COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 11-Nov-2021

Data Lock Date: 10-Nov-2021 18:30:19

All UK spontaneous reports received up to and including 10/11/2021 for COVID-19 vaccine Moderna.

A report of a suspected ADR to the Yellow Card scheme does not necessarily mean that it was caused by the vaccine, only that the reporter has a suspicion it may have. Underlying or previously undiagnosed illness unrelated to vaccination can also be factors in such reports. The relative number and nature of reports should therefore not be used to compare the safety of the different vaccines. All reports are kept under continual review in order to identify possible new risks.

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| Reaction Name | Total | Fatal |
|---------------------------------|-------|-------|
| Blood disorders | | |
| Anaemia deficiencies | | |
| Iron deficiency anaemia | 1 | 0 |
| Anaemias NEC | | |
| Anaemia | 3 | 0 |
| Bleeding tendencies | | |
| Increased tendency to bruise | 3 | 0 |
| Spontaneous haematoma | 1 | 0 |
| Coagulopathies | | |
| Antiphospholipid syndrome | 1 | 0 |
| Coagulopathy | 1 | 0 |
| Haematological disorders | | |
| Blood disorder | 1 | 0 |
| Mast cell activation syndrome | 1 | 0 |
| Lymphatic system disorders NEC | | |
| Lymph node pain | 143 | 0 |
| Lymphadenitis | 10 | 0 |
| Lymphadenopathy | 842 | 0 |
| Neutropenias | | |
| Autoimmune neutropenia | 1 | 0 |
| Neutropenia | 1 | 0 |
| Sickle cell trait and disorders | | |
| Sickle cell anaemia with crisis | 1 | 0 |
| Thrombocytopenias | | |
| Immune thrombocytopenia | 4 | l o |
| Thrombocytopenia | 17 | 7 0 |
| Thrombocytopenic purpura | 1 | 0 |
| Blood disorders SOC TOTAL | 1032 | el o |

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Cardiac disorders | | |
| Cardiac conduction disorders | | |
| Atrioventricular block | 2 | 0 |
| Bundle branch block left | 1 | 0 |
| Bundle branch block right | 1 | 0 |
| Cardiac disorders NEC | | |
| Cardiac disorder | 6 | 0 |
| Cardiac signs and symptoms NEC | | |
| Cardiac discomfort | 2 | 0 |
| Palpitations | 436 | 0 |
| Heart failures NEC | | |
| Cardiac failure | 1 | 0 |
| Cardiac failure congestive | 1 | 0 |
| Cardiogenic shock | 1 | 0 |
| Ischaemic coronary artery disorders | | |
| Angina pectoris | 20 | 0 |
| Myocardial infarction | 8 | 0 |
| Mitral valvular disorders | | |
| Mitral valve incompetence | 1 | 0 |
| Mitral valve prolapse | 1 | 0 |
| Myocardial disorders NEC | | |
| Cardiomegaly | 2 | 0 |
| Left ventricular dysfunction | 1 | 0 |
| Left ventricular hypertrophy | 1 | 0 |
| Myocardial fibrosis | 1 | 0 |
| Myocardial injury | 1 | 0 |
| Noninfectious myocarditis | | J |
| Myocarditis | 93 | 0 |
| Noninfectious pericarditis | | |
| Pericarditis | 55 | 0 |
| Rate and rhythm disorders NEC | | J |
| Arrhythmia | 13 | 0 |
| Bradycardia | 8 | 0 |
| Cardiac fibrillation | 1 | 0 |
| Cardiac flutter | 39 | 0 |
| Extrasystoles | 14 | 0 |
| Tachycardia | 67 | 0 |
| Tachycardia foetal | 1 | 0 |
| Supraventricular arrhythmias | | J |
| Atrial fibrillation | 4 | 0 |
| Atrial flutter | 2 | 0 |
| Atrial tachycardia | 1 | 0 |
| Sinus arrhythmia | 1 | 0 |
| Sinus tachycardia | 2 | 0 |
| Supraventricular tachycardia | 2 | 0 |
| Ventricular arrhythmias and cardiac arrest | | 0 |
| Cardiac arrest | 3 | 0 |
| Ventricular extrasystoles | 1 | 0 |
| Ventricular extrasystoles Ventricular tachycardia | 1 | 0 |
| Cardiac disorders SOC TOTAL | 795 | 0 |

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Congenital disorders | | |
| Cardiac disorders congenital NEC | | |
| Heart disease congenital | | 1 0 |
| Cerebellar disorders congenital | | |
| Hereditary ataxia | | 1 0 |
| Connective tissue disorders congenital | | |
| Ehlers-Danlos syndrome | | 2 0 |
| Male reproductive tract disorders congenital | | |
| Micropenis | | 1 0 |
| Neurological disorders congenital NEC | | |
| Familial hemiplegic migraine | | 1 0 |
| Congenital disorders SOC TOTAL | | al o |

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| Reaction Name | Total | Fatal |
|--|-------|------------|
| Ear disorders | | |
| Ear disorders NEC | | |
| Ear congestion | 6 | 6 0 |
| Ear discomfort | 3 | 3 0 |
| Ear disorder | 2 | <u>2</u> 0 |
| Ear pain | 122 | 0 |
| Ear swelling | 2 | 0 |
| Eustachian tube disorders | | |
| Eustachian tube obstruction | 1 | ı o |
| External ear disorders NEC | | |
| Excessive cerumen production | 3 | 0 |
| Red ear syndrome | 1 | 0 |
| Hearing losses | | |
| Deafness | 18 | 3 0 |
| Deafness transitory | 1 | 0 |
| Deafness unilateral | 4 | ۱ o |
| Hypoacusis | 18 | 3 0 |
| Sudden hearing loss | 7 | 7 0 |
| Hyperacusia | | |
| Hyperacusis | 5 | 0 |
| Inner ear infections and inflammations | | |
| Inner ear inflammation | 1 | 0 |
| Inner ear signs and symptoms | | |
| Motion sickness | 13 | 3 0 |
| Tinnitus | 184 | 1 0 |
| Vertigo | 136 | 0 |
| Vertigo positional | 3 | 3 0 |
| Ear disorders SOC TOTAL | 530 | ol o |

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Endocrine disorders | | |
| Acute and chronic thyroiditis | | |
| Autoimmune thyroiditis | • | 1 0 |
| Endocrine abnormalities of puberty | | |
| Delayed menarche | 2 | 2 0 |
| Premature menarche | (| 3 0 |
| Female gonadal function disorders | | |
| Anovulatory cycle | ! | 5 0 |
| Ovulation delayed | | 8 0 |
| Hypothalamic and pituitary disorders NEC | | |
| Pituitary haemorrhage | • | 1 0 |
| Thyroid disorders NEC | | |
| Goitre | (| 3 0 |
| Thyroid hyperfunction disorders | | |
| Hyperthyroidism | , | 1 0 |
| Thyroid hypofunction disorders | | |
| Hypothyroidism | | 2 0 |
| Endocrine disorders SOC TOTAL | 20 | sl o |

| Reaction Name | Total | <u>Fatal</u> |
|--|-------|--------------|
| Eye disorders | | |
| Amblyopic vision impairment | | |
| Amblyopia | 1 | (|
| Cataract conditions | | |
| Cataract | 1 | (|
| Choroid and vitreous structural change, deposit and degeneration | | |
| Chorioretinopathy | 1 | (|
| Vitreous floaters | 7 | (|
| Conjunctival and corneal bleeding and vascular disorders | | |
| Conjunctival haemorrhage | 3 | (|
| Eyelid movement disorders | | |
| Blepharospasm | 19 | |
| Eyelid ptosis | 1 | |
| Iris and uveal tract infections, irritations and inflammations | | |
| Uveitis | 4 | (|
| Lacrimation disorders | | |
| Dry eye | 14 | (|
| Lacrimation increased | 6 | |
| Lid, lash and lacrimal infections, irritations and inflammations | | |
| Eyelid rash | 1 | |
| Swelling of eyelid | 8 | |
| Ocular bleeding and vascular disorders NEC | | |
| Eye haematoma | 1 | |
| Ocular disorders NEC | | |
| Eye disorder | 2 | |
| Eye pain | 132 | |
| Eye swelling | 40 | |
| Eyelids pruritus | 1 | |
| Ocular discomfort | 4 | |
| Periorbital oedema | 2 | |
| | 9 | |
| Periorbital swelling | 9 | |
| Ocular infections, inflammations and associated manifestations | | |
| Eye allergy | 2 | |
| Eye inflammation | 1 | |
| Eye irritation | 10 | |
| Eye pruritus | 18 | |
| Ocular hyperaemia | 17 | |
| Ocular nerve and muscle disorders | _ | |
| Eye movement disorder | 5 | |
| Ocular sensation disorders | | |
| Abnormal sensation in eye | 1 | |
| Asthenopia | 9 | |
| Foreign body sensation in eyes | 2 | |
| Hypoaesthesia eye | 1 | |
| Photophobia | 55 | |
| Optic disc abnormalities NEC | | |
| Optic discs blurred | 1 | |
| Papilloedema | 1 | |
| Optic nerve bleeding and vascular disorders | | |
| Optic ischaemic neuropathy | 1 | |
| Orbital infections, inflammations and irritations | | |
| Orbital myositis | 1 | |
| Pupil disorders | | |
| Mydriasis | 3 | |

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Eve disorders Eye disorders cont'd | | |
| Refractive and accommodative disorders | | |
| Accommodation disorder | 1 | 0 |
| Astigmatism | 2 | 0 |
| Retinal bleeding and vascular disorders (excl retinopathy) | | |
| Retinal haemorrhage | 1 | 0 |
| Retinal vein occlusion | 3 | 0 |
| Retinopathies NEC | | |
| Acute macular neuroretinopathy | 1 | 0 |
| Serous retinopathy | 1 | 0 |
| Scleral infections, irritations and inflammations | | |
| Episcleritis | 4 | 0 |
| Structural change, deposit and degeneration of eye NEC | | |
| Exophthalmos | 1 | 0 |
| Visual colour distortions | | |
| Cyanopsia | 1 | 0 |
| Visual disorders NEC | | |
| Diplopia | 15 | 0 |
| Halo vision | 1 | 0 |
| Metamorphopsia | 1 | 0 |
| Photopsia | 9 | 0 |
| Vision blurred | 163 | 0 |
| Visual field disorders | | |
| Visual field defect | 2 | 0 |
| Visual impairment and blindness (excl colour blindness) | | |
| Blindness | 18 | 0 |
| Blindness transient | 3 | 0 |
| Blindness unilateral | 1 | 0 |
| Visual acuity reduced | 2 | 0 |
| Visual impairment | 25 | _ |
| Eve disorders SOC TOTAL | 640 | l o |

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| Reaction Name | Total | <u> Fatal</u> |
|---|----------|---------------|
| Gastrointestinal disorders | | |
| Abdominal findings abnormal | | |
| Gastrointestinal sounds abnormal | 1 | (|
| Acute and chronic pancreatitis | | |
| Pancreatitis | 1 | (|
| Anal and rectal pains | | |
| Proctalgia | 4 | . (|
| Anal and rectal signs and symptoms | | |
| Anal pruritus | 1 | |
| Anorectal discomfort | 1 | (|
| Colitis (excl infective) | | |
| Colitis | 3 | (|
| Colitis ulcerative | 5 | (|
| Crohn's disease | 7 | |
| Inflammatory bowel disease | 1 | (|
| Dental and periodontal infections and inflammations | | |
| Dental caries | 1 | (|
| Dental disorders NEC | | |
| Teething | 1 | (|
| Tooth disorder | 1 | |
| Dental pain and sensation disorders | | |
| Dental paraesthesia | 2 | |
| Hyperaesthesia teeth | 4 | |
| Toothache | 13 | |
| Dental pulp disorders | | |
| Dental pulp disorder | 1 | (|
| Diarrhoea (excl infective) | | |
| Diarrhoea | 491 | (|
| Diarrhoea haemorrhagic | 1 | |
| Dyspeptic signs and symptoms | | |
| Dyspepsia | 58 | (|
| Epigastric discomfort | 1 | |
| Eructation | 6 | |
| Faecal abnormalities NEC | | |
| Faeces discoloured | 5 | ; |
| Flatulence, bloating and distension | | |
| Abdominal distension | 36 | |
| Flatulence | 18 | 1 |
| Gastric ulcers and perforation | | |
| Gastric ulcer | 1 | |
| Gastritis erosive | 1 | |
| Gastritis (excl infective) | | |
| Gastritis | 3 | |
| Gastrointestinal and abdominal pains (excl oral and throat) | | |
| Abdominal pain | 153 | ; |
| Abdominal pain lower | 14 | 1 |
| Abdominal pain upper | 343 | |
| Abdominal rigidity | 1 | |
| Abdominal rigidity Abdominal tenderness | 2 | |
| | 13 | |
| Gastrointestinal pain | 13 | |
| Oesophageal pain | | |
| Gastrointestinal atonic and hypomotility disorders NEC | 0.4 | |
| Constipation Gastrooesophageal reflux disease | 21 15 | 1 |

