

COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 14-Oct-2021
Data Lock Date: 13-Oct-2021 18:30:20

All UK spontaneous reports received between 04/01/21 and 13/10/21 for COVID-19 vaccine Oxford University/AstraZeneca

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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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemia deficiencies</i>		
Anaemia folate deficiency	2	0
Anaemia vitamin B12 deficiency	14	0
Iron deficiency anaemia	16	0
Pernicious anaemia	6	0
<i>Anaemias NEC</i>		
Anaemia	167	0
Autoimmune anaemia	1	0
Blood loss anaemia	4	0
Hypochromic anaemia	2	0
Microcytic anaemia	1	0
Normocytic anaemia	4	0
<i>Anaemias haemolytic NEC</i>		
Haemolytic anaemia	11	0
<i>Anaemias haemolytic immune</i>		
Autoimmune haemolytic anaemia	8	0
<i>Anaemias haemolytic mechanical factor</i>		
Atypical haemolytic uraemic syndrome	1	0
Red cell fragmentation syndrome	1	0
<i>Bleeding tendencies</i>		
Increased tendency to bruise	133	0
Spontaneous haematoma	8	0
Spontaneous haemorrhage	2	0
<i>Coagulation factor deficiencies</i>		
Acquired haemophilia	1	0
Hypofibrinogenaemia	4	0
<i>Coagulopathies</i>		
Abnormal clotting factor	10	0
Antiphospholipid syndrome	28	0
Coagulopathy	77	0
Disseminated intravascular coagulation	18	2
Hypercoagulation	24	1
Hypocoagulable state	1	0
<i>Eosinophilic disorders</i>		
Eosinophilia	19	0
Hypereosinophilic syndrome	1	0
<i>Haematological cysts and polyps</i>		
Splenic cyst	1	0
<i>Haematological disorders</i>		
Blood disorder	12	0
Bone marrow disorder	2	0
Bone marrow oedema	1	0
Mast cell activation syndrome	9	0
Mastocytosis	3	0
Methaemoglobinaemia	1	0
<i>Haemolyses NEC</i>		
Haemolysis	11	0
<i>Leukocytoses NEC</i>		
Leukocytosis	4	0
Lymphocytosis	11	0
Monocytosis	2	0
Neutrophilia	14	0
<i>Leukopenias NEC</i>		

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Reaction Name	Total	Fatal
Blood disorders Blood disorders cont'd		
Leukopenia	11	0
Lymphopenia	9	0
Lymphatic system disorders NEC		
Abdominal lymphadenopathy	1	0
Hilar lymphadenopathy	1	0
Lymph node fibrosis	1	0
Lymph node pain	573	0
Lymphadenitis	32	0
Lymphadenopathy	4880	0
Lymphadenopathy mediastinal	1	0
Lymphatic disorder	2	0
Lymphoid tissue hyperplasia	1	0
Pseudolymphoma	4	0
Marrow depression and hypoplastic anaemias		
Aplastic anaemia	6	0
Cytopenia	1	0
Myelosuppression	5	0
Pancytopenia	18	0
Neutropenias		
Agranulocytosis	4	0
Autoimmune neutropenia	2	0
Febrile neutropenia	1	0
Neutropenia	82	0
Platelet disorders NEC		
Platelet anisocytosis	4	0
Platelet disorder	6	0
Polycythaemia (excl rubra vera)		
Polycythaemia	2	0
Stress polycythaemia	3	0
Purpuras (excl thrombocytopenic)		
Purpura non-thrombocytopenic	3	0
Red blood cell abnormal findings NEC		
Anisocytosis	3	0
Macrocytosis	3	0
Poikilocytosis	1	0
Polychromasia	4	0
Rouleaux formation	1	0
Sickle cell trait and disorders		
Sickle cell anaemia with crisis	6	0
Spleen disorders		
Spleen disorder	1	0
Splenic artery thrombosis	3	0
Splenic haemorrhage	1	0
Splenic infarction	16	0
Splenic thrombosis	1	0
Splenic varices	1	0
Splenic vein thrombosis	11	0
Splenomegaly	7	0
Splenorenal shunt	1	0
Thrombocytopenias		
Autoimmune heparin-induced thrombocytopenia	1	0
Heparin-induced thrombocytopenia	12	0
Immune thrombocytopenia	229	1

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Blood disorders Blood disorders cont'd		
Thrombocytopenia	870	7
Thrombocytopenic purpura	10	0
Thrombotic thrombocytopenic purpura	9	0
Thrombocytoses		
Thrombocytosis	12	0
White blood cell abnormal findings NEC		
White blood cell disorder	3	0
Blood disorders SOC TOTAL	7494	11

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Aortic valvular disorders</i>		
Aortic valve incompetence	2	0
Aortic valve sclerosis	1	0
Aortic valve stenosis	1	0
<i>Cardiac conduction disorders</i>		
Atrioventricular block	28	1
Atrioventricular block complete	3	0
Atrioventricular block first degree	2	0
Atrioventricular block second degree	5	0
Brugada syndrome	1	0
Bundle branch block	2	0
Bundle branch block left	9	0
Bundle branch block right	4	0
Long QT syndrome	1	0
Trifascicular block	1	0
<i>Cardiac disorders NEC</i>		
Acute cardiac event	4	2
Atrial thrombosis	5	0
Cardiac disorder	77	1
Cardiac dysfunction	2	0
Cardiac ventricular thrombosis	12	2
Cardiovascular disorder	9	0
Cardiovascular insufficiency	10	0
Intracardiac thrombus	14	2
<i>Cardiac hypertensive complications</i>		
Hypertensive heart disease	2	0
<i>Cardiac infections and inflammations NEC</i>		
Carditis	2	0
<i>Cardiac signs and symptoms NEC</i>		
Cardiac discomfort	14	0
Cardiovascular symptom	3	0
Palpitations	5257	1
<i>Cardiac valve disorders NEC</i>		
Cardiac valve disease	3	1
Heart valve incompetence	4	0
<i>Cardiomyopathies</i>		
Cardiomyopathy	14	1
Congestive cardiomyopathy	13	2
Stress cardiomyopathy	5	0
<i>Coronary artery disorders NEC</i>		
Arteriosclerosis coronary artery	7	1
Coronary artery disease	7	0
Coronary artery dissection	5	1
Coronary artery embolism	1	0
Coronary artery occlusion	2	0
Coronary artery thrombosis	23	3
<i>Heart failures NEC</i>		
Cardiac failure	90	12
Cardiac failure acute	13	4
Cardiac failure chronic	2	1
Cardiac failure congestive	5	2
Cardiogenic shock	10	2
Cardiopulmonary failure	1	1

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Reaction Name	Total	Fatal
Cardiac disorders Cardiac disorders cont'd		
Ventricular failure	1	0
Ischaemic coronary artery disorders		
Acute coronary syndrome	9	0
Acute myocardial infarction	84	13
Angina pectoris	230	0
Angina unstable	17	0
Arteriospasm coronary	5	0
Microvascular coronary artery disease	2	0
Myocardial infarction	409	52
Myocardial ischaemia	28	12
Prinzmetal angina	1	0
Left ventricular failures		
Acute left ventricular failure	2	0
Left ventricular failure	8	1
Mitral valvular disorders		
Ischaemic mitral regurgitation	1	0
Mitral valve disease	1	0
Mitral valve incompetence	7	0
Mitral valve prolapse	3	0
Myocardial disorders NEC		
Cardiac aneurysm	1	0
Cardiac sarcoidosis	1	0
Cardiomegaly	25	1
Diastolic dysfunction	2	0
Dilatation ventricular	1	0
Left atrial dilatation	1	0
Left ventricular dilatation	2	0
Left ventricular dysfunction	19	0
Left ventricular hypertrophy	1	0
Myocardial fibrosis	1	0
Myocardial rupture	1	0
Right atrial dilatation	2	0
Right ventricular dilatation	3	0
Right ventricular dysfunction	4	0
Systolic dysfunction	1	0
Ventricular hypertrophy	5	1
Ventricular hypokinesia	1	0
Noninfectious myocarditis		
Myocarditis	120	2
Noninfectious pericarditis		
Pericarditis	177	0
Pericardial disorders NEC		
Cardiac tamponade	2	2
Pericardial effusion	33	0
Pericardial haemorrhage	6	3
Pericardial rub	1	0
Rate and rhythm disorders NEC		
Arrhythmia	141	3
Arrhythmia neonatal	1	0
Bradycardia	79	0
Cardiac fibrillation	9	0
Cardiac flutter	270	0
Extrasystoles	147	0

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Cardiac disorders Cardiac disorders cont'd		
Heart alternation	3	0
Paroxysmal arrhythmia	2	0
Postural orthostatic tachycardia syndrome	21	0
Tachyarrhythmia	11	0
Tachycardia	1251	0
Right ventricular failures		
Right ventricular failure	3	1
Supraventricular arrhythmias		
Arrhythmia supraventricular	16	0
Atrial fibrillation	321	0
Atrial flutter	42	0
Atrial tachycardia	3	0
Sinus arrest	1	0
Sinus arrhythmia	2	0
Sinus bradycardia	4	0
Sinus node dysfunction	2	0
Sinus tachycardia	69	1
Supraventricular extrasystoles	1	0
Supraventricular tachycardia	42	0
Tricuspid valvular disorders		
Tricuspid valve incompetence	6	0
Ventricular arrhythmias and cardiac arrest		
Cardiac arrest	171	36
Cardio-respiratory arrest	2	1
Pulseless electrical activity	7	0
Ventricular arrhythmia	1	0
Ventricular extrasystoles	16	0
Ventricular fibrillation	8	1
Ventricular tachycardia	15	0
Cardiac disorders SOC TOTAL	9561	170

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Autosomal chromosomal abnormalities</i>		
Trisomy 18	1	0
Trisomy 21	1	0
<i>Cardiac disorders congenital NEC</i>		
Heart disease congenital	12	0
<i>Cardiac septal defects congenital</i>		
Hypertrophic cardiomyopathy	3	0
Ventricular septal defect	1	0
<i>Central nervous system disorders congenital NEC</i>		
Brain malformation	1	0
Encephalocele	1	0
Neural tube defect	1	1
Syringomyelia	1	0
<i>Cerebellar disorders congenital</i>		
Arnold-Chiari malformation	2	0
<i>Cerebral disorders congenital</i>		
Anencephaly	1	0
Cerebral palsy	2	0
<i>Coagulation disorders congenital</i>		
Factor VII deficiency	1	0
Protein C deficiency	1	0
<i>Congenital disorders NEC</i>		
Congenital anomaly	2	0
Congenital midline defect	1	0
Multiple congenital abnormalities	1	0
Young's syndrome	1	0
<i>Connective tissue disorders congenital</i>		
Ehlers-Danlos syndrome	6	0
<i>Diaphragmatic disorders congenital</i>		
Congenital diaphragmatic hernia	2	0
<i>Gene mutations and other alterations NEC</i>		
Tuberous sclerosis complex	1	0
<i>Great vessel disorders congenital</i>		
Coarctation of the aorta	1	0
Transposition of the great vessels	1	0
<i>Haemoglobinopathies congenital</i>		
Sickle cell trait	1	0
<i>Immune system abnormalities congenital</i>		
Combined immunodeficiency	1	0
<i>Inborn errors of porphyrin metabolism</i>		
Porphyria acute	1	0
<i>Lacrimal system disorders congenital</i>		
Dacryostenosis congenital	1	0
<i>Lysosomal storage disorders</i>		
Mucopolysaccharidosis	1	0
<i>Male reproductive tract disorders congenital</i>		
Hydrocele	2	0
Micropenis	2	0
Penoscrotal fusion	3	0
<i>Musculoskeletal and connective tissue disorders of face, neck and jaw congenital</i>		
Branchial cyst	2	0
<i>Musculoskeletal and connective tissue disorders of limbs congenital</i>		

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Reaction Name	Total	Fatal
Congenital disorders Congenital disorders cont'd		
Limb reduction defect	2	0
Musculoskeletal disorders congenital NEC		
Congenital multiplex arthrogyposis	1	0
Dysmorphism	2	0
Neurological disorders congenital NEC		
Epilepsy with myoclonic-atonic seizures	1	0
Familial hemiplegic migraine	1	0
Spinal muscular atrophy	1	0
Tourette's disorder	2	0
Ocular disorders congenital NEC		
Colour blindness	8	0
Pancreatic disorders congenital		
Hereditary pancreatitis	1	0
Peripheral nervous system disorders congenital NEC		
Paroxysmal extreme pain disorder	12	0
Pulmonary and bronchial disorders congenital		
Cystic fibrosis	2	0
Sex chromosomal abnormalities		
Klinefelter's syndrome	1	0
Tongue disorders congenital		
Ankyloglossia congenital	1	0
Macroglossia	1	0
Vascular anomalies congenital NEC		
Arteriovenous malformation	1	0
Congenital disorders SOC TOTAL	96	1

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear canal erythema	1	0
Ear congestion	34	0
Ear discomfort	119	0
Ear disorder	21	0
Ear haemorrhage	18	0
Ear pain	2057	0
Ear pruritus	7	0
Ear swelling	72	0
Otorrhoea	8	0
Paraesthesia ear	1	0
<i>Eustachian tube disorders</i>		
Eustachian tube disorder	7	0
Eustachian tube dysfunction	5	0
Eustachian tube obstruction	7	0
<i>External ear disorders NEC</i>		
Excessive cerumen production	38	0
External ear pain	14	0
Juvenile spring eruption	1	0
Red ear syndrome	5	0
<i>External ear infections and inflammations</i>		
External ear inflammation	4	0
<i>Hearing disorders NEC</i>		
Auditory disorder	8	0
<i>Hearing losses</i>		
Conductive deafness	1	0
Deafness	378	0
Deafness bilateral	18	0
Deafness neurosensory	38	0
Deafness transitory	4	0
Deafness unilateral	53	0
Hypoacusis	235	0
Mixed deafness	3	0
Neurosensory hypoacusis	2	0
Sudden hearing loss	75	0
<i>Hyperacusia</i>		
Hyperacusis	168	0
<i>Inner ear disorders NEC</i>		
Inner ear disorder	6	0
Meniere's disease	30	0
Vestibular disorder	8	0
<i>Inner ear infections and inflammations</i>		
Autoimmune inner ear disease	1	0
Inner ear inflammation	5	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	127	0
Phobic postural vertigo	2	0
Tinnitus	4096	0
Vertigo	2192	0
Vertigo labyrinthine	13	0
Vertigo positional	154	0
<i>Middle ear disorders NEC</i>		
Middle ear disorder	1	0

