

COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 25-Aug-2022
Data Lock Date: 24-Aug-2022 18:30:05

All UK spontaneous reports received up to and including 24/08/22 for the 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		
<i>Anaemia deficiencies</i>		
Iron deficiency anaemia	3	0
<i>Anaemias NEC</i>		
Anaemia	20	0
Autoimmune anaemia	1	0
Microcytic anaemia	1	0
Normocytic anaemia	1	0
<i>Anaemias haemolytic NEC</i>		
Haemolytic anaemia	3	0
<i>Anaemias haemolytic immune</i>		
Autoimmune haemolytic anaemia	1	0
<i>Bleeding tendencies</i>		
Increased tendency to bruise	7	0
Spontaneous haematoma	1	0
<i>Coagulopathies</i>		
Abnormal clotting factor	2	0
Antiphospholipid syndrome	3	0
Coagulopathy	3	0
Hypercoagulation	2	0
<i>Eosinophilic disorders</i>		
Eosinophilia	2	0
<i>Haematological disorders</i>		
Blood disorder	1	0
Mast cell activation syndrome	3	0
Mastocytosis	1	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	354	0
Lymph node ulcer	1	0
Lymphadenitis	27	0
Lymphadenopathy	2107	0
Lymphatic disorder	1	0
<i>Marrow depression and hypoplastic anaemias</i>		
Aplastic anaemia	1	0
<i>Neutropenias</i>		
Autoimmune neutropenia	1	0
Neutropenia	3	0
<i>Platelet disorders NEC</i>		
Platelet disorder	1	0
<i>Polycythaemia (excl rubra vera)</i>		
Stress polycythaemia	1	0
<i>Sickle cell trait and disorders</i>		
Sickle cell anaemia with crisis	1	0
<i>Spleen disorders</i>		
Splenic infarction	1	0
Splenic vein thrombosis	1	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	11	0
Thrombocytopenia	34	0
Thrombocytopenic purpura	2	0
Blood disorders SOC TOTAL	2602	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac conduction disorders</i>		
Atrioventricular block	4	0
Atrioventricular block complete	1	0
Bundle branch block left	1	0
Bundle branch block right	2	0
Sinoatrial block	1	0
<i>Cardiac disorders NEC</i>		
Cardiac disorder	20	0
Cardiac dysfunction	3	0
Cardiac ventricular thrombosis	1	0
<i>Cardiac infections and inflammations NEC</i>		
Carditis	3	0
<i>Cardiac signs and symptoms NEC</i>		
Cardiac discomfort	6	0
Palpitations	1808	0
<i>Cardiomyopathies</i>		
Cardiomyopathy	2	0
Congestive cardiomyopathy	1	0
Restrictive cardiomyopathy	1	0
Stress cardiomyopathy	1	0
Toxic cardiomyopathy	1	0
<i>Coronary artery disorders NEC</i>		
Arteriosclerosis coronary artery	1	1
Coronary artery disease	1	0
Coronary artery occlusion	1	0
Coronary artery stenosis	1	0
Coronary artery thrombosis	1	0
<i>Heart failures NEC</i>		
Cardiac failure	8	0
Cardiac failure acute	1	0
Cardiac failure congestive	1	0
Cardiogenic shock	1	0
Cardiopulmonary failure	1	1
<i>Ischaemic coronary artery disorders</i>		
Acute coronary syndrome	2	0
Acute myocardial infarction	4	1
Angina pectoris	70	0
Angina unstable	3	0
Myocardial infarction	42	2
Myocardial ischaemia	1	0
<i>Left ventricular failures</i>		
Left ventricular failure	1	0
<i>Mitral valvular disorders</i>		
Mitral valve incompetence	1	0
Mitral valve prolapse	1	0
<i>Myocardial disorders NEC</i>		
Cardiomegaly	9	0
Left ventricular dilatation	1	0
Left ventricular dysfunction	5	0
Left ventricular enlargement	1	0
Left ventricular hypertrophy	2	0
Myocardial fibrosis	2	0
Myocardial injury	1	0

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Reaction Name	Total	Fatal
Cardiac disorders Cardiac disorders cont'd		
Myocardial oedema	2	0
Noninfectious myocarditis		
Hypersensitivity myocarditis	1	0
Myocarditis	200	0
Myopericarditis	28	0
Noninfectious pericarditis		
Pericarditis	136	0
Pleuropericarditis	1	0
Pericardial disorders NEC		
Pericardial effusion	4	0
Pericardial haemorrhage	1	1
Pericardial rub	1	0
Rate and rhythm disorders NEC		
Arrhythmia	32	0
Bradycardia	18	0
Cardiac fibrillation	1	0
Cardiac flutter	144	0
Extrasystoles	59	0
Heart alternation	1	0
Paroxysmal arrhythmia	1	0
Postural orthostatic tachycardia syndrome	3	0
Tachyarrhythmia	3	0
Tachycardia	791	1
Tachycardia foetal	1	0
Supraventricular arrhythmias		
Atrial fibrillation	51	0
Atrial flutter	13	0
Atrial tachycardia	3	0
Sinus arrhythmia	3	0
Sinus tachycardia	11	0
Supraventricular extrasystoles	2	0
Supraventricular tachycardia	9	0
Ventricular arrhythmias and cardiac arrest		
Cardiac arrest	20	7
Ventricular arrhythmia	1	0
Ventricular extrasystoles	5	0
Ventricular fibrillation	2	0
Ventricular tachycardia	6	0
Cardiac disorders SOC TOTAL	3573	14

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Cardiac disorders congenital NEC</i>		
Heart disease congenital	3	0
<i>Cerebellar disorders congenital</i>		
Arnold-Chiari malformation	1	0
Hereditary ataxia	1	0
<i>Connective tissue disorders congenital</i>		
Ehlers-Danlos syndrome	2	0
<i>Gene mutations and other alterations NEC</i>		
Hereditary angioedema	1	0
<i>Haematological disorders congenital NEC</i>		
Neonatal alloimmune thrombocytopenia	1	0
<i>Male reproductive tract disorders congenital</i>		
Micropenis	1	0
<i>Musculoskeletal disorders congenital NEC</i>		
Dysmorphism	1	0
<i>Neurological disorders congenital NEC</i>		
Familial hemiplegic migraine	1	0
<i>Ocular disorders congenital NEC</i>		
Colour blindness	1	0
<i>Peripheral nervous system disorders congenital NEC</i>		
Paroxysmal extreme pain disorder	1	0
Congenital disorders SOC TOTAL	14	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear canal erythema	1	0
Ear congestion	8	0
Ear discomfort	10	0
Ear disorder	6	0
Ear inflammation	1	0
Ear pain	310	0
Ear swelling	6	0
<i>Eustachian tube disorders</i>		
Eustachian tube obstruction	2	0
<i>External ear disorders NEC</i>		
Excessive cerumen production	3	0
Red ear syndrome	1	0
<i>External ear infections and inflammations</i>		
External ear inflammation	1	0
<i>Hearing losses</i>		
Deafness	54	0
Deafness neurosensory	2	0
Deafness transitory	1	0
Deafness unilateral	10	0
Hypoacusis	43	0
Sudden hearing loss	13	0
<i>Hyperacusia</i>		
Hyperacusis	10	0
<i>Inner ear disorders NEC</i>		
Meniere's disease	2	0
Vestibular disorder	1	0
<i>Inner ear infections and inflammations</i>		
Inner ear inflammation	4	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	20	0
Tinnitus	470	0
Vertigo	325	0
Vertigo labyrinthine	2	0
Vertigo positional	17	0
<i>Middle ear infections and inflammations</i>		
Middle ear inflammation	1	0
Ear disorders SOC TOTAL	1324	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Autoimmune thyroiditis	1	0
Thyroiditis	2	0
Thyroiditis subacute	2	0
<i>Adrenal cortical hypofunctions</i>		
Adrenal insufficiency	2	0
Adrenocortical insufficiency acute	6	0
<i>Anterior pituitary hypofunction</i>		
Hypopituitarism	1	0
<i>Endocrine abnormalities of puberty</i>		
Delayed menarche	2	0
Premature menarche	3	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	7	0
Ovulation delayed	11	0
<i>Hyperparathyroid disorders</i>		
Hyperparathyroidism	1	0
<i>Hypoparathyroid disorders</i>		
Hypoparathyroidism	1	0
<i>Hypothalamic and pituitary disorders NEC</i>		
Pituitary haemorrhage	1	0
<i>Polyglandular endocrine disorders</i>		
Polyglandular disorder	1	0
<i>Thyroid disorders NEC</i>		
Goitre	6	0
Thyroid disorder	2	0
Thyroid pain	2	0
<i>Thyroid hyperfunction disorders</i>		
Basedow's disease	2	0
Hyperthyroidism	6	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	5	0
Endocrine disorders SOC TOTAL	64	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Amblyopic vision impairment</i>		
Amblyopia	5	0
<i>Cataract conditions</i>		
Cataract	1	0
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Vitreous detachment	2	0
Vitreous floaters	20	0
<i>Colour blindness (incl acquired)</i>		
Dyschromatopsia	2	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	9	0
<i>Corneal infections, oedemas and inflammations</i>		
Ulcerative keratitis	1	0
<i>Eyelid movement disorders</i>		
Blepharospasm	35	0
Eyelid ptosis	5	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Iridocyclitis	2	0
Iritis	2	0
Uveitis	11	0
<i>Lacrimation disorders</i>		
Dry eye	38	0
Lacrimation increased	18	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Blepharitis	2	0
Erythema of eyelid	2	0
Eyelid cyst	1	0
Eyelid irritation	2	0
Eyelid oedema	2	0
Eyelid rash	2	0
Swelling of eyelid	33	0
<i>Lid, lash and lacrimal structural disorders</i>		
Lagophthalmos	1	0
<i>Ocular bleeding and vascular disorders NEC</i>		
Eye haematoma	1	0
Eye haemorrhage	4	0
<i>Ocular disorders NEC</i>		
Eye disorder	4	0
Eye oedema	1	0
Eye pain	369	0
Eye swelling	136	0
Eyelid disorder	4	0
Eyelids pruritus	3	0
Ocular discomfort	17	0
Periorbital oedema	3	0
Periorbital swelling	22	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye allergy	5	0
Eye discharge	3	0
Eye inflammation	8	0
Eye irritation	21	0
Eye pruritus	41	0
Limbal swelling	1	0

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Ocular hyperaemia	50	0
Ocular nerve and muscle disorders		
Eye movement disorder	9	0
Gaze palsy	1	0
Ophthalmoplegia	1	0
Ocular sensation disorders		
Abnormal sensation in eye	2	0
Asthenopia	30	0
Foreign body sensation in eyes	8	0
Hypoaesthesia eye	6	0
Photophobia	137	0
Optic disc abnormalities NEC		
Optic discs blurred	1	0
Papilloedema	1	0
Optic nerve bleeding and vascular disorders		
Optic ischaemic neuropathy	1	0
Orbital infections, inflammations and irritations		
Orbital myositis	2	0
Orbital structural change, deposit and degeneration		
Lid sulcus deepened	2	0
Pupil disorders		
Mydriasis	5	0
Refractive and accommodative disorders		
Accommodation disorder	1	0
Astigmatism	3	0
Retinal bleeding and vascular disorders (excl retinopathy)		
Papillophlebitis	1	0
Retinal haemorrhage	1	0
Retinal ischaemia	1	0
Retinal vein occlusion	11	0
Retinal structural change, deposit and degeneration		
Macular degeneration	1	0
Macular hole	1	0
Retinal detachment	1	0
Retinal, choroid and vitreous infections and inflammations		
Retinal oedema	1	0
Retinopathies NEC		
Acute macular neuroretinopathy	1	0
Central serous chorioretinopathy	4	0
Serous retinopathy	1	0
Scleral infections, irritations and inflammations		
Episcleritis	5	0
Scleritis	1	0
Scleral structural change, deposit and degeneration		
Scleral disorder	1	0
Structural change, deposit and degeneration of eye NEC		
Exophthalmos	2	0
Visual colour distortions		
Cyanopsia	1	0
Xanthopsia	2	0
Visual disorders NEC		
Diplopia	40	0
Halo vision	4	0