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Gastrointestinal disorders Gastrointestinal disorders cont'd | | |
| Gastrointestinal disorders NEC | | |
| Food poisoning | 1 | 0 |
| Gastric disorder | 1 | 0 |
| Gastrointestinal disorder | 1 | 0 |
| Stomach mass | 1 | 0 |
| Gastrointestinal dyskinetic disorders | | |
| Bowel movement irregularity | 1 | 0 |
| Change of bowel habit | 1 | 0 |
| Gastrointestinal motility disorder | 1 | 0 |
| Oesophageal achalasia | 1 | 0 |
| Gastrointestinal inflammatory disorders NEC | | |
| Gastrointestinal inflammation | 1 | 0 |
| Gastrointestinal mucosal dystrophies and secretion disorders | | |
| Hyperchlorhydria | 1 | 0 |
| Gastrointestinal signs and symptoms NEC | | |
| Abdominal discomfort | 64 | 0 |
| Anal incontinence | 3 | 0 |
| Breath odour | 4 | 0 |
| Dysphagia | 18 | |
| Odynophagia | 6 | 0 |
| Gastrointestinal spastic and hypermotility disorders | | |
| Defaecation urgency | 1 | 0 |
| Frequent bowel movements | 4 | |
| Irritable bowel syndrome | 8 | 0 |
| Gastrointestinal stenosis and obstruction NEC | | |
| Intestinal obstruction | 1 | 0 |
| Gastrointestinal vascular malformations | | |
| Gastric antral vascular ectasia | 1 | 0 |
| Gingival disorders, signs and symptoms NEC | | |
| Gingival pain | 6 | 0 |
| Gingival swelling | 4 | |
| Noninfective gingivitis | 1 | 0 |
| Gingival haemorrhages | | |
| Gingival bleeding | 6 | 0 |
| Haemorrhoids and gastrointestinal varices (excl oesophageal) | | |
| Haemorrhoids | 3 | 0 |
| Intestinal haemorrhages | | |
| Anal haemorrhage | 1 | 0 |
| Rectal haemorrhage | 9 | 0 |
| Malabsorption syndromes | | |
| Coeliac disease | 1 | 0 |
| Nausea and vomiting symptoms | | |
| Discoloured vomit | 1 | 0 |
| Nausea | 2003 | 0 |
| Retching | 12 | 0 |
| Vomiting | 702 | 0 |
| Vomiting projectile | 2 | 0 |
| Non-site specific gastrointestinal haemorrhages | | |
| Gastrointestinal haemorrhage | 1 | 0 |
| Haematemesis | 1 | 0 |
| Haematochezia | 5 | O |
| Melaena | 1 | O |
| Upper gastrointestinal haemorrhage | 3 | |

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Gastrointestinal disorders Gastrointestinal disorders cont'd | | |
| Oral dryness and saliva altered | | |
| Aptyalism | 1 | 0 |
| Dry mouth | 53 | 0 |
| Lip dry | 4 | 0 |
| Saliva altered | 2 | 0 |
| Salivary hypersecretion | 6 | 0 |
| Oral soft tissue disorders NEC | | |
| Chapped lips | 1 | 0 |
| Cheilitis | 1 | 0 |
| Enlarged uvula | 1 | 0 |
| Lip blister | 2 | 0 |
| Lip disorder | 1 | 0 |
| Oral soft tissue haemorrhages | | |
| Mouth haemorrhage | 2 | 0 |
| Oral blood blister | 2 | 0 |
| Oral soft tissue signs and symptoms | | |
| Coating in mouth | 2 | 0 |
| Hypoaesthesia oral | 44 | 0 |
| Lip discolouration | 1 | 0 |
| Lip pain | 3 | 0 |
| Lip pruritus | 1 | 0 |
| Oral discomfort | 4 | 0 |
| Oral mucosal roughening | 1 | 0 |
| Oral pain | 10 | 0 |
| Oral pruritus | 1 | 0 |
| Paraesthesia oral | 68 | 0 |
| Oral soft tissue swelling and oedema | | |
| Lip swelling | 78 | 0 |
| Mouth swelling | 10 | 0 |
| Peptic ulcers and perforation | | |
| Peptic ulcer haemorrhage | 2 | 0 |
| Peritoneal and retroperitoneal disorders | | |
| Ascites | 1 | 0 |
| Rectal inflammations NEC | | |
| Proctitis | 1 | 0 |
| Salivary gland disorders NEC | | |
| Salivary gland pain | 1 | 0 |
| Salivary gland enlargements | | |
| Parotid gland enlargement | 1 | 0 |
| Submaxillary gland enlargement | 1 | 0 |
| Stomatitis and ulceration | | |
| Aphthous ulcer | 3 | 0 |
| Lip ulceration | 3 | 0 |
| Mouth ulceration | 42 | 0 |
| Stomatitis | 3 | 0 |
| Tongue disorders | | |
| Glossitis | 2 | 0 |
| Tongue disorder | 4 | 0 |
| Tongue haemorrhage | 1 | 0 |
| Tongue ulceration | 4 | 0 |
| Tongue signs and symptoms | | |
| Glossodynia | 16 | 0 |
| Swollen tongue | 40 | 0 |

| Reaction Name | Tota | ıl | Fatal |
|--|------|----|-------|
| Gastrointestinal disorders Gastrointestinal disorders cont'd | | | |
| Tongue blistering | | 1 | 0 |
| Tongue coated | | 2 | 0 |
| Tongue discolouration | | 2 | 0 |
| Tongue discomfort | | 2 | 0 |
| Tongue dry | | 2 | 0 |
| Tongue movement disturbance | | 1 | 0 |
| Tongue oedema | | 1 | 0 |
| Tooth missing | | | |
| Tooth loss | | 1 | 0 |
| Gastrointestinal disorders SOC TOTAL | 45 | 49 | ol |

| Reaction Name | Total | Fatal |
|---|-------|-------|
| General disorders | | |
| Administration site reactions NEC | | |
| Administration site extravasation | 1 | 0 |
| Administration site lymphadenopathy | 1 | 0 |
| Administration site pain | 2 | 0 |
| Puncture site bruise | 5 | 0 |
| Puncture site pain | 1 | 0 |
| Application and instillation site reactions | | |
| Application site bruise | 1 | 0 |
| Application site burn | 1 | 0 |
| Application site erythema | 6 | 0 |
| Application site joint erythema | 1 | 0 |
| Application site pain | 1 | 0 |
| Application site pruritus | 9 | 0 |
| Application site rash | 1 | 0 |
| Application site swelling | 2 | 0 |
| Application site vesicles | 4 | 0 |
| Application site warmth | 1 | 0 |
| Instillation site erythema | 1 | 0 |
| Instillation site warmth | 2 | 0 |
| Asthenic conditions | | |
| Asthenia | 248 | 0 |
| Chronic fatigue syndrome | 4 | 0 |
| Fatigue | 2669 | 0 |
| Malaise | 464 | 0 |
| Death and sudden death | | |
| Death | 8 | 8 |
| Febrile disorders | | |
| Pyrexia | 3004 | 1 |
| Feelings and sensations NEC | | |
| Chills | 1629 | 0 |
| Feeling abnormal | 241 | 0 |
| Feeling cold | 110 | |
| Feeling drunk | 11 | 0 |
| Feeling hot | 185 | |
| Feeling jittery | 9 | 0 |
| Feeling of body temperature change | 58 | - |
| Hangover | 12 | 0 |
| Hunger | 13 | |
| Sensation of blood flow | 1 | 0 |
| Sensation of foreign body | 5 | 0 |
| Temperature intolerance | 17 | 0 |
| Thirst | 49 | 0 |
| Gait disturbances | 10 | J |
| Gait disturbance | 16 | 0 |
| Gait inability | 3 | 0 |
| General signs and symptoms NEC | J | J |
| Condition aggravated | 11 | 0 |
| Crying | 23 | |
| Discharge | 3 | 0 |
| Effusion | 1 | 0 |
| Energy increased | 1 | 0 |
| Exercise tolerance decreased | I F | 0 |
| | 5 | 0 |
| Foaming at mouth | 2 | 0 |