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Reaction Name	Total	Fatal
Ear disorders Ear disorders cont'd		
Middle ear effusion	6	0
<i>Tympanic membrane disorders (excl infections)</i>		
Tympanic membrane perforation	5	0
Ear disorders SOC TOTAL	10048	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Autoimmune thyroiditis	7	0
Thyroiditis	19	0
Thyroiditis acute	7	0
Thyroiditis chronic	1	0
Thyroiditis subacute	8	0
<i>Adrenal cortical hyperfunctions</i>		
Cushing's syndrome	2	0
Cushingoid	5	0
<i>Adrenal cortical hypofunctions</i>		
Addison's disease	2	0
Adrenal insufficiency	22	0
Adrenocortical insufficiency acute	30	0
Glucocorticoid deficiency	1	0
Secondary adrenocortical insufficiency	1	0
<i>Adrenal gland disorders NEC</i>		
Adrenal disorder	1	0
Adrenal haemorrhage	7	0
Adrenal mass	1	0
Adrenal thrombosis	1	0
Adrenomegaly	2	0
Haemorrhagic adrenal infarction	4	0
<i>Anterior pituitary hyperfunction</i>		
Hyperprolactinaemia	2	0
<i>Anterior pituitary hypofunction</i>		
Hypopituitarism	2	0
Luteal phase deficiency	2	0
<i>Ectopic endocrine disorders</i>		
Carcinoid syndrome	1	0
<i>Endocrine abnormalities of gonadal function NEC</i>		
Oestrogenic effect	1	0
<i>Endocrine abnormalities of puberty</i>		
Delayed menarche	1	0
Premature menarche	17	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	22	0
Ovulation delayed	15	0
<i>Hyperparathyroid disorders</i>		
Hyperparathyroidism	2	0
<i>Hypoparathyroid disorders</i>		
Hypoparathyroidism	2	0
Primary hypoparathyroidism	1	0
<i>Hypothalamic and pituitary disorders NEC</i>		
Hypothalamo-pituitary disorder	2	0
Pituitary apoplexy	2	0
Pituitary haemorrhage	1	0
<i>Posterior pituitary disorders</i>		
Diabetes insipidus	8	0
Inappropriate antidiuretic hormone secretion	1	0
<i>Thyroid disorders NEC</i>		
Autoimmune thyroid disorder	1	0
Euthyroid sick syndrome	1	0
Goitre	23	0

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Reaction Name	Total	Fatal
Endocrine disorders Endocrine disorders cont'd		
Thyroid disorder	18	0
Thyroid mass	6	0
Thyroid pain	17	0
Thyroid hyperfunction disorders		
Basedow's disease	17	0
Hyperthyroidism	57	0
Thyrotoxic crisis	6	0
Thyroid hypofunction disorders		
Hypothyroidism	54	0
Thyroid neoplasms		
Thyroid cyst	1	0
Endocrine disorders SOC TOTAL	404	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Amblyopic vision impairment</i>		
Amblyopia	12	0
<i>Cataract conditions</i>		
Cataract	19	0
Cataract cortical	2	0
Cataract subcapsular	4	0
<i>Choroid and vitreous haemorrhages and vascular disorders</i>		
Vitreous haematoma	1	0
Vitreous haemorrhage	7	0
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Chorioretinopathy	2	0
Vitreous detachment	56	0
Vitreous floaters	198	0
Vitreous opacities	1	0
<i>Colour blindness (incl acquired)</i>		
Dyschromatopsia	17	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	124	0
Corneal neovascularisation	1	0
Scleral haemorrhage	1	0
<i>Conjunctival infections, irritations and inflammations</i>		
Conjunctival hyperaemia	2	0
Conjunctivitis allergic	2	0
<i>Conjunctival structural change, deposit and degeneration</i>		
Conjunctival bleb	1	0
Conjunctival disorder	1	0
<i>Corneal infections, oedemas and inflammations</i>		
Keratitis	4	0
Ulcerative keratitis	4	0
<i>Corneal structural change, deposit and degeneration</i>		
Corneal perforation	1	0
Corneal scar	1	0
<i>Eyelid movement disorders</i>		
Blepharospasm	149	0
Excessive eye blinking	8	0
Eyelid function disorder	1	0
Eyelid myokymia	2	0
Eyelid ptosis	59	0
Paralytic lagophthalmos	1	0
<i>Glaucomas (excl congenital)</i>		
Angle closure glaucoma	5	0
Glaucoma	12	0
<i>Iris and ciliary body structural change, deposit and degeneration</i>		
Eye colour change	9	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Autoimmune uveitis	1	0
Iridocyclitis	23	0
Iritis	13	0
Uveitis	46	0
<i>Lacrimation disorders</i>		
Dry eye	309	0
Lacrimation increased	258	0
<i>Lens structural change, deposit and degeneration (excl cataracts)</i>		

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Eye disorders Eye disorders cont'd		
Anterior capsule contraction	1	0
<i>Lid bleeding and vascular disorders</i>		
Eyelid bleeding	3	0
Eyelid haematoma	3	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Blepharitis	29	0
Chalazion	2	0
Eczema eyelids	5	0
Erythema of eyelid	7	0
Eyelid cyst	16	0
Eyelid irritation	4	0
Eyelid margin crusting	1	0
Eyelid oedema	12	0
Eyelid rash	15	0
Meibomianitis	1	0
Swelling of eyelid	128	0
<i>Lid, lash and lacrimal structural disorders</i>		
Blepharal pigmentation	1	0
Ectropion	1	0
Eyelid exfoliation	3	0
Eyelid skin dryness	5	0
Eyelid thickening	4	0
Growth of eyelashes	10	0
Lagophthalmos	4	0
<i>Ocular bleeding and vascular disorders NEC</i>		
Eye haematoma	4	0
Eye haemorrhage	109	0
Ocular retrobulbar haemorrhage	1	0
Ocular vascular disorder	2	0
Ophthalmic vein thrombosis	3	0
<i>Ocular cysts and polyps</i>		
Vitreous cyst	1	0
<i>Ocular disorders NEC</i>		
Dark circles under eyes	9	0
Eye disorder	36	0
Eye oedema	18	0
Eye pain	3312	0
Eye swelling	618	0
Eye symptom	11	0
Eye ulcer	10	0
Eyelid disorder	16	0
Eyelid pain	20	0
Eyelids pruritus	11	0
Ocular discomfort	81	0
Periorbital discomfort	1	0
Periorbital oedema	17	0
Periorbital pain	4	0
Periorbital swelling	106	0
Retinal disorder	1	0
Retinal fovea disorder	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Autoimmune eye disorder	1	0
Eye allergy	31	0

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Eye disorders Eye disorders cont'd		
Eye discharge	27	0
Eye inflammation	32	0
Eye irritation	202	0
Eye pruritus	301	0
Limbal swelling	8	0
Ocular hyperaemia	456	0
Ocular rosacea	1	0
Ocular nerve and muscle disorders		
Extraocular muscle paresis	13	0
Eye movement disorder	55	0
Gaze palsy	4	0
Ocular myasthenia	2	0
Ophthalmoplegia	1	0
Parinaud syndrome	1	0
Strabismus	5	0
Ocular sensation disorders		
Abnormal sensation in eye	26	0
Asthenopia	357	0
Eye paraesthesia	5	0
Eyelid sensory disorder	5	0
Foreign body sensation in eyes	36	0
Hypoaesthesia eye	29	0
Photophobia	1058	0
Optic disc abnormalities NEC		
Optic atrophy	1	0
Optic discs blurred	3	0
Papilloedema	15	0
Optic nerve bleeding and vascular disorders		
Optic disc haemorrhage	2	0
Optic ischaemic neuropathy	11	0
Optic nerve sheath haemorrhage	1	0
Orbital infections, inflammations and irritations		
Parophthalmia	1	0
Orbital structural change, deposit and degeneration		
Lid sulcus deepened	3	0
Pupil disorders		
Holmes-Adie pupil	1	0
Miosis	14	0
Mydriasis	35	0
Pupil fixed	14	0
Pupillary deformity	1	0
Pupillary reflex impaired	3	0
Pupils unequal	11	0
Refractive and accommodative disorders		
Altered visual depth perception	5	0
Hypermetropia	2	0
Myopia	5	0
Refraction disorder	1	0
Retinal bleeding and vascular disorders (excl retinopathy)		
Retinal aneurysm	2	0
Retinal artery embolism	5	0
Retinal artery occlusion	22	0
Retinal haemorrhage	18	0

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Retinal infarction	1	0
Retinal ischaemia	2	0
Retinal vascular occlusion	3	0
Retinal vascular thrombosis	4	0
Retinal vein occlusion	93	0
Retinal vein thrombosis	7	0
Retinal vein varices	1	0
Retinal vessel avulsion	1	0
<i>Retinal structural change, deposit and degeneration</i>		
Macular cyst	1	0
Macular degeneration	9	0
Macular detachment	1	0
Macular hole	2	0
Macular rupture	1	0
Maculopathy	3	0
Neovascular age-related macular degeneration	12	0
Retinal detachment	28	0
Retinal drusen	1	0
Retinal tear	19	0
Retinal toxicity	5	0
Vitreoretinal traction syndrome	1	0
<i>Retinal, choroid and vitreous infections and inflammations</i>		
Cystoid macular oedema	1	0
Macular oedema	7	0
Retinal oedema	2	0
Retinal vasculitis	1	0
<i>Retinopathies NEC</i>		
Acute macular outer retinopathy	4	0
Acute zonal occult outer retinopathy	1	0
Diabetic retinopathy	2	0
Retinal exudates	18	0
Retinopathy	7	0
<i>Scleral infections, irritations and inflammations</i>		
Episcleritis	18	0
Scleritis	13	0
<i>Scleral structural change, deposit and degeneration</i>		
Scleral discolouration	1	0
<i>Structural change, deposit and degeneration of eye NEC</i>		
Deposit eye	1	0
Endocrine ophthalmopathy	4	0
Exophthalmos	6	0
Eye opacity	1	0
<i>Visual colour distortions</i>		
Chloropsia	2	0
Chromatopsia	1	0
Cyanopsia	3	0
Erythropsia	7	0
Xanthopsia	9	0
<i>Visual disorders NEC</i>		
Charles Bonnet syndrome	1	0
Delayed dark adaptation	1	0
Diplopia	335	0
Dysmetropsia	1	0

