0	0	0
Faeces soft	2	0	18	0	3	0	49	0	67	0	0	0
Flatulence	14	0	358	0	37	0	375	0	733	0	0	0
Food poisoning	0	0	9	0	1	0	10	0	19	0	0	0
Frequent bowel movements	4	0	47	0	8	0	92	0	139	0	0	0
Functional gastrointestinal disorder	6	0	36	0	3	0	18	0	54	0	0	0
Gastric antral vascular ectasia	0	0	10	0	0	0	2	0	12	0	0	0
Gastric dilatation	0	0	17	0	0	0	6	0	23	0	0	0
Gastric disorder	4	0	17	0	4	0	60	0	77	0	0	0
Gastric haemorrhage	2	0	25	0	0	0	3	0	28	0	0	0
Gastric hypertonia	0	0	0	0	0	0	1	0	1	0	0	0
Gastric polyps	2	0	2	0	0	0	0	0	2	0	0	0
Gastric ulcer	2	0	26	0	0	0	11	0	37	0	0	0
Gastric ulcer haemorrhage	0	0	5	0	0	0	0	0	5	0	0	0
Gastric ulcer perforation	0	0	1	0	0	0	0	0	1	0	0	0
Gastric varices haemorrhage	0	0	2	0	0	0	0	0	2	0	0	0
Gastritis	7	0	146	0	13	0	111	0	257	0	0	0
Gastritis erosive	0	0	3	0	0	0	0	0	3	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Gastritis haemorrhagic	1	0	1	0	0	0	0	0	1	0	0	0
Gastroduodenal haemorrhage	0	0	1	0	0	0	0	0	1	0	0	0
Gastroduodenal ulcer	0	0	1	0	0	0	0	0	1	0	0	0
Gastrointestinal disorder	9	0	106	0	27	0	318	0	424	0	0	0
Gastrointestinal haemorrhage	5	0	76	0	1	0	14	0	90	0	0	0
Gastrointestinal hypermotility	0	0	0	0	0	0	8	0	8	0	0	0
Gastrointestinal hypomotility	0	0	2	0	0	0	1	0	3	0	0	0
Gastrointestinal inflammation	1	0	13	0	3	0	21	0	34	0	0	0
Gastrointestinal motility disorder	1	0	10	0	0	0	15	0	25	0	0	0
Gastrointestinal mucosal disorder	0	0	1	0	0	0	0	0	1	0	0	0
Gastrointestinal necrosis	0	0	11	0	0	0	0	0	11	0	0	0
Gastrointestinal obstruction	0	0	2	0	0	0	0	0	2	0	0	0
Gastrointestinal oedema	0	0	4	0	0	0	0	0	4	0	0	0
Gastrointestinal pain	8	0	351	0	28	0	355	0	706	0	0	0
Gastrointestinal perforation	0	0	1	0	0	0	0	0	1	0	0	0
Gastrointestinal polyp haemorrhage	0	0	1	0	0	0	0	0	1	0	0	0
Gastrointestinal scarring	1	0	1	0	0	0	0	0	1	0	0	0
Gastrointestinal sounds abnormal	3	0	23	0	3	0	30	0	53	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Gastrointestinal tract irritation	0	0	4	0	0	0	6	0	10	0	0	0
Gastrointestinal tract mucosal discolouration	0	0	0	0	0	0	1	0	1	0	0	0
Gastrointestinal ulcer	0	0	1	0	0	0	1	0	2	0	0	0
Gastrointestinal vascular malformation haemorrhagic	0	0	1	0	0	0	0	0	1	0	0	0
Gastrointestinal wall thickening	0	0	2	0	0	0	0	0	2	0	0	0
Gastrooesophageal reflux disease	11	0	220	0	21	0	235	1	455	1	0	1
Gastroptosis	0	0	1	0	0	0	0	0	1	0	0	0
Gingival atrophy	0	0	0	0	0	0	1	0	1	0	0	0
Gingival bleeding	6	0	174	0	30	0	369	0	543	0	0	1
Gingival blister	0	0	17	0	1	0	14	0	31	0	0	0
Gingival discolouration	0	0	1	0	0	0	5	0	6	0	0	0
Gingival discomfort	1	0	9	0	0	0	14	0	23	0	0	0
Gingival disorder	2	0	14	0	3	0	20	0	34	0	0	0
Gingival erosion	0	0	0	0	0	0	2	0	2	0	0	0
Gingival erythema	2	0	2	0	2	0	10	0	12	0	0	0
Gingival hypertrophy	0	0	1	0	0	0	1	0	2	0	0	0
Gingival oedema	0	0	1	0	0	0	12	0	13	0	0	0
Gingival pain	4	0	190	0	20	0	234	0	424	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Gingival pruritus	0	0	1	0	0	0	1	0	2	0	0	0
Gingival recession	0	0	2	0	1	0	5	0	7	0	0	0
Gingival swelling	2	0	37	0	6	0	87	0	124	0	0	0
Gingival ulceration	0	0	2	0	0	0	10	0	12	0	0	0
Gingivitis ulcerative	0	0	1	0	0	0	1	0	2	0	0	0
Glossitis	1	0	21	0	3	0	41	0	62	0	0	0
Glossodynia	2	0	175	0	13	0	210	0	385	0	0	0
Haematemesis	9	0	199	0	0	0	0	0	199	0	0	0
Haematochezia	23	0	205	0	6	0	186	0	391	0	0	0
Haemoperitoneum	0	0	14	0	0	0	0	0	14	0	0	0
Haemorrhagic ascites	0	0	1	0	0	0	0	0	1	0	0	0
Haemorrhagic erosive gastritis	1	0	1	0	0	0	0	0	1	0	0	0
Haemorrhagic gastroenteritis	0	0	0	0	0	0	1	0	1	0	0	0
Haemorrhagic necrotic pancreatitis	0	0	1	0	0	0	0	0	1	0	0	0
Haemorrhoidal haemorrhage	0	0	9	0	2	0	25	0	34	0	0	0
Haemorrhoids	3	0	70	0	14	0	127	0	197	0	0	0
Haemorrhoids thrombosed	1	0	52	0	3	0	57	0	109	0	0	0
Hiatus hernia	2	0	21	0	2	0	13	0	34	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Hyperaesthesia teeth	0	0	46	0	5	0	61	0	107	0	0	0
Hyperchlorhydria	0	0	2	0	1	0	70	0	72	0	0	0
Hypertrophy of tongue papillae	0	0	0	0	0	0	2	0	2	0	0	0
Hypoaesthesia oral	8	0	498	0	56	0	814	0	1312	0	0	0
Hypoaesthesia teeth	0	0	1	0	0	0	2	0	3	0	0	0
Ileus	1	0	4	0	0	0	0	0	4	0	0	0
Ileus paralytic	2	0	6	0	0	0	0	0	6	0	0	0
Immune-mediated enterocolitis	1	0	1	0	0	0	0	0	1	0	0	0
Impaired gastric emptying	0	0	11	0	0	0	2	0	13	0	0	0
Incarcerated inguinal hernia	0	0	1	0	0	0	0	0	1	0	0	0
Increased intraperitoneal volume	0	0	1	0	0	0	0	0	1	0	0	0
Infantile spitting up	0	0	3	0	0	0	1	0	4	0	0	0
Infantile vomiting	0	0	3	0	0	0	4	0	7	0	0	0
Inflammatory bowel disease	0	0	20	0	0	0	7	0	27	0	0	0
Infrequent bowel movements	4	0	5	0	0	0	3	0	8	0	0	0
Inguinal hernia	1	0	11	0	0	0	6	0	17	0	0	0
Internal hernia	0	0	1	0	0	0	0	0	1	0	0	0
Intestinal angioedema	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Intestinal atony	0	0	1	0	0	0	0	0	1	0	0	0
Intestinal congestion	0	0	1	0	0	0	2	0	3	0	0	0
Intestinal dilatation	0	0	5	0	0	0	0	0	5	0	0	0
Intestinal haemorrhage	2	0	30	0	0	0	13	0	43	0	0	0
Intestinal infarction	1	0	20	0	0	0	0	0	20	0	0	1
Intestinal ischaemia	4	0	97	0	0	0	0	0	97	0	0	1
Intestinal mass	0	0	0	0	0	0	1	0	1	0	0	0
Intestinal obstruction	5	0	40	0	0	0	0	0	40	0	0	0
Intestinal perforation	0	0	10	0	0	0	0	0	10	0	0	0
Intestinal polyp	0	0	1	0	0	0	0	0	1	0	0	0
Intestinal stenosis	0	0	1	0	0	0	0	0	1	0	0	0
Intestinal ulcer	0	0	1	0	0	0	0	0	1	0	0	0
Intra-abdominal fluid collection	0	0	2	0	0	0	0	0	2	0	0	0
Intra-abdominal haematoma	1	0	16	0	0	0	0	0	16	0	0	0
Intra-abdominal haemorrhage	1	0	7	0	0	0	0	0	7	0	0	0
Intussusception	0	0	21	0	0	0	0	0	21	0	0	0
Irritable bowel syndrome	6	0	141	0	7	0	67	0	208	0	0	0
Ischaemic enteritis	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Large intestinal haemorrhage	0	0	0	0	1	0	2	0	2	0	0	0
Large intestinal obstruction	0	0	1	0	0	0	0	0	1	0	0	0
Large intestinal stenosis	1	0	2	0	0	0	0	0	2	0	0	0
Large intestine perforation	0	0	5	0	0	0	0	0	5	0	0	0
Leukoplakia oral	0	0	2	0	0	0	0	0	2	0	0	0
Levator syndrome	0	0	0	0	0	0	1	0	1	0	0	0
Lip blister	0	0	14	0	3	0	54	0	68	0	0	0
Lip discolouration	1	0	5	0	1	0	14	0	19	0	0	0
Lip disorder	0	0	7	0	0	0	13	0	20	0	0	0
Lip dry	2	0	59	0	1	0	69	0	128	0	0	0
Lip erythema	0	0	5	0	1	0	11	0	16	0	0	0
Lip exfoliation	0	0	8	0	0	0	3	0	11	0	0	0
Lip haematoma	0	0	1	0	0	0	7	0	8	0	0	0
Lip haemorrhage	0	0	5	0	3	0	9	0	14	0	0	0
Lip oedema	2	0	75	0	9	0	174	0	249	0	0	0
Lip pain	0	0	42	0	5	0	58	0	100	0	0	0
Lip pruritus	2	0	19	0	2	0	22	0	41	0	0	0
Lip swelling	13	0	735	0	84	0	1066	0	1801	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Lip ulceration	1	0	18	0	0	0	10	0	28	0	0	0
Loose tooth	1	0	2	0	1	0	4	0	6	0	0	0
Lower gastrointestinal haemorrhage	0	0	3	0	0	0	1	0	4	0	0	0
Lumbar hernia	0	0	1	0	0	0	0	0	1	0	0	0
Malabsorption	0	0	0	0	1	0	3	0	3	0	0	0
Malignant dysphagia	0	0	0	0	0	0	1	0	1	0	0	0
Malocclusion	0	0	0	0	0	0	1	0	1	0	0	0
Malpositioned teeth	0	0	3	0	0	0	0	0	3	0	0	0
Megacolon	0	0	1	0	0	0	0	0	1	0	0	0
Melaena	5	0	55	0	1	0	19	0	74	0	0	0
Mesenteric arterial occlusion	0	0	2	0	0	0	0	0	2	0	0	0
Mesenteric artery embolism	1	0	2	0	0	0	1	0	3	0	0	0
Mesenteric artery stenosis	0	0	3	0	0	0	0	0	3	0	0	0
Mesenteric artery thrombosis	1	0	27	0	0	0	0	0	27	0	0	2
Mesenteric haemorrhage	0	0	5	0	0	0	1	0	6	0	0	0
Mesenteric panniculitis	0	0	2	0	0	0	3	0	5	0	0	0
Mesenteric vascular occlusion	1	0	2	0	0	0	0	0	2	0	0	0
Mesenteric vein thrombosis	6	0	124	0	0	0	0	0	124	0	3	4

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Mesenteric venous occlusion	0	0	2	0	0	0	1	0	3	0	0	0
Mouth cyst	0	0	9	0	1	0	9	0	18	0	0	0
Mouth haemorrhage	1	0	69	0	10	0	117	0	186	0	0	0
Mouth swelling	3	0	121	0	18	0	155	0	276	0	0	0
Mouth ulceration	5	0	463	0	20	0	501	0	964	0	0	0
Mucous stools	2	0	20	0	0	0	7	0	27	0	0	0
Nausea	559	0	32680	1	7132	0	74513	3	107193	4	1	6
Necrotising enterocolitis neonatal	0	0	0	0	0	0	0	0	0	0	1	1
Neurogenic bowel	0	0	1	0	0	0	1	0	2	0	0	0
Noninfective gingivitis	2	0	18	0	10	0	71	0	89	0	0	0
Noninfective sialoadenitis	0	0	2	0	3	0	13	0	15	0	0	0
Obstructive pancreatitis	1	0	5	0	0	0	0	0	5	0	0	0
Odynophagia	2	0	64	0	122	0	789	0	853	0	0	0
Oedema mouth	0	0	13	0	2	0	30	0	43	0	0	0
Oedematous pancreatitis	0	0	1	0	0	0	1	0	2	0	0	0
Oesophageal achalasia	1	0	6	0	1	0	2	0	8	0	0	0
Oesophageal discomfort	1	0	2	0	2	0	3	0	5	0	0	0
Oesophageal disorder	0	0	1	0	0	0	1	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Oesophageal haemorrhage	0	0	1	0	0	0	0	0	1	0	0	0
Oesophageal hypomotility	0	0	1	0	0	0	0	0	1	0	0	0
Oesophageal irritation	0	0	0	0	0	0	1	0	1	0	0	0
Oesophageal motility disorder	0	0	1	0	0	0	0	0	1	0	0	0
Oesophageal obstruction	0	0	1	0	0	0	0	0	1	0	0	0
Oesophageal oedema	0	0	2	0	0	0	0	0	2	0	0	0
Oesophageal pain	2	0	11	0	10	0	34	0	45	0	0	0
Oesophageal rupture	0	0	2	0	0	0	0	0	2	0	0	0
Oesophageal spasm	0	0	8	0	0	0	7	0	15	0	0	0
Oesophageal ulcer	0	0	1	0	0	0	0	0	1	0	0	0
Oesophageal varices haemorrhage	0	0	2	0	0	0	0	0	2	0	0	0
Oesophagitis	1	0	25	0	3	0	16	0	41	0	0	0
Oesophagitis ulcerative	0	0	1	0	0	0	0	0	1	0	0	0
Omental infarction	0	0	3	0	0	0	4	0	7	0	0	0
Oral blood blister	1	0	33	0	3	0	38	0	71	0	0	0
Oral discharge	0	0	1	0	0	0	1	0	2	0	0	0
Oral discomfort	5	0	100	0	15	0	184	0	284	0	0	0
Oral disorder	2	0	22	0	5	0	41	0	63	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Oral dysaesthesia	1	0	5	0	1	0	13	0	18	0	0	0
Oral lichen planus	2	0	17	0	0	0	12	0	29	0	0	0
Oral lichenoid reaction	0	0	1	0	0	0	1	0	2	0	0	0
Oral macule	0	0	0	0	0	0	1	0	1	0	0	0
Oral mucosa erosion	0	0	2	0	0	0	4	0	6	0	0	0
Oral mucosa haematoma	0	0	0	0	0	0	3	0	3	0	0	0
Oral mucosal blistering	2	0	31	0	26	0	136	0	167	0	0	0
Oral mucosal discolouration	0	0	1	0	0	0	3	0	4	0	0	0
Oral mucosal eruption	0	0	16	0	5	0	34	0	50	0	0	0
Oral mucosal erythema	0	0	5	0	2	0	27	0	32	0	0	0
Oral mucosal exfoliation	0	0	7	0	0	0	14	0	21	0	0	0
Oral mucosal roughening	0	0	1	0	1	0	5	0	6	0	0	0
Oral pain	3	0	263	0	25	0	302	0	565	0	0	0
Oral papule	0	0	1	0	0	0	2	0	3	0	0	0
Oral pruritus	0	0	16	0	2	0	44	0	60	0	0	0
Oral purpura	0	0	2	0	0	0	1	0	3	0	0	0
Palatal disorder	0	0	2	0	0	0	14	0	16	0	0	0
Palatal oedema	0	0	17	0	0	0	8	0	25	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Palatal swelling	0	0	15	0	2	0	15	0	30	0	0	0
Palatal ulcer	0	0	0	0	0	0	2	0	2	0	0	0
Pancreatic cyst	0	0	2	0	1	0	2	0	4	0	0	0
Pancreatic disorder	0	0	1	0	2	0	5	0	6	0	0	0
Pancreatic enlargement	0	0	2	0	0	0	0	0	2	0	0	0
Pancreatic failure	0	0	3	0	0	0	0	0	3	0	0	0
Pancreatic haemorrhage	0	0	2	0	0	0	0	0	2	0	0	0
Pancreatic infarction	0	0	1	0	0	0	0	0	1	0	0	0
Pancreatic mass	0	0	2	0	0	0	0	0	2	0	0	0
Pancreatic pseudocyst	0	0	1	0	0	0	0	0	1	0	0	0
Pancreatic steatosis	0	0	2	0	0	0	1	0	3	0	0	0
Pancreatitis	4	0	114	0	0	0	0	0	114	0	0	0
Pancreatitis acute	3	0	56	0	0	0	0	0	56	0	0	0
Pancreatitis chronic	1	0	2	0	0	0	0	0	2	0	0	0
Pancreatitis haemorrhagic	0	0	3	0	0	0	0	0	3	0	0	0
Pancreatitis necrotising	0	0	3	0	0	0	0	0	3	0	0	0
Pancreatitis relapsing	0	0	1	0	0	0	0	0	1	0	0	0
Paraesthesia oral	10	0	647	0	65	0	1269	0	1916	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Parotid duct obstruction	0	0	0	0	0	0	1	0	1	0	0	0
Parotid gland enlargement	1	0	10	0	2	0	24	0	34	0	0	0
Peptic ulcer	1	0	6	0	0	0	0	0	6	0	0	0
Peptic ulcer haemorrhage	1	0	10	0	0	0	0	0	10	0	0	0
Periodontal disease	0	0	0	0	0	0	1	0	1	0	0	0
Peristalsis visible	0	0	0	0	0	0	1	0	1	0	0	0
Peritoneal disorder	0	0	0	0	0	0	1	0	1	0	0	0
Pigmentation lip	0	0	0	0	0	0	3	0	3	0	0	0
Plicated tongue	0	0	1	0	0	0	9	0	10	0	0	0
Pneumatosis intestinalis	0	0	1	0	0	0	0	0	1	0	0	0
Pneumoperitoneum	0	0	1	0	0	0	0	0	1	0	0	0
Poor dental condition	1	0	1	0	0	0	0	0	1	0	0	0
Portal hypertensive gastropathy	2	0	2	0	0	0	1	0	3	0	0	0
Pouchitis	1	0	1	0	0	0	1	0	2	0	0	0
Proctalgia	0	0	30	0	0	0	25	0	55	0	0	0
Proctitis	0	0	6	0	0	0	1	0	7	0	0	0
Pulpless tooth	0	0	0	0	0	0	1	0	1	0	0	0
Rectal discharge	0	0	2	0	0	0	0	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Rectal fissure	0	0	1	0	0	0	0	0	1	0	0	0
Rectal haemorrhage	9	0	184	0	5	0	123	0	307	0	0	0
Rectal prolapse	0	0	0	0	0	0	1	0	1	0	0	0
Rectal spasm	0	0	2	0	0	0	2	0	4	0	0	0
Rectal tenesmus	0	0	4	0	0	0	6	0	10	0	0	0
Rectal ulcer	0	0	1	0	0	0	0	0	1	0	0	0
Reflux gastritis	1	0	20	0	2	0	18	0	38	0	0	0
Regurgitation	1	0	5	0	2	0	10	0	15	0	0	0
Retching	9	0	296	0	17	0	452	0	748	0	0	0
Retroperitoneal effusion	0	0	0	0	1	0	1	0	1	0	0	0
Retroperitoneal fibrosis	0	0	1	0	0	0	0	0	1	0	0	0
Retroperitoneal haematoma	0	0	8	0	0	0	0	0	8	0	0	0
Retroperitoneal haemorrhage	1	0	7	0	0	0	0	0	7	0	0	0
Saliva altered	0	0	8	0	2	0	17	0	25	0	0	0
Saliva discolouration	0	0	0	0	0	0	3	0	3	0	0	0
Salivary gland calculus	0	0	3	0	0	0	4	0	7	0	0	0
Salivary gland cyst	0	0	1	0	0	0	0	0	1	0	0	0
Salivary gland disorder	0	0	2	0	0	0	3	0	5	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Salivary gland enlargement	2	0	9	0	1	0	11	0	20	0	0	0
Salivary gland mass	0	0	1	0	0	0	2	0	3	0	0	0
Salivary gland mucocoele	0	0	0	0	0	0	1	0	1	0	0	0
Salivary gland pain	1	0	14	0	3	0	13	0	27	0	0	0
Salivary hypersecretion	3	0	84	0	10	0	97	0	181	0	0	0
Scalloped tongue	0	0	2	0	0	0	5	0	7	0	0	0
Short-bowel syndrome	0	0	0	0	0	0	1	0	1	0	0	0
Small intestinal haemorrhage	1	0	27	0	0	0	4	0	31	0	0	0
Small intestinal obstruction	0	0	4	0	0	0	0	0	4	0	0	0
Small intestinal stenosis	1	0	1	0	0	0	0	0	1	0	0	0
Splanchnic hypoperfusion	0	0	1	0	0	0	0	0	1	0	0	0
Steatorrhoea	0	0	2	0	0	0	2	0	4	0	0	0
Stiff tongue	0	0	6	0	0	0	3	0	9	0	0	0
Stomach mass	1	0	3	0	0	0	0	0	3	0	0	0
Stomatitis	3	0	79	0	15	0	200	0	279	0	0	0
Stomatitis necrotising	0	0	1	0	0	0	0	0	1	0	0	0
Strawberry tongue	0	0	0	0	0	0	1	0	1	0	0	0
Subileus	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Submaxillary gland enlargement	0	0	1	0	1	0	3	0	4	0	0	0
Superior mesenteric artery syndrome	0	0	1	0	0	0	0	0	1	0	0	0
Swollen tongue	7	0	537	0	36	0	584	0	1121	0	0	0
Teeth brittle	0	0	0	0	0	0	4	0	4	0	0	0
Teething	0	0	18	0	0	0	16	0	34	0	0	0
Terminal ileitis	0	0	1	0	0	0	1	0	2	0	0	0
Thrombosis mesenteric vessel	2	0	22	0	0	0	0	0	22	0	0	0
Tongue atrophy	0	0	0	0	0	0	1	0	1	0	0	0
Tongue blistering	0	0	18	0	5	0	39	0	57	0	0	0
Tongue coated	1	0	29	0	4	0	40	0	69	0	0	0
Tongue cyst	0	0	1	0	0	0	5	0	6	0	0	0
Tongue discolouration	1	0	27	0	3	0	53	0	80	0	0	0
Tongue discomfort	1	0	49	0	16	0	137	0	186	0	0	0
Tongue disorder	0	0	30	0	3	0	52	0	82	0	0	0
Tongue dry	0	0	16	0	6	0	26	0	42	0	0	0
Tongue eruption	0	0	7	0	4	0	24	0	31	0	0	0
Tongue erythema	0	0	7	0	2	0	20	0	27	0	0	0
Tongue exfoliation	0	0	3	0	0	0	4	0	7	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Tongue geographic	0	0	3	0	0	0	9	0	12	0	0	0
Tongue haematoma	0	0	0	0	0	0	8	0	8	0	0	0
Tongue haemorrhage	0	0	4	0	1	0	7	0	11	0	0	0
Tongue induration	0	0	0	0	0	0	1	0	1	0	0	0
Tongue movement disturbance	1	0	10	0	1	0	10	0	20	0	0	0
Tongue oedema	7	0	132	0	0	0	0	0	132	0	0	0
Tongue polyp	0	0	0	0	0	0	2	0	2	0	0	0
Tongue pruritus	2	0	7	0	0	0	24	0	31	0	0	0
Tongue rough	0	0	4	0	2	0	11	0	15	0	0	0
Tongue spasm	0	0	0	0	0	0	12	0	12	0	0	0
Tongue ulceration	0	0	19	0	4	0	39	0	58	0	0	0
Tooth deposit	0	0	0	0	0	0	2	0	2	0	0	0
Tooth discolouration	0	0	12	0	2	0	11	0	23	0	0	0
Tooth disorder	4	0	8	0	1	0	11	0	19	0	0	0
Tooth erosion	0	0	1	0	0	0	0	0	1	0	0	0
Tooth impacted	0	0	0	0	0	0	1	0	1	0	0	0
Tooth loss	1	0	13	0	5	1	14	2	27	2	0	0
Tooth malformation	0	0	0	0	1	0	1	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Tooth socket haemorrhage	0	0	3	0	0	0	4	0	7	0	0	0
Toothache	9	0	303	0	75	0	592	0	895	0	0	0
Trichoglossia	0	0	2	0	0	0	6	0	8	0	0	0
Truncus coeliacus thrombosis	0	0	3	0	0	0	0	0	3	0	0	0
Umbilical hernia	1	0	1	0	0	0	0	0	1	0	0	0
Upper gastrointestinal haemorrhage	1	0	17	0	0	0	0	0	17	0	0	0
Uvulitis	0	0	3	0	0	0	5	0	8	0	0	0
Varices oesophageal	1	0	6	0	0	0	2	0	8	0	0	0
Vasculitis gastrointestinal	0	0	1	0	0	0	0	0	1	0	0	0
Visceral venous thrombosis	5	0	38	0	0	0	3	0	41	0	2	3
Volvulus	0	0	3	0	0	0	0	0	3	0	0	0
Vomiting	235	0	11965	1	1977	0	20477	1	32442	2	1	6
Vomiting projectile	0	0	145	0	8	0	57	0	202	0	0	0
Hepatobiliary disorders	**100**	**0**	**1239**	**0**	**42**	**0**	**325**	**1**	**1564**	**1**	**26**	**34**
Acute hepatic failure	0	0	13	0	0	0	0	0	13	0	0	0
Acute on chronic liver failure	1	0	1	0	0	0	0	0	1	0	0	0
Acute yellow liver atrophy	0	0	1	0	0	0	0	0	1	0	0	0
Allergic hepatitis	0	0	0	0	0	0	1	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Autoimmune hepatitis	13	0	60	0	2	0	8	0	68	0	1	1
Bile duct stenosis	0	0	1	0	0	0	0	0	1	0	0	0
Bile duct stone	0	0	0	0	0	0	1	0	1	0	0	0
Biliary cirrhosis	0	0	0	0	0	0	1	0	1	0	0	0
Biliary colic	3	0	36	0	3	0	18	0	54	0	0	0
Biliary cyst	0	0	0	0	0	0	1	0	1	0	0	0
Biliary dilatation	1	0	1	0	0	0	0	0	1	0	0	0
Biliary ischaemia	0	0	1	0	0	0	0	0	1	0	0	0
Biliary obstruction	0	0	2	0	0	0	0	0	2	0	0	0
Biliary tract disorder	0	0	1	0	1	0	2	0	3	0	0	0
Budd-Chiari syndrome	0	0	5	0	0	0	0	0	5	0	0	0
Cholangitis	0	0	8	0	0	0	0	0	8	0	0	0
Cholangitis sclerosing	2	0	4	0	0	0	0	0	4	0	0	0
Cholecystitis	3	0	33	0	1	0	12	0	45	0	1	1
Cholecystitis acute	0	0	14	0	0	0	0	0	14	0	0	1
Cholelithiasis	7	0	32	0	2	0	13	1	45	1	0	0
Cholestasis	0	0	17	0	0	0	6	0	23	0	0	0
Cholestasis of pregnancy	1	0	2	0	0	0	0	0	2	0	0	1