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Metamorphopsia	5	0
Photopsia	33	0
Scintillating scotoma	1	0
Vision blurred	330	0
Visual brightness	1	0
Visual field disorders		
Visual field defect	5	0
Visual impairment and blindness (excl colour blindness)		
Amaurosis fugax	2	0
Blindness	44	0
Blindness transient	8	0
Blindness unilateral	2	0
Night blindness	1	0
Visual acuity reduced	3	0
Visual impairment	70	0
Eye disorders SOC TOTAL	1684	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Abdominal findings abnormal</i>		
Gastrointestinal sounds abnormal	1	0
<i>Acute and chronic pancreatitis</i>		
Pancreatitis	4	0
Pancreatitis acute	1	0
<i>Anal and rectal disorders NEC</i>		
Anal sphincter atony	1	0
<i>Anal and rectal pains</i>		
Proctalgia	9	0
<i>Anal and rectal signs and symptoms</i>		
Anal pruritus	1	0
Anal rash	1	0
Anorectal discomfort	1	0
<i>Colitis (excl infective)</i>		
Colitis	6	0
Colitis ischaemic	1	0
Colitis ulcerative	10	0
Crohn's disease	8	0
Inflammatory bowel disease	8	0
<i>Dental and periodontal infections and inflammations</i>		
Dental caries	1	0
<i>Dental disorders NEC</i>		
Loose tooth	1	0
Teething	2	0
Tooth disorder	1	0
<i>Dental pain and sensation disorders</i>		
Dental discomfort	1	0
Dental paraesthesia	5	0
Hyperaesthesia teeth	7	0
Toothache	39	0
<i>Dental pulp disorders</i>		
Dental pulp disorder	1	0
<i>Diaphragmatic hernias</i>		
Hiatus hernia	2	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	1304	0
Diarrhoea haemorrhagic	7	0
<i>Diverticula</i>		
Diverticulum	1	0
<i>Duodenal ulcers and perforation</i>		
Duodenal ulcer	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	162	0
Epigastric discomfort	4	0
Eructation	20	0
<i>Faecal abnormalities NEC</i>		
Faeces discoloured	10	0
Faeces hard	1	0
Faeces soft	1	0
Mucous stools	2	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	86	0
Flatulence	42	0

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Gastric ulcers and perforation</i>		
Gastric ulcer	2	0
Gastritis erosive	1	0
<i>Gastritis (excl infective)</i>		
Gastritis	12	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	370	0
Abdominal pain lower	27	0
Abdominal pain upper	953	0
Abdominal rigidity	3	0
Abdominal tenderness	5	0
Gastrointestinal pain	45	0
Oesophageal pain	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	46	0
Gastric dilatation	3	0
Gastrooesophageal reflux disease	40	0
<i>Gastrointestinal disorders NEC</i>		
Food poisoning	3	0
Functional gastrointestinal disorder	3	0
Gastric disorder	2	0
Gastrointestinal disorder	4	0
Lymphoid hyperplasia of intestine	1	0
Stomach mass	1	0
<i>Gastrointestinal dyskinetic disorders</i>		
Bowel movement irregularity	1	0
Change of bowel habit	4	0
Gastrointestinal motility disorder	2	0
Oesophageal achalasia	1	0
<i>Gastrointestinal inflammatory disorders NEC</i>		
Gastrointestinal inflammation	2	0
<i>Gastrointestinal mucosal dystrophies and secretion disorders</i>		
Hyperchlorhydria	2	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	186	0
Acute abdomen	1	0
Anal incontinence	4	0
Breath odour	8	0
Dysphagia	41	0
Odynophagia	9	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Defaecation urgency	1	0
Frequent bowel movements	10	0
Irritable bowel syndrome	21	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Intestinal obstruction	1	0
<i>Gastrointestinal vascular malformations</i>		
Gastric antral vascular ectasia	2	0
<i>Gastrointestinal vascular occlusion and infarction</i>		
Intestinal ischaemia	2	0
Mesenteric vein thrombosis	1	0
Visceral venous thrombosis	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		

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Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Gingival discomfort	2	0
Gingival disorder	3	0
Gingival pain	25	0
Gingival swelling	9	0
Noninfective gingivitis	2	0
Gingival haemorrhages		
Gingival bleeding	14	0
Haemorrhoids and gastrointestinal varices (excl oesophageal)		
Haemorrhoids	7	0
Intestinal haemorrhages		
Anal haemorrhage	1	0
Rectal haemorrhage	20	0
Intestinal ulcers and perforation NEC		
Intestinal perforation	1	0
Malabsorption syndromes		
Coeliac disease	2	0
Nausea and vomiting symptoms		
Discoloured vomit	1	0
Nausea	5050	0
Regurgitation	2	0
Retching	36	0
Vomiting	1987	0
Vomiting projectile	28	0
Non-site specific gastrointestinal haemorrhages		
Gastrointestinal haemorrhage	3	0
Haematemesis	8	0
Haematochezia	17	0
Melaena	1	0
Upper gastrointestinal haemorrhage	4	0
Oesophageal disorders NEC		
Oesophageal disorder	1	0
Oesophagitis (excl infective)		
Oesophagitis	1	0
Oral dryness and saliva altered		
Aptyalism	2	0
Dry mouth	115	0
Lip dry	11	0
Saliva altered	2	0
Salivary hypersecretion	13	0
Oral soft tissue disorders NEC		
Chapped lips	3	0
Cheilitis	5	0
Enlarged uvula	1	0
Lip blister	4	0
Lip disorder	1	0
Oral disorder	1	0
Uvulitis	1	0
Oral soft tissue haemorrhages		
Mouth haemorrhage	5	0
Oral blood blister	4	0
Oral soft tissue signs and symptoms		
Coating in mouth	2	0
Hypoaesthesia oral	94	0

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Gastrointestinal disorders		
Lip discolouration	1	0
Lip exfoliation	1	0
Lip pain	12	0
Lip pruritus	3	0
Oral discomfort	13	0
Oral mucosal blistering	2	0
Oral mucosal eruption	3	0
Oral mucosal erythema	1	0
Oral mucosal exfoliation	2	0
Oral mucosal roughening	1	0
Oral pain	38	0
Oral pruritus	2	0
Paraesthesia oral	135	0
Oral soft tissue swelling and oedema		
Lip oedema	1	0
Lip swelling	232	0
Mouth swelling	24	0
Peptic ulcers and perforation		
Peptic ulcer	1	0
Peptic ulcer haemorrhage	3	0
Peritoneal and retroperitoneal disorders		
Ascites	1	0
Peritoneal and retroperitoneal fibrosis and adhesions		
Retroperitoneal fibrosis	1	0
Rectal inflammations NEC		
Proctitis	1	0
Salivary gland disorders NEC		
Salivary gland mass	1	0
Salivary gland pain	3	0
Salivary gland enlargements		
Parotid gland enlargement	3	0
Submaxillary gland enlargement	3	0
Stomatitis and ulceration		
Aphthous ulcer	7	0
Lip ulceration	5	0
Mouth ulceration	106	0
Oral mucosa erosion	1	0
Stomatitis	6	0
Tongue disorders		
Glossitis	8	0
Tongue disorder	11	0
Tongue haemorrhage	1	0
Tongue ulceration	5	0
Tongue signs and symptoms		
Glossodynia	34	0
Stiff tongue	1	0
Swollen tongue	96	0
Tongue blistering	3	0
Tongue coated	5	0
Tongue discolouration	3	0
Tongue discomfort	7	0
Tongue dry	3	0
Tongue eruption	1	0

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Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Tongue exfoliation	1	0
Tongue movement disturbance	1	0
Tongue oedema	3	0
Tongue pruritus	1	0
Tongue rough	1	0
Tongue spasm	1	0
<i>Tooth missing</i>		
Tooth loss	2	0
Gastrointestinal disorders SOC TOTAL	11865	0

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site bruise	3	0
Administration site erythema	1	0
Administration site extravasation	1	0
Administration site lymphadenopathy	1	0
Administration site pain	2	0
Administration site reaction	2	0
Administration site warmth	1	0
Puncture site bruise	6	0
Puncture site pain	4	0
Vessel puncture site bruise	2	0
<i>Adverse effect absent</i>		
No adverse event	2	0
<i>Application and instillation site reactions</i>		
Application site bruise	1	0
Application site burn	1	0
Application site erythema	11	0
Application site inflammation	1	0
Application site joint erythema	1	0
Application site pain	5	0
Application site pruritus	10	0
Application site rash	1	0
Application site reaction	1	0
Application site swelling	3	0
Application site vesicles	5	0
Application site warmth	2	0
Instillation site erythema	1	0
Instillation site warmth	5	0
<i>Asthenic conditions</i>		
Asthenia	696	0
Chronic fatigue syndrome	9	0
Decreased activity	1	0
Fatigue	7088	0
Malaise	1269	0
Sluggishness	2	0
<i>Body temperature altered</i>		
Hyperthermia	2	0
Hypothermia	5	0
Temperature regulation disorder	3	0
<i>Complications associated with device NEC</i>		
Complication associated with device	1	0
Injury associated with device	1	0
<i>Death and sudden death</i>		
Cardiac death	2	2
Death	26	26
Sudden cardiac death	1	1
Sudden death	1	1
<i>Febrile disorders</i>		
Pyrexia	7222	1
<i>Feelings and sensations NEC</i>		
Chills	4424	0
Feeling abnormal	499	0
Feeling cold	472	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Feeling drunk	17	0
Feeling hot	396	0
Feeling jittery	13	0
Feeling of body temperature change	137	0
Hangover	22	0
Hunger	18	0
Sensation of blood flow	1	0
Sensation of foreign body	9	0
Temperature intolerance	22	0
Thirst	131	0
Thirst decreased	1	0
Fibrosis NEC		
Fibrosis	1	0
Gait disturbances		
Gait disturbance	49	0
Gait inability	29	0
Loss of control of legs	4	0
General signs and symptoms NEC		
Condition aggravated	48	0
Crepitations	1	0
Crying	38	0
Discharge	4	0
Effusion	1	0
Energy increased	1	0
Exercise tolerance decreased	20	0
Fat tissue increased	1	0
Foaming at mouth	2	0
General physical health deterioration	4	0
Glassy eyes	1	0
High-pitched crying	1	0
Illness	772	0
Induration	11	0
Influenza like illness	863	0
Irritability postvaccinal	1	0
Local reaction	30	0
Moaning	1	0
Multiple organ dysfunction syndrome	1	1
Perforation	1	0
Peripheral swelling	2300	0
Pre-existing disease	1	0
Screaming	8	0
Secretion discharge	2	0
Swelling	1293	0
Swelling face	223	0
Healing abnormal NEC		
Impaired healing	1	0
Implant and catheter site reactions		
Catheter site related reaction	1	0
Implant site warmth	3	0
Inflammations		
Granuloma	1	0
Inflammation	216	0
Scar inflammation	1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Soft tissue inflammation	1	0
Systemic inflammatory response syndrome	2	0
Infusion site reactions		
Infusion site erythema	2	0
Infusion site mass	1	0
Infusion site pain	5	0
Infusion site pruritus	2	0
Infusion site urticaria	5	0
Infusion site warmth	1	0
Injection site reactions		
Injected limb mobility decreased	10	0
Injection site bruising	15	0
Injection site cyst	1	0
Injection site dermatitis	1	0
Injection site discolouration	1	0
Injection site erythema	229	0
Injection site haemorrhage	4	0
Injection site hypersensitivity	6	0
Injection site hypoaesthesia	6	0
Injection site indentation	2	0
Injection site inflammation	20	0
Injection site irritation	3	0
Injection site joint erythema	5	0
Injection site joint pain	2	0
Injection site mass	222	0
Injection site movement impairment	1	0
Injection site nodule	1	0
Injection site oedema	6	0
Injection site pain	938	0
Injection site paraesthesia	2	0
Injection site plaque	1	0
Injection site pruritus	144	0
Injection site rash	213	0
Injection site reaction	25	0
Injection site swelling	124	0
Injection site urticaria	58	0
Injection site vesicles	3	0
Injection site warmth	105	0
Interactions		
Alcohol interaction	2	0
Drug interaction	4	0
Drug-device interaction	2	0
Mass conditions NEC		
Cyst	10	0
Mass	32	0
Nodule	6	0
Mucosal findings abnormal		
Enanthema	1	0
Mucosal discolouration	2	0
Mucosal inflammation	2	0
Mucosal pain	1	0
Oedema mucosal	1	0
Polyp	2	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
<i>Necrosis NEC</i>		
Necrosis	1	0
<i>Oedema NEC</i>		
Face oedema	11	0
Localised oedema	7	0
Oedema	21	0
Oedema peripheral	17	0
<i>Pain and discomfort NEC</i>		
Axillary pain	930	0
Chest discomfort	495	0
Chest pain	1900	0
Discomfort	148	0
Facial discomfort	1	0
Facial pain	48	0
Hernia pain	1	0
Inflammatory pain	6	0
Non-cardiac chest pain	3	0
Pain	2901	0
Tenderness	213	0
Visceral pain	1	0
<i>Therapeutic and nontherapeutic responses</i>		
Adverse drug reaction	181	0
Adverse reaction	5	0
Drug ineffective	32	0
Drug intolerance	1	0
Immediate post-injection reaction	1	0
Inadequate analgesia	3	0
No reaction on previous exposure to drug	1	0
Therapeutic product effect decreased	1	0
Therapeutic response changed	1	0
Therapeutic response unexpected	3	0
Treatment failure	1	0
Vaccination failure	17	0
<i>Ulcers NEC</i>		
Ulcer	6	0
<i>Vaccination site reactions</i>		
Extensive swelling of vaccinated limb	1	0
Shoulder injury related to vaccine administration	20	0
Vaccination site bruising	28	0
Vaccination site discolouration	2	0
Vaccination site discomfort	9	0
Vaccination site eczema	1	0
Vaccination site erythema	314	0
Vaccination site haemorrhage	6	0
Vaccination site hypoaesthesia	5	0
Vaccination site induration	23	0
Vaccination site inflammation	23	0
Vaccination site irritation	3	0
Vaccination site joint erythema	3	0
Vaccination site joint movement impairment	2	0
Vaccination site joint pain	4	0
Vaccination site joint warmth	1	0
Vaccination site lymphadenopathy	3	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site macule	1	0
Vaccination site mass	86	0
Vaccination site movement impairment	25	0
Vaccination site oedema	1	0
Vaccination site pain	436	0
Vaccination site papule	2	0
Vaccination site paraesthesia	2	0
Vaccination site pruritus	75	0
Vaccination site rash	153	0
Vaccination site reaction	9	0
Vaccination site scar	1	0
Vaccination site swelling	216	0
Vaccination site urticaria	14	0
Vaccination site vesicles	3	0
Vaccination site warmth	147	0
<i>Withdrawal and rebound effects</i>		
Drug withdrawal syndrome	1	0
Rebound effect	1	0
Withdrawal syndrome	8	0
General disorders SOC TOTAL	39317	32