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Halo vision	13	0
Metamorphopsia	39	0
Oscillopsia	1	0
Photopsia	332	0
Scintillating scotoma	10	0
Vision blurred	3002	0
Visual brightness	10	0
Visual snow syndrome	5	0
Visual field disorders		
Visual field defect	38	0
Visual impairment and blindness (excl colour blindness)		
Amaurosis fugax	9	0
Blindness	293	0
Blindness day	1	0
Blindness transient	25	0
Blindness unilateral	40	0
Central vision loss	2	0
Night blindness	5	0
Sudden visual loss	5	0
Visual acuity reduced	40	0
Visual acuity reduced transiently	1	0
Visual impairment	771	0
Visual pathway disorders		
Optic nerve compression	1	0
Optic nerve disorder	4	0
Optic neuropathy	9	0
Eye disorders SOC TOTAL	14134	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Abdominal findings abnormal</i>		
Abdominal mass	4	0
Gastrointestinal sounds abnormal	26	0
<i>Abdominal hernias NEC</i>		
Internal hernia	1	0
<i>Acute and chronic pancreatitis</i>		
Obstructive pancreatitis	1	1
Pancreatitis	38	2
Pancreatitis acute	18	0
Pancreatitis chronic	1	0
Pancreatitis necrotising	1	0
<i>Anal and rectal disorders NEC</i>		
Anal fissure	2	0
<i>Anal and rectal pains</i>		
Proctalgia	27	0
<i>Anal and rectal signs and symptoms</i>		
Anal blister	2	0
Anal hypoaesthesia	6	0
Anal inflammation	2	0
Anal paraesthesia	2	0
Anal pruritus	6	0
Anal spasm	1	0
Anorectal discomfort	12	0
Anorectal swelling	1	0
Rectal discharge	1	0
Rectal spasm	2	0
Rectal tenesmus	2	0
<i>Anal and rectal ulcers and perforation</i>		
Anal ulcer	2	0
<i>Benign oral cavity neoplasms</i>		
Mouth cyst	14	0
Tongue cyst	5	0
Tongue polyp	2	0
<i>Colitis (excl infective)</i>		
Autoimmune colitis	4	0
Colitis	59	0
Colitis ischaemic	7	1
Colitis microscopic	6	0
Colitis ulcerative	104	0
Crohn's disease	100	0
Inflammatory bowel disease	12	0
Terminal ileitis	1	0
<i>Cystic pancreatic disorders</i>		
Pancreatic cyst	1	0
<i>Dental and periodontal infections and inflammations</i>		
Dental caries	5	0
<i>Dental disorders NEC</i>		
Diastema	1	0
Loose tooth	2	0
Malpositioned teeth	3	0
Teething	21	0
Tooth disorder	4	0
Tooth impacted	1	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Tooth socket haemorrhage	2	0
<i>Dental pain and sensation disorders</i>		
Dental discomfort	12	0
Dental paraesthesia	18	0
Hyperaesthesia teeth	65	0
Hypoaesthesia teeth	2	0
Toothache	339	0
<i>Dental pulp disorders</i>		
Dental pulp disorder	1	0
<i>Dental surface disorders</i>		
Tooth discolouration	19	0
<i>Diaphragmatic hernias</i>		
Hiatus hernia	19	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	8845	0
Diarrhoea haemorrhagic	34	0
<i>Diverticula</i>		
Diverticulum	10	0
<i>Duodenal and small intestinal stenosis and obstruction</i>		
Small intestinal obstruction	1	0
Superior mesenteric artery syndrome	1	0
<i>Duodenal ulcers and perforation</i>		
Duodenal ulcer	2	0
Duodenal ulcer haemorrhage	2	1
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	885	0
Epigastric discomfort	20	0
Eructation	105	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	23	0
Faecaloma	4	0
Faeces discoloured	54	0
Faeces hard	4	0
Faeces pale	7	0
Faeces soft	23	0
Mucous stools	15	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	696	1
Flatulence	398	0
<i>Gastric and oesophageal haemorrhages</i>		
Gastric haemorrhage	14	1
<i>Gastric ulcers and perforation</i>		
Gastric ulcer	14	0
Gastric ulcer haemorrhage	1	0
Gastric ulcer perforation	1	0
<i>Gastritis (excl infective)</i>		
Chronic gastritis	5	0
Gastritis	106	0
Reflux gastritis	16	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal migraine	3	0
Abdominal pain	4541	0
Abdominal pain lower	263	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Abdominal pain upper	5222	0
Abdominal rigidity	62	0
Abdominal tenderness	22	0
Gastrointestinal pain	326	0
Oesophageal pain	8	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	487	0
Duodenogastric reflux	2	0
Gastric dilatation	18	0
Gastrooesophageal reflux disease	238	0
Impaired gastric emptying	6	0
Infrequent bowel movements	3	0
Intestinal dilatation	1	0
<i>Gastrointestinal disorders NEC</i>		
Appendix disorder	3	0
Food poisoning	13	0
Functional gastrointestinal disorder	18	0
Gastric disorder	13	0
Gastrointestinal disorder	43	0
Gastrointestinal oedema	3	0
Gastroptosis	1	0
Neurogenic bowel	3	0
Stomach mass	2	0
<i>Gastrointestinal dyskinetic disorders</i>		
Bowel movement irregularity	8	0
Change of bowel habit	20	0
Dyschezia	13	0
Gastrointestinal motility disorder	5	0
Oesophageal achalasia	4	0
<i>Gastrointestinal fistulae</i>		
Anal fistula	1	0
<i>Gastrointestinal inflammatory disorders NEC</i>		
Appendicitis noninfective	2	0
Enteritis	1	0
Gastrointestinal inflammation	2	0
Gastrointestinal tract irritation	4	0
Intestinal angioedema	1	0
Ischaemic enteritis	1	0
<i>Gastrointestinal mucosal dystrophies and secretion disorders</i>		
Achlorhydria	1	0
Barrett's oesophagus	1	0
Hyperchlorhydria	4	0
<i>Gastrointestinal necrosis and gangrene (excl gangrenous hernia)</i>		
Gastrointestinal necrosis	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	1586	0
Abdominal symptom	6	0
Acute abdomen	18	0
Anal incontinence	53	0
Breath odour	25	0
Dysphagia	279	0
Intestinal congestion	1	0
Odynophagia	34	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Oesophageal discomfort	1	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Cardiospasm	2	1
Defaecation urgency	17	0
Frequent bowel movements	49	0
Irritable bowel syndrome	146	0
Oesophageal spasm	6	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Intestinal obstruction	4	0
Intussusception	1	0
Volvulus	1	1
<i>Gastrointestinal ulcers and perforation, site unspecified</i>		
Diverticular perforation	2	0
Gastrointestinal perforation	1	0
Gastrointestinal ulcer	1	0
<i>Gastrointestinal vascular malformations</i>		
Gastric antral vascular ectasia	11	0
<i>Gastrointestinal vascular occlusion and infarction</i>		
Intestinal infarction	6	1
Intestinal ischaemia	34	1
Mesenteric artery embolism	1	0
Mesenteric artery stenosis	1	0
Mesenteric artery thrombosis	3	0
Mesenteric vein thrombosis	20	0
Mesenteric venous occlusion	1	0
Thrombosis mesenteric vessel	4	0
Visceral venous thrombosis	14	1
<i>Gingival disorders, signs and symptoms NEC</i>		
Amalgam tattoo	1	0
Epulis	1	0
Gingival atrophy	1	0
Gingival blister	23	0
Gingival discomfort	6	0
Gingival disorder	17	0
Gingival hypertrophy	1	0
Gingival oedema	2	0
Gingival pain	234	0
Gingival pruritus	1	0
Gingival recession	2	0
Gingival swelling	50	0
Gingival ulceration	8	0
Gingivitis ulcerative	2	0
Noninfective gingivitis	24	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	173	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Anorectal varices	1	0
Haemorrhoidal haemorrhage	4	0
Haemorrhoids	68	0
Haemorrhoids thrombosed	13	0
<i>Inguinal hernias</i>		
Inguinal hernia	3	0
<i>Intestinal haemorrhages</i>		

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Anal haemorrhage	44	0
Intestinal haemorrhage	1	0
Lower gastrointestinal haemorrhage	2	0
Mesenteric haemorrhage	5	0
Rectal haemorrhage	118	0
Small intestinal haemorrhage	27	0
<i>Intestinal ulcers and perforation NEC</i>		
Intestinal perforation	4	0
Large intestine perforation	1	0
<i>Large intestinal stenosis and obstruction</i>		
Large intestinal obstruction	1	0
Large intestinal stenosis	1	0
<i>Malabsorption syndromes</i>		
Bile acid malabsorption	1	0
Coeliac disease	22	0
Steatorrhoea	1	0
<i>Nausea and vomiting symptoms</i>		
Acetonaemic vomiting	1	0
Cyclic vomiting syndrome	1	0
Discoloured vomit	19	0
Faecal vomiting	3	0
Infantile spitting up	1	0
Infantile vomiting	6	0
Nausea	33278	0
Regurgitation	3	0
Retching	234	0
Vomiting	11292	0
Vomiting projectile	153	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Gastrointestinal haemorrhage	38	1
Haematemesis	79	0
Haematochezia	105	0
Intra-abdominal haematoma	2	0
Intra-abdominal haemorrhage	2	0
Melaena	10	0
Upper gastrointestinal haemorrhage	8	0
<i>Oesophageal disorders NEC</i>		
Oesophageal disorder	2	0
<i>Oesophageal stenosis and obstruction</i>		
Acquired oesophageal web	1	0
Oesophageal obstruction	1	0
<i>Oesophageal ulcers and perforation</i>		
Oesophageal rupture	1	1
Oesophageal ulcer	1	0
<i>Oesophageal varices</i>		
Varices oesophageal	1	0
<i>Oesophagitis (excl infective)</i>		
Eosinophilic oesophagitis	3	0
Oesophagitis	19	0
<i>Oral dryness and saliva altered</i>		
Aptyalism	4	0
Dry mouth	1146	0
Lip dry	78	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Saliva altered	7	0
Saliva discolouration	1	0
Salivary hypersecretion	94	0
Oral soft tissue disorders NEC		
Angina bullosa haemorrhagica	4	0
Chapped lips	23	0
Cheilitis	37	0
Chronic cheek biting	1	0
Enlarged uvula	11	0
Leukoplakia oral	2	0
Lip blister	36	0
Lip disorder	4	0
Oral disorder	19	0
Oral lichen planus	14	0
Oral papule	2	0
Palatal disorder	2	0
Uvulitis	5	0
Oral soft tissue haemorrhages		
Lip haemorrhage	4	0
Mouth haemorrhage	55	0
Oral blood blister	53	0
Oral purpura	2	0
Oral soft tissue infections		
Angular cheilitis	11	0
Oral soft tissue signs and symptoms		
Anaesthesia oral	8	0
Burning mouth syndrome	16	0
Coating in mouth	4	0
Hypoaesthesia oral	653	0
Lip discolouration	1	0
Lip erythema	4	0
Lip exfoliation	9	0
Lip pain	61	0
Lip pruritus	16	0
Oral discharge	1	0
Oral discomfort	104	0
Oral mucosal blistering	34	0
Oral mucosal discolouration	1	0
Oral mucosal eruption	28	0
Oral mucosal erythema	4	0
Oral mucosal exfoliation	10	0
Oral mucosal roughening	3	0
Oral pain	358	0
Oral pruritus	20	0
Paraesthesia oral	851	0
Oral soft tissue swelling and oedema		
Lip oedema	10	0
Lip swelling	970	0
Mouth swelling	129	0
Oedema mouth	1	0
Palatal oedema	1	0
Palatal swelling	14	0
Pancreatic disorders NEC		

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Pancreatic disorder	1	0
Pancreatic mass	1	0
Pancreatic steatosis	1	0
<i>Peptic ulcers and perforation</i>		
Peptic ulcer	2	0
Peptic ulcer haemorrhage	8	0
<i>Peritoneal and retroperitoneal disorders</i>		
Ascites	6	0
<i>Peritoneal and retroperitoneal fibrosis and adhesions</i>		
Abdominal adhesions	2	0
<i>Peritoneal and retroperitoneal haemorrhages</i>		
Haemoperitoneum	2	0
Retroperitoneal haemorrhage	1	0
<i>Rectal inflammations NEC</i>		
Proctitis	5	0
<i>Salivary gland disorders NEC</i>		
Salivary gland calculus	4	0
Salivary gland cyst	1	0
Salivary gland mass	2	0
Salivary gland pain	13	0
<i>Salivary gland enlargements</i>		
Parotid gland enlargement	13	0
Salivary gland enlargement	6	0
<i>Salivary gland infections and inflammations</i>		
Noninfective sialoadenitis	3	0
<i>Stomatitis and ulceration</i>		
Aphthous ulcer	63	0
Lip ulceration	16	0
Mouth ulceration	761	0
Stomatitis	107	0
<i>Tongue disorders</i>		
Acquired macroglossia	1	0
Glossitis	18	0
Plicated tongue	4	0
Tongue disorder	31	0
Tongue geographic	5	0
Tongue haemorrhage	2	0
Tongue ulceration	32	0
Trichoglossia	7	0
<i>Tongue signs and symptoms</i>		
Glossodynia	261	0
Scalloped tongue	4	0
Stiff tongue	6	0
Strawberry tongue	1	0
Swollen tongue	621	0
Tongue blistering	28	0
Tongue coated	36	0
Tongue discolouration	40	0
Tongue discomfort	57	0
Tongue dry	22	0
Tongue eruption	12	0
Tongue erythema	7	0
Tongue exfoliation	2	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Tongue movement disturbance	9	0
Tongue oedema	17	0
Tongue pruritus	3	0
Tongue rough	2	0
Tongue spasm	5	0
Tooth missing		
Tooth loss	8	0
Gastrointestinal disorders SOC TOTAL	79283	14