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Cholestatic liver injury	0	0	0	0	0	0	1	0	1	0	0	0
Cirrhosis alcoholic	1	0	1	0	0	0	0	0	1	0	0	0
Congestive hepatopathy	0	0	1	0	0	0	0	0	1	0	0	0
Diabetic hepatopathy	0	0	1	0	0	0	0	0	1	0	0	0
Dilatation intrahepatic duct acquired	1	0	1	0	0	0	0	0	1	0	0	0
Drug-induced liver injury	2	0	9	0	0	0	0	0	9	0	0	0
Flood syndrome	0	0	0	0	0	0	1	0	1	0	0	0
Gallbladder disorder	1	0	8	0	0	0	6	0	14	0	0	0
Gallbladder enlargement	0	0	0	0	0	0	1	0	1	0	0	0
Gallbladder haematoma	0	0	0	0	0	0	1	0	1	0	0	0
Gallbladder mass	0	0	2	0	0	0	0	0	2	0	0	0
Gallbladder necrosis	0	0	1	0	0	0	0	0	1	0	0	0
Gallbladder oedema	0	0	1	0	0	0	0	0	1	0	0	0
Gallbladder polyp	0	0	1	0	0	0	0	0	1	0	0	0
Gallbladder rupture	0	0	1	0	0	0	0	0	1	0	0	0
Hepatic artery embolism	0	0	1	0	0	0	0	0	1	0	0	0
Hepatic artery occlusion	0	0	2	0	0	0	0	0	2	0	0	0
Hepatic artery thrombosis	0	0	5	0	0	0	0	0	5	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Hepatic cirrhosis	3	0	21	0	1	0	4	0	25	0	1	1
Hepatic cyst	1	0	4	0	0	0	1	0	5	0	0	0
Hepatic cytolysis	2	0	21	0	0	0	11	0	32	0	0	0
Hepatic failure	3	0	38	0	0	0	0	0	38	0	0	0
Hepatic fibrosis	0	0	0	0	1	0	1	0	1	0	0	0
Hepatic function abnormal	1	0	19	0	3	0	14	0	33	0	0	0
Hepatic haematoma	0	0	2	0	0	0	0	0	2	0	0	0
Hepatic haemorrhage	0	0	3	0	0	0	0	0	3	0	0	0
Hepatic infarction	1	0	8	0	0	0	0	0	8	0	0	0
Hepatic ischaemia	0	0	1	0	0	0	0	0	1	0	0	0
Hepatic lesion	0	0	6	0	1	0	3	0	9	0	0	0
Hepatic mass	0	0	1	0	0	0	1	0	2	0	0	0
Hepatic necrosis	0	0	2	0	0	0	0	0	2	0	0	0
Hepatic pain	2	0	77	0	8	0	71	0	148	0	0	0
Hepatic perfusion disorder	0	0	2	0	0	0	1	0	3	0	0	0
Hepatic steatosis	6	0	24	0	3	0	15	0	39	0	0	0
Hepatic vascular thrombosis	1	0	9	0	0	0	3	0	12	0	0	0
Hepatic vein embolism	0	0	0	0	0	0	1	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Hepatic vein occlusion	0	0	1	0	0	0	0	0	1	0	0	0
Hepatic vein thrombosis	1	0	45	0	0	0	2	0	47	0	0	0
Hepatitis	1	0	74	0	0	0	0	0	74	0	0	0
Hepatitis acute	3	0	26	0	0	0	0	0	26	0	13	13
Hepatitis cholestatic	0	0	1	0	0	0	0	0	1	0	0	0
Hepatitis fulminant	2	0	2	0	0	0	0	0	2	0	0	0
Hepatocellular injury	0	0	2	0	0	0	2	0	4	0	0	0
Hepatomegaly	2	0	12	0	0	0	11	0	23	0	0	0
Hepatorenal failure	0	0	1	0	0	0	0	0	1	0	0	0
Hepatorenal syndrome	0	0	2	0	0	0	0	0	2	0	0	0
Hepatosplenomegaly	0	0	1	0	1	0	1	0	2	0	0	0
Hepatotoxicity	0	0	2	0	0	0	0	0	2	0	0	0
Hyperbilirubinaemia	0	0	3	0	0	0	3	0	6	0	0	0
Hypertransaminasaemia	0	0	14	0	0	0	9	0	23	0	0	0
Immune-mediated hepatitis	0	0	4	0	0	0	0	0	4	0	0	0
Ischaemic hepatitis	0	0	3	0	0	0	0	0	3	0	0	0
Jaundice	9	0	87	0	3	0	30	0	117	0	0	0
Jaundice cholestatic	0	0	7	0	0	0	6	0	13	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Liver disorder	2	0	36	0	9	0	30	0	66	0	0	0
Liver injury	0	0	39	0	1	0	8	0	47	0	0	0
Liver tenderness	0	0	6	0	1	0	8	0	14	0	0	0
Mixed liver injury	0	0	1	0	0	0	0	0	1	0	0	0
Non-alcoholic fatty liver	0	0	1	0	0	0	0	0	1	0	0	0
Non-alcoholic steatohepatitis	0	0	1	0	0	0	0	0	1	0	0	0
Ocular icterus	0	0	8	0	1	0	10	0	18	0	0	0
Peliosis hepatis	0	0	0	0	0	0	1	0	1	0	0	0
Perihepatic discomfort	0	0	2	0	0	0	1	0	3	0	0	0
Porcelain gallbladder	1	0	1	0	0	0	0	0	1	0	0	0
Portal hypertension	0	0	5	0	0	0	2	0	7	0	0	0
Portal shunt	0	0	1	0	0	0	0	0	1	0	0	0
Portal vein cavernous transformation	0	0	1	0	0	0	0	0	1	0	0	0
Portal vein embolism	1	0	2	0	0	0	0	0	2	0	0	0
Portal vein occlusion	0	0	3	0	0	0	0	0	3	0	0	0
Portal vein phlebitis	0	0	2	0	0	0	0	0	2	0	0	0
Portal vein thrombosis	20	0	304	0	0	0	0	0	304	0	10	16
Portosplenomesenteric venous thrombosis	2	0	26	0	0	0	2	0	28	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Reye's syndrome	0	0	1	0	0	0	0	0	1	0	0	0
Sphincter of Oddi dysfunction	0	0	3	0	0	0	0	0	3	0	0	0
Subacute hepatic failure	0	0	3	0	0	0	0	0	3	0	0	0
Venoocclusive liver disease	0	0	1	0	0	0	0	0	1	0	0	0
Skin and subcutaneous tissue disorders	**1082**	**0**	**40263**	**1**	**6905**	**1**	**75429**	**11**	**115692**	**12**	**20**	**29**
Acanthosis	0	0	1	0	0	0	0	0	1	0	0	0
Acne	3	0	106	0	17	0	210	0	316	0	0	0
Acne cystic	0	0	7	0	0	0	6	0	13	0	0	0
Acne varioliformis	0	0	0	0	0	0	1	0	1	0	0	0
Actinic keratosis	1	0	3	0	2	0	3	0	6	0	0	0
Acute cutaneous lupus erythematosus	0	0	1	0	0	0	0	0	1	0	0	0
Acute febrile neutrophilic dermatosis	0	0	10	0	3	0	6	0	16	0	0	0
Acute generalised exanthematous pustulosis	0	0	10	0	0	0	0	0	10	0	0	0
Alopecia	28	0	427	0	84	0	667	0	1094	0	0	0
Alopecia areata	4	0	45	0	7	0	66	0	111	0	0	0
Alopecia scarring	0	0	1	0	0	0	2	0	3	0	0	0
Alopecia totalis	1	0	5	0	1	0	2	0	7	0	0	0
Alopecia universalis	0	0	3	0	1	0	3	0	6	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Androgenetic alopecia	0	0	0	0	0	0	3	0	3	0	0	0
Angiodermatitis	0	0	2	0	0	0	3	0	5	0	0	0
Angioedema	57	0	1004	0	0	0	0	0	1004	0	4	4
Angiokeratoma	0	0	0	0	0	0	1	0	1	0	0	0
Anhidrosis	1	0	3	0	0	0	1	0	4	0	0	0
Annular elastolytic giant cell granuloma	0	0	0	0	1	0	1	0	1	0	0	0
Anonychia	0	0	0	0	0	0	1	0	1	0	0	0
Aquagenic pruritus	0	0	0	0	0	0	1	0	1	0	0	0
Autoimmune blistering disease	0	0	4	0	0	0	0	0	4	0	0	0
Autoimmune dermatitis	0	0	2	0	0	0	1	0	3	0	0	0
Blister	11	0	474	0	59	0	649	0	1123	0	0	0
Blister rupture	0	0	5	0	0	0	2	0	7	0	0	0
Blood blister	0	0	73	0	9	0	138	0	211	0	0	0
Brachioradial pruritus	0	0	0	0	1	0	1	0	1	0	0	0
Bromhidrosis	0	0	0	0	0	0	1	0	1	0	0	0
Bullous haemorrhagic dermatosis	0	0	3	0	0	0	1	0	4	0	0	0
Butterfly rash	1	0	11	0	1	0	10	0	21	0	0	0
Cafe au lait spots	0	0	0	0	0	0	1	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Capillaritis	0	0	4	0	3	0	10	0	14	0	0	0
Cellulite	1	0	2	0	18	0	43	0	45	0	0	0
Chloasma	1	0	1	0	1	0	5	0	6	0	0	0
Chronic cutaneous lupus erythematosus	0	0	3	0	1	0	5	0	8	0	0	0
Chronic pigmented purpura	0	0	1	0	0	0	4	0	5	0	0	0
Chronic spontaneous urticaria	4	0	12	0	3	0	10	0	22	0	0	0
Circumoral oedema	0	0	6	0	0	0	4	0	10	0	0	0
Circumoral swelling	0	0	2	0	0	0	7	0	9	0	0	0
Cold sweat	18	0	1520	0	179	0	1380	0	2900	0	0	0
Cold urticaria	1	0	7	0	5	0	23	0	30	0	0	0
Cullen's sign	0	0	0	0	0	0	1	0	1	0	0	0
Cutaneous lupus erythematosus	0	0	0	0	2	0	4	0	4	0	0	0
Cutaneous sarcoidosis	1	0	2	0	0	0	1	0	3	0	0	0
Cutaneous symptom	1	0	5	0	1	0	19	0	24	0	0	0
Cutaneous vasculitis	14	0	125	0	0	0	0	0	125	0	0	0
Dandruff	2	0	4	0	2	0	7	0	11	0	0	0
Decubitus ulcer	2	0	10	0	2	0	9	0	19	0	0	0
Dermal absorption impaired	0	0	0	0	0	0	1	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Dermal cyst	0	0	19	0	1	0	15	0	34	0	0	0
Dermatitis	5	0	146	0	16	0	238	0	384	0	0	0
Dermatitis acneiform	0	0	11	0	2	0	40	0	51	0	0	0
Dermatitis allergic	3	0	244	0	38	0	442	0	686	0	0	0
Dermatitis atopic	0	0	35	0	7	0	50	0	85	0	0	0
Dermatitis bullous	8	0	120	0	0	0	0	0	120	0	0	0
Dermatitis contact	2	0	25	0	0	0	21	0	46	0	0	0
Dermatitis diaper	0	0	1	0	0	0	3	0	4	0	0	0
Dermatitis exfoliative	0	0	4	0	0	0	0	0	4	0	0	0
Dermatitis exfoliative generalised	5	0	28	0	0	0	0	0	28	0	0	0
Dermatitis herpetiformis	0	0	3	0	0	0	1	0	4	0	0	0
Dermatitis papillaris capillitii	0	0	0	0	0	0	1	0	1	0	0	0
Dermatitis psoriasiform	0	0	6	0	1	0	9	0	15	0	0	0
Dermatomyositis	4	0	26	0	2	0	3	0	29	0	2	2
Dermatosis	1	0	6	0	2	0	12	0	18	0	0	0
Diabetic foot	1	0	8	0	1	0	2	0	10	0	0	0
Diabetic ulcer	0	0	1	0	0	0	1	0	2	0	0	0
Diffuse alopecia	1	0	6	0	3	0	14	0	20	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Drug eruption	1	0	29	0	1	0	41	1	70	1	1	1
Drug reaction with eosinophilia and systemic symptoms	1	0	29	0	0	0	0	0	29	0	0	0
Dry skin	11	0	303	0	33	0	390	0	693	0	0	0
Dyshidrotic eczema	0	0	19	0	4	0	19	0	38	0	0	0
Ecchymosis	3	0	125	0	21	0	336	0	461	0	0	0
Eczema	16	0	287	0	68	0	501	0	788	0	0	0
Eczema asteatotic	0	0	13	0	1	0	12	0	25	0	0	0
Eczema nummular	0	0	4	0	1	0	14	0	18	0	0	0
Eczema vesicular	0	0	0	0	0	0	1	0	1	0	0	0
Eczema weeping	0	0	3	0	0	0	2	0	5	0	0	0
Eosinophilic cellulitis	1	0	1	0	0	0	0	0	1	0	0	0
Ephelides	0	0	0	0	0	0	4	0	4	0	0	0
Epidermal necrosis	1	0	1	0	0	0	0	0	1	0	0	0
Erythema	57	0	2267	0	768	0	7770	0	10037	0	0	1
Erythema ab igne	0	0	0	0	0	0	2	0	2	0	0	0
Erythema annulare	0	0	1	0	0	0	6	0	7	0	0	0
Erythema dyschromicum perstans	0	0	1	0	0	0	0	0	1	0	0	0
Erythema elevatum diutinum	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Erythema multiforme	15	0	122	0	0	0	0	0	122	0	1	1
Erythema nodosum	2	0	45	0	17	0	67	0	112	0	0	0
Erythematotelangiectatic rosacea	0	0	2	0	0	0	1	0	3	0	0	0
Erythrodermic atopic dermatitis	0	0	0	0	0	0	1	0	1	0	0	0
Erythrodermic psoriasis	0	0	7	0	0	0	1	0	8	0	0	0
Erythrosis	0	0	0	0	1	0	4	0	4	0	0	0
Excessive granulation tissue	0	0	0	0	1	0	1	0	1	0	0	0
Excessive skin	0	0	0	0	1	0	1	0	1	0	0	0
Exfoliative rash	0	0	15	0	2	0	16	0	31	0	0	0
Facial wasting	0	0	0	0	1	0	2	0	2	0	0	0
Fixed eruption	1	0	7	0	3	0	14	0	21	0	0	0
Generalised bullous fixed drug eruption	0	0	2	0	0	0	0	0	2	0	0	0
Granuloma annulare	0	0	6	0	3	0	22	0	28	0	0	0
Granuloma skin	0	0	0	0	1	0	3	0	3	0	0	0
Granulomatous rosacea	0	0	0	0	0	0	1	0	1	0	0	0
Guttate psoriasis	2	0	20	0	1	0	25	0	45	0	0	0
Haemangioma-thrombocytopenia syndrome	0	0	4	0	0	0	0	0	4	0	0	0
Haemorrhage subcutaneous	6	0	35	0	6	0	63	0	98	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Haemorrhage subepidermal	0	0	1	0	0	0	0	0	1	0	0	0
Haemorrhagic urticaria	0	0	0	0	0	0	1	0	1	0	0	0
Haemosiderin stain	1	0	1	0	0	0	2	0	3	0	0	0
Hair colour changes	0	0	9	0	2	0	17	0	26	0	0	0
Hair disorder	0	0	0	0	1	0	10	0	10	0	0	0
Hair growth abnormal	0	0	4	0	0	0	8	0	12	0	0	0
Hair growth rate abnormal	0	0	0	0	1	0	1	0	1	0	0	0
Hair texture abnormal	0	0	9	0	1	0	15	0	24	0	0	0
Hand dermatitis	0	0	3	0	1	0	17	0	20	0	0	0
Henoch-Schonlein purpura	4	0	27	0	4	0	20	0	47	0	0	0
Hidradenitis	1	0	5	0	2	0	10	0	15	0	0	0
Hirsutism	0	0	0	0	0	0	1	0	1	0	0	0
Hyperhidrosis	109	0	8449	0	1147	0	10141	0	18590	0	0	0
Hyperkeratosis	1	0	4	0	0	0	2	0	6	0	0	0
Hypersensitivity vasculitis	3	0	19	0	0	0	0	0	19	0	0	0
Hypertrichosis	0	0	3	0	1	0	3	0	6	0	0	0
Hypertrophic scar	0	0	0	0	0	0	1	0	1	0	0	0
Hypohidrosis	0	0	3	0	0	0	8	0	11	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Hypotrichosis	0	0	1	0	0	0	2	0	3	0	0	0
Ichthyosis acquired	0	0	0	0	0	0	1	0	1	0	0	0
Idiopathic angioedema	0	0	3	0	0	0	0	0	3	0	0	0
Idiopathic urticaria	0	0	8	0	1	0	6	0	14	0	0	0
Ingrowing nail	2	0	2	0	0	0	2	1	4	1	0	0
Ingrown hair	0	0	0	0	0	0	1	0	1	0	0	0
Intertrigo	0	0	2	0	0	0	2	0	4	0	0	0
Ischaemic skin ulcer	0	0	1	0	0	0	0	0	1	0	0	0
Itching scar	0	0	3	0	1	0	4	0	7	0	0	0
Keloid scar	0	0	1	0	0	0	3	0	4	0	0	0
Keratosis pilaris	0	0	0	0	0	0	3	0	3	0	0	0
Leukoplakia	0	0	1	0	0	0	0	0	1	0	0	0
Lichen planopilaris	0	0	2	0	2	0	3	0	5	0	0	0
Lichen planus	5	0	45	0	16	0	69	0	114	0	0	0
Lichen sclerosus	2	0	11	0	1	0	9	0	20	0	0	0
Lichen striatus	0	0	1	0	0	0	0	0	1	0	0	0
Lichenoid keratosis	0	0	4	0	1	0	5	0	9	0	0	0
Linear IgA disease	0	0	2	0	0	0	2	0	4	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Lipoatrophy	0	0	2	0	1	0	2	0	4	0	0	0
Lipodystrophy acquired	0	0	0	0	0	0	2	0	2	0	0	0
Lipohypertrophy	0	0	0	0	0	0	3	0	3	0	0	0
Livedo reticularis	3	0	74	0	9	0	93	0	167	0	0	0
Lividity	1	0	16	0	0	0	11	0	27	0	0	0
Lymphomatoid papulosis	0	0	1	0	0	0	2	0	3	0	0	0
Macule	0	0	9	0	4	0	56	0	65	0	0	0
Madarosis	0	0	4	0	1	0	14	0	18	0	0	0
Mechanical acne	0	0	1	0	0	0	0	0	1	0	0	0
Mechanical urticaria	0	0	10	0	0	0	24	0	34	0	0	0
Melanoderma	0	0	2	0	1	0	2	0	4	0	0	0
Miliaria	2	0	131	0	3	0	124	0	255	0	0	0
Mucocutaneous haemorrhage	0	0	3	0	0	0	1	0	4	0	0	0
Myxoid cyst	0	0	1	0	0	0	1	0	2	0	0	0
Nail bed bleeding	0	0	0	0	1	0	6	0	6	0	0	0
Nail bed disorder	0	0	2	0	0	0	0	0	2	0	0	0
Nail bed inflammation	0	0	0	0	0	0	4	0	4	0	0	0
Nail bed tenderness	0	0	1	0	1	0	3	0	4	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Nail cuticle fissure	0	0	0	0	0	0	1	0	1	0	0	0
Nail discolouration	0	0	17	0	1	0	44	0	61	0	0	0
Nail disorder	0	0	6	0	0	0	8	0	14	0	0	0
Nail dystrophy	0	0	0	0	0	0	1	0	1	0	0	0
Nail growth abnormal	0	0	3	0	1	0	3	0	6	0	0	0
Nail hypertrophy	0	0	1	0	0	0	0	0	1	0	0	0
Nail necrosis	0	0	1	0	0	0	0	0	1	0	0	0
Nail pigmentation	0	0	0	0	0	0	2	0	2	0	0	0
Nail pitting	0	0	1	0	0	0	1	0	2	0	0	0
Nail psoriasis	1	0	2	0	0	0	3	0	5	0	0	0
Nail ridging	0	0	4	0	0	0	9	0	13	0	0	0
Necrolytic acral erythema	1	0	1	0	0	0	0	0	1	0	0	0
Needle track marks	0	0	2	0	0	0	4	0	6	0	0	0
Neurodermatitis	2	0	9	0	8	0	39	0	48	0	0	0
Neuropathic pruritus	0	0	0	0	1	0	1	0	1	0	0	0
Neutrophilic dermatosis	0	0	2	0	0	0	2	0	4	0	0	0
Night sweats	30	0	1625	0	126	0	1343	0	2968	0	0	0
Nikolsky's sign	0	0	0	0	0	0	1	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Nodular rash	0	0	1	0	1	0	5	0	6	0	0	0
Nodular vasculitis	1	0	2	0	0	0	0	0	2	0	0	0
Oedema blister	0	0	1	0	0	0	0	0	1	0	0	0
Onychalgia	0	0	6	0	0	0	13	0	19	0	0	0
Onychoclasis	2	0	12	0	1	0	6	0	18	0	0	0
Onycholysis	0	0	3	0	0	0	2	0	5	0	0	0
Onychomadesis	0	0	4	0	1	0	6	0	10	0	0	0
PASH syndrome	0	0	0	0	0	0	1	0	1	0	0	0
Pain of skin	11	0	828	0	224	0	1205	0	2033	0	0	0
Palmar erythema	0	0	6	0	2	0	18	0	24	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	1	0	3	0	2	0	9	0	12	0	0	0
Palmoplantar keratoderma	0	0	1	0	0	0	0	0	1	0	0	0
Palmoplantar pustulosis	0	0	6	0	3	0	4	0	10	0	0	0
Palpable purpura	0	0	4	0	0	0	5	0	9	0	0	0
Panniculitis	2	0	6	0	0	0	6	0	12	0	0	0
Panniculitis lobular	0	0	0	0	0	0	1	0	1	0	0	0
Papule	1	0	72	0	9	0	142	0	214	0	0	0
Papulopustular rosacea	0	0	1	0	0	0	1	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Parakeratosis	0	0	1	0	1	0	1	0	2	0	0	0
Paraneoplastic dermatomyositis	1	0	1	0	0	0	0	0	1	0	0	0
Parapsoriasis	0	0	1	0	0	0	7	0	8	0	0	0
Pemphigoid	11	0	70	0	0	0	0	0	70	0	2	3
Pemphigus	7	0	31	0	0	0	0	0	31	0	0	0
Perioral dermatitis	0	0	5	0	2	0	11	0	16	0	0	0
Pernio-like erythema	3	0	5	0	1	0	6	0	11	0	0	0
Petechiae	21	0	609	0	155	0	1496	0	2105	0	0	2
Photodermatosis	0	0	0	0	0	0	3	0	3	0	0	0
Photosensitivity reaction	1	0	156	0	28	0	268	0	424	0	0	0
Pigmentation disorder	0	0	18	0	9	0	71	0	89	0	0	0
Piloerection	3	0	92	0	14	0	85	0	177	0	0	0
Pityriasis	0	0	7	0	1	0	12	0	19	0	0	0
Pityriasis lichenoides et varioliformis acuta	0	0	1	0	0	0	2	0	3	0	0	0
Pityriasis rosea	1	0	35	0	5	0	93	0	128	0	0	0
Pityriasis rubra pilaris	0	0	4	0	6	0	10	0	14	0	0	0
Plantar erythema	0	0	2	0	0	0	4	0	6	0	0	0
Polymorphic eruption of pregnancy	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Polymorphic light eruption	0	0	2	0	0	0	4	0	6	0	0	0
Progressive facial hemiatrophy	0	0	1	0	0	0	0	0	1	0	0	0
Prurigo	0	0	1	0	0	0	10	0	11	0	0	0
Pruritus	86	0	5132	0	941	0	12787	2	17919	2	0	0
Pruritus allergic	0	0	1	0	1	0	14	0	15	0	0	0
Pseudofolliculitis	0	0	0	0	0	0	4	0	4	0	0	0
Psoriasis	28	0	269	0	51	0	300	0	569	0	0	1
Purpura	10	0	205	0	15	0	266	0	471	0	0	0
Pustular psoriasis	0	0	10	0	2	0	5	0	15	0	0	0
Pyoderma gangrenosum	1	0	5	0	0	0	2	0	7	0	0	0
Rash	129	0	5618	0	946	1	14603	1	20221	1	2	3
Rash erythematous	15	0	1107	0	113	0	2038	0	3145	0	1	1
Rash follicular	0	0	2	0	2	0	6	0	8	0	0	0
Rash macular	17	0	514	0	135	0	1509	0	2023	0	0	0
Rash maculo-papular	2	0	71	0	11	0	167	0	238	0	0	0
Rash maculovesicular	0	0	0	0	0	0	2	0	2	0	0	0
Rash morbilliform	3	0	39	0	7	0	54	0	93	0	0	0
Rash papular	4	0	293	0	15	0	545	0	838	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Rash pruritic	20	0	1088	0	150	0	2289	0	3377	0	0	1
Rash rubelliform	1	0	4	0	1	0	4	0	8	0	0	0
Rash scarlatiniform	0	0	2	0	0	0	2	0	4	0	0	0
Rash vesicular	3	0	80	0	10	0	240	0	320	0	0	0
Rebound eczema	0	0	0	0	0	0	1	0	1	0	0	0
Rebound psoriasis	0	0	0	0	0	0	1	0	1	0	0	0
Rosacea	2	0	37	0	3	0	40	0	77	0	0	0
Scab	1	0	17	0	1	0	43	0	60	0	0	0
Scar discomfort	0	0	0	0	1	0	4	1	4	1	0	0
Scar pain	0	0	15	0	1	0	18	1	33	1	0	0
Scleroedema	2	0	2	0	0	0	0	0	2	0	0	0
Sebaceous gland disorder	0	0	0	0	0	0	4	0	4	0	0	0
Sebaceous glands overactivity	0	0	1	0	0	0	0	0	1	0	0	0
Seborrhoea	1	0	11	0	0	0	10	0	21	0	0	0
Seborrhoeic dermatitis	3	0	16	0	2	0	13	0	29	0	0	0
Segmented hyalinising vasculitis	0	0	1	0	0	0	1	0	2	0	0	0
Senile pruritus	0	0	1	0	0	0	1	0	2	0	0	0
Sensitive skin	8	0	505	0	69	0	835	0	1340	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Severe cutaneous adverse reaction	1	0	1	0	0	0	0	0	1	0	0	0
Skin adhesion	0	0	0	0	1	0	2	0	2	0	0	0
Skin atrophy	1	0	11	0	0	0	8	1	19	1	0	0
Skin burning sensation	17	0	529	0	72	0	693	0	1222	0	0	0
Skin depigmentation	1	0	5	0	2	0	19	0	24	0	0	0
Skin discharge	0	0	1	0	0	0	2	0	3	0	0	0
Skin discolouration	12	0	228	0	93	0	842	0	1070	0	0	1
Skin discomfort	0	0	9	0	13	0	66	0	75	0	0	0
Skin disorder	42	0	253	0	226	0	574	0	827	0	0	0
Skin erosion	0	0	52	0	0	0	20	0	72	0	0	0
Skin exfoliation	7	0	142	0	25	0	255	0	397	0	0	0
Skin fissures	2	0	17	0	2	0	19	0	36	0	0	0
Skin fragility	1	0	3	0	1	0	3	0	6	0	0	0
Skin haemorrhage	4	0	78	0	54	0	254	0	332	0	0	1
Skin hyperpigmentation	0	0	2	0	2	0	29	0	31	0	0	0
Skin hypertrophy	0	0	3	0	2	0	14	0	17	0	0	0
Skin hypopigmentation	0	0	3	0	1	0	2	0	5	0	0	0
Skin indentation	0	0	9	0	1	0	13	0	22	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Skin induration	0	0	14	0	12	0	168	0	182	0	1	1
Skin irritation	2	0	109	0	19	0	215	0	324	0	0	0
Skin laxity	0	0	1	0	0	0	0	0	1	0	0	0
Skin lesion	9	0	69	0	24	0	117	0	186	0	0	0
Skin lesion inflammation	0	0	1	0	0	0	0	0	1	0	0	0
Skin mass	2	0	38	0	12	0	148	0	186	0	0	0
Skin necrosis	0	0	7	0	0	0	4	0	11	0	0	0
Skin odour abnormal	0	0	37	0	2	0	68	0	105	0	0	0
Skin oedema	0	0	6	0	0	0	16	0	22	0	0	0
Skin plaque	1	0	7	0	8	0	51	0	58	0	1	1
Skin reaction	1	0	174	0	21	0	366	1	540	1	0	0
Skin sensitisation	1	0	86	0	11	0	116	0	202	0	0	0
Skin striae	1	0	11	0	0	0	12	0	23	0	0	0
Skin swelling	1	0	61	0	9	0	100	0	161	0	0	0
Skin texture abnormal	0	0	3	0	2	0	8	0	11	0	0	0
Skin tightness	0	0	31	0	4	0	51	0	82	0	0	0
Skin ulcer	6	0	40	0	6	0	34	1	74	1	0	0
Skin ulcer haemorrhage	0	0	0	0	1	0	2	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Skin warm	3	0	358	0	24	0	709	0	1067	0	0	0
Skin weeping	1	0	12	0	0	0	4	0	16	0	0	0
Skin wrinkling	0	0	3	0	2	0	9	0	12	0	0	0
Solar dermatitis	0	0	1	0	0	0	3	0	4	0	0	0
Solar lentigo	0	0	2	0	0	0	7	0	9	0	0	0
Solar urticaria	0	0	1	0	0	0	6	0	7	0	0	0
Spider naevus	0	0	4	0	0	0	5	0	9	0	0	0
Splinter haemorrhages	2	0	7	0	0	0	3	0	10	0	0	0
Stasis dermatitis	0	0	8	0	1	0	8	0	16	0	0	0
Stevens-Johnson syndrome	11	0	35	0	0	0	0	0	35	0	0	0
Sticky skin	0	0	8	0	0	0	6	0	14	0	0	0
Subacute cutaneous lupus erythematosus	0	0	2	0	2	0	3	0	5	0	0	0
Subcutaneous emphysema	0	0	0	0	0	0	1	0	1	0	0	0
Superficial inflammatory dermatosis	0	0	2	0	1	0	2	0	4	0	0	0
Sweat discolouration	0	0	1	0	0	0	2	0	3	0	0	0
Sweat gland disorder	0	0	1	0	0	0	1	0	2	0	0	0
Symmetrical drug-related intertriginous and flexural exanthema	2	0	2	0	3	0	5	0	7	0	0	0
Systemic lupus erythematosus rash	0	0	7	0	0	0	4	0	11	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Target skin lesion	0	0	3	0	0	0	2	0	5	0	0	0
Telangiectasia	2	0	10	0	4	0	29	0	39	0	0	0
Toxic epidermal necrolysis	1	0	5	0	0	0	0	0	5	0	0	0
Toxic skin eruption	1	0	3	0	0	0	8	0	11	0	0	0
Transient acantholytic dermatosis	0	0	2	0	1	0	3	0	5	0	0	0
Trichodynia	1	0	5	0	0	0	11	0	16	0	0	0
Trichorrhexis	0	0	6	0	1	0	5	0	11	0	0	0
Umbilical haemorrhage	0	0	2	0	0	0	0	0	2	0	0	0
Urticaria	57	0	2013	1	517	0	5094	1	7107	2	4	4
Urticaria cholinergic	0	0	1	0	0	0	1	0	2	0	0	0
Urticaria chronic	5	0	55	0	5	0	40	0	95	0	0	0
Urticaria contact	0	0	2	0	0	0	1	0	3	0	0	0
Urticaria papular	3	0	6	0	0	0	14	0	20	0	0	0
Urticaria physical	0	0	0	0	0	0	5	0	5	0	0	0
Urticaria pigmentosa	0	0	0	0	0	0	1	0	1	0	0	0
Urticaria pressure	0	0	0	0	0	0	2	0	2	0	0	0
Urticaria thermal	0	0	3	0	0	0	4	0	7	0	0	0
Urticarial dermatitis	1	0	2	0	0	0	3	0	5	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Urticarial vasculitis	5	0	12	0	0	0	0	0	12	0	1	1
Vancomycin infusion reaction	0	0	1	0	0	0	0	0	1	0	0	0
Vascular purpura	0	0	16	0	0	0	8	0	24	0	0	0
Vascular skin disorder	0	0	1	0	1	0	3	0	4	0	0	0
Vasculitic rash	0	0	17	0	2	0	29	0	46	0	0	0
Vasculitic ulcer	0	0	3	0	0	0	0	0	3	0	0	0
Venous ulcer pain	0	0	1	0	0	0	0	0	1	0	0	0
Vitiligo	4	0	30	0	19	0	75	0	105	0	0	0
Xanthelasma	0	0	0	0	0	0	1	0	1	0	0	0
Xeroderma	0	0	0	0	1	0	1	0	1	0	0	0
Yellow skin	2	0	27	0	3	0	40	0	67	0	0	0
Musculoskeletal and connective tissue disorders	**3074**	**0**	**100775**	**4**	**32207**	**3**	**294716**	**30**	**395491**	**34**	**16**	**59**
Acquired claw toe	0	0	1	0	0	0	0	0	1	0	0	0
Acral overgrowth	0	0	0	0	0	0	1	0	1	0	0	0
Acute aseptic arthritis	0	0	3	0	0	0	0	0	3	0	0	0
Amplified musculoskeletal pain syndrome	0	0	1	0	0	0	4	0	5	0	0	0
Amyotrophy	1	0	5	0	0	0	1	0	6	0	0	0
Ankle impingement	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Ankylosing spondylitis	4	0	41	0	3	0	25	0	66	0	0	0
Antisynthetase syndrome	2	0	4	0	0	0	0	0	4	0	0	0
Arthralgia	628	0	23198	2	8407	1	74586	5	97784	7	1	10
Arthritis	30	0	640	0	48	0	451	0	1091	0	0	0
Arthritis enteropathic	0	0	3	0	0	0	0	0	3	0	0	0
Arthritis reactive	6	0	78	0	2	0	26	0	104	0	0	0
Arthropathy	6	0	49	0	9	0	61	0	110	0	0	0
Articular disc disorder	0	0	0	0	0	0	1	0	1	0	0	0
Autoimmune arthritis	1	0	14	0	1	0	2	0	16	0	0	0
Autoimmune myositis	3	0	7	0	0	0	0	0	7	0	0	0
Axial spondyloarthritis	0	0	1	0	0	0	1	0	2	0	0	0
Axillary mass	0	0	54	0	16	0	111	0	165	0	0	0
Back disorder	1	0	6	0	2	0	14	0	20	0	0	0
Back pain	118	0	5596	0	834	0	9498	0	15094	0	0	0
Bone disorder	4	0	7	0	0	0	9	0	16	0	0	0
Bone erosion	0	0	1	0	0	0	0	0	1	0	0	0
Bone infarction	0	0	1	0	0	0	0	0	1	0	0	0
Bone lesion	0	0	0	0	0	0	1	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Bone loss	0	0	2	0	0	0	1	0	3	0	0	0
Bone pain	20	0	1138	0	322	0	3108	2	4246	2	0	0
Bone swelling	1	0	9	0	0	0	8	0	17	0	0	0
Bursa disorder	0	0	0	0	0	0	9	0	9	0	0	0
Bursal fluid accumulation	0	0	2	0	0	0	0	0	2	0	0	0
Bursitis	11	0	230	0	23	0	233	0	463	0	0	0
Camptocormia	0	0	1	0	0	0	1	0	2	0	0	0
Cartilage atrophy	0	0	0	0	0	0	1	0	1	0	0	0
Cervical spinal stenosis	0	0	0	0	1	0	1	0	1	0	0	0
Chest wall cyst	1	0	1	0	0	0	0	0	1	0	0	0
Chest wall haematoma	0	0	1	0	0	0	3	0	4	0	0	0
Chest wall mass	0	0	0	0	1	0	2	0	2	0	0	0
Chondritis	0	0	1	0	0	0	1	0	2	0	0	0
Chondrocalcinosis	1	0	7	0	0	0	1	0	8	0	0	0
Chondromalacia	1	0	1	0	0	0	0	0	1	0	0	0
Chondropathy	0	0	2	0	1	0	2	0	4	0	0	0
Chronic kidney disease-mineral and bone disorder	0	0	1	0	0	0	0	0	1	0	0	0
Clubbing	0	0	0	0	0	0	1	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Coccydynia	1	0	13	0	4	0	18	0	31	0	0	0
Collagen disorder	1	0	3	0	0	0	3	0	6	0	0	0
Compartment syndrome	0	0	11	0	0	0	0	0	11	0	0	0
Connective tissue disorder	2	0	10	0	1	0	7	0	17	0	0	0
Connective tissue inflammation	0	0	4	0	0	0	2	0	6	0	0	0
Costochondritis	3	0	93	0	4	0	48	0	141	0	0	0
Crystal arthropathy	0	0	1	0	2	0	2	0	3	0	0	0
Dactylitis	0	0	3	0	1	0	5	0	8	0	0	0
Dupuytren's contracture	0	0	6	0	0	0	1	0	7	0	0	0
Dwarfism	0	0	0	0	0	0	1	0	1	0	0	0
Dysponesis	0	0	0	0	0	0	2	0	2	0	0	0
Elbow deformity	1	0	2	0	0	0	0	0	2	0	0	0
Enthesopathy	1	0	6	0	1	0	4	0	10	0	0	0
Eosinophilic fasciitis	0	0	4	0	0	0	1	0	5	0	0	0
Epiphyses premature fusion	0	0	1	0	0	0	0	0	1	0	0	0
Exostosis	0	0	3	0	0	0	1	0	4	0	0	0
Extremity contracture	0	0	4	0	0	0	1	0	5	0	0	0
Facet joint syndrome	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Facial asymmetry	1	0	36	0	1	0	16	0	52	0	0	0
Fasciitis	0	0	2	0	0	0	0	0	2	0	0	0
Felty's syndrome	0	0	0	0	0	0	1	0	1	0	0	0
Femoroacetabular impingement	0	0	2	0	0	0	1	0	3	0	0	0
Fibromyalgia	13	0	349	0	17	0	139	0	488	0	0	0
Finger deformity	1	0	5	0	3	0	7	0	12	0	0	0
Fistula	2	0	6	0	1	0	4	0	10	0	0	0
Fistula discharge	1	0	1	0	0	0	0	0	1	0	0	0
Fistula inflammation	1	0	1	0	0	0	0	0	1	0	0	0
Flank pain	3	0	120	0	10	0	161	0	281	0	0	0
Fluctuance	0	0	1	0	0	0	1	0	2	0	0	0
Focal myositis	0	0	0	0	0	0	1	0	1	0	0	0
Foot deformity	0	0	14	1	1	0	11	0	25	1	0	0
Fracture pain	0	0	0	0	0	0	2	0	2	0	0	0
Gouty arthritis	1	0	2	0	0	0	2	0	4	0	0	0
Gouty tophus	0	0	1	0	0	0	0	0	1	0	0	0
Greater trochanteric pain syndrome	0	0	10	0	0	0	3	0	13	0	0	0
Groin pain	6	0	222	0	33	0	298	1	520	1	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Growing pains	0	0	6	0	1	0	5	0	11	0	0	0
Growth retardation	0	0	1	0	0	0	0	0	1	0	1	1
Haemarthrosis	1	0	24	0	3	0	7	0	31	0	0	0
Haematoma muscle	0	0	17	0	7	0	37	0	54	0	0	0
Haemophilic arthropathy	0	0	0	0	0	0	1	0	1	0	0	0
Hand deformity	3	0	6	0	1	0	6	0	12	0	0	0
Head deformity	1	0	3	0	0	0	1	0	4	0	0	0
Immobilisation syndrome	0	0	0	0	0	0	1	0	1	0	0	0
Immune-mediated myositis	0	0	4	0	0	0	0	0	4	0	0	0
Infantile back arching	0	0	0	0	0	0	1	0	1	0	0	0
Inguinal mass	0	0	1	0	0	0	0	0	1	0	0	0
Intervertebral disc degeneration	1	0	4	0	1	0	5	0	9	0	0	0
Intervertebral disc disorder	0	0	2	0	1	0	9	0	11	0	0	0
Intervertebral disc protrusion	4	0	24	0	6	0	20	0	44	0	0	0
Jaw clicking	0	0	6	0	1	0	5	0	11	0	0	0
Jaw cyst	0	0	1	0	0	0	2	0	3	0	0	0
Jaw disorder	0	0	4	0	2	0	9	0	13	0	0	0
Joint adhesion	0	0	0	0	0	0	1	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Joint ankylosis	0	0	2	0	1	0	15	0	17	0	0	0
Joint contracture	0	0	2	0	0	0	6	0	8	0	0	0
Joint destruction	0	0	0	0	0	0	1	0	1	0	0	0
Joint effusion	1	0	16	0	2	0	34	0	50	0	0	0
Joint hyperextension	0	0	0	0	0	0	1	0	1	0	0	0
Joint instability	0	0	4	0	0	0	6	0	10	0	0	0
Joint laxity	0	0	5	0	0	0	3	0	8	0	0	0
Joint lock	3	0	64	0	3	0	17	0	81	0	0	0
Joint noise	5	0	42	0	1	0	30	0	72	0	0	0
Joint range of motion decreased	3	0	20	0	9	0	37	0	57	0	0	0
Joint stiffness	8	0	438	0	43	0	372	0	810	0	0	0
Joint swelling	49	0	1000	0	97	0	1023	0	2023	0	0	0
Joint vibration	1	0	4	0	0	0	6	0	10	0	0	0
Joint warmth	0	0	31	0	2	0	28	0	59	0	0	0
Juvenile idiopathic arthritis	0	0	4	0	0	0	0	0	4	0	0	0
Knee deformity	1	0	3	0	3	0	5	0	8	0	0	0
Kyphosis	0	0	5	0	1	0	2	0	7	0	0	0
Ligament disorder	0	0	1	0	0	0	1	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Ligament laxity	0	0	1	0	1	0	3	0	4	0	0	0
Ligament pain	0	0	7	0	0	0	7	0	14	0	0	0
Ligamentitis	0	0	0	0	0	0	2	0	2	0	0	0
Limb deformity	1	0	9	0	1	0	10	0	19	0	0	0
Limb discomfort	80	0	2295	0	518	0	11226	1	13521	1	0	0
Limb mass	2	0	27	0	3	0	55	0	82	0	0	0
Locomotive syndrome	1	0	8	0	0	0	21	0	29	0	0	0
Loose body in joint	0	0	1	0	0	0	1	0	2	0	0	0
Low turnover osteopathy	0	0	0	0	0	0	1	0	1	0	0	0
Lumbar spinal stenosis	0	0	1	0	0	0	0	0	1	0	0	0
Lupus-like syndrome	1	0	8	0	0	0	0	0	8	0	0	0
Mandibular mass	0	0	1	0	1	0	2	0	3	0	0	0
Mastication disorder	2	0	22	0	0	0	20	0	42	0	0	0
Masticatory pain	0	0	0	0	0	0	5	0	5	0	0	0
Medial tibial stress syndrome	0	0	7	0	0	0	5	0	12	0	0	0
Metatarsalgia	0	0	0	0	2	0	3	0	3	0	0	0
Mixed connective tissue disease	1	0	5	0	0	0	1	0	6	0	0	0
Mobility decreased	41	0	391	0	223	0	832	0	1223	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Morphoea	1	0	5	0	3	0	9	0	14	0	0	0
Muscle atrophy	9	0	65	0	10	0	47	0	112	0	0	0
Muscle contracture	1	0	17	0	7	0	54	0	71	0	0	0
Muscle discomfort	2	0	20	0	28	0	147	0	167	0	0	0
Muscle disorder	2	0	19	0	6	0	41	0	60	0	0	0
Muscle fatigue	13	0	917	0	50	0	457	0	1374	0	0	0
Muscle fibrosis	0	0	1	0	0	0	0	0	1	0	0	0
Muscle haemorrhage	0	0	8	0	1	0	4	0	12	0	0	0
Muscle hypertrophy	1	0	2	0	0	0	1	0	3	0	0	0
Muscle hypoxia	0	0	1	0	1	0	1	0	2	0	0	0
Muscle mass	3	0	13	0	0	0	9	0	22	0	0	0
Muscle necrosis	0	0	6	0	0	0	0	0	6	0	0	0
Muscle oedema	0	0	6	0	0	0	9	0	15	0	0	0
Muscle rigidity	1	0	83	0	10	0	104	0	187	0	0	0
Muscle spasms	91	0	3247	0	345	1	3846	1	7093	1	0	2
Muscle swelling	1	0	32	0	5	0	37	0	69	0	0	0
Muscle tightness	16	0	228	0	74	0	418	0	646	0	0	0
Muscle twitching	32	0	504	0	83	0	750	0	1254	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Muscular weakness	121	0	2725	0	306	0	2880	3	5605	3	0	1
Musculoskeletal chest pain	15	0	420	0	49	0	437	0	857	0	0	0
Musculoskeletal deformity	0	0	0	0	0	0	1	0	1	0	0	0
Musculoskeletal discomfort	16	0	153	0	72	0	458	0	611	0	0	0
Musculoskeletal disorder	6	0	24	0	11	0	37	0	61	0	0	0
Musculoskeletal pain	6	0	298	0	151	0	1717	0	2015	0	0	0
Musculoskeletal stiffness	77	0	2227	0	366	0	2440	1	4667	1	0	0
Myalgia	788	0	27877	0	14715	0	134748	6	162625	6	2	13
Myalgia intercostal	0	0	4	0	4	0	25	0	29	0	0	0
Myofascial pain syndrome	1	0	25	0	3	0	18	0	43	0	0	0
Myofascial spasm	0	0	0	0	0	0	1	0	1	0	0	0
Myokymia	0	0	3	0	0	0	8	0	11	0	0	0
Myopathy	1	0	20	0	1	0	13	0	33	0	0	0
Myopathy toxic	1	0	2	0	0	0	0	0	2	0	0	0
Myosclerosis	0	0	8	0	2	0	14	0	22	0	0	0
Myositis	11	0	100	0	9	0	85	1	185	1	0	0
Neck deformity	0	0	1	0	1	0	2	0	3	0	0	0
Neck mass	3	0	29	0	4	0	42	0	71	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Neck pain	76	0	2937	0	531	0	3998	0	6935	0	0	0
Necrotising myositis	0	0	1	0	0	0	0	0	1	0	0	0
Neurogenic fracture	0	0	1	0	0	0	0	0	1	0	0	0
Neuropathic arthropathy	0	0	1	0	0	0	0	0	1	0	0	0
Neuropathic muscular atrophy	1	0	2	0	0	0	2	0	4	0	0	0
Nodal osteoarthritis	0	0	2	0	1	0	1	0	3	0	0	0
Nose deformity	0	0	0	0	0	0	3	0	3	0	0	0
Nuchal rigidity	2	0	54	0	13	0	121	0	175	0	0	0
Oligoarthritis	2	0	4	0	2	0	5	0	9	0	0	0
Osteitis	0	0	12	0	0	0	13	0	25	0	0	0
Osteoarthritis	11	0	121	0	19	0	92	0	213	0	0	0
Osteoarthropathy	0	0	0	0	0	0	1	0	1	0	0	0
Osteochondrosis	1	0	3	0	1	0	2	0	5	0	0	0
Osteolysis	1	0	1	0	0	0	0	0	1	0	0	0
Osteonecrosis	0	0	11	0	1	0	3	0	14	0	0	0
Osteonecrosis of jaw	0	0	5	0	0	0	1	0	6	0	0	0
Osteopenia	1	0	3	0	1	0	2	0	5	0	0	0
Osteoporosis	6	0	19	0	0	0	5	0	24	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Osteoporotic fracture	0	0	5	0	0	0	0	0	5	0	0	0
Osteosclerosis	0	0	0	0	0	0	1	0	1	0	0	0
Pain in extremity	426	0	18859	1	4311	1	36192	5	55051	6	2	21
Pain in jaw	12	0	579	0	68	0	623	0	1202	0	0	0
Palindromic rheumatism	0	0	8	0	0	0	2	0	10	0	0	0
Patellofemoral pain syndrome	1	0	7	0	0	0	4	0	11	0	0	0
Pathological fracture	0	0	1	0	1	0	3	0	4	0	0	0
Pelvic misalignment	0	0	1	0	0	0	0	0	1	0	0	0
Periarthritis	17	0	531	0	8	0	152	0	683	0	0	0
Periostitis	0	0	1	0	0	0	5	0	6	0	0	0
Peripheral spondyloarthritis	0	0	0	0	2	0	2	0	2	0	1	1
Plantar fascial fibromatosis	0	0	1	0	1	0	1	0	2	0	0	0
Plantar fasciitis	1	0	16	0	3	0	15	0	31	0	0	0
Polyarthritis	4	0	59	0	2	0	28	0	87	0	0	0
Polychondritis	0	0	3	0	0	0	0	0	3	0	0	0
Polymyalgia rheumatica	33	0	218	0	8	0	95	0	313	0	4	4
Polymyositis	4	0	18	0	0	0	7	0	25	0	0	0
Posture abnormal	0	0	2	0	0	0	5	0	7	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Psoriatic arthropathy	15	0	59	0	7	0	26	0	85	0	0	0
Pubic pain	0	0	4	0	0	0	2	0	6	0	0	0
Reynold's syndrome	1	0	6	0	0	0	1	0	7	0	0	0
Rhabdomyolysis	4	0	56	0	0	0	0	0	56	0	0	0
Rheumatic disorder	6	0	55	0	10	0	66	0	121	0	0	0
Rheumatic fever	0	0	10	0	0	0	0	0	10	0	0	0
Rheumatoid arthritis	50	0	329	0	13	0	109	4	438	4	2	2
Rheumatoid nodule	0	0	1	0	1	0	1	0	2	0	0	0
Rotator cuff syndrome	7	0	124	0	5	0	52	0	176	0	0	0
Sacral pain	0	0	10	0	5	0	45	0	55	0	0	0
Sacroiliac joint dysfunction	0	0	0	0	3	0	4	0	4	0	0	0
Sacroiliitis	0	0	4	0	0	0	6	0	10	0	0	0
Sarcopenia	1	0	3	0	1	0	3	0	6	0	0	0
Scleroderma	3	0	9	0	0	0	2	0	11	0	0	0
Scoliosis	0	0	5	0	2	0	3	0	8	0	0	0
Seronegative arthritis	1	0	9	0	0	0	7	0	16	0	0	0
Shoulder girdle pain	0	0	0	0	1	0	1	0	1	0	0	0
Sjogren's syndrome	3	0	22	0	2	0	6	0	28	0	2	2

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Snapping hip syndrome	0	0	0	0	1	0	1	0	1	0	0	0
Soft tissue atrophy	0	0	0	0	0	0	1	0	1	0	0	0
Soft tissue disorder	1	0	4	0	0	0	3	0	7	0	0	0
Soft tissue mass	0	0	2	0	0	0	6	0	8	0	0	0
Soft tissue necrosis	0	0	2	0	0	0	0	0	2	0	0	0
Soft tissue swelling	0	0	2	0	1	0	17	0	19	0	0	0
Somatic dysfunction	1	0	2	0	0	0	0	0	2	0	0	0
Spinal deformity	1	0	2	0	0	0	2	0	4	0	0	0
Spinal disorder	2	0	9	0	2	0	9	0	18	0	0	0
Spinal osteoarthritis	2	0	17	0	2	0	9	0	26	0	0	0
Spinal pain	6	0	296	0	71	0	554	0	850	0	0	0
Spinal segmental dysfunction	0	0	0	0	1	0	1	0	1	0	0	0
Spinal stenosis	1	0	5	0	0	0	1	0	6	0	0	0
Spondylitis	1	0	9	0	0	0	10	0	19	0	0	0
Spondyloarthropathy	0	0	7	0	0	0	0	0	7	0	0	0
Still's disease	11	0	36	0	1	0	6	0	42	0	0	0
Sympathetic posterior cervical syndrome	0	0	1	0	0	0	0	0	1	0	0	0
Symphysiolysis	0	0	0	0	1	0	2	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Synovial cyst	2	0	19	0	3	0	72	0	91	0	0	0
Synovial disorder	0	0	1	0	0	0	3	0	4	0	0	0
Synovitis	4	0	24	0	1	0	21	0	45	0	0	0
Systemic lupus erythematosus	7	0	67	0	4	0	28	0	95	0	1	2
Systemic scleroderma	2	0	6	0	1	0	1	0	7	0	0	0
Temporomandibular joint syndrome	3	0	29	0	3	0	21	0	50	0	0	0
Tendinous contracture	0	0	0	0	2	0	4	0	4	0	0	0
Tendon calcification	1	0	1	0	0	0	0	0	1	0	0	0
Tendon discomfort	1	0	6	0	1	0	19	0	25	0	0	0
Tendon disorder	0	0	18	0	2	0	38	0	56	0	0	0
Tendon pain	2	0	56	0	12	0	77	0	133	0	0	0
Tendon sheath disorder	0	0	1	0	0	0	4	0	5	0	0	0
Tendonitis	7	0	127	0	17	0	126	0	253	0	0	0
Tenosynovitis	0	0	10	0	2	0	24	0	34	0	0	0
Tenosynovitis stenosans	0	0	5	0	0	0	1	0	6	0	0	0
Thoracic spinal stenosis	0	0	1	0	0	0	0	0	1	0	0	0
Torticollis	0	0	9	0	7	0	56	0	65	0	0	0
Trigger finger	1	0	32	0	2	0	18	0	50	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Trigger points	0	0	0	0	1	0	4	0	4	0	0	0
Trismus	4	0	60	0	7	0	69	0	129	0	0	0
Undifferentiated connective tissue disease	0	0	1	0	0	0	0	0	1	0	0	0
Vertebral end plate impression	0	0	0	0	1	0	1	0	1	0	0	0
Vertebral foraminal stenosis	0	0	0	0	2	0	2	0	2	0	0	0
Vertebral lesion	0	0	0	0	1	0	1	0	1	0	0	0
Vertebral osteophyte	0	0	0	0	1	0	1	0	1	0	0	0
Weight bearing difficulty	18	0	51	0	33	0	125	0	176	0	0	0
Winged scapula	0	0	3	0	1	0	1	0	4	0	0	0
Wrist deformity	0	0	1	0	0	0	1	0	2	0	0	0
Renal and urinary disorders	**241**	**0**	**3651**	**1**	**247**	**0**	**3196**	**4**	**6847**	**5**	**1**	**12**
Acquired cystic kidney disease	0	0	1	0	0	0	0	0	1	0	0	0
Acute kidney injury	26	0	246	0	0	0	0	0	246	0	0	2
Albuminuria	0	0	1	0	0	0	1	0	2	0	0	0
Anti-glomerular basement membrane disease	0	0	1	0	0	0	0	0	1	0	0	0
Anuria	3	0	33	0	0	0	0	0	33	0	0	0
Atonic urinary bladder	0	0	1	0	0	0	1	0	2	0	0	0
Automatic bladder	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Azotaemia	0	0	1	0	0	0	1	0	2	0	0	0
Bence Jones proteinuria	1	0	1	0	0	0	0	0	1	0	0	0
Bilirubinuria	0	0	0	0	0	0	1	0	1	0	0	0
Bladder cyst	0	0	1	0	0	0	0	0	1	0	0	0
Bladder dilatation	0	0	2	0	0	0	0	0	2	0	0	0
Bladder discomfort	2	0	10	0	2	0	18	0	28	0	0	0
Bladder disorder	3	0	25	0	0	0	15	0	40	0	0	0
Bladder dysfunction	4	0	17	0	6	0	12	0	29	0	0	0
Bladder irritation	0	0	6	0	0	0	5	0	11	0	0	0
Bladder mass	0	0	1	0	0	0	0	0	1	0	0	0
Bladder obstruction	0	0	1	0	0	0	0	0	1	0	0	0
Bladder pain	3	0	66	0	9	0	46	0	112	0	0	0
Bladder prolapse	0	0	1	0	0	0	0	0	1	0	0	0
Bladder spasm	0	0	1	0	0	0	1	0	2	0	0	0
Bladder sphincter atony	0	0	4	0	0	0	1	0	5	0	0	0
Bladder stenosis	0	0	0	0	1	0	1	0	1	0	0	0
C3 glomerulopathy	0	0	2	0	0	0	0	0	2	0	0	0
Calculus urinary	1	0	4	0	1	0	2	0	6	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Choluria	0	0	0	0	0	0	5	0	5	0	0	0
Chromaturia	8	0	115	0	7	0	154	1	269	1	0	0
Chronic kidney disease	6	0	35	0	0	0	3	0	38	0	0	0
Costovertebral angle tenderness	0	0	3	0	0	0	11	0	14	0	0	0
Crush syndrome	0	0	1	0	0	0	0	0	1	0	0	0
Cystitis haemorrhagic	0	0	8	0	0	0	5	0	13	0	0	0
Cystitis interstitial	0	0	12	0	0	0	4	0	16	0	0	0
Cystitis noninfective	0	0	8	0	9	0	63	0	71	0	0	0
Cystitis-like symptom	0	0	1	0	1	0	7	0	8	0	0	0
Diabetic nephropathy	4	0	8	0	0	0	1	0	9	0	0	1
Dysuria	8	0	130	0	20	0	266	0	396	0	0	0
End stage renal disease	2	0	10	0	0	0	0	0	10	0	0	0
Faecaluria	0	0	0	0	0	0	1	0	1	0	0	0
Focal segmental glomerulosclerosis	4	0	11	0	1	0	1	0	12	0	0	0
Genitourinary symptom	0	0	1	0	0	0	0	0	1	0	0	0
Glomerulonephritis	2	0	11	0	0	0	0	0	11	0	0	0
Glomerulonephritis acute	0	0	0	0	0	0	1	0	1	0	0	0
Glomerulonephritis chronic	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Glomerulonephritis membranoproliferative	0	0	3	0	2	0	2	0	5	0	0	0
Glomerulonephritis membranous	0	0	4	0	0	0	1	0	5	0	0	0
Glomerulonephritis minimal lesion	3	0	13	0	2	0	4	0	17	0	0	3
Glomerulonephritis proliferative	0	0	1	0	0	0	0	0	1	0	0	0
Glomerulonephritis rapidly progressive	4	0	9	0	0	0	0	0	9	0	0	0
Glomerulonephropathy	0	0	1	0	0	0	1	0	2	0	0	0
Glycosuria	0	0	1	0	0	0	0	0	1	0	0	0
Goodpasture's syndrome	0	0	3	0	1	0	1	0	4	0	0	0
Haematinuria	0	0	1	0	0	0	0	0	1	0	0	0
Haematuria	3	0	122	0	9	0	185	0	307	0	0	1
Haemoglobinuria	0	0	1	0	0	0	0	0	1	0	0	0
Haemorrhage urinary tract	3	0	64	0	0	0	32	0	96	0	0	0
Henoch-Schonlein purpura nephritis	0	0	1	0	0	0	1	0	2	0	0	0
Hydronephrosis	1	0	4	0	1	0	1	0	5	0	0	0
Hypertensive nephropathy	0	0	3	0	0	0	0	0	3	0	0	0
Hypertonic bladder	0	0	13	0	2	0	13	0	26	0	0	0
Hypotonic urinary bladder	0	0	0	0	0	0	1	0	1	0	0	0
IgA nephropathy	4	0	12	0	8	0	11	0	23	0	0	1