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	6	0
<i>Cholecystitis and cholelithiasis</i>		
Cholelithiasis	2	0
<i>Cholestasis and jaundice</i>		
Cholestasis	1	0
Jaundice	6	0
Jaundice cholestatic	2	0
<i>Hepatic and hepatobiliary disorders NEC</i>		
Hepatic cyst	1	0
<i>Hepatic enzymes and function abnormalities</i>		
Hepatic function abnormal	2	0
Hypertransaminasaemia	1	0
<i>Hepatic failure and associated disorders</i>		
Acute hepatic failure	1	0
Acute on chronic liver failure	1	0
<i>Hepatic vascular disorders</i>		
Portal vein thrombosis	2	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	13	0
Liver tenderness	2	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Autoimmune hepatitis	3	0
Drug-induced liver injury	1	0
Hepatic steatosis	1	0
Hepatitis	3	0
Immune-mediated hepatitis	1	0
Liver injury	5	0
Hepatic disorders SOC TOTAL	54	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	2	0
<i>Allergic conditions NEC</i>		
Allergic oedema	4	0
Allergy to animal	1	0
Allergy to metals	1	0
Hypersensitivity	377	0
Infusion related hypersensitivity reaction	15	0
Multiple allergies	4	0
Serum sickness	3	0
Serum sickness-like reaction	1	0
Type I hypersensitivity	2	0
Type III immune complex mediated reaction	1	0
Type IV hypersensitivity reaction	13	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to chemicals	2	0
Allergy to vaccine	15	0
Drug hypersensitivity	16	0
Food allergy	4	0
Milk allergy	1	0
Perfume sensitivity	1	0
Reaction to excipient	2	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	76	0
Anaphylactic shock	8	0
Anaphylactoid reaction	11	0
<i>Atopic disorders</i>		
Seasonal allergy	17	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	4	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	53	0
Immune system disorder	5	0
Immune-mediated adverse reaction	1	0
Immunisation reaction	27	0
Sensitisation	4	0
Systemic immune activation	1	0
<i>Immunodeficiency disorders NEC</i>		
Hypogammaglobulinaemia	1	0
Immunodeficiency	1	0
Immunosuppression	1	0
Immune system disorders SOC TOTAL	675	0

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Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Appendicitis	10	0
Appendicitis perforated	1	0
Diverticulitis	6	0
Dysentery	1	0
Gastroenteritis	7	0
Peritonitis	1	0
<i>Bacterial infections NEC</i>		
Administration site cellulitis	1	0
Application site cellulitis	1	0
Arthritis bacterial	1	0
Bacterial infection	3	0
Bacterial vaginosis	1	0
Cellulitis	84	0
Folliculitis	1	0
Injection site cellulitis	2	0
Meningitis bacterial	1	0
Paronychia	1	0
Skin bacterial infection	1	0
Vaccination site cellulitis	4	0
<i>Bone and joint infections</i>		
Arthritis infective	1	0
Osteomyelitis	1	0
<i>Borrelial infections</i>		
Lyme disease	1	0
Relapsing fever	1	0
<i>Breast infections</i>		
Breast abscess	2	0
Mastitis	11	0
<i>Candida infections</i>		
Anal candidiasis	1	0
Candida infection	11	0
Oral candidiasis	7	0
Vulvovaginal candidiasis	12	0
<i>Cardiac infections</i>		
Endocarditis	1	0
<i>Central nervous system and spinal infections</i>		
Central nervous system infection	1	0
Encephalitis	4	0
Meningitis	6	0
Meningitis aseptic	1	0
Myelitis	1	0
<i>Chlamydial infections</i>		
Eye infection chlamydial	1	0
<i>Coronavirus infections</i>		
Asymptomatic COVID-19	1	0
COVID-19	468	0
COVID-19 pneumonia	6	0
Coronavirus infection	1	0
Post-acute COVID-19 syndrome	6	0
Suspected COVID-19	5	0
<i>Coxiella infections</i>		
Q fever	9	0

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Reaction Name	Total	Fatal
Infections Infections cont'd		
<i>Cytomegaloviral infections</i>		
Cytomegalovirus infection	2	0
Cytomegalovirus infection reactivation	2	0
Pneumonia cytomegaloviral	1	0
<i>Dental and oral soft tissue infections</i>		
Abscess oral	1	0
Gingivitis	2	0
Oral infection	1	0
Sialoadenitis	2	0
Tooth abscess	2	0
Tooth infection	2	0
<i>Ear infections</i>		
Ear infection	11	0
Labyrinthitis	17	0
Otitis externa	1	0
<i>Ectoparasitic infestations</i>		
Acarodermatitis	1	0
Lice infestation	1	0
<i>Enteroviral infections NEC</i>		
Hand-foot-and-mouth disease	1	0
<i>Epstein-Barr viral infections</i>		
Epstein-Barr virus infection	1	0
Infectious mononucleosis	2	0
<i>Eye and eyelid infections</i>		
Chorioretinitis	1	0
Conjunctivitis	13	0
Eye infection	5	0
Eyelid boil	1	0
Eyelid infection	1	0
Hordeolum	5	0
<i>Female reproductive tract infections</i>		
Vaginal infection	1	0
<i>Flaviviral infections</i>		
Dengue fever	2	0
Encephalitis Japanese B	1	0
<i>Fungal infections NEC</i>		
Fungal infection	4	0
Fungal skin infection	3	0
Overgrowth fungal	1	0
Pneumonia fungal	1	0
<i>Fusobacterium infections</i>		
Necrotising ulcerative gingivostomatitis	1	0
<i>Helicobacter infections</i>		
Helicobacter infection	1	0
<i>Hepatitis virus infections</i>		
Hepatitis A	1	0
<i>Herpes viral infections</i>		
Eczema herpeticum	1	0
Genital herpes	15	0
Herpes ophthalmic	2	0
Herpes simplex	8	0
Herpes simplex reactivation	1	0
Herpes virus infection	1	0

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Herpes zoster	142	0
Herpes zoster oticus	3	0
Nasal herpes	1	0
Ophthalmic herpes simplex	1	0
Ophthalmic herpes zoster	1	0
Oral herpes	100	0
Varicella	3	0
Varicella zoster virus infection	1	0
<i>Infections NEC</i>		
Abscess	2	0
Abscess limb	2	0
Abscess rupture	1	0
Empyema	1	1
Groin infection	1	0
Infection	96	0
Injection site infection	1	0
Localised infection	19	0
Lymph gland infection	2	0
Lymph node abscess	3	0
Respiratory tract infection	2	0
Vaccination site abscess	2	0
Vaccination site infection	5	0
Vaccine breakthrough infection	1	0
Vestibulitis	1	0
Wound infection	1	0
<i>Infectious disorders carrier</i>		
SARS-CoV-2 carrier	2	0
<i>Infectious transmissions</i>		
Secondary transmission	2	0
<i>Influenza viral infections</i>		
Influenza	639	0
<i>Lower respiratory tract and lung infections</i>		
Atypical pneumonia	1	0
Bronchitis	7	0
Lower respiratory tract infection	88	1
Pleural infection	1	0
Pneumonia	24	5
Pneumonia aspiration	3	1
<i>Male reproductive tract infections</i>		
Epididymitis	1	0
Orchitis	4	0
<i>Mumps viral infections</i>		
Mumps	1	0
<i>Nematode infections</i>		
Enterobiasis	1	0
<i>Orthopox viral infections</i>		
Vaccinia virus infection	1	0
<i>Parvoviral infections</i>		
Erythema infectiosum	1	0
<i>Rabies viral infections</i>		
Rabies	1	1
<i>Rotaviral infections</i>		
Gastroenteritis rotavirus	1	0

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Reaction Name	Total	Fatal
Infections Infections cont'd		
<i>Rubella viral infections</i>		
Rubella	2	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Intestinal sepsis	1	0
Sepsis	9	0
Septic shock	1	0
Urosepsis	1	0
<i>Skin structures and soft tissue infections</i>		
Acne pustular	1	0
Blister infected	1	0
Dermatitis infected	1	0
Eczema infected	1	0
Impetigo	6	0
Infected skin ulcer	1	0
Nail infection	1	0
Pustule	11	0
Pyoderma	1	0
Rash pustular	3	0
Skin infection	15	0
Vaccination site pustule	1	0
<i>Staphylococcal infections</i>		
Furuncle	12	0
<i>Streptococcal infections</i>		
Meningitis pneumococcal	1	0
Pharyngitis streptococcal	1	0
<i>Tinea infections</i>		
Body tinea	3	0
Tinea capitis	1	0
Tinea infection	1	0
<i>Tuberculous infections</i>		
Lymph node tuberculosis	1	0
<i>Upper respiratory tract infections</i>		
Acute sinusitis	2	0
Chronic sinusitis	1	0
Laryngitis	7	0
Nasopharyngitis	332	0
Peritonsillar abscess	1	0
Pharyngitis	6	0
Rhinitis	8	0
Sinusitis	39	0
Tonsillitis	15	0
Upper respiratory tract infection	3	0
<i>Urinary tract infections</i>		
Cystitis	12	0
Kidney infection	6	0
Urinary tract infection	44	0
<i>Vascular infections</i>		
Lymphangitis	3	0
<i>Viral infections NEC</i>		
Arthritis viral	1	0
Conjunctivitis viral	2	0
Gastroenteritis viral	4	0
Meningitis viral	2	0

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Pneumonia viral	2	0
Post viral fatigue syndrome	10	0
Sweating fever	65	0
Vestibular neuronitis	4	0
Viral infection	10	0
Viral labyrinthitis	2	0
Viral myocarditis	1	0
Viral pharyngitis	6	0
Viral rash	7	0
Infections SOC TOTAL	2648	9