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site bruise	18	0
Administration site coldness	1	0
Administration site erythema	6	0
Administration site extravasation	1	0
Administration site haemorrhage	1	0
Administration site indentation	1	0
Administration site induration	1	0
Administration site injury	1	0
Administration site irritation	1	0
Administration site mass	1	0
Administration site movement impairment	1	0
Administration site pain	44	0
Administration site rash	5	0
Administration site reaction	6	0
Administration site swelling	3	0
Administration site urticaria	5	0
Administration site warmth	2	0
Puncture site bruise	60	0
Puncture site haemorrhage	1	0
Puncture site pain	22	0
Puncture site reaction	3	0
Puncture site swelling	1	0
Vessel puncture site bruise	2	0
<i>Adverse effect absent</i>		
No adverse event	1	0
<i>Application and instillation site reactions</i>		
Application site acne	1	0
Application site bruise	25	0
Application site burn	4	0
Application site coldness	2	0
Application site discharge	1	0
Application site discolouration	2	0
Application site erythema	29	0
Application site exfoliation	1	0
Application site haemorrhage	1	0
Application site hypersensitivity	1	0
Application site hypoaesthesia	2	0
Application site inflammation	2	0
Application site joint pain	1	0
Application site laceration	1	0
Application site movement impairment	1	0
Application site odour	1	0
Application site pain	52	0
Application site pruritus	20	0
Application site rash	4	0
Application site reaction	1	0
Application site scar	1	0
Application site swelling	4	0
Application site vesicles	13	0
Application site warmth	2	0
Application site wound	1	0
Instillation site bruise	1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Instillation site discomfort	1	0
Instillation site pain	5	0
Instillation site pruritus	1	0
Instillation site warmth	12	0
<i>Asthenic conditions</i>		
Asthenia	4964	0
Chronic fatigue syndrome	154	0
Decreased activity	16	0
Fatigue	49908	0
Malaise	12518	0
Sluggishness	29	0
<i>Body temperature altered</i>		
Hyperthermia	13	0
Hypothermia	56	0
Temperature regulation disorder	29	0
<i>Breast complications associated with device</i>		
Capsular contracture associated with breast implant	1	0
<i>Complications associated with device NEC</i>		
Complication of device removal	1	0
Injury associated with device	10	0
Medical device site joint pain	1	0
Phantom shocks	4	0
<i>Death and sudden death</i>		
Brain death	4	3
Cardiac death	4	4
Clinical death	1	0
Death	303	303
Drowning	1	0
Hanging	1	1
Sudden death	38	38
Sudden unexplained death in epilepsy	1	1
<i>Febrile disorders</i>		
Hyperpyrexia	42	0
Masked fever	1	0
PFAPA syndrome	1	0
Pyrexia	54941	0
<i>Feelings and sensations NEC</i>		
Chills	42987	0
Early satiety	1	0
Feeling abnormal	3281	0
Feeling cold	5241	0
Feeling drunk	131	0
Feeling hot	2433	0
Feeling jittery	43	0
Feeling of body temperature change	958	0
Feeling of relaxation	1	0
Hangover	196	0
Humidity intolerance	1	0
Hunger	82	0
Sensation of blood flow	15	0
Sensation of foreign body	51	0
Temperature intolerance	88	0
Thirst	1260	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Thirst decreased	11	0
Fibrosis NEC		
Fibrosis	6	0
Gait disturbances		
Decreased gait velocity	3	0
Gait disturbance	461	0
Gait inability	213	0
Loss of control of legs	57	0
General signs and symptoms NEC		
Apparent death	1	0
Chronic disease	1	0
Condition aggravated	302	0
Crepitations	10	0
Crying	299	0
Deformity	1	0
Developmental delay	3	0
Discharge	10	0
Disease progression	2	1
Disease recurrence	2	0
Effusion	1	0
Energy increased	27	0
Exercise tolerance decreased	41	0
Foaming at mouth	6	0
General physical health deterioration	32	2
General symptom	11	0
Glassy eyes	7	0
High-pitched crying	8	0
Ill-defined disorder	11	0
Illness	5039	0
Induration	21	0
Influenza like illness	9556	0
Irritability postvaccinal	3	0
Local reaction	155	0
Moaning	9	0
Multiple organ dysfunction syndrome	22	11
Nonspecific reaction	3	0
Organ failure	2	0
Perforation	3	0
Performance status decreased	1	0
Peripheral swelling	5868	0
Pre-existing condition improved	17	0
Premature ageing	1	0
Prolapse	1	0
Screaming	30	0
Secretion discharge	33	0
Sensitivity to weather change	3	0
Stenosis	2	0
Swelling	2752	0
Swelling face	1074	0
Symptom masked	1	0
Symptom recurrence	4	0
Tissue discolouration	1	0
Tissue infiltration	1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Unevaluable event	10	0
Healing abnormal NEC		
Impaired healing	5	0
Hernias NEC		
Hernia	6	0
Implant and catheter site reactions		
Catheter site urticaria	1	0
Implant site coldness	1	0
Implant site discharge	1	0
Implant site discolouration	4	0
Implant site hypoaesthesia	2	0
Implant site pain	4	0
Implant site rash	1	0
Implant site swelling	3	0
Implant site urticaria	3	0
Implant site vesicles	1	0
Implant site warmth	7	0
Inflamations		
Granuloma	1	0
Inflammation	821	0
Papillitis	1	0
Systemic inflammatory response syndrome	5	0
Infusion site reactions		
Infusion site bruising	1	0
Infusion site discomfort	1	0
Infusion site erythema	3	0
Infusion site joint pain	1	0
Infusion site mass	5	0
Infusion site nodule	2	0
Infusion site pain	14	0
Infusion site urticaria	2	0
Infusion site warmth	6	0
Injection site reactions		
Injected limb mobility decreased	45	0
Injection site atrophy	9	0
Injection site bruising	126	0
Injection site coldness	6	0
Injection site cyst	6	0
Injection site deformation	1	0
Injection site discharge	1	0
Injection site discolouration	7	0
Injection site discomfort	22	0
Injection site dryness	1	0
Injection site erythema	590	0
Injection site exfoliation	1	0
Injection site extravasation	2	0
Injection site haematoma	3	0
Injection site haemorrhage	19	0
Injection site hypersensitivity	5	0
Injection site hypoaesthesia	15	0
Injection site indentation	22	0
Injection site induration	10	0
Injection site inflammation	66	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Injection site injury	4	0
Injection site irritation	4	0
Injection site joint discomfort	1	0
Injection site joint erythema	8	0
Injection site joint pain	35	0
Injection site joint swelling	1	0
Injection site mass	1419	0
Injection site movement impairment	5	0
Injection site muscle weakness	2	0
Injection site necrosis	6	0
Injection site nerve damage	1	0
Injection site nodule	4	0
Injection site oedema	27	0
Injection site pain	4476	0
Injection site papule	2	0
Injection site paraesthesia	26	0
Injection site pruritus	298	0
Injection site rash	306	0
Injection site reaction	122	0
Injection site scab	4	0
Injection site scar	6	0
Injection site swelling	256	0
Injection site thrombosis	1	0
Injection site ulcer	1	0
Injection site urticaria	41	0
Injection site vesicles	15	0
Injection site warmth	354	0
Interactions		
Drug interaction	33	0
Food interaction	2	0
Inhibitory drug interaction	12	0
Mass conditions NEC		
Cyst	32	0
Mass	91	0
Nodule	24	0
Pelvic mass	1	0
Mucosal findings abnormal		
Mucosa vesicle	2	0
Mucosal disorder	1	0
Mucosal dryness	1	0
Mucosal haemorrhage	11	0
Mucosal inflammation	10	0
Mucosal pain	2	0
Mucosal ulceration	1	0
Oedema mucosal	3	0
Polyp	4	0
Necrosis NEC		
Fat necrosis	4	0
Necrosis	8	0
Oedema NEC		
Face oedema	34	0
Localised oedema	11	0
Oedema	86	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Oedema peripheral	162	0
<i>Pain and discomfort NEC</i>		
Axillary pain	752	0
Chest discomfort	2065	0
Chest pain	5464	0
Discomfort	629	0
Facial discomfort	21	0
Facial pain	282	0
Hernia pain	2	0
Inflammatory pain	30	0
Non-cardiac chest pain	45	0
Pain	17329	0
Suprapubic pain	1	0
Tenderness	1835	0
Visceral pain	2	0
<i>Therapeutic and nontherapeutic responses</i>		
Adverse drug reaction	28	0
Adverse event	5	0
Adverse food reaction	1	0
Adverse reaction	12	0
Diet failure	1	0
Drug effect less than expected	1	0
Drug ineffective	171	1
Drug intolerance	9	0
Idiosyncratic drug reaction	1	0
Immediate post-injection reaction	4	0
Inadequate analgesia	32	0
No reaction on previous exposure to drug	17	0
Remission not achieved	1	0
Similar reaction on previous exposure to drug	1	0
Therapeutic product effect decreased	3	0
Therapeutic product effect delayed	1	0
Therapeutic product effect incomplete	2	0
Therapeutic product effect prolonged	1	0
Therapeutic product ineffective	9	0
Therapeutic reaction time decreased	1	0
Therapeutic response decreased	1	0
Therapeutic response delayed	1	0
Therapeutic response shortened	2	0
Therapeutic response unexpected	172	0
Therapy non-responder	3	0
Treatment failure	12	0
Treatment noncompliance	1	0
Vaccination failure	41	0
Vaccine positive rechallenge	1	0
<i>Trophic disorders</i>		
Atrophy	4	0
Calcinosis	2	0
Dysplasia	3	0
Hyperplasia	2	0
<i>Ulcers NEC</i>		
Ulcer	48	0
Ulcer haemorrhage	3	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
<i>Vaccination site reactions</i>		
Extensive swelling of vaccinated limb	19	0
Shoulder injury related to vaccine administration	69	0
Vaccination site atrophy	1	0
Vaccination site bruising	137	0
Vaccination site coldness	1	0
Vaccination site cyst	3	0
Vaccination site discharge	1	0
Vaccination site discolouration	17	0
Vaccination site discomfort	48	0
Vaccination site dryness	1	0
Vaccination site erythema	709	0
Vaccination site extravasation	1	0
Vaccination site granuloma	8	0
Vaccination site haematoma	1	0
Vaccination site haemorrhage	10	0
Vaccination site hyperaesthesia	1	0
Vaccination site hypersensitivity	4	0
Vaccination site hypoaesthesia	25	0
Vaccination site induration	70	0
Vaccination site inflammation	55	0
Vaccination site injury	4	0
Vaccination site irritation	15	0
Vaccination site joint discomfort	2	0
Vaccination site joint erythema	5	0
Vaccination site joint inflammation	1	0
Vaccination site joint movement impairment	16	0
Vaccination site joint pain	52	0
Vaccination site joint swelling	3	0
Vaccination site joint warmth	2	0
Vaccination site lymphadenopathy	2	0
Vaccination site mass	563	0
Vaccination site movement impairment	95	0
Vaccination site nodule	1	0
Vaccination site oedema	3	0
Vaccination site pain	2072	0
Vaccination site papule	3	0
Vaccination site paraesthesia	12	0
Vaccination site pruritus	111	0
Vaccination site rash	191	0
Vaccination site reaction	26	0
Vaccination site scab	2	0
Vaccination site scar	7	0
Vaccination site swelling	507	0
Vaccination site urticaria	12	0
Vaccination site vesicles	11	0
Vaccination site warmth	379	0
<i>Vascular complications associated with device</i>		
Vascular stent occlusion	1	0
Vascular stent thrombosis	1	0
<i>Withdrawal and rebound effects</i>		
Drug withdrawal syndrome	8	0
Withdrawal syndrome	102	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
General disorders SOC TOTAL	250593	365

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	31	0
Cholangitis	3	0
<i>Cholecystitis and cholelithiasis</i>		
Cholecystitis	16	0
Cholecystitis acute	2	0
Cholelithiasis	15	0
<i>Cholestasis and jaundice</i>		
Cholestasis	6	0
Jaundice	54	0
Jaundice cholestatic	12	0
Ocular icterus	1	0
<i>Gallbladder disorders NEC</i>		
Gallbladder disorder	2	0
Gallbladder oedema	1	0
Gallbladder polyp	1	0
<i>Hepatic and hepatobiliary disorders NEC</i>		
Liver disorder	18	0
<i>Hepatic enzymes and function abnormalities</i>		
Hepatic function abnormal	12	0
<i>Hepatic failure and associated disorders</i>		
Acute hepatic failure	2	0
Hepatic failure	12	1
Subacute hepatic failure	3	0
<i>Hepatic fibrosis and cirrhosis</i>		
Hepatic cirrhosis	8	0
Primary biliary cholangitis	1	0
<i>Hepatic vascular disorders</i>		
Budd-Chiari syndrome	2	1
Hepatic artery thrombosis	1	0
Hepatic haemorrhage	1	0
Hepatic infarction	2	1
Hepatic vascular thrombosis	2	0
Hepatic vein thrombosis	16	0
Portal hypertension	3	0
Portal vein phlebitis	1	0
Portal vein thrombosis	68	4
Portosplenomesenteric venous thrombosis	2	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	74	0
Hepatomegaly	5	0
Liver tenderness	6	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Acute yellow liver atrophy	1	0
Autoimmune hepatitis	7	0
Cholestatic liver injury	1	0
Drug-induced liver injury	1	0
Hepatic necrosis	1	0
Hepatic steatosis	12	0
Hepatitis	30	0
Hepatitis acute	7	1
Immune-mediated hepatitis	1	0
Ischaemic hepatitis	1	0

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Reaction Name	Total	Fatal
Hepatic disorders Hepatic disorders cont'd		
Liver injury	23	0
Nonalcoholic fatty liver disease	1	0
Reye's syndrome	1	0
<i>Obstructive bile duct disorders (excl neoplasms)</i>		
Biliary obstruction	1	0
Sphincter of Oddi dysfunction	3	0
Hepatic disorders SOC TOTAL	474	8

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	27	0
<i>Allergic conditions NEC</i>		
Allergic oedema	19	0
Allergy to animal	1	0
Allergy to arthropod bite	1	0
Allergy to arthropod sting	4	0
Allergy to metals	1	0
Allergy to sting	1	0
Allergy to venom	1	0
Dust allergy	2	0
Hypersensitivity	1478	1
Infusion related hypersensitivity reaction	5	0
Mite allergy	2	0
Multiple allergies	21	0
Serum sickness	15	0
Serum sickness-like reaction	13	0
Type I hypersensitivity	1	0
Type III immune complex mediated reaction	7	0
Type IV hypersensitivity reaction	4	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergic reaction to excipient	3	0
Allergy to chemicals	7	0
Allergy to vaccine	61	0
Contrast media reaction	4	0
Drug hypersensitivity	69	0
Food allergy	46	0
Milk allergy	1	0
Oral allergy syndrome	4	0
Reaction to colouring	2	0
Reaction to excipient	14	0
Reaction to preservatives	15	0
Rubber sensitivity	2	0
Smoke sensitivity	3	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	679	2
Anaphylactic shock	120	0
Anaphylactoid reaction	22	0
Anaphylactoid shock	4	0
<i>Atopic disorders</i>		
Atopy	3	0
Seasonal allergy	140	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	60	0
<i>Autoinflammatory diseases</i>		
Autoinflammatory disease	1	0
<i>Endocrine autoimmune disorders</i>		
Hashitoxicosis	1	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	35	0
Cytokine release syndrome	2	0
Cytokine storm	4	0
Haemophagocytic lymphohistiocytosis	14	1

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Reaction Name	Total	Fatal
Immune system disorders		
Immune system disorders cont'd		
Hypocomplementaemia	1	0
Immune system disorder	47	0
Immune-mediated adverse reaction	10	0
Immunisation reaction	1	0
Multiple chemical sensitivity	2	0
Pre-engraftment immune reaction	1	0
Sensitisation	32	0
<i>Immunodeficiency disorders NEC</i>		
Immunodeficiency	9	0
Immunosuppression	6	0
<i>Transplant rejections</i>		
Corneal graft rejection	3	0
Transplant rejection	7	0
<i>Vasculitides</i>		
Anti-neutrophil cytoplasmic antibody positive vasculitis	4	1
Eosinophilic granulomatosis with polyangiitis	2	0
Immune system disorders SOC TOTAL	3044	5