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Incontinence	3	0	113	0	3	0	69	0	182	0	0	0
Ketonuria	0	0	0	0	0	0	1	0	1	0	0	0
Kidney congestion	0	0	1	0	0	0	8	0	9	0	0	0
Kidney enlargement	0	0	1	0	0	0	0	0	1	0	0	0
Kidney fibrosis	0	0	1	0	0	0	0	0	1	0	0	0
Leukocyturia	0	0	1	0	0	0	2	0	3	0	0	0
Loss of bladder sensation	0	0	13	0	0	0	3	0	16	0	0	0
Lower urinary tract symptoms	0	0	0	0	1	0	3	0	3	0	0	0
Lupus nephritis	3	0	6	0	1	0	2	0	8	0	0	0
Malnutrition-inflammation-atherosclerosis syndrome	0	0	1	0	0	0	0	0	1	0	0	0
Mesangioproliferative glomerulonephritis	0	0	1	0	0	0	0	0	1	0	0	0
Microalbuminuria	0	0	1	0	0	0	1	0	2	0	0	0
Micturition disorder	2	0	8	0	5	0	27	1	35	1	0	0
Micturition frequency decreased	0	0	0	0	0	0	3	0	3	0	0	0
Micturition urgency	1	0	81	0	11	0	165	0	246	0	0	0
Mixed incontinence	0	0	1	0	0	0	0	0	1	0	0	0
Nephritis	1	0	12	1	0	0	1	0	13	1	0	0
Nephroangiosclerosis	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Nephrolithiasis	5	0	46	0	1	0	16	0	62	0	0	0
Nephropathy	3	0	8	0	0	0	3	0	11	0	0	0
Nephropathy toxic	0	0	1	0	0	0	0	0	1	0	0	0
Nephrosclerosis	0	0	3	0	0	0	0	0	3	0	0	0
Nephrotic syndrome	6	0	40	0	0	0	9	0	49	0	0	0
Neurogenic bladder	4	0	12	0	1	0	2	0	14	0	0	0
Nocturia	0	0	23	0	4	0	56	0	79	0	0	0
Oedematous kidney	1	0	2	0	0	0	1	0	3	0	0	0
Oliguria	1	0	22	0	1	0	22	0	44	0	0	0
Paroxysmal nocturnal haemoglobinuria	0	0	1	0	0	0	0	0	1	0	0	0
Pneumaturia	0	0	0	0	0	0	1	0	1	0	0	0
Pollakiuria	14	0	258	0	35	0	468	0	726	0	0	0
Polyuria	0	0	39	0	10	0	167	1	206	1	0	0
Prerenal failure	0	0	3	0	0	0	0	0	3	0	0	0
Proteinuria	2	0	24	0	4	0	17	0	41	0	0	0
Pyelocaliectasis	0	0	1	0	0	0	0	0	1	0	0	0
Reflux nephropathy	0	0	0	0	0	0	1	0	1	0	0	0
Renal aneurysm	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Renal artery dissection	0	0	1	0	0	0	0	0	1	0	0	0
Renal artery occlusion	0	0	3	0	0	0	0	0	3	0	0	0
Renal artery stenosis	0	0	1	0	0	0	0	0	1	0	0	0
Renal artery thrombosis	3	0	15	0	0	0	0	0	15	0	0	1
Renal atrophy	2	0	5	0	0	0	0	0	5	0	0	0
Renal colic	0	0	23	0	1	0	30	0	53	0	0	0
Renal cortical necrosis	0	0	1	0	0	0	0	0	1	0	0	0
Renal cyst	4	0	4	0	1	0	4	0	8	0	0	0
Renal disorder	15	0	58	0	6	0	40	0	98	0	0	0
Renal embolism	0	0	2	0	0	0	0	0	2	0	0	0
Renal failure	15	0	164	0	0	0	0	0	164	0	0	0
Renal haemorrhage	1	0	7	0	0	0	0	0	7	0	0	0
Renal hypertension	0	0	0	0	0	0	1	0	1	0	0	0
Renal impairment	13	0	59	0	2	0	17	0	76	0	0	0
Renal infarct	2	0	56	0	0	0	0	0	56	0	0	1
Renal injury	0	0	12	0	0	0	0	0	12	0	0	0
Renal ischaemia	0	0	8	0	0	0	0	0	8	0	0	0
Renal pain	9	0	877	0	45	0	820	0	1697	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Renal tubular acidosis	0	0	0	0	0	0	1	0	1	0	0	0
Renal tubular atrophy	0	0	1	0	0	0	0	0	1	0	0	0
Renal tubular disorder	0	0	2	0	0	0	0	0	2	0	0	0
Renal tubular injury	0	0	2	0	0	0	0	0	2	0	0	0
Renal tubular necrosis	0	0	6	0	0	0	0	0	6	0	0	0
Renal vascular thrombosis	0	0	8	0	0	0	0	0	8	0	0	0
Renal vasculitis	0	0	2	0	0	0	0	0	2	0	0	0
Renal vein embolism	0	0	2	0	0	0	0	0	2	0	0	0
Renal vein occlusion	0	0	2	0	0	0	1	0	3	0	0	0
Renal vein thrombosis	1	0	35	0	0	0	0	0	35	0	0	0
Renal-limited thrombotic microangiopathy	0	0	2	0	0	0	0	0	2	0	0	0
Single functional kidney	0	0	2	0	0	0	0	0	2	0	0	0
Strangury	1	0	2	0	0	0	1	0	3	0	0	0
Stress urinary incontinence	1	0	3	0	0	0	1	0	4	0	0	0
Subcapsular renal haematoma	0	0	1	0	0	0	0	0	1	0	0	0
Tubulointerstitial nephritis	3	0	21	0	0	0	0	0	21	0	1	1
Urate nephropathy	1	0	1	0	0	0	0	0	1	0	0	0
Ureteral disorder	0	0	2	0	0	0	0	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Ureteric obstruction	0	0	1	0	0	0	0	0	1	0	0	0
Urethral dilatation	0	0	0	0	0	0	1	0	1	0	0	0
Urethral discharge	0	0	0	0	0	0	1	0	1	0	0	0
Urethral disorder	0	0	0	0	0	0	1	0	1	0	0	0
Urethral haemorrhage	1	0	1	0	0	0	1	0	2	0	0	0
Urethral intrinsic sphincter deficiency	0	0	0	0	0	0	1	0	1	0	0	0
Urethral pain	0	0	3	0	1	0	6	0	9	0	0	0
Urethral prolapse	0	0	0	0	0	0	1	0	1	0	0	0
Urethral spasm	0	0	0	0	0	0	2	0	2	0	0	0
Urethral stenosis	0	0	1	0	0	0	1	0	2	0	0	0
Urethritis noninfective	0	0	0	0	0	0	1	0	1	0	0	0
Urge incontinence	0	0	4	0	0	0	4	0	8	0	0	0
Urinary bladder haemorrhage	1	0	32	0	0	0	10	0	42	0	0	0
Urinary bladder rupture	0	0	1	0	0	0	0	0	1	0	0	0
Urinary hesitation	0	0	10	0	1	0	13	0	23	0	0	0
Urinary incontinence	12	0	191	0	17	0	156	0	347	0	0	0
Urinary retention	10	0	150	0	3	0	38	0	188	0	0	1
Urinary straining	0	0	0	0	0	0	3	0	3	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Urinary tract discomfort	0	0	4	0	1	0	7	0	11	0	0	0
Urinary tract disorder	1	0	13	0	1	0	9	0	22	0	0	0
Urinary tract inflammation	0	0	3	0	2	0	7	1	10	1	0	0
Urinary tract obstruction	0	0	3	0	0	0	1	0	4	0	0	0
Urinary tract pain	0	0	15	0	0	0	6	0	21	0	0	0
Urine abnormality	2	0	17	0	6	0	33	0	50	0	0	0
Urine flow decreased	1	0	23	0	0	0	6	0	29	0	0	0
Urine odour abnormal	1	0	24	0	1	0	43	0	67	0	0	0
Urogenital haemorrhage	0	0	1	0	0	0	0	0	1	0	0	0
Pregnancy, puerperium and perinatal conditions	**59**	**0**	**785**	**0**	**16**	**0**	**152**	**0**	**937**	**0**	**32**	**112**
Abortion	2	0	43	0	0	0	5	0	48	0	0	0
Abortion early	0	0	2	0	0	0	2	0	4	0	0	0
Abortion incomplete	2	0	2	0	0	0	0	0	2	0	0	0
Abortion missed	0	0	14	0	0	0	0	0	14	0	0	0
Abortion spontaneous	14	0	379	0	0	0	0	0	379	0	2	12
Abortion spontaneous complete	0	0	1	0	0	0	0	0	1	0	0	0
Abortion threatened	1	0	3	0	0	0	0	0	3	0	0	0
Amniorrhoea	0	0	2	0	0	0	0	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Anaphylactoid syndrome of pregnancy	0	0	1	0	0	0	0	0	1	0	0	0
Anembryonic gestation	0	0	2	0	0	0	0	0	2	0	0	0
Arrested labour	0	0	2	0	0	0	0	0	2	0	0	0
Biochemical pregnancy	0	0	3	0	0	0	0	0	3	0	0	0
Breech presentation	1	0	1	0	0	0	0	0	1	0	1	11
Cephalo-pelvic disproportion	1	0	1	0	0	0	0	0	1	0	0	0
Chronic villitis of unknown etiology	0	0	1	0	0	0	0	0	1	0	0	0
Complication of pregnancy	0	0	1	0	0	0	0	0	1	0	0	0
Decidual cast	0	0	3	0	0	0	0	0	3	0	0	0
Delivery	0	0	1	0	0	0	1	0	2	0	0	0
Eclampsia	0	0	2	0	0	0	0	0	2	0	0	2
Ectopic pregnancy	1	0	15	0	0	0	0	0	15	0	0	0
Ectopic pregnancy with contraceptive device	0	0	0	0	0	0	1	0	1	0	0	0
Face presentation	0	0	2	0	0	0	0	0	2	0	0	0
False labour	0	0	1	0	0	0	0	0	1	0	0	0
Foetal cardiac disorder	0	0	1	0	0	0	0	0	1	0	0	0
Foetal damage	0	0	1	0	0	0	0	0	1	0	0	0
Foetal death	5	0	19	0	0	0	0	0	19	0	0	1

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Foetal disorder	1	0	2	0	0	0	2	0	4	0	1	1
Foetal distress syndrome	0	0	2	0	0	0	0	0	2	0	0	0
Foetal growth restriction	1	0	5	0	0	0	0	0	5	0	0	3
Foetal hypokinesia	0	0	1	0	0	0	0	0	1	0	0	4
Foetal vascular malperfusion	0	0	4	0	0	0	0	0	4	0	1	1
Gestational diabetes	2	0	9	0	0	0	2	0	11	0	10	22
Gestational hypertension	0	0	2	0	0	0	0	0	2	0	0	1
HELLP syndrome	2	0	3	0	0	0	0	0	3	0	0	0
Haemorrhage foetal	0	0	2	0	0	0	0	0	2	0	0	0
Haemorrhage in pregnancy	1	0	5	0	0	0	0	0	5	0	1	1
Hyperemesis gravidarum	0	0	4	0	0	0	0	0	4	0	0	1
Hypoxic ischaemic encephalopathy neonatal	0	0	0	0	0	0	0	0	0	0	1	1
Imminent abortion	0	0	1	0	0	0	1	0	2	0	0	0
Labour pain	2	0	26	0	5	0	20	0	46	0	0	0
Large for dates baby	1	0	1	0	0	0	0	0	1	0	1	3
Live birth	0	0	7	0	1	0	4	0	11	0	0	0
Low birth weight baby	0	0	2	0	0	0	0	0	2	0	1	2
Morning sickness	2	0	45	0	3	0	42	0	87	0	0	1

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Multiple pregnancy	1	0	1	0	0	0	0	0	1	0	0	0
Neonatal disorder	0	0	1	0	0	0	0	0	1	0	0	0
Normal newborn	1	0	1	0	3	0	5	0	6	0	0	0
Oligohydramnios	1	0	3	0	0	0	0	0	3	0	2	4
Pelvic girdle pain	0	0	1	0	0	0	3	0	4	0	0	1
Peripartum cardiomyopathy	0	0	1	0	0	0	0	0	1	0	0	0
Placenta accreta	0	0	0	0	0	0	1	0	1	0	0	0
Placenta praevia	0	0	1	0	0	0	0	0	1	0	1	4
Placental calcification	0	0	1	0	0	0	0	0	1	0	0	0
Placental disorder	0	0	1	0	0	0	0	0	1	0	0	0
Placental infarction	0	0	3	0	0	0	0	0	3	0	0	0
Placental insufficiency	0	0	1	0	0	0	0	0	1	0	1	1
Placental lake	0	0	0	0	0	0	1	0	1	0	0	0
Polyhydramnios	0	0	0	0	0	0	0	0	0	0	1	2
Postmature baby	0	0	1	0	0	0	0	0	1	0	0	0
Postpartum disorder	0	0	0	0	0	0	1	0	1	0	0	0
Postpartum haemorrhage	1	0	3	0	0	0	0	0	3	0	0	2
Pre-eclampsia	3	0	11	0	0	0	0	0	11	0	1	4

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Precipitate labour	0	0	1	0	0	0	0	0	1	0	0	0
Pregnancy	0	0	31	0	1	0	32	0	63	0	0	0
Pregnancy after post coital contraception	0	0	2	0	0	0	0	0	2	0	0	0
Pregnancy of unknown location	0	0	1	0	0	0	0	0	1	0	0	0
Pregnancy on contraceptive	0	0	3	0	0	0	1	0	4	0	0	0
Pregnancy on oral contraceptive	1	0	4	0	0	0	1	0	5	0	0	0
Pregnancy with contraceptive device	0	0	1	0	0	0	0	0	1	0	0	0
Pregnancy with contraceptive patch	0	0	1	0	0	0	0	0	1	0	0	0
Pregnancy with implant contraceptive	0	0	5	0	0	0	1	0	6	0	0	0
Premature baby	1	0	9	0	0	0	0	0	9	0	1	2
Premature delivery	1	0	7	0	0	0	3	0	10	0	0	0
Premature labour	1	0	8	0	0	0	0	0	8	0	0	1
Premature rupture of membranes	1	0	6	0	0	0	0	0	6	0	1	1
Premature separation of placenta	1	0	7	0	1	0	1	0	8	0	0	1
Preterm premature rupture of membranes	0	0	3	0	0	0	0	0	3	0	0	0
Prolonged labour	3	0	4	0	0	0	1	0	5	0	3	14
Prolonged pregnancy	0	0	1	0	0	0	0	0	1	0	0	0
Risk of future pregnancy miscarriage	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Small for dates baby	0	0	0	0	0	0	0	0	0	0	1	1
Somatic symptom disorder of pregnancy	0	0	2	0	0	0	0	0	2	0	0	0
Stillbirth	0	0	6	0	0	0	0	0	6	0	0	1
Subchorionic haematoma	0	0	1	0	0	0	0	0	1	0	0	0
Subchorionic haemorrhage	1	0	3	0	0	0	0	0	3	0	0	3
Term birth	1	0	1	0	1	0	2	0	3	0	0	0
Threatened labour	0	0	3	0	0	0	1	0	4	0	0	0
Traumatic delivery	0	0	1	0	0	0	0	0	1	0	0	0
Twin pregnancy	0	0	3	0	0	0	0	0	3	0	0	0
Umbilical cord around neck	0	0	1	0	0	0	0	0	1	0	1	2
Unintended pregnancy	0	0	4	0	0	0	1	0	5	0	0	0
Unwanted pregnancy	0	0	0	0	0	0	2	0	2	0	0	0
Uterine atony	0	0	0	0	0	0	1	0	1	0	0	0
Uterine contractions abnormal	0	0	4	0	1	0	4	0	8	0	0	0
Uterine contractions during pregnancy	1	0	2	0	0	0	1	0	3	0	0	0
Uterine hypertonus	1	0	5	0	0	0	7	0	12	0	0	0
Uterine hypotonus	0	0	0	0	0	0	2	0	2	0	0	0
Weight decrease neonatal	0	0	0	0	0	0	0	0	0	0	0	1

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Reproductive system and breast disorders	**248**	**0**	**12371**	**2**	**1110**	**0**	**20239**	**4**	**32610**	**6**	**1**	**3**
Abnormal uterine bleeding	2	0	11	0	1	0	14	0	25	0	0	0
Abnormal withdrawal bleeding	1	0	5	0	2	0	16	0	21	0	0	0
Adenomyosis	0	0	13	0	1	0	7	0	20	0	0	0
Adnexa uteri pain	0	0	46	0	3	0	66	0	112	0	0	0
Amenorrhoea	16	0	378	0	72	0	979	1	1357	1	0	0
Anisomastia	0	0	1	0	0	0	0	0	1	0	0	0
Artificial menopause	0	0	0	0	0	0	2	0	2	0	0	0
Aspermia	0	0	1	0	0	0	1	0	2	0	0	0
Atrophic vulvovaginitis	0	0	1	0	0	0	0	0	1	0	0	0
Balanoposthitis	1	0	4	0	0	0	3	0	7	0	0	0
Bartholin's cyst	0	0	5	0	0	0	1	0	6	0	0	0
Benign prostatic hyperplasia	1	0	7	0	1	0	1	0	8	0	0	0
Bleeding anovulatory	0	0	0	0	0	0	1	0	1	0	0	0
Breast calcifications	1	0	2	0	0	0	0	0	2	0	0	0
Breast cyst	0	0	11	0	2	0	16	0	27	0	0	0
Breast discharge	0	0	6	0	1	0	16	0	22	0	0	0
Breast discolouration	0	0	0	0	0	0	2	0	2	0	0	0
Breast discomfort	1	0	11	0	5	0	36	0	47	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Breast disorder	0	0	4	0	1	0	8	0	12	0	0	0
Breast disorder female	0	0	0	0	0	0	3	0	3	0	0	0
Breast engorgement	0	0	3	0	1	0	16	0	19	0	0	0
Breast enlargement	0	0	3	0	3	0	43	0	46	0	0	0
Breast haematoma	0	0	2	0	2	0	11	0	13	0	0	0
Breast haemorrhage	0	0	2	0	0	0	1	0	3	0	0	0
Breast hyperplasia	0	0	1	0	0	0	0	0	1	0	0	1
Breast induration	0	0	2	0	0	0	3	0	5	0	0	0
Breast inflammation	0	0	9	0	3	0	26	0	35	0	0	0
Breast mass	2	0	66	0	4	0	59	0	125	0	0	0
Breast milk discolouration	0	0	0	0	0	0	1	0	1	0	0	0
Breast oedema	0	0	7	0	0	0	8	0	15	0	0	0
Breast pain	9	0	379	0	46	0	627	0	1006	0	0	0
Breast swelling	2	0	56	0	4	0	81	0	137	0	0	0
Breast tenderness	0	0	46	0	6	0	68	0	114	0	0	0
Cervical friability	0	0	1	0	0	0	0	0	1	0	0	0
Cervical polyp	0	0	2	0	0	0	0	0	2	0	0	0
Cervix disorder	0	0	0	0	1	0	1	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Cervix haemorrhage uterine	0	0	1	0	0	0	0	0	1	0	0	0
Cervix oedema	0	0	0	0	0	0	1	0	1	0	0	0
Clitoral engorgement	0	0	1	0	0	0	0	0	1	0	0	0
Coital bleeding	0	0	5	0	0	0	8	0	13	0	0	0
Cystocele	0	0	1	0	0	0	0	0	1	0	0	0
Dysmenorrhoea	15	0	1102	0	59	0	995	1	2097	1	0	0
Dyspareunia	0	0	6	0	0	0	4	0	10	0	0	0
Ectropion of cervix	0	0	1	0	0	0	1	0	2	0	0	0
Ejaculation delayed	0	0	1	0	1	0	3	0	4	0	0	0
Ejaculation disorder	0	0	2	0	0	0	9	0	11	0	0	0
Ejaculation failure	0	0	3	0	0	0	7	0	10	0	0	0
Endometrial hyperplasia	0	0	2	0	0	0	1	0	3	0	0	0
Endometrial thickening	0	0	2	0	0	0	3	0	5	0	0	0
Endometriosis	1	0	75	0	2	0	36	0	111	0	0	0
Enlarged clitoris	0	0	0	0	0	0	2	0	2	0	0	0
Epididymal cyst	0	0	0	0	0	0	1	0	1	0	0	0
Erectile dysfunction	9	0	114	0	5	0	98	0	212	0	0	0
Erection increased	0	0	7	0	0	0	8	0	15	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Fallopian tube spasm	0	0	1	0	0	0	0	0	1	0	0	0
Female genital tract fistula	0	0	1	0	0	0	0	0	1	0	0	0
Female reproductive tract disorder	0	0	0	0	0	0	2	0	2	0	0	0
Female sexual arousal disorder	0	0	1	0	0	0	0	0	1	0	0	0
Female sexual dysfunction	0	0	1	0	0	0	0	0	1	0	0	0
Fibrocystic breast disease	0	0	0	0	0	0	2	0	2	0	0	0
Foreskin oedema	0	0	1	0	0	0	0	0	1	0	0	0
Galactorrhoea	1	0	4	0	0	0	8	0	12	0	0	0
Galactostasis	0	0	2	0	0	0	0	0	2	0	0	0
Genital blister	0	0	4	0	0	0	2	0	6	0	0	0
Genital burning sensation	0	0	6	0	0	0	6	0	12	0	0	0
Genital cyst	0	0	2	0	0	0	0	0	2	0	0	0
Genital discharge	1	0	2	0	0	0	3	0	5	0	0	0
Genital discomfort	0	0	5	0	0	0	7	0	12	0	0	0
Genital disorder	0	0	0	0	0	0	3	0	3	0	0	0
Genital dysaesthesia	0	0	1	0	0	0	1	0	2	0	0	0
Genital erythema	0	0	1	0	0	0	3	0	4	0	0	0
Genital haemorrhage	1	0	29	0	1	0	32	0	61	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Genital hyperaesthesia	0	0	1	0	0	0	0	0	1	0	0	0
Genital hypoaesthesia	0	0	2	0	0	0	0	0	2	0	0	0
Genital lesion	0	0	3	0	0	0	2	0	5	0	0	0
Genital pain	1	0	9	0	3	0	24	0	33	0	0	0
Genital paraesthesia	0	0	2	0	1	0	6	0	8	0	0	0
Genital rash	1	0	6	0	2	0	13	0	19	0	0	0
Genital swelling	0	0	2	0	0	0	5	0	7	0	0	0
Genital tract inflammation	0	0	2	0	2	0	6	0	8	0	0	0
Genital ulceration	0	0	8	0	0	0	14	0	22	0	0	0
Gynaecomastia	1	0	7	0	0	0	10	0	17	0	0	0
Haematospermia	0	0	16	0	0	0	19	0	35	0	0	0
Haemorrhagic ovarian cyst	0	0	2	0	0	0	0	0	2	0	0	0
Heavy menstrual bleeding	35	0	3139	1	198	0	3583	0	6722	1	0	0
Hydrosalpinx	0	0	2	0	0	0	0	0	2	0	0	0
Hypomenorrhoea	1	0	178	0	12	0	395	0	573	0	0	0
Hypospermia	0	0	1	0	0	0	0	0	1	0	0	0
Infertility	2	0	11	0	0	0	10	0	21	0	0	0
Infertility female	0	0	6	0	0	0	1	0	7	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Infertility male	0	0	3	0	1	0	1	0	4	0	0	0
Intermenstrual bleeding	8	0	408	0	69	0	1208	0	1616	0	0	0
Labia enlarged	0	0	3	0	0	0	1	0	4	0	0	0
Lactation disorder	0	0	2	0	2	0	8	0	10	0	0	0
Lactation puerperal increased	0	0	4	0	0	0	5	0	9	0	0	0
Male reproductive tract disorder	0	0	0	0	0	0	1	0	1	0	0	0
Male sexual dysfunction	0	0	1	0	0	0	2	0	3	0	0	0
Mammary duct ectasia	0	0	1	0	0	0	0	0	1	0	0	0
Menometrorrhagia	2	0	21	0	16	0	67	0	88	0	0	0
Menopausal disorder	0	0	3	0	0	0	0	0	3	0	0	0
Menopausal symptoms	2	0	34	0	3	0	78	0	112	0	0	0
Menopause delayed	0	0	0	0	0	0	6	0	6	0	0	0
Menstrual discomfort	0	0	13	0	5	0	79	0	92	0	0	0
Menstrual disorder	26	0	894	0	153	0	2488	1	3382	1	0	0
Menstruation delayed	5	0	1258	0	60	0	2630	1	3888	1	0	0
Menstruation irregular	22	0	1113	0	120	0	2396	0	3509	0	0	0
Metrorrhoea	0	0	1	0	0	0	0	0	1	0	0	0
Nipple disorder	0	0	2	0	0	0	3	0	5	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Nipple enlargement	0	0	1	0	0	0	0	0	1	0	0	0
Nipple exudate bloody	0	0	1	0	0	0	2	0	3	0	0	0
Nipple inflammation	0	0	1	0	1	0	3	0	4	0	0	0
Nipple pain	0	0	23	0	3	0	38	0	61	0	0	0
Nipple swelling	0	0	4	0	0	0	2	0	6	0	0	0
Nocturnal emission	0	0	0	0	0	0	2	0	2	0	0	0
Noninfective oophoritis	0	0	1	0	0	0	2	0	3	0	0	0
Oedema genital	1	0	1	0	0	0	2	0	3	0	0	0
Oligomenorrhoea	1	0	72	0	27	0	343	0	415	0	0	0
Orchitis noninfective	0	0	2	0	2	0	5	0	7	0	0	0
Organic erectile dysfunction	0	0	16	0	0	0	3	0	19	0	0	0
Ovarian adhesion	0	0	1	0	0	0	0	0	1	0	0	0
Ovarian cyst	0	0	32	0	7	0	29	0	61	0	0	0
Ovarian cyst ruptured	1	0	11	0	0	0	3	0	14	0	0	0
Ovarian disorder	0	0	0	0	0	0	1	0	1	0	0	0
Ovarian enlargement	0	0	3	0	0	0	1	0	4	0	0	0
Ovarian failure	0	0	3	0	0	0	1	0	4	0	0	0
Ovarian haemorrhage	1	0	5	0	1	0	1	0	6	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Ovarian hyperstimulation syndrome	0	0	0	0	0	0	2	0	2	0	0	0
Ovarian mass	1	0	2	0	0	0	0	0	2	0	0	0
Ovarian necrosis	1	0	1	0	0	0	0	0	1	0	0	0
Ovarian oedema	0	0	1	0	0	0	0	0	1	0	0	0
Ovarian vein thrombosis	1	0	8	0	0	0	0	0	8	0	0	0
Ovulation disorder	0	0	2	0	0	0	3	0	5	0	0	0
Ovulation pain	1	0	40	0	3	0	41	0	81	0	0	0
Painful ejaculation	0	0	2	0	0	0	0	0	2	0	0	0
Painful erection	0	0	2	0	0	0	2	0	4	0	0	0
Pelvic congestion	0	0	1	0	0	0	0	0	1	0	0	0
Pelvic discomfort	0	0	5	0	1	0	10	0	15	0	0	0
Pelvic floor muscle weakness	1	0	1	0	0	0	0	0	1	0	0	0
Pelvic fluid collection	1	0	1	0	1	0	1	0	2	0	0	0
Pelvic haematoma	0	0	1	0	0	0	0	0	1	0	0	0
Pelvic haemorrhage	4	0	22	0	0	0	10	0	32	0	0	0
Pelvic organ prolapse	0	0	1	0	0	0	0	0	1	0	0	0
Pelvic pain	9	0	196	0	28	0	201	0	397	0	0	0
Penile blister	0	0	2	0	0	0	4	0	6	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Penile burning sensation	0	0	1	0	0	0	1	0	2	0	0	0
Penile curvature	0	0	4	0	0	0	0	0	4	0	0	0
Penile dermatitis	0	0	0	0	0	0	2	0	2	0	0	0
Penile discharge	0	0	4	0	0	0	1	0	5	0	0	0
Penile discomfort	0	0	1	0	0	0	1	0	2	0	0	0
Penile erosion	0	0	1	0	0	0	0	0	1	0	0	0
Penile erythema	0	0	0	0	0	0	1	0	1	0	0	0
Penile exfoliation	0	0	1	0	0	0	1	0	2	0	0	0
Penile haematoma	0	0	0	0	0	0	2	0	2	0	0	0
Penile haemorrhage	1	0	8	0	0	0	1	0	9	0	0	0
Penile oedema	0	0	1	0	0	0	4	0	5	0	0	0
Penile pain	0	0	2	0	0	0	5	0	7	0	0	0
Penile size reduced	0	0	1	0	0	0	2	0	3	0	0	0
Penile swelling	0	0	0	0	0	0	1	0	1	0	0	0
Penile vascular disorder	0	0	0	0	0	0	1	0	1	0	0	0
Penile vein thrombosis	0	0	9	0	0	0	1	0	10	0	0	0
Penis disorder	0	0	7	0	0	0	9	0	16	0	0	0
Perineal disorder	0	0	1	0	0	0	1	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Perineal erythema	0	0	0	0	0	0	1	0	1	0	0	0
Perineal pain	0	0	2	0	1	0	4	0	6	0	0	0
Peyronie's disease	1	0	6	0	0	0	0	0	6	0	0	0
Polycystic ovaries	0	0	22	0	2	0	29	0	51	0	0	0
Polymenorrhagia	0	0	0	0	0	0	2	0	2	0	0	0
Polymenorrhoea	5	0	349	0	60	0	908	0	1257	0	0	0
Postmenopausal haemorrhage	10	0	271	0	18	0	299	0	570	0	0	0
Premature menopause	4	0	36	0	0	0	25	0	61	0	0	0
Premature ovulation	0	0	8	0	0	0	1	0	9	0	0	0
Premenstrual dysphoric disorder	0	0	5	0	0	0	5	0	10	0	0	0
Premenstrual pain	0	0	65	0	4	0	51	0	116	0	0	0
Premenstrual syndrome	0	0	52	0	3	0	62	0	114	0	0	0
Priapism	0	0	15	0	0	0	0	0	15	0	0	0
Prostate tenderness	0	0	0	0	0	0	1	0	1	0	0	0
Prostatic haemorrhage	0	0	2	0	0	0	1	0	3	0	0	0
Prostatic pain	0	0	2	0	0	0	3	0	5	0	0	0
Prostatism	0	0	1	0	0	0	0	0	1	0	0	0
Prostatitis	0	0	11	0	2	0	18	0	29	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Prostatomegaly	1	0	6	0	1	0	3	0	9	0	0	0
Pruritus genital	0	0	9	0	4	0	33	0	42	0	0	0
Reproductive tract disorder	0	0	0	0	1	0	1	0	1	0	0	0
Retrograde ejaculation	0	0	1	0	0	0	5	0	6	0	0	0
Retrograde menstruation	0	0	1	0	0	0	4	0	5	0	0	0
Scrotal cyst	1	0	1	0	0	0	0	0	1	0	0	0
Scrotal dermatitis	0	0	0	0	0	0	1	0	1	0	0	0
Scrotal discomfort	0	0	0	0	0	0	2	0	2	0	0	0
Scrotal oedema	0	0	1	0	2	0	3	0	4	0	0	0
Scrotal pain	0	0	13	0	1	0	8	0	21	0	0	0
Scrotal swelling	0	0	6	0	0	0	7	0	13	0	0	0
Semen discolouration	0	0	1	0	1	0	2	0	3	0	0	0
Sexual dysfunction	2	0	13	0	1	0	13	0	26	0	0	0
Spontaneous penile erection	0	0	3	0	2	0	5	0	8	0	0	0
Suppressed lactation	2	0	18	0	5	0	26	0	44	0	0	0
Testicular atrophy	0	0	1	0	0	0	1	0	2	0	0	0
Testicular cyst	0	0	1	0	0	0	1	0	2	0	0	0
Testicular disorder	0	0	6	0	0	0	4	0	10	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Testicular haemorrhage	0	0	0	0	0	0	1	0	1	0	0	0
Testicular mass	0	0	1	0	0	0	1	0	2	0	0	0
Testicular oedema	0	0	2	0	0	0	5	0	7	0	0	0
Testicular pain	0	0	74	0	5	0	102	0	176	0	0	0
Testicular retraction	0	0	1	0	0	0	4	0	5	0	0	0
Testicular swelling	0	0	21	1	1	0	20	0	41	1	0	0
Testicular torsion	0	0	1	0	0	0	0	0	1	0	0	0
Testis discomfort	0	0	4	0	0	0	9	0	13	0	0	0
Uterine cyst	0	0	1	0	0	0	2	0	3	0	0	0
Uterine disorder	0	0	1	0	0	0	1	0	2	0	0	0
Uterine enlargement	0	0	2	0	0	0	1	0	3	0	0	0
Uterine haemorrhage	2	0	62	0	0	0	42	0	104	0	0	1
Uterine inflammation	0	0	0	0	0	0	1	0	1	0	0	0
Uterine mass	2	0	2	0	0	0	0	0	2	0	0	0
Uterine pain	0	0	16	0	3	0	20	0	36	0	0	0
Uterine polyp	0	0	3	0	0	0	3	0	6	0	0	0
Uterine prolapse	0	0	1	0	0	0	0	0	1	0	0	0
Uterine spasm	0	0	19	0	5	0	23	0	42	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Vaginal cyst	0	0	12	0	1	0	6	0	18	0	0	0
Vaginal discharge	0	0	58	0	5	0	85	0	143	0	0	0
Vaginal disorder	0	0	1	0	1	0	3	0	4	0	0	0
Vaginal erosion	0	0	0	0	0	0	1	0	1	0	0	0
Vaginal haematoma	0	0	0	0	0	0	1	0	1	0	0	0
Vaginal haemorrhage	21	0	880	0	26	0	1034	0	1914	0	1	1
Vaginal lesion	0	0	4	0	0	0	5	0	9	0	0	0
Vaginal mucosal blistering	0	0	1	0	0	0	0	0	1	0	0	0
Vaginal odour	0	0	4	0	0	0	6	0	10	0	0	0
Vaginal prolapse	0	0	2	0	0	0	2	0	4	0	0	0
Vaginal ulceration	0	0	6	0	1	0	8	0	14	0	0	0
Varicocele	0	0	2	0	0	0	1	0	3	0	0	0
Varicose veins pelvic	0	0	2	0	0	0	0	0	2	0	0	0
Vulva cyst	0	0	1	0	0	0	0	0	1	0	0	0
Vulval disorder	0	0	0	0	0	0	6	0	6	0	0	0
Vulval haematoma	0	0	0	0	0	0	1	0	1	0	0	0
Vulval haemorrhage	0	0	17	0	0	0	17	0	34	0	0	0
Vulval oedema	0	0	1	0	0	0	1	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Vulval ulceration	1	0	9	0	0	0	14	0	23	0	0	0
Vulvovaginal burning sensation	0	0	8	0	0	0	13	0	21	0	0	0
Vulvovaginal discomfort	0	0	9	0	2	0	17	0	26	0	0	0
Vulvovaginal disorder	0	0	0	0	1	0	2	0	2	0	0	0
Vulvovaginal dryness	1	0	12	0	1	0	16	0	28	0	0	0
Vulvovaginal erythema	0	0	1	0	0	0	2	0	3	0	0	0
Vulvovaginal inflammation	0	0	4	0	0	0	1	0	5	0	0	0
Vulvovaginal pain	0	0	34	0	0	0	26	0	60	0	0	0
Vulvovaginal pruritus	0	0	11	0	1	0	15	0	26	0	0	0
Vulvovaginal rash	0	0	2	0	0	0	2	0	4	0	0	0
Vulvovaginal swelling	1	0	7	0	0	0	5	0	12	0	0	0
Vulvovaginal ulceration	0	0	3	0	1	0	3	0	6	0	0	0
Withdrawal bleed	0	0	8	0	0	0	12	0	20	0	0	0
Congenital, familial and genetic disorders	**48**	**0**	**347**	**0**	**0**	**0**	**0**	**0**	**347**	**0**	**17**	**21**
11-beta-hydroxylase deficiency	2	0	5	0	0	0	0	0	5	0	0	0
17,20-desmolase deficiency	0	0	1	0	0	0	0	0	1	0	0	0
17-alpha-hydroxylase deficiency	0	0	3	0	0	0	0	0	3	0	0	0
1p36 deletion syndrome	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
20,22-desmolase deficiency	1	0	2	0	0	0	0	0	2	0	0	0
21-hydroxylase deficiency	0	0	1	0	0	0	0	0	1	0	0	0
Accessory spleen	0	0	1	0	0	0	0	0	1	0	0	0
Acquired gene mutation	1	0	1	0	0	0	0	0	1	0	0	0
Alagille syndrome	0	0	1	0	0	0	0	0	1	0	0	0
Alport's syndrome	0	0	1	0	0	0	0	0	1	0	0	0
Amegakaryocytic thrombocytopenia	0	0	1	0	0	0	0	0	1	0	0	0
Anencephaly	0	0	3	0	0	0	0	0	3	0	0	0
Ankyloglossia congenital	0	0	1	0	0	0	0	0	1	0	2	2
Aplasia	0	0	1	0	0	0	0	0	1	0	0	0
Arnold-Chiari malformation	0	0	2	0	0	0	0	0	2	0	0	0
Arrhythmogenic right ventricular dysplasia	1	0	1	0	0	0	0	0	1	0	0	0
Arteriovenous malformation	2	0	11	0	0	0	0	0	11	0	0	0
Ataxia telangiectasia	1	0	1	0	0	0	0	0	1	0	0	0
Atrial septal defect	2	0	7	0	0	0	0	0	7	0	0	1
BRAF gene mutation	1	0	1	0	0	0	0	0	1	0	0	0
Benign familial pemphigus	0	0	2	0	0	0	0	0	2	0	0	0
Bicuspid aortic valve	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Brachyolmia	0	0	1	0	0	0	0	0	1	0	0	0
Brain malformation	1	0	2	0	0	0	0	0	2	0	0	0
Branchial cyst	0	0	2	0	0	0	0	0	2	0	0	0
Brugada syndrome	0	0	1	0	0	0	0	0	1	0	0	0
CANDLE syndrome	0	0	2	0	0	0	0	0	2	0	0	0
Cancer gene carrier	0	0	1	0	0	0	0	0	1	0	0	0
Cerebral arteriovenous malformation haemorrhagic	0	0	1	0	0	0	0	0	1	0	0	0
Cerebral cavernous malformation	2	0	2	0	0	0	0	0	2	0	0	0
Cerebral palsy	0	0	5	0	0	0	0	0	5	0	0	0
Chronic granulomatous disease	0	0	1	0	0	0	0	0	1	0	0	0
Cleft lip and palate	0	0	1	0	0	0	0	0	1	0	0	0
Coarctation of the aorta	0	0	2	0	0	0	0	0	2	0	0	0
Colour blindness	0	0	13	0	0	0	0	0	13	0	0	0
Combined immunodeficiency	0	0	2	0	0	0	0	0	2	0	0	0
Congenital anomaly	0	0	5	0	0	0	0	0	5	0	0	0
Congenital arterial malformation	0	0	2	0	0	0	0	0	2	0	0	0
Congenital cerebrovascular anomaly	1	0	1	0	0	0	0	0	1	0	0	0
Congenital cystic kidney disease	0	0	1	0	0	0	0	0	1	0	1	1

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Congenital diaphragmatic hernia	0	0	2	0	0	0	0	0	2	0	0	0
Congenital hearing disorder	0	0	1	0	0	0	0	0	1	0	0	0
Congenital hydrocephalus	0	0	0	0	0	0	0	0	0	0	1	1
Congenital hydronephrosis	0	0	0	0	0	0	0	0	0	0	1	1
Congenital hyperthyroidism	1	0	2	0	0	0	0	0	2	0	0	0
Congenital knee deformity	0	0	1	0	0	0	0	0	1	0	0	0
Congenital midline defect	0	0	1	0	0	0	0	0	1	0	0	0
Congenital multiplex arthrogryposis	0	0	1	0	0	0	0	0	1	0	0	0
Congenital musculoskeletal disorder of limbs	1	0	1	0	0	0	0	0	1	0	0	0
Congenital musculoskeletal disorder of skull	0	0	3	0	0	0	0	0	3	0	0	0
Congenital musculoskeletal disorder of spine	0	0	2	0	0	0	0	0	2	0	0	0
Congenital ureterocele	0	0	0	0	0	0	0	0	0	0	1	1
Cryptorchism	0	0	0	0	0	0	0	0	0	0	1	1
Cystic fibrosis	1	0	3	0	0	0	0	0	3	0	0	0
Cystic lymphangioma	0	0	1	0	0	0	0	0	1	0	0	0
Cytogenetic abnormality	0	0	0	0	0	0	0	0	0	0	0	1
Dacryostenosis congenital	0	0	1	0	0	0	0	0	1	0	0	0
Deafness congenital	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Deficiency of the interleukin-36 receptor antagonist	0	0	1	0	0	0	0	0	1	0	0	0
Dermoid cyst	0	0	0	0	0	0	0	0	0	0	1	1
Developmental hip dysplasia	0	0	0	0	0	0	0	0	0	0	1	1
Double outlet right ventricle	1	0	1	0	0	0	0	0	1	0	0	0
Dysmorphism	0	0	3	0	0	0	0	0	3	0	0	0
Eagle Barrett syndrome	0	0	1	0	0	0	0	0	1	0	0	0
Ectrodactyly	0	0	1	0	0	0	0	0	1	0	0	0
Ehlers-Danlos syndrome	0	0	8	0	0	0	0	0	8	0	0	0
Endocardial fibroelastosis	1	0	1	0	0	0	0	0	1	0	0	0
Epilepsy with myoclonic-atonic seizures	0	0	2	0	0	0	0	0	2	0	0	0
Factor II mutation	1	0	1	0	0	0	0	0	1	0	0	0
Factor V Leiden mutation	1	0	4	0	0	0	0	0	4	0	0	0
Factor VII deficiency	0	0	1	0	0	0	0	0	1	0	0	0
Factor VIII deficiency	0	0	2	0	0	0	0	0	2	0	0	0
Factor XI deficiency	0	0	1	0	0	0	0	0	1	0	0	0
Factor XIII deficiency	1	0	4	0	0	0	0	0	4	0	0	0
Fallot's tetralogy	0	0	0	0	0	0	0	0	0	0	0	1
Familial hemiplegic migraine	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Foetal chromosome abnormality	0	0	1	0	0	0	0	0	1	0	0	0
Foetal malformation	0	0	7	0	0	0	0	0	7	0	0	0
Gastrointestinal malformation	0	0	2	0	0	0	0	0	2	0	0	0
Gastroschisis	1	0	2	0	0	0	0	0	2	0	0	0
Gilbert's syndrome	2	0	5	0	0	0	0	0	5	0	0	0
Glucose-6-phosphate dehydrogenase deficiency	0	0	0	0	0	0	0	0	0	0	2	2
Glycogen storage disease type I	0	0	1	0	0	0	0	0	1	0	0	0
Grey matter heterotopia	0	0	1	0	0	0	0	0	1	0	0	0
Haemangioma of retina	0	0	1	0	0	0	0	0	1	0	0	0
Haemophilia	0	0	2	0	0	0	0	0	2	0	0	0
Haemorrhagic arteriovenous malformation	1	0	3	0	0	0	0	0	3	0	0	0
Heart disease congenital	5	0	22	0	0	0	0	0	22	0	0	0
Hereditary disorder	0	0	1	0	0	0	0	0	1	0	0	0
Hereditary pancreatitis	0	0	1	0	0	0	0	0	1	0	0	0
Heterotaxia	0	0	3	0	0	0	0	0	3	0	0	0
Holoprosencephaly	0	0	1	0	0	0	0	0	1	0	0	0
Huntington's disease	0	0	2	0	0	0	0	0	2	0	0	0
Hydrocele	0	0	6	0	0	0	0	0	6	0	1	1