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Reaction Name	Total	Fatal
Injuries		
<i>Abdominal and gastrointestinal injuries NEC</i>		
Oral contusion	1	0
Palate injury	1	0
<i>Accidental exposures to product</i>		
Accidental exposure to product	2	0
<i>Anaesthetic and allied procedural complications</i>		
Anaesthetic complication	1	0
<i>Atmospheric pressure injuries</i>		
Barotrauma	1	0
<i>Bone and joint injuries NEC</i>		
Joint injury	3	0
<i>Cardiovascular injuries</i>		
Vascular injury	1	0
<i>Cerebral injuries NEC</i>		
Brain herniation	1	0
Concussion	8	0
Subdural haematoma	1	0
<i>Chest and respiratory tract injuries NEC</i>		
Chest crushing	3	0
<i>Conditions caused by cold</i>		
Chillblains	18	0
<i>Cranial nerve injuries</i>		
Cranial nerve injury	1	0
Optic nerve injury	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure via breast milk	25	0
Foetal exposure during pregnancy	11	0
Maternal exposure before pregnancy	2	0
Maternal exposure during breast feeding	600	0
Maternal exposure during pregnancy	278	0
Maternal exposure timing unspecified	1	0
<i>Exposures to agents or circumstances NEC</i>		
Exposure to SARS-CoV-2	3	0
<i>Eye injuries NEC</i>		
Blindness traumatic	1	0
Eye contusion	2	0
Eye injury	7	0
<i>Fractures and dislocations NEC</i>		
Compression fracture	1	0
Joint dislocation	1	0
<i>Gastrointestinal and hepatobiliary procedural complications</i>		
Procedural vomiting	1	0
<i>Heat injuries (excl thermal burns)</i>		
Heat exhaustion	1	0
Heat illness	1	0
Heat oedema	9	0
Heat stroke	9	0
<i>Limb fractures and dislocations</i>		
Clavicle fracture	8	0
Upper limb fracture	1	0
<i>Medication errors, product use errors and issues NEC</i>		
Circumstance or information capable of leading to medication error	6	0
Medication error	66	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Wrong schedule	1	0
Wrong technique in device usage process	2	0
Wrong technique in product usage process	1	0
Muscle, tendon and ligament injuries		
Epicondylitis	3	0
Ligament sprain	2	0
Muscle injury	8	0
Muscle rupture	1	0
Muscle strain	5	0
Tendon injury	2	0
Tendon rupture	1	0
Nerve injuries NEC		
Nerve injury	25	0
Nerve root injury lumbar	1	0
Neurological and psychiatric procedural complications		
Procedural dizziness	5	0
Non-occupational environmental exposures		
Exposure to extreme temperature	1	0
Non-site specific injuries NEC		
Arthropod bite	5	0
Bite	1	0
Electric shock	7	0
Fall	65	0
Inflammation of wound	2	0
Injury	5	0
Multiple injuries	1	0
Nervous system injury	1	0
Stab wound	1	0
Struck by lightning	1	0
Wound complication	8	0
Wound haemorrhage	2	0
Non-site specific procedural complications		
Incision site pain	1	0
Infusion related reaction	1	0
Injection related reaction	41	0
Post procedural complication	1	0
Post procedural erythema	1	0
Procedural pain	1	0
Occupational exposures		
Occupational exposure to toxic agent	1	0
Off label uses		
Off label use	34	0
Overdoses NEC		
Overdose	6	0
Peripheral nerve injuries		
Sciatic nerve injury	1	0
Ulnar nerve injury	1	0
Poisoning and toxicity		
Systemic toxicity	1	0
Toxicity to various agents	2	0
Product administration errors and issues		
Accidental overdose	73	0
Accidental underdose	3	0

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Reaction Name	Total	Fatal
Injuries		
Injuries cont'd		
Expired product administered	88	0
Extra dose administered	93	0
Inappropriate schedule of product administration	105	0
Inappropriate schedule of product discontinuation	1	0
Incorrect dose administered	15	0
Incorrect product administration duration	1	0
Incorrect route of product administration	3	0
Poor quality product administered	2	0
Product administered at inappropriate site	6	0
Product administered to patient of inappropriate age	1	0
Product administration error	1	0
Product administration interrupted	1	0
Product dose omission issue	5	0
Wrong product administered	3	0
Product confusion errors and issues		
Product label confusion	12	0
Product dispensing errors and issues		
Product dispensing error	1	0
Product prescribing errors and issues		
Contraindicated product prescribed	1	0
Product selection errors and issues		
Product selection error	7	0
Product storage errors and issues in the product use system		
Product storage error	11	0
Product transcribing errors and communication issues		
Product communication issue	1	0
Radiation injuries		
Sunburn	16	0
Renal and urinary tract injuries NEC		
Bladder injury	1	0
Respiratory tract and thoracic cavity procedural complications		
Post procedural pulmonary embolism	1	0
Site specific injuries NEC		
Back injury	2	0
Head injury	10	0
Limb crushing injury	1	0
Limb injury	58	0
Nasal injury	1	0
Skin injuries NEC		
Contusion	363	0
Scar	12	0
Scratch	2	0
Skin abrasion	1	0
Skin injury	1	0
Skin laceration	1	0
Skin wound	3	0
Subcutaneous haematoma	2	0
Skin procedural complications		
Dermal filler reaction	1	0
Skull fractures, facial bone fractures and dislocations		
Jaw fracture	1	0
Spinal cord injuries NEC		
Spinal cord injury cervical	1	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
<i>Stoma complications</i>		
Stoma site discomfort	1	0
Stoma site oedema	1	0
<i>Thermal burns</i>		
Burn oesophageal	1	0
Cold burn	1	0
Thermal burn	14	0
Thermal burns of eye	6	0
<i>Thoracic cage fractures and dislocations</i>		
Sternal fracture	1	0
<i>Vaccination related complications</i>		
Vaccination complication	4	0
Injuries SOC TOTAL	2267	0

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Reaction Name	Total	Fatal
Investigations		
<i>Adrenal medulla tests</i>		
Norepinephrine increased	2	0
<i>Auditory and vestibular diagnostic procedures</i>		
Audiogram abnormal	1	0
<i>Autoimmunity analyses</i>		
Rheumatoid factor increased	1	0
<i>Bacteria identification and serology (excl mycobacteria)</i>		
Campylobacter test positive	1	0
<i>Blood counts NEC</i>		
Full blood count abnormal	1	0
<i>Blood gas and acid base analyses</i>		
Blood lactic acid	1	0
Oxygen consumption decreased	1	0
Oxygen saturation	3	0
Oxygen saturation decreased	21	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose	1	0
Blood glucose abnormal	2	0
Blood glucose decreased	3	0
Blood glucose increased	7	0
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	4	0
Heart sounds	6	0
Heart sounds abnormal	1	0
<i>Cardiac function diagnostic procedures</i>		
Ejection fraction decreased	1	0
<i>Central nervous system imaging procedures</i>		
Computerised tomogram head	1	0
<i>Chemistry analyses NEC</i>		
Histamine abnormal	1	0
<i>Cholesterol analyses</i>		
Blood cholesterol increased	2	0
Low density lipoprotein increased	1	0
<i>Coagulation and bleeding analyses</i>		
Bleeding time	1	0
Bleeding time abnormal	1	0
Blood fibrinogen	1	0
Blood thrombin	1	0
Coagulation time shortened	1	0
Fibrin D dimer increased	5	0
Fibrin degradation products increased	1	0
International normalised ratio decreased	1	0
International normalised ratio increased	2	0
<i>Digestive enzymes</i>		
Amylase increased	1	0
<i>ECG investigations</i>		
Electrocardiogram	1	0
Electrocardiogram P wave abnormal	1	0
Electrocardiogram QT prolonged	1	0
Electrocardiogram ST segment elevation	2	0
Electrocardiogram ST-T segment abnormal	3	0
Electrocardiogram T wave inversion	2	0
Electrocardiogram abnormal	3	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Electrocardiogram change	1	0
Endocrine analyses and imaging NEC		
Hormone level abnormal	16	0
Faecal analyses NEC		
Faecal volume	1	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
Gastrointestinal function diagnostic procedures		
Gastric pH decreased	1	0
Haematological analyses NEC		
Blood viscosity increased	1	0
Red blood cell sedimentation rate increased	1	0
Heart rate and pulse investigations		
Heart rate	282	0
Heart rate abnormal	22	0
Heart rate decreased	19	0
Heart rate increased	429	0
Heart rate irregular	96	0
Heart rate variability decreased	1	0
Maximum heart rate	1	0
Maximum heart rate increased	1	0
Pulse abnormal	3	0
Pulse absent	1	0
Sinus rhythm	3	0
Hepatobiliary function diagnostic procedures		
Alanine aminotransferase increased	6	0
Aspartate aminotransferase	2	0
Bile output	3	0
Blood bilirubin increased	1	0
Liver function test abnormal	8	0
Liver function test increased	1	0
Imaging procedures NEC		
X-ray	1	0
Immunology analyses NEC		
Immunology test	1	0
Immunology skin tests NEC		
Allergy alert test	1	0
Allergy alert test positive	1	0
Investigations NEC		
Blood test	1	0
Blood test abnormal	5	0
Blood test normal	2	0
Polymerase chain reaction positive	2	0
Mineral and electrolyte analyses		
Blood calcium increased	2	0
Blood iron	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Blood iron decreased	3	0
Blood magnesium decreased	1	0
Blood potassium decreased	3	0
Blood sodium decreased	1	0
Serum ferritin increased	3	0
Urine copper	1	0
<i>Musculoskeletal and soft tissue imaging procedures</i>		
Bone scan	1	0
Face and mouth X-ray abnormal	1	0
X-ray limb normal	1	0
<i>Musculoskeletal and soft tissue tests NEC</i>		
Tender joint count	1	0
<i>Neurologic diagnostic procedures</i>		
Coma scale abnormal	2	0
Electromyogram abnormal	1	0
Sensory level	1	0
<i>Ophthalmic function diagnostic procedures</i>		
Corneal reflex decreased	1	0
Intraocular pressure increased	2	0
Visual tracking test	1	0
Visual tracking test abnormal	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature	111	0
Body temperature abnormal	12	0
Body temperature decreased	18	0
Body temperature fluctuation	28	0
Body temperature increased	146	0
Breath sounds	1	0
Breath sounds abnormal	2	0
Grip strength	1	0
Grip strength decreased	4	0
Head lag	4	0
Lymph node palpable	5	0
Muscle strength abnormal	3	0
Ophthalmological examination	1	0
Palpatory finding abnormal	1	0
Product residue present	1	0
Respiratory rate	6	0
Respiratory rate decreased	6	0
Respiratory rate increased	10	0
Skin temperature	25	0
Temperature difference of extremities	6	0
Weight decreased	31	0
Weight increased	11	0
<i>Pituitary analyses anterior</i>		
Blood thyroid stimulating hormone decreased	1	0
Blood thyroid stimulating hormone increased	2	0
<i>Platelet analyses</i>		
Platelet count decreased	12	0
Platelet count normal	1	0
<i>Protein analyses NEC</i>		
C-reactive protein increased	11	0
<i>Red blood cell analyses</i>		

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Haemoglobin E	1	0
Haemoglobin decreased	2	0
Renal function analyses		
Blood creatinine increased	1	0
Reproductive hormone analyses		
Blood testosterone decreased	1	0
False negative pregnancy test	2	0
Pregnancy test	1	0
Pregnancy test false positive	1	0
Reproductive organ and breast histopathology procedures		
Smear cervix	1	0
Reproductive organ and breast imaging procedures		
Hysteroscopy	1	0
Respiratory and pulmonary function diagnostic procedures		
Forced expiratory volume decreased	1	0
Forced expiratory volume increased	3	0
Pulmonary function test decreased	1	0
Skeletal and cardiac muscle analyses		
Blood creatine phosphokinase increased	1	0
Myocardial necrosis marker increased	1	0
Troponin I increased	1	0
Troponin T increased	1	0
Troponin increased	5	0
Therapeutic drug monitoring analyses		
Analgesic drug level	5	0
Thyroid analyses		
Tri-iodothyronine decreased	1	0
Tissue enzyme analyses NEC		
Blood alkaline phosphatase increased	1	0
Blood lactate dehydrogenase increased	1	0
Phospholipase A2 activity increased	1	0
Urinalysis NEC		
Blood urine	5	0
Blood urine present	28	0
Protein urine	1	0
pH urine	1	0
Urinary tract function analyses NEC		
Urine output	12	0
Urine output decreased	1	0
Urinary tract imaging procedures		
Bladder scan	1	0
Vascular tests NEC (incl blood pressure)		
Blood pressure abnormal	3	0
Blood pressure decreased	11	0
Blood pressure diastolic increased	1	0
Blood pressure increased	45	0
Blood pressure measurement	11	0
Blood pressure normal	1	0
Virus identification and serology		
Coronavirus test	5	0
Influenza A virus test	1	0
SARS-CoV-2 antibody test	2	0
SARS-CoV-2 antibody test negative	1	0