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Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Abdominal infection	1	0
Abdominal wall infection	1	0
Anal abscess	1	0
Appendicitis	40	0
Appendicitis perforated	3	0
Diarrhoea infectious	4	0
Diverticulitis	31	0
Dysentery	5	0
Gastric infection	1	0
Gastroenteritis	43	0
Gastrointestinal infection	5	0
Large intestine infection	2	0
Peritonitis	3	0
<i>Adenoviral infections</i>		
Adenovirus infection	1	0
<i>Bacillary infections</i>		
Bacillus infection	1	0
<i>Bacterial infections NEC</i>		
Administration site cellulitis	1	0
Arthritis bacterial	9	0
Bacterial infection	34	1
Bacterial vaginosis	3	0
Bacterial vulvovaginitis	1	0
Cellulitis	525	0
Cellulitis orbital	2	0
Ear infection bacterial	2	0
Endocarditis bacterial	2	0
Eye infection bacterial	1	0
Folliculitis	10	0
Gangrene	3	0
Injection site cellulitis	8	0
Meningitis bacterial	1	0
Perichondritis	1	0
Periorbital cellulitis	5	0
Pneumonia bacterial	6	1
Post procedural cellulitis	1	0
Skin bacterial infection	6	0
Urinary tract infection bacterial	5	0
Vaccination site cellulitis	22	0
<i>Bone and joint infections</i>		
Abscess jaw	1	0
Arthritis infective	3	0
Bursitis infective	2	0
Intervertebral discitis	3	0
Osteomyelitis	2	1
<i>Bordetella infections</i>		
Pertussis	3	0
<i>Borreliac infections</i>		
Erythema migrans	2	0
Lyme disease	8	0
Relapsing fever	1	0
<i>Breast infections</i>		

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Breast abscess	1	0
Mastitis	47	0
<i>Brucella infections</i>		
Brucellosis	1	0
<i>Caliciviral infections</i>		
Gastroenteritis norovirus	1	0
Norovirus infection	1	0
<i>Campylobacter infections</i>		
Campylobacter colitis	1	0
Campylobacter gastroenteritis	1	0
Campylobacter infection	1	0
<i>Candida infections</i>		
Anal candidiasis	2	0
Balanitis candida	1	0
Candida infection	78	0
Oral candidiasis	59	0
Skin candida	3	0
Vulvovaginal candidiasis	58	0
<i>Cardiac infections</i>		
Acute endocarditis	1	0
Cardiac infection	1	0
Endocarditis	4	0
Myocarditis infectious	1	0
<i>Central nervous system and spinal infections</i>		
Brain abscess	1	0
Cavernous sinus thrombosis	9	0
Central nervous system infection	2	0
Encephalitis	43	0
Encephalomyelitis	3	0
Extradural abscess	1	0
Meningitis	28	0
Myelitis	20	0
<i>Chlamydial infections</i>		
Chlamydial infection	1	0
<i>Clostridia infections</i>		
Clostridium difficile colitis	4	0
Clostridium difficile infection	2	0
Tetanus	4	0
<i>Coronavirus infections</i>		
Asymptomatic COVID-19	5	0
COVID-19	963	28
COVID-19 pneumonia	69	10
Coronavirus infection	7	0
Post-acute COVID-19 syndrome	13	0
Severe acute respiratory syndrome	5	0
Suspected COVID-19	43	0
Vaccine derived SARS-CoV-2 infection	1	0
<i>Corynebacteria infections</i>		
Diphtheria	2	0
<i>Coxiella infections</i>		
Q fever	113	0
<i>Coxsackie viral infections</i>		
Coxsackie bronchitis	1	0

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Reaction Name	Total	Fatal
Infections Infections cont'd		
<i>Cytomegaloviral infections</i>		
Encephalitis cytomegalovirus	1	0
<i>Dental and oral soft tissue infections</i>		
Abscess oral	4	0
Gingival abscess	9	0
Gingivitis	30	0
Lip infection	1	0
Oral infection	1	0
Oral pustule	3	0
Parotitis	15	0
Pericoronitis	3	0
Periodontitis	2	0
Pulpitis dental	1	0
Sialoadenitis	3	0
Tongue abscess	4	0
Tooth abscess	16	0
Tooth infection	14	0
<i>Ear infections</i>		
Ear infection	139	0
Labyrinthitis	182	0
Mastoiditis	5	0
Otitis externa	7	0
Otitis media	21	0
Otosalpingitis	1	0
<i>Ectoparasitic infestations</i>		
Acarodermatitis	9	0
Infestation	1	0
Trombidiasis	3	0
<i>Epstein-Barr viral infections</i>		
Epstein-Barr virus infection	3	0
Epstein-Barr virus infection reactivation	1	0
Infectious mononucleosis	57	0
<i>Escherichia infections</i>		
Escherichia infection	2	0
Escherichia sepsis	2	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	85	0
Eye infection	44	0
Eyelid boil	3	0
Eyelid infection	4	0
Hordeolum	41	0
Keratouveitis	1	0
Retinitis	2	0
<i>Female reproductive tract infections</i>		
Endometritis	2	0
Fallopian tube abscess	1	0
Genital infection female	1	0
Ovarian abscess	1	0
Pelvic inflammatory disease	2	0
Pyometra	1	1
Vaginal abscess	3	0
Vaginal infection	5	0
Vulval abscess	1	0

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Reaction Name	Total	Fatal
Infections Infections cont'd		
<i>Flaviviral infections</i>		
Dengue fever	1	0
Yellow fever	1	0
Yellow fever vaccine-associated neurotropic disease	1	0
<i>Fungal infections NEC</i>		
Ear infection fungal	2	0
Fungal infection	26	0
Fungal skin infection	10	0
Oral fungal infection	1	0
Overgrowth fungal	1	0
Severe asthma with fungal sensitisation	5	0
Tonsillitis fungal	1	0
Vulvovaginal mycotic infection	4	0
<i>Hepatitis virus infections</i>		
Hepatitis E	1	0
<i>Hepatobiliary and spleen infections</i>		
Biliary sepsis	5	1
Liver abscess	1	0
Splenic infection	1	0
<i>Herpes viral infections</i>		
Disseminated varicella zoster virus infection	1	0
Eczema herpeticum	3	0
Genital herpes	75	0
Genital herpes simplex	1	0
Genital herpes zoster	1	0
Haemorrhagic varicella syndrome	1	0
Herpes dermatitis	2	0
Herpes ophthalmic	16	0
Herpes pharyngitis	1	0
Herpes simplex	46	0
Herpes simplex reactivation	4	0
Herpes virus infection	14	0
Herpes zoster	1582	0
Herpes zoster oticus	13	0
Herpes zoster reactivation	2	0
Meningoencephalitis herpetic	1	0
Nasal herpes	15	0
Ophthalmic herpes simplex	2	0
Ophthalmic herpes zoster	10	0
Oral herpes	707	0
Varicella	41	0
Varicella zoster virus infection	4	0
<i>Infections NEC</i>		
Abscess	51	0
Abscess limb	25	0
Abscess soft tissue	3	0
Catheter site infection	1	0
Coinfection	1	0
Device related infection	3	0
Empyema	1	0
Genital abscess	1	0
Groin abscess	2	0
Groin infection	1	0

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Infected bite	4	0
Infected cyst	4	0
Infection	525	4
Infection in an immunocompromised host	3	0
Infectious thyroiditis	1	0
Injection site abscess	3	0
Injection site infection	21	0
Localised infection	105	0
Lymph gland infection	8	0
Lymph node abscess	2	0
Omphalitis	1	0
Pathogen resistance	3	0
Pelvic infection	1	0
Pyuria	1	0
Respiratory tract infection	7	0
Toxic shock syndrome	1	0
Vaccination site abscess	7	0
Vaccination site infection	23	0
Vaccine breakthrough infection	2	0
Vestibulitis	4	0
Wound abscess	1	0
<i>Infectious disorders carrier</i>		
SARS-CoV-2 carrier	1	0
<i>Infectious transmissions</i>		
Secondary transmission	16	0
Vaccine virus shedding	1	0
<i>Influenza viral infections</i>		
H1N1 influenza	1	0
H2N2 influenza	3	0
Influenza	6767	0
<i>Klebsiella infections</i>		
Pneumonia klebsiella	1	0
<i>Lower respiratory tract and lung infections</i>		
Atypical pneumonia	2	0
Bronchitis	28	0
Infectious pleural effusion	4	0
Infective exacerbation of bronchiectasis	1	0
Infective pulmonary exacerbation of cystic fibrosis	1	1
Lower respiratory tract infection	308	4
Pleural infection	1	0
Pneumonia	258	27
Sputum purulent	1	0
<i>Male reproductive tract infections</i>		
Epididymitis	8	0
Orchitis	4	0
<i>Molluscum contagiosum viral infections</i>		
Molluscum contagiosum	1	0
<i>Mumps viral infections</i>		
Mumps	13	0
<i>Muscle and soft tissue infections</i>		
Muscle abscess	1	0
Necrotising fasciitis	1	0
Soft tissue infection	5	0

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Reaction Name	Total	Fatal
Infections Infections cont'd		
<i>Neisseria infections</i>		
Gonorrhoea	1	0
<i>Orthopox viral infections</i>		
Cow pox	1	0
Vaccinia virus infection	1	0
<i>Papilloma viral infections</i>		
Papilloma viral infection	1	0
<i>Paravaccinia infections</i>		
Paravaccinia	1	0
<i>Phleboviral infections</i>		
Severe fever with thrombocytopenia syndrome	2	0
<i>Plasmodia infections</i>		
Malaria	6	0
<i>Pneumocystis infections</i>		
Pneumocystis jirovecii pneumonia	1	0
<i>Prion-associated disorders</i>		
Creutzfeldt-Jakob disease	3	0
<i>Pseudomonal infections</i>		
Pseudomonas infection	1	0
<i>Retroviral infections</i>		
Acquired immunodeficiency syndrome	2	0
HIV infection	2	0
HIV-associated neurocognitive disorder	1	0
Persistent generalised lymphadenopathy	1	0
<i>Rotaviral infections</i>		
Gastroenteritis rotavirus	1	0
Rotavirus infection	1	0
<i>Rubella viral infections</i>		
Rubella	1	0
<i>Rubeola viral infections</i>		
Measles	5	0
<i>Salmonella infections</i>		
Typhoid fever	2	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Abdominal sepsis	1	0
Bacteraemia	1	0
Neutropenic sepsis	8	0
Pelvic sepsis	1	0
Sepsis	112	13
Sepsis syndrome	1	0
Septic pulmonary embolism	1	0
Septic rash	13	0
Septic shock	4	1
Urosepsis	10	1
Viraemia	4	0
<i>Skin structures and soft tissue infections</i>		
Blister infected	1	0
Carbuncle	1	0
Dermatitis infected	10	0
Dermo-hypodermatitis	1	0
Eczema infected	3	0
Impetigo	12	0
Infected dermal cyst	3	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Pilonidal cyst	2	0
Pustule	25	0
Rash pustular	20	0
Skin infection	73	0
Subcutaneous abscess	9	0
Vaccination site pustule	5	0
<i>Staphylococcal infections</i>		
Furuncle	54	0
Pneumonia staphylococcal	1	0
Staphylococcal bacteraemia	2	0
Staphylococcal infection	2	0
Staphylococcal scalded skin syndrome	1	0
Staphylococcal sepsis	4	1
Toxic shock syndrome staphylococcal	1	0
Vulvovaginitis staphylococcal	1	0
<i>Streptococcal infections</i>		
Beta haemolytic streptococcal infection	1	0
Cellulitis streptococcal	1	0
Erysipelas	1	0
Meningitis pneumococcal	2	1
Pharyngitis streptococcal	9	0
Pneumonia pneumococcal	1	0
Scarlet fever	1	0
Streptococcal infection	3	0
Tonsillitis streptococcal	1	0
<i>Tinea infections</i>		
Body tinea	8	0
Tinea cruris	2	0
Tinea infection	3	0
Tinea pedis	4	0
Tinea versicolour	2	0
<i>Treponema infections</i>		
Neurosyphilis	1	0
Syphilis	3	0
<i>Trypanosomal infections</i>		
African trypanosomiasis	6	0
<i>Tuberculous infections</i>		
Disseminated Bacillus Calmette-Guerin infection	1	0
Erythema induratum	1	0
Lymph node tuberculosis	3	0
Meningitis tuberculous	1	0
Pulmonary tuberculosis	2	0
Tuberculosis	4	0
<i>Upper respiratory tract infections</i>		
Acute sinusitis	6	0
Chronic sinusitis	15	0
Croup infectious	1	0
Epiglottitis	1	0
Laryngitis	37	0
Nasal vestibulitis	1	0
Nasopharyngitis	1883	0
Peritonsillar abscess	1	0
Pharyngeal abscess	1	0

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Pharyngitis	41	0
Rhinitis	53	0
Sinobronchitis	1	0
Sinusitis	383	0
Tonsillitis	87	0
Tracheitis	2	0
Upper respiratory tract infection	10	0
Urinary tract infections		
Cystitis	98	0
Genitourinary tract infection	1	0
Kidney infection	60	0
Pyelonephritis	6	0
Pyelonephritis acute	1	0
Pyelonephritis chronic	1	0
Renal abscess	2	0
Urethritis	1	0
Urinary tract infection	256	0
Vascular infections		
Haematoma infection	2	0
Infected lymphocele	1	0
Infected varicose vein	1	0
Lymphangitis	6	0
Viral infections NEC		
Arthritis viral	2	0
Bronchitis viral	1	0
Conjunctivitis viral	1	0
Ear infection viral	2	0
Encephalitis viral	8	0
Eye infection viral	1	0
Gastritis viral	1	0
Gastroenteritis viral	68	0
Gastrointestinal viral infection	1	0
Hepatitis viral	2	0
Meningitis viral	20	0
Pleurisy viral	1	0
Pneumonia viral	10	1
Post viral fatigue syndrome	138	0
Sweating fever	739	0
Vestibular neuronitis	36	0
Viral diarrhoea	4	0
Viral infection	86	0
Viral labyrinthitis	7	0
Viral myelitis	1	0
Viral myocarditis	2	0
Viral pericarditis	5	0
Viral pharyngitis	31	0
Viral rash	80	0
Viral sepsis	1	0
Viral sinusitis	1	0
Viral tonsillitis	1	0
Viral upper respiratory tract infection	1	0
Infections SOC TOTAL	18692	97