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Hyper IgD syndrome	1	0	2	0	0	0	0	0	2	0	0	0
Hyperglycinaemia	0	0	1	0	0	0	0	0	1	0	0	0
Hypermobility syndrome	0	0	3	0	0	0	0	0	3	0	0	0
Hypertrophic cardiomyopathy	1	0	10	0	0	0	0	0	10	0	0	0
Hypoplastic left heart syndrome	0	0	1	0	0	0	0	0	1	0	0	0
Hypoplastic right heart syndrome	0	0	1	0	0	0	0	0	1	0	0	0
Hypospadias	0	0	0	0	0	0	0	0	0	0	0	1
Ichthyosis	0	0	1	0	0	0	0	0	1	0	0	0
Intestinal atresia	0	0	1	0	0	0	0	0	1	0	0	0
Intracranial lipoma	0	0	1	0	0	0	0	0	1	0	0	0
Keratosis follicular	0	0	1	0	0	0	0	0	1	0	0	0
Kidney duplex	0	0	0	0	0	0	0	0	0	0	1	1
Klinefelter's syndrome	0	0	1	0	0	0	0	0	1	0	0	0
Klippel-Trenaunay syndrome	0	0	1	0	0	0	0	0	1	0	0	0
Larsen syndrome	0	0	1	0	0	0	0	0	1	0	0	0
Left ventricle outflow tract obstruction	0	0	1	0	0	0	0	0	1	0	0	0
Limb reduction defect	3	0	5	0	0	0	0	0	5	0	0	0
Macroglossia	0	0	4	0	0	0	0	0	4	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Malformation venous	1	0	1	0	0	0	0	0	1	0	0	0
Melkersson-Rosenthal syndrome	1	0	1	0	0	0	0	0	1	0	0	0
Meningomyelocele	0	0	1	0	0	0	0	0	1	0	0	0
Micropenis	0	0	2	0	0	0	0	0	2	0	0	0
Mitral valve atresia	0	0	1	0	0	0	0	0	1	0	0	0
Monolid eyes	0	0	1	0	0	0	0	0	1	0	0	0
Mucolipidosis	0	0	1	0	0	0	0	0	1	0	0	0
Multiple cardiac defects	0	0	1	0	0	0	0	0	1	0	0	0
Multiple congenital abnormalities	0	0	3	0	0	0	0	0	3	0	0	0
Myoclonic dystonia	0	0	1	0	0	0	0	0	1	0	0	0
Myotonic dystrophy	0	0	1	0	0	0	0	0	1	0	0	0
Naevus flammeus	0	0	2	0	0	0	0	0	2	0	0	0
Neonatal alloimmune thrombocytopenia	0	0	2	0	0	0	0	0	2	0	0	0
Neural tube defect	0	0	1	0	0	0	0	0	1	0	0	0
Neurofibromatosis	1	0	2	0	0	0	0	0	2	0	0	0
Opitz-G/BBB syndrome	1	0	1	0	0	0	0	0	1	0	0	0
Os trigonum	0	0	1	0	0	0	0	0	1	0	0	0
Otocephaly	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Paroxysmal extreme pain disorder	1	0	20	0	0	0	0	0	20	0	0	0
Pelizaeus-Merzbacher disease	0	0	2	0	0	0	0	0	2	0	0	0
Penoscrotal fusion	0	0	3	0	0	0	0	0	3	0	0	0
Plagiocephaly	0	0	1	0	0	0	0	0	1	0	0	0
Polycystic liver disease	0	0	1	0	0	0	0	0	1	0	0	0
Porphyria acute	1	0	2	0	0	0	0	0	2	0	0	0
Porphyria non-acute	0	0	1	0	0	0	0	0	1	0	0	0
Preauricular cyst	0	0	0	0	0	0	0	0	0	0	1	1
Protein C deficiency	0	0	1	0	0	0	0	0	1	0	0	0
Pseudotruncus arteriosus	0	0	1	0	0	0	0	0	1	0	0	0
Pyloric stenosis	0	0	0	0	0	0	0	0	0	0	1	1
Retinitis pigmentosa	0	0	1	0	0	0	0	0	1	0	0	0
Rippling muscle disease	0	0	1	0	0	0	0	0	1	0	0	0
SADDAN syndrome	0	0	2	0	0	0	0	0	2	0	0	0
Sickle cell anaemia	1	0	1	0	0	0	0	0	1	0	0	0
Sickle cell disease	0	0	1	0	0	0	0	0	1	0	0	0
Spina bifida	0	0	4	0	0	0	0	0	4	0	0	0
Spinal muscular atrophy	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Spinal vessel congenital anomaly	0	0	1	0	0	0	0	0	1	0	0	0
Syndactyly	0	0	1	0	0	0	0	0	1	0	0	0
Syringomyelia	2	0	3	0	0	0	0	0	3	0	0	0
Talipes	0	0	1	0	0	0	0	0	1	0	2	2
Thalassaemia	0	0	1	0	0	0	0	0	1	0	0	0
Thalassaemia beta	0	0	1	0	0	0	0	0	1	0	0	0
Thyroglossal cyst	0	0	2	0	0	0	0	0	2	0	0	0
Tourette's disorder	0	0	3	0	0	0	0	0	3	0	0	0
Transposition of the great vessels	0	0	3	0	0	0	0	0	3	0	0	0
Trisomy 18	0	0	2	0	0	0	0	0	2	0	0	0
Trisomy 21	0	0	1	0	0	0	0	0	1	0	0	0
Tuberous sclerosis complex	0	0	1	0	0	0	0	0	1	0	0	0
Turner's syndrome	0	0	1	0	0	0	0	0	1	0	0	0
Type IIa hyperlipidaemia	1	0	2	0	0	0	0	0	2	0	0	0
Vascular malformation	1	0	6	0	0	0	0	0	6	0	0	0
Vein of Galen aneurysmal malformation	0	0	1	0	0	0	0	0	1	0	0	0
Venous angioma of brain	0	0	1	0	0	0	0	0	1	0	0	0
Ventricular hypoplasia	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Ventricular septal defect	0	0	1	0	0	0	0	0	1	0	0	0
Vertebral artery hypoplasia	0	0	2	0	0	0	0	0	2	0	0	0
Vestibulocerebellar syndrome	0	0	1	0	0	0	0	0	1	0	0	0
Von Willebrand's disease	0	0	1	0	0	0	0	0	1	0	0	0
Young's syndrome	0	0	1	0	0	0	0	0	1	0	0	0
General disorders and administration site conditions	**9071**	**1**	**278469**	**11**	**92550**	**2**	**884194**	**47**	**1162663**	**58**	**21**	**101**
Abscess sterile	0	0	1	0	0	0	1	0	2	0	0	0
Absence of immediate treatment response	0	0	0	0	0	0	1	0	1	0	0	0
Acute phase reaction	0	0	0	0	0	0	2	0	2	0	0	0
Adhesion	1	0	3	0	0	0	3	0	6	0	0	0
Administration site anaesthesia	0	0	0	0	0	0	1	0	1	0	0	0
Administration site bruise	0	0	6	0	1	0	40	0	46	0	0	0
Administration site coldness	0	0	1	0	0	0	2	0	3	0	0	0
Administration site dermatitis	0	0	0	0	0	0	1	0	1	0	0	0
Administration site discolouration	0	0	0	0	0	0	2	0	2	0	0	0
Administration site discomfort	0	0	0	0	2	0	5	0	5	0	0	0
Administration site dysaesthesia	0	0	0	0	0	0	1	0	1	0	0	0
Administration site erythema	1	0	6	0	42	0	182	0	188	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Administration site extravasation	0	0	0	0	0	0	2	0	2	0	0	0
Administration site haematoma	0	0	2	0	3	0	12	0	14	0	0	0
Administration site haemorrhage	0	0	1	0	0	0	0	0	1	0	0	0
Administration site hyperaesthesia	0	0	0	0	0	0	1	0	1	0	0	0
Administration site hypersensitivity	0	0	0	0	0	0	10	0	10	0	0	0
Administration site indentation	0	0	0	0	1	0	5	0	5	0	0	0
Administration site induration	0	0	1	0	8	0	83	0	84	0	0	0
Administration site inflammation	0	0	1	0	0	0	7	0	8	0	0	0
Administration site injury	0	0	1	0	0	0	0	0	1	0	0	0
Administration site irritation	0	0	0	0	0	0	1	0	1	0	0	0
Administration site joint erythema	0	0	0	0	0	0	2	0	2	0	0	0
Administration site joint inflammation	0	0	0	0	0	0	1	0	1	0	0	0
Administration site joint movement impairment	1	0	1	0	0	0	1	0	2	0	0	0
Administration site joint pain	0	0	1	0	0	0	17	0	18	0	0	0
Administration site joint warmth	0	0	0	0	0	0	1	0	1	0	0	0
Administration site lymphadenopathy	0	0	1	0	0	0	2	0	3	0	0	0
Administration site macule	0	0	0	0	0	0	1	0	1	0	0	0
Administration site mass	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Administration site movement impairment	0	0	1	0	1	0	7	0	8	0	0	0
Administration site nodule	0	0	1	0	0	0	1	0	2	0	0	0
Administration site odour	0	0	0	0	0	0	1	0	1	0	0	0
Administration site oedema	1	0	2	0	36	0	169	0	171	0	0	0
Administration site pain	2	0	77	0	228	0	1281	0	1358	0	0	0
Administration site pallor	0	0	0	0	0	0	1	0	1	0	0	0
Administration site papule	0	0	0	0	0	0	1	0	1	0	0	0
Administration site paraesthesia	0	0	0	0	0	0	3	0	3	0	0	0
Administration site pruritus	0	0	1	0	0	0	15	0	16	0	0	0
Administration site rash	0	0	2	0	1	0	19	0	21	0	0	0
Administration site reaction	0	0	11	0	14	0	99	0	110	0	0	0
Administration site scar	0	0	0	0	0	0	1	0	1	0	0	0
Administration site swelling	0	0	1	0	2	0	25	0	26	0	0	0
Administration site urticaria	0	0	4	0	1	0	4	0	8	0	0	0
Administration site warmth	0	0	3	0	2	0	18	0	21	0	0	0
Administration site wound	0	0	0	0	0	0	1	0	1	0	0	0
Adverse drug reaction	73	0	358	0	34	0	304	0	662	0	0	0
Adverse event	7	0	21	0	22	0	2117	0	2138	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Adverse food reaction	0	0	3	0	0	0	3	0	6	0	0	0
Adverse reaction	4	0	25	0	11	0	121	0	146	0	0	0
Agonal death struggle	0	0	2	0	0	0	0	0	2	0	0	0
Alcohol interaction	0	0	1	0	0	0	3	0	4	0	0	0
Antidepressant discontinuation syndrome	0	0	0	0	0	0	1	0	1	0	0	0
Apparent death	1	0	2	0	0	0	0	0	2	0	0	0
Application site acne	0	0	0	0	1	0	5	0	5	0	0	0
Application site anaesthesia	0	0	0	0	0	0	2	0	2	0	0	0
Application site atrophy	0	0	0	0	0	0	4	0	4	0	0	0
Application site bruise	1	0	19	0	2	0	45	0	64	0	0	0
Application site burn	0	0	3	0	0	0	2	0	5	0	0	0
Application site coldness	0	0	2	0	1	0	9	0	11	0	0	0
Application site cyst	0	0	0	0	0	0	1	0	1	0	0	0
Application site dermatitis	0	0	0	0	3	0	17	0	17	0	0	0
Application site discharge	0	0	1	0	1	0	1	0	2	0	0	0
Application site discolouration	0	0	3	0	1	0	23	0	26	0	0	0
Application site discomfort	0	0	2	0	3	0	76	0	78	0	0	0
Application site dryness	0	0	0	0	0	0	1	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Application site dysaesthesia	0	0	0	0	0	0	1	0	1	0	0	0
Application site eczema	0	0	0	0	0	0	2	0	2	0	0	0
Application site erosion	0	0	0	0	0	0	1	0	1	0	0	0
Application site erythema	0	0	22	0	54	0	1075	0	1097	0	0	0
Application site exfoliation	0	0	1	0	2	0	4	0	5	0	0	0
Application site extravasation	0	0	0	0	0	0	1	0	1	0	0	0
Application site fibrosis	0	0	0	0	0	0	1	0	1	0	0	0
Application site granuloma	0	0	1	0	0	0	0	0	1	0	0	0
Application site haematoma	0	0	2	0	6	0	76	0	78	0	0	0
Application site haemorrhage	0	0	0	0	1	0	23	0	23	0	0	0
Application site hyperaesthesia	0	0	0	0	0	0	1	0	1	0	0	0
Application site hypersensitivity	0	0	2	0	4	0	136	0	138	0	0	0
Application site hypoaesthesia	0	0	6	0	2	0	50	0	56	0	0	0
Application site induration	0	0	1	0	9	0	306	0	307	0	0	0
Application site inflammation	0	0	1	0	0	0	15	0	16	0	0	0
Application site injury	0	0	2	0	0	0	3	0	5	0	0	0
Application site irritation	0	0	1	0	0	0	6	0	7	0	0	0
Application site ischaemia	0	0	0	0	0	0	1	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Application site joint erythema	0	0	0	0	0	0	2	0	2	0	0	0
Application site joint inflammation	0	0	0	0	0	0	1	0	1	0	0	0
Application site joint movement impairment	0	0	0	0	0	0	1	0	1	0	0	0
Application site joint pain	0	0	1	0	0	0	58	0	59	0	0	0
Application site joint swelling	0	0	1	0	1	0	8	0	9	0	0	0
Application site joint warmth	0	0	0	0	0	0	1	0	1	0	0	0
Application site laceration	0	0	1	0	0	0	0	0	1	0	0	0
Application site lymphadenopathy	0	0	0	0	0	0	12	0	12	0	0	0
Application site macule	0	0	0	0	0	0	1	0	1	0	0	0
Application site mass	0	0	0	0	2	0	11	0	11	0	0	0
Application site movement impairment	0	0	0	0	0	0	13	0	13	0	0	0
Application site necrosis	0	0	1	0	0	0	0	0	1	0	0	0
Application site nodule	0	0	0	0	5	0	33	0	33	0	0	0
Application site odour	0	0	1	0	2	0	122	0	123	0	0	0
Application site oedema	1	0	11	0	97	0	2414	0	2425	0	0	0
Application site pain	3	0	115	0	631	0	13174	0	13289	0	0	1
Application site pallor	0	0	0	0	0	0	1	0	1	0	0	0
Application site paraesthesia	0	0	1	0	0	0	15	0	16	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Application site perspiration	0	0	0	0	0	0	1	0	1	0	0	0
Application site plaque	0	0	0	0	0	0	1	0	1	0	0	0
Application site pruritus	1	0	20	0	47	0	797	0	817	0	0	0
Application site purpura	0	0	0	0	0	0	1	0	1	0	0	0
Application site rash	0	0	2	0	1	0	16	0	18	0	0	0
Application site reaction	0	0	6	0	4	0	639	0	645	0	0	0
Application site scar	0	0	1	0	0	0	1	0	2	0	0	0
Application site streaking	0	0	0	0	0	0	1	0	1	0	0	0
Application site swelling	0	0	8	0	28	0	1173	0	1181	0	0	0
Application site ulcer	0	0	0	0	0	0	1	0	1	0	0	0
Application site urticaria	0	0	0	0	1	0	2	0	2	0	0	0
Application site vesicles	0	0	7	0	0	0	14	0	21	0	0	0
Application site warmth	0	0	5	0	71	0	334	0	339	0	0	0
Application site wound	0	0	1	0	0	0	6	0	7	0	0	0
Asthenia	314	0	7032	1	2521	0	27681	1	34713	2	0	0
Atrophy	0	0	3	0	2	0	17	0	20	0	0	0
Axillary pain	13	0	577	0	124	0	927	0	1504	0	0	0
Brain death	2	0	28	0	0	0	0	0	28	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Breakthrough pain	0	0	1	0	2	0	3	0	4	0	0	0
Calcinosis	0	0	2	0	0	0	1	0	3	0	0	0
Capsular contracture associated with breast implant	0	0	2	0	0	0	0	0	2	0	0	0
Cardiac death	0	0	18	0	0	0	0	0	18	0	0	0
Catheter site haemorrhage	1	0	3	0	0	0	0	0	3	0	0	0
Catheter site pain	1	0	1	0	0	0	0	0	1	0	0	0
Catheter site swelling	1	0	1	0	0	0	0	0	1	0	0	0
Catheter site thrombosis	0	0	1	0	0	0	0	0	1	0	0	0
Catheter site urticaria	0	0	0	0	0	0	1	0	1	0	0	0
Chest discomfort	80	0	2313	0	386	0	3583	0	5896	0	1	2
Chest pain	244	0	6840	1	566	0	7105	0	13945	1	0	0
Chills	675	0	41286	0	14331	0	136082	3	177368	3	0	20
Chronic disease	0	0	3	0	0	0	0	0	3	0	0	0
Chronic fatigue syndrome	25	0	210	0	22	0	76	0	286	0	0	0
Chronic inflammatory response syndrome	0	0	0	0	2	0	2	0	2	0	0	0
Clinical death	0	0	2	0	0	0	0	0	2	0	0	0
Complication associated with device	1	0	2	0	0	0	0	0	2	0	0	0
Complication of device removal	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Concomitant disease aggravated	0	0	49	0	17	0	392	0	441	0	0	0
Concomitant disease progression	0	0	28	0	0	0	10	0	38	0	0	0
Condition aggravated	54	0	644	0	75	0	596	1	1240	1	0	0
Crepitations	1	0	11	0	2	0	9	0	20	0	0	0
Critical illness	1	0	4	0	0	0	0	0	4	0	0	0
Crying	3	0	271	0	13	0	255	0	526	0	0	0
Cyst	2	0	38	0	5	0	44	0	82	0	0	0
Cyst rupture	1	0	3	0	0	0	2	0	5	0	0	0
Death	167	1	1592	6	0	0	0	0	1592	6	4	4
Death neonatal	0	0	1	0	0	0	0	0	1	0	0	0
Decreased activity	0	0	15	0	5	0	40	0	55	0	0	0
Decreased gait velocity	0	0	5	0	0	0	1	0	6	0	0	0
Deformity	0	0	1	0	0	0	1	0	2	0	0	0
Developmental delay	0	0	3	0	0	0	1	0	4	0	0	0
Device related thrombosis	0	0	3	0	0	0	0	0	3	0	0	0
Diet failure	0	0	1	0	0	0	0	0	1	0	0	0
Discharge	0	0	16	0	1	0	27	0	43	0	0	0
Discomfort	22	0	593	0	278	0	1703	1	2296	1	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Disease complication	0	0	0	0	0	0	1	0	1	0	0	0
Disease prodromal stage	0	0	1	0	0	0	0	0	1	0	0	0
Disease progression	2	0	8	0	1	0	6	0	14	0	0	0
Disease recurrence	12	0	57	0	2	0	31	0	88	0	0	0
Disease susceptibility	0	0	0	0	0	0	4	0	4	0	0	0
Drowning	1	0	4	0	0	0	0	0	4	0	0	0
Drug effect less than expected	0	0	0	0	0	0	4	0	4	0	0	0
Drug ineffective	155	0	482	0	70	0	738	0	1220	0	3	8
Drug ineffective for unapproved indication	1	0	1	0	0	0	0	0	1	0	0	0
Drug interaction	9	0	54	0	7	0	53	0	107	0	0	0
Drug intolerance	3	0	12	0	3	0	13	0	25	0	0	0
Drug resistance	1	0	1	0	0	0	0	0	1	0	0	0
Drug tolerance	0	0	0	0	0	0	4	0	4	0	0	0
Drug withdrawal syndrome	0	0	9	0	0	0	0	0	9	0	0	0
Drug withdrawal syndrome neonatal	0	0	0	0	0	0	0	0	0	0	0	1
Drug-device interaction	0	0	1	0	0	0	1	0	2	0	0	0
Drug-disease interaction	0	0	1	0	0	0	0	0	1	0	0	0
Dysplasia	0	0	2	0	1	0	3	0	5	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Early satiety	0	0	2	0	1	0	2	0	4	0	0	0
Effusion	0	0	9	0	3	0	16	0	25	0	0	0
Electrocution	0	0	1	0	0	0	0	0	1	0	0	0
Enanthema	0	0	0	0	0	0	7	0	7	0	0	0
Encapsulation reaction	0	0	1	0	0	0	0	0	1	0	0	0
Energy increased	1	0	15	0	2	0	40	0	55	0	0	0
Exercise tolerance decreased	23	0	141	0	68	0	330	0	471	0	0	0
Extensive swelling of vaccinated limb	31	0	285	0	145	0	1084	0	1369	0	0	0
Extravasation	0	0	3	0	1	0	6	0	9	0	0	0
Face oedema	5	0	145	0	28	0	436	0	581	0	0	0
Facial discomfort	2	0	24	0	11	0	80	0	104	0	0	0
Facial pain	11	0	301	0	39	0	368	0	669	0	0	0
Fat necrosis	0	0	4	0	2	0	11	0	15	0	0	0
Fat tissue decreased	0	0	0	0	1	0	3	0	3	0	0	0
Fatigue	1144	0	48672	1	12776	1	121101	7	169773	8	0	17
Feeling abnormal	81	0	2886	0	404	0	3306	3	6192	3	0	0
Feeling cold	56	0	4533	0	741	0	6557	0	11090	0	0	0
Feeling drunk	3	0	108	0	11	0	134	0	242	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Feeling hot	39	0	2037	0	463	0	5478	0	7515	0	0	0
Feeling jittery	1	0	46	0	0	0	55	0	101	0	0	0
Feeling of body temperature change	17	0	866	0	100	0	1081	0	1947	0	0	0
Feeling of relaxation	0	0	3	0	0	0	15	0	18	0	0	0
Fibrosis	0	0	8	0	1	0	5	0	13	0	0	0
Foaming at mouth	3	0	8	0	0	0	5	0	13	0	0	0
Food interaction	0	0	3	0	0	0	0	0	3	0	0	0
Foreign body reaction	0	0	0	0	0	0	2	0	2	0	0	0
Gait deviation	0	0	2	0	0	0	1	0	3	0	0	0
Gait disturbance	99	0	1001	0	138	0	1172	0	2173	0	0	2
Gait inability	18	0	332	0	10	0	225	1	557	1	0	0
General physical health deterioration	24	0	181	0	75	0	571	0	752	0	0	0
General symptom	3	0	15	0	3	0	32	0	47	0	0	0
Generalised oedema	5	0	30	0	7	0	51	0	81	0	0	0
Glassy eyes	0	0	9	0	0	0	15	0	24	0	0	0
Granuloma	1	0	4	0	3	0	13	0	17	0	0	0
Gravitational oedema	1	0	5	0	0	0	6	0	11	0	0	0
Haemorrhagic cyst	0	0	0	0	0	0	2	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Hanging	0	0	1	0	0	0	1	0	2	0	0	0
Hangover	1	0	159	0	15	0	148	0	307	0	0	0
Hernia	2	0	12	0	1	0	7	0	19	0	0	0
Hernia pain	0	0	3	0	1	0	7	0	10	0	0	0
Heteroplasia	0	0	1	0	0	0	0	0	1	0	0	0
High-pitched crying	0	0	6	0	0	0	2	0	8	0	0	0
Humidity intolerance	0	0	1	0	0	0	0	0	1	0	0	0
Hunger	3	0	57	0	10	0	124	0	181	0	0	0
Hyperplasia	0	0	3	0	0	0	0	0	3	0	0	0
Hyperpyrexia	4	0	841	0	12	0	851	0	1692	0	0	0
Hyperthermia	3	0	47	0	22	0	329	0	376	0	0	0
Hyperthermia malignant	0	0	6	0	0	0	0	0	6	0	0	0
Hypertrophy	0	0	0	0	0	0	1	0	1	0	0	0
Hypothermia	10	0	142	0	8	0	187	0	329	0	0	0
Idiopathic environmental intolerance	0	0	2	0	0	0	2	0	4	0	0	0
Idiosyncratic drug reaction	0	0	1	0	0	0	0	0	1	0	0	0
Ill-defined disorder	7	0	23	0	16	0	1133	1	1156	1	0	0
Illness	41	0	4322	0	131	0	1799	4	6121	4	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Immediate post-injection reaction	0	0	1	0	0	0	3	0	4	0	0	0
Impaired healing	1	0	10	0	3	0	35	0	45	0	0	0
Impaired self-care	0	0	5	0	0	0	1	0	6	0	0	0
Implant site coldness	0	0	1	0	0	0	0	0	1	0	0	0
Implant site dermatitis	0	0	0	0	1	0	1	0	1	0	0	0
Implant site discharge	0	0	1	0	0	0	0	0	1	0	0	0
Implant site discolouration	0	0	2	0	0	0	2	0	4	0	0	0
Implant site extravasation	0	0	0	0	1	0	2	0	2	0	0	0
Implant site haemorrhage	0	0	0	0	0	0	1	0	1	0	0	0
Implant site hypoaesthesia	1	0	2	0	0	0	0	0	2	0	0	0
Implant site induration	0	0	0	0	1	0	1	0	1	0	0	0
Implant site inflammation	0	0	0	0	0	0	1	0	1	0	0	0
Implant site mass	0	0	0	0	1	0	1	0	1	0	0	0
Implant site pain	0	0	3	0	1	0	7	0	10	0	0	0
Implant site pruritus	0	0	0	0	0	0	1	0	1	0	0	0
Implant site rash	0	0	0	0	0	0	2	0	2	0	0	0
Implant site scar	0	0	0	0	0	0	1	0	1	0	0	0
Implant site swelling	0	0	1	0	0	0	3	0	4	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Implant site urticaria	0	0	1	0	0	0	3	0	4	0	0	0
Implant site vesicles	0	0	0	0	0	0	1	0	1	0	0	0
Implant site warmth	0	0	4	0	0	0	4	0	8	0	0	0
Inadequate analgesia	0	0	30	0	0	0	23	0	53	0	0	0
Induration	2	0	30	0	24	0	940	0	970	0	0	0
Inflammation	39	0	861	1	82	0	1398	0	2259	1	0	0
Inflammatory pain	5	0	39	0	1	0	15	0	54	0	0	0
Influenza like illness	145	0	10253	0	1337	0	27448	2	37701	2	0	0
Infusion site bruising	2	0	4	0	0	0	2	0	6	0	0	0
Infusion site discolouration	1	0	1	0	0	0	0	0	1	0	0	0
Infusion site discomfort	0	0	0	0	0	0	1	0	1	0	0	0
Infusion site erythema	1	0	4	0	0	0	5	0	9	0	0	0
Infusion site extravasation	1	0	2	0	0	0	2	0	4	0	0	0
Infusion site haematoma	0	0	0	0	0	0	6	0	6	0	0	0
Infusion site haemorrhage	1	0	3	0	0	0	0	0	3	0	0	0
Infusion site hypoaesthesia	0	0	0	0	0	0	1	0	1	0	0	0
Infusion site joint pain	0	0	1	0	0	0	0	0	1	0	0	0
Infusion site joint swelling	0	0	0	0	0	0	2	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Infusion site mass	0	0	3	0	0	0	3	0	6	0	0	0
Infusion site mobility decreased	0	0	2	0	0	0	6	0	8	0	0	0
Infusion site nodule	0	0	0	0	0	0	2	0	2	0	0	0
Infusion site pain	4	0	19	0	1	0	13	0	32	0	0	0
Infusion site pruritus	1	0	1	0	0	0	3	0	4	0	0	0
Infusion site rash	0	0	0	0	0	0	1	0	1	0	0	0
Infusion site reaction	0	0	0	0	0	0	1	0	1	0	0	0
Infusion site swelling	1	0	3	0	0	0	0	0	3	0	0	0
Infusion site urticaria	0	0	1	0	0	0	1	0	2	0	0	0
Infusion site warmth	0	0	2	0	0	0	4	0	6	0	0	0
Inhibitory drug interaction	0	0	10	0	0	0	3	0	13	0	0	0
Injected limb mobility decreased	8	0	147	0	61	0	392	0	539	0	0	0
Injection site abscess sterile	0	0	1	0	0	0	4	0	5	0	0	0
Injection site anaesthesia	0	0	0	0	0	0	2	0	2	0	0	0
Injection site atrophy	0	0	6	0	2	0	15	0	21	0	0	0
Injection site bruising	2	0	102	0	21	0	310	0	412	0	0	0
Injection site coldness	0	0	6	0	0	0	9	0	15	0	0	0
Injection site cyst	0	0	2	0	1	0	8	0	10	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Injection site deformation	2	0	2	0	0	0	15	0	17	0	0	0
Injection site dermatitis	0	0	0	0	0	0	3	0	3	0	0	0
Injection site discharge	1	0	3	0	0	0	7	0	10	0	0	0
Injection site discolouration	0	0	2	0	10	0	79	0	81	0	0	0
Injection site discomfort	0	0	20	0	22	0	756	0	776	0	0	0
Injection site dryness	0	0	1	0	0	0	2	0	3	0	0	0
Injection site dysaesthesia	0	0	0	0	0	0	11	0	11	0	0	0
Injection site eczema	0	0	0	0	0	0	1	0	1	0	0	0
Injection site erosion	0	0	0	0	0	0	4	0	4	0	0	0
Injection site erythema	13	0	514	0	335	0	6633	0	7147	0	0	0
Injection site exfoliation	0	0	0	0	1	0	5	0	5	0	0	0
Injection site extravasation	0	0	0	0	3	0	12	0	12	0	0	0
Injection site fibrosis	0	0	0	0	0	0	1	0	1	0	0	0
Injection site granuloma	0	0	0	0	0	0	2	0	2	0	0	0
Injection site haematoma	0	0	13	0	37	0	1582	0	1595	0	1	1
Injection site haemorrhage	2	0	23	0	12	0	116	0	139	0	0	0
Injection site hyperaesthesia	0	0	0	0	0	0	8	0	8	0	0	0
Injection site hypersensitivity	0	0	7	0	11	0	190	0	197	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Injection site hypertrophy	0	0	0	0	0	0	4	0	4	0	0	0
Injection site hypoaesthesia	0	0	16	0	13	0	170	0	186	0	0	0
Injection site indentation	0	0	12	0	1	0	22	0	34	0	0	0
Injection site induration	4	0	65	0	95	0	3756	0	3821	0	0	0
Injection site inflammation	1	0	49	0	124	0	8513	0	8562	0	0	0
Injection site injury	0	0	7	0	0	0	26	0	33	0	0	0
Injection site irritation	1	0	3	0	3	0	26	0	29	0	0	0
Injection site joint discomfort	0	0	0	0	0	0	4	0	4	0	0	0
Injection site joint erythema	0	0	3	0	0	0	14	0	17	0	0	0
Injection site joint inflammation	0	0	0	0	0	0	6	0	6	0	0	0
Injection site joint movement impairment	0	0	7	0	1	0	30	0	37	0	0	0
Injection site joint pain	0	0	39	0	7	0	96	0	135	0	0	0
Injection site joint swelling	0	0	2	0	2	0	32	0	34	0	0	0
Injection site joint warmth	0	0	0	0	0	0	8	0	8	0	0	0
Injection site lymphadenopathy	0	0	0	0	1	0	20	0	20	0	0	0
Injection site macule	0	0	0	0	3	0	4	0	4	0	0	0
Injection site mass	3	0	891	0	15	0	843	0	1734	0	0	0
Injection site movement impairment	3	0	15	0	14	0	96	0	111	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Injection site muscle atrophy	1	0	2	0	0	0	2	0	4	0	0	0
Injection site muscle weakness	1	0	8	0	5	0	24	0	32	0	0	0
Injection site necrosis	1	0	8	0	0	0	6	0	14	0	0	0
Injection site nerve damage	0	0	2	0	0	0	0	0	2	0	0	0
Injection site nodule	0	0	3	0	1	0	86	0	89	0	0	0
Injection site oedema	0	0	44	0	13	0	366	0	410	0	0	0
Injection site pain	112	0	4397	0	3516	0	54305	1	58702	1	0	0
Injection site papule	0	0	2	0	0	0	10	0	12	0	0	0
Injection site paraesthesia	2	0	30	0	15	0	140	0	170	0	0	0
Injection site phlebitis	0	0	0	0	0	0	5	0	5	0	0	0
Injection site plaque	0	0	2	0	3	0	10	0	12	0	0	0
Injection site pruritus	3	0	212	0	122	0	2235	0	2447	0	0	0
Injection site rash	2	0	176	0	14	0	444	0	620	0	0	0
Injection site reaction	210	0	1671	0	499	0	5679	0	7350	0	0	0
Injection site scab	0	0	3	0	0	0	6	0	9	0	0	0
Injection site scar	0	0	4	0	2	0	11	0	15	0	0	0
Injection site streaking	0	0	0	0	0	0	1	0	1	0	0	0
Injection site swelling	33	0	371	0	999	0	9696	0	10067	0	0	4