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
SARS-CoV-2 antibody test positive	2	0
SARS-CoV-2 test	5	0
SARS-CoV-2 test negative	4	0
SARS-CoV-2 test positive	7	0
Vitamin analyses		
Blood folate decreased	1	0
Vitamin D decreased	1	0
White blood cell analyses		
Neutrophil count	1	0
Neutrophil count decreased	1	0
White blood cell count	1	0
White blood cell count decreased	1	0
White blood cell count increased	3	0
Investigations SOC TOTAL	1688	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	3	0
Decreased appetite	477	0
Eating disorder symptom	1	0
Food craving	2	0
Food refusal	4	0
Hyperphagia	5	0
Hypophagia	3	0
Increased appetite	9	0
Salt craving	1	0
<i>Copper metabolism disorders</i>		
Copper deficiency	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	6	0
Diabetes mellitus inadequate control	4	0
Type 1 diabetes mellitus	2	0
Type 2 diabetes mellitus	1	0
<i>Diabetic complications NEC</i>		
Diabetic ketoacidosis	2	0
<i>Disorders of purine metabolism</i>		
Gout	25	0
<i>Fat soluble vitamin deficiencies and disorders</i>		
Vitamin D deficiency	1	0
<i>Fluid intake decreased</i>		
Fluid intake reduced	1	0
<i>Fluid intake increased</i>		
Polydipsia	1	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Alcohol intolerance	2	0
Food intolerance	3	0
Gluten sensitivity	1	0
Histamine intolerance	1	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	6	0
Abnormal weight gain	9	0
Feeding disorder	58	0
Food aversion	6	0
Neonatal insufficient breast milk syndrome	4	0
Overweight	1	0
Poor feeding infant	1	0
Weight loss poor	1	0
<i>Hyperglycaemic conditions NEC</i>		
Hyperglycaemia	8	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	12	0
<i>Iron excess</i>		
Haemochromatosis	1	0
<i>Potassium imbalance</i>		
Hypokalaemia	2	0
<i>Sodium imbalance</i>		
Hyponatraemia	1	0
<i>Sugar intolerance (excl glucose intolerance)</i>		
Lactose intolerance	2	0

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Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
<i>Total fluid volume decreased</i>		
Dehydration	114	0
<i>Total fluid volume increased</i>		
Fluid retention	12	0
<i>Water soluble vitamin deficiencies</i>		
Folate deficiency	2	0
Metabolic disorders SOC TOTAL	796	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	66	0
Arthritis allergic	1	0
Arthritis enteropathic	1	0
Arthropathy	9	0
Autoimmune arthritis	1	0
Palindromic rheumatism	1	0
Polyarthritis	2	0
Rheumatic fever	1	0
<i>Bone disorders NEC</i>		
Bone erosion	1	0
Exostosis	2	0
Jaw cyst	1	0
Jaw disorder	2	0
Medial tibial stress syndrome	1	0
Osteitis	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	123	0
Bone swelling	2	0
Coccydynia	1	0
Pain in jaw	110	0
Pubic pain	1	0
Spinal pain	23	0
<i>Bursal disorders</i>		
Bursitis	25	0
<i>Cartilage disorders</i>		
Chondritis	1	0
Costochondritis	23	0
<i>Connective tissue disorders NEC</i>		
Morphoea	1	0
Polymyalgia rheumatica	7	0
Reynold's syndrome	2	0
Systemic scleroderma	2	0
<i>Extremity deformities</i>		
Finger deformity	1	0
Foot deformity	2	0
Hand deformity	2	0
<i>Intervertebral disc disorders NEC</i>		
Intervertebral disc protrusion	2	0
<i>Joint related disorders NEC</i>		
Greater trochanteric pain syndrome	1	0
Hypermobility syndrome	1	0
Joint lock	12	0
Periarthritis	59	0
Rotator cuff syndrome	7	0
Temporomandibular joint syndrome	3	0
<i>Joint related signs and symptoms</i>		
Arthralgia	2757	0
Joint effusion	1	0
Joint noise	4	0
Joint range of motion decreased	1	0
Joint stiffness	85	0
Joint swelling	95	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Muscle & tissue disorders cont'd		
Joint vibration	2	0
Joint warmth	7	0
Lupus erythematosus (incl subtypes)		
Lupus-like syndrome	1	0
Systemic lupus erythematosus	3	0
Muscle infections and inflammations		
Myositis	10	0
Muscle pains		
Fibromyalgia	27	0
Myalgia	3536	0
Myalgia intercostal	1	0
Muscle related signs and symptoms NEC		
Muscle atrophy	3	0
Muscle discomfort	3	0
Muscle disorder	1	0
Muscle fatigue	120	0
Muscle haemorrhage	1	0
Muscle mass	1	0
Muscle spasms	531	0
Muscle swelling	17	0
Muscle tightness	34	0
Muscle twitching	97	0
Myosclerosis	1	0
Muscle tone abnormalities		
Muscle rigidity	6	0
Nuchal rigidity	5	0
Trismus	11	0
Muscle weakness conditions		
Muscular weakness	297	0
Musculoskeletal and connective tissue conditions NEC		
Growth retardation	1	0
Limb mass	3	0
Mastication disorder	2	0
Mobility decreased	37	0
Muscle contracture	1	0
Musculoskeletal disorder	3	0
Musculoskeletal stiffness	515	0
Weight bearing difficulty	1	0
Musculoskeletal and connective tissue deformities of skull, face and buccal cavity		
Facial asymmetry	2	0
Musculoskeletal and connective tissue infections and inflammations NEC		
Dupuytren's contracture	1	0
Fasciitis	1	0
Plantar fasciitis	1	0
Musculoskeletal and connective tissue pain and discomfort		
Back pain	888	0
Flank pain	19	0
Limb discomfort	417	0
Musculoskeletal chest pain	72	0
Musculoskeletal discomfort	31	0
Musculoskeletal pain	27	0
Neck pain	520	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Muscle & tissue disorders cont'd		
Pain in extremity	4223	1
Sacral pain	1	0
Myopathies		
Rhabdomyolysis	1	0
Osteoarthropathies		
Osteoarthritis	6	0
Psoriatic arthropathies		
Psoriatic arthropathy	4	0
Rheumatoid arthropathies		
Rheumatoid arthritis	25	0
Soft tissue disorders NEC		
Axillary mass	59	0
Fluctuance	1	0
Groin pain	28	0
Neck mass	14	0
Soft tissue swelling	2	0
Spine and neck deformities		
Scoliosis	1	0
Spinal stenosis	1	0
Spondyloarthropathies		
Ankylosing spondylitis	5	0
Arthritis reactive	20	0
Axial spondyloarthritis	1	0
Spondylitis	1	0
Synovial disorders		
Synovial cyst	5	0
Synovitis	2	0
Tendon disorders		
Tendon pain	5	0
Tendonitis	8	0
Trigger finger	3	0
Trunk deformities		
Shoulder deformity	2	0
Muscle & tissue disorders SOC TOTAL	15119	1

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Reaction Name	Total	Fatal
Neoplasms		
<i>B-cell lymphomas NEC</i>		
B-cell lymphoma stage II	1	0
B-cell lymphoma stage III	1	0
<i>Breast and nipple neoplasms benign</i>		
Benign breast neoplasm	2	0
Fibroadenoma of breast	1	0
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	4	0
<i>Breast neoplasms unspecified malignancy</i>		
Phyllodes tumour	1	0
<i>Cardiovascular neoplasms benign</i>		
Haemangioma	1	0
<i>Gastrointestinal neoplasms malignant NEC</i>		
Gastrointestinal carcinoma	1	1
<i>Leukaemias NEC</i>		
Leukaemia	1	0
<i>Leukaemias chronic lymphocytic</i>		
Chronic lymphocytic leukaemia	1	0
<i>Lymphomas unspecified NEC</i>		
Lymphoma	9	0
<i>Mediastinal neoplasms malignancy unspecified NEC</i>		
Good syndrome	1	0
<i>Metastases to specified sites</i>		
Metastases to lymph nodes	1	0
<i>Metastases to unknown and unspecified sites</i>		
Metastasis	1	0
<i>Neoplasms malignant site unspecified NEC</i>		
Neoplasm malignant	1	0
<i>Oesophageal neoplasms malignant</i>		
Oesophageal carcinoma	1	0
<i>Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified</i>		
Tonsil cancer	2	0
<i>Plasma cell neoplasms NEC</i>		
Hypergammaglobulinaemia benign monoclonal	1	0
<i>Respiratory tract and pleural neoplasms malignant cell type unspecified NEC</i>		
Bronchial carcinoma	1	0
<i>Skin neoplasms benign</i>		
Acrochordon	2	0
Anogenital warts	1	0
Haemangioma of skin	3	0
Melanocytic naevus	1	0
Skin papilloma	4	0
<i>Skin neoplasms malignant and unspecified (excl melanoma)</i>		
Keratoacanthoma	1	0
<i>Small intestinal neoplasms malignant</i>		
Small intestine adenocarcinoma	1	0
Small intestine carcinoma	1	0
<i>Soft tissue neoplasms benign NEC</i>		
Lipoma	2	0
<i>Urinary tract neoplasms unspecified malignancy NEC</i>		
Renal neoplasm	1	0

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	3	0
<i>Uterine neoplasms malignant NEC</i>		
Uterine cancer	1	0
Neoplasms SOC TOTAL	53	1

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal sleep-related events</i>		
Sleep paralysis	5	0
<i>Absence seizures</i>		
Petit mal epilepsy	1	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	25	1
<i>Autonomic nervous system disorders</i>		
Autonomic nervous system imbalance	3	0
Orthostatic intolerance	3	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Brain stem infarction	1	0
Cerebral artery embolism	1	0
Cerebral haemorrhage	5	2
Cerebral infarction	1	0
Cerebrovascular accident	46	2
Haemorrhage intracranial	2	0
Haemorrhagic stroke	2	1
Intracranial haematoma	1	0
Intraventricular haemorrhage	1	0
Ischaemic stroke	6	0
Lacunar infarction	1	0
Ruptured cerebral aneurysm	1	1
Subarachnoid haemorrhage	8	0
<i>Central nervous system inflammatory disorders NEC</i>		
Central nervous system inflammation	2	0
<i>Central nervous system vascular disorders NEC</i>		
Cerebral congestion	2	0
<i>Cerebrovascular venous and sinus thrombosis</i>		
Cerebral venous sinus thrombosis	4	0
Cerebral venous thrombosis	1	0
<i>Cervical spinal cord and nerve root disorders</i>		
Cervical radiculopathy	1	0
<i>Choreiform movements</i>		
Chorea	1	0
<i>Chronic polyneuropathies</i>		
Chronic inflammatory demyelinating polyradiculoneuropathy	3	0
Demyelinating polyneuropathy	1	0
<i>Coordination and balance disturbances</i>		
Ataxia	6	0
Balance disorder	115	0
Coordination abnormal	8	0
Dysstasia	23	0
Nystagmus	3	0
<i>Cortical dysfunction NEC</i>		
Aphasia	10	0
Dysgraphia	1	0
<i>Cranial nerve disorders NEC</i>		
Cranial nerve disorder	2	0
<i>Dementia (excl Alzheimer's type)</i>		
Dementia	3	0
<i>Demyelinating disorders NEC</i>		
Demyelination	2	0
<i>Disturbances in consciousness NEC</i>		