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Reaction Name	Total	Fatal
Injuries		
<i>Abdominal and gastrointestinal injuries NEC</i>		
Abdomen crushing	3	0
Abdominal injury	1	0
Colon injury	1	0
Lip injury	2	0
Mouth injury	3	0
Oral contusion	13	0
Palate injury	2	0
Splenic rupture	4	0
Tongue injury	3	0
Tooth fracture	1	0
Tooth injury	2	0
<i>Accidental exposures to product</i>		
Accidental exposure to product	21	0
Accidental exposure to product packaging	1	0
<i>Anaesthetic and allied procedural complications</i>		
Anaesthetic complication	3	0
Anaesthetic complication neurological	1	0
Delayed recovery from anaesthesia	5	0
Sedation complication	4	0
<i>Atmospheric pressure injuries</i>		
Barotrauma	1	0
Decompression sickness	2	0
Hypobarism	3	0
<i>Bone and joint injuries NEC</i>		
Bursa injury	2	0
Cartilage injury	2	0
Joint injury	10	0
Synovial rupture	2	0
<i>Cardiac and vascular procedural complications</i>		
Deep vein thrombosis postoperative	1	0
Ischaemic contracture of the left ventricle	1	0
Vascular access site bruising	1	0
Vascular graft occlusion	1	0
Vascular graft thrombosis	1	0
Vascular pseudoaneurysm	1	0
Vasoplegia syndrome	1	0
<i>Cardiovascular injuries</i>		
Heart injury	10	0
Vascular injury	11	0
Venous injury	1	0
<i>Cerebral injuries NEC</i>		
Brain contusion	16	0
Brain herniation	5	0
Concussion	8	0
Craniocerebral injury	1	0
Epidural haemorrhage	1	0
Extradural haematoma	2	0
Subarachnoid haematoma	3	0
Subdural haematoma	13	1
Subdural haemorrhage	5	0
Traumatic intracranial haemorrhage	1	0
<i>Chemical injuries</i>		

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Chemical burn	2	0
Chemical burn of oral cavity	2	0
Chemical burn of skin	6	0
Chemical phlebitis	2	0
<i>Chest and respiratory tract injuries NEC</i>		
Asbestosis	1	0
Chest crushing	14	0
Chest injury	2	0
Foreign body in throat	1	0
Traumatic haemothorax	1	0
Traumatic lung injury	1	0
<i>Conditions caused by cold</i>		
Chillblains	75	0
Frostbite	1	0
<i>Cranial nerve injuries</i>		
Cranial nerve injury	1	0
Optic nerve injury	7	0
Vth nerve injury	1	0
<i>Ear injuries NEC</i>		
Deafness traumatic	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Drug exposure before pregnancy	1	0
Exposure during pregnancy	15	0
Exposure via breast milk	111	0
Foetal exposure during pregnancy	28	0
Maternal exposure before pregnancy	9	0
Maternal exposure during breast feeding	1362	0
Maternal exposure during pregnancy	362	0
Maternal exposure timing unspecified	1	0
Paternal exposure during pregnancy	2	0
<i>Exposures to agents or circumstances NEC</i>		
Exposure to SARS-CoV-2	6	0
Exposure to household chemicals	1	0
Exposure to toxic agent	1	0
Exposure to vaccinated person	3	0
<i>Eye injuries NEC</i>		
Cataract traumatic	1	0
Eye contusion	56	0
Eye injury	47	0
Eyelid contusion	5	0
Foreign body in eye	2	0
Hyphaema	1	0
Injury corneal	1	0
Periorbital haematoma	1	0
Periorbital haemorrhage	1	0
Retinal injury	4	0
Superficial injury of eye	1	0
Traumatic iritis	1	0
<i>Foetal and neonatal conditions associated with product exposure</i>		
Intoxication by breast feeding	1	0
<i>Fractures and dislocations NEC</i>		
Fracture	2	0
Joint dislocation	12	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Multiple fractures	2	0
Stress fracture	4	0
Traumatic fracture	1	0
<i>Gastrointestinal and hepatobiliary procedural complications</i>		
Anastomotic ulcer	1	0
Peripancreatic fluid collection	1	0
Procedural nausea	26	0
Procedural vomiting	7	0
<i>Heat injuries (excl thermal burns)</i>		
Heat cramps	2	0
Heat exhaustion	4	0
Heat illness	4	0
Heat oedema	13	0
Heat stroke	11	0
<i>Intentional product misuses</i>		
Intentional product misuse	10	0
<i>Intentional product use issues</i>		
Intentional dose omission	12	0
Intentional product use issue	1	0
<i>Limb fractures and dislocations</i>		
Ankle fracture	3	0
Atypical femur fracture	1	0
Clavicle fracture	22	0
Femoral neck fracture	2	0
Femur fracture	2	0
Foot fracture	2	0
Humerus fracture	1	0
Lower limb fracture	2	0
Patella fracture	1	0
Tibia fracture	1	0
Upper limb fracture	3	0
Wrist fracture	3	0
<i>Medication errors, product use errors and issues NEC</i>		
Circumstance or information capable of leading to medication error	12	0
Device use issue	1	0
Dose calculation error	3	0
Drug titration error	1	0
Inadequate aseptic technique in use of product	2	0
Intercepted medication error	5	0
Medication error	91	0
Prescription drug used without a prescription	2	0
Product use in unapproved indication	1	0
Product use issue	8	0
Vaccination error	9	0
Wrong device used	1	0
Wrong drug	5	0
Wrong route	1	0
Wrong schedule	2	0
Wrong technique in product usage process	9	0
<i>Muscle, tendon and ligament injuries</i>		
Epicondylitis	27	0
Ligament injury	3	0
Ligament rupture	2	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Ligament sprain	19	0
Muscle injury	58	0
Muscle rupture	19	0
Muscle strain	50	0
Post-traumatic neck syndrome	4	0
Repetitive strain injury	3	0
Tendon injury	5	0
Tendon rupture	27	0
<i>Nerve injuries NEC</i>		
Nerve injury	169	0
<i>Neurological and psychiatric procedural complications</i>		
Post lumbar puncture syndrome	8	0
Procedural dizziness	36	0
<i>Non-occupational environmental exposures</i>		
Exposure to chemical pollution	1	0
Exposure to extreme temperature	4	0
Exposure to noise	2	0
<i>Non-site specific injuries NEC</i>		
Accident	1	0
Animal bite	1	0
Arthropod bite	7	0
Arthropod sting	13	0
Bite	1	0
Child maltreatment syndrome	1	0
Electric shock	34	0
Fall	277	0
Foreign body	2	0
Inflammation of wound	4	0
Injury	20	0
Internal injury	1	0
Nervous system injury	4	0
Post concussion syndrome	2	0
Road traffic accident	2	0
Soft tissue injury	6	0
Sports injury	1	0
Struck by lightning	1	0
Tissue injury	3	0
Traumatic haematoma	3	0
Traumatic shock	1	0
Wound	10	0
Wound complication	14	0
Wound haemorrhage	11	0
Wound secretion	4	0
<i>Non-site specific procedural complications</i>		
Administration related reaction	1	0
Incision site erythema	1	0
Incision site haemorrhage	1	0
Incision site oedema	1	0
Incision site pain	10	0
Infusion related reaction	19	0
Injection related reaction	611	0
Needle fatigue	1	0
Post procedural complication	35	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Post procedural contusion	2	0
Post procedural discomfort	1	0
Post procedural haematoma	1	0
Post procedural haemorrhage	1	0
Procedural hypertension	1	0
Procedural pain	8	0
Procedural site reaction	1	0
Suture related complication	1	0
Occupational exposures		
Occupational exposure to product	1	0
Off label uses		
Off label use	44	0
Overdoses NEC		
Intentional overdose	12	0
Overdose	50	0
Prescribed overdose	1	0
Pathways and sources of exposure		
Exposure via body fluid	1	0
Exposure via partner	1	0
Exposure via unknown route	1	0
Peripheral nerve injuries		
Brachial plexus injury	2	0
Median nerve injury	2	0
Radial nerve injury	1	0
Sciatic nerve injury	1	0
Ulnar nerve injury	3	0
Poisoning and toxicity		
Alcohol poisoning	3	0
Chemical poisoning	1	0
Metal poisoning	2	0
Poisoning	6	0
Systemic toxicity	2	0
Toxicity to various agents	10	0
Product administration errors and issues		
Accidental overdose	4	0
Accidental underdose	2	0
Contraindicated product administered	5	0
Drug administered in wrong device	1	0
Duplicate therapy error	2	0
Expired product administered	26	0
Extra dose administered	10	0
Inappropriate schedule of product administration	100	0
Incomplete course of vaccination	37	0
Incorrect dose administered	12	0
Incorrect product administration duration	2	0
Incorrect product formulation administered	1	0
Incorrect route of product administration	50	0
Intercepted product administration error	2	0
Lack of vaccination site rotation	1	0
Poor quality product administered	2	0
Product administered at inappropriate site	23	0
Product administered to patient of inappropriate age	29	0
Product administration error	26	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Product dose omission issue	25	0
Wrong patient received product	1	0
Wrong product administered	22	0
Product confusion errors and issues		
Product label confusion	1	0
Product name confusion	2	0
Product packaging confusion	1	0
Product dispensing errors and issues		
Product dispensing error	15	0
Product monitoring errors and issues		
Documented hypersensitivity to administered product	1	0
Labelled drug-drug interaction medication error	1	0
Product monitoring error	1	0
Product prescribing errors and issues		
Contraindicated product prescribed	10	0
Product prescribing error	5	0
Product selection errors and issues		
Product selection error	3	0
Product storage errors and issues in the product use system		
Intercepted product storage error	1	0
Product storage error	7	0
Product transcribing errors and communication issues		
Product communication issue	1	0
Radiation injuries		
Sunburn	53	0
Renal and urinary tract injuries NEC		
Bladder injury	1	0
Kidney rupture	2	0
Reproductive system and breast injuries		
Penile contusion	3	0
Penis injury	1	0
Uterine rupture	1	0
Reproductive tract and breast procedural complications		
Ovarian injury	1	0
Postmastectomy lymphoedema syndrome	1	0
Respiratory tract and thoracic cavity procedural complications		
Pulmonary oil microembolism	2	0
Site specific injuries NEC		
Back injury	7	0
Central nervous system injury	1	0
Face crushing	1	0
Face injury	2	0
Head injury	41	0
Limb crushing injury	9	0
Limb injury	293	0
Nasal injury	2	0
Neck crushing	1	0
Neck injury	3	0
Pharyngeal contusion	2	0
Site specific procedural complications NEC		
Axillary web syndrome	3	0
Skin injuries NEC		
Contusion	3302	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Hair injury	1	0
Nail injury	1	0
Scar	40	0
Scratch	6	0
Skin abrasion	5	0
Skin injury	19	0
Skin laceration	3	0
Skin pressure mark	1	0
Skin wound	7	0
Subcutaneous haematoma	3	0
Skin procedural complications		
Dermal filler overcorrection	1	0
Recall phenomenon	2	0
Spinal cord injuries NEC		
Prevertebral soft tissue swelling of cervical space	1	0
Spinal cord injury	2	0
Spinal cord injury sacral	1	0
Spinal cord injury thoracic	1	0
Spinal fractures and dislocations		
Spinal compression fracture	3	0
Spinal fracture	8	0
Stoma complications		
Gastrointestinal stoma complication	2	0
Stoma obstruction	1	0
Stoma site haemorrhage	1	0
Stoma site pain	2	0
Stoma site rash	1	0
Thermal burns		
Airway burns	1	0
Burn oesophageal	1	0
Burn of internal organs	4	0
Burn oral cavity	11	0
Burns second degree	11	0
Cold burn	3	0
Thermal burn	51	0
Thermal burns of eye	47	0
Thoracic cage fractures and dislocations		
Rib fracture	1	0
Transplantation complications		
Transplant failure	1	0
Underdoses NEC		
Intentional underdose	1	0
Underdose	10	0
Vaccination related complications		
Adverse event following immunisation	4	0
Post vaccination syndrome	5	0
Reaction to previous exposure to any vaccine	1	0
Vaccination complication	104	0
Injuries SOC TOTAL	8860	1