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Injection site telangiectasia	0	0	0	0	0	0	1	0	1	0	0	0
Injection site thrombosis	2	0	8	0	0	0	5	0	13	0	0	0
Injection site ulcer	0	0	1	0	0	0	2	0	3	0	0	0
Injection site urticaria	1	0	26	0	7	0	73	0	99	0	0	0
Injection site vasculitis	0	0	1	0	0	0	0	0	1	0	0	0
Injection site vesicles	2	0	11	0	5	0	50	0	61	0	0	0
Injection site warmth	8	0	284	0	132	0	5298	0	5582	0	0	0
Injury associated with device	1	0	9	0	0	0	9	0	18	0	0	0
Instillation site bruise	0	0	0	0	0	0	1	0	1	0	0	0
Instillation site discomfort	0	0	0	0	0	0	2	0	2	0	0	0
Instillation site erythema	0	0	0	0	0	0	1	0	1	0	0	0
Instillation site pain	0	0	1	0	2	0	6	0	7	0	0	0
Instillation site pruritus	0	0	1	0	0	0	1	0	2	0	0	0
Instillation site vesicles	0	0	0	0	0	0	1	0	1	0	0	0
Instillation site warmth	0	0	8	0	0	0	7	0	15	0	0	0
Irritability postvaccinal	0	0	3	0	0	0	8	0	11	0	0	0
Lithiasis	0	0	2	0	0	0	0	0	2	0	0	0
Local reaction	3	0	84	0	30	0	1119	0	1203	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Localised oedema	5	0	52	0	14	0	276	0	328	0	0	0
Loss of control of legs	1	0	66	0	0	0	26	0	92	0	0	0
Macrosomia	0	0	0	0	0	0	0	0	0	0	1	1
Malaise	606	0	14127	0	5849	1	71845	9	85972	9	1	14
Masked fever	0	0	1	0	0	0	0	0	1	0	0	0
Mass	5	0	61	0	12	0	135	0	196	0	0	0
Maxillofacial pain	0	0	0	0	1	0	1	0	1	0	0	0
Medical device pain	0	0	0	0	0	0	3	0	3	0	0	0
Medical device site dysaesthesia	0	0	0	0	0	0	1	0	1	0	0	0
Medical device site hypersensitivity	0	0	0	0	0	0	1	0	1	0	0	0
Medical device site hypoaesthesia	0	0	0	0	0	0	1	0	1	0	0	0
Medical device site joint discomfort	0	0	1	0	0	0	0	0	1	0	0	0
Medical device site joint pain	0	0	1	0	0	0	1	0	2	0	0	0
Medical device site pain	0	0	0	0	0	0	1	0	1	0	0	0
Medical device site papule	0	0	0	0	0	0	1	0	1	0	0	0
Medical device site reaction	0	0	0	0	0	0	1	0	1	0	0	0
Meteoropathy	0	0	0	0	1	0	1	0	1	0	0	0
Moaning	0	0	9	0	0	0	8	0	17	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Mucosa vesicle	0	0	0	0	0	0	6	0	6	0	0	0
Mucosal atrophy	0	0	0	0	0	0	1	0	1	0	0	0
Mucosal discolouration	0	0	0	0	0	0	2	0	2	0	0	0
Mucosal disorder	2	0	3	0	5	0	16	0	19	0	0	0
Mucosal dryness	1	0	4	0	5	0	26	0	30	0	0	0
Mucosal erosion	1	0	2	0	0	0	0	0	2	0	0	0
Mucosal haemorrhage	0	0	17	0	5	0	18	0	35	0	0	0
Mucosal hyperaemia	0	0	1	0	0	0	0	0	1	0	0	0
Mucosal hypertrophy	0	0	0	0	0	0	2	0	2	0	0	0
Mucosal inflammation	1	0	13	0	3	0	19	1	32	1	0	0
Mucosal necrosis	0	0	1	0	0	0	0	0	1	0	0	0
Mucosal pain	0	0	2	0	1	0	9	0	11	0	0	0
Mucosal roughness	0	0	0	0	0	0	1	0	1	0	0	0
Mucosal ulceration	0	0	5	0	0	0	0	0	5	0	0	0
Multi-organ disorder	0	0	2	0	0	0	0	0	2	0	0	0
Multiple organ dysfunction syndrome	5	0	96	0	0	0	0	0	96	0	1	1
Necrosis	2	0	14	0	1	0	11	0	25	0	0	0
Neurological complication associated with device	0	0	1	0	0	0	1	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
No adverse event	0	0	3	0	22	0	90	0	93	0	0	0
No reaction on previous exposure to drug	0	0	4	0	0	0	76	0	80	0	0	0
Nodule	4	0	43	0	33	0	811	0	854	0	0	0
Non-cardiac chest pain	3	0	49	0	6	0	64	0	113	0	0	0
Non-pitting oedema	0	0	0	0	0	0	1	0	1	0	0	0
Nonspecific reaction	2	0	6	0	0	0	3	0	9	0	0	0
Obstruction	1	0	3	0	0	0	2	0	5	0	0	0
Oedema	30	0	268	0	291	0	2785	0	3053	0	0	0
Oedema mucosal	1	0	10	0	3	0	20	0	30	0	0	0
Oedema peripheral	38	0	533	0	105	0	1187	0	1720	0	0	0
Organ failure	1	0	15	0	0	0	0	0	15	0	0	0
PFAPA syndrome	0	0	1	0	0	0	1	0	2	0	0	0
Pain	255	0	15606	0	5128	0	39126	4	54732	4	1	2
Papillitis	1	0	4	0	0	0	0	0	4	0	0	0
Paradoxical drug reaction	0	0	1	0	0	0	1	0	2	0	0	0
Pelvic mass	0	0	1	0	1	0	1	0	2	0	0	0
Perforation	0	0	1	0	0	0	1	0	2	0	0	0
Performance status decreased	8	0	17	0	10	0	78	0	95	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Peripheral swelling	98	0	4724	0	492	0	5227	0	9951	0	0	1
Phantom shocks	0	0	3	0	0	0	2	0	5	0	0	0
Physical deconditioning	0	0	8	0	4	0	11	0	19	0	0	0
Polyp	3	0	9	0	0	0	3	0	12	0	0	0
Polyserositis	2	0	11	0	0	0	0	0	11	0	0	0
Pre-existing condition improved	0	0	5	0	2	0	38	0	43	0	0	0
Pre-existing disease	0	0	2	0	0	0	6	0	8	0	0	0
Premature ageing	0	0	1	0	0	0	2	0	3	0	0	0
Procedural failure	0	0	0	0	0	0	1	0	1	0	0	0
Product intolerance	0	0	0	0	1	0	2	0	2	0	0	0
Prolapse	1	0	2	0	0	0	2	0	4	0	0	0
Prosthetic cardiac valve thrombosis	1	0	4	0	0	0	0	0	4	0	0	0
Pseudocyst	0	0	0	0	0	0	1	0	1	0	0	0
Puncture site bruise	0	0	39	0	3	0	32	0	71	0	0	0
Puncture site erythema	0	0	2	0	0	0	8	0	10	0	0	0
Puncture site haematoma	0	0	0	0	0	0	3	0	3	0	0	0
Puncture site haemorrhage	0	0	1	0	0	0	1	0	2	0	0	0
Puncture site induration	0	0	1	0	0	0	6	0	7	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Puncture site oedema	0	0	7	0	1	0	21	0	28	0	0	0
Puncture site pain	0	0	26	0	7	0	194	0	220	0	0	0
Puncture site pruritus	0	0	0	0	0	0	4	0	4	0	0	0
Puncture site reaction	0	0	1	0	0	0	15	0	16	0	0	0
Puncture site swelling	0	0	1	0	0	0	6	0	7	0	0	0
Pyrexia	1122	0	56479	1	26059	0	216501	5	272980	6	4	16
Rebound effect	0	0	0	0	0	0	2	0	2	0	0	0
Remission not achieved	0	0	0	0	0	0	1	0	1	0	0	0
Scar inflammation	0	0	0	0	1	0	6	0	6	0	0	0
Screaming	0	0	28	0	1	0	8	0	36	0	0	0
Secretion discharge	3	0	29	0	10	0	74	0	103	0	0	0
Sensation of blood flow	1	0	13	0	3	0	34	0	47	0	0	0
Sensation of foreign body	5	0	93	0	16	0	165	0	258	0	0	0
Sense of oppression	3	0	44	0	8	0	78	0	122	0	0	0
Sensitivity to weather change	0	0	2	0	0	0	10	0	12	0	0	0
Serositis	0	0	3	0	0	0	0	0	3	0	0	0
Shoulder injury related to vaccine administration	4	0	125	0	7	0	62	0	187	0	0	0
Sick building syndrome	0	0	1	0	0	0	6	0	7	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Similar reaction on previous exposure to drug	0	0	1	0	0	0	3	0	4	0	0	0
Sluggishness	0	0	38	0	49	0	472	0	510	0	0	0
Soft tissue inflammation	1	0	1	0	0	0	3	0	4	0	0	0
Stenosis	0	0	5	0	0	0	5	0	10	0	0	0
Stent-graft endoleak	0	0	0	0	0	0	1	0	1	0	0	0
Steroid dependence	0	0	0	0	0	0	2	0	2	0	0	0
Strangulated hernia	0	0	2	0	0	0	0	0	2	0	0	0
Sudden cardiac death	30	0	180	0	0	0	0	0	180	0	0	0
Sudden death	8	0	218	0	0	0	0	0	218	0	4	4
Sudden infant death syndrome	0	0	7	0	0	0	0	0	7	0	0	0
Sudden unexplained death in epilepsy	0	0	1	0	0	0	0	0	1	0	0	0
Supraclavicular fossa pain	0	0	0	0	0	0	3	0	3	0	0	0
Suprapubic pain	0	0	3	0	0	0	6	0	9	0	0	0
Swelling	42	0	1940	0	346	0	3669	0	5609	0	0	0
Swelling face	32	0	992	0	123	0	1512	0	2504	0	0	0
Symptom masked	0	0	3	0	0	0	8	0	11	0	0	0
Symptom recurrence	1	0	7	0	0	0	16	0	23	0	0	0
Systemic inflammatory response syndrome	1	0	18	0	0	0	0	0	18	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Temperature intolerance	4	0	88	0	11	0	64	0	152	0	0	0
Temperature regulation disorder	3	0	45	0	10	0	153	0	198	0	0	0
Tenderness	12	0	1306	0	524	0	7862	0	9168	0	0	0
Terminal state	2	0	4	0	0	0	0	0	4	0	0	0
Therapeutic product effect decreased	11	0	17	0	10	0	19	0	36	0	0	0
Therapeutic product effect delayed	1	0	1	0	0	0	2	0	3	0	0	0
Therapeutic product effect incomplete	4	0	6	0	5	0	11	0	17	0	0	0
Therapeutic product effect prolonged	0	0	1	0	0	0	2	0	3	0	0	0
Therapeutic product ineffective	1	0	10	0	0	0	25	0	35	0	0	0
Therapeutic reaction time decreased	0	0	1	0	0	0	1	0	2	0	0	0
Therapeutic response changed	0	0	1	0	0	0	0	0	1	0	0	0
Therapeutic response decreased	5	0	6	0	0	0	3	0	9	0	0	0
Therapeutic response delayed	0	0	0	0	0	0	1	0	1	0	0	0
Therapeutic response increased	0	0	0	0	0	0	1	0	1	0	0	0
Therapeutic response shortened	3	0	4	0	6	0	7	0	11	0	0	0
Therapeutic response unexpected	5	0	72	0	17	0	316	0	388	0	0	0
Therapy non-responder	1	0	6	0	0	0	2	0	8	0	0	0
Therapy partial responder	0	0	0	0	1	0	69	0	69	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Therapy responder	0	0	0	0	0	0	1	0	1	0	0	0
Thirst	10	0	1101	0	107	0	1284	1	2385	1	0	0
Thirst decreased	0	0	11	0	5	0	23	0	34	0	0	0
Tissue discolouration	0	0	2	0	0	0	1	0	3	0	0	0
Tissue infiltration	0	0	1	0	0	0	3	0	4	0	0	0
Tissue rupture	0	0	0	0	0	0	1	0	1	0	0	0
Treatment failure	0	0	18	0	0	0	2	0	20	0	0	0
Treatment noncompliance	2	0	2	0	0	0	2	0	4	0	0	0
Ulcer	0	0	39	0	6	0	52	0	91	0	0	0
Ulcer haemorrhage	0	0	1	0	1	0	7	0	8	0	0	0
Unevaluable event	7	0	19	0	13	0	128	0	147	0	0	0
Unmasking of previously unidentified disease	0	0	1	0	0	0	0	0	1	0	0	0
Vaccination failure	2304	0	23120	0	76	0	660	0	23780	0	0	2
Vaccination site abscess sterile	0	0	1	0	0	0	2	0	3	0	0	0
Vaccination site anaesthesia	0	0	1	0	1	0	7	0	8	0	0	0
Vaccination site atrophy	0	0	6	0	4	0	14	0	20	0	0	0
Vaccination site bruising	2	0	90	0	116	0	341	0	431	0	0	0
Vaccination site coldness	0	0	2	0	3	0	14	0	16	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Vaccination site cyst	0	0	3	0	0	0	5	0	8	0	0	0
Vaccination site dermatitis	0	0	0	0	1	0	8	0	8	0	0	0
Vaccination site discharge	1	0	3	0	0	0	4	0	7	0	0	0
Vaccination site discolouration	2	0	19	0	13	0	59	0	78	0	0	0
Vaccination site discomfort	1	0	29	0	41	0	1159	0	1188	0	0	0
Vaccination site dryness	0	0	1	0	0	0	3	0	4	0	0	0
Vaccination site dysaesthesia	0	0	1	0	3	0	14	0	15	0	0	0
Vaccination site eczema	0	0	0	0	1	0	16	0	16	0	0	0
Vaccination site erosion	0	0	2	0	1	0	1	0	3	0	0	0
Vaccination site erythema	20	0	519	0	914	0	3626	0	4145	0	0	0
Vaccination site exfoliation	0	0	2	0	1	0	6	0	8	0	0	0
Vaccination site extravasation	0	0	1	0	0	0	5	0	6	0	0	0
Vaccination site granuloma	0	0	1	0	2	0	14	0	15	0	0	0
Vaccination site haematoma	3	0	43	0	42	0	312	0	355	0	0	0
Vaccination site haemorrhage	4	0	17	0	11	0	35	0	52	0	0	0
Vaccination site hyperaesthesia	0	0	5	0	3	0	22	0	27	0	0	0
Vaccination site hypersensitivity	0	0	5	0	8	0	64	0	69	0	0	0
Vaccination site hypoaesthesia	0	0	27	0	5	0	47	0	74	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Vaccination site induration	0	0	72	0	152	0	461	0	533	0	0	0
Vaccination site inflammation	0	0	79	0	53	0	534	0	613	0	0	0
Vaccination site injury	1	0	5	0	2	0	14	0	19	0	0	0
Vaccination site irritation	1	0	8	0	8	0	39	0	47	0	0	0
Vaccination site joint discomfort	0	0	1	0	0	0	7	0	8	0	0	0
Vaccination site joint effusion	0	0	1	0	0	0	1	0	2	0	0	0
Vaccination site joint erythema	0	0	10	0	5	0	56	0	66	0	0	0
Vaccination site joint inflammation	1	0	2	0	1	0	9	0	11	0	0	0
Vaccination site joint movement impairment	1	0	34	0	1	0	45	0	79	0	0	0
Vaccination site joint pain	1	0	50	0	12	0	149	0	199	0	0	0
Vaccination site joint swelling	1	0	8	0	2	0	43	0	51	0	0	0
Vaccination site joint warmth	0	0	1	0	0	0	4	0	5	0	0	0
Vaccination site lymphadenopathy	1	0	20	0	16	0	119	0	139	0	0	0
Vaccination site macule	0	0	0	0	1	0	11	0	11	0	0	0
Vaccination site mass	0	0	298	0	68	0	509	0	807	0	0	0
Vaccination site movement impairment	8	0	165	0	29	0	375	0	540	0	0	0
Vaccination site necrosis	0	0	1	0	0	0	1	0	2	0	0	0
Vaccination site nerve damage	0	0	1	0	0	0	1	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Vaccination site nodule	0	0	6	0	9	0	38	0	44	0	0	0
Vaccination site oedema	3	0	83	0	129	0	544	0	627	0	0	0
Vaccination site pain	78	0	2534	0	5733	0	25999	2	28533	2	0	0
Vaccination site pallor	0	0	0	0	0	0	3	0	3	0	0	0
Vaccination site papule	0	0	1	0	0	0	12	0	13	0	0	0
Vaccination site paraesthesia	0	0	27	0	19	0	107	0	134	0	0	0
Vaccination site phlebitis	0	0	2	0	0	0	3	0	5	0	0	0
Vaccination site plaque	0	0	0	0	0	0	9	0	9	0	0	0
Vaccination site pruritus	7	0	129	0	276	0	744	0	873	0	0	0
Vaccination site rash	1	0	107	0	59	0	346	0	453	0	0	0
Vaccination site reaction	49	0	216	0	820	0	2791	0	3007	0	0	0
Vaccination site recall reaction	0	0	0	0	1	0	5	0	5	0	0	0
Vaccination site scab	0	0	1	0	0	0	1	0	2	0	0	0
Vaccination site scar	1	0	5	0	0	0	11	0	16	0	0	0
Vaccination site swelling	17	0	451	0	1498	0	3719	0	4170	0	0	0
Vaccination site thrombosis	0	0	2	0	0	0	3	0	5	0	0	0
Vaccination site ulcer	0	0	0	0	3	0	6	0	6	0	0	0
Vaccination site urticaria	0	0	9	0	11	0	41	0	50	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Vaccination site vasculitis	0	0	1	0	0	0	0	0	1	0	0	0
Vaccination site vesicles	1	0	10	0	8	0	31	0	41	0	0	0
Vaccination site warmth	0	0	278	0	354	0	1032	0	1310	0	0	0
Vaccine positive rechallenge	0	0	1	0	0	0	0	0	1	0	0	0
Vascular stent occlusion	0	0	5	0	0	0	0	0	5	0	0	0
Vascular stent stenosis	0	0	4	0	0	0	0	0	4	0	0	0
Vascular stent thrombosis	2	0	19	0	0	0	0	0	19	0	0	0
Vessel puncture site bruise	1	0	2	0	0	0	1	0	3	0	0	0
Vessel puncture site haematoma	0	0	0	0	0	0	1	0	1	0	0	0
Vessel puncture site haemorrhage	0	0	0	0	1	0	2	0	2	0	0	0
Visceral pain	1	0	5	0	0	0	8	0	13	0	0	0
Withdrawal syndrome	1	0	61	0	1	0	43	0	104	0	0	0
Xerosis	0	0	0	0	0	0	4	0	4	0	0	0
Investigations	**811**	**0**	**14815**	**2**	**3131**	**0**	**36494**	**20**	**51309**	**22**	**6**	**20**
17 ketosteroids urine	0	0	0	0	0	0	1	0	1	0	0	0
17 ketosteroids urine decreased	0	0	0	0	0	0	1	0	1	0	0	0
5'nucleotidase increased	0	0	0	0	0	0	2	0	2	0	0	0
5-hydroxyindolacetic acid increased	0	0	0	0	0	0	1	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
ADAMTS13 activity abnormal	0	0	1	0	0	0	0	0	1	0	0	0
ADAMTS13 activity decreased	0	0	1	0	0	0	0	0	1	0	0	0
APACHE II score	0	0	0	0	0	0	1	0	1	0	0	0
Abdominal bruit	0	0	1	0	0	0	0	0	1	0	0	0
Acid base balance abnormal	0	0	1	0	0	0	0	0	1	0	0	0
Acoustic stimulation tests	0	0	6	0	0	0	2	0	8	0	0	0
Acoustic stimulation tests abnormal	0	0	0	0	0	0	1	0	1	0	0	0
Activated partial thromboplastin time	0	0	0	0	0	0	3	0	3	0	0	0
Activated partial thromboplastin time abnormal	0	0	0	0	0	0	1	0	1	0	0	0
Activated partial thromboplastin time normal	0	0	0	0	1	0	1	0	1	0	0	0
Activated partial thromboplastin time prolonged	1	0	141	0	0	0	21	0	162	0	0	0
Activated partial thromboplastin time shortened	0	0	4	0	0	0	1	0	5	0	0	0
Adenovirus test positive	0	0	0	0	0	0	1	0	1	0	0	0
Alanine aminotransferase abnormal	0	0	1	0	0	0	0	0	1	0	0	0
Alanine aminotransferase decreased	1	0	1	0	0	0	1	0	2	0	0	0
Alanine aminotransferase increased	3	0	37	0	1	0	29	0	66	0	0	1
Alanine aminotransferase normal	0	0	0	0	1	0	1	0	1	0	0	0
Albumin globulin ratio	0	0	6	0	8	0	46	0	52	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Albumin globulin ratio normal	0	0	3	0	13	0	45	0	48	0	0	0
Albumin urine present	0	0	0	0	1	0	1	0	1	0	0	0
Allergy alert test	0	0	3	0	0	0	2	0	5	0	0	0
Allergy test negative	0	0	0	0	0	0	1	0	1	0	0	0
Allergy test positive	0	0	0	0	0	0	2	0	2	0	0	0
Alpha 1 foetoprotein abnormal	0	0	1	0	0	0	0	0	1	0	0	0
Amniotic fluid volume	0	0	1	0	0	0	0	0	1	0	0	0
Amylase	0	0	0	0	0	0	1	0	1	0	0	0
Amylase abnormal	0	0	1	0	0	0	0	0	1	0	0	0
Amylase increased	0	0	3	0	0	0	1	0	4	0	0	0
Analgesic drug level	0	0	14	0	0	0	5	0	19	0	0	0
Analgesic drug level decreased	0	0	0	0	0	0	1	0	1	0	0	0
Analgesic drug level increased	0	0	2	0	0	0	0	0	2	0	0	0
Analgesic drug level therapeutic	0	0	1	0	0	0	1	0	2	0	0	0
Angiocardiogram	0	0	3	0	0	0	1	0	4	0	0	0
Angiogram	1	0	2	0	0	0	1	0	3	0	0	0
Angiogram abnormal	0	0	2	0	0	0	0	0	2	0	0	0
Angiogram peripheral abnormal	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Anion gap abnormal	0	0	1	0	0	0	0	0	1	0	0	0
Anion gap decreased	2	0	2	0	0	0	0	0	2	0	0	0
Anion gap increased	0	0	1	0	0	0	0	0	1	0	0	0
Anti factor VIII antibody increased	0	0	0	0	0	0	1	0	1	0	0	0
Anti factor VIII antibody positive	0	0	1	0	0	0	0	0	1	0	0	0
Anti-Muellerian hormone level decreased	0	0	4	0	0	0	1	0	5	0	0	0
Anti-ganglioside antibody negative	0	0	1	0	0	0	0	0	1	0	0	0
Anti-myelin-associated glycoprotein antibodies positive	1	0	3	0	0	0	0	0	3	0	0	0
Anti-platelet antibody	0	0	4	0	0	0	2	0	6	0	0	0
Anti-platelet antibody negative	0	0	1	0	0	0	0	0	1	0	0	0
Anti-platelet antibody positive	0	0	6	0	0	0	0	0	6	0	0	0
Anti-platelet factor 4 antibody positive	0	0	10	0	0	0	1	0	11	0	0	0
Anti-sperm antibody	0	0	0	0	0	0	1	0	1	0	0	0
Anti-thyroid antibody	0	0	2	0	0	0	0	0	2	0	0	0
Anti-thyroid antibody increased	0	0	1	0	0	0	2	0	3	0	0	0
Anti-thyroid antibody positive	0	0	0	0	0	0	2	0	2	0	0	0
Antiacetylcholine receptor antibody positive	0	0	1	0	0	0	0	0	1	0	0	0
Antibody test	0	0	3	0	0	0	25	0	28	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Antibody test abnormal	3	0	3	0	2	0	95	0	98	0	0	0
Antibody test negative	0	0	3	0	2	0	70	0	73	0	0	0
Antibody test normal	0	0	0	0	0	0	2	0	2	0	0	0
Antibody test positive	1	0	2	0	3	0	13	0	15	0	0	0
Anticoagulation drug level above therapeutic	0	0	1	0	0	0	2	0	3	0	0	0
Anticoagulation drug level below therapeutic	0	0	2	0	0	0	4	0	6	0	0	0
Anticoagulation drug level increased	0	0	1	0	0	0	0	0	1	0	0	0
Anticoagulation drug level therapeutic	0	0	0	0	0	0	1	0	1	0	0	0
Antidepressant drug level decreased	0	0	1	0	0	0	0	0	1	0	0	0
Antimitochondrial antibody positive	0	0	0	0	0	0	2	0	2	0	0	0
Antineutrophil cytoplasmic antibody increased	0	0	0	0	2	0	4	0	4	0	0	0
Antineutrophil cytoplasmic antibody negative	0	0	1	0	0	0	0	0	1	0	0	0
Antineutrophil cytoplasmic antibody positive	1	0	3	0	1	0	1	0	4	0	0	0
Antinuclear antibody	0	0	4	0	0	0	3	0	7	0	0	0
Antinuclear antibody increased	0	0	2	0	0	0	5	0	7	0	0	0
Antinuclear antibody positive	0	0	6	0	3	0	11	0	17	0	0	0
Antiphospholipid antibodies	0	0	3	0	1	0	2	0	5	0	0	0
Antiphospholipid antibodies positive	1	0	9	0	0	0	1	0	10	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Antithrombin III abnormal	0	0	2	0	0	0	3	0	5	0	0	0
Antithrombin III decreased	0	0	2	0	0	0	0	0	2	0	0	0
Antithrombin III increased	1	0	3	0	0	0	1	0	4	0	0	0
Aortic bruit	0	0	1	0	0	0	0	0	1	0	0	0
Apolipoprotein	0	0	1	0	0	0	0	0	1	0	0	0
Arteriogram carotid	0	0	1	0	0	0	0	0	1	0	0	0
Arteriogram coronary abnormal	0	0	1	0	0	0	0	0	1	0	0	0
Arteriogram coronary normal	0	0	1	0	0	0	0	0	1	0	0	0
Arthroscopy	1	0	1	0	0	0	0	0	1	0	0	0
Aspartate aminotransferase	0	0	1	0	0	0	1	0	2	0	0	0
Aspartate aminotransferase abnormal	0	0	0	0	0	0	1	0	1	0	0	0
Aspartate aminotransferase decreased	1	0	1	0	0	0	0	0	1	0	0	0
Aspartate aminotransferase increased	1	0	11	0	0	0	11	0	22	0	0	0
Aspiration joint	0	0	1	0	0	0	1	0	2	0	0	0
Atrial pressure increased	0	0	0	0	0	0	1	0	1	0	0	0
Audiogram	0	0	1	0	0	0	0	0	1	0	0	0
Audiogram abnormal	0	0	0	0	0	0	1	0	1	0	0	0
Auscultation	0	0	0	0	1	0	1	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Autoantibody positive	7	0	10	0	5	0	7	0	17	0	0	0
Autoantibody test	1	0	1	0	0	0	0	0	1	0	0	0
B-lymphocyte count decreased	0	0	0	0	0	0	1	0	1	0	0	0
Babinski reflex test	0	0	2	0	0	0	0	0	2	0	0	0
Bacterial test	0	0	0	0	0	0	1	0	1	0	0	0
Bacterial test positive	1	0	1	0	0	0	0	0	1	0	0	0
Balance test	1	0	1	0	0	0	0	0	1	0	0	0
Barium swallow	0	0	1	0	0	0	1	0	2	0	0	0
Base excess	0	0	1	0	0	0	0	0	1	0	0	0
Basophil count increased	0	0	2	0	0	0	0	0	2	0	0	0
Basophil percentage increased	0	0	1	0	0	0	0	0	1	0	0	0
Beta 2 microglobulin increased	0	0	0	0	0	0	1	0	1	0	0	0
Beta-2 glycoprotein antibody	0	0	2	0	0	0	0	0	2	0	0	0
Bile duct pressure	0	0	0	0	1	0	1	0	1	0	0	0
Bile output	0	0	4	0	0	0	0	0	4	0	0	0
Bile output increased	0	0	0	0	0	0	1	0	1	0	0	0
Bilirubin conjugated increased	0	0	2	0	0	0	1	0	3	0	0	0
Biopsy	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Biopsy brain	0	0	1	0	0	0	0	0	1	0	0	0
Biopsy breast	0	0	1	0	0	0	0	0	1	0	0	0
Biopsy endometrium	1	0	1	0	0	0	0	0	1	0	0	0
Biopsy kidney	0	0	1	0	0	0	0	0	1	0	0	0
Biopsy lymph gland	0	0	1	0	0	0	3	0	4	0	0	0
Biopsy pharynx normal	0	0	0	0	0	0	1	0	1	0	0	0
Biopsy skin	0	0	1	0	0	0	1	0	2	0	0	0
Biopsy vagina	0	0	1	0	0	0	0	0	1	0	0	0
Bladder scan	1	0	1	0	0	0	0	0	1	0	0	0
Bleeding time	0	0	5	0	0	0	5	0	10	0	0	0
Bleeding time abnormal	0	0	1	0	0	0	4	0	5	0	0	0
Bleeding time prolonged	0	0	9	0	4	0	25	0	34	0	0	0
Bleeding time shortened	0	0	0	0	0	0	3	0	3	0	0	0
Blood HIV RNA increased	0	0	2	0	0	0	1	0	3	0	0	0
Blood albumin abnormal	0	0	1	0	0	0	0	0	1	0	0	0
Blood albumin decreased	0	0	3	0	0	0	0	0	3	0	0	0
Blood alkaline phosphatase	0	0	1	0	1	0	1	0	2	0	0	0
Blood alkaline phosphatase abnormal	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Blood alkaline phosphatase decreased	0	0	0	0	0	0	1	0	1	0	0	0
Blood alkaline phosphatase increased	0	0	8	0	0	0	9	0	17	0	0	0
Blood aluminium	0	0	1	0	0	0	0	0	1	0	0	0
Blood arsenic normal	0	0	0	0	0	0	1	0	1	0	0	0
Blood bicarbonate abnormal	0	0	1	0	0	0	0	0	1	0	0	0
Blood bilirubin	0	0	0	0	0	0	1	0	1	0	0	0
Blood bilirubin abnormal	0	0	1	0	0	0	0	0	1	0	0	0
Blood bilirubin increased	0	0	14	0	1	0	10	0	24	0	0	1
Blood bilirubin unconjugated increased	0	0	0	0	0	0	2	0	2	0	0	0
Blood caffeine decreased	0	0	0	0	0	0	1	0	1	0	0	0
Blood calcitonin increased	0	0	0	0	0	0	1	0	1	0	0	0
Blood calcium	0	0	2	0	0	0	0	0	2	0	0	0
Blood calcium decreased	2	0	2	0	0	0	2	0	4	0	0	0
Blood calcium increased	1	0	3	0	0	0	4	0	7	0	0	0
Blood cannabinoids	0	0	1	0	0	0	0	0	1	0	0	0
Blood carbon monoxide decreased	0	0	0	0	0	0	1	0	1	0	0	0
Blood carbon monoxide increased	0	0	2	0	0	0	1	0	3	0	0	0
Blood cholesterol	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Blood cholesterol abnormal	0	0	0	0	0	0	2	0	2	0	0	0
Blood cholesterol decreased	0	0	1	0	0	0	1	0	2	0	0	0
Blood cholesterol increased	4	0	23	0	1	0	28	0	51	0	0	0
Blood corticotrophin	1	0	2	0	0	0	0	0	2	0	0	0
Blood corticotrophin abnormal	1	0	1	0	0	0	0	0	1	0	0	0
Blood cortisol	0	0	1	0	0	0	0	0	1	0	0	0
Blood creatine abnormal	0	0	0	0	1	0	3	0	3	0	0	0
Blood creatine increased	0	0	3	0	1	0	6	0	9	0	0	0
Blood creatine normal	0	0	0	0	0	0	1	0	1	0	0	0
Blood creatine phosphokinase	0	0	1	0	0	0	0	0	1	0	0	0
Blood creatine phosphokinase MB abnormal	0	0	0	0	0	0	1	0	1	0	0	0
Blood creatine phosphokinase MB increased	0	0	0	0	0	0	3	0	3	0	0	0
Blood creatine phosphokinase abnormal	0	0	0	0	0	0	3	0	3	0	0	0
Blood creatine phosphokinase increased	4	0	25	0	3	0	25	0	50	0	0	0
Blood creatine phosphokinase normal	0	0	0	0	0	0	1	0	1	0	0	0
Blood creatinine	0	0	0	0	0	0	1	0	1	0	0	0
Blood creatinine abnormal	1	0	1	0	0	0	2	0	3	0	0	0
Blood creatinine decreased	1	0	3	0	1	0	3	0	6	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Blood creatinine increased	2	0	20	1	1	0	16	1	36	2	0	0
Blood culture	1	0	3	0	0	0	0	0	3	0	0	0
Blood culture negative	0	0	0	0	0	0	2	0	2	0	0	0
Blood cyanide	0	0	1	0	0	0	0	0	1	0	0	0
Blood electrolytes abnormal	0	0	1	0	0	0	1	0	2	0	0	0
Blood electrolytes decreased	0	0	2	0	0	0	1	0	3	0	0	0
Blood fibrinogen	0	0	1	0	0	0	4	0	5	0	0	0
Blood fibrinogen abnormal	0	0	1	0	0	0	7	0	8	0	0	0
Blood fibrinogen decreased	1	0	22	0	1	0	10	0	32	0	0	0
Blood fibrinogen increased	0	0	53	0	2	0	53	0	106	0	0	0
Blood folate	0	0	2	0	0	0	1	0	3	0	0	0
Blood folate abnormal	0	0	1	0	0	0	0	0	1	0	0	0
Blood folate decreased	4	0	15	0	2	0	8	0	23	0	0	0
Blood folate increased	0	0	0	0	1	0	1	0	1	0	0	0
Blood follicle stimulating hormone increased	0	0	1	0	0	0	3	0	4	0	0	0
Blood gases	0	0	1	0	0	0	0	0	1	0	0	0
Blood gases abnormal	0	0	1	0	1	0	1	0	2	0	0	0
Blood gastrin	0	0	0	0	0	0	1	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Blood gastrin normal	0	0	1	0	0	0	0	0	1	0	0	0
Blood glucagon increased	0	0	0	0	0	0	4	0	4	0	0	0
Blood glucose	0	0	16	0	0	0	7	0	23	0	0	0
Blood glucose abnormal	3	0	27	0	7	0	44	0	71	0	0	0
Blood glucose decreased	0	0	41	0	3	0	71	0	112	0	1	1
Blood glucose false positive	0	0	0	0	0	0	1	0	1	0	0	0
Blood glucose fluctuation	1	0	39	0	0	0	56	0	95	0	0	0
Blood glucose increased	13	0	200	0	27	0	360	0	560	0	0	0
Blood group O	0	0	1	0	0	0	1	0	2	0	0	0
Blood grouping	0	0	0	0	0	0	1	0	1	0	0	0
Blood growth hormone increased	0	0	1	0	0	0	0	0	1	0	0	0
Blood homocysteine	0	0	0	0	0	0	1	0	1	0	0	0
Blood homocysteine increased	0	0	0	0	1	0	9	0	9	0	0	0
Blood immunoglobulin A decreased	0	0	0	0	1	0	1	0	1	0	0	0
Blood immunoglobulin A increased	0	0	1	0	0	0	2	0	3	0	0	0
Blood immunoglobulin E	0	0	1	0	0	0	0	0	1	0	0	0
Blood immunoglobulin E abnormal	0	0	1	0	0	0	1	0	2	0	0	0
Blood immunoglobulin E increased	0	0	1	0	1	0	11	0	12	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Blood immunoglobulin G	0	0	1	0	0	0	7	0	8	0	0	0
Blood immunoglobulin G decreased	2	0	2	0	1	0	6	0	8	0	0	0
Blood immunoglobulin G increased	0	0	0	0	0	0	5	0	5	0	0	0
Blood immunoglobulin M	0	0	1	0	0	0	5	0	6	0	0	0
Blood immunoglobulin M abnormal	0	0	0	0	0	0	1	0	1	0	0	0
Blood immunoglobulin M decreased	0	0	0	0	0	0	1	0	1	0	0	0
Blood immunoglobulin M increased	0	0	1	0	0	0	2	0	3	0	0	0
Blood insulin	0	0	4	0	0	0	1	0	5	0	0	0
Blood insulin abnormal	0	0	0	0	1	0	2	0	2	0	0	0
Blood insulin decreased	0	0	1	0	0	0	2	0	3	0	0	0
Blood insulin increased	0	0	3	0	1	0	4	0	7	0	0	0
Blood iron	0	0	12	0	0	0	2	0	14	0	0	0
Blood iron abnormal	0	0	0	0	0	0	2	0	2	0	0	0
Blood iron decreased	8	0	45	0	4	0	21	0	66	0	0	0
Blood iron increased	0	0	2	0	0	0	7	0	9	0	0	0
Blood ketone body	0	0	9	0	0	0	1	0	10	0	0	0
Blood ketone body increased	0	0	1	0	1	0	2	0	3	0	0	0
Blood ketone body present	0	0	2	0	0	0	0	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Blood lactate dehydrogenase	0	0	1	0	0	0	0	0	1	0	0	0
Blood lactate dehydrogenase abnormal	0	0	0	0	0	0	2	0	2	0	0	0
Blood lactate dehydrogenase increased	0	0	4	0	2	0	9	0	13	0	0	0
Blood lactic acid	0	0	2	0	2	0	4	0	6	0	0	0
Blood lactic acid abnormal	0	0	1	0	0	0	0	0	1	0	0	0
Blood lactic acid increased	0	0	10	0	0	0	3	0	13	0	0	0
Blood lead	0	0	1	0	0	0	0	0	1	0	0	0
Blood luteinising hormone decreased	0	0	1	0	0	0	0	0	1	0	0	0
Blood magnesium	0	0	0	0	0	0	1	0	1	0	0	0
Blood magnesium decreased	0	0	3	0	0	0	3	0	6	0	0	0
Blood oestrogen	0	0	1	0	0	0	1	0	2	0	0	0
Blood oestrogen abnormal	1	0	1	0	0	0	1	0	2	0	0	0
Blood oestrogen decreased	0	0	0	0	0	0	1	0	1	0	0	0
Blood oestrogen increased	0	0	0	0	0	0	3	0	3	0	0	0
Blood osmolarity	0	0	1	0	0	0	0	0	1	0	0	0
Blood osmolarity increased	0	0	0	0	0	0	1	0	1	0	0	0
Blood pH	0	0	15	0	0	0	5	0	20	0	0	0
Blood pH decreased	0	0	2	0	0	0	0	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Blood pH increased	0	0	13	0	0	0	2	0	15	0	0	0
Blood parathyroid hormone decreased	0	0	1	0	0	0	0	0	1	0	0	0
Blood phosphorus abnormal	0	0	1	0	0	0	0	0	1	0	0	0
Blood phosphorus decreased	1	0	7	0	0	0	3	0	10	0	0	0
Blood phosphorus increased	0	0	3	0	0	0	1	0	4	0	0	0
Blood potassium abnormal	0	0	2	0	0	0	1	0	3	0	0	0
Blood potassium decreased	0	0	24	0	0	0	8	0	32	0	0	0
Blood potassium increased	1	0	10	0	1	0	4	0	14	0	0	0
Blood pregnenolone increased	0	0	0	0	0	0	1	0	1	0	0	0
Blood pressure abnormal	7	0	63	0	46	0	280	0	343	0	0	0
Blood pressure ambulatory decreased	0	0	0	0	0	0	3	0	3	0	0	0
Blood pressure ambulatory increased	0	0	0	0	0	0	11	0	11	0	0	0
Blood pressure decreased	21	0	270	0	93	0	789	0	1059	0	0	0
Blood pressure diastolic	0	0	2	0	0	0	0	0	2	0	0	0
Blood pressure diastolic abnormal	6	0	7	0	0	0	1	0	8	0	0	0
Blood pressure diastolic decreased	1	0	5	0	0	0	11	0	16	0	0	0
Blood pressure diastolic increased	7	0	20	0	3	0	34	0	54	0	0	0
Blood pressure difference of extremities	0	0	3	0	0	0	0	0	3	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Blood pressure immeasurable	0	0	3	0	0	0	0	0	3	0	0	0
Blood pressure increased	63	0	932	0	341	0	7399	0	8331	0	2	5
Blood pressure measurement	5	0	114	0	1	0	109	0	223	0	0	0
Blood pressure normal	0	0	6	0	1	0	8	0	14	0	0	0
Blood pressure orthostatic decreased	1	0	1	0	1	0	3	0	4	0	0	0
Blood pressure systolic	0	0	2	0	1	0	6	0	8	0	0	0
Blood pressure systolic abnormal	3	0	4	0	1	0	2	0	6	0	0	0
Blood pressure systolic decreased	0	0	2	0	3	0	8	0	10	0	0	0
Blood pressure systolic increased	11	0	25	0	2	0	37	0	62	0	0	0
Blood prolactin abnormal	0	0	0	0	0	0	1	0	1	0	0	0
Blood prolactin increased	0	0	1	0	0	0	1	0	2	0	0	0
Blood pyruvic acid increased	0	0	0	0	0	0	1	0	1	0	0	0
Blood sodium	0	0	1	0	0	0	1	0	2	0	0	0
Blood sodium decreased	3	0	15	0	1	0	9	0	24	0	0	0
Blood test	0	0	45	0	0	0	13	0	58	0	0	0
Blood test abnormal	5	0	103	0	4	0	37	0	140	0	0	0
Blood test normal	0	0	1	0	0	0	1	0	2	0	0	0
Blood testosterone decreased	1	0	3	0	0	0	0	0	3	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Blood testosterone increased	0	0	1	0	0	0	0	0	1	0	0	0
Blood thrombin	0	0	0	0	0	0	1	0	1	0	0	0
Blood thrombin abnormal	0	0	1	0	0	0	0	0	1	0	0	0
Blood thromboplastin	0	0	1	0	0	0	1	0	2	0	0	0
Blood thromboplastin increased	0	0	0	0	1	0	3	0	3	0	0	0
Blood thyroid stimulating hormone	0	0	2	0	0	0	2	0	4	0	0	0
Blood thyroid stimulating hormone abnormal	1	0	2	0	0	0	3	0	5	0	0	0
Blood thyroid stimulating hormone decreased	1	0	7	0	1	0	7	0	14	0	0	0
Blood thyroid stimulating hormone increased	1	0	9	0	0	0	25	0	34	0	0	0
Blood triglycerides	0	0	1	0	0	0	0	0	1	0	0	0
Blood triglycerides abnormal	0	0	0	0	0	0	2	0	2	0	0	0
Blood triglycerides increased	2	0	8	0	1	0	6	0	14	0	0	0
Blood urea	0	0	4	0	0	0	3	0	7	0	0	0
Blood urea abnormal	0	0	0	0	1	0	3	0	3	0	0	0
Blood urea decreased	0	0	0	0	0	0	1	0	1	0	0	0
Blood urea increased	0	0	1	0	0	0	5	0	6	0	0	0
Blood uric acid abnormal	0	0	0	0	1	0	1	0	1	0	0	0
Blood uric acid increased	0	0	2	0	1	0	11	0	13	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Blood urine	1	0	40	0	1	0	19	0	59	0	0	0
Blood urine present	7	0	105	0	13	0	123	0	228	0	0	0
Blood viscosity abnormal	0	0	1	0	0	0	0	0	1	0	0	0
Blood viscosity decreased	0	0	0	0	0	0	1	0	1	0	0	0
Blood viscosity increased	1	0	6	0	0	0	4	0	10	0	0	0
Blood zinc decreased	0	0	1	0	0	0	0	0	1	0	0	0
Blood zinc increased	0	0	0	0	0	0	1	0	1	0	0	0
Body height	0	0	0	0	0	0	1	0	1	0	0	0
Body height decreased	0	0	0	0	0	0	1	0	1	0	0	0
Body mass index decreased	0	0	0	0	1	0	2	0	2	0	0	0
Body mass index increased	0	0	0	0	0	0	1	0	1	0	0	0
Body surface area	0	0	2	0	0	0	2	0	4	0	0	0
Body surface area decreased	0	0	0	0	0	0	1	0	1	0	0	0
Body surface area increased	0	0	0	0	0	0	1	0	1	0	0	0
Body temperature	2	0	810	0	15	0	617	0	1427	0	0	0
Body temperature abnormal	4	0	70	0	121	0	935	1	1005	1	0	0
Body temperature decreased	6	0	151	0	17	0	376	1	527	1	0	0
Body temperature fluctuation	6	0	173	0	22	0	189	0	362	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Body temperature increased	17	0	1079	0	1171	0	12055	2	13134	2	0	0
Body temperature normal	0	0	5	0	2	0	30	0	35	0	0	0
Bone densitometry	0	0	0	0	0	0	1	0	1	0	0	0
Bone density decreased	0	0	0	0	1	0	1	0	1	0	0	0
Bone marrow myelogram abnormal	0	0	0	0	0	0	1	0	1	0	0	0
Borrelia test	0	0	0	0	0	0	1	0	1	0	0	0
Borrelia test positive	1	0	3	0	1	0	4	0	7	0	0	0
Brachial pulse abnormal	0	0	1	0	0	0	0	0	1	0	0	0
Brachial pulse decreased	0	0	0	0	0	0	2	0	2	0	0	0
Brachial pulse increased	0	0	2	0	0	0	3	0	5	0	0	0
Brain natriuretic peptide increased	0	0	4	0	0	0	2	0	6	0	0	0
Brain scan abnormal	0	0	2	0	0	0	1	0	3	0	0	0
Brain stem auditory evoked response abnormal	0	0	1	0	0	0	0	0	1	0	0	0
Breath sounds	0	0	3	0	1	0	5	0	8	0	0	0
Breath sounds abnormal	6	0	14	0	1	0	6	0	20	0	0	0
Breath sounds absent	0	0	1	0	0	0	0	0	1	0	0	0
Breath sounds normal	0	0	0	0	0	0	1	0	1	0	0	0
C-reactive protein	0	0	2	0	0	0	1	0	3	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
C-reactive protein abnormal	0	0	6	0	1	0	4	0	10	0	0	0
C-reactive protein decreased	0	0	1	0	0	0	2	0	3	0	0	0
C-reactive protein increased	10	0	175	0	14	0	144	0	319	0	0	0
CD4 lymphocytes abnormal	0	0	0	0	0	0	1	0	1	0	0	0
CD4 lymphocytes decreased	0	0	0	0	0	0	2	0	2	0	0	0
CD4 lymphocytes increased	0	0	0	0	0	0	1	0	1	0	0	0
CD8 lymphocytes decreased	0	0	0	0	0	0	1	0	1	0	0	0
CSF cell count abnormal	0	0	1	0	0	0	0	0	1	0	0	0
CSF cell count increased	0	0	1	0	1	0	1	0	2	0	0	0
CSF glucose decreased	0	0	1	0	0	0	0	0	1	0	0	0
CSF glucose increased	0	0	1	0	0	0	0	0	1	0	0	0
CSF lactate dehydrogenase increased	0	0	1	0	0	0	0	0	1	0	0	0
CSF lymphocyte count abnormal	0	0	1	0	0	0	0	0	1	0	0	0
CSF oligoclonal band present	0	0	2	0	0	0	0	0	2	0	0	0
CSF pressure	1	0	5	0	0	0	0	0	5	0	0	0
CSF pressure increased	0	0	2	0	0	0	1	0	3	0	0	0
CSF protein	0	0	1	0	0	0	0	0	1	0	0	0
CSF protein increased	1	0	11	0	0	0	1	0	12	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
CSF test abnormal	0	0	3	0	0	0	2	0	5	0	0	0
CSF white blood cell count increased	1	0	1	0	0	0	1	0	2	0	0	0
CSF white blood cell count positive	1	0	1	0	0	0	0	0	1	0	0	0
Capillary fragility abnormal	0	0	0	0	0	0	3	0	3	0	0	0
Capillary nail refill test	0	0	1	0	0	0	0	0	1	0	0	0
Capillary nail refill test abnormal	0	0	1	0	0	0	1	0	2	0	0	0
Capillary permeability increased	0	0	2	0	0	0	0	0	2	0	0	0
Carbohydrate antigen 125 increased	0	0	0	0	1	0	2	0	2	0	0	0
Carbohydrate antigen 15-3	0	0	0	0	0	0	1	0	1	0	0	0
Carbohydrate antigen 15-3 increased	0	0	0	0	0	0	1	0	1	0	0	0
Carbon dioxide abnormal	0	0	1	0	0	0	0	0	1	0	0	0
Carbon dioxide increased	0	0	1	0	0	0	1	0	2	0	0	0
Carcinoembryonic antigen decreased	1	0	1	0	0	0	0	0	1	0	0	0
Carcinoembryonic antigen increased	0	0	2	0	0	0	0	0	2	0	0	0
Cardiac imaging procedure	0	0	1	0	0	0	0	0	1	0	0	0
Cardiac monitoring	0	0	1	0	0	0	3	0	4	0	0	0
Cardiac murmur	4	0	39	0	1	0	24	0	63	0	0	0
Cardiac murmur functional	0	0	1	0	0	0	3	0	4	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Cardiac output decreased	0	0	0	0	0	0	1	0	1	0	0	0
Cardiac stress test abnormal	0	0	2	0	0	0	0	0	2	0	0	0
Cardiac telemetry	0	0	0	0	0	0	1	0	1	0	0	0
Cardiolipin antibody	0	0	1	0	0	0	1	0	2	0	0	0
Cardiolipin antibody positive	0	0	1	0	0	0	0	0	1	0	0	0
Cardiovascular examination abnormal	0	0	1	0	0	0	0	0	1	0	0	0
Carotid bruit	0	0	2	0	0	0	0	0	2	0	0	0
Carotid pulse	0	0	1	0	0	0	0	0	1	0	0	0
Carotid pulse abnormal	0	0	0	0	0	0	2	0	2	0	0	0
Carotid pulse increased	0	0	0	0	0	0	2	0	2	0	0	0
Catheterisation cardiac	0	0	1	0	0	0	0	0	1	0	0	0
Cells in urine	0	0	1	0	0	0	1	0	2	0	0	0
Central nervous system function test abnormal	0	0	0	0	0	0	1	0	1	0	0	0
Central venous pressure	0	0	1	0	0	0	0	0	1	0	0	0
Ceruloplasmin increased	0	0	0	0	0	0	1	0	1	0	0	0
Chest X-ray	0	0	17	0	0	0	5	0	22	0	0	0
Chest X-ray abnormal	0	0	3	0	1	0	5	0	8	0	0	0
Chest expansion decreased	0	0	0	0	0	0	1	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Cholangiogram	0	0	0	0	0	0	1	0	1	0	0	0
Cholesterol absorption efficiency decreased	0	0	0	0	0	0	1	0	1	0	0	0
Clostridium test positive	0	0	2	0	0	0	0	0	2	0	0	0
Clot retraction	0	0	1	0	0	0	0	0	1	0	0	0
Clot retraction abnormal	0	0	0	0	0	0	1	0	1	0	0	0
Clot retraction time prolonged	0	0	1	0	0	0	0	0	1	0	0	0
Coagulation factor	0	0	1	0	0	0	1	0	2	0	0	0
Coagulation factor VIII level abnormal	0	0	1	0	0	0	0	0	1	0	0	0
Coagulation factor VIII level decreased	0	0	5	0	0	0	1	0	6	0	0	0
Coagulation factor decreased	0	0	0	0	0	0	1	0	1	0	0	0
Coagulation factor increased	0	0	4	0	0	0	2	0	6	0	0	0
Coagulation test abnormal	0	0	8	0	1	0	8	0	16	0	0	0
Coagulation time	0	0	8	0	0	0	2	0	10	0	0	0
Coagulation time abnormal	0	0	0	0	0	0	1	0	1	0	0	0
Coagulation time prolonged	0	0	15	0	4	0	13	0	28	0	0	0
Coagulation time shortened	0	0	4	0	0	0	6	0	10	0	0	0
Cold agglutinins	0	0	1	0	0	0	0	0	1	0	0	0
Cold agglutinins positive	0	0	1	0	0	0	1	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Colonoscopy	0	0	0	0	0	0	0	1	0	1	0	0
Colour vision tests abnormal	0	0	0	0	0	0	1	0	1	0	0	0
Coma scale	0	0	1	0	0	0	1	0	2	0	0	0
Coma scale abnormal	2	0	34	0	0	0	8	0	42	0	0	0
Coma scale normal	0	0	1	0	0	0	1	0	2	0	0	0
Complement factor C3 decreased	0	0	0	0	0	0	1	0	1	0	0	0
Complement factor decreased	0	0	0	0	0	0	1	0	1	0	0	0
Computerised tomogram	0	0	7	0	0	0	1	0	8	0	0	0
Computerised tomogram abdomen	0	0	2	0	0	0	1	0	3	0	0	0
Computerised tomogram abnormal	0	0	2	0	0	0	2	0	4	0	0	0
Computerised tomogram head	1	0	31	0	0	0	4	0	35	0	0	0
Computerised tomogram head abnormal	0	0	0	0	0	0	1	0	1	0	0	0
Computerised tomogram normal	0	0	1	0	0	0	1	0	2	0	0	0
Computerised tomogram thorax	0	0	5	0	0	0	2	0	7	0	0	0
Coombs test positive	0	0	1	0	1	0	1	0	2	0	0	0
Corneal reflex decreased	0	0	2	0	0	0	2	0	4	0	0	0
Coronavirus test	0	0	35	0	0	0	6	0	41	0	0	0
Coronavirus test negative	0	0	0	0	1	0	2	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Coronavirus test positive	0	0	1	0	2	0	12	0	13	0	0	0
Cortisol decreased	0	0	4	0	0	0	0	0	4	0	0	0
Cortisol increased	0	0	1	0	0	0	1	0	2	0	0	0
Creatine urine abnormal	0	0	0	0	0	0	1	0	1	0	0	0
Creatinine renal clearance decreased	0	0	0	0	0	0	1	0	1	0	0	0
Cryoglobulins present	0	0	0	0	0	0	1	0	1	0	0	0
Crystal urine	0	0	2	0	0	0	2	0	4	0	0	0
Culture urine negative	0	0	0	0	0	0	1	0	1	0	0	0
Culture urine positive	1	0	1	0	0	0	0	0	1	0	0	0
Cystoscopy	0	0	2	0	0	0	1	0	3	0	0	0
Cytokine abnormal	1	0	1	0	0	0	0	0	1	0	0	0
Cytokine increased	0	0	0	0	3	0	3	0	3	0	0	0
Cytomegalovirus test	0	0	1	0	0	0	0	0	1	0	0	0
Cytomegalovirus test positive	0	0	0	0	0	0	2	0	2	0	0	0
DNA antibody negative	0	0	0	0	0	0	1	0	1	0	0	0
DNA antibody positive	0	0	1	0	0	0	0	0	1	0	0	0
Dengue virus test positive	1	0	1	0	0	0	1	0	2	0	0	0
Dermatologic examination	0	0	0	0	0	0	1	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Dermatologic examination abnormal	0	0	1	0	0	0	0	0	1	0	0	0
Dihydrotestosterone decreased	0	0	1	0	0	0	0	0	1	0	0	0
Disability assessment scale	0	0	1	0	0	0	0	0	1	0	0	0
Disability assessment scale score increased	1	0	1	0	0	0	0	0	1	0	0	0
Discogram abnormal	0	0	1	0	0	0	0	0	1	0	0	0
Double stranded DNA antibody positive	0	0	1	0	0	0	0	0	1	0	0	0
Drug level abnormal	1	0	1	0	0	0	0	0	1	0	0	0
Drug level decreased	1	0	1	0	0	0	1	0	2	0	0	0
Drug level increased	0	0	2	0	0	0	1	0	3	0	0	0
Drug screen positive	0	0	4	0	0	0	1	0	5	0	0	0
Drug specific antibody	0	0	0	0	1	0	4	0	4	0	0	0
Ear, nose and throat examination	0	0	0	0	0	0	1	0	1	0	0	0
Eastern Cooperative Oncology Group performance status improved	0	0	0	0	1	0	1	0	1	0	0	0
Eastern Cooperative Oncology Group performance status worsened	0	0	0	0	0	0	1	0	1	0	0	0
Echocardiogram	0	0	4	0	0	0	6	0	10	0	0	0
Echocardiogram abnormal	0	0	1	0	1	0	3	0	4	0	0	0
Echocardiogram normal	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Effective peritoneal surface area increased	0	0	0	0	0	0	1	0	1	0	0	0
Ejection fraction abnormal	1	0	1	0	0	0	0	0	1	0	0	0
Ejection fraction decreased	4	0	15	0	1	0	6	0	21	0	0	0
Electrocardiogram	0	0	8	0	1	0	11	0	19	0	0	0
Electrocardiogram P wave abnormal	0	0	1	0	0	0	0	0	1	0	0	0
Electrocardiogram PR prolongation	0	0	1	0	0	0	0	0	1	0	0	0
Electrocardiogram PR segment depression	0	0	0	0	0	0	1	0	1	0	0	0
Electrocardiogram QRS complex shortened	0	0	1	0	0	0	0	0	1	0	0	0
Electrocardiogram QT prolonged	1	0	11	0	0	0	0	0	11	0	0	0
Electrocardiogram QT shortened	0	0	1	0	0	0	0	0	1	0	0	0
Electrocardiogram ST segment abnormal	0	0	2	0	0	0	1	0	3	0	0	0
Electrocardiogram ST segment depression	2	0	7	0	0	0	1	0	8	0	0	0
Electrocardiogram ST segment elevation	0	0	14	0	0	0	6	0	20	0	0	0
Electrocardiogram ST-T segment abnormal	0	0	8	0	0	0	0	0	8	0	0	0
Electrocardiogram T wave abnormal	0	0	2	0	0	0	0	0	2	0	0	0
Electrocardiogram T wave inversion	0	0	10	0	0	0	1	0	11	0	0	0
Electrocardiogram abnormal	3	0	41	0	2	0	27	0	68	0	0	0
Electrocardiogram ambulatory	0	0	0	0	1	0	1	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Electrocardiogram change	1	0	4	0	0	0	0	0	4	0	0	0
Electrocardiogram normal	0	0	1	0	0	0	3	0	4	0	0	0
Electrocardiogram pacemaker spike	0	0	1	0	0	0	0	0	1	0	0	0
Electrocardiogram repolarisation abnormality	0	0	1	0	0	0	0	0	1	0	0	0
Electroencephalogram	0	0	1	0	0	0	1	0	2	0	0	0
Electroencephalogram abnormal	1	0	3	0	0	0	3	0	6	0	0	0
Electroencephalogram normal	0	0	2	0	0	0	0	0	2	0	0	0
Electromyogram abnormal	1	0	5	0	0	0	4	0	9	0	0	0
Electroneuromyography	0	0	1	0	0	0	0	0	1	0	0	0
Electronystagmogram abnormal	0	0	0	0	0	0	1	0	1	0	0	0
Emergency care examination	0	0	1	0	0	0	2	0	3	0	0	0
Endoscopy upper gastrointestinal tract	0	0	0	0	0	0	1	0	1	0	0	0
Enterococcus test positive	0	0	0	0	0	0	1	0	1	0	0	0
Eosinophil count	0	0	1	0	0	0	0	0	1	0	0	0
Eosinophil count abnormal	0	0	0	0	0	0	3	0	3	0	0	0
Eosinophil count decreased	0	0	1	0	1	0	3	0	4	0	0	0
Eosinophil count increased	1	0	9	0	0	0	8	0	17	0	0	0
Epinephrine abnormal	0	0	0	0	0	0	1	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Epinephrine increased	0	0	1	0	0	0	2	0	3	0	0	0
Episcleral venous pressure increased	0	0	0	0	0	0	1	0	1	0	0	0
Epstein-Barr virus antibody positive	0	0	2	0	0	0	1	0	3	0	0	0
Epstein-Barr virus antigen positive	0	0	0	0	1	0	1	0	1	0	0	0
Epstein-Barr virus test positive	1	0	2	0	0	0	1	0	3	0	0	0
Exercise electrocardiogram	0	0	1	0	1	0	1	0	2	0	0	0
Exercise electrocardiogram abnormal	0	0	1	0	0	0	0	0	1	0	0	0
Exocrine pancreatic function test abnormal	0	0	0	0	0	0	1	0	1	0	0	0
Face and mouth X-ray	0	0	1	0	0	0	0	0	1	0	0	0
Faecal calprotectin	1	0	2	0	0	0	0	0	2	0	0	0
Faecal calprotectin increased	1	0	7	0	1	0	5	0	12	0	0	0
Faecal elastase concentration decreased	0	0	0	0	0	0	1	0	1	0	0	0
Faecal volume decreased	1	0	1	0	0	0	0	0	1	0	0	0
Faecal volume increased	0	0	1	0	0	0	1	0	2	0	0	0
False negative pregnancy test	0	0	1	0	0	0	2	0	3	0	0	0
False positive investigation result	0	0	0	0	1	0	3	0	3	0	0	0
Female sex hormone level	0	0	1	0	0	0	0	0	1	0	0	0
Femoral pulse	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Femoral pulse abnormal	0	0	0	0	0	0	1	0	1	0	0	0
Femoral pulse increased	0	0	0	0	0	0	1	0	1	0	0	0
Fibrin D dimer	0	0	11	0	1	0	24	0	35	0	0	0
Fibrin D dimer decreased	1	0	3	0	0	0	13	0	16	0	0	0
Fibrin D dimer increased	15	0	789	0	39	0	959	0	1748	0	0	0
Fibrin D dimer normal	0	0	0	0	0	0	9	0	9	0	0	0
Fibrinolysis abnormal	0	0	0	0	0	0	1	0	1	0	0	0
Foetal heart rate	0	0	1	0	0	0	0	0	1	0	0	0
Foetal heart rate abnormal	2	0	3	0	0	0	0	0	3	0	0	1
Foetal heart rate decreased	1	0	3	0	0	0	0	0	3	0	2	4
Foetal heart rate increased	0	0	0	0	0	0	1	0	1	0	0	0
Forced expiratory volume	0	0	2	0	1	0	1	0	3	0	0	0
Forced expiratory volume decreased	0	0	2	0	0	0	1	0	3	0	0	0
Forced expiratory volume increased	0	0	13	0	0	0	1	0	14	0	0	0
Forced expiratory volume normal	0	0	1	0	0	0	0	0	1	0	0	0
Forced vital capacity decreased	0	0	2	0	0	0	0	0	2	0	0	0
Fractional exhaled nitric oxide normal	0	0	0	0	0	0	1	0	1	0	0	0
Full blood count	0	0	15	0	0	0	11	0	26	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Full blood count abnormal	5	0	27	0	4	0	31	0	58	0	0	0
Full blood count decreased	1	0	3	0	0	0	3	0	6	0	0	0
Full blood count increased	0	0	1	0	0	0	0	0	1	0	0	0
Full blood count normal	0	0	0	0	0	0	4	0	4	0	0	0
Functional residual capacity	0	0	0	0	1	0	1	0	1	0	0	0
Fungal test	0	0	0	0	0	0	1	0	1	0	0	0
Gamma-glutamyltransferase abnormal	0	0	1	0	0	0	1	0	2	0	0	0
Gamma-glutamyltransferase increased	1	0	10	0	1	0	17	0	27	0	0	0
Gastric pH	0	0	2	0	0	0	0	0	2	0	0	0
Gastric pH decreased	1	0	4	0	1	0	10	0	14	0	0	0
Gastric pH increased	0	0	0	0	0	0	2	0	2	0	0	0
Gastrointestinal stoma output increased	0	0	2	0	0	0	1	0	3	0	0	0
General physical condition abnormal	0	0	8	0	1	0	27	0	35	0	0	0
General physical condition normal	0	0	0	0	0	0	3	0	3	0	0	0
Glomerular filtration rate abnormal	0	0	1	0	0	0	0	0	1	0	0	0
Glomerular filtration rate decreased	1	0	7	0	1	0	10	0	17	0	0	0
Glomerular filtration rate increased	1	0	1	0	0	0	0	0	1	0	0	0
Glucose urine	0	0	1	0	0	0	1	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Glycosylated haemoglobin increased	0	0	4	0	1	0	6	0	10	0	0	0
Granulocyte count increased	0	0	0	0	0	0	1	0	1	0	0	0
Granulocyte-colony stimulating factor level increased	0	0	0	0	0	0	1	0	1	0	0	0
Grip strength	0	0	12	0	0	0	5	0	17	0	0	0
Grip strength decreased	1	0	40	0	5	0	32	0	72	0	0	0
Gynaecological examination	0	0	0	0	0	0	1	0	1	0	0	0
HIV antibody negative	0	0	2	0	0	0	0	0	2	0	0	0
HIV test false positive	0	0	0	0	0	0	2	0	2	0	0	0
HIV test positive	0	0	2	0	0	0	0	0	2	0	0	1
HLA-B*27 positive	1	0	1	0	0	0	0	0	1	0	0	0
HTLV test positive	0	0	0	0	0	0	1	0	1	0	0	0
Haematocrit	0	0	9	0	1	0	3	0	12	0	0	0
Haematocrit abnormal	0	0	2	0	0	0	1	0	3	0	0	0
Haematocrit decreased	2	0	12	0	1	0	8	0	20	0	0	0
Haematocrit increased	1	0	7	0	0	0	9	0	16	0	0	0
Haematology test abnormal	0	0	1	0	0	0	3	0	4	0	0	0
Haematology test normal	0	0	0	0	0	0	1	0	1	0	0	0
Haemoglobin	0	0	6	0	1	0	5	0	11	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Haemoglobin abnormal	2	0	5	0	0	0	2	0	7	0	0	0
Haemoglobin decreased	7	0	63	0	6	0	43	0	106	0	0	0
Haemoglobin increased	2	0	10	0	0	0	2	0	12	0	0	0
Haemoglobin urine	0	0	2	0	0	0	0	0	2	0	0	0
Haptoglobin decreased	0	0	0	0	0	0	1	0	1	0	0	0
Haptoglobin increased	0	0	0	0	0	0	1	0	1	0	0	0
Head lag	0	0	15	0	0	0	5	0	20	0	0	0
Head lag abnormal	0	0	0	0	0	0	2	0	2	0	0	0
Heart rate	9	0	960	0	6	0	266	0	1226	0	0	0
Heart rate abnormal	4	0	86	0	31	0	160	0	246	0	0	0
Heart rate decreased	13	0	159	0	22	0	164	0	323	0	0	0
Heart rate increased	86	0	2226	0	447	0	3755	0	5981	0	0	2
Heart rate irregular	16	0	288	0	48	0	323	0	611	0	0	0
Heart rate normal	0	0	2	0	1	0	7	0	9	0	0	0
Heart rate variability decreased	0	0	1	0	0	0	1	0	2	0	0	0
Heart rate variability increased	0	0	3	0	0	0	4	0	7	0	0	0
Heart sounds	1	0	11	0	0	0	9	0	20	0	0	0
Heart sounds abnormal	0	0	7	0	0	0	6	0	13	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Heart sounds normal	0	0	0	0	0	0	1	0	1	0	0	0
Heavy metal abnormal	0	0	0	0	1	0	1	0	1	0	0	0
Heavy metal test	0	0	1	0	0	0	0	0	1	0	0	0
Heel-knee-shin test abnormal	0	0	1	0	0	0	0	0	1	0	0	0
Helicobacter test positive	1	0	2	0	0	0	0	0	2	0	0	0
Heparin-induced thrombocytopenia test	0	0	5	0	0	0	1	0	6	0	0	0
Heparin-induced thrombocytopenia test positive	1	0	48	0	2	0	7	0	55	0	0	0
Hepatic enzyme abnormal	1	0	3	0	0	0	4	0	7	0	0	0
Hepatic enzyme increased	4	0	31	0	8	0	47	0	78	0	0	0
Hepatitis A virus test positive	0	0	0	0	0	0	1	0	1	0	0	0
Hepatitis B core antibody positive	0	0	1	0	0	0	0	0	1	0	0	0
Hepatitis B surface antibody positive	0	0	0	0	0	0	2	0	2	0	0	0
Hepatitis B surface antigen positive	0	0	1	0	0	0	0	0	1	0	0	0
Hepatitis C antibody positive	0	0	0	0	0	0	1	0	1	0	0	0
Herpes virus test	0	0	1	0	0	0	0	0	1	0	0	0
High density lipoprotein decreased	0	0	1	0	0	0	2	0	3	0	0	0
Histamine abnormal	1	0	3	0	0	0	3	0	6	0	0	0
Histamine level	0	0	4	0	0	0	0	0	4	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Histamine level increased	0	0	1	0	0	0	0	0	1	0	0	0
Homans' sign negative	0	0	0	0	0	0	1	0	1	0	0	0
Homans' sign positive	0	0	3	0	0	0	0	0	3	0	0	0
Hoover's sign of leg paresis	0	0	1	0	0	0	0	0	1	0	0	0
Hormone level abnormal	1	0	49	0	6	0	73	0	122	0	0	0
Human chorionic gonadotropin decreased	0	0	0	0	0	0	1	0	1	0	0	0
Human papilloma virus test negative	0	0	1	0	0	0	0	0	1	0	0	0
Human papilloma virus test positive	0	0	1	0	0	0	0	0	1	0	0	0
Hydroxycorticosteroids urine increased	0	0	0	0	1	0	2	0	2	0	0	0
Hypophonesis	1	0	2	0	0	0	0	0	2	0	0	0
Immunoglobulins abnormal	0	0	1	0	0	0	0	0	1	0	0	0
Immunoglobulins decreased	0	0	1	0	0	0	1	1	2	1	0	0
Immunology test	1	0	14	0	1	0	6	0	20	0	0	0
Immunology test abnormal	0	0	2	0	0	0	0	0	2	0	0	0
Immunology test normal	0	0	0	0	0	0	1	0	1	0	0	0
Increased steroid activity	0	0	0	0	0	0	5	0	5	0	0	0
Infertility tests	0	0	1	0	0	0	0	0	1	0	0	0
Inflammation scan	1	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Inflammatory marker decreased	0	0	0	0	0	0	1	0	1	0	0	0
Inflammatory marker increased	5	0	36	0	1	0	25	0	61	0	0	0
Influenza A virus test negative	0	0	1	0	0	0	0	0	1	0	0	0
Influenza virus test	0	0	0	0	0	0	1	0	1	0	0	0
Inhibiting antibodies positive	0	0	0	0	0	0	1	0	1	0	0	0
Inspiratory capacity decreased	0	0	1	0	0	0	2	0	3	0	0	0
Interferon alpha level	0	0	0	0	0	0	1	0	1	0	0	0
Interferon gamma release assay positive	0	0	3	0	0	0	1	0	4	0	0	0
Interleukin level increased	0	0	3	0	1	0	3	0	6	0	0	0
International normalised ratio	0	0	1	0	0	0	3	0	4	0	0	0
International normalised ratio abnormal	0	0	7	0	0	0	10	0	17	0	0	0
International normalised ratio decreased	1	0	36	0	0	0	40	0	76	0	0	0
International normalised ratio fluctuation	0	0	4	0	0	0	7	0	11	0	0	0
International normalised ratio increased	1	0	73	0	3	0	75	0	148	0	0	0
Intestinal transit time	0	0	1	0	0	0	0	0	1	0	0	0
Intestinal transit time abnormal	0	0	1	0	0	0	3	0	4	0	0	0
Intestinal transit time decreased	0	0	1	0	0	0	1	0	2	0	0	0
Intestinal transit time increased	0	0	1	0	0	0	1	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Intraocular pressure increased	2	0	16	0	2	0	23	0	39	0	0	0
Intraocular pressure test	0	0	6	0	2	0	10	0	16	0	0	0
Intraocular pressure test abnormal	0	0	0	0	0	0	3	0	3	0	0	0
Investigation	0	0	0	0	0	0	2	0	2	0	0	0
Investigation abnormal	1	0	1	0	0	0	0	0	1	0	0	0
Investigation normal	0	0	0	0	0	0	1	0	1	0	0	0
Iron binding capacity total decreased	0	0	1	0	0	0	0	0	1	0	0	0
Joint position sense decreased	0	0	2	0	0	0	0	0	2	0	0	0
Laboratory test	0	0	1	0	0	0	2	0	3	0	0	0
Laboratory test abnormal	3	0	7	0	3	0	13	0	20	0	0	0
Laboratory test normal	0	0	0	0	0	0	2	0	2	0	0	0
Lactate dehydrogenase urine increased	0	0	1	0	0	0	0	0	1	0	0	0
Laparoscopy	0	0	1	0	0	0	0	0	1	0	0	0
Laryngoscopy	0	0	1	0	0	0	0	0	1	0	0	0
Legionella test positive	0	0	1	0	0	0	0	0	1	0	0	0
Lipase increased	0	0	1	0	0	0	3	0	4	0	0	0
Lipids increased	0	0	0	0	0	0	1	0	1	0	0	0
Lipoprotein (a) increased	0	0	0	0	1	0	2	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Lipoprotein abnormal	0	0	0	0	0	0	1	0	1	0	0	0
Lipoprotein increased	0	0	0	0	0	0	1	0	1	0	0	0
Liver function test	0	0	2	0	0	0	4	0	6	0	0	0
Liver function test abnormal	3	0	69	0	0	0	57	0	126	0	0	0
Liver function test decreased	0	0	2	0	0	0	0	0	2	0	0	0
Liver function test increased	1	0	19	0	3	0	23	0	42	0	0	0
Liver palpable	1	0	1	0	0	0	0	0	1	0	0	0
Low density lipoprotein	0	0	0	0	0	0	1	0	1	0	0	0
Low density lipoprotein increased	1	0	1	0	1	0	5	0	6	0	0	0
Lumbar puncture	1	0	24	0	0	0	0	0	24	0	0	0
Lumbar puncture abnormal	1	0	1	0	0	0	0	0	1	0	0	0
Lung diffusion test abnormal	0	0	1	0	0	0	0	0	1	0	0	0
Lymph node palpable	0	0	6	0	3	0	37	0	43	0	0	0
Lymph nodes scan abnormal	0	0	1	0	0	0	1	0	2	0	0	0
Lymphocyte count	0	0	3	0	0	0	3	0	6	0	0	0
Lymphocyte count abnormal	1	0	2	0	0	0	2	0	4	0	0	0
Lymphocyte count decreased	4	0	10	0	2	0	12	0	22	0	0	0
Lymphocyte count increased	1	0	10	0	1	0	8	0	18	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Lymphocyte morphology abnormal	0	0	0	0	0	0	1	0	1	0	0	0
Lymphocyte percentage decreased	0	0	0	0	0	0	1	0	1	0	0	0
Magnetic resonance imaging	0	0	4	0	0	0	1	0	5	0	0	0
Magnetic resonance imaging abdominal	0	0	1	0	0	0	0	0	1	0	0	0
Magnetic resonance imaging abnormal	0	0	2	0	0	0	2	0	4	0	0	0
Magnetic resonance imaging head	0	0	38	0	0	0	15	0	53	0	0	0
Magnetic resonance imaging head abnormal	0	0	2	0	2	0	2	0	4	0	0	0
Magnetic resonance imaging head normal	0	0	1	0	0	0	0	0	1	0	0	0
Magnetic resonance imaging heart	0	0	2	0	0	0	0	0	2	0	0	0
Magnetic resonance imaging neck	0	0	1	0	0	0	0	0	1	0	0	0
Magnetic resonance imaging normal	0	0	0	0	0	0	1	0	1	0	0	0
Magnetic resonance imaging whole body	0	0	1	0	0	0	0	0	1	0	0	0
Male genital examination abnormal	0	0	1	0	0	0	1	0	2	0	0	0
Mammogram	0	0	0	0	0	0	1	0	1	0	0	0
Mast cell degranulation present	0	0	1	0	0	0	0	0	1	0	0	0
Maximal voluntary ventilation	0	0	1	0	0	0	1	0	2	0	0	0
Maximum heart rate	0	0	9	0	0	0	0	0	9	0	0	0
Maximum heart rate decreased	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Maximum heart rate increased	0	0	2	0	0	0	1	0	3	0	0	0
Mean arterial pressure decreased	0	0	1	0	0	0	3	0	4	0	0	0
Mean arterial pressure increased	0	0	0	0	0	0	1	0	1	0	0	0
Mean cell haemoglobin concentration	0	0	1	0	0	0	0	0	1	0	0	0
Mean cell haemoglobin concentration increased	1	0	1	0	0	0	0	0	1	0	0	0
Mean cell haemoglobin decreased	2	0	2	0	0	0	1	0	3	0	0	0
Mean cell haemoglobin increased	1	0	1	0	0	0	1	0	2	0	0	0
Mean cell volume abnormal	1	0	4	0	0	0	0	0	4	0	0	0
Mean cell volume decreased	2	0	2	0	0	0	2	0	4	0	0	0
Mean cell volume increased	2	0	2	0	0	0	0	0	2	0	0	0
Mean platelet volume decreased	0	0	2	0	1	0	1	0	3	0	0	0
Mean platelet volume increased	0	0	0	0	0	0	2	0	2	0	0	0
Measles antibody positive	0	0	1	0	0	0	0	0	1	0	0	0
Medical observation	0	0	0	0	0	0	2	0	2	0	0	0
Medication crystals in urine present	0	0	0	0	0	0	1	0	1	0	0	0
Megakaryocytes abnormal	0	0	0	0	0	0	1	0	1	0	0	0
Menstruation normal	0	0	3	0	0	0	15	0	18	0	0	0
Mini mental status examination	0	0	0	0	0	0	1	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Modified Rankin score decreased	0	0	1	0	0	0	0	0	1	0	0	0
Modified Rankin score increased	0	0	2	0	0	0	0	0	2	0	0	0
Monoclonal immunoglobulin increased	0	0	1	0	0	0	1	0	2	0	0	0
Monoclonal immunoglobulin present	1	0	1	0	0	0	1	0	2	0	0	0
Monocyte count abnormal	1	0	1	0	0	0	1	0	2	0	0	0
Monocyte count decreased	0	0	0	0	0	0	1	0	1	0	0	0
Monocyte count increased	0	0	4	0	0	0	6	0	10	0	0	0
Mononuclear cell count abnormal	0	0	0	0	0	0	1	0	1	0	0	0
Muscle enzyme increased	2	0	3	0	0	0	1	0	4	0	0	0
Muscle mass percentage	0	0	1	0	0	0	0	0	1	0	0	0
Muscle strength abnormal	3	0	20	0	7	0	51	0	71	0	0	0
Muscle strength normal	1	0	1	0	0	0	0	0	1	0	0	0
Mycoplasma test positive	0	0	0	0	0	0	1	0	1	0	0	0
Myocardial necrosis marker	1	0	2	0	0	0	0	0	2	0	0	0
Myocardial necrosis marker increased	2	0	5	0	0	0	0	0	5	0	0	0
Myocardial strain imaging	1	0	34	0	0	0	8	0	42	0	0	0
Myocardial strain imaging abnormal	0	0	1	0	0	0	1	0	2	0	0	0
Myoglobin blood increased	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Myoglobin urine	0	0	1	0	0	0	0	0	1	0	0	0
N-terminal prohormone brain natriuretic peptide increased	0	0	7	0	1	0	3	0	10	0	0	0
NIH stroke scale score decreased	0	0	1	0	0	0	0	0	1	0	0	0
NIH stroke scale score increased	0	0	1	0	0	0	0	0	1	0	0	0
Natural killer cell count decreased	0	0	1	0	0	0	0	0	1	0	0	0
Natural killer cell count increased	0	0	0	0	0	0	1	0	1	0	0	0
Nerve conduction studies	0	0	3	0	0	0	0	0	3	0	0	0
Nerve conduction studies abnormal	0	0	1	0	0	0	2	0	3	0	0	0
Nerve stimulation test abnormal	0	0	2	0	0	0	1	0	3	0	0	0
Neuro-ophthalmological test abnormal	1	0	1	0	0	0	0	0	1	0	0	0
Neurological examination	0	0	2	0	0	0	2	0	4	0	0	0
Neurological examination abnormal	0	0	4	0	0	0	4	0	8	0	0	0
Neurological examination normal	0	0	0	0	0	0	2	0	2	0	0	0
Neuropsychological test	0	0	0	0	0	0	2	0	2	0	0	0
Neurotransmitter level altered	0	0	1	0	0	0	0	0	1	0	0	0
Neutralising antibodies	0	0	0	0	0	0	2	0	2	0	0	0
Neutralising antibodies negative	0	0	0	0	0	0	7	0	7	0	0	0
Neutrophil count	0	0	3	0	0	0	3	0	6	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Neutrophil count abnormal	1	0	2	0	0	0	2	0	4	0	0	0
Neutrophil count decreased	2	0	24	0	2	0	19	0	43	0	0	0
Neutrophil count increased	2	0	8	0	0	0	5	0	13	0	0	0
Neutrophil toxic granulation present	0	0	2	0	0	0	0	0	2	0	0	0
Nitrite urine present	1	0	1	0	0	0	0	0	1	0	0	0
Non-neutralising antibodies	0	0	0	0	0	0	1	0	1	0	0	0
Norepinephrine increased	0	0	2	0	0	0	2	0	4	0	0	0
Nutritional condition abnormal	0	0	0	0	1	0	1	0	1	0	0	0
Occult blood	0	0	0	0	0	0	1	0	1	0	0	0
Occult blood positive	1	0	1	0	0	0	0	0	1	0	0	0
Oculomotor study abnormal	0	0	0	0	0	0	1	0	1	0	0	0
Oestradiol	0	0	2	0	0	0	0	0	2	0	0	0
Oestradiol decreased	0	0	0	0	0	0	1	0	1	0	0	0
Oestradiol increased	0	0	0	0	0	0	2	0	2	0	0	0
Oestriol	0	0	1	0	0	0	0	0	1	0	0	0
Olfactory test	0	0	1	0	0	0	0	0	1	0	0	0
Olfactory test abnormal	0	0	0	0	0	0	1	0	1	0	0	0
Ophthalmological examination	0	0	5	0	0	0	0	0	5	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Ophthalmological examination abnormal	0	0	1	0	0	0	0	0	1	0	0	0
Ophthalmological examination normal	0	0	0	0	0	0	1	0	1	0	0	0
Opiates	0	0	0	0	1	0	1	0	1	0	0	0
Orthostatic heart rate response increased	0	0	1	0	0	0	0	0	1	0	0	0
Osteocalcin	0	0	1	0	0	0	0	0	1	0	0	0
Oxycorticosteroids increased	0	0	0	0	0	0	16	0	16	0	0	0
Oxygen consumption	0	0	1	0	0	0	2	0	3	0	0	0
Oxygen consumption decreased	0	0	0	0	0	0	2	0	2	0	0	0
Oxygen consumption increased	0	0	2	0	0	0	1	0	3	0	0	0
Oxygen saturation	2	0	66	0	3	0	25	0	91	0	0	0
Oxygen saturation abnormal	3	0	9	0	4	0	33	1	42	1	0	0
Oxygen saturation decreased	25	0	459	0	19	0	283	1	742	1	0	0
Oxygen saturation increased	0	0	0	0	0	0	1	0	1	0	0	0
Oxygen saturation normal	1	0	2	0	0	0	7	0	9	0	0	0
Oxygenation index	0	0	0	0	1	0	3	0	3	0	0	0
PCO2 abnormal	0	0	2	0	0	0	0	0	2	0	0	0
PO2 abnormal	0	0	1	0	0	0	1	0	2	0	0	0
PO2 decreased	0	0	0	0	0	0	1	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Pain assessment	0	0	0	0	0	0	1	0	1	0	0	0
Pain threshold decreased	0	0	2	0	0	0	2	0	4	0	0	0
Palpatory finding abnormal	0	0	1	0	0	0	1	0	2	0	0	0
Pancreatic enzymes increased	0	0	1	0	0	0	1	0	2	0	0	0
Paracentesis	0	0	0	0	0	0	1	0	1	0	0	0
Paracentesis eye	0	0	1	0	0	0	0	0	1	0	0	0
Paranasal biopsy	0	0	0	0	0	0	1	0	1	0	0	0
Pathology test	0	0	0	0	0	0	1	0	1	0	0	0
Peak expiratory flow rate	0	0	0	0	0	0	1	0	1	0	0	0
Peak expiratory flow rate abnormal	0	0	0	0	0	0	1	0	1	0	0	0
Peak expiratory flow rate decreased	1	0	7	0	0	0	4	0	11	0	0	0
Pedal pulse abnormal	0	0	0	0	0	0	1	0	1	0	0	0
Pedal pulse decreased	0	0	0	0	0	0	1	0	1	0	0	0
Plasma viscosity abnormal	0	0	1	0	0	0	0	0	1	0	0	0
Platelet aggregation abnormal	0	0	1	0	0	0	5	0	6	0	0	0
Platelet aggregation test	0	0	1	0	0	0	0	0	1	0	0	0
Platelet count	0	0	8	0	0	0	9	0	17	0	0	0
Platelet count abnormal	2	0	10	0	0	0	12	0	22	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Platelet count decreased	29	0	543	0	15	0	321	0	864	0	0	0
Platelet count increased	2	0	35	0	4	0	76	0	111	0	0	0
Platelet count normal	0	0	1	0	1	0	5	0	6	0	0	0
Platelet distribution width decreased	0	0	0	0	0	0	1	0	1	0	0	0
Platelet distribution width increased	0	0	1	0	0	0	0	0	1	0	0	0
Platelet factor 4	0	0	2	0	0	0	0	0	2	0	0	0
Platelet factor 4 decreased	0	0	1	0	0	0	0	0	1	0	0	0
Platelet factor 4 increased	0	0	0	0	0	0	1	0	1	0	0	0
Platelet function test abnormal	0	0	0	0	0	0	2	0	2	0	0	0
Platelet morphology abnormal	0	0	3	0	0	0	1	0	4	0	0	0
Plateletcrit	0	0	1	0	0	0	0	0	1	0	0	0
Plateletcrit abnormal	0	0	1	0	0	0	0	0	1	0	0	0
Plateletcrit decreased	0	0	3	0	1	0	3	0	6	0	0	0
Polymerase chain reaction	0	0	4	0	0	0	6	0	10	0	0	0
Polymerase chain reaction positive	1	0	9	0	0	0	19	0	28	0	0	0
Popliteal pulse	0	0	1	0	0	0	2	0	3	0	0	0
Positron emission tomogram	0	0	3	0	0	0	0	0	3	0	0	0
Positron emission tomogram abnormal	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Pregnancy test	0	0	4	0	0	0	12	0	16	0	0	0
Pregnancy test false positive	0	0	1	0	0	0	1	0	2	0	0	0
Pregnancy test negative	0	0	2	0	0	0	3	0	5	0	0	0
Pregnancy test positive	0	0	0	0	0	0	1	0	1	0	0	0
Prenatal screening test abnormal	0	0	0	0	0	0	0	0	0	0	0	1
Procalcitonin increased	0	0	4	0	0	0	0	0	4	0	0	0
Procalcitonin normal	0	0	0	0	0	0	1	0	1	0	0	0
Product residue present	0	0	2	0	1	0	2	0	4	0	0	0
Progesterone decreased	0	0	1	0	0	0	3	0	4	0	0	0
Prostate examination abnormal	0	0	0	0	0	0	1	0	1	0	0	0
Prostatic specific antigen abnormal	0	0	0	0	0	0	2	0	2	0	0	0
Prostatic specific antigen decreased	0	0	1	0	1	0	2	0	3	0	0	0
Prostatic specific antigen increased	0	0	8	0	1	0	12	0	20	0	0	0
Protein C decreased	0	0	0	0	0	0	1	0	1	0	0	0
Protein C increased	0	0	4	0	2	0	5	0	9	0	0	0
Protein S abnormal	0	0	1	0	0	0	0	0	1	0	0	0
Protein total	0	0	2	0	0	0	0	0	2	0	0	0
Protein total abnormal	0	0	2	0	0	0	3	0	5	0	0	1