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Consciousness fluctuating	1	0
Depressed level of consciousness	16	0
Lethargy	580	0
Loss of consciousness	306	0
Postictal state	1	0
Somnolence	302	0
Stupor	1	0
Syncope	1181	0
<i>Disturbances in sleep phase rhythm</i>		
Delayed sleep phase	1	0
<i>Dyskinesias and movement disorders NEC</i>		
Akathisia	2	0
Bradykinesia	5	0
Clumsiness	4	0
Dyskinesia	17	0
Extrapyramidal disorder	2	0
Fine motor delay	1	0
Fine motor skill dysfunction	4	0
Foetal movement disorder	1	0
Hyperkinesia	1	0
Hypokinesia	24	0
Motor dysfunction	3	0
Movement disorder	13	0
Psychomotor hyperactivity	5	0
<i>Dystonias</i>		
Dystonia	1	0
<i>Encephalitis NEC</i>		
Encephalitis allergic	1	0
Encephalitis autoimmune	1	0
Noninfective encephalitis	1	0
<i>Eye movement disorders</i>		
IVth nerve paresis	1	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	108	0
Facial nerve disorder	1	0
Facial paralysis	63	0
Facial paresis	13	0
Facial spasm	7	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	11	0
<i>Glossopharyngeal nerve disorders</i>		
Glossopharyngeal neuralgia	1	0
<i>Headaches NEC</i>		
Cluster headache	67	0
Cold-stimulus headache	12	0
Drug withdrawal headache	2	0
Headache	8820	0
Medication overuse headache	1	0
New daily persistent headache	2	0
Occipital neuralgia	1	0
Primary cough headache	1	0
Primary headache associated with sexual activity	1	0
Sinus headache	111	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Tension headache	178	0
Thunderclap headache	3	0
Vascular headache	8	0
Hydrocephalic conditions		
Hydrocephalus	1	0
Hypoglossal nerve disorders		
Tongue paralysis	1	0
Increased intracranial pressure disorders		
Idiopathic intracranial hypertension	2	0
Intracranial pressure increased	3	0
Lumbar spinal cord and nerve root disorders		
Sciatica	17	0
Memory loss (excl dementia)		
Amnesia	67	0
Memory impairment	47	0
Transient global amnesia	2	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	29	0
Disturbance in attention	97	0
Mental impairment	18	0
Migraine headaches		
Basilar migraine	1	0
Hemiplegic migraine	7	0
Migraine	879	0
Migraine with aura	52	0
Migraine without aura	3	0
Retinal migraine	5	0
Typical aura without headache	1	0
Vestibular migraine	5	0
Mononeuropathies		
Carpal tunnel syndrome	7	0
Cubital tunnel syndrome	1	0
Mononeuritis	2	0
Nerve compression	4	0
Multiple sclerosis acute and progressive		
Band sensation	1	0
Multiple sclerosis	6	0
Multiple sclerosis pseudo relapse	1	0
Multiple sclerosis relapse	6	0
Progressive multiple sclerosis	1	0
Uhthoff's phenomenon	1	0
Muscle tone abnormal		
Drop attacks	1	0
Hypotonia	10	0
Stiff leg syndrome	3	0
Myelitis (incl infective)		
Myelitis transverse	7	0
Narcolepsy and hypersomnia		
Hypersomnia	35	0
Narcolepsy	1	0
Nervous system disorders NEC		
Nervous system disorder	6	0
Psychomotor skills impaired	1	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Neurologic visual problems NEC		
Hemianopia	1	0
Tunnel vision	13	0
Neurological signs and symptoms NEC		
Agitation neonatal	1	0
Clonus	2	0
Dizziness	3549	0
Dizziness exertional	14	0
Dizziness postural	238	0
Drooling	2	0
Exaggerated startle response	1	0
Head discomfort	73	0
Meningism	1	0
Neurological symptom	14	0
Persistent postural-perceptual dizziness	5	0
Presyncope	270	0
Tongue biting	2	0
Unresponsive to stimuli	13	0
Neuromuscular disorders NEC		
Muscle contractions involuntary	2	0
Muscle spasticity	4	0
Neuromuscular pain	1	0
Neuromuscular junction dysfunction		
Myasthenia gravis	1	0
Myasthenic syndrome	1	0
Olfactory nerve disorders		
Anosmia	40	0
Hyposmia	3	0
Parosmia	50	0
Optic nerve disorders NEC		
Optic neuritis	5	0
Paraesthesias and dysaesthesias		
Burning feet syndrome	7	0
Burning sensation	138	0
Dysaesthesia	2	0
Formication	8	0
Hemianaesthesia	1	0
Hemihypoaesthesia	1	0
Hyperaesthesia	58	0
Hypoaesthesia	711	0
Paraesthesia	1032	0
Paralysis and paresis (excl cranial nerve)		
Diplegia	7	0
Hemiparesis	6	0
Hemiplegia	12	0
Monoparesis	25	0
Monoplegia	32	0
Paralysis	41	0
Paraparesis	2	0
Paresis	2	0
Quadriplegia	1	0
Parkinson's disease and parkinsonism		
Freezing phenomenon	12	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Reduced facial expression	1	0
Partial complex seizures		
Focal dyscognitive seizures	2	0
Peripheral neuropathies NEC		
Autoimmune neuropathy	2	0
Neuralgic amyotrophy	4	0
Neuritis	3	0
Neuropathy peripheral	19	0
Peripheral sensory neuropathy	1	0
Polyneuropathy	2	0
Small fibre neuropathy	1	0
Seizures and seizure disorders NEC		
Atonic seizures	1	0
Epilepsy	26	0
Febrile convulsion	6	0
Myoclonic epilepsy	1	0
Partial seizures	8	0
Psychogenic seizure	1	0
Seizure	221	0
Seizure anoxic	2	0
Seizure cluster	1	0
Status epilepticus	30	0
Tonic clonic movements	3	0
Tonic convulsion	5	0
Sensory abnormalities NEC		
Ageusia	98	0
Allodynia	3	0
Aura	4	0
Complex regional pain syndrome	1	0
Dysgeusia	240	0
Electric shock sensation	15	0
Hypogeusia	1	0
Loss of proprioception	1	0
Neuralgia	162	0
Post herpetic neuralgia	3	0
Restless legs syndrome	50	0
Sensory disturbance	29	0
Sensory loss	37	0
Taste disorder	55	0
Vibratory sense increased	2	0
Sleep disturbances NEC		
Sleep deficit	6	0
Speech and language abnormalities		
Dysarthria	49	0
Incoherent	12	0
Slow speech	5	0
Speech disorder	22	0
Spinal cord and nerve root disorders NEC		
Radicular pain	1	0
Radiculitis brachial	4	0
Radiculopathy	1	0
Transient cerebrovascular events		
Transient ischaemic attack	29	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
<i>Tremor (excl congenital)</i>		
Essential tremor	2	0
Head titubation	2	0
Tremor	777	0
<i>Trigeminal disorders</i>		
Trigeminal neuralgia	14	0
Trigeminal neuritis	1	0
Nervous system disorders SOC TOTAL	21889	7

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	71	0
<i>Foetal complications NEC</i>		
Foetal hypokinesia	4	0
Hydrops foetalis	1	0
<i>Foetal growth complications</i>		
Foetal growth restriction	2	0
<i>Gestational age and weight conditions</i>		
Premature baby	2	0
<i>Haemorrhagic complications of pregnancy</i>		
Premature separation of placenta	1	0
Subchorionic haemorrhage	1	0
<i>Labour onset and length abnormalities</i>		
Premature labour	5	0
<i>Maternal complications of labour NEC</i>		
Uterine atony	1	0
Uterine hypertonus	3	0
<i>Maternal complications of pregnancy NEC</i>		
Decidual cast	1	0
Ectopic pregnancy	3	0
Morning sickness	1	0
Somatic symptom disorder of pregnancy	1	0
Uterine irritability	1	0
<i>Multiple pregnancies</i>		
Twin pregnancy	1	0
<i>Normal pregnancy, labour and delivery</i>		
Live birth	2	0
Pregnancy	4	0
<i>Postpartum complications NEC</i>		
Postpartum haemorrhage	1	0
<i>Pregnancy complicated by maternal disorders</i>		
Gestational diabetes	1	0
<i>Stillbirth and foetal death</i>		
Stillbirth	1	1
<i>Umbilical cord complications</i>		
Umbilical cord thrombosis	1	0
Pregnancy conditions SOC TOTAL	109	1