| General physical health deterioration Illness 256 Induration 7 Influenza like illness 299 Irritability postvaccinal 1 Local reaction 15 Moaning 1 Multiple organ dysfunction syndrome 1 Perforation 1 Peripheral swelling 1216 Screaming 4 Secretion discharge 2 Swelling 645 Swelling face 73 Implant and catheter site reactions Implant site warmth 3 Inflammations 3 Inflammations 3 Soft tissue inflammation 1 Infusion site erythema 1 Infusion site pruritus 1 Infusion site pruritus 1 Infusion site reactions 1 Infusion site reactions 1 Infusion site reactions 1 Infusion site reactions 1 Infusion site pruritus 1 Infusion site pruritus 1 Infusion site reactions 1 Infusion site warmth 1 Infection site reactions 1 Infusion site warmth 1 Infection site reactions 1 Injection site discolouration 1 Injection site discolouration 1 Injection site hypersensitivity 6 Injection site hypersensitivity 6 Injection site inflammation 9 Injection sit | Reaction Name | Total | Fatal |
|--|--|-------|-------|
| Illness | General disorders General disorders cont'd | | |
| Induration | General physical health deterioration | 1 | 0 |
| Influenza like illness | Illness | 256 | 0 |
| Irritability postvaccinal 1 Local reaction 15 Moaning 1 Multiple organ dysfunction syndrome 1 Perforation 1 Perforation 1 Peripheral swelling 1216 Screaming 4 Secretion discharge 2 Swelling Swelling 645 Swelling face 73 Implant and catheter site reactions Implant site warmth 3 Inflammations Granuloma 1 Inflammations Soft tissue inflammation 85 Systemic inflammation 1 Systemic inflammatory response syndrome 1 Infusion site reactions Infusion site experiment 1 Infusion site print 1 Infusion site print 1 Infusion site print 1 Infusion site print 1 Infusion site warmth 1 Infusion site warmth 1 Injection site warmth 1 Injection site focusions Injection site inflammation 9 Injection site hypersensitivity 1 Injection site hypersensitivity 1 Injection site inflammation 1 Injection site inflammation 9 Injection site mass Injection site mass Injection site wass Injection site wass Injection site pain Inje | Induration | 7 | 0 |
| Local reaction 15 Moaning | Influenza like illness | 299 | 0 |
| Multiple organ dysfunction syndrome | Irritability postvaccinal | 1 | 0 |
| Multiple organ dysfunction syndrome Perforation 1 Peripheral swelling 1216 Screaming 4 Secretion discharge 2 Swelling 645 Swelling face 73 Implant and catheter site reactions Implant site warmth 3 Inflammations Granuloma 1 Inflammation 85 Soft tissue inflammatory response syndrome 1 Infusion site reactions Infusion site exite mass 1 Infusion site pain 4 Infusion site varmth 1 Injection site varmth 1 Injection site varmth 1 Injection site varmth 1 Injection site organization 1 Injection site organization 1 Injection site organization 1 Injection site varmth 1 Injection site varmth 1 Injection site varmth 1 Injection site organization 1 Injection site organization 1 Injection site organization 1 Injection site haemorrhage 1 Injection site haemorrhage 1 Injection site hypoaesthesia 1 Injection site inflammation 2 Injection site inflammation 3 Injection site paraesthesia 3 | Local reaction | 15 | 0 |
| Perforation | Moaning | 1 | 0 |
| Peripheral swelling | Multiple organ dysfunction syndrome | 1 | 1 |
| Screaming Secretion discharge 2 2 2 3 5 5 5 5 5 5 5 5 5 | Perforation | 1 | 0 |
| Secretion discharge Swelling 645 | Peripheral swelling | 1216 | 0 |
| Swelling face 73 Implant and catheter site reactions 73 Implant site warmth 3 Inflammations 75 Granuloma 1 1 Inflammation 85 Soft tissue inflammatory response syndrome 1 1 Infusion site reactions 1 1 Infusion site erythema 1 1 Infusion site pain 4 1 Infusion site pruritus 1 1 Infusion site varmth 1 1 Infusion site warmth 1 1 Injection site reactions 1 1 Injection site reactions 1 1 Injection site reactions 1 1 Injection site varmth 1 1 Injection site reactions 1 1 Injection site indentation 1 1 Injection site bruising 9 9 Injection site hyporesensitivity 1 6 Injection site hyporesensitivity 1 6 Injection site indentation 1 2 Injection site inflammation 9 9 Injection site inflammation 9 1 Injection site inflammation 9 1 Injection site inflammation 9 1 Injection site inflammation 1 2 Injection site inflammation 2 2 Injection site inflammation 1 2 Injection site inflammation 2 2 Injection site inflammation 2 2 Injection site inflammation 3 384 Injection site pain 384 Injection site pain 384 Injection site paraesthesia 1 | Screaming | 4 | 0 |
| Swelling face Implant and catheter site reactions Implant site warmth Implant site warmth Inflammations Granuloma Inflammation Soft tissue inflammation Soft tissue inflammation Influsion site reactions Infusion site reactions Infusion site eythema Infusion site pruritus Infusion site pruritus Infusion site pruritus Infusion site viticaria Infusion site viticaria Infusion site reactions Injection site reactions Injection site reactions Injection site indentation Injection site bruising Injection site indentation Injection site haemorrhage Injection site hypersensitivity Injection site inflammation Injection site inflammation Injection site irritation Injection site irritation Injection site inflammation Injection site irritation Injection site inflammation Injection site irritation Injection site pain Injection site pain Injection site pain Injection site pain Injection site paraesthesia | Secretion discharge | 2 | 0 |
| Implant and catheter site reactions Implant site warmth 3 Inflammations 1 Granuloma 1 Inflammation 85 Soft tissue inflammatory response syndrome 1 Infusion site reactions 1 Infusion site erythema 1 Infusion site erythema 1 Infusion site pain 4 Infusion site pruritus 1 Infusion site warnth 1 Injection site warnth 1 Injected limb mobility decreased 5 Injected limb mobility decreased 5 Injection site bruising 9 Injection site discolouration 1 Injection site haemorrhage 3 Injection site haemorrhage 3 Injection site hypoaesthesia 5 Injection site indentation 2 Injection site inflammation 9 Injection site joint erythema 4 Injection site joint erythema 4 Injection site oedema 2 Injection site pain 384 Injection site pain 1 | Swelling | 645 | 0 |
| Implant and catheter site reactions Implant site warmth 3 Inflammations 1 Granuloma 1 Inflammation 85 Soft tissue inflammatory response syndrome 1 Infusion site reactions 1 Infusion site erythema 1 Infusion site erythema 1 Infusion site pain 4 Infusion site pruritus 1 Infusion site warmth 1 Injection site warmth 1 Injected limb mobility decreased 5 Injected limb mobility decreased 5 Injection site discolouration 1 Injection site bruising 9 Injection site haemorrhage 3 Injection site haemorrhage 3 Injection site hypoaesthesia 5 Injection site indentation 2 Injection site inflammation 9 Injection site joint erythema 4 Injection site joint erythema 4 Injection site oedema 2 Injection site pain 384 Injection site pairaesthesia 1 | Swelling face | 73 | 0 |
| Implant site warmth Inflammations Granuloma Inflammation Soft tissue inflammation Soft tissue inflammatory response syndrome Infusion site reactions Infusion site erythema Infusion site pain Infusion site pain Infusion site urticaria Infusion site warmth Injection site reactions Injected limb mobility decreased Injection site bruising Injection site erythema Injection site erythema Injection site erythema Injection site hypersensitivity Injection site hyposesthesia Injection site inflammation Injection site pain Injection site pain Injection site pain Injection site pain Injection site paraesthesia | | | |
| Inflammations 1 Granuloma 1 Inflammation 85 Soft tissue inflammatory response syndrome 1 Infusion site reactions 1 Infusion site erythema 1 Infusion site mass 1 Infusion site pain 4 Infusion site pruritus 1 Infusion site urticaria 1 Infusion site warmth 1 Injection site warmth 1 Injection site reactions 5 Injected limb mobility decreased 5 Injection site bruising 9 Injection site discolouration 1 Injection site erythema 112 Injection site hyporesensitivity 6 Injection site hypoaesthesia 5 Injection site inflammation 2 Injection site inflammation 2 Injection site inflammation 2 Injection site mass 117 Injection site mass 117 Injection site pain 384 Injection site pain 384 </td <td>Implant site warmth</td> <td>3</td> <td>0</td> | Implant site warmth | 3 | 0 |
| Inflammation 85 Soft tissue inflammation 1 Systemic inflammatory response syndrome 1 Infusion site reactions Infusion site erythema 1 Infusion site pain 4 Infusion site pruritus 1 Infusion site urticaria 1 Infusion site warmth 1 Injection site reactions Injected limb mobility decreased 5 Injection site discolouration 1 Injection site erythema 112 Injection site haemorrhage 3 Injection site hypersensitivity 6 Injection site hypersensitivity 1 Injection site inflammation 9 Injection site irritation 2 Injection site irritation 2 Injection site inflammation 9 Injection site inflammation 2 Injection site inflammation 3 Injection site | | | |
| Soft tissue inflammation Systemic inflammatory response syndrome Infusion site reactions Infusion site erythema Infusion site mass Infusion site pain Infusion site pruritus Infusion site urticaria Infusion site warmth Infection site reactions Injected limb mobility decreased Injection site discolouration Injection site erythema Injection site haemorrhage Injection site hypersensitivity Injection site inflammation Injection site inflammation Injection site irritation Injection site irritation Injection site irritation Injection site oedema Injection site mass Injection site oedema Injection site oedema Injection site paraesthesia | Granuloma | 1 | 0 |
| Soft tissue inflammation Systemic inflammatory response syndrome Infusion site reactions Infusion site erythema Infusion site mass Infusion site pain Infusion site printius Infusion site urticaria Infusion site warmth Infusion site warmth Infusion site reactions Injected limb mobility decreased Injection site bruising Injection site discolouration Injection site erythema Injection site haemorrhage Injection site hypersensitivity Injection site inflammation Injection site i | Inflammation | 85 | 0 |
| Infusion site reactions Infusion site erythema Infusion site mass Infusion site mass Infusion site pain Infusion site pruritus Infusion site urticaria Infusion site warmth Infusion site reactions Injection site reactions Injection site bruising Injection site discolouration Injection site erythema Injection site haemorrhage Injection site hypersensitivity Injection site inflammation Injection site inflammation Injection site irritation Injection site irritation Injection site insite mass Injection site oedema Injection site pain Injection site paraesthesia | Soft tissue inflammation | 1 | 0 |
| Infusion site reactions Infusion site erythema Infusion site mass Infusion site mass Infusion site pain Infusion site pruritus Infusion site urticaria Infusion site warmth Infusion site reactions Injection site reactions Injection site bruising Injection site discolouration Injection site erythema Injection site haemorrhage Injection site hypersensitivity Injection site inflammation Injection site inflammation Injection site irritation Injection site irritation Injection site insite mass Injection site oedema Injection site pain Injection site paraesthesia | Systemic inflammatory response syndrome | 1 | 0 |
| Infusion site erythema Infusion site mass Infusion site pain Infusion site pruritus Infusion site urticaria Infusion site warmth Infusion site warmth Injection site reactions Injected limb mobility decreased Injection site bruising Injection site erythema Injection site erythema Injection site erythema Injection site haemorrhage Injection site hypersensitivity Injection site inflammation Injection site inflammation Injection site irritation Injection site joint erythema Injection site mass Injection site mass Injection site oedema Injection site pain Injection site paraesthesia | | | |
| Infusion site mass Infusion site pain Infusion site pruritus Infusion site urticaria Infusion site warmth Infusion site reactions Injection site reactions Injection site bruising Injection site discolouration Injection site erythema Injection site haemorrhage Injection site hypersensitivity Injection site hypoaesthesia Injection site inflammation Injection site irritation Injection site joint erythema Injection site joint erythema Injection site mass Injection site oedema Injection site pain Injection site paraesthesia | | 1 | 0 |
| Infusion site pain Infusion site pruritus Infusion site urticaria Infusion site warmth Infusion site reactions Injection site reactions Injected limb mobility decreased Injection site bruising Injection site discolouration Injection site erythema Injection site haemorrhage Injection site hypersensitivity Injection site hypoaesthesia Injection site indentation Injection site inflammation Injection site irritation Injection site irritation Injection site irritation Injection site irritation Injection site indentation Injection site irritation Injection site irritation Injection site irritation Injection site mass Injection site mass Injection site oedema Injection site pain Injection site paraesthesia | • | 1 | 0 |
| Infusion site pruritus Infusion site urticaria Infusion site warmth Injection site reactions Injected limb mobility decreased Injection site bruising Injection site discolouration Injection site erythema Injection site haemorrhage Injection site hypersensitivity Injection site hypoaesthesia Injection site indentation Injection site inflammation Injection site irritation Injection site irritation Injection site joint erythema Injection site mass Injection site oedema Injection site oedema Injection site pain Injection site paraesthesia | | 4 | 0 |
| Infusion site urticaria Infusion site warmth Injection site reactions Injected limb mobility decreased Injection site bruising Injection site discolouration Injection site erythema Injection site haemorrhage Injection site hypersensitivity Injection site hypoaesthesia Injection site indentation Injection site inflammation Injection site irritation Injection site irritation Injection site joint erythema Injection site mass Injection site oedema Injection site pain Injection site paraesthesia | | 1 | 0 |
| Infusion site warmth Injection site reactions Injected limb mobility decreased Injection site bruising Injection site discolouration Injection site erythema Injection site haemorrhage Injection site hypersensitivity Injection site hypoaesthesia Injection site indentation Injection site inflammation Injection site irritation Injection site joint erythema Injection site mass Injection site oedema Injection site pain Injection site paraesthesia | | 1 | 0 |
| Injection site reactionsInjected limb mobility decreased5Injection site bruising9Injection site discolouration1Injection site erythema112Injection site haemorrhage3Injection site hypersensitivity6Injection site hypoaesthesia5Injection site indentation2Injection site inflammation9Injection site irritation2Injection site joint erythema4Injection site mass117Injection site oedema2Injection site pain384Injection site paraesthesia1 | | 1 | 0 |
| Injected limb mobility decreased Injection site bruising Injection site discolouration Injection site erythema Injection site haemorrhage Injection site hypersensitivity Injection site hypoaesthesia Injection site indentation Injection site inflammation Injection site irritation Injection site joint erythema Injection site oedema Injection site oedema Injection site pain Injection site paraesthesia | | | |
| Injection site bruising9Injection site discolouration1Injection site erythema112Injection site haemorrhage3Injection site hypersensitivity6Injection site hypoaesthesia5Injection site indentation2Injection site inflammation9Injection site irritation2Injection site joint erythema4Injection site mass117Injection site oedema2Injection site pain384Injection site paraesthesia1 | | 5 | 0 |
| Injection site discolouration Injection site erythema Injection site haemorrhage Injection site hypersensitivity Injection site hypoaesthesia Injection site indentation Injection site inflammation Injection site irritation Injection site joint erythema Injection site mass Injection site oedema Injection site pain Injection site paraesthesia | | | 0 |
| Injection site erythema Injection site haemorrhage Injection site hypersensitivity Injection site hypoaesthesia Injection site indentation Injection site inflammation Injection site irritation Injection site joint erythema Injection site mass Injection site oedema Injection site pain Injection site paraesthesia | | 1 | 0 |
| Injection site haemorrhage Injection site hypersensitivity Injection site hypoaesthesia Injection site indentation Injection site inflammation Injection site irritation Injection site joint erythema Injection site mass Injection site oedema Injection site pain Injection site paraesthesia | | 112 | 0 |
| Injection site hypersensitivity Injection site hypoaesthesia Injection site indentation Injection site inflammation Injection site irritation Injection site joint erythema Injection site mass Injection site oedema Injection site pain Injection site paraesthesia | | | 0 |
| Injection site hypoaesthesia Injection site indentation Injection site inflammation Injection site irritation Injection site joint erythema Injection site mass Injection site oedema Injection site pain Injection site paraesthesia | • | | |
| Injection site indentation2Injection site inflammation9Injection site irritation2Injection site joint erythema4Injection site mass117Injection site oedema2Injection site pain384Injection site paraesthesia1 | | _ | 0 |
| Injection site inflammation Injection site irritation Injection site joint erythema Injection site mass Injection site oedema Injection site pain Injection site paraesthesia | | 2 | 0 |
| Injection site irritation Injection site joint erythema Injection site mass Injection site oedema Injection site pain Injection site paraesthesia | • | 9 | 0 |
| Injection site joint erythema Injection site mass Injection site oedema Injection site pain Injection site paraesthesia 4 4 117 128 1384 1384 1384 | | | 0 |
| Injection site mass 117 Injection site oedema 2 Injection site pain 384 Injection site paraesthesia 1 | • | | 0 |
| Injection site oedema 2 Injection site pain 384 Injection site paraesthesia 1 | • | - | 0 |
| Injection site pain 384 Injection site paraesthesia 1 | | 2 | 0 |
| Injection site paraesthesia 1 | · | 384 | 0 |
| • | | 1 | 0 |
| | Injection site plaque | 1 | 0 |
| Injection site pruritus 85 | | 85 | 0 |
| Injection site rash 153 | • | | |
| Injection site reaction 14 | • | | 0 |
| Injection site swelling 56 | · | | |
| Injection site awaiing Injection site urticaria 43 | • | | 0 |
| Injection site vesicles | · | 1 | 0 |
| Injection site vesicles Injection site warmth 58 | • | 52 | |
| Interactions | · | 30 | U |

| Reaction Name | Total | Fatal |
|--|-------|-------|
| General disorders General disorders cont'd | | |
| Alcohol interaction | 1 | 0 |
| Drug interaction | 1 | 0 |
| Mass conditions NEC | | |
| Cyst | 4 | 0 |
| Mass | 18 | 0 |
| Nodule | 3 | 0 |
| Mucosal findings abnormal | | |
| Enanthema | 1 | 0 |
| Mucosal discolouration | 1 | 0 |
| Mucosal pain | 1 | 0 |
| Oedema NEC | i i | |
| Face oedema | 2 | 0 |
| Localised oedema | 1 | 0 |
| Oedema | 6 | 0 |
| Oedema peripheral | 6 | 0 |
| Pain and discomfort NEC | 1 0 | J |
| | 420 | 0 |
| Axillary pain Chest discomfort | 187 | 0 |
| | | |
| Chest pain | 534 | 0 |
| Discomfort | 75 | 0 |
| Facial pain | 15 | 0 |
| Inflammatory pain | 2 | 0 |
| Non-cardiac chest pain | 2 | 0 |
| Pain | 1296 | |
| Tenderness | 109 | 0 |
| Therapeutic and nontherapeutic responses | | |
| Adverse drug reaction | 11 | 0 |
| Adverse event | 1 | 0 |
| Drug ineffective | 11 | 0 |
| Drug intolerance | 1 | 0 |
| Immediate post-injection reaction | 1 | 0 |
| Inadequate analgesia | 3 | 0 |
| No reaction on previous exposure to drug | 2 | 0 |
| Therapeutic product effect decreased | 1 | 0 |
| Therapeutic response unexpected | 2 | 0 |
| Treatment failure | 1 | 0 |
| Vaccination failure | 1 | 0 |
| Ulcers NEC | | |
| Ulcer | 3 | 0 |
| Vaccination site reactions | | |
| Extensive swelling of vaccinated limb | 1 | 0 |
| Shoulder injury related to vaccine administration | 3 | 0 |
| Vaccination site bruising | 11 | 0 |
| Vaccination site discolouration | 1 | 0 |
| Vaccination site discomfort | 6 | 0 |
| Vaccination site eczema | 1 | 0 |
| Vaccination site erythema | 220 | 0 |
| Vaccination site haemorrhage | 2 | 0 |
| Vaccination site hypoaesthesia | 3 | 0 |
| Vaccination site induration | 15 | 0 |
| Vaccination site inflammation | 9 | 0 |
| Vaccination site irritation | 1 | 0 |
| Vaccination site initiation Vaccination site joint erythema | 3 | 0 |

| Reaction Name | Total | Fatal |
|--|-------|-------|
| General disorders General disorders cont'd | | |
| Vaccination site joint movement impairment | 2 | . 0 |
| Vaccination site joint pain | 2 | . 0 |
| Vaccination site mass | 51 | 0 |
| Vaccination site movement impairment | 7 | 0 |
| Vaccination site oedema | 1 | 0 |
| Vaccination site pain | 205 | 0 |
| Vaccination site papule | 2 | . 0 |
| Vaccination site paraesthesia | | 0 |
| Vaccination site pruritus | 57 | 0 |
| Vaccination site rash | 117 | 0 |
| Vaccination site reaction | 4 | . 0 |
| Vaccination site scar | | 0 |
| Vaccination site swelling | 138 | 0 |
| Vaccination site urticaria | 10 | 0 |
| Vaccination site vesicles | 1 | 0 |
| Vaccination site warmth | 99 | 0 |
| Withdrawal and rebound effects | | |
| Drug withdrawal syndrome | 1 | 0 |
| Withdrawal syndrome | 3 | 0 |
| General disorders SOC TOTAL | 16238 | 10 |