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Protein total decreased	1	0	1	0	0	0	2	0	3	0	0	0
Protein total increased	0	0	2	0	0	0	3	0	5	0	0	0
Protein urine	0	0	6	0	0	0	3	0	9	0	0	0
Protein urine present	2	0	5	0	0	0	1	0	6	0	0	0
Prothrombin level	0	0	0	0	0	0	1	0	1	0	0	0
Prothrombin level abnormal	0	0	1	0	1	0	1	0	2	0	0	0
Prothrombin level decreased	0	0	0	0	0	0	2	0	2	0	0	0
Prothrombin level increased	0	0	3	0	0	0	4	0	7	0	0	0
Prothrombin level normal	0	0	0	0	1	0	1	0	1	0	0	0
Prothrombin time	0	0	3	0	0	0	1	0	4	0	0	0
Prothrombin time abnormal	0	0	1	0	0	0	0	0	1	0	0	0
Prothrombin time prolonged	0	0	4	0	0	0	2	0	6	0	0	0
Prothrombin time ratio abnormal	0	0	0	0	0	0	1	0	1	0	0	0
Prothrombin time ratio increased	0	0	0	0	0	0	1	0	1	0	0	0
Prothrombin time shortened	0	0	4	0	1	0	4	0	8	0	0	0
Psoriasis area severity index decreased	0	0	0	0	0	0	1	0	1	0	0	0
Psoriasis area severity index increased	0	0	1	0	0	0	0	0	1	0	0	0
Psychiatric evaluation abnormal	0	0	0	0	0	0	1	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Pulmonary arterial pressure abnormal	0	0	1	0	0	0	2	0	3	0	0	0
Pulmonary arterial pressure increased	0	0	2	0	0	0	0	0	2	0	0	0
Pulmonary function test	0	0	5	0	0	0	1	0	6	0	0	0
Pulmonary function test abnormal	0	0	1	0	0	0	1	0	2	0	0	0
Pulmonary function test decreased	2	0	13	0	4	0	18	0	31	0	0	0
Pulmonary imaging procedure abnormal	0	0	1	0	0	0	0	0	1	0	0	0
Pulse abnormal	4	0	45	0	29	0	141	0	186	0	0	0
Pulse absent	0	0	15	0	0	0	0	0	15	0	0	0
Pulse pressure abnormal	0	0	0	0	0	0	2	0	2	0	0	0
Pulse pressure decreased	0	0	2	0	0	0	0	0	2	0	0	0
Pulse pressure increased	0	0	3	0	1	0	10	0	13	0	0	0
Pulse waveform abnormal	0	0	0	0	0	0	1	0	1	0	0	0
Pupillary light reflex tests abnormal	0	0	6	0	0	0	2	0	8	0	0	0
Pupillary light reflex tests normal	0	0	1	0	0	0	0	0	1	0	0	0
Pus in stool	0	0	1	0	0	0	0	0	1	0	0	0
QRS axis abnormal	2	0	4	0	0	0	0	0	4	0	0	0
Quality of life decreased	6	0	13	0	3	0	23	0	36	0	0	0
Quantitative sensory testing	0	0	0	0	0	0	1	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Radial pulse	0	0	0	0	0	0	1	0	1	0	0	0
Red blood cell Heinz bodies present	0	0	2	0	0	0	3	0	5	0	0	0
Red blood cell count	0	0	1	0	1	0	5	0	6	0	0	0
Red blood cell count abnormal	1	0	1	0	1	0	1	0	2	0	0	0
Red blood cell count decreased	3	0	14	0	1	0	9	0	23	0	0	1
Red blood cell count increased	1	0	5	0	1	0	9	0	14	0	0	0
Red blood cell elliptocytes present	0	0	1	0	0	0	0	0	1	0	0	0
Red blood cell morphology abnormal	0	0	2	0	0	0	0	0	2	0	0	0
Red blood cell sedimentation rate	0	0	1	0	0	0	0	0	1	0	0	0
Red blood cell sedimentation rate abnormal	0	0	2	0	0	0	8	0	10	0	0	0
Red blood cell sedimentation rate increased	4	0	34	0	4	0	37	0	71	0	0	0
Red blood cell target cells present	0	0	1	0	0	0	0	0	1	0	0	0
Red blood cells urine	0	0	1	0	0	0	0	0	1	0	0	0
Red blood cells urine positive	1	0	2	0	0	0	2	0	4	0	0	0
Red cell distribution width decreased	1	0	1	0	0	0	0	0	1	0	0	0
Red cell distribution width increased	1	0	2	0	0	0	1	0	3	0	0	0
Renal function test abnormal	0	0	1	0	1	0	5	0	6	0	0	0
Renin decreased	1	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Reproductive hormone	0	0	1	0	0	0	0	0	1	0	0	0
Respiratory rate	1	0	10	0	0	0	5	0	15	0	0	0
Respiratory rate decreased	0	0	29	0	3	0	25	0	54	0	0	0
Respiratory rate increased	9	0	104	0	17	0	129	0	233	0	0	0
Respiratory sinus arrhythmia magnitude increased	0	0	1	0	0	0	0	0	1	0	0	0
Retinal function test abnormal	0	0	1	0	0	0	0	0	1	0	0	0
Rhesus antigen negative	0	0	1	0	0	0	0	0	1	0	0	0
Rheumatoid factor	0	0	3	0	0	0	1	0	4	0	0	0
Rheumatoid factor increased	0	0	3	0	1	0	11	0	14	0	0	0
Rheumatoid factor negative	0	0	0	0	0	0	1	0	1	0	0	0
Rheumatoid factor positive	0	0	1	0	0	0	2	0	3	0	0	0
Romberg test positive	0	0	4	0	0	0	4	0	8	0	0	0
SARS-CoV-1 test negative	0	0	0	0	0	0	3	0	3	0	0	0
SARS-CoV-1 test positive	0	0	0	0	0	0	5	1	5	1	0	0
SARS-CoV-2 RNA	0	0	0	0	0	0	1	0	1	0	0	0
SARS-CoV-2 antibody test	0	0	10	0	1	0	34	0	44	0	0	0
SARS-CoV-2 antibody test negative	0	0	19	0	29	0	674	0	693	0	0	0
SARS-CoV-2 antibody test positive	0	0	5	0	2	0	46	0	51	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
SARS-CoV-2 test	0	0	28	0	3	0	33	0	61	0	0	0
SARS-CoV-2 test false negative	0	0	5	0	0	0	3	0	8	0	0	0
SARS-CoV-2 test false positive	1	0	3	0	0	0	3	0	6	0	0	0
SARS-CoV-2 test negative	2	0	54	0	1	0	191	0	245	0	0	0
SARS-CoV-2 test positive	9	0	228	1	126	0	1108	7	1336	8	0	0
Scan	0	0	2	0	0	0	0	0	2	0	0	0
Scan brain	1	0	2	0	0	0	0	0	2	0	0	0
Scan lymph nodes	0	0	2	0	0	0	0	0	2	0	0	0
Scan myocardial perfusion abnormal	0	0	1	0	0	0	0	0	1	0	0	0
Semen analysis abnormal	0	0	1	0	0	0	1	0	2	0	0	0
Semen viscosity increased	0	0	0	0	1	0	1	0	1	0	0	0
Semen volume decreased	0	0	2	0	2	0	3	0	5	0	0	0
Semen volume increased	0	0	0	0	0	0	1	0	1	0	0	0
Sensory level	0	0	1	0	0	0	0	0	1	0	0	0
Sensory level abnormal	1	0	20	0	3	0	63	0	83	0	0	0
Septic screen	0	0	1	0	0	0	0	0	1	0	0	0
Seroconversion test negative	0	0	0	0	0	0	1	0	1	0	0	0
Serology positive	0	0	0	0	0	0	1	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Serology test	0	0	1	0	0	0	2	0	3	0	0	0
Serum ferritin	0	0	1	0	0	0	0	0	1	0	0	0
Serum ferritin abnormal	0	0	0	0	0	0	1	0	1	0	0	0
Serum ferritin decreased	0	0	7	0	2	0	11	0	18	0	0	0
Serum ferritin increased	0	0	15	0	0	0	14	0	29	0	0	0
Serum serotonin increased	0	0	0	0	0	0	1	0	1	0	0	0
Sinus rhythm	3	0	8	0	0	0	4	0	12	0	0	0
Skin temperature	0	0	146	0	0	0	35	0	181	0	0	0
Skin test	0	0	0	0	1	0	1	0	1	0	0	0
Skin test positive	0	0	3	0	0	0	9	0	12	0	0	0
Skin turgor decreased	0	0	2	0	0	0	2	0	4	0	0	0
Skull X-ray	0	0	10	0	0	0	0	0	10	0	0	0
Sleep study normal	0	0	1	0	0	0	0	0	1	0	0	0
Slow vital capacity	0	0	1	0	0	0	1	0	2	0	0	0
Smear cervix	0	0	0	0	0	0	2	0	2	0	0	0
Smear cervix abnormal	0	0	1	0	0	0	0	0	1	0	0	0
Smear test	0	0	2	0	1	0	1	0	3	0	0	0
Smooth muscle antibody	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Specific gravity urine abnormal	0	0	0	0	0	0	1	0	1	0	0	0
Specific gravity urine decreased	1	0	1	0	0	0	0	0	1	0	0	0
Sperm analysis abnormal	0	0	0	0	0	0	1	0	1	0	0	0
Sperm concentration	0	0	1	0	0	0	0	0	1	0	0	0
Spermatozoa abnormal	0	0	1	0	0	0	2	0	3	0	0	0
Spinal myelogram	0	0	0	0	0	0	1	0	1	0	0	0
Spleen palpable	0	0	1	0	0	0	0	0	1	0	0	0
Sputum abnormal	0	0	2	0	0	0	3	0	5	0	0	0
Sputum culture positive	0	0	0	0	1	0	1	0	1	0	0	0
Staphylococcus test positive	0	0	2	0	0	0	0	0	2	0	0	0
Steroid activity	0	0	0	0	0	0	1	0	1	0	0	0
Stomach scan	0	0	1	0	0	0	0	0	1	0	0	0
Stool analysis abnormal	0	0	2	0	0	0	0	0	2	0	0	0
Streptococcus test positive	0	0	3	0	0	0	0	0	3	0	0	0
Stroke volume decreased	0	0	1	0	0	0	1	0	2	0	0	0
Stroke volume increased	0	0	3	0	0	0	0	0	3	0	0	0
Sulphur dioxide test	0	0	0	0	0	0	1	0	1	0	0	0
Swallow study	0	0	0	0	0	0	3	0	3	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Sweat test	0	0	1	0	0	0	3	0	4	0	0	0
Swollen joint count	0	0	2	0	0	0	1	0	3	0	0	0
Swollen joint count increased	0	0	4	0	0	0	1	0	5	0	0	0
T-lymphocyte count increased	0	0	1	0	0	0	0	0	1	0	0	0
Tartrate-resistant acid phosphatase decreased	0	0	1	0	0	0	0	0	1	0	0	0
Temperature difference of extremities	1	0	6	0	1	0	13	0	19	0	0	0
Temperature perception test abnormal	0	0	0	0	0	0	3	0	3	0	0	0
Temperature perception test decreased	0	0	0	0	0	0	1	0	1	0	0	0
Temperature perception test increased	0	0	1	0	0	0	8	0	9	0	0	0
Tender joint count	0	0	3	0	0	0	1	0	4	0	0	0
Tender joint count decreased	0	0	0	0	0	0	1	0	1	0	0	0
Thrombin time	0	0	1	0	0	0	0	0	1	0	0	0
Thrombin time abnormal	0	0	0	0	0	0	2	0	2	0	0	0
Thyroid function test	0	0	1	0	0	0	0	0	1	0	0	0
Thyroid function test abnormal	1	0	7	0	0	0	5	0	12	0	0	0
Thyroid hormones increased	2	0	2	0	1	0	4	0	6	0	0	0
Thyroxine	0	0	2	0	0	0	0	0	2	0	0	0
Thyroxine abnormal	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Thyroxine free decreased	0	0	1	0	0	0	2	0	3	0	0	0
Thyroxine free increased	0	0	1	0	0	0	3	0	4	0	0	0
Thyroxine increased	0	0	1	0	0	0	4	0	5	0	0	0
Total lung capacity abnormal	1	0	1	0	0	0	0	0	1	0	0	0
Total lung capacity decreased	0	0	6	0	3	0	16	0	22	0	0	0
Transaminases	0	0	0	0	0	0	2	0	2	0	0	0
Transaminases abnormal	1	0	3	0	0	0	1	0	4	0	0	0
Transaminases increased	2	0	22	0	1	0	19	0	41	0	0	0
Transferrin decreased	0	0	1	0	0	0	1	0	2	0	0	0
Transferrin saturation decreased	0	0	1	0	0	0	0	0	1	0	0	0
Treponema test positive	0	0	0	0	0	0	1	0	1	0	0	0
Tri-iodothyronine	0	0	0	0	0	0	1	0	1	0	0	0
Tri-iodothyronine decreased	0	0	8	0	0	0	4	0	12	0	0	0
Tri-iodothyronine increased	0	0	0	0	1	0	1	0	1	0	0	0
Troponin	0	0	6	0	0	0	3	0	9	0	0	0
Troponin I	0	0	1	0	0	0	0	0	1	0	0	0
Troponin I abnormal	0	0	1	0	0	0	0	0	1	0	0	0
Troponin I increased	0	0	9	0	1	0	6	0	15	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Troponin I normal	0	0	1	0	0	0	0	0	1	0	0	0
Troponin T	0	0	1	0	0	0	1	0	2	0	0	0
Troponin T increased	2	0	7	0	0	0	2	0	9	0	0	0
Troponin abnormal	0	0	4	0	0	0	8	0	12	0	0	0
Troponin decreased	0	0	1	0	0	0	0	0	1	0	0	0
Troponin increased	2	0	94	0	4	0	63	1	157	1	0	0
Troponin normal	0	0	0	0	0	0	2	0	2	0	0	0
Tryptase	0	0	0	0	0	0	1	0	1	0	0	0
Tryptase increased	1	0	2	0	0	0	1	0	3	0	0	0
Tumour marker increased	1	0	3	0	0	0	1	0	4	0	0	0
Ubiquinone	0	0	0	0	0	0	4	0	4	0	0	0
Ubiquinone decreased	0	0	0	0	0	0	2	0	2	0	0	0
Ultrasound Doppler	0	0	1	0	0	0	2	0	3	0	0	0
Ultrasound Doppler abnormal	0	0	0	0	0	0	3	0	3	0	1	1
Ultrasound kidney	0	0	1	0	0	0	0	0	1	0	0	0
Ultrasound liver abnormal	0	0	0	0	0	0	1	0	1	0	0	0
Ultrasound scan	0	0	1	0	0	0	1	0	2	0	0	0
Ultrasound scan abnormal	0	0	0	0	1	0	2	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Ultrasound scan vagina abnormal	0	0	1	0	0	0	0	0	1	0	0	0
Ultrasound scan vagina normal	0	0	0	0	0	0	1	0	1	0	0	0
Unevaluable investigation	0	0	1	0	0	0	0	0	1	0	0	0
Urea urine increased	0	0	1	0	0	0	0	0	1	0	0	0
Urinary casts	0	0	1	0	0	0	0	0	1	0	0	0
Urinary occult blood	0	0	0	0	0	0	1	0	1	0	0	0
Urinary sediment	0	0	0	0	0	0	1	0	1	0	0	0
Urine analysis	0	0	1	0	0	0	0	0	1	0	0	0
Urine analysis abnormal	1	0	15	0	0	0	22	0	37	0	0	0
Urine analysis normal	0	0	2	0	0	0	2	0	4	0	0	0
Urine bilirubin increased	0	0	1	0	0	0	0	0	1	0	0	0
Urine copper	0	0	2	0	0	0	0	0	2	0	0	0
Urine ketone body present	1	0	3	0	0	0	1	0	4	0	0	0
Urine output	1	0	39	0	0	0	15	0	54	0	0	0
Urine output decreased	2	0	20	0	0	0	13	0	33	0	0	0
Urine output increased	0	0	12	0	2	0	30	0	42	0	0	0
Urine uric acid increased	0	0	0	0	0	0	1	0	1	0	0	0
Urobilinogen urine increased	1	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Urological examination	0	0	1	0	0	0	0	0	1	0	0	0
Vaccine induced antibody absent	2	0	2	0	1	0	1	0	3	0	0	0
Varicella virus test positive	0	0	2	0	0	0	0	0	2	0	0	0
Vascular resistance systemic decreased	0	0	0	0	0	0	1	0	1	0	0	0
Venogram	0	0	1	0	0	0	2	0	3	0	0	0
Venous oxygen saturation	0	0	1	0	0	0	0	0	1	0	0	0
Venous oxygen saturation decreased	0	0	1	0	1	0	2	0	3	0	0	0
Venous pressure	1	0	1	0	1	0	2	0	3	0	0	0
Venous pressure increased	0	0	1	0	0	0	0	0	1	0	0	0
Venous pressure jugular	0	0	0	0	0	0	1	0	1	0	0	0
Venous pressure jugular increased	0	0	1	0	0	0	0	0	1	0	0	0
Ventilation/perfusion scan	0	0	1	0	0	0	0	0	1	0	0	0
Ventilation/perfusion scan abnormal	0	0	3	0	0	0	0	0	3	0	0	0
Very low density lipoprotein decreased	0	0	1	0	0	0	0	0	1	0	0	0
Vibration test abnormal	0	0	0	0	1	0	1	0	1	0	0	0
Viral load	0	0	1	0	0	0	1	0	2	0	0	0
Viral load decreased	0	0	0	0	1	0	1	0	1	0	0	0
Viral test	1	0	5	0	0	0	0	0	5	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Viral test negative	0	0	0	0	0	0	1	0	1	0	0	0
Viral test positive	0	0	3	0	0	0	2	0	5	0	0	0
Visual acuity tests abnormal	1	0	2	0	0	0	0	0	2	0	0	0
Visual analogue scale	0	0	1	0	0	0	0	0	1	0	0	0
Visual field tests abnormal	0	0	1	0	0	0	0	0	1	0	0	0
Visual field tests normal	0	0	1	0	0	0	0	0	1	0	0	0
Visual tracking test	0	0	1	0	0	0	0	0	1	0	0	0
Vital capacity decreased	0	0	1	0	0	0	1	0	2	0	0	0
Vital functions abnormal	0	0	1	0	0	0	1	0	2	0	0	0
Vital signs measurement	0	0	2	0	0	0	1	0	3	0	0	0
Vitamin B12	0	0	2	0	0	0	1	0	3	0	0	0
Vitamin B12 abnormal	0	0	3	0	0	0	1	0	4	0	0	0
Vitamin B12 decreased	2	0	9	0	1	0	5	0	14	0	0	0
Vitamin B12 increased	0	0	1	0	0	0	0	0	1	0	0	0
Vitamin B6 increased	0	0	0	0	0	0	1	0	1	0	0	0
Vitamin D	0	0	4	0	0	0	1	0	5	0	0	0
Vitamin D abnormal	0	0	0	0	0	0	1	0	1	0	0	0
Vitamin D decreased	2	0	9	0	1	0	9	1	18	1	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Vitamin D increased	0	0	0	0	0	0	1	0	1	0	0	0
Vitamin E decreased	0	0	0	0	0	0	1	0	1	0	0	0
Volume blood	0	0	5	0	0	0	2	0	7	0	0	0
Volume blood increased	0	0	0	0	0	0	1	0	1	0	0	0
Weight	0	0	1	0	0	0	0	0	1	0	0	0
Weight abnormal	1	0	1	0	0	0	3	0	4	0	0	0
Weight decreased	59	0	421	0	68	0	433	1	854	1	0	0
Weight increased	28	0	106	0	28	0	132	0	238	0	0	0
White blood cell analysis abnormal	0	0	1	0	0	0	0	0	1	0	0	0
White blood cell count	0	0	15	0	0	0	11	0	26	0	0	0
White blood cell count abnormal	1	0	2	0	0	0	5	0	7	0	0	0
White blood cell count decreased	0	0	34	0	4	0	52	0	86	0	0	0
White blood cell count increased	3	0	35	0	1	0	34	0	69	0	0	0
White blood cell count normal	0	0	0	0	0	0	2	0	2	0	0	0
White blood cells urine positive	2	0	4	0	0	0	2	0	6	0	0	0
X-ray	0	0	1	0	0	0	1	0	2	0	0	0
X-ray abnormal	0	0	2	0	0	0	0	0	2	0	0	0
X-ray limb	0	0	2	0	0	0	0	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
X-ray limb abnormal	0	0	1	0	0	0	0	0	1	0	0	0
X-ray of pelvis and hip	0	0	2	0	0	0	0	0	2	0	0	0
Xanthochromia	0	0	1	0	0	0	0	0	1	0	0	0
Zinc sulphate turbidity increased	0	0	1	0	0	0	0	0	1	0	0	0
pH urine	1	0	6	0	0	0	7	0	13	0	0	0
pH urine decreased	0	0	2	0	0	0	0	0	2	0	0	0
pH urine increased	0	0	2	0	0	0	1	0	3	0	0	0
Injury, poisoning and procedural complications	**594**	**0**	**8528**	**0**	**1333**	**2**	**14554**	**22**	**23082**	**22**	**44**	**109**
Abdomen crushing	1	0	4	0	0	0	0	0	4	0	0	0
Abdominal injury	0	0	1	0	0	0	0	0	1	0	0	0
Accident	0	0	3	0	0	0	4	0	7	0	0	0
Accident at home	0	0	0	0	0	0	1	0	1	0	0	0
Accident at work	1	0	2	0	1	0	2	0	4	0	0	0
Accidental exposure to product	0	0	20	0	4	0	35	0	55	0	0	0
Accidental exposure to product packaging	0	0	0	0	0	0	1	0	1	0	0	0
Accidental overdose	1	0	4	0	0	0	13	0	17	0	0	0
Accidental underdose	0	0	1	0	0	0	4	0	5	0	0	0
Administration related reaction	0	0	0	0	0	0	5	0	5	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Adverse event following immunisation	6	0	124	0	10	0	126	0	250	0	1	1
Airway burns	0	0	1	0	0	0	1	0	2	0	0	0
Airway complication of anaesthesia	0	0	1	0	0	0	0	0	1	0	0	0
Alcohol poisoning	0	0	2	0	0	0	4	0	6	0	0	0
Anaesthetic complication	0	0	2	0	0	0	1	0	3	0	0	0
Anaesthetic complication neurological	0	0	2	0	0	0	0	0	2	0	0	0
Anastomotic ulcer	0	0	1	0	0	0	0	0	1	0	0	0
Animal bite	2	0	3	0	1	0	9	0	12	0	0	0
Animal scratch	0	0	0	0	0	0	1	0	1	0	0	0
Ankle fracture	2	0	9	0	1	0	9	0	18	0	0	0
Aortic injury	0	0	1	0	0	0	0	0	1	0	0	0
Aortic pseudoaneurysm	0	0	0	0	0	0	1	0	1	0	0	0
Arterial injury	0	0	2	0	0	0	1	0	3	0	0	0
Arteriovenous fistula thrombosis	0	0	3	0	0	0	0	0	3	0	0	0
Arteriovenous graft thrombosis	0	0	0	0	0	0	0	0	0	0	1	1
Arthropod bite	1	0	4	0	1	0	12	0	16	0	0	0
Arthropod sting	3	0	17	0	2	0	11	0	28	0	0	0
Asbestosis	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Atypical femur fracture	0	0	1	0	0	0	0	0	1	0	0	0
Auricular haematoma	0	0	1	0	0	0	2	0	3	0	0	0
Autonomic dysreflexia	0	0	1	0	0	0	1	0	2	0	0	0
Axillary nerve injury	0	0	1	0	0	0	2	0	3	0	0	0
Axillary web syndrome	0	0	2	0	0	0	3	0	5	0	0	0
Back injury	3	0	8	0	1	0	5	1	13	1	0	0
Barotitis media	0	0	0	0	0	0	1	0	1	0	0	0
Barotrauma	0	0	1	0	0	0	1	0	2	0	0	0
Bite	0	0	0	0	2	0	11	0	11	0	0	0
Bladder injury	0	0	2	0	0	0	0	0	2	0	0	0
Bone contusion	2	0	4	0	1	0	3	0	7	0	0	0
Bone fragmentation	0	0	0	0	0	0	1	0	1	0	0	0
Booster dose missed	0	0	0	0	0	0	9	0	9	0	0	0
Brachial plexus injury	0	0	3	0	0	0	0	0	3	0	0	0
Brain contusion	0	0	20	0	0	0	0	0	20	0	0	0
Brain herniation	4	0	23	0	0	0	0	0	23	0	0	1
Breast injury	0	0	0	0	0	0	1	0	1	0	0	0
Burn oesophageal	0	0	3	0	0	0	4	0	7	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Burn of internal organs	0	0	4	0	0	0	1	0	5	0	0	0
Burn oral cavity	0	0	6	0	0	0	8	0	14	0	0	0
Burns first degree	0	0	0	0	0	0	2	0	2	0	0	0
Burns second degree	0	0	4	0	0	0	6	0	10	0	0	0
Bursa injury	1	0	3	0	0	0	0	0	3	0	0	0
Cardiac procedure complication	0	0	1	0	0	0	0	0	1	0	0	0
Cartilage injury	1	0	4	0	0	0	0	0	4	0	1	1
Cataract traumatic	0	0	1	0	0	0	0	0	1	0	0	0
Central cord syndrome	0	0	2	0	0	0	0	0	2	0	0	0
Central nervous system injury	0	0	1	0	0	0	0	0	1	0	0	0
Cerebral ventricle collapse	0	0	1	0	0	0	0	0	1	0	0	0
Cervical vertebral fracture	0	0	2	0	0	0	0	0	2	0	0	0
Cervix injury	0	0	1	0	0	0	0	0	1	0	0	0
Chemical burn	0	0	2	0	0	0	0	0	2	0	0	0
Chemical burn of oral cavity	0	0	1	0	0	0	1	0	2	0	0	0
Chemical burn of skin	0	0	4	0	0	0	2	0	6	0	0	0
Chemical phlebitis	0	0	0	0	0	0	2	0	2	0	0	0
Chemical poisoning	0	0	1	0	0	0	1	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Chest crushing	0	0	17	0	0	0	2	0	19	0	0	0
Chest injury	0	0	6	0	0	0	1	0	7	0	0	0
Child maltreatment syndrome	0	0	0	0	0	0	1	0	1	0	0	0
Chillblains	2	0	41	0	3	0	98	0	139	0	0	0
Circumstance or information capable of leading to medication error	0	0	4	0	1	0	91	0	95	0	0	0
Clavicle fracture	0	0	23	0	0	0	6	0	29	0	0	0
Cold burn	0	0	3	0	0	0	0	0	3	0	0	0
Cold exposure injury	0	0	0	0	0	0	2	0	2	0	0	0
Colon injury	0	0	2	0	0	0	0	0	2	0	0	0
Compensatory sweating	0	0	0	0	0	0	2	0	2	0	0	0
Complications of transplant surgery	0	0	0	0	0	0	1	0	1	0	0	0
Complications of transplanted kidney	0	0	1	0	0	0	0	0	1	0	0	0
Complications of transplanted pancreas	0	0	1	0	0	0	0	0	1	0	0	0
Compression fracture	1	0	1	0	1	0	1	0	2	0	0	0
Concussion	4	0	21	0	0	0	9	0	30	0	0	0
Contraindicated product administered	0	0	3	0	0	0	3	0	6	0	0	0
Contraindicated product prescribed	0	0	8	0	0	0	2	0	10	0	0	0
Contusion	75	0	2281	0	609	0	4046	1	6327	1	0	1