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Reaction Name	Total	Fatal
<i>Device issues NEC</i>		
Device expulsion	1	0
Device leakage	1	0
<i>Device malfunction events NEC</i>		
Oversensing	2	0
Thrombosis in device	2	0
Undersensing	2	0
<i>Manufacturing materials issues</i>		
Manufacturing materials issue	1	0
<i>Product contamination and sterility issues</i>		
Product contamination physical	8	0
Suspected product contamination	1	0
<i>Product label issues</i>		
Product label issue	6	0
<i>Product physical issues</i>		
Product after taste	1	0
Product taste abnormal	1	0
<i>Product quality issues NEC</i>		
Product complaint	1	0
Product impurity	1	0
Product quality issue	1	0
Product tampering	1	0
<i>Product supply and availability issues</i>		
Product availability issue	2	0
null SOC TOTAL	32	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	6	0
Breath holding	4	0
Staring	1	0
<i>Affect alterations NEC</i>		
Affect lability	2	0
Constricted affect	2	0
Flat affect	4	0
Inappropriate affect	3	0
<i>Amnesic symptoms</i>		
Paramnesia	2	0
<i>Anxiety disorders NEC</i>		
Anxiety disorder	1	0
Separation anxiety disorder	1	0
<i>Anxiety symptoms</i>		
Agitation	26	0
Anxiety	271	0
Nervousness	53	0
Stress	25	0
Tension	10	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	5	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	2	0
Disinhibition	1	0
Homicidal ideation	1	0
Impatience	1	0
Paranoia	7	0
Personality change	3	0
Social avoidant behaviour	1	0
Soliloquy	1	0
Violence-related symptom	1	0
<i>Bipolar disorders</i>		
Bipolar disorder	1	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Daydreaming	1	0
Distractibility	1	0
Mental fatigue	64	0
<i>Communications disorders</i>		
Mutism	1	0
<i>Confusion and disorientation</i>		
Confusional state	253	0
Disorientation	104	0
<i>Deliria</i>		
Delirium	64	0
<i>Delusional disorders</i>		
Alice in wonderland syndrome	1	0
<i>Delusional symptoms</i>		
Delusion	3	0
Delusion of parasitosis	1	0
<i>Depressive disorders</i>		
Depression	103	0
Depression suicidal	4	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Major depression	3	0
Mixed anxiety and depressive disorder	1	0
<i>Dissociative states</i>		
Depersonalisation/derealisation disorder	3	0
Dissociation	13	0
<i>Disturbances in initiating and maintaining sleep</i>		
Initial insomnia	7	0
Insomnia	534	0
Middle insomnia	14	0
Terminal insomnia	13	0
<i>Dyssomnias</i>		
Poor quality sleep	105	0
<i>Eating disorders NEC</i>		
Binge eating	1	0
Eating disorder	1	0
<i>Emotional and mood disturbances NEC</i>		
Anger	15	0
Emotional disorder	21	0
Emotional distress	12	0
Emotional poverty	1	0
Euphoric mood	12	0
Frustration tolerance decreased	4	0
Irritability	56	0
Mood altered	21	0
<i>Factitious disorders</i>		
Factitious disorder	1	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Fear	7	0
Fear of death	1	0
Fear of eating	1	0
Fear of injection	6	0
Paruresis	1	0
Phobia	1	0
Phonophobia	1	0
Social fear	1	0
<i>Fluctuating mood symptoms</i>		
Mood swings	19	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	140	0
Hallucination, auditory	7	0
Hallucination, olfactory	1	0
Hallucination, tactile	1	0
Hallucination, visual	6	0
Hallucinations, mixed	3	0
Somatic hallucination	1	0
<i>Increased physical activity levels</i>		
Restlessness	63	0
<i>Mental disorders NEC</i>		
Mental disorder	4	0
<i>Mood alterations with depressive symptoms</i>		
Decreased interest	3	0
Depressed mood	102	0
Feeling of despair	5	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Negative thoughts	2	0
Sense of a foreshortened future	1	0
Tearfulness	7	0
Mood alterations with manic symptoms		
Mania	5	0
Mood disorders NEC		
Affective disorder	2	0
Apathy	13	0
Listless	13	0
Narcolepsy and associated conditions		
Hypnagogic hallucination	1	0
Obsessive-compulsive disorders and symptoms		
Dermatophagia	3	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	58	0
Panic disorder	1	0
Panic reaction	14	0
Paraphilias and paraphilic disorders		
Exhibitionism	1	0
Parasomnias		
Abnormal dreams	43	0
Abnormal sleep-related event	1	0
Exploding head syndrome	1	0
Nightmare	68	0
Sleep inertia	1	0
Sleep talking	3	0
Sleep terror	5	0
Somnambulism	1	0
Perception disturbances NEC		
Autoscopy	3	0
Deja vu	1	0
Derealisation	3	0
Illusion	1	0
Psychiatric elimination disorders		
Enuresis	14	0
Psychiatric symptoms NEC		
Helplessness	1	0
Hypervigilance	2	0
Psychiatric symptom	6	0
Psychological trauma	1	0
Psychotic disorder NEC		
Acute psychosis	1	0
Psychotic disorder	3	0
Sexual arousal disorders		
Disturbance in sexual arousal	1	0
Sexual desire disorders		
Libido decreased	6	0
Libido increased	1	0
Loss of libido	6	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Sexual dysfunction NEC</i>		
Genito-pelvic pain/penetration disorder	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	82	0
<i>Somatic symptom disorders</i>		
Conversion disorder	5	0
Habit cough	7	0
<i>Speech and language usage disturbances</i>		
Disorganised speech	2	0
<i>Speech articulation and rhythm disturbances</i>		
Dysphemia	4	0
Lack of spontaneous speech	1	0
<i>Stereotypies and automatisms</i>		
Bruxism	4	0
Head banging	7	0
<i>Stress disorders</i>		
Acute stress disorder	1	0
Post-traumatic stress disorder	1	0
<i>Substance related and addictive disorders</i>		
Alcoholism	1	0
<i>Suicidal and self-injurious behaviour</i>		
Intentional self-injury	2	0
Suicidal behaviour	2	0
Suicidal ideation	20	0
Suicide attempt	3	0
<i>Thinking disturbances</i>		
Bradyphrenia	5	0
Intrusive thoughts	1	0
Tachyphrenia	5	0
Thinking abnormal	5	0
Thought blocking	2	0
<i>Tic disorders</i>		
Tic	1	0
Psychiatric disorders SOC TOTAL	2706	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder irritation	2	0
Bladder pain	12	0
Dysuria	11	0
Incontinence	18	0
Micturition urgency	16	0
Pollakiuria	49	0
Stress urinary incontinence	1	0
Urethral pain	2	0
Urinary incontinence	24	0
Urinary retention	10	0
Urinary straining	2	0
Urine flow decreased	2	0
<i>Bladder disorders NEC</i>		
Bladder dilatation	1	0
Bladder disorder	4	0
Urinary bladder haemorrhage	2	0
<i>Bladder infections and inflammations</i>		
Cystitis interstitial	1	0
<i>Genitourinary tract infections and inflammations NEC</i>		
Urinary tract inflammation	1	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
Glomerulonephritis acute	1	0
Glomerulonephritis membranous	1	0
IgA nephropathy	2	0
<i>Myoneurogenic bladder disorders</i>		
Bladder dysfunction	1	0
Hypertonic bladder	4	0
Loss of bladder sensation	2	0
<i>Nephritis NEC</i>		
Nephritis	1	0
<i>Renal disorders NEC</i>		
Renal disorder	2	0
<i>Renal failure and impairment</i>		
Acute kidney injury	9	0
Chronic kidney disease	2	0
Oliguria	1	0
Renal failure	2	0
Renal impairment	3	0
Renal injury	1	0
<i>Renal lithiasis</i>		
Nephrolithiasis	1	0
<i>Renal vascular and ischaemic conditions</i>		
Renal vein thrombosis	1	0
<i>Urinary abnormalities</i>		
Chromaturia	24	0
Haematuria	12	0
Loin pain haematuria syndrome	1	0
Urine abnormality	5	0
Urine odour abnormal	4	0
<i>Urinary tract signs and symptoms NEC</i>		
Haemorrhage urinary tract	9	0
Nocturia	1	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
Renal & urinary disorders cont'd		
Polyuria	1	0
Renal pain	121	0
Urinary tract pain	1	0
Renal & urinary disorders SOC TOTAL	371	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Benign and malignant breast neoplasms</i>		
Breast cyst	6	0
<i>Breast disorders NEC</i>		
Breast enlargement	4	0
Breast mass	21	0
Fibrocystic breast disease	1	0
Retracted nipple	1	0
<i>Breast infections and inflammations</i>		
Breast inflammation	4	0
<i>Breast signs and symptoms</i>		
Breast discharge	3	0
Breast discomfort	2	0
Breast haemorrhage	1	0
Breast oedema	1	0
Breast pain	159	0
Breast swelling	23	0
Breast tenderness	16	0
Nipple pain	2	0
Nipple swelling	2	0
<i>Cervix disorders NEC</i>		
Cervix haemorrhage uterine	1	0
Ectropion of cervix	1	0
<i>Erection and ejaculation conditions and disorders</i>		
Ejaculation delayed	1	0
Ejaculation failure	3	0
Erectile dysfunction	15	0
Erection increased	1	0
Nocturnal emission	1	0
Organic erectile dysfunction	9	0
Painful ejaculation	1	0
Priapism	1	0
Spontaneous penile erection	1	0
<i>Gender disorders</i>		
Feminisation acquired	1	0
<i>Lactation disorders</i>		
Galactorrhoea	2	0
Lactation disorder	3	0
Lactation puerperal increased	2	0
Suppressed lactation	10	0
<i>Menopausal effects NEC</i>		
Menopausal symptoms	10	0
Premature menopause	5	0
<i>Menopausal effects on the genitourinary tract</i>		
Postmenopausal haemorrhage	24	0
<i>Menstruation and uterine bleeding NEC</i>		
Abnormal uterine bleeding	1	0
Dysmenorrhoea	488	0
Intermenstrual bleeding	258	0
Menstrual discomfort	4	0
Menstrual disorder	428	0
Menstruation irregular	700	0
Premenstrual dysphoric disorder	1	0
Premenstrual headache	2	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Premenstrual pain	23	0
Premenstrual syndrome	19	0
Withdrawal bleed	2	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	106	0
Hypomenorrhoea	118	0
Menstruation delayed	857	0
Oligomenorrhoea	35	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	1082	0
Menometrorrhagia	9	0
Polymenorrhoea	182	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>		
Ovarian cyst	7	0
Polycystic ovaries	11	0
<i>Ovarian and fallopian tube disorders NEC</i>		
Fallopian tube spasm	1	0
Ovulation pain	21	0
Premature ovulation	1	0
<i>Pelvis and broad ligament disorders NEC</i>		
Adnexa uteri pain	22	0
Pelvic haemorrhage	2	0
<i>Penile disorders NEC (excl erection and ejaculation)</i>		
Penile pain	1	0
Penis disorder	4	0
<i>Prostate and seminal vesicles infections and inflammations</i>		
Prostatitis	2	0
<i>Prostatic signs, symptoms and disorders NEC</i>		
Prostatic pain	2	0
<i>Reproductive tract disorders NEC (excl neoplasms)</i>		
Genital blister	1	0
Genital haemorrhage	3	0
Genital paraesthesia	1	0
Genital ulceration	3	0
<i>Reproductive tract signs and symptoms NEC</i>		
Genital odour	1	0
Genital pain	4	0
Genital rash	1	0
Pelvic discomfort	1	0
Pelvic pain	37	0
<i>Scrotal disorders NEC</i>		
Scrotal dermatitis	1	0
Scrotal pain	8	0
Scrotal swelling	1	0
Varicocele	2	0
<i>Sexual function and fertility disorders NEC</i>		
Infertility	5	0
Infertility female	1	0
Sexual dysfunction	2	0
<i>Spermatogenesis and semen disorders</i>		
Haematospermia	1	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular disorder	2	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Testicular mass	1	0
Testicular pain	21	0
Testicular swelling	7	0
<i>Uterine disorders NEC</i>		
Adenomyosis	1	0
Endometrial hyperplasia	1	0
Endometriosis	22	0
Metrorrhoea	1	0
Uterine haemorrhage	13	0
Uterine pain	8	0
<i>Uterine neoplasms</i>		
Uterine polyp	1	0
<i>Uterine tone disorders</i>		
Uterine spasm	18	0
<i>Vulvovaginal cysts and neoplasms</i>		
Vaginal cyst	1	0
Vulva cyst	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	353	0
Vaginal ulceration	4	0
Vulval haemorrhage	10	0
Vulval ulceration	5	0
<i>Vulvovaginal signs and symptoms</i>		
Coital bleeding	1	0
Labia enlarged	1	0
Vaginal discharge	21	0
Vaginal odour	1	0
Vulvovaginal burning sensation	2	0
Vulvovaginal discomfort	2	0
Vulvovaginal dryness	1	0
Vulvovaginal pain	6	0
Vulvovaginal pruritus	1	0
Vulvovaginal swelling	1	0
Reproductive & breast disorders SOC TOTAL	5307	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Agonal respiration	1	0
Apnoea	1	0
Dyspnoea	1766	0
Dyspnoea at rest	1	0
Dyspnoea exertional	7	0
Hyperventilation	15	0
Hypopnoea	36	0
Hypoventilation	1	0
Irregular breathing	7	0
Mouth breathing	1	0
Obstructive sleep apnoea syndrome	2	0
Respiration abnormal	23	0
Respiratory arrest	2	1
Respiratory distress	2	0
Sleep apnoea syndrome	5	0
Tachypnoea	8	0
<i>Bronchospasm and obstruction</i>		
Asthma	87	0
Asthma exercise induced	2	0
Asthma late onset	1	0
Asthmatic crisis	1	0
Bronchospasm	2	0
Childhood asthma	2	0
Chronic obstructive pulmonary disease	1	0
Obstructive airways disorder	1	0
Wheezing	142	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	5	0
<i>Coughing and associated symptoms</i>		
Allergic cough	3	0
Cough	684	0
Haemoptysis	6	0
Productive cough	40	0
Sputum discoloured	7	0
<i>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</i>		
Reflux laryngitis	1	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Stridor	3	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Hypersensitivity pneumonitis	2	0
Pneumonitis	5	0
Pulmonary sarcoidosis	1	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	16	0
Lower respiratory tract congestion	2	0
Pleuritic pain	4	0
Pulmonary haemorrhage	1	0
Pulmonary pain	32	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	78	0
Nasal inflammation	1	0

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Rhinitis allergic	1	0
Nasal disorders NEC		
Epistaxis	213	0
Nasal crusting	1	0
Nasal dryness	3	0
Nasal oedema	2	0
Nasal pruritus	4	0
Paranasal sinus disorders (excl infections and neoplasms)		
Sinonasal obstruction	5	0
Sinus congestion	13	0
Sinus disorder	4	0
Parenchymal lung disorders NEC		
Emphysema	1	0
Interstitial lung disease	2	0
Pharyngeal disorders (excl infections and neoplasms)		
Pharyngeal erythema	3	0
Pharyngeal hypoaesthesia	5	0
Pharyngeal oedema	4	0
Pharyngeal paraesthesia	6	0
Pharyngeal swelling	67	0
Tonsillar erythema	3	0
Tonsillar hypertrophy	18	0
Tonsillar inflammation	1	0
Pleural infections and inflammations		
Pleurisy	11	0
Pneumothorax and pleural effusions NEC		
Pleural effusion	4	0
Pulmonary hypertensions		
Pulmonary hypertension	1	0
Pulmonary oedemas		
Acute pulmonary oedema	1	0
Pulmonary congestion	2	0
Pulmonary oedema	6	0
Pulmonary thrombotic and embolic conditions		
Pulmonary embolism	86	3
Pulmonary thrombosis	3	0
Respiratory failures (excl neonatal)		
Respiratory failure	2	0
Respiratory signs and symptoms NEC		
Diaphragmalgia	4	0
Painful respiration	4	0
Respiratory symptom	4	0
Use of accessory respiratory muscles	2	0
Respiratory tract disorders NEC		
Allergic respiratory disease	2	0
Lung disorder	1	0
Pulmonary mass	1	0
Respiratory disorder	3	0
Respiratory tract congestion	1	0
Respiratory tract irritation	1	0
Thoracic musculoskeletal disorders		
Respiratory muscle weakness	1	0
Tracheal disorders (excl infections and neoplasms)		