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Reaction Name	Total	Fatal
Investigations		
<i>Adrenal cortex tests</i>		
Blood cortisol	1	0
Cortisol decreased	3	0
Cortisol increased	2	0
<i>Adrenal medulla tests</i>		
Epinephrine increased	1	0
Norepinephrine increased	2	0
<i>Auditory and vestibular diagnostic procedures</i>		
Acoustic stimulation tests	8	0
Audiogram	1	0
<i>Autoimmunity analyses</i>		
Anti-sperm antibody	1	0
Antimitochondrial antibody positive	2	0
Antineutrophil cytoplasmic antibody positive	1	0
Antinuclear antibody	1	0
Antinuclear antibody positive	2	0
Antiphospholipid antibodies	3	0
Antiphospholipid antibodies positive	3	0
Cold agglutinins positive	2	0
DNA antibody negative	1	0
DNA antibody positive	1	0
Rheumatoid factor	3	0
Rheumatoid factor increased	3	0
Smooth muscle antibody	1	0
<i>Bacteria identification and serology (excl mycobacteria)</i>		
Bacterial test	1	0
Staphylococcus test positive	1	0
Treponema test positive	1	0
<i>Blood counts NEC</i>		
Blood count	14	0
Blood count abnormal	9	0
Full blood count	7	0
Full blood count abnormal	3	0
Full blood count decreased	3	0
Full blood count increased	1	0
<i>Blood gas and acid base analyses</i>		
Blood gases	1	0
Blood gases abnormal	1	0
Blood lactic acid	4	0
Blood lactic acid increased	5	0
Blood pH	16	0
Blood pH increased	14	0
Carbon dioxide increased	1	0
Oxygen consumption	2	0
Oxygen saturation	25	0
Oxygen saturation abnormal	2	0
Oxygen saturation decreased	191	0
Oxygen saturation normal	1	0
PO2 decreased	1	0
<i>Blood grouping and cross-matching analyses</i>		
Blood group O	2	0
Blood grouping	1	0
Rhesus antigen negative	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
<i>Bone marrow and immune tissue imaging procedures</i>		
Scan lymph nodes	2	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose	20	0
Blood glucose abnormal	20	0
Blood glucose decreased	42	0
Blood glucose fluctuation	33	0
Blood glucose increased	189	0
Glycosylated haemoglobin increased	2	0
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	35	0
Heart sounds	17	0
Heart sounds abnormal	8	0
<i>Cardiac function diagnostic procedures</i>		
Cardiac monitoring	1	0
Central venous pressure	1	0
Echocardiogram	3	0
Ejection fraction decreased	2	0
Myocardial strain	20	0
Stroke volume decreased	2	0
Venous pressure jugular increased	1	0
<i>Cardiac imaging procedures</i>		
Magnetic resonance imaging heart	1	0
<i>Cell marker analyses</i>		
Carbohydrate antigen 15-3	1	0
Carcinoembryonic antigen increased	2	0
Prostatic specific antigen decreased	1	0
Prostatic specific antigen increased	3	0
Tumour marker increased	1	0
<i>Central nervous system histopathology procedures</i>		
Biopsy brain	1	0
<i>Central nervous system imaging procedures</i>		
Brain scan abnormal	1	0
Computerised tomogram head	27	0
Magnetic resonance imaging head	46	0
Magnetic resonance imaging head abnormal	1	0
Scan brain	1	0
<i>Cerebrospinal fluid tests (excl microbiology)</i>		
CSF cell count abnormal	1	0
CSF pressure	4	0
CSF test abnormal	1	0
CSF white blood cell count increased	1	0
Xanthochromia	1	0
<i>Chemistry analyses NEC</i>		
Histamine abnormal	4	0
Histamine level	3	0
Histamine level increased	1	0
Inflammatory marker decreased	1	0
Inflammatory marker increased	12	0
Serum serotonin increased	1	0
<i>Cholesterol analyses</i>		
Blood cholesterol increased	17	0
Low density lipoprotein	1	0

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Low density lipoprotein increased	1	0
Very low density lipoprotein decreased	1	0
Coagulation and bleeding analyses		
ADAMTS13 activity abnormal	1	0
Activated partial thromboplastin time	1	0
Activated partial thromboplastin time abnormal	1	0
Activated partial thromboplastin time prolonged	124	0
Anti factor VIII antibody positive	1	0
Bleeding time	10	0
Bleeding time abnormal	3	0
Bleeding time prolonged	6	0
Bleeding time shortened	1	0
Blood fibrinogen abnormal	2	0
Blood fibrinogen decreased	7	0
Blood fibrinogen increased	2	0
Blood thromboplastin	1	0
Blood thromboplastin abnormal	1	0
Clot retraction	1	0
Coagulation factor	1	0
Coagulation factor VIII level decreased	5	0
Coagulation test abnormal	1	0
Coagulation time	9	0
Coagulation time prolonged	14	0
Coagulation time shortened	4	0
Fibrin D dimer	1	0
Fibrin D dimer decreased	1	0
Fibrin D dimer increased	59	0
International normalised ratio	3	0
International normalised ratio abnormal	11	0
International normalised ratio decreased	44	0
International normalised ratio fluctuation	5	0
International normalised ratio increased	88	0
Prothrombin level increased	1	0
Prothrombin time prolonged	1	0
Thrombin time	1	0
Thrombin time abnormal	2	0
Digestive enzymes		
Amylase increased	1	0
Lipase increased	1	0
Pancreatic enzymes increased	1	0
ECG investigations		
Cardiac telemetry	1	0
Electrocardiogram	8	0
Electrocardiogram P wave abnormal	1	0
Electrocardiogram QT prolonged	3	0
Electrocardiogram ST segment elevation	5	0
Electrocardiogram ST-T segment abnormal	6	0
Electrocardiogram T wave inversion	4	0
Electrocardiogram abnormal	21	0
Electrocardiogram change	1	0
Electrocardiogram normal	1	0
Exercise electrocardiogram	1	0
Endocrine analyses and imaging NEC		

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Hormone level abnormal	56	0
Faecal analyses NEC		
Faecal calprotectin	1	0
Faecal calprotectin increased	9	0
Occult blood	1	0
Stool analysis abnormal	2	0
Fertility analyses		
Semen analysis abnormal	1	0
Semen volume decreased	2	0
Sperm concentration	1	0
Spermatozoa abnormal	1	0
Foetal and neonatal diagnostic procedures		
Foetal heart rate	1	0
Foetal heart rate abnormal	1	0
Fungus identification and serology		
Fungal test	1	0
Gastrointestinal and abdominal imaging procedures		
Barium swallow	1	0
Computerised tomogram abdomen	4	0
Stomach scan	1	0
Gastrointestinal function diagnostic procedures		
Gastric pH	2	0
Gastric pH decreased	2	0
Gastrointestinal stoma output increased	1	0
Swallow study	3	0
Gastrointestinal, pancreatic and APUD hormone analyses		
Blood gastrin	1	0
Blood gastrin normal	1	0
Blood insulin	4	0
Blood insulin abnormal	1	0
Blood insulin decreased	2	0
Blood insulin increased	3	0
Haematological analyses NEC		
Blood viscosity abnormal	1	0
Blood viscosity decreased	1	0
Blood viscosity increased	3	0
Haematology test abnormal	2	0
Plasma viscosity abnormal	1	0
Red blood cell sedimentation rate	1	0
Red blood cell sedimentation rate abnormal	1	0
Red blood cell sedimentation rate increased	11	0
Heart rate and pulse investigations		
Brachial pulse decreased	1	0
Carotid pulse	1	0
Femoral pulse	1	0
Heart rate	1094	0
Heart rate abnormal	61	0
Heart rate decreased	133	0
Heart rate increased	2075	0
Heart rate irregular	232	0
Heart rate variability decreased	1	0
Heart rate variability increased	2	0
Maximum heart rate	7	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Maximum heart rate decreased	1	0
Maximum heart rate increased	1	0
Orthostatic heart rate response increased	1	0
Popliteal pulse	1	0
Pulse abnormal	29	0
Pulse absent	4	0
Pulse pressure increased	3	0
Pulse waveform abnormal	1	0
Radial pulse	1	0
Sinus rhythm	7	0
<i>Histopathology procedures NEC</i>		
Biopsy	1	0
Smear test	1	0
<i>Imaging procedures NEC</i>		
Computerised tomogram	7	0
Computerised tomogram normal	1	0
Magnetic resonance imaging	2	0
Magnetic resonance imaging abnormal	1	0
Magnetic resonance imaging whole body	1	0
Scan	1	0
Ultrasound scan	1	0
X-ray	1	0
<i>Immunoglobulin analyses</i>		
Blood immunoglobulin A increased	1	0
Blood immunoglobulin E	1	0
Blood immunoglobulin E increased	2	0
Blood immunoglobulin G	1	0
Blood immunoglobulin M	1	0
Blood immunoglobulin M increased	1	0
Immunoglobulins decreased	2	0
<i>Immunology analyses NEC</i>		
Antibody test	4	0
Antibody test abnormal	6	0
Antibody test negative	15	0
Antibody test positive	1	0
Immunology test	11	0
Immunology test normal	1	0
Mast cell degranulation present	1	0
Tryptase increased	1	0
<i>Immunology skin tests NEC</i>		
Allergy alert test	3	0
Skin test positive	7	0
<i>Investigations NEC</i>		
APACHE II score	1	0
Blood test	53	0
Blood test abnormal	93	0
Laboratory test	1	0
Laboratory test abnormal	1	0
Polymerase chain reaction positive	2	0
Quality of life decreased	3	0
<i>Liver function analyses</i>		
Alanine aminotransferase decreased	1	0
Alanine aminotransferase increased	32	0

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Ammonia	1	0
Aspartate aminotransferase	1	0
Aspartate aminotransferase increased	4	0
Bile output	4	0
Blood bilirubin	1	0
Blood bilirubin increased	6	0
Gamma-glutamyltransferase increased	5	0
Hepatic enzyme abnormal	1	0
Hepatic enzyme increased	14	0
Liver function test	3	0
Liver function test abnormal	51	0
Liver function test increased	16	0
Transaminases increased	12	0
Metabolism tests NEC		
Blood ketone body	10	0
Blood ketone body increased	1	0
Blood uric acid increased	4	0
Ubiquinone	4	0
Ubiquinone decreased	2	0
Urine ketone body present	2	0
Microbiology and serology tests NEC		
Blood culture	2	0
Blood culture negative	1	0
Septic screen	1	0
Mineral and electrolyte analyses		
Blood calcium	2	0
Blood calcium increased	1	0
Blood cyanide	1	0
Blood iron	11	0
Blood iron decreased	27	0
Blood iron increased	4	0
Blood magnesium decreased	3	0
Blood phosphorus abnormal	1	0
Blood phosphorus decreased	7	0
Blood phosphorus increased	4	0
Blood potassium decreased	11	0
Blood potassium increased	9	0
Blood sodium	2	0
Blood sodium decreased	5	0
Blood zinc increased	1	0
Serum ferritin	1	0
Serum ferritin decreased	3	0
Serum ferritin increased	5	0
Sweat test	3	0
Urine copper	1	0
Musculoskeletal and soft tissue imaging procedures		
Bone densitometry	1	0
Discogram abnormal	1	0
Magnetic resonance imaging neck	1	0
Skull X-ray	10	0
X-ray limb	2	0
X-ray of pelvis and hip	1	0
Musculoskeletal and soft tissue tests NEC		

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Swollen joint count	2	0
Swollen joint count increased	4	0
Tender joint count	4	0
<i>Mycobacteria identification and serology</i>		
Interferon gamma release assay positive	2	0
<i>Neurologic diagnostic procedures</i>		
Coma scale abnormal	20	0
Electroencephalogram abnormal	1	0
Electromyogram abnormal	3	0
Hoover's sign of leg paresis	1	0
Joint position sense decreased	2	0
Lumbar puncture	19	0
Nerve conduction studies abnormal	1	0
Neurotransmitter level altered	1	0
Sensory level abnormal	1	0
Sleep study normal	1	0
<i>Ophthalmic function diagnostic procedures</i>		
Corneal reflex decreased	2	0
Intraocular pressure increased	6	0
Intraocular pressure test	8	0
Pupillary light reflex tests abnormal	1	0
Retinal function test abnormal	1	0
Visual tracking test	1	0
<i>Parathyroid analyses</i>		
Blood parathyroid hormone decreased	1	0
<i>Physical examination procedures and organ system status</i>		
Body height decreased	1	0
Body surface area	3	0
Body surface area decreased	1	0
Body temperature	1030	0
Body temperature abnormal	88	0
Body temperature decreased	135	0
Body temperature fluctuation	187	0
Body temperature increased	1149	0
Body temperature normal	3	0
Breath sounds	3	0
Breath sounds abnormal	7	0
Dermatologic examination abnormal	1	0
General physical condition abnormal	4	0
Grip strength	11	0
Grip strength decreased	35	0
Head lag	19	0
Lymph node palpable	6	0
Male genital examination abnormal	1	0
Menstruation normal	3	0
Muscle strength abnormal	6	0
Neurological examination	1	0
Neurological examination normal	1	0
Ophthalmological examination	3	0
Palpatory finding abnormal	1	0
Product residue present	3	0
Psoriasis area severity index decreased	1	0
Psoriasis area severity index increased	1	0