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Hepatic disorders | | |
| Bile duct infections and inflammations | | |
| Biliary colic | 4 | 1 0 |
| Cholestasis and jaundice | | |
| Jaundice | 1 | 0 |
| Jaundice cholestatic | 2 | 2 0 |
| Hepatic and hepatobiliary disorders NEC | | |
| Hepatic cyst | 1 | 0 |
| Hepatic enzymes and function abnormalities | | |
| Hepatic function abnormal | 1 | 0 |
| Hepatic vascular disorders | | |
| Portal vein thrombosis | 1 | 0 |
| Hepatobiliary signs and symptoms | | |
| Hepatic pain | 3 | 3 0 |
| Hepatocellular damage and hepatitis NEC | | |
| Autoimmune hepatitis | 1 | 0 |
| Hepatic steatosis | 1 | 0 |
| Hepatic disorders SOC TOTAL | 15 | sl o |

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Immune system disorders | | |
| Acute and chronic sarcoidosis | | |
| Sarcoidosis | 1 | 0 |
| Allergic conditions NEC | | |
| Allergic oedema | 4 | 0 |
| Allergy to animal | 1 | 0 |
| Allergy to metals | 1 | 0 |
| Hypersensitivity | 187 | 0 |
| Infusion related hypersensitivity reaction | 11 | 0 |
| Multiple allergies | 1 | 0 |
| Type IV hypersensitivity reaction | 13 | 0 |
| Allergies to foods, food additives, drugs and other chemicals | | |
| Allergy to chemicals | 1 | 0 |
| Allergy to vaccine | 9 | 0 |
| Drug hypersensitivity | 8 | 0 |
| Milk allergy | 1 | 0 |
| Reaction to excipient | 1 | 0 |
| Anaphylactic and anaphylactoid responses | | |
| Anaphylactic reaction | 35 | 0 |
| Anaphylactic shock | 4 | 0 |
| Anaphylactoid reaction | 2 | 0 |
| Atopic disorders | | |
| Seasonal allergy | 14 | 0 |
| Autoimmune disorders NEC | | |
| Autoimmune disorder | 2 | 0 |
| Immune and associated conditions NEC | | |
| Bacille Calmette-Guerin scar reactivation | 31 | 0 |
| Immune-mediated adverse reaction | 1 | 0 |
| Sensitisation | 3 | 0 |
| Systemic immune activation | 1 | 0 |
| Immunodeficiency disorders NEC | | |
| Hypogammaglobulinaemia | 1 | 0 |
| Immunodeficiency | 1 | 0 |
| Immune system disorders SOC TOTAL | 334 | |

| eaction Name | Total | Fata |
|--|-------|------|
| fections | | |
| Abdominal and gastrointestinal infections | | |
| Appendicitis | 4 | |
| Diverticulitis | 2 | 2 |
| Gastroenteritis | 2 | 2 |
| Bacterial infections NEC | | |
| Application site cellulitis | 1 | |
| Bacterial infection | 2 | 2 |
| Cellulitis | 48 | 3 |
| Folliculitis | 1 | |
| Injection site cellulitis | 2 | 2 |
| Skin bacterial infection | 1 | |
| Vaccination site cellulitis | 1 | |
| Breast infections | | |
| Breast abscess | 1 | |
| Mastitis | 3 | |
| Candida infections | | |
| Candida infection | 4 | ι |
| Oral candidiasis | 1 | |
| Vulvovaginal candidiasis | 7 | |
| Cardiac infections | , | |
| Endocarditis | 1 | |
| | | |
| Central nervous system and spinal infections | | |
| Central nervous system infection | 1 | |
| Meningitis | 2 | 4 |
| Coronavirus infections | | |
| COVID-19 | 71 | |
| COVID-19 pneumonia | 3 | |
| Suspected COVID-19 | 1 | |
| Coxiella infections | | |
| Q fever | 3 | 3 |
| Cytomegaloviral infections | | |
| Cytomegalovirus infection | 1 | |
| Cytomegalovirus infection reactivation | 1 | |
| Dental and oral soft tissue infections | | |
| Gingivitis | 1 | |
| Tooth abscess | 1 | |
| Tooth infection | 1 | |
| Ear infections | | |
| Ear infection | 3 | 3 |
| Labyrinthitis | 2 | |
| Otitis externa | 1 | |
| Ectoparasitic infestations | | |
| Acarodermatitis | 1 | |
| Enteroviral infections NEC | | |
| Hand-foot-and-mouth disease | 1 | |
| Epstein-Barr viral infections | | |
| Infectious mononucleosis | 2 | |
| | 4 | |
| Eye and eyelid infections | | |
| Conjunctivitis | 9 | |
| Eye infection | 2 | 1 |
| | | I |
| Eyelid boil Hordeolum | | |

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Infections Infections cont'd | | |
| Vaginal infection | 1 | 0 |
| Flaviviral infections | | |
| Dengue fever | 2 | 0 |
| Encephalitis Japanese B | 1 | 0 |
| Fungal infections NEC | | |
| Fungal infection | 2 2 | 0 |
| Fungal skin infection | | 0 |
| Overgrowth fungal | 1 | 1 |
| Pneumonia fungal | 1 | 0 |
| Fusobacterium infections | | |
| Necrotising ulcerative gingivostomatitis | 1 | 0 |
| Herpes viral infections | | |
| Eczema herpeticum | 1 | 0 |
| Genital herpes | 8 | 0 |
| Herpes ophthalmic | 1 | 0 |
| Herpes simplex | 1 | 0 |
| Herpes zoster | 44 | 0 |
| Herpes zoster oticus | 1 | 0 |
| Ophthalmic herpes simplex | 1 | 0 |
| Oral herpes | 38 | 0 |
| Varicella | 1 | 0 |
| Infections NEC | | |
| Abscess limb | 1 | 0 |
| Abscess rupture | 1 | 0 |
| Infection | 54 | 0 |
| Injection site infection | 1 | 0 |
| Localised infection | 13 | 0 |
| Respiratory tract infection | 1 | 0 |
| Vaccination site infection | 3 | |
| Vestibulitis | 1 | 0 |
| Infectious disorders carrier | | |
| SARS-CoV-2 carrier | 2 | 0 |
| Infectious transmissions | | |
| Secondary transmission | 2 | 0 |
| Influenza viral infections | | |
| Influenza | 231 | 0 |
| Lower respiratory tract and lung infections | | |
| Atypical pneumonia | 1 | 0 |
| Bronchitis | 3 | 0 |
| Lower respiratory tract infection | 21 | 1 |
| Pneumonia | 9 | 1 |
| Male reproductive tract infections | | |
| Epididymitis | 1 | 0 |
| Orchitis | 1 1 | ő |
| Mumps viral infections | · | Ĭ |
| Mumps | 1 | 0 |
| Nematode infections | · · | ľ |
| Enterobiasis | 1 | 0 |
| Rabies viral infections | | |
| Rabies | 1 | 1 |
| Rubella viral infections | | |
| Rubella Rubella | 2 | 0 |
| | - | |
| Sepsis, bacteraemia, viraemia and fungaemia NEC | | |

| Reaction Name Infections Infections cont'd | Total | <u>Fatal</u> |
|---|-------|--------------|
| modono | 1 | |
| Sepsis | | |
| Septic shock | | |
| Urosepsis | 1 | (|
| Skin structures and soft tissue infections | | |
| Eczema infected | 1 | (|
| Impetigo | 2 | |
| Pustule | 9 | |
| Pyoderma | 1 | (|
| Rash pustular | 2 | |
| Skin infection | 9 | (|
| Staphylococcal infections | | |
| Furuncle | 4 | (|
| Tinea infections | | |
| Body tinea | 3 | (|
| Tinea infection | 1 | (|
| Tuberculous infections | | |
| Disseminated Bacillus Calmette-Guerin infection | 1 | (|
| Lymph node tuberculosis | 1 | |
| Upper respiratory tract infections | | |
| Laryngitis | 1 | (|
| Nasopharyngitis | 151 | (|
| Peritonsillar abscess | 1 | ì |
| Pharyngitis | 2 | |
| Rhinitis | 3 | |
| Sinusitis | 8 | |
| Tonsillitis | 10 | |
| Upper respiratory tract infection | 10 | |
| | | |
| Urinary tract infections | _ | , |
| Cystitis | 5 2 | |
| Kidney infection | | |
| Urinary tract infection | 18 | (|
| Vascular infections | | l , |
| Lymphangitis | 2 | (|
| Viral infections NEC | | |
| Conjunctivitis viral | 1 | |
| Gastroenteritis viral | 1 | |
| Meningitis viral | 1 | (|
| Post viral fatigue syndrome | 4 | (|
| Sweating fever | 25 | |
| Viral infection | 2 | (|
| Viral labyrinthitis | 1 | (|
| Viral pharyngitis | 2 | (|
| Viral rash | 5 | (|
| Infections SOC TOTAL | 931 | 4 |

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Injuries | | |
| Abdominal and gastrointestinal injuries NEC | | |
| Oral contusion | 1 | 0 |
| Accidental exposures to product | | _ |
| Accidental exposure to product | 1 | 0 |
| Anaesthetic and allied procedural complications | | |
| Anaesthetic complication | 1 | 0 |
| Atmospheric pressure injuries | | |
| Barotrauma | 1 | 0 |
| Cardiovascular injuries | | |
| Vascular injury | 1 | 0 |
| Cerebral injuries NEC | | |
| Concussion | 6 | 0 |
| Chest and respiratory tract injuries NEC | | |
| Chest crushing | 1 | 0 |
| Conditions caused by cold | | |
| Chillblains | 8 | 0 |
| Cranial nerve injuries | | |
| Optic nerve injury | 1 | 0 |
| Exposures associated with pregnancy, delivery and lactation | | |
| Exposure via breast milk | 10 | 0 |
| Foetal exposure during pregnancy | 7 | 0 |
| Maternal exposure during breast feeding | 361 | 0 |
| Maternal exposure during pregnancy | 177 | 0 |
| Maternal exposure timing unspecified | 1 | 0 |
| Exposures to agents or circumstances NEC | | |
| Exposure to SARS-CoV-2 | 2 | 0 |
| Fractures and dislocations NEC | | |
| Joint dislocation | 1 | 0 |
| Heat injuries (excl thermal burns) | | |
| Heat oedema | 3 | 0 |
| Heat stroke | 6 | 0 |
| Limb fractures and dislocations | | |
| Clavicle fracture | 3 | 0 |
| Medication errors, product use errors and issues NEC | | |
| Medication error | 7 | 0 |
| Wrong schedule | 1 | 0 |
| Wrong technique in device usage process | 1 | 0 |
| Muscle, tendon and ligament injuries | | |
| Epicondylitis | 2 | 0 |
| Muscle injury | 1 | 0 |
| Muscle strain | 2 | 0 |
| Nerve injuries NEC | | |
| Nerve injury | 9 | 0 |
| Neurological and psychiatric procedural complications | | |
| Procedural dizziness | 3 | 0 |
| Non-occupational environmental exposures | | |
| Exposure to extreme temperature | 1 | 0 |
| Non-site specific injuries NEC | | |
| Arthropod bite | 3 | 0 |
| Bite | 1 | 0 |
| Electric shock | 4 | 0 |
| Fall | 17 | 0 |
| Injury | 3 | 0 |

| Reaction Name Injuries cont'd | Total | <u>Fatal</u> |
|---|-------|--------------|
| Nervous system injury | 1 | |
| Wound complication | 2 | |
| Wound haemorrhage | 1 | |
| Non-site specific procedural complications | | |
| Injection related reaction | 3 | |
| Procedural pain | 3 | |
| Occupational exposures | · · | |
| Occupational exposures Occupational exposure to toxic agent | 1 | |
| Occupational exposure to toxic agent Off label uses | | |
| Off label use | 1 | |
| Overdoses NEC | | |
| Overdose Overdose | G | |
| | 6 | |
| Peripheral nerve injuries | 4 | |
| Sciatic nerve injury | 1 | |
| Poisoning and toxicity | 4 | |
| Toxicity to various agents | 1 | |
| Product administration errors and issues | 00 | |
| Expired product administered | 20 | |
| Inappropriate schedule of product administration | 14 | |
| Incorrect dose administered | 1 | |
| Incorrect route of product administration | 1 | |
| Poor quality product administered | 1 | |
| Product administered at inappropriate site | 1 | |
| Product administration interrupted | 1 | |
| Product dose omission issue | 5 | |
| Wrong product administered | 1 | (|
| Product dispensing errors and issues | | |
| Product dispensing error | 1 | |
| Radiation injuries | | |
| Sunburn | 11 | |
| Site specific injuries NEC | | |
| Head injury | 5 | |
| Limb injury | 18 | |
| Skin injuries NEC | | |
| Contusion | 172 | |
| Scar | 8 | |
| Scratch | 1 | |
| Skin injury | 1 | |
| Skin wound | 1 | |
| Subcutaneous haematoma | 2 | |
| Spinal cord injuries NEC | | |
| Spinal cord injury cervical | 1 | |
| Stoma complications | | |
| Stoma site oedema | 1 | |
| Thermal burns | | |
| Burn oesophageal | 1 | |
| Burns third degree | 2 | |
| Cold burn | 1 | |
| Thermal burn | 6 | |
| Thermal burns of eye | 1 | |
| Vaccination related complications | | |
| Vaccination complication | 4 | |
| niuries SOC TOTAL | 947 | |