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Tracheal inflammation	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	24	0
Catarrh	8	0
Choking	8	0
Dry throat	33	0
Dysphonia	26	0
Increased viscosity of upper respiratory secretion	5	0
Nasal discomfort	9	0
Oropharyngeal blistering	2	0
Oropharyngeal discomfort	6	0
Oropharyngeal pain	626	0
Paranasal sinus discomfort	8	0
Rhinalgia	6	0
Rhinorrhoea	183	0
Sinus pain	78	0
Sneezing	63	0
Throat clearing	1	0
Throat irritation	44	0
Throat tightness	56	0
Upper-airway cough syndrome	5	0
Yawning	10	0
Respiratory disorders SOC TOTAL	4706	4

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	38	0
Acne cystic	2	0
Dermatitis acneiform	1	0
<i>Alopecias</i>		
Alopecia	80	0
Alopecia areata	19	0
Alopecia totalis	2	0
<i>Angioedemas</i>		
Angioedema	70	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	300	0
Hidradenitis	2	0
Hyperhidrosis	1063	0
Miliaria	71	0
Night sweats	334	0
<i>Bullous conditions</i>		
Blister	109	0
Blister rupture	2	0
Blood blister	3	0
Dermatitis bullous	5	0
Erythema multiforme	16	0
Pemphigoid	2	0
Pemphigus	1	0
Stevens-Johnson syndrome	1	0
<i>Connective tissue disorders</i>		
Cutaneous lupus erythematosus	1	0
Dermatomyositis	2	0
<i>Dermal and epidermal conditions NEC</i>		
Acute febrile neutrophilic dermatosis	1	0
Dry skin	110	0
Pain of skin	153	0
Papule	22	0
Scab	5	0
Scar pain	7	0
Sensitive skin	156	0
Skin burning sensation	83	0
Skin discolouration	47	0
Skin discomfort	2	0
Skin disorder	2	0
Skin induration	8	0
Skin lesion	26	0
Skin necrosis	2	0
Skin odour abnormal	3	0
Skin plaque	1	0
Skin reaction	126	0
Skin sensitisation	16	0
Skin swelling	32	0
Skin texture abnormal	1	0
Skin tightness	7	0
Skin warm	240	0
Skin weeping	4	0
Yellow skin	5	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
<i>Dermatitis and eczema</i>		
Autoimmune dermatitis	1	0
Dermatitis	50	0
Dermatitis allergic	121	0
Dermatitis atopic	20	0
Dermatitis contact	10	0
Dyshidrotic eczema	12	0
Eczema	100	0
Eczema asteatotic	1	0
Eczema nummular	2	0
Eczema weeping	2	0
Flagellate dermatitis	1	0
Hand dermatitis	1	0
Neurodermatitis	1	0
Seborrhoeic dermatitis	1	0
Skin irritation	42	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	5	0
Fixed eruption	2	0
Palmar-plantar erythrodysesthesia syndrome	1	0
<i>Erythemas</i>		
Erythema	1260	0
Vancomycin infusion reaction	1	0
<i>Exfoliative conditions</i>		
Dermatitis exfoliative generalised	2	1
Exfoliative rash	4	0
Skin exfoliation	24	0
<i>Hyperkeratoses</i>		
Hyperkeratosis	1	0
<i>Hyperpigmentation disorders</i>		
Ephelides	2	0
Skin hyperpigmentation	1	0
Solar lentigo	1	0
<i>Hypopigmentation disorders</i>		
Skin hypopigmentation	2	0
Vitiligo	3	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
Nail discolouration	1	0
Nail disorder	1	0
Nail ridging	1	0
Onychalgia	1	0
Onychoclasia	3	0
Onychomadesis	1	0
<i>Panniculitides</i>		
Erythema nodosum	11	0
<i>Papulosquamous conditions</i>		
Lichen planus	5	0
Lichen sclerosus	1	0
Parapsoriasis	1	0
Pityriasis rosea	22	0
<i>Photosensitivity and photodermatitis conditions</i>		
Photosensitivity reaction	22	0
<i>Pigmentation changes NEC</i>		

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Pigmentation disorder	2	0
Pilar disorders NEC		
Hair growth abnormal	2	0
Hair texture abnormal	1	0
Piloerection	16	0
Trichodynia	1	0
Trichorrhexis	1	0
Pruritus NEC		
Itching scar	4	0
Pruritus	2635	0
Psoriatic conditions		
Guttate psoriasis	4	0
Palmoplantar pustulosis	1	0
Psoriasis	41	0
Rebound psoriasis	1	0
Purpura and related conditions		
Henoch-Schonlein purpura	1	0
Petechiae	27	0
Purpura	14	0
Rashes, eruptions and exanthems NEC		
Butterfly rash	1	0
Rash	3024	0
Rash erythematous	1161	0
Rash macular	207	0
Rash maculo-papular	8	0
Rash morbilliform	9	0
Rash papular	194	0
Rash pruritic	649	0
Rash vesicular	14	0
Rosaceas		
Rosacea	2	0
Scaly conditions		
Pityriasis	6	0
Sebaceous gland disorders		
Seborrhoea	2	0
Skin and subcutaneous conditions NEC		
Cutaneous symptom	5	0
Skin mass	13	0
Skin and subcutaneous tissue ulcerations		
Skin erosion	8	0
Skin ulcer	6	0
Skin cysts and polyps		
Dermal cyst	8	0
Skin dystrophies		
Keloid scar	2	0
Skin wrinkling	1	0
Skin haemorrhages		
Haemorrhage subcutaneous	1	0
Skin haemorrhage	4	0
Skin hypoplasias and atrophies		
Skin atrophy	3	0
Skin injuries and mechanical dermatoses		
Decubitus ulcer	1	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Needle track marks	2	0
Skin vasculitides		
Capillaritis	1	0
Cutaneous vasculitis	3	0
Hypersensitivity vasculitis	1	0
Vasculitic rash	3	0
Skin vasomotor conditions		
Livedo reticularis	5	0
Telangiectasia and related conditions		
Spider naevus	1	0
Urticarias		
Chronic spontaneous urticaria	6	0
Cold urticaria	1	0
Idiopathic urticaria	5	0
Mechanical urticaria	28	0
Urticaria	741	0
Urticaria aquagenic	1	0
Urticaria cholinergic	1	0
Urticaria chronic	8	0
Urticaria contact	1	0
Urticaria papular	1	0
Urticarial vasculitis	1	0
Skin disorders SOC TOTAL	13817	1

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Reaction Name	Total	Fatal
Social circumstances		
<i>Age related issues</i>		
Menarche	2	0
Menopause	11	0
Postmenopause	2	0
<i>Disability issues</i>		
Bedridden	13	0
Disability	1	0
Immobile	7	0
Impaired driving ability	2	0
Impaired work ability	4	0
Loss of personal independence in daily activities	14	0
Sight disability	2	0
Walking aid user	1	0
<i>Employment issues</i>		
Retirement	2	0
<i>Non-occupational and unspecified environmental problems</i>		
Water pollution	2	0
<i>Pregnancy related circumstances</i>		
Breast feeding	6	0
<i>Social issues NEC</i>		
Social problem	1	0
Tattoo	1	0
Social circumstances SOC TOTAL	71	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Anaesthesia and allied procedures</i>		
Light anaesthesia	1	0
<i>Analgesia supportive care</i>		
Analgesic therapy	1	0
<i>Breast therapeutic procedures NEC</i>		
Axillary lymphadenectomy	2	0
<i>Contraceptive methods female</i>		
Post coital contraception	1	0
<i>Dental and gingival therapeutic procedures</i>		
Tooth extraction	1	0
<i>Dietary and nutritional therapies</i>		
Medical diet	1	0
<i>Eye therapeutic procedures NEC</i>		
Eye irrigation	1	0
<i>Gastrointestinal therapeutic procedures NEC</i>		
Prophylaxis of nausea and vomiting	2	0
<i>Gynaecological therapeutic procedures NEC</i>		
Menstrual cycle management	3	0
<i>Haematological therapeutic procedures NEC</i>		
Bone marrow transplant	1	0
<i>Hormonal therapeutic procedures NEC</i>		
Hormone replacement therapy	1	0
<i>Immunisations</i>		
COVID-19 immunisation	26	0
Immunisation	22	0
Influenza immunisation	1	0
Vaccine coadministration	1	0
<i>Joint therapeutic procedures</i>		
Joint injection	1	0
Joint stabilisation	1	0
<i>Limb therapeutic procedures</i>		
Limb immobilisation	1	0
<i>Psychiatric therapies</i>		
Electroconvulsive therapy	1	0
<i>Respiratory tract therapeutic procedures NEC</i>		
Asthma prophylaxis	2	0
<i>Skin and subcutaneous tissue therapeutic procedures NEC</i>		
Dermal filler injection	3	0
<i>Therapeutic procedures NEC</i>		
Bed rest	6	0
Botulinum toxin injection	1	0
Hospitalisation	4	0
Injection	17	0
Interchange of vaccine products	57	0
Mass excision	1	0
Polypectomy	1	0
Surgical & medical procedures SOC TOTAL	161	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Accelerated and malignant hypertension</i>		
Hypertensive urgency	1	0
<i>Aneurysms and dissections non-site specific</i>		
Aneurysm ruptured	1	0
<i>Aortic necrosis and vascular insufficiency</i>		
Aortic stenosis	1	0
<i>Arterial infections and inflammations</i>		
Giant cell arteritis	5	0
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	3	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	13	0
Neurogenic shock	1	0
Shock	6	0
<i>Haemorrhages NEC</i>		
Bloody discharge	2	0
Haematoma	10	0
Haemorrhage	246	0
Internal haemorrhage	3	0
<i>Lymphangiopathies</i>		
Lymphocele	1	0
<i>Lymphoedemas</i>		
Lymphoedema	30	0
<i>Non-site specific embolism and thrombosis</i>		
Embolism	3	0
Embolism venous	1	0
Thrombosis	79	0
Venous thrombosis	1	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Arterial spasm	1	0
Arteriosclerosis	1	0
Haemorrhagic infarction	1	0
Infarction	1	0
Ischaemia	1	0
Peripheral venous disease	1	0
Vasospasm	1	0
<i>Non-site specific vascular disorders NEC</i>		
Vascular pain	8	0
Vasodilatation	3	0
Vein discolouration	1	0
Vein rupture	2	0
<i>Peripheral embolism and thrombosis</i>		
Axillary vein thrombosis	1	0
Blue toe syndrome	8	0
Deep vein thrombosis	66	0
Pelvic venous thrombosis	2	0
Superficial vein thrombosis	3	0
Thrombophlebitis	6	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	14	0
Erythromelalgia	1	0
Flushing	62	0
Hot flush	325	0

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Reaction Name	Total	Fatal
Vascular disorders <small>Vascular disorders cont'd</small>		
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Extremity necrosis	1	0
Peripheral coldness	114	0
Peripheral ischaemia	1	0
Poor peripheral circulation	2	0
Raynaud's phenomenon	14	0
<i>Phlebitis NEC</i>		
Phlebitis	2	0
Phlebitis superficial	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	92	0
<i>Varicose veins NEC</i>		
Spider vein	1	0
Varicophlebitis	1	0
Varicose vein	8	0
Varicose vein ruptured	1	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	132	0
Prehypertension	1	0
White coat hypertension	1	0
<i>Vascular hypotensive disorders</i>		
Capillary leak syndrome	2	0
Hypotension	120	0
Orthostatic hypotension	6	0
<i>Vasculitides NEC</i>		
MAGIC syndrome	1	0
Vasculitis	10	0
<i>Vena caval embolism and thrombosis</i>		
Vena cava thrombosis	1	0
Vascular disorders SOC TOTAL	1428	0
TOTAL REACTIONS FOR DRUG	134340	70
TOTAL REPORTS	40576	
TOTAL FATAL OUTCOME REPORTS		70