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Corneal abrasion	0	0	1	0	0	0	0	0	1	0	0	0
Coronary artery restenosis	0	0	1	0	0	0	0	0	1	0	0	0
Coronary bypass thrombosis	0	0	1	0	0	0	0	0	1	0	0	0
Counterfeit product administered	0	0	0	0	0	0	1	0	1	0	0	0
Cranial nerve injury	0	0	0	0	0	0	2	0	2	0	0	0
Craniocerebral injury	2	0	21	0	0	0	0	0	21	0	0	0
Deafness traumatic	0	0	0	0	0	0	1	0	1	0	0	0
Decerebration	0	0	1	0	0	0	0	0	1	0	0	0
Decompression sickness	0	0	1	0	0	0	1	0	2	0	0	0
Deep vein thrombosis postoperative	0	0	1	0	0	0	0	0	1	0	0	0
Delayed effects of radiation	0	0	0	0	1	0	1	0	1	0	0	0
Delayed recovery from anaesthesia	0	0	4	0	0	0	1	0	5	0	0	0
Dental restoration failure	0	0	0	0	0	0	2	0	2	0	0	0
Dermal filler overcorrection	0	0	1	0	0	0	0	0	1	0	0	0
Dermal filler reaction	0	0	0	0	3	0	4	0	4	0	0	0
Device dispensing error	0	0	0	0	0	0	1	0	1	0	0	0
Device use confusion	0	0	0	0	0	0	1	0	1	0	0	0
Device use error	0	0	0	0	0	0	2	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Device use issue	0	0	1	0	1	0	2	0	3	0	0	0
Diffuse axonal injury	0	0	1	0	0	0	0	0	1	0	0	0
Dislocation of vertebra	0	0	1	0	0	0	0	0	1	0	0	0
Documented hypersensitivity to administered product	0	0	0	0	0	0	1	0	1	0	0	0
Dose calculation error	0	0	1	0	0	0	7	0	8	0	0	0
Drug administered in wrong device	0	0	1	0	0	0	0	0	1	0	0	0
Drug exposure before pregnancy	1	0	2	0	0	0	2	0	4	0	0	0
Drug monitoring procedure not performed	0	0	0	0	0	0	1	0	1	0	0	0
Drug titration error	2	0	2	0	0	0	1	0	3	0	0	0
Duplicate therapy error	0	0	0	0	0	0	1	0	1	0	0	0
Dysphotopsia	0	0	0	0	0	0	1	0	1	0	0	0
Ear canal injury	2	0	2	0	0	0	1	0	3	0	0	0
Electric shock	3	0	30	0	1	0	14	0	44	0	0	0
Electrical burn	0	0	1	0	0	0	0	0	1	0	0	0
Environmental exposure	0	0	0	0	0	0	1	0	1	0	0	0
Epicondylitis	2	0	26	0	2	0	27	0	53	0	0	0
Epidural haemorrhage	0	0	1	0	0	0	0	0	1	0	0	0
Eschar	0	0	0	0	1	0	2	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Expired product administered	0	0	23	0	15	0	168	0	191	0	0	0
Exposure during pregnancy	7	0	154	0	26	0	461	0	615	0	4	9
Exposure to SARS-CoV-2	0	0	6	0	0	0	19	0	25	0	0	0
Exposure to chemical pollution	0	0	0	0	0	0	2	0	2	0	0	0
Exposure to communicable disease	1	0	2	0	1	0	5	0	7	0	0	0
Exposure to contaminated device	0	0	1	0	0	0	0	0	1	0	0	0
Exposure to extreme temperature	0	0	6	0	0	0	4	0	10	0	0	0
Exposure to household chemicals	0	0	0	0	0	0	0	1	0	1	0	0
Exposure to noise	0	0	2	0	0	0	0	0	2	0	0	0
Exposure to toxic agent	0	0	0	0	0	0	1	0	1	0	0	0
Exposure to vaccinated person	0	0	3	0	0	0	1	0	4	0	0	0
Exposure to violent event	0	0	1	0	0	0	0	0	1	0	0	0
Exposure via body fluid	0	0	1	0	0	0	0	0	1	0	0	0
Exposure via breast milk	1	0	65	0	6	0	128	0	193	0	0	0
Exposure via direct contact	0	0	0	0	0	0	1	0	1	0	0	0
Exposure via partner	0	0	1	0	0	0	0	0	1	0	0	0
Exposure via unknown route	0	0	0	0	0	0	1	0	1	0	0	0
Extra dose administered	0	0	3	0	1	0	28	0	31	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Extradural haematoma	1	0	5	0	0	0	0	0	5	0	0	0
Extraskeletal ossification	0	0	1	0	0	0	1	0	2	0	0	0
Eye contusion	0	0	30	0	4	0	55	0	85	0	0	0
Eye injury	2	0	60	0	2	0	49	0	109	0	0	0
Eye laser scar	0	0	0	0	0	0	1	0	1	0	0	0
Eye luxation	0	0	3	0	0	0	0	0	3	0	0	0
Eyeball avulsion	0	0	0	0	0	0	2	0	2	0	0	0
Eyelid abrasion	0	0	0	0	1	0	1	0	1	0	0	0
Eyelid contusion	0	0	4	0	1	0	6	0	10	0	0	0
Eyelid injury	0	0	0	0	0	0	1	0	1	0	0	0
Face crushing	0	0	1	0	0	0	0	0	1	0	0	0
Face injury	1	0	8	0	2	0	7	0	15	0	0	0
Facial bones fracture	1	0	1	0	0	0	0	0	1	0	0	0
Fall	41	0	545	0	41	0	422	0	967	0	0	0
Fat adherence syndrome	0	0	0	0	0	0	1	0	1	0	0	0
Femoral neck fracture	1	0	4	0	0	0	0	0	4	0	0	0
Femur fracture	1	0	11	0	0	0	0	0	11	0	0	0
Flail chest	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Foetal exposure during pregnancy	2	0	55	0	1	0	16	0	71	0	9	30
Foot fracture	0	0	7	0	0	0	8	1	15	1	0	0
Foreign body	0	0	2	0	0	0	3	0	5	0	0	0
Foreign body in eye	0	0	2	0	0	0	0	0	2	0	0	0
Foreign body in respiratory tract	0	0	1	0	0	0	0	0	1	0	0	0
Foreign body in throat	0	0	3	0	0	0	4	0	7	0	0	0
Fracture	1	0	11	0	7	0	31	0	42	0	0	0
Fracture displacement	0	0	0	0	0	0	1	0	1	0	0	0
Frostbite	0	0	1	0	1	0	17	0	18	0	0	0
Gastrointestinal injury	0	0	0	0	0	0	1	0	1	0	0	0
Gastrointestinal stoma complication	1	0	2	0	0	0	0	0	2	0	0	0
Genital injury	0	0	0	0	0	0	1	0	1	0	0	0
Gingival injury	0	0	0	0	0	0	3	0	3	0	0	0
Graft thrombosis	0	0	1	0	0	0	0	0	1	0	0	0
Hair injury	0	0	2	0	0	0	2	0	4	0	0	0
Hand fracture	0	0	2	0	0	0	0	0	2	0	0	0
Head and neck procedural complication	0	0	1	0	0	0	0	0	1	0	0	0
Head injury	5	0	85	0	5	0	39	1	124	1	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Heat cramps	0	0	2	0	0	0	1	0	3	0	0	0
Heat exhaustion	0	0	3	0	0	0	6	0	9	0	0	0
Heat illness	0	0	4	0	1	0	10	0	14	0	0	0
Heat oedema	0	0	8	0	0	0	10	0	18	0	0	0
Heat stroke	0	0	11	0	7	0	35	0	46	0	0	0
Heavy exposure to ultraviolet light	0	0	1	0	0	0	0	0	1	0	0	0
Hip fracture	2	0	5	0	0	0	0	0	5	0	0	0
Humerus fracture	0	0	4	0	0	0	1	0	5	0	0	0
Hyphaema	0	0	0	0	0	0	4	0	4	0	0	0
Hypobarism	0	0	2	0	0	0	1	0	3	0	0	0
Inadequate aseptic technique in use of product	0	0	1	0	0	0	1	0	2	0	0	0
Inappropriate schedule of product administration	35	0	51	0	23	0	752	3	803	3	0	0
Incision site discharge	1	0	1	0	0	0	0	0	1	0	0	0
Incision site erythema	0	0	0	0	0	0	1	0	1	0	0	0
Incision site haemorrhage	0	0	0	0	0	0	2	0	2	0	0	0
Incision site oedema	0	0	0	0	0	0	1	0	1	0	0	0
Incision site pain	0	0	4	0	0	0	9	0	13	0	0	0
Incision site pruritus	0	0	0	0	0	0	2	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Incision site swelling	0	0	0	0	1	0	3	0	3	0	0	0
Incisional hernia	0	0	1	0	0	0	0	0	1	0	0	0
Incomplete course of vaccination	0	0	11	0	7	0	229	1	240	1	0	0
Incorrect dosage administered	0	0	0	0	0	0	12	0	12	0	0	0
Incorrect dose administered	2	0	19	0	7	0	242	0	261	0	0	0
Incorrect dose administered by device	0	0	0	0	1	0	2	0	2	0	0	0
Incorrect dose administered by product	0	0	0	0	0	0	2	0	2	0	0	0
Incorrect product administration duration	1	0	1	0	0	0	6	0	7	0	0	0
Incorrect product dosage form administered	0	0	1	0	0	0	1	0	2	0	0	0
Incorrect product formulation administered	0	0	0	0	0	0	2	0	2	0	0	0
Incorrect route of product administration	5	0	51	0	9	0	606	1	657	1	0	0
Inflammation of wound	0	0	6	0	0	0	4	0	10	0	0	0
Infusion related reaction	16	0	31	0	1	0	16	0	47	0	0	0
Injection related reaction	4	0	513	0	11	0	186	0	699	0	0	0
Injury	7	0	49	0	7	0	67	0	116	0	0	0
Injury corneal	1	0	2	0	0	0	0	0	2	0	0	0
Injury to brachial plexus due to birth trauma	1	0	1	0	0	0	0	0	1	0	0	0
Intentional device misuse	0	0	0	0	0	0	1	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Intentional dose omission	3	0	4	0	3	0	145	0	149	0	0	0
Intentional overdose	0	0	15	0	0	0	1	0	16	0	0	0
Intentional product misuse	1	0	2	0	3	0	91	1	93	1	0	0
Intentional product use issue	3	0	3	0	1	0	11	0	14	0	0	0
Intentional underdose	1	0	1	0	0	0	2	0	3	0	0	0
Intercepted medication error	0	0	1	0	0	0	37	0	38	0	0	0
Intercepted product administration error	0	0	1	0	0	0	2	0	3	0	0	0
Intercepted product storage error	0	0	0	0	0	0	20	0	20	0	0	0
Internal injury	0	0	0	0	0	0	1	0	1	0	0	0
Intoxication by breast feeding	0	0	0	0	0	0	1	0	1	0	0	0
Ischaemic contracture of the left ventricle	0	0	1	0	0	0	0	0	1	0	0	0
Jaw fracture	0	0	1	0	0	0	1	0	2	0	0	0
Joint dislocation	5	0	38	0	0	0	0	0	38	0	0	0
Joint injury	1	0	19	0	3	0	37	0	56	0	0	0
Kidney rupture	0	0	3	0	0	0	0	0	3	0	0	0
Labelled drug-drug interaction issue	1	0	1	0	0	0	1	0	2	0	0	0
Labelled drug-drug interaction medication error	1	0	2	0	0	0	0	0	2	0	0	0
Lack of vaccination site rotation	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Lacrimal structure injury	0	0	1	0	0	0	0	0	1	0	0	0
Ligament injury	1	0	5	0	1	0	1	0	6	0	1	1
Ligament rupture	0	0	2	0	1	0	2	0	4	0	0	0
Ligament sprain	3	0	30	0	4	0	29	0	59	0	0	0
Limb crushing injury	0	0	12	0	0	0	0	0	12	0	0	0
Limb injury	13	0	339	0	11	0	134	1	473	1	0	0
Lip injury	1	0	5	0	0	1	4	1	9	1	0	0
Liver contusion	0	0	1	0	0	0	1	0	2	0	0	0
Lower limb fracture	1	0	7	0	0	0	6	1	13	1	0	0
Lumbar vertebral fracture	2	0	5	0	0	0	0	0	5	0	0	0
Lymphatic duct injury	0	0	0	0	0	0	1	0	1	0	0	0
Maternal exposure before pregnancy	0	0	14	0	3	0	17	0	31	0	1	1
Maternal exposure during breast feeding	7	0	974	0	15	0	779	0	1753	0	0	1
Maternal exposure during pregnancy	19	0	428	0	15	0	249	0	677	0	25	60
Maternal exposure timing unspecified	3	0	7	0	0	0	6	0	13	0	0	0
Maternal exposure via partner during pregnancy	0	0	0	0	1	0	1	0	1	0	0	0
Median nerve injury	0	0	2	0	0	0	0	0	2	0	0	0
Medication error	41	0	128	0	10	0	456	0	584	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Meniscus injury	1	0	2	0	1	0	3	0	5	0	1	1
Metal fume fever	0	0	0	0	0	0	1	0	1	0	0	0
Metal poisoning	0	0	2	0	0	0	0	0	2	0	0	0
Metallosis of globe	0	0	0	0	0	0	1	0	1	0	0	0
Mouth injury	0	0	3	0	2	0	16	0	19	0	0	0
Multiple fractures	2	0	9	0	0	0	6	0	15	0	0	0
Multiple injuries	1	0	5	0	1	0	8	0	13	0	0	0
Muscle contusion	0	0	0	0	0	0	1	0	1	0	0	0
Muscle injury	3	0	63	0	0	0	23	0	86	0	0	0
Muscle rupture	2	0	31	0	0	0	15	0	46	0	0	0
Muscle strain	4	0	59	0	9	0	124	0	183	0	0	0
Musculoskeletal injury	0	0	1	0	0	0	2	0	3	0	0	0
Nail avulsion	0	0	0	0	0	0	1	0	1	0	0	0
Nail injury	0	0	0	0	0	0	3	0	3	0	0	0
Nasal injury	0	0	3	0	0	0	8	0	11	0	0	0
Neck crushing	0	0	1	0	0	0	0	0	1	0	0	0
Neck injury	1	0	4	0	0	0	1	0	5	0	0	0
Needle fatigue	0	0	1	0	0	0	1	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Nerve injury	12	0	225	0	4	0	69	0	294	0	0	0
Nerve root injury	1	0	1	0	0	0	0	0	1	0	0	0
Nervous system injury	0	0	7	0	0	0	0	0	7	0	0	0
Occupational exposure to product	0	0	3	0	0	0	6	0	9	0	0	0
Ocular procedural complication	0	0	0	0	0	0	3	0	3	0	0	0
Off label use	46	0	120	0	221	0	1610	1	1730	1	0	0
Open fracture	0	0	1	0	0	0	0	0	1	0	0	0
Optic nerve injury	1	0	23	0	0	0	0	0	23	0	0	0
Oral contusion	0	0	7	0	6	0	34	0	41	0	0	0
Osteochondral fracture	0	0	0	0	1	0	1	0	1	0	0	0
Ovarian injury	0	0	1	0	0	0	0	0	1	0	0	0
Overdose	0	0	41	0	0	0	88	0	129	0	0	0
Palate injury	0	0	1	0	0	0	7	0	8	0	0	0
Parasympathetic nerve injury	0	0	0	0	0	0	1	0	1	0	0	0
Patella fracture	0	0	2	0	0	0	0	0	2	0	0	0
Paternal exposure before pregnancy	0	0	1	0	0	0	2	0	3	0	0	0
Paternal exposure during pregnancy	0	0	5	0	0	0	3	0	8	0	0	0
Pelvic bone injury	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Pelvic fracture	2	0	3	0	0	0	0	0	3	0	0	0
Penile contusion	0	0	1	0	0	0	2	0	3	0	0	0
Penis injury	0	0	1	0	0	0	1	0	2	0	0	0
Periorbital haematoma	0	0	1	0	1	0	15	0	16	0	0	0
Periorbital haemorrhage	1	0	4	0	3	0	17	0	21	0	0	0
Peripancreatic fluid collection	0	0	1	0	0	0	0	0	1	0	0	0
Peripheral nerve injury	0	0	2	0	0	0	2	0	4	0	0	0
Peroneal nerve injury	0	0	0	0	0	0	1	0	1	0	0	0
Persistent corneal epithelial defect	0	0	1	0	0	0	0	0	1	0	0	0
Pharyngeal contusion	0	0	3	0	0	0	1	0	4	0	0	0
Pharyngeal injury	0	0	0	0	0	0	9	0	9	0	0	0
Poisoning	2	0	10	0	1	0	12	0	22	0	0	0
Poor quality product administered	0	0	3	0	1	0	7	0	10	0	0	0
Post concussion syndrome	0	0	2	0	0	0	1	0	3	0	0	0
Post lumbar puncture syndrome	1	0	12	0	0	0	6	0	18	0	0	0
Post procedural complication	2	0	29	0	3	0	18	0	47	0	0	0
Post procedural contusion	1	0	2	0	0	0	1	0	3	0	0	0
Post procedural diarrhoea	0	0	0	0	0	0	2	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Post procedural discomfort	0	0	0	0	0	0	2	0	2	0	0	0
Post procedural fever	0	0	0	0	0	0	2	0	2	0	0	0
Post procedural fistula	0	0	0	0	0	0	1	0	1	0	0	0
Post procedural haematoma	0	0	0	0	0	0	1	0	1	0	0	0
Post procedural haemorrhage	0	0	4	0	1	0	4	0	8	0	0	0
Post procedural hypothyroidism	1	0	1	0	0	0	0	0	1	0	0	0
Post procedural stroke	0	0	7	0	0	0	1	0	8	0	0	0
Post vaccination syndrome	20	0	29	0	11	0	23	0	52	0	0	0
Post-traumatic neck syndrome	0	0	4	0	1	0	3	0	7	0	0	0
Post-traumatic pain	0	0	0	0	1	0	5	0	5	0	0	0
Post-traumatic punctate intraepidermal haemorrhage	0	0	0	0	0	0	1	0	1	0	0	0
Posterior fossa syndrome	0	0	1	0	0	0	0	0	1	0	0	0
Postmastectomy lymphoedema syndrome	0	0	1	0	0	0	0	0	1	0	0	0
Postoperative thrombosis	0	0	1	0	0	0	0	0	1	0	0	0
Postoperative wound complication	0	0	2	0	0	0	0	0	2	0	0	0
Prescribed overdose	0	0	0	0	0	0	1	0	1	0	0	0
Prescribed underdose	2	0	3	0	0	0	3	0	6	0	0	0
Prescription drug used without a prescription	0	0	2	0	0	0	0	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Prevertebral soft tissue swelling of cervical space	0	0	1	0	0	0	1	0	2	0	0	0
Procedural complication	0	0	0	0	0	0	1	0	1	0	0	0
Procedural dizziness	0	0	29	0	0	0	12	0	41	0	0	0
Procedural haemorrhage	1	0	3	0	0	0	1	0	4	0	0	0
Procedural headache	0	0	0	0	0	0	18	0	18	0	0	0
Procedural hypertension	0	0	1	0	0	0	0	0	1	0	0	0
Procedural intestinal perforation	0	0	1	0	0	0	0	0	1	0	0	0
Procedural nausea	0	0	26	0	2	0	14	0	40	0	0	0
Procedural pain	1	0	10	0	1	0	25	0	35	0	0	0
Procedural pneumothorax	0	0	1	0	0	0	0	0	1	0	0	0
Procedural site reaction	0	0	1	0	0	0	2	0	3	0	0	0
Procedural vomiting	0	0	4	0	0	0	10	0	14	0	0	0
Product administered at inappropriate site	1	0	43	0	2	0	75	0	118	0	0	0
Product administered to patient of inappropriate age	3	0	9	0	21	0	173	0	182	0	0	0
Product administration error	1	0	17	0	12	0	211	0	228	0	0	0
Product administration interrupted	0	0	0	0	0	0	1	0	1	0	0	0
Product communication issue	0	0	0	0	0	0	3	0	3	0	0	0
Product confusion	0	0	0	0	0	0	2	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Product dispensing error	0	0	11	0	0	0	7	0	18	0	0	0
Product dose omission in error	0	0	0	0	1	0	15	0	15	0	0	0
Product dose omission issue	17	0	22	0	10	0	275	3	297	3	0	0
Product label confusion	0	0	0	0	0	0	1	0	1	0	0	0
Product monitoring error	0	0	1	0	0	0	3	0	4	0	0	0
Product name confusion	0	0	1	0	0	0	1	0	2	0	0	0
Product packaging confusion	0	0	0	0	0	0	2	0	2	0	0	0
Product preparation error	0	0	0	0	0	0	4	0	4	0	0	0
Product preparation issue	2	0	2	0	0	0	6	0	8	0	0	0
Product prescribing error	1	0	2	0	0	0	10	0	12	0	0	0
Product prescribing issue	0	0	0	0	0	0	1	0	1	0	0	0
Product selection error	0	0	0	0	0	0	2	0	2	0	0	0
Product storage error	2	0	2	0	0	0	76	0	78	0	0	0
Product substitution error	0	0	0	0	0	0	1	0	1	0	0	0
Product use complaint	0	0	0	0	1	0	1	0	1	0	0	0
Product use in unapproved indication	1	0	3	0	0	0	5	0	8	0	0	0
Product use issue	6	0	15	0	2	0	54	0	69	0	0	0
Pulmonary oil microembolism	0	0	2	0	0	0	0	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Radial nerve injury	0	0	5	0	0	0	1	0	6	0	0	0
Radiation associated pain	0	0	0	0	0	0	1	0	1	0	0	0
Radiation injury affecting foetus	0	0	0	0	0	0	1	0	1	0	0	0
Radius fracture	0	0	3	0	0	0	2	0	5	0	0	0
Reaction to previous exposure to any vaccine	0	0	1	0	0	0	1	0	2	0	0	0
Reactive gastropathy	0	0	1	0	0	0	1	0	2	0	0	0
Recall phenomenon	0	0	2	0	1	0	3	0	5	0	0	0
Rectal injury	0	0	0	0	0	0	1	0	1	0	0	0
Recurrence of neuromuscular blockade	0	0	2	0	0	0	0	0	2	0	0	0
Repetitive strain injury	0	0	3	0	0	0	0	0	3	0	0	0
Restenosis	0	0	1	0	0	0	0	0	1	0	0	0
Retinal injury	0	0	9	0	0	0	3	0	12	0	0	0
Rib fracture	3	0	17	0	3	0	11	0	28	0	0	0
Road traffic accident	6	0	24	0	0	0	4	0	28	0	0	0
Scar	2	0	41	0	6	0	36	0	77	0	0	0
Sciatic nerve injury	0	0	1	0	1	0	2	0	3	0	0	0
Scratch	2	0	3	0	1	0	21	0	24	0	0	0
Scrotal injury	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Sedation complication	0	0	4	0	0	0	1	0	5	0	0	0
Seroma	0	0	0	0	1	0	4	0	4	0	0	0
Shunt thrombosis	0	0	1	0	0	0	0	0	1	0	0	0
Skeletal injury	1	0	5	0	0	0	7	0	12	0	0	0
Skin abrasion	0	0	5	0	5	0	26	0	31	0	0	0
Skin injury	2	0	25	0	2	0	20	0	45	0	0	0
Skin laceration	0	0	11	0	2	0	9	0	20	0	0	0
Skin pressure mark	0	0	0	0	0	0	3	0	3	0	0	0
Skin procedural complication	0	0	1	0	0	0	0	0	1	0	0	0
Skin wound	2	0	9	0	3	0	15	0	24	0	0	0
Skull fracture	1	0	7	0	0	0	0	0	7	0	0	0
Skull fractured base	0	0	2	0	0	0	0	0	2	0	0	0
Snake bite	0	0	0	0	0	0	1	0	1	0	0	0
Soft tissue foreign body	0	0	0	0	0	0	1	0	1	0	0	0
Soft tissue injury	0	0	6	0	0	0	2	0	8	0	0	0
Spinal column injury	3	0	6	0	0	0	0	0	6	0	0	0
Spinal compression fracture	0	0	6	0	0	0	4	0	10	0	0	0
Spinal cord injury	1	0	11	0	0	0	0	0	11	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Spinal cord injury sacral	0	0	1	0	0	0	0	0	1	0	0	0
Spinal cord injury thoracic	0	0	3	0	0	0	0	0	3	0	0	0
Spinal fracture	3	0	23	0	1	0	2	0	25	0	0	0
Spinal shock	0	0	1	0	0	0	0	0	1	0	0	0
Splenic injury	0	0	2	0	0	0	0	0	2	0	0	0
Splenic rupture	1	0	11	0	0	0	0	0	11	0	0	0
Splinter	0	0	0	0	0	0	2	0	2	0	0	0
Sports injury	0	0	1	0	0	0	0	0	1	0	0	0
[redacted]wound	0	0	0	0	0	0	3	0	3	0	0	0
Sternal fracture	0	0	2	0	0	0	0	0	2	0	0	0
Stoma obstruction	0	0	1	0	0	0	0	0	1	0	0	0
Stoma site haemorrhage	0	0	2	0	0	0	0	0	2	0	0	0
Stoma site pain	0	0	2	0	0	0	1	0	3	0	0	0
Stoma site rash	0	0	0	0	0	0	1	0	1	0	0	0
Stress fracture	1	0	6	0	1	0	2	0	8	0	0	0
Stroke-like migraine attacks after radiation therapy	0	0	1	0	0	0	1	0	2	0	0	0
Struck by lightning	0	0	1	0	0	0	0	0	1	0	0	0
Subarachnoid haematoma	0	0	2	0	0	0	0	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Subcutaneous haematoma	0	0	7	0	4	0	30	0	37	0	0	0
Subdural haematoma	6	0	69	0	0	0	0	0	69	0	0	0
Subdural haemorrhage	1	0	22	0	0	0	0	0	22	0	0	0
Sunburn	1	0	35	0	3	0	32	0	67	0	0	0
Superficial injury of eye	0	0	1	0	0	0	1	0	2	0	0	0
Suture related complication	0	0	0	0	0	0	1	0	1	0	0	0
Synovial rupture	0	0	5	0	0	0	0	0	5	0	0	0
Systemic toxicity	0	0	3	0	0	0	0	0	3	0	0	0
Tendon injury	1	0	10	0	0	0	10	0	20	0	0	0
Tendon rupture	2	0	39	0	3	0	11	1	50	1	0	0
Thermal burn	1	0	52	0	6	0	46	1	98	1	0	0
Thermal burns of eye	1	0	35	0	0	0	30	0	65	0	0	0
Tibia fracture	0	0	4	0	0	0	0	0	4	0	0	0
Tissue injury	0	0	6	0	0	0	3	0	9	0	0	0
Tongue injury	0	0	1	0	0	0	9	0	10	0	0	0
Tooth fracture	0	0	1	0	1	0	5	0	6	0	0	0
Tooth injury	0	0	5	0	3	1	6	1	11	1	0	0
Toxicity to various agents	1	0	20	0	0	0	0	0	20	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Transcription medication error	0	0	0	0	0	0	2	0	2	0	0	0
Transfusion-related acute lung injury	0	0	1	0	0	0	0	0	1	0	0	0
Transplant dysfunction	0	0	2	0	0	0	0	0	2	0	0	0
Transplant failure	0	0	1	0	0	0	1	0	2	0	0	0
Traumatic fracture	0	0	2	0	0	0	0	0	2	0	0	0
Traumatic haematoma	0	0	7	0	0	0	8	0	15	0	0	0
Traumatic haemorrhage	1	0	2	0	0	0	0	0	2	0	0	0
Traumatic haemothorax	0	0	1	0	0	0	0	0	1	0	0	0
Traumatic intracranial haemorrhage	1	0	4	0	0	0	0	0	4	0	0	0
Traumatic iritis	0	0	1	0	0	0	0	0	1	0	0	0
Traumatic liver injury	1	0	1	0	0	0	0	0	1	0	0	0
Traumatic lung injury	0	0	2	0	0	0	4	0	6	0	0	0
Traumatic shock	0	0	0	0	0	0	1	0	1	0	0	0
Ulnar nerve injury	0	0	4	0	0	0	3	0	7	0	0	0
Underdose	1	0	3	0	2	0	53	0	56	0	0	0
Unintentional use for unapproved indication	0	0	0	0	0	0	1	0	1	0	0	0
Unknown vaccine product administered	0	0	0	0	1	0	1	0	1	0	0	0
Unwanted awareness during anaesthesia	1	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Upper limb fracture	5	0	12	0	0	0	7	0	19	0	0	0
Urinary tract stoma complication	0	0	0	0	0	0	1	0	1	0	0	0
Uterine rupture	0	0	2	0	0	0	0	0	2	0	0	1
VIIIth nerve injury	0	0	3	0	0	0	1	0	4	0	0	0
VIIth nerve injury	0	0	2	0	0	0	0	0	2	0	0	0
VIth nerve injury	0	0	1	0	0	0	0	0	1	0	0	0
Vaccination complication	8	0	19	0	3	0	19	0	38	0	0	0
Vaccination error	0	0	8	0	4	0	81	0	89	0	0	0
Vascular access site bruising	0	0	1	0	0	0	1	0	2	0	0	0
Vascular access site haemorrhage	0	0	1	0	0	0	0	0	1	0	0	0
Vascular graft occlusion	0	0	4	0	0	0	0	0	4	0	0	0
Vascular graft stenosis	0	0	1	0	0	0	0	0	1	0	0	0
Vascular graft thrombosis	0	0	8	0	0	0	0	0	8	0	0	0
Vascular injury	0	0	17	0	4	0	15	0	32	0	0	0
Vascular pseudoaneurysm	0	0	2	0	0	0	3	0	5	0	0	0
Vasoplegia syndrome	0	0	4	0	0	0	0	0	4	0	0	0
Venous injury	1	0	3	0	1	0	4	0	7	0	0	0
Vth nerve injury	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Vulvovaginal injury	0	0	2	0	0	0	1	0	3	0	0	0
Weaning failure	0	0	0	0	0	0	1	0	1	0	0	0
Wound	8	0	29	0	24	0	91	1	120	1	0	0
Wound complication	2	0	11	0	0	0	13	0	24	0	0	0
Wound decomposition	0	0	0	0	0	0	2	0	2	0	0	0
Wound haematoma	0	0	0	0	0	0	1	0	1	0	0	0
Wound haemorrhage	5	0	9	0	2	0	26	0	35	0	0	0
Wound necrosis	0	0	0	0	0	0	1	0	1	0	0	0
Wound secretion	1	0	5	0	0	0	3	0	8	0	0	0
Wrist fracture	1	0	3	0	1	0	6	0	9	0	0	0
Wrong device used	0	0	0	0	0	0	1	0	1	0	0	0
Wrong dosage form	0	0	0	0	0	0	1	0	1	0	0	0
Wrong dose	0	0	0	0	0	0	2	0	2	0	0	0
Wrong drug	0	0	0	0	0	0	4	0	4	0	0	0
Wrong patient received product	0	0	0	0	0	0	1	0	1	0	0	0
Wrong product administered	3	0	9	0	15	0	194	0	203	0	0	0
Wrong route	0	0	0	0	0	0	2	0	2	0	0	0
Wrong schedule	0	0	0	0	0	0	8	0	8	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Wrong technique in device usage process	0	0	0	0	1	0	2	0	2	0	0	0
Wrong technique in product usage process	1	0	10	0	1	0	25	0	35	0	0	0
Surgical and medical procedures	**192**	**0**	**1357**	**0**	**569**	**0**	**3005**	**1**	**4362**	**1**	**1**	**1**
Abdominal cavity drainage	0	0	1	0	0	0	0	0	1	0	0	0
Abortion induced	1	0	4	0	0	0	1	0	5	0	0	0
Abscess drainage	1	0	5	0	1	0	9	0	14	0	0	0
Abscess management	0	0	1	0	1	0	8	0	9	0	0	0
Adrenalectomy	0	0	0	0	0	0	1	0	1	0	0	0
Adrenocortical steroid therapy	0	0	1	0	0	0	2	0	3	0	0	0
Airway secretion clearance therapy	0	0	1	0	0	0	0	0	1	0	0	0
Amputation	0	0	4	0	0	0	1	0	5	0	0	0
Analgesic therapy	0	0	0	0	0	0	12	0	12	0	0	0
Anaphylaxis prophylaxis	0	0	2	0	0	0	0	0	2	0	0	0
Anaphylaxis treatment	0	0	4	0	0	0	2	0	6	0	0	0
Angioplasty	0	0	3	0	0	0	1	0	4	0	0	0
Anorectal operation	1	0	1	0	0	0	0	0	1	0	0	0
Antacid therapy	0	0	0	0	0	0	1	0	1	0	0	0
Antiallergic therapy	0	0	2	0	0	0	1	0	3	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Antibiotic prophylaxis	0	0	0	0	0	0	0	1	0	1	0	0
Antibiotic therapy	0	0	1	0	0	0	4	0	5	0	0	0
Anticoagulant therapy	0	0	0	0	0	0	3	0	3	0	0	0
Antidepressant therapy	0	0	0	0	0	0	1	0	1	0	0	0
Antiinflammatory therapy	0	0	0	0	0	0	1	0	1	0	0	0
Antitussive therapy	0	0	1	0	0	0	1	0	2	0	0	0
Aortic valve replacement	0	0	0	0	0	0	1	0	1	0	0	0
Apicectomy	0	0	0	0	0	0	1	0	1	0	0	0
Appendicectomy	1	0	15	0	0	0	1	0	16	0	0	0
Arm amputation	0	0	1	0	0	0	2	0	3	0	0	0
Arterial stent insertion	0	0	1	0	0	0	1	0	2	0	0	0
Arteriovenous fistula operation	1	0	1	0	0	0	0	0	1	0	0	0
Arthrodesis	0	0	1	0	0	0	0	0	1	0	0	0
Asthma prophylaxis	0	0	1	0	0	0	0	0	1	0	0	0
Astringent therapy	0	0	0	0	0	0	1	0	1	0	0	0
Axillary lymphadenectomy	0	0	2	0	0	0	1	0	3	0	0	0
Bed rest	6	0	34	0	13	0	69	0	103	0	0	0
Bilateral orchidectomy	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Bladder catheter permanent	0	0	1	0	0	0	0	0	1	0	0	0
Bladder catheterisation	0	0	2	0	0	0	1	0	3	0	0	0
Bladder fistula repair	1	0	1	0	0	0	0	0	1	0	0	0
Bladder neoplasm surgery	0	0	1	0	0	0	0	0	1	0	0	0
Bladder training	0	0	1	0	0	0	0	0	1	0	0	0
Blood donation	0	0	0	0	0	0	2	0	2	0	0	0
Blood pressure management	0	0	1	0	0	0	0	0	1	0	0	0
Brachytherapy to breast	0	0	0	0	0	0	1	0	1	0	0	0
Brain operation	0	0	1	0	0	0	0	0	1	0	0	0
Breast conserving surgery	0	0	2	0	0	0	2	0	4	0	0	0
Breast cyst drainage	0	0	0	0	1	0	1	0	1	0	0	0
Breast operation	0	0	1	0	0	0	0	0	1	0	0	0
Bursa removal	0	0	1	0	0	0	0	0	1	0	0	0
COVID-19 immunisation	40	0	316	0	227	0	626	0	942	0	0	0
COVID-19 prophylaxis	0	0	2	0	0	0	3	0	5	0	0	0
COVID-19 treatment	0	0	4	0	0	0	4	0	8	0	0	0
Caesarean section	5	0	11	0	0	0	1	0	12	0	0	0
Cardiac ablation	1	0	3	0	0	0	1	0	4	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Cardiac operation	0	0	3	0	0	0	0	0	3	0	0	0
Cardiac pacemaker insertion	2	0	7	0	0	0	2	0	9	0	0	0
Cardiac pacemaker replacement	0	0	1	0	0	0	0	0	1	0	0	0
Cardioversion	0	0	4	0	0	0	2	0	6	0	0	0
Carpal tunnel decompression	0	0	1	0	0	0	0	0	1	0	0	0
Catheter management	0	0	2	0	0	0	2	0	4	0	0	0
Catheter placement	1	0	3	0	0	0	0	0	3	0	0	0
Central nervous system stimulation	0	0	2	0	0	0	5	0	7	0	0	0
Cerebral revascularisation	0	0	1	0	0	0	0	0	1	0	0	0
Cerumen removal	0	0	2	0	0	0	0	0	2	0	0	0
Chemotherapy	1	0	1	0	0	0	2	0	3	0	0	0
Chemotherapy toxicity attenuation	0	0	0	0	0	0	1	0	1	0	0	0
Chest tube removal	0	0	1	0	0	0	0	0	1	0	0	0
Cholecystectomy	3	0	5	0	0	0	0	0	5	0	0	0
Cholelithotomy	0	0	1	0	0	0	0	0	1	0	0	0
Ciliary body operation	0	0	1	0	0	0	0	0	1	0	0	0
Clamping of blood vessel	0	0	0	0	0	0	2	0	2	0	0	0
Colectomy	0	0	2	0	0	0	0	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Colectomy total	0	0	0	0	0	0	1	0	1	0	0	0
Colon operation	0	0	1	0	0	0	0	0	1	0	0	0
Compression garment application	0	0	0	0	0	0	2	0	2	0	0	0
Continuous passive motion machine therapy	0	0	1	0	0	0	0	0	1	0	0	0
Contraception	0	0	1	0	0	0	2	0	3	0	0	0
Contraceptive diaphragm	0	0	3	0	0	0	0	0	3	0	0	0
Cooling therapy	0	0	4	0	0	0	9	0	13	0	0	0
Corneal transplant	0	0	2	0	0	0	0	0	2	0	0	0
Coronary angioplasty	0	0	3	0	0	0	0	0	3	0	0	0
Coronary arterial stent insertion	2	0	4	0	0	0	0	0	4	0	0	0
Coronary artery bypass	0	0	5	0	0	0	0	0	5	0	0	0
Craniectomy	0	0	1	0	0	0	0	0	1	0	0	0
Cranioplasty	0	0	1	0	0	0	0	0	1	0	0	0
Craniotomy	1	0	3	0	0	0	0	0	3	0	0	0
Decompressive craniectomy	0	0	4	0	0	0	0	0	4	0	0	0
Dental care	0	0	2	0	0	0	1	0	3	0	0	0
Dental local anaesthesia	0	0	0	0	0	0	1	0	1	0	0	0
Dental operation	0	0	0	0	0	0	1	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Dermabrasion	0	0	1	0	0	0	0	0	1	0	0	0
Dermal filler injection	0	0	0	0	0	0	1	0	1	0	0	0
Diabetes mellitus management	0	0	0	0	0	0	2	0	2	0	0	0
Dialysis	1	0	5	0	0	0	2	0	7	0	0	0
Distraction osteogenesis	0	0	1	0	0	0	2	0	3	0	0	0
Drug toxicity prophylaxis	0	0	0	0	0	0	2	0	2	0	0	0
Dry skin prophylaxis	0	0	0	0	1	0	1	0	1	0	0	0
Electroconvulsive therapy	0	0	0	0	0	0	1	0	1	0	0	0
Emergency care	3	0	7	0	0	0	4	0	11	0	0	0
Endodontic procedure	2	0	2	0	0	0	0	0	2	0	0	0
Endometrial ablation	0	0	4	0	0	0	3	0	7	0	0	0
Endometrial scratching	0	0	4	0	0	0	4	0	8	0	0	0
Endometriosis ablation	1	0	1	0	0	0	0	0	1	0	0	0
Endotracheal intubation	1	0	13	0	0	0	1	0	14	0	0	0
Endovenous ablation	0	0	0	0	0	0	1	0	1	0	0	0
Enteral nutrition	0	0	1	0	0	0	0	0	1	0	0	0
Epidural anaesthesia	0	0	1	0	0	0	0	0	1	0	0	0
Epidural injection	1	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Explorative laparotomy	0	0	1	0	0	0	0	0	1	0	0	0
External counterpulsation	0	0	0	0	0	0	1	0	1	0	0	0
Extradural haematoma evacuation	0	0	1	0	0	0	0	0	1	0	0	0
Eye irrigation	0	0	3	0	0	0	1	0	4	0	0	0
Eye laser surgery	0	0	2	0	0	0	0	0	2	0	0	0
Eye muscle operation	0	0	0	0	0	0	1	0	1	0	0	0
Eye operation	0	0	0	0	0	0	1	0	1	0	0	0
Eyelid operation	0	0	0	0	0	0	1	0	1	0	0	0
Face lift	0	0	1	0	0	0	2	0	3	0	0	0
Fallopian tube operation	0	0	0	0	0	0	1	0	1	0	0	0
Fasciotomy	0	0	2	0	0	0	1	0	3	0	0	0
Fatigue management	0	0	1	0	0	0	2	0	3	0	0	0
Finger amputation	0	0	0	0	0	0	1	0	1	0	0	0
Fluid replacement	0	0	2	0	0	0	0	0	2	0	0	0
Foot amputation	0	0	2	0	0	0	1	0	3	0	0	0
Fraction of inspired oxygen	0	0	2	0	0	0	1	0	3	0	0	0
Fracture reduction	0	0	0	0	0	0	1	0	1	0	0	0
Gallbladder operation	0	0	1	0	0	0	1	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Gastrooesophageal variceal haemorrhage prophylaxis	0	0	1	0	0	0	0	0	1	0	0	0
General anaesthesia	0	0	1	0	0	0	0	0	1	0	0	0
Genital labial operation	0	0	1	0	0	0	0	0	1	0	0	0
Gluten free diet	1	0	2	0	0	0	0	0	2	0	0	0
Gynaecological disorder prophylaxis	0	0	1	0	0	0	0	0	1	0	0	0
Haematoma evacuation	0	0	1	0	0	0	1	0	2	0	0	0
Haemodialysis	0	0	2	0	0	0	0	0	2	0	0	0
Haemofiltration	0	0	1	0	0	0	0	0	1	0	0	0
Haemorrhoid operation	0	0	0	0	0	0	1	0	1	0	0	0
Hand amputation	0	0	0	0	0	0	1	0	1	0	0	0
Heart valve replacement	0	0	1	0	0	0	0	0	1	0	0	0
Heat therapy	0	0	1	0	0	0	9	0	10	0	0	0
Heparin neutralisation therapy	0	0	0	0	0	0	1	0	1	0	0	0
High frequency ablation	0	0	1	0	0	0	0	0	1	0	0	0
High intensity focused ultrasound	0	0	2	0	0	0	0	0	2	0	0	0
Hip arthroplasty	1	0	1	0	0	0	1	0	2	0	0	0
Hip surgery	1	0	1	0	0	0	1	0	2	0	0	0
Home care	0	0	0	0	0	0	1	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Hormone replacement therapy	0	0	3	0	0	0	3	0	6	0	0	0
Hormone therapy	0	0	6	0	0	0	3	0	9	0	0	0
Hospitalisation	7	0	98	0	0	0	9	0	107	0	0	0
Hyperthermia therapy	0	0	0	0	0	0	1	0	1	0	0	0
Hysterectomy	0	0	4	0	0	0	0	0	4	0	0	0
Ileocolostomy	0	0	1	0	0	0	0	0	1	0	0	0
Ileostomy	0	0	4	0	0	0	0	0	4	0	0	0
Immobilisation bandage	0	0	2	0	0	0	0	0	2	0	0	0
Immunisation	4	0	97	0	4	0	74	0	171	0	0	0
Immunoadsorption therapy	0	0	1	0	0	0	0	0	1	0	0	0
Immunoglobulin therapy	0	0	2	0	0	0	0	0	2	0	0	0
Influenza immunisation	0	0	0	0	0	0	4	0	4	0	0	0
Infusion	0	0	0	0	0	0	2	0	2	0	0	0
Inguinal hernia repair	0	0	1	0	0	0	0	0	1	0	0	0
Inhalation therapy	0	0	1	0	0	0	0	0	1	0	0	0
Injection	0	0	28	0	0	0	33	0	61	0	0	0
Intensive care	0	0	6	0	0	0	1	0	7	0	0	0
Interchange of vaccine products	61	0	128	0	299	0	1780	0	1908	0	1	1