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Investigations | | |
| Adrenal medulla tests | | |
| Norepinephrine increased | 2 | 0 |
| Bacteria identification and serology (excl mycobacteria) | | |
| Campylobacter test positive | 1 | 0 |
| Blood counts NEC | | |
| Full blood count abnormal | 1 | 0 |
| Blood gas and acid base analyses | | |
| Oxygen consumption decreased | 1 | 0 |
| Oxygen saturation decreased | 6 | 0 |
| Carbohydrate tolerance analyses (incl diabetes) | | |
| Blood glucose | 1 | 0 |
| Blood glucose decreased | 1 | 0 |
| Blood glucose increased | 2 | 0 |
| Cardiac auscultatory investigations | | |
| Cardiac murmur | 1 | 0 |
| Heart sounds | 3 | 0 |
| Central nervous system imaging procedures | | |
| Computerised tomogram head | 1 | 0 |
| Cholesterol analyses | | |
| Low density lipoprotein increased | 1 | 0 |
| Coagulation and bleeding analyses | | |
| Fibrin D dimer increased | 1 | 0 |
| ECG investigations | | |
| Electrocardiogram P wave abnormal | 1 | 0 |
| Electrocardiogram QT prolonged | 1 | 0 |
| Electrocardiogram ST segment elevation | 1 | 0 |
| Electrocardiogram ST-T segment abnormal | 1 | 0 |
| Electrocardiogram T wave inversion | 2 | 0 |
| Electrocardiogram abnormal | 1 | 0 |
| Electrocardiogram change | 1 | 0 |
| Endocrine analyses and imaging NEC | | |
| Hormone level abnormal | 7 | 0 |
| Fertility analyses | | |
| Semen analysis abnormal | 1 | 0 |
| Foetal and neonatal diagnostic procedures | | |
| Foetal heart rate decreased | 1 | 0 |
| Foetal heart rate increased | 1 | 0 |
| Fungus identification and serology | | |
| Fungal test | 1 | 0 |
| Gastrointestinal and abdominal imaging procedures | | |
| X-ray with contrast upper gastrointestinal tract | 1 | 0 |
| Heart rate and pulse investigations | | |
| Heart rate | 86 | 0 |
| Heart rate abnormal | 8 | 0 |
| Heart rate decreased | 7 | 0 |
| Heart rate increased | 147 | 0 |
| Heart rate irregular | 24 | 0 |
| Heart rate variability decreased | 1 | O |
| Investigations NEC | | |
| Blood test abnormal | 3 | O |
| Liver function analyses | | |
| Alanine aminotransferase increased | 4 | C |
| Aspartate aminotransferase | 2 | O |

| Reaction Name | Total | <u>Fatal</u> |
|--|-------|--------------|
| nvestigations Investigations cont'd | | |
| Blood bilirubin increased | 1 | (|
| Liver function test abnormal | 6 | (|
| Liver function test increased | 1 | (|
| Mineral and electrolyte analyses | | |
| Blood iron decreased | 2 | ı |
| Blood magnesium decreased | 1 | |
| Blood potassium decreased | 2 | |
| Serum ferritin increased | 1 | (|
| Musculoskeletal and soft tissue imaging procedures | | |
| Bone scan | 1 | (|
| Neurologic diagnostic procedures | | |
| Coma scale abnormal | 1 | (|
| Sensory level | 1 | (|
| Ophthalmic function diagnostic procedures | | |
| Visual tracking test abnormal | 1 | (|
| Physical examination procedures and organ system status | | |
| Body temperature | 40 | (|
| Body temperature abnormal | 2 | (|
| Body temperature decreased | 3 | |
| Body temperature fluctuation | 12 | |
| Body temperature increased | 38 | |
| Grip strength | 1 | |
| Grip strength decreased | 1 | (|
| Lymph node palpable | 1 | |
| Palpatory finding abnormal | 1 | (|
| Product residue present | 1 | |
| Respiratory rate | 2 | |
| Respiratory rate decreased | 2 6 | |
| Respiratory rate increased | 6 | |
| Skin temperature | 8 | |
| Temperature difference of extremities | 1 | (|
| Weight decreased | 11 | (|
| Weight increased | 6 | (|
| Pituitary analyses anterior | | |
| Blood thyroid stimulating hormone increased | 1 | (|
| Platelet analyses | | |
| Platelet count decreased | 7 | (|
| Protein analyses NEC | | |
| C-reactive protein increased | 3 | (|
| Red blood cell analyses | | |
| Haemoglobin E | 1 | (|
| Haemoglobin decreased | 1 | |
| Renal function analyses | | |
| Blood creatinine increased | 1 | |
| Reproductive hormone analyses | | |
| Pregnancy test | 1 | (|
| Reproductive organ and breast histopathology procedures | · | |
| Smear cervix | 1 | (|
| Respiratory and pulmonary function diagnostic procedures | ' | l` |
| Forced expiratory volume increased | 1 | (|
| Skeletal and cardiac muscle analyses | | l ' |
| Blood creatine phosphokinase increased | 1 | |
| Troponin I increased | 1 | |

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Investigations Investigations cont'd | | |
| Troponin T increased | 1 | _ |
| Troponin increased | 2 | . 0 |
| Therapeutic drug monitoring analyses | | |
| Analgesic drug level | 3 | 0 |
| Tissue enzyme analyses NEC | | |
| Blood lactate dehydrogenase increased | 1 | 0 |
| Urinalysis NEC | | |
| Blood urine present | 7 |] 0 |
| Protein urine | 1 | 0 |
| Urinary tract function analyses NEC | | |
| Urine output | 3 | |
| Urine output decreased | 1 | 0 |
| Urinary tract imaging procedures | | |
| Bladder scan | 1 | 0 |
| Vascular tests NEC (incl blood pressure) | | |
| Blood pressure abnormal | 1 | _ |
| Blood pressure decreased | 6 | |
| Blood pressure diastolic increased | 1 | 0 |
| Blood pressure increased | 11 | 0 |
| Blood pressure measurement | 3 | 0 |
| Virus identification and serology | | |
| Coronavirus test | 4 | |
| SARS-CoV-2 antibody test | 2 2 | . 0 |
| SARS-CoV-2 antibody test negative | | |
| SARS-CoV-2 test | 4 | . 0 |
| SARS-CoV-2 test negative | 3 | |
| SARS-CoV-2 test positive | 2 | . 0 |
| Vitamin analyses | | |
| Blood folate decreased | 1 | 0 |
| White blood cell analyses | | |
| Neutrophil count | 1 | 0 |
| White blood cell count | 1 | 0 |
| White blood cell count decreased | 1 | 0 |
| White blood cell count increased | 1 | 0 |
| Investigations SOC TOTAL | 561 | l o |

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Metabolic disorders | | |
| Appetite disorders | | |
| Appetite disorder | 2 | (|
| Decreased appetite | 166 | (|
| Food craving | 1 | (|
| Food refusal | 1 | (|
| Hyperphagia | 5 | (|
| Hypophagia | 1 | (|
| Increased appetite | 6 | (|
| Salt craving | 1 | (|
| Diabetes mellitus (incl subtypes) | | |
| Diabetes mellitus | 3 | (|
| Diabetes mellitus inadequate control | 1 | (|
| Type 1 diabetes mellitus | 1 | (|
| Type 2 diabetes mellitus | 1 | (|
| Diabetic complications NEC | | |
| Diabetic ketoacidosis | 2 | (|
| Disorders of purine metabolism | | |
| Gout | 10 | C |
| Fluid intake decreased | | |
| Fluid intake reduced | 1 | C |
| Fluid intake increased | | |
| Polydipsia | 1 | C |
| Food malabsorption and intolerance syndromes (excl sugar intolerance) | | |
| Alcohol intolerance | 1 | (|
| Food intolerance | 2 | Č |
| General nutritional disorders NEC | | |
| Abnormal loss of weight | 1 | (|
| Abnormal weight gain | 5 | Ò |
| Feeding disorder | 20 | (|
| Food aversion | 3 | (|
| Neonatal insufficient breast milk syndrome | 4 | (|
| Hyperglycaemic conditions NEC | i i | |
| Hyperglycaemia | 1 | (|
| Hypoglycaemic conditions NEC | · · | |
| Hypoglycaemia | 5 | (|
| Potassium imbalance | Ŭ | • |
| Hypokalaemia | 1 | (|
| Total fluid volume decreased | ' | , |
| Dehydration | 45 | (|
| Total fluid volume increased | 45 | |
| Fluid retention | 8 | |
| | ° | (|
| Water soluble vitamin deficiencies | | |
| Folate deficiency Metabolic disorders SOC TOTAL | 300 | (|

| Reaction Name | Total | Fatal |
|---------------------------------------|-------|-------|
| Muscle & tissue disorders | | |
| Arthropathies NEC | | |
| Arthritis | 13 | 0 |
| Arthritis enteropathic | 1 | C |
| Arthropathy | 5 | C |
| Autoimmune arthritis | 1 | |
| Bone disorders NEC | | |
| Jaw cyst | 1 | |
| Jaw disorder | 1 | C |
| Osteitis | 1 | C |
| Bone related signs and symptoms | | |
| Bone pain | 33 | |
| Bone swelling | 1 | C |
| Pain in jaw | 39 | |
| Spinal pain | 8 | C |
| Bursal disorders | | |
| Bursitis | 7 | |
| Cartilage disorders | | |
| Costochondritis | 10 | C |
| Connective tissue disorders NEC | | |
| Polymyalgia rheumatica | 1 | |
| Reynold's syndrome | 1 | |
| Intervertebral disc disorders NEC | | |
| Intervertebral disc protrusion | 2 | C |
| Joint related disorders NEC | | |
| Joint lock | 3 | C |
| Periarthritis | 18 | |
| Rotator cuff syndrome | 3 | C |
| Temporomandibular joint syndrome | 1 | |
| Joint related signs and symptoms | | |
| Arthralgia | 922 | |
| Joint noise | 3 | |
| Joint stiffness | 32 | |
| Joint swelling | 30 | |
| Joint vibration | 1 | |
| Joint warmth | 2 | |
| Lupus erythematosus (incl subtypes) | _ | |
| Lupus-like syndrome | 1 | C |
| Muscle infections and inflammations | , | |
| Myositis | 5 | C |
| Muscle pains | J | |
| Fibromyalgia | 9 | C |
| Myalgia | 1433 | |
| Muscle related signs and symptoms NEC | 1400 | |
| Muscle atrophy | 2 | |
| Muscle discomfort | 1 | |
| Muscle fatigue | 45 | |
| Muscle hatigue Muscle haemorrhage | 43 | |
| | 250 | |
| Muscle spasms | 259 | |
| Muscle swelling | 9 | |
| Muscle tightness | | (|
| Muscle twitching | 48 | (|
| Myosclerosis | 1 | |
| Muscle tone abnormalities | | |

| Reaction Name | Muscle & tissue disorders cont'd | Total | <u>Fatal</u> |
|-----------------------------|--|-------|--------------|
| Muscle & tissue disorders | Muscle & lissue disorders cont d | 0 | |
| Muscle rigidity | | 2 | 0 |
| Nuchal rigidity | | 3 | 0 |
| Trismus | | 3 | 0 |
| Muscle weakness condition | ons | | |
| Muscular weakness | | 93 | 0 |
| | ective tissue conditions NEC | | _ |
| Growth retardation | | 1 | 0 |
| Mastication disorder | | 2 | 0 |
| Mobility decreased | | 6 | C |
| Muscle contracture | | 1 | C |
| Musculoskeletal disorde | | 1 | C |
| Musculoskeletal stiffnes | | 222 | C |
| buccal cavity | ective tissue deformities of skull, face and | | |
| Facial asymmetry | | 1 | C |
| Musculoskeletal and conn | ective tissue infections and inflammations NEC | | |
| Dupuytren's contracture | | 1 | 0 |
| Fasciitis | | 1 | 0 |
| Musculoskeletal and conn | ective tissue pain and discomfort | | |
| Back pain | | 343 | 0 |
| Flank pain | | 7 | 0 |
| Limb discomfort | | 203 | 0 |
| Musculoskeletal chest p | ain | 20 | O |
| Musculoskeletal discom | fort | 9 | O |
| Musculoskeletal pain | | 8 | C |
| Neck pain | | 179 | 0 |
| Pain in extremity | | 1959 | O |
| Sacral pain | | 1 | 0 |
| Myopathies | | | |
| Rhabdomyolysis | | 1 | O |
| Osteoarthropathies | | | |
| Osteoarthritis | | 2 | 0 |
| Psoriatic arthropathies | | | |
| Psoriatic arthropathy | | 1 | 0 |
| Rheumatoid arthropathies | • | | |
| Rheumatoid arthritis | | 4 | 0 |
| Soft tissue disorders NEC | | | |
| Axillary mass | | 23 | 0 |
| Groin pain | | 10 | 0 |
| Neck mass | | 5 | C |
| Soft tissue swelling | | 1 | C |
| Spondyloarthropathies | | | |
| Ankylosing spondylitis | | 2 | C |
| Arthritis reactive | | 4 | C |
| Axial spondyloarthritis | | 1 | C |
| Synovial disorders | | | |
| Synovial cyst | | 3 | C |
| Tendon disorders | | | |
| Tendon pain | | 1 | (|
| Trigger finger | | 2 | (|
| Trunk deformities | | | |
| Shoulder deformity | | 1 | (|
| Muscle & tissue disorders S | OC TOTAL | 6098 | Č |

| Reaction Name | <u>Total</u> | <u>Fatal</u> |
|---|--------------|--------------|
| Neoplasms | | |
| B-cell lymphomas NEC | | |
| B-cell lymphoma stage III | 1 | 0 |
| Breast and nipple neoplasms benign | | |
| Benign breast neoplasm | 1 | 0 |
| Breast and nipple neoplasms malignant | | |
| Breast cancer | 1 | 0 |
| Leukaemias NEC | | |
| Leukaemia | 1 | 0 |
| Lymphomas unspecified NEC | | |
| Lymphoma | 4 | 0 |
| Mediastinal neoplasms malignancy unspecified NEC | | |
| Good syndrome | 1 | 0 |
| Metastases to specified sites | | |
| Metastases to lymph nodes | 1 | C |
| Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and | | |
| unspecified | | |
| Tonsil cancer | 2 | C |
| Skin neoplasms benign | | |
| Anogenital warts | 1 | C |
| Haemangioma of skin | 3 | C |
| Skin papilloma | 3 | C |
| Small intestinal neoplasms malignant | | |
| Small intestine adenocarcinoma | 1 | C |
| Soft tissue neoplasms benign NEC | | |
| Lipoma | 1 | C |
| Uterine neoplasms benign | | |
| Uterine leiomyoma | 1 | C |
| Neoplasms SOC TOTAL | 22 | (|

| Reaction Name | Total | Fatal |
|---|-------|-------|
| ervous system disorders | | |
| Abnormal sleep-related events | | |
| Sleep paralysis | 2 | |
| Acute polyneuropathies | | |
| Guillain-Barre syndrome | 5 | |
| Autonomic nervous system disorders | | |
| Orthostatic intolerance | 1 | |
| Central nervous system haemorrhages and cerebrovascular accidents | | |
| Brain stem infarction | 1 | |
| Cerebral haemorrhage | 2 | |
| Cerebral infarction | 1 | |
| Cerebrovascular accident | 11 | |
| Haemorrhage intracranial | 1 | |
| Intracranial haematoma | 1 | |
| Ischaemic stroke | 1 | |
| Subarachnoid haemorrhage | 2 | |
| Central nervous system inflammatory disorders NEC | | |
| Central nervous system inflammation | 1 | |
| Central nervous system vascular disorders NEC | | |
| Cerebral congestion | 1 | |
| Cerebrovascular venous and sinus thrombosis | | |
| Cerebral venous sinus thrombosis | 1 | |
| Chronic polyneuropathies | | |
| Demyelinating polyneuropathy | 1 | |
| Coordination and balance disturbances | | |
| Balance disorder | 25 | |
| Coordination abnormal | 1 | |
| Dysstasia | 4 | |
| Nystagmus | 1 | |
| Cortical dysfunction NEC | · | |
| Aphasia | 1 | |
| Demyelinating disorders NEC | | |
| Demyelination | 1 | |
| Disturbances in consciousness NEC | · | |
| Depressed level of consciousness | 8 | |
| Lethargy | 215 | |
| Loss of consciousness | 124 | |
| Somnolence | 129 | |
| Stupor | 1 | |
| Syncope | 601 | |
| Dyskinesias and movement disorders NEC | | |
| Bradykinesia | 2 | |
| Clumsiness | 2 2 | |
| Dyskinesia | 5 | |
| Extrapyramidal disorder | 1 | |
| Fine motor delay | 1 | |
| Fine motor skill dysfunction | 3 | |
| Foetal movement disorder | 1 | |
| Hyperkinesia | 1 | |
| Hypokinesia | 6 | |
| Movement disorder | 5 | |
| Psychomotor hyperactivity | 1 | |
| Dystonias | | |
| Dystonia Dystonia | 1 | |

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Nervous system disorders Nervous system disorders cont'd | | |
| Eye movement disorders | | |
| IVth nerve paresis | 1 | 0 |
| Facial cranial nerve disorders | | |
| Bell's palsy | 38 | 0 |
| Facial paralysis | 25 | 0 |
| Facial paresis | 4 | 0 |
| Facial spasm | 4 | 0 |
| Generalised tonic-clonic seizures | | |
| Generalised tonic-clonic seizure | 2 | 0 |
| Glossopharyngeal nerve disorders | | |
| Glossopharyngeal neuralgia | 1 | 0 |
| Headaches NEC | | |
| Cluster headache | 27 | 0 |
| Cold-stimulus headache | 3 | 0 |
| Drug withdrawal headache | 2 | 0 |
| Headache | 3299 | 0 |
| New daily persistent headache | 1 | 0 |
| Occipital neuralgia | 1 | 0 |
| Sinus headache | 35 | 0 |
| Tension headache | 66 | 0 |
| Thunderclap headache | 1 | 0 |
| Vascular headache | 2 | 0 |
| Increased intracranial pressure disorders | | |
| Idiopathic intracranial hypertension | 1 | 0 |
| Intracranial pressure increased | 3 | 0 |
| Lumbar spinal cord and nerve root disorders | | |
| Sciatica | 3 | 0 |
| Memory loss (excl dementia) | | |
| Amnesia | 20 | 0 |
| Memory impairment | 17 | 0 |
| Transient global amnesia | 1 | 0 |
| Mental impairment (excl dementia and memory loss) | | |
| Cognitive disorder | 10 | 0 |
| Disturbance in attention | 46 | 0 |
| Mental impairment | 6 | 0 |
| Migraine headaches | | |
| Hemiplegic migraine | 3 | 0 |
| Migraine | 368 | 0 |
| Migraine with aura | 28 | 0 |
| Migraine without aura | 2 | 0 |
| Retinal migraine | 2 | 0 |
| Typical aura without headache | 1 | 0 |
| Vestibular migraine | 2 | 0 |
| Mononeuropathies | | |
| Carpal tunnel syndrome | 1 | 0 |
| Cubital tunnel syndrome | 1 | 0 |
| Mononeuritis | 2 | 0 |
| Multiple sclerosis acute and progressive | | |
| Band sensation | 1 | 0 |
| Multiple sclerosis | 1 | 0 |
| Muscle tone abnormal | | |
| Hypotonia | 3 | 0 |
| Stiff leg syndrome | 2 | 0 |

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Nervous system disorders Nervous system disorders cont'd | | |
| Myelitis (incl infective) | | |
| Myelitis transverse | 1 | 0 |
| Narcolepsy and hypersomnia | | |
| Hypersomnia | 10 | 0 |
| Narcolepsy | 1 | 0 |
| Nervous system disorders NEC | | |
| Nervous system disorder | 2 | 0 |
| Psychomotor skills impaired | 1 | 0 |
| Neurologic visual problems NEC | | |
| Tunnel vision | 6 | 0 |
| Neurological signs and symptoms NEC | | |
| Agitation neonatal | 1 | 0 |
| Clonus | 1 | 0 |
| Dizziness | 1670 | 0 |
| Dizziness exertional | 3 | 0 |
| Dizziness postural | 73 | 0 |
| Drooling | 2 | 0 |
| Exaggerated startle response | 1 | 0 |
| Head discomfort | 33 | 0 |
| Inability to crawl | 1 | 0 |
| Neurological symptom | 5 | 0 |
| Persistent postural-perceptual dizziness | 1 | 0 |
| Presyncope | 147 | 0 |
| Unresponsive to stimuli | 9 | 0 |
| Neuromuscular disorders NEC | | |
| Muscle contractions involuntary | 2 | 0 |
| Muscle spasticity | 3 | 0 |
| Olfactory nerve disorders | | |
| Anosmia | 16 | 0 |
| Parosmia | 15 | |
| Optic nerve disorders NEC | | |
| Optic neuritis | 2 | 0 |
| Paraesthesias and dysaesthesias | | |
| Burning feet syndrome | 1 | 0 |
| Burning sensation | 57 | 0 |
| Formication | 2 | 0 |
| Hemianaesthesia | 2 | 0 |
| Hyperaesthesia | 31 | 0 |
| Hypoaesthesia | 340 | |
| Paraesthesia | 480 | |
| Paralysis and paresis (excl cranial nerve) | | Ĭ |
| Hemiparesis | 4 | 0 |
| Hemiplegia | 5 | ő |
| Monoparesis | 9 | ٥ |
| Monoplegia | 13 | ő |
| Paralysis | 13 | |
| Paresis | 2 | 0 |
| | | · · |
| Parkinson's disease and parkinsonism | 1 | ^ |
| Freezing phenomenon | 1 1 | 0 |
| Reduced facial expression | 1 | 0 |
| Peripheral neuropathies NEC | 1 | _ |
| Autoimmune neuropathy | 1 1 | 0 |
| Neuralgic amyotrophy | 1 | C |

| Reaction Name | Name and a state of a surface a south | Total | Fatal |
|--------------------------|---|-------|-------|
| Nervous system disorders | Nervous system disorders cont'd | | |
| Neuritis | | 1 | 0 |
| Neuropathy peripheral | | 6 | 0 |
| Peripheral sensory neu | uropathy | 1 | 0 |
| Polyneuropathy | | 1 | 0 |
| Seizures and seizure dis | sorders NEC | | |
| Epilepsy | | 9 | 0 |
| Febrile convulsion | | 2 | 0 |
| Partial seizures | | 2 | 0 |
| Psychogenic seizure | | 1 | 0 |
| Seizure | | 102 | 0 |
| Seizure anoxic | | 1 | 0 |
| Status epilepticus | | 24 | 0 |
| Tonic clonic movemen | ts | 2 | 0 |
| Tonic convulsion | | 2 | 0 |
| Sensory abnormalities N | IEC | | |
| Ageusia | | 35 | 0 |
| Allodynia | | 1 | 0 |
| Complex regional pain | syndrome | 1 | 0 |
| Dysgeusia | | 107 | 0 |
| Electric shock sensation | on | 4 | 0 |
| Hypogeusia | | 1 | 0 |
| Neuralgia | | 46 | 0 |
| Post herpetic neuralgia | a e e e e e e e e e e e e e e e e e e e | 2 | 0 |
| Restless legs syndrom | e | 25 | 0 |
| Sensory disturbance | | 8 | 0 |
| Sensory loss | | 13 | 0 |
| Taste disorder | | 19 | 0 |
| Vibratory sense increa | sed | 1 | 0 |
| Sleep disturbances NEC | | | |
| Sleep deficit | | 2 | 0 |
| Speech and language al | bnormalities | | |
| Dysarthria | | 19 | 0 |
| Incoherent | | 5 | 0 |
| Slow speech | | 3 | 0 |
| Speech disorder | | 10 | 0 |
| Spinal cord and nerve ro | oot disorders NEC | | |
| Radiculopathy | | 1 | 0 |
| Transient cerebrovascul | ar events | | |
| Transient ischaemic at | tack | 6 | 0 |
| Tremor (excl congenital) | | | |
| Tremor | | 223 | 0 |
| Trigeminal disorders | | | |
| Trigeminal neuralgia | | 2 | 0 |
| Nervous system disorders | SOC TOTAL | 8865 | ر ا |

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Pregnancy conditions | | |
| Abortions spontaneous | | |
| Abortion spontaneous | 36 | |
| Foetal complications NEC | | |
| Foetal hypokinesia | 3 | |
| Hydrops foetalis | 1 | |
| Foetal growth complications | | |
| Foetal growth restriction | 1 | |
| Gestational age and weight conditions | | |
| Premature baby | 1 | |
| Labour onset and length abnormalities | | |
| Premature labour | 3 | |
| Maternal complications of labour NEC | | |
| Uterine atony | 1 | |
| Uterine hypertonus | 2 | |
| Maternal complications of pregnancy NEC | | |
| Decidual cast | 1 | |
| Ectopic pregnancy | 3 | |
| Somatic symptom disorder of pregnancy | 1 | |
| Normal pregnancy, labour and delivery | | |
| Live birth | 2 | . (|
| Pregnancy | 4 | |
| Postpartum complications NEC | | |
| Postpartum haemorrhage | 1 | |
| Pregnancy complicated by maternal disorders | | |
| Gestational diabetes | 1 | |
| Stillbirth and foetal death | | |
| Foetal death | 1 | |
| Unintended pregnancies | | |
| Unintended pregnancy | 1 | |
| Pregnancy conditions SOC TOTAL | 63 | 1 |