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Intestinal resection	4	0	6	0	0	0	0	0	6	0	0	0
Intra-uterine contraceptive device insertion	0	0	0	0	0	0	1	0	1	0	0	0
Intracerebral haematoma evacuation	0	0	2	0	0	0	0	0	2	0	0	0
Intrauterine contraception	0	0	1	0	0	0	2	0	3	0	0	0
Intravesical immunotherapy	0	0	1	0	0	0	0	0	1	0	0	0
Involuntary commitment	0	0	9	0	0	0	0	0	9	0	0	0
Joint injection	0	0	6	0	0	0	1	0	7	0	0	0
Joint stabilisation	1	0	5	0	0	0	1	0	6	0	0	0
Knee operation	1	0	5	0	1	0	2	0	7	0	0	0
Laparotomy	0	0	2	0	0	0	1	0	3	0	0	0
Laryngeal prosthesis placement	0	0	1	0	0	0	0	0	1	0	0	0
Leg amputation	0	0	17	0	1	0	1	0	18	0	0	0
Lesion excision	0	0	1	0	0	0	0	0	1	0	0	0
Light anaesthesia	0	0	0	0	0	0	1	0	1	0	0	0
Limb amputation	1	0	3	0	0	0	0	0	3	0	0	0
Limb immobilisation	2	0	31	0	1	0	13	0	44	0	0	0
Limb operation	0	0	12	0	0	0	5	0	17	0	0	0
Limb reattachment surgery	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Limb reconstructive surgery	0	0	1	0	0	0	0	0	1	0	0	0
Liposuction	0	0	0	0	0	0	1	0	1	0	0	0
Liver transplant	1	0	1	0	0	0	0	0	1	0	0	0
Local anaesthesia	0	0	2	0	0	0	5	0	7	0	0	0
Localised alternating hot and cold therapy	0	0	3	0	0	0	5	0	8	0	0	0
Lung operation	0	0	1	0	0	0	0	0	1	0	0	0
Lung transplant	1	0	1	0	0	0	0	0	1	0	0	0
Lymphadenectomy	0	0	0	0	0	0	3	0	3	0	0	0
Magnetic therapy	0	0	0	0	0	0	1	0	1	0	0	0
Manipulation	0	0	0	0	0	0	1	0	1	0	0	0
Manual lymphatic drainage	0	0	0	0	0	0	1	0	1	0	0	0
Mass excision	1	0	9	0	0	0	11	0	20	0	0	0
Mastectomy	0	0	1	0	0	0	0	0	1	0	0	0
Maxillary antrum operation	0	0	0	0	0	0	1	0	1	0	0	0
Measles immunisation	0	0	0	0	0	0	1	0	1	0	0	0
Mechanical ventilation	0	0	5	0	0	0	0	0	5	0	0	0
Medical counselling	0	0	0	0	0	0	1	0	1	0	0	0
Medical device removal	0	0	0	0	0	0	1	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Medical diet	0	0	4	0	0	0	3	0	7	0	0	0
Medical induction of coma	0	0	3	0	0	0	0	0	3	0	0	0
Medication dilution	0	0	3	0	0	0	0	0	3	0	0	0
Menstrual cycle management	0	0	4	0	5	0	43	0	47	0	0	0
Mesenteric artery stent insertion	0	0	1	0	0	0	0	0	1	0	0	0
Mineral supplementation	0	0	1	0	0	0	0	0	1	0	0	0
Mitral valve repair	0	0	1	0	0	0	0	0	1	0	0	0
Multiple sclerosis relapse prophylaxis	0	0	2	0	0	0	0	0	2	0	0	0
Muscle relaxant therapy	0	0	3	0	0	0	1	0	4	0	0	0
Muscle suture	0	0	0	0	0	0	1	0	1	0	0	0
Nail operation	0	0	1	0	0	0	1	0	2	0	0	0
Nasal cavity packing	0	0	0	0	0	0	3	0	3	0	0	0
Nasal irrigation	0	0	1	0	0	0	0	0	1	0	0	0
Neck lift	0	0	1	0	0	0	0	0	1	0	0	0
Neonatal warming therapy	0	0	0	0	0	0	1	0	1	0	0	0
Nephrectomy	0	0	3	0	0	0	0	0	3	0	0	0
Nerve block	0	0	6	0	0	0	2	0	8	0	0	0
Neurological rehabilitation	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Nothing by mouth order	0	0	1	0	1	0	9	0	10	0	0	0
Nutritional supplementation	0	0	0	0	0	0	1	0	1	0	0	0
Occupational therapy	0	0	1	0	0	0	0	0	1	0	0	0
Oesophageal tamponade	0	0	0	0	0	0	1	0	1	0	0	0
Oophorectomy	0	0	2	0	0	0	0	0	2	0	0	0
Oral contraception	0	0	0	0	0	0	7	0	7	0	0	0
Orthodontic procedure	0	0	1	0	0	0	0	0	1	0	0	0
Ovulation induction	0	0	0	0	0	0	2	0	2	0	0	0
Oxygen therapy	2	0	4	0	0	0	1	0	5	0	0	0
Pacemaker generated rhythm	0	0	1	0	0	0	0	0	1	0	0	0
Parathyroidectomy	0	0	1	0	0	0	0	0	1	0	0	0
Parenteral nutrition	0	0	0	0	0	0	1	0	1	0	0	0
Patient isolation	0	0	0	0	0	0	1	0	1	0	0	0
Percutaneous coronary intervention	0	0	4	0	0	0	0	0	4	0	0	0
Pericardial drainage	0	0	2	0	0	0	0	0	2	0	0	0
Pericardial excision	0	0	2	0	0	0	0	0	2	0	0	0
Phlebotomy	2	0	3	0	1	0	3	0	6	0	0	0
Photopheresis	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Physical fitness training	0	0	2	0	0	0	3	0	5	0	0	0
Physiotherapy	0	0	1	0	0	0	0	0	1	0	0	0
Plastic surgery to the face	0	0	0	0	0	0	1	0	1	0	0	0
Platelet transfusion	0	0	1	0	0	0	0	0	1	0	0	0
Positive airway pressure therapy	0	0	0	0	0	0	2	0	2	0	0	0
Post coital contraception	0	0	0	0	0	0	1	0	1	0	0	0
Posterior lens capsulotomy	0	0	0	0	1	0	1	0	1	0	0	0
Postoperative care	0	0	0	0	0	0	1	0	1	0	0	0
Product substitution	0	0	1	0	0	0	2	0	3	0	0	0
Product used for unknown indication	0	0	1	0	0	0	2	0	3	0	0	0
Promotion of wound healing	0	0	1	0	0	0	0	0	1	0	0	0
Prone position	0	0	2	0	0	0	1	0	3	0	0	0
Prophylaxis	0	0	0	0	0	0	1	0	1	0	0	0
Prophylaxis against gastrointestinal ulcer	0	0	1	0	0	0	0	0	1	0	0	0
Prophylaxis of nausea and vomiting	0	0	23	0	1	0	11	0	34	0	0	0
Prostate ablation	1	0	1	0	0	0	0	0	1	0	0	0
Prosthetic vessel removal	0	0	0	0	0	0	1	0	1	0	0	0
Psychotherapy	0	0	1	0	0	0	1	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Pterygium operation	0	0	1	0	0	0	0	0	1	0	0	0
Pupil constriction procedure	0	0	0	0	0	0	1	0	1	0	0	0
Quarantine	0	0	0	0	0	0	3	0	3	0	0	0
Radiotherapy	0	0	0	0	0	0	1	0	1	0	0	0
Red blood cell transfusion	0	0	1	0	0	0	0	0	1	0	0	0
Rehabilitation therapy	0	0	1	0	0	0	2	0	3	0	0	0
Renal transplant	0	0	1	0	0	0	0	0	1	0	0	0
Renal tumour excision	0	0	1	0	0	0	0	0	1	0	0	0
Reproductive system disorder prophylaxis	0	0	1	0	0	0	0	0	1	0	0	0
Respiratory therapy	0	0	1	0	0	0	0	0	1	0	0	0
Resuscitation	2	0	18	0	0	0	3	0	21	0	0	0
Retained placenta operation	0	0	1	0	0	0	0	0	1	0	0	0
Retinal laser coagulation	0	0	1	0	0	0	0	0	1	0	0	0
Rubella immunisation	0	0	0	0	0	0	1	0	1	0	0	0
Salpingectomy	0	0	1	0	0	0	0	0	1	0	0	0
Self-medication	0	0	1	0	0	0	0	0	1	0	0	0
Shoulder operation	0	0	3	0	0	0	0	0	3	0	0	0
Sinus antrostomy	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Skin graft	1	0	1	0	0	0	0	0	1	0	0	0
Skin neoplasm excision	1	0	2	0	0	0	0	0	2	0	0	0
Skin operation	0	0	1	0	0	0	0	0	1	0	0	0
Smoking cessation therapy	0	0	0	0	0	0	1	0	1	0	0	0
Specialist consultation	0	0	1	0	1	0	4	0	5	0	0	0
Spinal decompression	0	0	0	0	0	0	1	0	1	0	0	0
Spinal fusion surgery	1	0	1	0	0	0	0	0	1	0	0	0
Spinal operation	0	0	1	0	0	0	0	0	1	0	0	0
Spinal rod insertion	0	0	0	0	1	0	1	0	1	0	0	0
Splenectomy	1	0	4	0	0	0	0	0	4	0	0	0
Splenic artery embolisation	0	0	1	0	0	0	0	0	1	0	0	0
Stent placement	0	0	5	0	0	0	1	0	6	0	0	0
Steroid therapy	0	0	1	0	0	0	1	0	2	0	0	0
Stoma care	0	0	1	0	0	0	0	0	1	0	0	0
Subdural haematoma evacuation	0	0	2	0	0	0	0	0	2	0	0	0
Supine position	0	0	1	0	0	0	0	0	1	0	0	0
Surgery	1	0	13	0	0	0	7	0	20	0	0	0
Suture insertion	2	0	3	0	0	0	2	0	5	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Tattoo excision	0	0	0	0	0	0	1	0	1	0	0	0
Tenodesis	0	0	1	0	0	0	0	0	1	0	0	0
Testes exploration	0	0	1	0	0	0	0	0	1	0	0	0
Tetanus immunisation	0	0	0	0	0	0	1	0	1	0	0	0
Therapeutic hypothermia	0	0	2	0	0	0	1	0	3	0	0	0
Therapeutic procedure	0	0	1	0	0	0	0	0	1	0	0	0
Therapy change	0	0	3	0	0	0	4	0	7	0	0	0
Therapy interrupted	3	0	5	0	0	0	1	0	6	0	0	0
Thoracic cavity drainage	1	0	2	0	0	0	0	0	2	0	0	0
Thrombectomy	0	0	11	0	0	0	0	0	11	0	0	0
Thromboembolectomy	0	0	4	0	0	0	0	0	4	0	0	0
Thrombolysis	1	0	12	0	1	0	2	0	14	0	0	0
Thrombosis prophylaxis	0	0	3	0	0	0	1	0	4	0	0	0
Thyroidectomy	0	0	1	0	0	0	0	0	1	0	0	0
Toe amputation	0	0	6	0	0	0	1	0	7	0	0	0
Tonsillectomy	0	0	2	0	0	0	0	0	2	0	0	0
Tooth extraction	5	0	8	0	2	0	6	0	14	0	0	0
Tooth restoration	0	0	2	0	0	0	2	0	4	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Tracheostomy	0	0	4	0	0	0	1	0	5	0	0	0
Transfusion	1	0	6	0	1	0	1	0	7	0	0	0
Transgender operation	0	0	1	0	0	0	0	0	1	0	0	0
Transurethral bladder resection	0	0	1	0	0	0	0	0	1	0	0	0
Treatment delayed	0	0	0	0	0	0	1	0	1	0	0	0
Trigeminal nerve ablation	0	0	1	0	0	0	0	0	1	0	0	0
Tuberculosis immunisation	0	0	1	0	0	0	0	0	1	0	0	0
Tumour excision	0	0	1	0	0	0	0	0	1	0	0	0
Tumour vaccine therapy	0	0	0	0	0	0	1	0	1	0	0	0
UV light therapy	0	0	1	0	0	0	0	0	1	0	0	0
Unrelated donor bone marrow transplantation therapy	0	0	0	0	0	0	1	0	1	0	0	0
Uterine dilation and curettage	0	0	3	0	1	0	1	0	4	0	0	0
Uterine dilation and evacuation	0	0	0	0	0	0	1	0	1	0	0	0
Vaccine coadministration	0	0	0	0	0	0	1	0	1	0	0	0
Vagotomy	0	0	1	0	0	0	2	0	3	0	0	0
Vascular anastomosis	0	0	0	0	1	0	1	0	1	0	0	0
Vascular compression therapy	0	0	0	0	0	0	1	0	1	0	0	0
Vascular graft	0	0	2	0	0	0	0	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Vascular operation	0	0	2	0	0	0	1	0	3	0	0	0
Vena cava filter insertion	0	0	1	0	1	0	1	0	2	0	0	0
Venipuncture	0	0	0	0	1	0	1	0	1	0	0	0
Ventricular drainage	1	0	2	0	0	0	0	0	2	0	0	0
Ventriculo-peritoneal shunt	0	0	0	0	0	0	1	0	1	0	0	0
Vessel harvesting	0	0	0	0	0	0	2	0	2	0	0	0
Vitamin supplementation	0	0	1	0	0	0	1	0	2	0	0	0
Vitrectomy	0	0	1	0	0	0	0	0	1	0	0	0
Weight loss diet	0	0	1	0	0	0	1	0	2	0	0	0
Wisdom teeth removal	1	0	1	0	0	0	0	0	1	0	0	0
Wound closure	0	0	1	0	0	0	0	0	1	0	0	0
Wound drainage	0	0	1	0	0	0	0	0	1	0	0	0
Wound treatment	1	0	2	0	0	0	0	0	2	0	0	0
X-ray therapy to lung	0	0	1	0	0	0	0	0	1	0	0	0
Social circumstances	**104**	**0**	**1150**	**0**	**203**	**0**	**1900**	**1**	**3050**	**1**	**0**	**0**
Abstains from alcohol	0	0	0	0	0	0	2	0	2	0	0	0
Alcohol use	0	0	0	0	0	0	1	0	1	0	0	0
Alcoholic	0	0	4	0	0	0	1	0	5	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Anal sex	0	0	1	0	0	0	0	0	1	0	0	0
Bedridden	11	0	194	0	22	0	392	1	586	1	0	0
Bereavement	0	0	1	0	0	0	0	0	1	0	0	0
Blood donor	0	0	2	0	0	0	0	0	2	0	0	0
Blood product transfusion dependent	0	0	1	0	0	0	0	0	1	0	0	0
Breast feeding	0	0	8	0	0	0	9	0	17	0	0	0
Breast prosthesis user	0	0	1	0	0	0	0	0	1	0	0	0
Cardiac assistance device user	0	0	1	0	0	0	0	0	1	0	0	0
Chemical submission	0	0	0	0	0	0	1	0	1	0	0	0
Childhood	0	0	0	0	0	0	1	0	1	0	0	0
Contraindication to medical treatment	0	0	0	0	0	0	1	0	1	0	0	0
Contraindication to vaccination	0	0	7	0	5	0	48	0	55	0	0	0
Convalescent	0	0	1	0	0	0	2	0	3	0	0	0
Corrective lens user	0	0	1	0	1	0	1	0	2	0	0	0
Death of pet	0	0	1	0	0	0	0	0	1	0	0	0
Death of relative	0	0	2	0	0	0	0	0	2	0	0	0
Dependence on oxygen therapy	0	0	3	0	0	0	2	0	5	0	0	0
Disability	9	0	33	0	1	0	9	0	42	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Disease risk factor	0	0	2	0	0	0	3	0	5	0	0	0
Economic problem	0	0	2	0	0	0	3	0	5	0	0	0
Educational problem	0	0	0	0	0	0	1	0	1	0	0	0
Ex-tobacco user	0	0	0	0	0	0	1	0	1	0	0	0
Excessive exercise	0	0	0	0	0	0	2	0	2	0	0	0
Exercise lack of	0	0	0	0	0	0	1	0	1	0	0	0
Food contamination	0	0	0	0	0	0	1	0	1	0	0	0
Hair dye user	0	0	0	0	0	0	1	0	1	0	0	0
Hearing aid user	0	0	3	0	0	0	1	0	4	0	0	0
Hearing disability	1	0	5	0	0	0	5	0	10	0	0	0
Homosexual parent	0	0	1	0	0	0	0	0	1	0	0	0
Homosexuality	0	0	0	0	0	0	1	0	1	0	0	0
Housebound	4	0	10	0	2	0	5	0	15	0	0	0
Illiteracy	0	0	4	0	0	0	0	0	4	0	0	0
Immobile	5	0	76	0	0	0	26	0	102	0	0	0
Immobilisation prolonged	0	0	8	0	0	0	0	0	8	0	0	0
Impaired driving ability	3	0	37	0	0	0	30	0	67	0	0	0
Impaired quality of life	6	0	37	0	8	0	30	0	67	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Impaired work ability	28	0	337	0	75	0	725	0	1062	0	0	0
Inability to afford medication	0	0	1	0	0	0	0	0	1	0	0	0
Inadequate diet	0	0	1	0	0	0	0	0	1	0	0	0
Infant	0	0	0	0	0	0	1	0	1	0	0	0
Job dissatisfaction	0	0	3	0	0	0	5	0	8	0	0	0
Kosher diet	0	0	0	0	0	0	1	0	1	0	0	0
Life expectancy shortened	0	0	1	0	0	0	1	0	2	0	0	0
Loss of personal independence in daily activities	18	0	166	0	72	0	404	0	570	0	0	0
Menarche	0	0	0	0	0	0	3	0	3	0	0	0
Menopause	5	0	57	0	1	0	38	0	95	0	0	0
Mental disability	0	0	3	0	0	0	2	0	5	0	0	0
Non-tobacco user	0	0	5	0	0	0	2	0	7	0	0	0
Occupational problem environmental	0	0	1	0	0	0	0	0	1	0	0	0
Orthosis user	0	0	1	0	0	0	1	0	2	0	0	0
Paralytic disability	0	0	1	0	0	0	0	0	1	0	0	0
Partner stress	0	0	0	0	0	0	1	0	1	0	0	0
Patient dissatisfaction with treatment	0	0	1	0	0	0	3	0	4	0	0	0
Patient uncooperative	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Personal relationship issue	0	0	2	0	0	0	0	0	2	0	0	0
Physical assault	0	0	1	0	0	0	0	0	1	0	0	0
Physical disability	0	0	7	0	3	0	14	0	21	0	0	0
Planning to become pregnant	0	0	1	0	0	0	0	0	1	0	0	0
Pollution	0	0	0	0	0	0	1	0	1	0	0	0
Postmenopause	0	0	11	0	0	0	8	0	19	0	0	0
Refusal of treatment by patient	0	0	0	0	0	0	2	0	2	0	0	0
Refusal of vaccination	0	0	0	0	0	0	8	0	8	0	0	0
Retirement	0	0	3	0	0	0	5	0	8	0	0	0
Sexual activity increased	0	0	0	0	0	0	2	0	2	0	0	0
Sexually active	0	0	0	0	0	0	1	0	1	0	0	0
Sick leave	6	0	11	0	11	0	37	0	48	0	0	0
Sick relative	0	0	3	0	0	0	1	0	4	0	0	0
Sight disability	1	0	28	0	0	0	8	0	36	0	0	0
Sitting disability	0	0	7	0	0	0	12	0	19	0	0	0
Social problem	0	0	0	0	0	0	1	0	1	0	0	0
Stress at work	0	0	2	0	0	0	1	0	3	0	0	0
Tanning	0	0	0	0	0	0	2	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Tattoo	0	0	1	0	0	0	0	0	1	0	0	0
Tobacco user	0	0	1	0	0	0	1	0	2	0	0	0
Unemployment	0	0	0	0	0	0	1	0	1	0	0	0
Unhealthy lifestyle	0	0	1	0	0	0	1	0	2	0	0	0
Verbal abuse	0	0	1	0	0	0	1	0	2	0	0	0
Victim[redacted]	0	0	1	0	0	0	0	0	1	0	0	0
Walking aid user	3	0	9	0	1	0	4	0	13	0	0	0
Walking disability	3	0	24	0	0	0	19	0	43	0	0	0
Water pollution	0	0	5	0	0	0	0	0	5	0	0	0
Wheelchair user	1	0	6	0	1	0	2	0	8	0	0	0
Product issues	**9**	**0**	**160**	**0**	**8**	**0**	**211**	**0**	**371**	**0**	**0**	**0**
Device breakage	1	0	1	0	0	0	1	0	2	0	0	0
Device delivery system issue	0	0	0	0	1	0	2	0	2	0	0	0
Device dislocation	1	0	3	0	0	0	0	0	3	0	0	0
Device electrical impedance issue	0	0	1	0	0	0	0	0	1	0	0	0
Device end of service	0	0	0	0	0	0	1	0	1	0	0	0
Device expulsion	0	0	2	0	0	0	2	0	4	0	0	0
Device inappropriate shock delivery	0	0	1	0	0	0	0	0	1	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Device issue	0	0	1	0	2	0	4	0	5	0	0	0
Device leakage	0	0	0	0	0	0	3	0	3	0	0	0
Device occlusion	0	0	3	0	0	0	1	0	4	0	0	0
Device physical property issue	0	0	0	0	0	0	3	0	3	0	0	0
Device power source issue	1	0	1	0	0	0	0	0	1	0	0	0
Drug delivery system issue	0	0	0	0	0	0	1	0	1	0	0	0
Electromagnetic interference	0	0	2	0	0	0	8	0	10	0	0	0
Liquid product physical issue	0	0	1	0	0	0	4	0	5	0	0	0
Manufacturing equipment issue	0	0	0	0	0	0	1	0	1	0	0	0
Needle issue	1	0	3	0	0	0	11	0	14	0	0	0
Oversensing	0	0	33	0	1	0	18	0	51	0	0	0
Patient-device incompatibility	0	0	1	0	0	0	1	0	2	0	0	0
Physical product label issue	1	0	1	0	0	0	0	0	1	0	0	0
Product after taste	0	0	3	0	0	0	6	0	9	0	0	0
Product availability issue	0	0	0	0	3	0	17	0	17	0	0	0
Product barcode issue	0	0	1	0	0	0	0	0	1	0	0	0
Product colour issue	0	0	0	0	0	0	4	0	4	0	0	0
Product complaint	1	0	3	0	0	0	2	0	5	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Product container issue	0	0	1	0	0	0	6	0	7	0	0	0
Product contamination	0	0	1	0	0	0	4	0	5	0	0	0
Product contamination microbial	0	0	0	0	0	0	1	0	1	0	0	0
Product contamination physical	0	0	0	0	0	0	2	0	2	0	0	0
Product counterfeit	0	0	0	0	0	0	2	0	2	0	0	0
Product deposit	0	0	0	0	0	0	1	0	1	0	0	0
Product formulation issue	0	0	1	0	0	0	0	0	1	0	0	0
Product identification number issue	0	0	0	0	0	0	1	0	1	0	0	0
Product impurity	0	0	0	0	0	0	2	0	2	0	0	0
Product label issue	0	0	0	0	0	0	2	0	2	0	0	0
Product leakage	0	0	0	0	0	0	1	0	1	0	0	0
Product lot number issue	0	0	0	0	0	0	1	0	1	0	0	0
Product odour abnormal	0	0	1	0	0	0	2	0	3	0	0	0
Product origin unknown	0	0	1	0	0	0	3	0	4	0	0	0
Product physical consistency issue	0	0	0	0	0	0	1	0	1	0	0	0
Product physical issue	0	0	1	0	0	0	1	0	2	0	0	0
Product quality issue	1	0	2	0	0	0	8	0	10	0	0	0
Product reconstitution quality issue	0	0	0	0	0	0	2	0	2	0	0	0

Table 2a - Number of Adverse Reactions by Term from Post Marketing Sources (split by causality)

System Organ Class Preferred Term	Spontaneous, including regulatory authority and literature								Total Spontaneous		Non-interventional post-marketing study	
	Serious				Non-serious						Serious	
	Interval		Cumulative		Interval		Cumulative		Cumulative all		Interval	Cumulative
	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated	Related	Unrelated		
Product substitution issue	0	0	0	0	0	0	1	0	1	0	0	0
Product supply issue	0	0	0	0	0	0	2	0	2	0	0	0
Product taste abnormal	0	0	9	0	0	0	5	0	14	0	0	0
Product temperature excursion issue	1	0	1	0	0	0	49	0	50	0	0	0
Stent malfunction	0	0	2	0	0	0	0	0	2	0	0	0
Suspected counterfeit product	0	0	0	0	0	0	8	0	8	0	0	0
Suspected product contamination	0	0	0	0	0	0	2	0	2	0	0	0
Suspected product quality issue	0	0	0	0	0	0	2	0	2	0	0	0
Suspected product tampering	0	0	0	0	0	0	1	0	1	0	0	0
Syringe issue	0	0	0	0	0	0	5	0	5	0	0	0
Thrombosis in device	1	0	75	0	0	0	0	0	75	0	0	0
Undersensing	0	0	4	0	1	0	6	0	10	0	0	0

Listing of MedDRA SOCs in the Internationally Agreed Order

MedDRA Version: 25.1

Infections and infestations
Neoplasms benign, malignant and unspecified (incl cysts and polyps)
Blood and lymphatic system disorders
Immune system disorders
Endocrine disorders
Metabolism and nutrition disorders
Psychiatric disorders
Nervous system disorders
Eye disorders
Ear and labyrinth disorders
Cardiac disorders
Vascular disorders
Respiratory, thoracic and mediastinal disorders
Gastrointestinal disorders
Hepatobiliary disorders
Skin and subcutaneous tissue disorders
Musculoskeletal and connective tissue disorders
Renal and urinary disorders
Pregnancy, puerperium and perinatal conditions
Reproductive system and breast disorders
Congenital, familial and genetic disorders
General disorders and administration site conditions
Investigations
Injury, poisoning and procedural complications
Surgical and medical procedures
Social circumstances
Product issues