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Device issues NEC | | |
| Device expulsion | | 1 0 |
| Device leakage | | 1 0 |
| Device malfunction events NEC | | |
| Thrombosis in device | | 1 0 |
| Manufacturing materials issues | | |
| Manufacturing materials issue | | 1 0 |
| Product contamination and sterility issues | | |
| Product contamination physical | 3 | 3 0 |
| Product physical issues | | |
| Product after taste | | 1 0 |
| Product taste abnormal | | 1 0 |
| Product quality issues NEC | | |
| Product impurity | | ı o |
| Product quality issue | | 1 0 |
| Product supply and availability issues | | |
| Product availability issue | | 2 0 |
| null SOC TOTAL | 18 | 3 0 |

| Reaction Name | Total | <u> Fatal</u> |
|--|-------|---------------|
| sychiatric disorders | | |
| Abnormal behaviour NEC | | |
| Abnormal behaviour | 3 | 3 |
| Affect alterations NEC | | |
| Affect lability | 2 | |
| Flat affect | 3 | 3 |
| Inappropriate affect | 1 | |
| Anxiety symptoms | | |
| Agitation | 12 | 2 |
| Anxiety | 156 | 6 |
| Nervousness | 24 | L |
| Stress | 14 | Ļ |
| Tension | 6 | 5 |
| Attention deficit and disruptive behaviour disorders | | |
| Attention deficit hyperactivity disorder | 3 | 3 |
| Behaviour and socialisation disturbances | | |
| Disinhibition | 1 | |
| Paranoia | | L |
| Personality change | 1 | |
| Social avoidant behaviour | | |
| Cognitive and attention disorders and disturbances NEC | | |
| Distractibility | | |
| | 27 | , |
| Mental fatigue | 21 | |
| Confusion and disorientation | 0.0 | , |
| Confusional state | 82 | |
| Disorientation | 36 | |
| Deliria | | |
| Delirium | 15 | |
| Delusional disorders | | |
| Alice in wonderland syndrome | | |
| Delusional symptoms | | |
| Delusion | 1 | |
| Depressive disorders | | |
| Depression | 48 | 3 |
| Depression suicidal | 3 | 3 |
| Major depression | | |
| Mixed anxiety and depressive disorder | 1 | |
| Dissociative states | | |
| Depersonalisation/derealisation disorder | 1 | |
| Dissociation | 8 | 3 |
| Disturbances in initiating and maintaining sleep | | |
| Initial insomnia | 2 | 2 |
| Insomnia | 179 | |
| Middle insomnia | 9 | 1 |
| Terminal insomnia | | |
| Dyssomnias | | |
| Poor quality sleep | 39 | , |
| Eating disorders NEC | 33 | Ί |
| Binge eating | 1 | |
| Emotional and mood disturbances NEC | | |
| | _ | , |
| Anger | 7 | |
| Emotional disorder | 14 | |
| Emotional distress Euphoric mood | 7 | |

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Psychiatric disorders Psychiatric disorders cont'd | | |
| Irritability | 34 | 0 |
| Mood altered | 8 | 0 |
| Fear symptoms and phobic disorders (incl social phobia) | | |
| Fear | 2 | 0 |
| Fear of death | 1 | 0 |
| Fear of injection | 6 | 0 |
| Paruresis | 1 | 0 |
| Phobia | 1 | 0 |
| Fluctuating mood symptoms | | |
| Mood swings | 11 | 0 |
| Hallucinations (excl sleep-related) | | |
| Hallucination | 52 | 0 |
| Hallucination, auditory | 2 | 0 |
| Hallucination, visual | 1 | 0 |
| Somatic hallucination | 1 | 0 |
| Increased physical activity levels | | _ |
| Restlessness | 30 | 0 |
| Mental disorders NEC | | • |
| Mental disorder | 3 | 0 |
| Mood alterations with depressive symptoms |] | J |
| Depressed mood | 52 | 0 |
| Feeling of despair | 3 | 0 |
| Tearfulness | 2 | 0 |
| Mood alterations with manic symptoms | | J |
| Mania | 4 | 0 |
| Mood disorders NEC | | J |
| Apathy | 6 | 0 |
| Listless | 2 | 0 |
| Narcolepsy and associated conditions | | _ |
| Hypnagogic hallucination | 1 | 0 |
| Orgasmic disorders and disturbances | | |
| Orgasm abnormal | 1 | 0 |
| Orgasmic sensation decreased | 1 | 0 |
| Panic attacks and disorders | | |
| Limited symptom panic attack | 1 | 0 |
| Panic attack | 36 | 0 |
| Panic reaction | 7 | 0 |
| Parasomnias | | |
| Abnormal dreams | 20 | 0 |
| Nightmare | 24 | 0 |
| Sleep talking | 2 | 0 |
| Sleep terror | 3 | 0 |
| Somnambulism | 1 | 0 |
| Perception disturbances NEC | | |
| Autoscopy | 3 | 0 |
| Derealisation | 2 | 0 |
| Illusion | 1 | 0 |
| Psychiatric elimination disorders | | |
| Enuresis | 7 | 0 |
| Psychiatric symptoms NEC | | |
| Psychiatric symptom | 1 | 0 |
| Psychological trauma | 1 | 0 |
| Psychotic disorder NEC | | |

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Psychiatric disorders Psychiatric disorders cont'd | | |
| Acute psychosis | 1 | 0 |
| Psychotic disorder | 1 | 0 |
| Sexual desire disorders | | |
| Libido decreased | 3 | 0 |
| Libido increased | 1 | 0 |
| Loss of libido | 1 | 0 |
| Sleep disorders NEC | | |
| Sleep disorder | 24 | 0 |
| Somatic symptom disorders | | |
| Conversion disorder | 3 | 0 |
| Habit cough | 4 | 0 |
| Speech and language usage disturbances | | |
| Disorganised speech | 1 | 0 |
| Speech articulation and rhythm disturbances | | |
| Dysphemia | 3 | 0 |
| Lack of spontaneous speech | 1 | 0 |
| Stereotypies and automatisms | | |
| Bruxism | 2 | 0 |
| Head banging | 1 | 0 |
| Substance related and addictive disorders | | |
| Alcoholism | 1 | 0 |
| Suicidal and self-injurious behaviour | | |
| Intentional self-injury | 1 | 0 |
| Suicidal behaviour | 2 | 0 |
| Suicidal ideation | 8 | 0 |
| Suicide attempt | 1 | 0 |
| Thinking disturbances | | |
| Bradyphrenia | 3 | 0 |
| Intrusive thoughts | 1 | 0 |
| Tachyphrenia | 1 | 0 |
| Thinking abnormal | 3 | 0 |
| Psychiatric disorders SOC TOTAL | 1130 | 0 |

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Renal & urinary disorders | | |
| Bladder and urethral symptoms | | |
| Bladder pain | 4 | · 0 |
| Dysuria | 6 | 0 |
| Incontinence | 2 | 0 |
| Micturition urgency | 4 | . 0 |
| Pollakiuria | 17 | 0 |
| Urethral pain | 1 | 0 |
| Urinary incontinence | 7 | 0 |
| Urinary retention | 1 | 0 |
| Urinary straining | 1 | 0 |
| Urine flow decreased | 1 | 0 |
| Bladder disorders NEC | | |
| Bladder disorder | 1 | 0 |
| Urinary bladder haemorrhage | 2 | 0 |
| Glomerulonephritis and nephrotic syndrome | | |
| IgA nephropathy | 2 | 0 |
| Renal failure and impairment | | |
| Acute kidney injury | 4 | · 0 |
| Oliguria | 1 | 0 |
| Renal impairment | 1 | 0 |
| Urinary abnormalities | | |
| Chromaturia | 3 | 0 |
| Haematuria | 2 | 2 0 |
| Urine abnormality | 4 | . 0 |
| Urine odour abnormal | 2 | 2 0 |
| Urinary tract signs and symptoms NEC | | |
| Haemorrhage urinary tract | 5 | 0 |
| Renal pain | 44 | 0 |
| Renal & urinary disorders SOC TOTAL | 120 | o l |

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Reproductive & breast disorders | | |
| Benign and malignant breast neoplasms | | |
| Breast cyst | 3 | 0 |
| Breast disorders NEC | | |
| Breast enlargement | 3 | 0 |
| Breast mass | 10 | 0 |
| Fibrocystic breast disease | 1 | 0 |
| Retracted nipple | 1 | 0 |
| Breast infections and inflammations | | |
| Breast inflammation | 1 | 0 |
| Breast signs and symptoms | | |
| Breast discharge | 1 | 0 |
| Breast discomfort | 1 | 0 |
| Breast pain | 67 | 0 |
| Breast swelling | 8 | 0 |
| Breast tenderness | 9 | 0 |
| Nipple pain | 1 | 0 |
| Nipple swelling | 2 | 0 |
| Cervix disorders NEC | | |
| Ectropion of cervix | 1 | 0 |
| Erection and ejaculation conditions and disorders | | |
| Ejaculation delayed | 1 | 0 |
| Ejaculation failure | 2 | 0 |
| Erectile dysfunction | 9 | 0 |
| Nocturnal emission | 1 | 0 |
| Organic erectile dysfunction | 5 | 0 |
| Painful ejaculation | 1 | 0 |
| Gender disorders | | |
| Feminisation acquired | 1 | 0 |
| Lactation disorders | | |
| Galactorrhoea | 1 | 0 |
| Lactation puerperal increased | 2 | 0 |
| Suppressed lactation | 5 | 0 |
| Menopausal effects NEC | | |
| Menopausal symptoms | 6 | 0 |
| Premature menopause | 2 | 0 |
| Menopausal effects on the genitourinary tract | | |
| Postmenopausal haemorrhage | 7 | 0 |
| Menstruation and uterine bleeding NEC | | |
| Dysmenorrhoea | 292 | 0 |
| Intermenstrual bleeding | 143 | 0 |
| Menstrual discomfort | 2 | 0 |
| Menstrual disorder | 252 | 0 |
| Menstruation irregular | 410 | 0 |
| Premenstrual dysphoric disorder | 1 | 0 |
| Premenstrual headache | 2 | 0 |
| Premenstrual pain | 12 | 0 |
| Premenstrual syndrome | 12 | 0 |
| Withdrawal bleed | 2 | 0 |
| Menstruation with decreased bleeding | | |
| Amenorrhoea | 59 | 0 |
| Hypomenorrhoea | 83 | |
| Menstruation delayed | 538 | |
| Oligomenorrhoea | 20 | |

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Reproductive & breast disorders Reproductive & breast disorders cont'd | | |
| Menstruation with increased bleeding | | |
| Heavy menstrual bleeding | 689 | 0 |
| Menometrorrhagia | 5 | 0 |
| Polymenorrhoea | 99 | 0 |
| Ovarian and fallopian tube cysts and neoplasms | | |
| Ovarian cyst | 5 | 0 |
| Polycystic ovaries | 5 | |
| Ovarian and fallopian tube disorders NEC | | |
| Ovulation pain | 14 | 0 |
| Premature ovulation | 1 | 0 |
| Pelvis and broad ligament disorders NEC | | |
| Adnexa uteri pain | 10 | 0 |
| Pelvic haemorrhage | 2 | 0 |
| Penile disorders NEC (excl erection and ejaculation) | | |
| Penile pain | 1 | 0 |
| Penis disorder | 3 | 0 |
| Prostate and seminal vesicles infections and inflammations | | |
| Prostatitis | 2 | 0 |
| Prostatic signs, symptoms and disorders NEC | | |
| Prostatic pain | 1 | 0 |
| Reproductive tract disorders NEC (excl neoplasms) | | |
| Genital haemorrhage | 2 | 0 |
| Genital paraesthesia | 1 | 0 |
| Genital ulceration | 1 | 0 |
| Reproductive tract signs and symptoms NEC | | |
| Pelvic pain | 14 | 0 |
| Scrotal disorders NEC | | |
| Scrotal pain | 2 | 0 |
| Varicocele | 2 | 0 |
| Sexual function and fertility disorders NEC | | |
| Infertility | 3 | 0 |
| Sexual dysfunction | 1 | 0 |
| Spermatogenesis and semen disorders | | |
| Haematospermia | 1 | 0 |
| Testicular and epididymal disorders NEC | | |
| Testicular disorder | 1 | 0 |
| Testicular mass | 1 | 0 |
| Testicular pain | 9 | 0 |
| Testicular swelling | 4 | 0 |
| Uterine disorders NEC | | |
| Endometriosis | 10 | 0 |
| Uterine haemorrhage | 6 | 0 |
| Uterine pain | 3 | 0 |
| Uterine tone disorders | | |
| Uterine spasm | 11 | 0 |
| Vulvovaginal cysts and neoplasms | | |
| Vaginal cyst | 1 | 0 |
| Vulva cyst | 1 | 0 |
| Vulvovaginal disorders NEC | | |
| Vaginal haemorrhage | 196 | 0 |
| Vaginal riderinage Vaginal ulceration | 1 1 | 0 |
| Vulval haemorrhage | 6 | 0 |
| Vulvovaginal signs and symptoms | | |

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Reproductive & breast disorders Reproductive & breast disorders cont'd | | |
| Labia enlarged | 1 | 0 |
| Vaginal discharge | 11 | 0 |
| Vulvovaginal burning sensation | 2 | 0 |
| Vulvovaginal discomfort | 1 | 0 |
| Vulvovaginal dryness | 1 | 0 |
| Vulvovaginal pain | 5 | 0 |
| Reproductive & breast disorders SOC TOTAL | 3114 | l o |

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Respiratory disorders | | |
| Breathing abnormalities | | |
| Apnoea | 1 | 0 |
| Dyspnoea | 474 | 0 |
| Dyspnoea exertional | 4 | 0 |
| Hyperventilation | 4 | 0 |
| Hypopnoea | 11 | 0 |
| Hypoventilation | 1 | 0 |
| Irregular breathing | 1 | 0 |
| Respiration abnormal | 9 | 0 |
| Respiratory arrest | 1 | 1 |
| Respiratory distress | 1 | 0 |
| Sleep apnoea syndrome | 1 | 0 |
| Tachypnoea | 2 | 0 |
| Bronchospasm and obstruction | | _ |
| Asthma | 28 | 0 |
| Asthma late onset | 1 | Ö |
| Childhood asthma | 1 | 0 |
| Chronic obstructive pulmonary disease | 1 | Ö |
| Wheezing | 44 | Ö |
| Conditions associated with abnormal gas exchange | | Ĭ |
| Hypoxia | 1 | 0 |
| Coughing and associated symptoms | | |
| Allergic cough | 1 | 0 |
| Cough | 225 | |
| Productive cough | 16 | |
| Sputum discoloured | 2 | Ö |
| Laryngeal and adjacent sites disorders NEC (excl infections and | | |
| neoplasms) | | _ |
| Reflux laryngitis | 1 | 0 |
| Laryngeal spasm, oedema and obstruction Stridor | 1 | 0 |
| Lower respiratory tract inflammatory and immunologic conditions | | |
| Pneumonitis | 2 | 0 |
| Pulmonary sarcoidosis | 1 | 0 |
| Lower respiratory tract signs and symptoms | | |
| Hiccups | 14 | 0 |
| Pulmonary haemorrhage | 1 | 0 |
| Pulmonary pain | 9 | 0 |
| Nasal congestion and inflammations | | |
| Nasal congestion | 30 | 0 |
| Nasal disorders NEC | | |
| Epistaxis | 82 | 0 |
| Nasal oedema | 1 | 0 |
| Nasal pruritus | 3 | |
| Paranasal sinus disorders (excl infections and neoplasms) | | |
| Sinonasal obstruction | 1 | 0 |
| Sinus congestion | 5 | |
| Sinus disorder | 1 | 0 |
| Parenchymal lung disorders NEC | | |
| Interstitial lung disease | 2 | O |
| Pharyngeal disorders (excl infections and neoplasms) | | |
| Pharyngeal erythema | 1 | O |
| Pharyngeal hypoaesthesia | 2 | Ö |

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Respiratory disorders Respiratory disorders cont'd | | |
| Pharyngeal oedema | 2 | 0 |
| Pharyngeal paraesthesia | 3 | 0 |
| Pharyngeal swelling | 38 | 0 |
| Tonsillar erythema | 1 | 0 |
| Tonsillar hypertrophy | 8 | 0 |
| Pleural infections and inflammations | | |
| Pleurisy | 4 | 0 |
| Pneumothorax and pleural effusions NEC | | |
| Pleural effusion | 2 | 0 |
| Pulmonary hypertensions | | |
| Pulmonary hypertension | 1 | 0 |
| Pulmonary oedemas | | |
| Pulmonary congestion | 1 | 0 |
| Pulmonary oedema | 2 | 0 |
| Pulmonary thrombotic and embolic conditions | | |
| Pulmonary embolism | 16 | 0 |
| Respiratory failures (excl neonatal) | | |
| Respiratory failure | 1 1 | 0 |
| Respiratory signs and symptoms NEC | | |
| Diaphragmalgia | 1 1 | 0 |
| Respiratory symptom | 1 | 0 |
| Respiratory tract disorders NEC | | |
| Respiratory disorder | 1 | 0 |
| Respiratory tract irritation | 1 | 0 |
| Upper respiratory tract signs and symptoms | | |
| Aphonia | 6 | 0 |
| Catarrh | 1 | 0 |
| Choking | 3 | 0 |
| Dry throat | 15 | 0 |
| Dysphonia | 6 | 0 |
| Increased viscosity of upper respiratory secretion | | 0 |
| Nasal discomfort | 2 3 | 0 |
| Oropharyngeal blistering | 1 1 | 0 |
| Oropharyngeal discomfort | 3 | 0 |
| Oropharyngeal pain | 263 | |
| Paranasal sinus discomfort | 5 | 0 |
| Rhinalgia | 2 | |
| Rhinorrhoea | 69 | 0 |
| | 29 | |
| Sinus pain | 19 | |
| Sneezing | | |
| Throat tightness | 20 | |
| Throat tightness | 33 | |
| Upper-airway cough syndrome | 1 | 0 |
| Yawning | 4 | 0 |
| Respiratory disorders SOC TOTAL | 1555 | 1 |

| Reaction Name | Total | Fatal |
|--------------------------------------|-------|-------|
| Skin disorders | | |
| Acnes | | |
| Acne | 25 | 0 |
| Alopecias | | |
| Alopecia | 32 | 0 |
| Alopecia areata | 5 | 0 |
| Alopecia totalis | 1 | 0 |
| Angioedemas | | |
| Angioedema | 22 | 0 |
| Apocrine and eccrine gland disorders | | |
| Cold sweat | 157 | 0 |
| Hidradenitis | 1 | 0 |
| Hyperhidrosis | 483 | 0 |
| Miliaria | 46 | 0 |
| Night sweats | 102 | 0 |
| Bullous conditions | | |
| Blister | 39 | 0 |
| Blister rupture | 1 | 0 |
| Blood blister | 1 | 0 |
| Dermatitis bullous | 1 | 0 |
| Erythema multiforme | 11 | 0 |
| Pemphigoid | 1 | 0 |
| Pemphigus | 1 | 0 |
| Stevens-Johnson syndrome | 1 | 0 |
| Connective tissue disorders | | |
| Cutaneous lupus erythematosus | 1 | 0 |
| Dermal and epidermal conditions NEC | | |
| Dry skin | 57 | 0 |
| Pain of skin | 53 | 0 |
| Papule | 20 | 0 |
| Scab | 4 | 0 |
| Scar pain | 2 | 0 |
| Sensitive skin | 77 | 0 |
| Skin burning sensation | 34 | 0 |
| Skin discolouration | 19 | 0 |
| Skin induration | 6 | 0 |
| Skin lesion | 21 | 0 |
| Skin reaction | 79 | 0 |
| Skin sensitisation | 9 | 0 |
| Skin swelling | 13 | 0 |
| Skin tightness | 4 | 0 |
| Skin warm | 155 | 0 |
| Yellow skin | 2 | 0 |
| Dermatitis and eczema | | |
| Autoimmune dermatitis | 1 | 0 |
| Dermatitis | 19 | 0 |
| Dermatitis allergic | 74 | 0 |
| Dermatitis atopic | 11 | 0 |
| Dermatitis contact | 5 | 0 |
| Dyshidrotic eczema | 9 | 0 |
| Eczema | 43 | 0 |
| Eczema nummular | 2 | 0 |
| Neurodermatitis | 1 | 0 |
| Skin irritation | 17 | 0 |

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Skin disorders Skin disorders cont'd | | |
| Dermatitis ascribed to specific agent | | |
| Drug eruption | 1 | 0 |
| Palmar-plantar erythrodysaesthesia syndrome | 1 | 0 |
| Erythemas | | |
| Erythema | 748 | 0 |
| Exfoliative conditions | | |
| Dermatitis exfoliative generalised | 1 | 1 |
| Exfoliative rash | 9 | 0 |
| Skin exfoliation | 9 | 0 |
| Hyperpigmentation disorders | | |
| Ephelides | 1 | 0 |
| Skin hyperpigmentation | 1 | 0 |
| Solar lentigo | 1 | 0 |
| Hypopigmentation disorders | | |
| Vitiligo | 1 | 0 |
| Nail and nail bed conditions (excl infections and infestations) | | |
| Onychoclasis | 1 | 0 |
| Panniculitides | | |
| Erythema nodosum | 3 | 0 |
| Papulosquamous conditions | | |
| Lichen planus | 2 | 0 |
| Pityriasis rosea | 8 | 0 |
| Photosensitivity and photodermatosis conditions | | |
| Photosensitivity reaction | 13 | 0 |
| Pilar disorders NEC | | |
| Piloerection | 8 | 0 |
| Pruritus NEC | | |
| Itching scar | 3 | 0 |
| Pruritus | 1594 | |
| Psoriatic conditions | | |
| Guttate psoriasis | 1 | 0 |
| Psoriasis | 16 | 0 |
| Purpura and related conditions | | _ |
| Petechiae | 14 | 0 |
| Purpura | 8 | |
| Rashes, eruptions and exanthems NEC | | |
| Butterfly rash | 1 | 0 |
| Rash | 1857 | Ö |
| Rash erythematous | 724 | I |
| Rash macular | 122 | |
| Rash maculo-papular | 2 | Ö |
| Rash morbilliform | 4 | 0 |
| Rash papular | 130 | |
| Rash pruritic | 418 | |
| Rash vesicular | 5 | l |
| Rosaceas | | |
| Rosacea | 2 | 0 |
| Scaly conditions | | |
| Pityriasis | 1 | C |
| | | |
| Sebaceous gland disorders Seborrhoea | 4 | |
| | 1 | 0 |
| Skin and subcutaneous conditions NEC | | |
| Cutaneous symptom | 3 | |

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Skin disorders Skin disorders cont'd | | |
| Skin mass | 4 | 0 |
| Skin and subcutaneous tissue ulcerations | | |
| Skin erosion | 1 | 0 |
| Skin ulcer | 2 | 0 |
| Skin cysts and polyps | | |
| Dermal cyst | 6 | 0 |
| Skin dystrophies | | |
| Keloid scar | 1 | 0 |
| Skin haemorrhages | | |
| Haemorrhage subcutaneous | 1 | 0 |
| Skin haemorrhage | 1 | 0 |
| Skin hypoplasias and atrophies | | |
| Skin atrophy | 2 | 0 |
| Skin injuries and mechanical dermatoses | | |
| Needle track marks | 1 | 0 |
| Skin vasculitides | | |
| Cutaneous vasculitis | 2 | 0 |
| Skin vasomotor conditions | | |
| Livedo reticularis | 3 | 0 |
| Telangiectasia and related conditions | | |
| Spider naevus | 1 | 0 |
| Urticarias | | |
| Chronic spontaneous urticaria | 1 | 0 |
| Mechanical urticaria | 1 | 0 |
| Urticaria | 277 | 0 |
| Urticaria cholinergic | 1 | 0 |
| Urticaria chronic | 2 | 0 |
| Skin disorders SOC TOTAL | 7682 | 1 |

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Social circumstances | | |
| Age related issues | | |
| Menarche | 1 | 0 |
| Menopause | 5 | 0 |
| Disability issues | | |
| Bedridden | 3 | 0 |
| Immobile | 2 | 0 |
| Impaired driving ability | 1 | 0 |
| Sight disability | 1 | 0 |
| Employment issues | | |
| Retirement | 1 | 0 |
| Non-occupational and unspecified environmental problems | | |
| Water pollution | 2 | 0 |
| Pregnancy related circumstances | | |
| Breast feeding | 5 | 0 |
| Social issues NEC | | |
| Social problem | 1 | 0 |
| Social circumstances SOC TOTAL | 22 | 0 |

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Surgical & medical procedures | | |
| Analgesia supportive care | | |
| Analgesic therapy | 1 | 0 |
| Breast therapeutic procedures NEC | | |
| Axillary lymphadenectomy | 1 | 0 |
| Dietary and nutritional therapies | | |
| Medical diet | 1 | 0 |
| Gastrointestinal therapeutic procedures NEC | | |
| Prophylaxis of nausea and vomiting | 1 | 0 |
| Gynaecological therapeutic procedures NEC | | |
| Menstrual cycle management | 2 | 0 |
| Immunisations | | |
| COVID-19 immunisation | 13 | 0 |
| Immunisation | 16 | 0 |
| Joint therapeutic procedures | | |
| Joint injection | 1 | 0 |
| Joint stabilisation | 1 | 0 |
| Skin and subcutaneous tissue therapeutic procedures NEC | | |
| Dermal filler injection | 4 | 0 |
| Therapeutic procedures NEC | | |
| Bed rest | 2 | 0 |
| Botulinum toxin injection | 1 | 0 |
| Hospitalisation | 2 | 0 |
| Injection | 16 | 0 |
| Interchange of vaccine products | 1 | 0 |
| Polypectomy | 1 | 0 |
| Surgical & medical procedures SOC TOTAL | 64 | 0 |

| leaction Name | Total | Fatal |
|--|-------|-------|
| ascular disorders | | |
| Accelerated and malignant hypertension | | |
| Hypertensive urgency | 1 | (|
| Arterial infections and inflammations | | |
| Giant cell arteritis | 1 | (|
| Blood pressure disorders NEC | | |
| Blood pressure fluctuation | 1 | (|
| Circulatory collapse and shock | | |
| Neurogenic shock | 1 | (|
| Shock | 2 | (|
| Haemorrhages NEC | | |
| Bloody discharge | 1 | (|
| Haematoma | 4 | (|
| Haemorrhage | 150 | (|
| Lymphangiopathies | | |
| Lymphocele | 1 | (|
| Lymphoedemas | | |
| Lymphoedema | 9 | (|
| Non-site specific embolism and thrombosis | | |
| Embolism | 1 | (|
| Embolism venous | 1 | (|
| Thrombosis | 29 | |
| Non-site specific necrosis and vascular insufficiency NEC | | |
| Arteriosclerosis | 1 | |
| Infarction | 1 | |
| Peripheral venous disease | 1 | |
| Vasospasm | 1 | |
| Non-site specific vascular disorders NEC | | |
| Vascular pain | 5 | |
| Vasodilatation | 2 | |
| Peripheral embolism and thrombosis | | |
| Axillary vein thrombosis | 1 | |
| Blue toe syndrome | 2 | |
| Deep vein thrombosis | 10 | |
| Superficial vein thrombosis | 1 | |
| Thrombophlebitis | 1 | |
| Peripheral vascular disorders NEC | | |
| Cyanosis | 6 | |
| Flushing | 29 | |
| Hot flush | 172 | |
| Peripheral vasoconstriction, necrosis and vascular insufficiency | .,_ | |
| Peripheral coldness | 38 | |
| Poor peripheral circulation | 2 | |
| Raynaud's phenomenon | 2 | |
| Site specific vascular disorders NEC | _ | |
| Pallor | 60 | |
| Varicose veins NEC | | |
| Spider vein | 1 | |
| Varicose vein | 3 | |
| | 3 | |
| Vascular hypertensive disorders NEC | 17 | |
| Hypertension | 47 | |
| Prehypertension White coat hypertension | 1 1 | |
| WITH A COST TWO DELICION | 1 1 | |

| Reaction Name | _ | Total | Fatal |
|--|---|-------|-------|
| Vascular disorders Vascular disorders cont'd | | | |
| Hypotension | | 57 | 0 |
| Orthostatic hypotension | | 5 | 0 |
| Vasculitides NEC | | | |
| Vasculitis | | 1 | 0 |
| Vascular disorders SOC TOTAL | | 653 | 0 |
| TOTAL REACTIONS FOR DRUG | | 56310 | 19 |
| | | | |
| TOTAL REPORTS | | 17546 | |
| TOTAL FATAL OUTCOME REPORTS | | | 19 |