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Respiratory rate	14	0
Respiratory rate decreased	31	0
Respiratory rate increased	80	0
Skin temperature	178	0
Temperature difference of extremities	8	0
Urological examination	1	0
Vital signs measurement	1	0
Weight decreased	221	0
Weight increased	62	0
<i>Pituitary analyses anterior</i>		
Blood corticotrophin	1	0
Blood follicle stimulating hormone increased	2	0
Blood prolactin increased	1	0
Blood thyroid stimulating hormone	1	0
Blood thyroid stimulating hormone decreased	4	0
Blood thyroid stimulating hormone increased	4	0
<i>Platelet analyses</i>		
Platelet count	3	0
Platelet count abnormal	3	0
Platelet count decreased	329	1
Platelet count increased	6	0
Platelet count normal	1	0
Platelet morphology abnormal	1	0
Plateletcrit	1	0
<i>Protein analyses NEC</i>		
Blood albumin abnormal	1	0
C-reactive protein	1	0
C-reactive protein abnormal	3	0
C-reactive protein decreased	1	0
C-reactive protein increased	36	0
Protein total	2	0
Protein total abnormal	1	0
Protein total increased	1	0
Zinc sulphate turbidity increased	1	0
<i>Red blood cell analyses</i>		
Haematocrit	10	0
Haematocrit decreased	1	0
Haematocrit increased	3	0
Haemoglobin	7	0
Haemoglobin decreased	19	0
Haemoglobin increased	2	0
Mean cell haemoglobin concentration	1	0
Mean cell volume abnormal	2	0
Red blood cell count	3	0
Red blood cell count decreased	2	0
Red blood cell count increased	1	0
Red blood cell elliptocytes present	1	0
Red blood cell morphology abnormal	1	0
Red blood cell target cells present	1	0
<i>Renal function analyses</i>		
Blood creatine increased	1	0
Blood creatinine abnormal	1	0
Blood creatinine decreased	2	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Blood creatinine increased	3	0
Blood urea	7	0
Blood urea increased	1	0
Glomerular filtration rate decreased	5	0
Reproductive hormone analyses		
17 ketosteroids urine decreased	1	0
Anti-Muellerian hormone level decreased	4	0
Blood oestrogen	1	0
Blood oestrogen increased	1	0
Blood testosterone decreased	2	0
Blood testosterone increased	1	0
Dihydrotestosterone decreased	1	0
False negative pregnancy test	4	0
Female sex hormone level	1	0
Human chorionic gonadotropin decreased	1	0
Oestradiol	2	0
Oestradiol decreased	1	0
Oestriol	1	0
Pregnancy test	17	0
Pregnancy test false positive	2	0
Pregnancy test negative	2	0
Reproductive organ and breast histopathology procedures		
Biopsy breast	1	0
Biopsy vagina	1	0
Smear cervix	1	0
Reproductive organ and breast imaging procedures		
Mammogram	1	0
Ultrasound scan vagina normal	1	0
Respiratory and pulmonary function diagnostic procedures		
Forced expiratory volume	2	0
Forced expiratory volume decreased	1	0
Forced expiratory volume increased	14	0
Forced expiratory volume normal	1	0
Forced vital capacity decreased	2	0
Fractional exhaled nitric oxide normal	1	0
Maximal voluntary ventilation	2	0
Peak expiratory flow rate	1	0
Peak expiratory flow rate decreased	7	0
Pulmonary function test	3	0
Pulmonary function test decreased	5	0
Slow vital capacity	1	0
Total lung capacity decreased	6	0
Respiratory tract and thoracic histopathology procedures		
Sputum abnormal	3	0
Respiratory tract and thoracic imaging procedures		
Chest X-ray	21	0
Computerised tomogram thorax	4	0
Laryngoscopy	1	0
Ventilation/perfusion scan	1	0
Skeletal and cardiac muscle analyses		
Blood creatine phosphokinase increased	8	0
Muscle enzyme increased	1	0
Myocardial necrosis marker	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Myocardial necrosis marker increased	1	0
Troponin	2	0
Troponin I increased	3	0
Troponin T	1	0
Troponin T increased	1	0
Troponin increased	5	0
Special sense investigations NEC		
Olfactory test	1	0
Therapeutic drug monitoring analyses		
Analgesic drug level	17	0
Analgesic drug level increased	1	0
Analgesic drug level therapeutic	1	0
Anticoagulation drug level above therapeutic	3	0
Anticoagulation drug level below therapeutic	4	0
Anticoagulation drug level increased	1	0
Antidepressant drug level decreased	1	0
Drug level increased	1	0
Thyroid analyses		
Anti-thyroid antibody	1	0
Thyroid function test abnormal	4	0
Thyroxine	1	0
Thyroxine abnormal	2	0
Thyroxine increased	2	0
Tri-iodothyronine decreased	7	0
Tissue enzyme analyses NEC		
Blood alkaline phosphatase decreased	1	0
Blood alkaline phosphatase increased	3	0
Blood lactate dehydrogenase	1	0
Blood lactate dehydrogenase increased	1	0
Lactate dehydrogenase urine increased	1	0
Toxicology laboratory analyses		
Blood aluminium	1	0
Blood arsenic normal	1	0
Blood cannabinoids	1	0
Blood carbon monoxide increased	3	0
Blood heavy metal test	1	0
Blood lead	1	0
Drug screen positive	4	0
Triglyceride analyses		
Blood triglycerides	1	0
Blood triglycerides increased	1	0
Urinalysis NEC		
Blood urine	38	0
Blood urine present	89	0
Cells in urine	2	0
Crystal urine	4	0
Glucose urine	1	0
Haemoglobin urine	1	0
Medication crystals in urine present	1	0
Protein urine	3	0
Protein urine present	1	0
Red blood cells urine	1	0
Urea urine increased	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Urine analysis	1	0
Urine analysis abnormal	15	0
Urine analysis normal	3	0
White blood cells urine positive	1	0
pH urine	10	0
pH urine decreased	2	0
pH urine increased	3	0
Urinary tract function analyses NEC		
Urine output	47	0
Urine output decreased	18	0
Urine output increased	11	0
Urinary tract imaging procedures		
Cystoscopy	3	0
Ultrasound kidney	1	0
Vascular auscultatory investigations		
Abdominal bruit	1	0
Carotid bruit	1	0
Vascular imaging procedures NEC		
Arteriogram carotid	1	0
Venogram	1	0
Vascular tests NEC (incl blood pressure)		
Blood pressure abnormal	13	0
Blood pressure decreased	101	0
Blood pressure diastolic	1	0
Blood pressure diastolic decreased	1	0
Blood pressure diastolic increased	4	0
Blood pressure difference of extremities	1	0
Blood pressure increased	328	0
Blood pressure measurement	113	0
Blood pressure normal	5	0
Blood pressure systolic	1	0
Blood pressure systolic abnormal	1	0
Blood pressure systolic increased	5	0
Capillary nail refill test	1	0
Pulmonary arterial pressure abnormal	1	0
Virus identification and serology		
Blood HIV RNA increased	1	0
Coronavirus test	42	0
Cytomegalovirus test	1	0
Epstein-Barr virus antibody positive	1	0
HIV antibody negative	2	0
Hepatitis B core antibody positive	1	0
Hepatitis B surface antibody positive	1	0
Herpes virus test	1	0
Human papilloma virus test positive	1	0
SARS-CoV-1 test positive	1	0
SARS-CoV-2 RNA	1	0
SARS-CoV-2 antibody test	9	0
SARS-CoV-2 antibody test negative	33	0
SARS-CoV-2 antibody test positive	8	0
SARS-CoV-2 test	27	0
SARS-CoV-2 test false negative	5	0
SARS-CoV-2 test false positive	4	0

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
SARS-CoV-2 test negative	18	0
SARS-CoV-2 test positive	108	0
Varicella virus test positive	1	0
Viral load	1	0
Viral test	4	0
Viral test positive	1	0
Vitamin analyses		
Blood folate	3	0
Blood folate abnormal	1	0
Blood folate decreased	11	0
Vitamin B12	2	0
Vitamin B12 abnormal	1	0
Vitamin B12 decreased	6	0
Vitamin D	3	0
Vitamin D decreased	5	0
Vitamin D increased	1	0
Water and electrolyte analyses NEC		
Blood electrolytes decreased	2	0
Blood osmolarity	1	0
Volume blood	7	0
White blood cell analyses		
CD4 lymphocytes decreased	1	0
Eosinophil count abnormal	1	0
Eosinophil count decreased	1	0
Eosinophil count increased	7	0
Lymphocyte count	3	0
Lymphocyte count abnormal	1	0
Lymphocyte count decreased	6	0
Lymphocyte count increased	3	0
Monocyte count increased	1	0
Mononuclear cell count abnormal	1	0
Neutrophil count	4	0
Neutrophil count abnormal	1	0
Neutrophil count decreased	19	0
Neutrophil count increased	1	0
Neutrophil toxic granulation present	1	0
White blood cell count	21	0
White blood cell count decreased	34	0
White blood cell count increased	14	0
Investigations SOC TOTAL	11006	1

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	37	0
Decreased appetite	6432	0
Diet refusal	2	0
Eating disorder symptom	1	0
Food craving	25	0
Food refusal	42	0
Hyperphagia	8	0
Hypophagia	37	0
Increased appetite	60	0
Salt craving	4	0
<i>Calcium metabolism disorders</i>		
Hypercalcaemia	2	0
Hypocalcaemia	8	0
Tetany	1	0
<i>Copper metabolism disorders</i>		
Copper deficiency	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	110	0
Diabetes mellitus inadequate control	29	0
Increased insulin requirement	1	0
Insulin resistant diabetes	1	0
Type 1 diabetes mellitus	24	0
Type 2 diabetes mellitus	5	0
<i>Diabetic complications NEC</i>		
Diabetic ketoacidosis	38	2
Diabetic ketosis	5	0
Euglycaemic diabetic ketoacidosis	1	0
<i>Diabetic complications neurological</i>		
Hyperglycaemic hyperosmolar nonketotic syndrome	1	0
<i>Disorders of purine metabolism</i>		
Gout	181	0
<i>Electrolyte imbalance NEC</i>		
Electrolyte imbalance	3	0
Fluid imbalance	1	0
Hyperosmolar state	1	0
<i>Fat soluble vitamin deficiencies and disorders</i>		
Vitamin D deficiency	16	0
<i>Fluid intake decreased</i>		
Fluid intake reduced	10	0
<i>Fluid intake increased</i>		
Polydipsia	14	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Alcohol intolerance	13	0
Dairy intolerance	4	0
Food intolerance	17	0
Gluten sensitivity	4	0
Histamine intolerance	4	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	72	0
Abnormal weight gain	36	0
Cachexia	2	0
Feeding disorder	208	0

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Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
Food aversion	57	0
Neonatal insufficient breast milk syndrome	4	0
Obesity	1	0
Overfeeding of infant	1	0
Overweight	2	0
Poor feeding infant	18	0
Starvation	1	0
Underweight	2	0
Weight loss poor	4	0
Hyperglycaemic conditions NEC		
Glucose tolerance impaired	2	0
Hyperglycaemia	129	0
Insulin resistance	9	0
Metabolic syndrome	1	0
Hyperlipidaemias NEC		
Hyperlipidaemia	4	0
Hypoglycaemic conditions NEC		
Hyperinsulinaemic hypoglycaemia	1	0
Hypoglycaemia	103	0
Hypoglycaemia unawareness	2	0
Postprandial hypoglycaemia	2	0
Iron deficiencies		
Iron deficiency	16	0
Iron excess		
Iron overload	1	0
Lipid metabolism and deposit disorders NEC		
Lipoedema	1	0
Magnesium metabolism disorders		
Hypomagnesaemia	1	0
Metabolic acidoses (excl diabetic acidoses)		
Hyperlactacidaemia	2	0
Ketoacidosis	1	0
Ketosis	5	0
Lactic acidosis	3	0
Metabolic acidosis	12	0
Metabolic disorders NEC		
Hypometabolism	1	0
Metabolic disorder	2	0
Mixed acid-base disorders		
Acidosis	5	0
Phosphorus metabolism disorders		
Hypophosphataemia	2	0
Potassium imbalance		
Hyperkalaemia	6	0
Hypokalaemia	6	0
Hypokalaemic syndrome	2	0
Protein metabolism disorders NEC		
Hypoalbuminaemia	1	0
Sodium imbalance		
Hypernatraemia	3	0
Hyponatraemia	27	0
Hyponatraemic syndrome	4	1
Sugar intolerance (excl glucose intolerance)		

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Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
Lactose intolerance	6	0
Total fluid volume decreased		
Dehydration	684	0
Hypovolaemia	2	0
Total fluid volume increased		
Fluid overload	12	0
Fluid retention	94	0
Vitamin deficiencies NEC		
Hypovitaminosis	3	0
Water soluble vitamin deficiencies		
Folate deficiency	12	0
Vitamin B12 deficiency	14	0
Metabolic disorders SOC TOTAL	8732	3

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	565	0
Arthritis enteropathic	1	0
Arthropathy	38	0
Autoimmune arthritis	10	0
Haemarthrosis	8	0
Oligoarthritis	1	0
Palindromic rheumatism	6	0
Polyarthritis	18	0
Rheumatic fever	8	0
Sacroiliitis	4	0
Seronegative arthritis	2	0
<i>Bone disorders NEC</i>		
Bone disorder	3	0
Bone erosion	1	0
Bone loss	2	0
Exostosis	2	0
Jaw disorder	5	0
Medial tibial stress syndrome	9	0
Osteitis	12	0
Osteonecrosis	2	0
Osteonecrosis of jaw	4	0
Osteosclerosis	2	0
Spinal disorder	2	0
<i>Bone related signs and symptoms</i>		
Bone pain	1072	0
Bone swelling	7	0
Coccydynia	8	0
Pain in jaw	611	0
Pubic pain	1	0
Spinal pain	259	0
<i>Bursal disorders</i>		
Bursitis	189	0
<i>Cartilage disorders</i>		
Chondritis	1	0
Chondropathy	2	0
Costochondritis	86	0
Osteochondrosis	1	0
Polychondritis	1	0
<i>Connective tissue disorders NEC</i>		
Collagen disorder	2	0
Connective tissue disorder	3	0
Eosinophilic fasciitis	1	0
Mixed connective tissue disease	1	0
Morphoea	3	0
Polymyalgia rheumatica	90	0
Reynold's syndrome	6	0
Scleroderma	4	0
Sjogren's syndrome	3	0
Systemic scleroderma	1	0
<i>Crystal arthropathic disorders</i>		
Chondrocalcinosis pyrophosphate	4	0
Gouty tophus	1	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
<i>Epiphyseal disorders</i>		
Epiphyses premature fusion	1	0
<i>Extremity deformities</i>		
Acquired claw toe	1	0
Finger deformity	3	0
Foot deformity	5	0
Hand deformity	4	0
Knee deformity	1	0
Limb deformity	8	0
Wrist deformity	2	0
<i>Fractures NEC</i>		
Osteoporotic fracture	3	0
Pathological fracture	1	0
<i>Intervertebral disc disorders NEC</i>		
Intervertebral disc degeneration	3	0
Intervertebral disc protrusion	9	0
<i>Joint related disorders NEC</i>		
Ankle impingement	1	0
Femoroacetabular impingement	2	0
Hypermobility syndrome	3	0
Joint ankylosis	2	0
Joint contracture	1	0
Joint instability	3	0
Joint laxity	6	0
Joint lock	60	0
Ligament laxity	1	0
Patellofemoral pain syndrome	7	0
Periarthritis	411	0
Rotator cuff syndrome	86	0
Temporomandibular joint syndrome	22	0
<i>Joint related signs and symptoms</i>		
Arthralgia	22841	0
Jaw clicking	5	0
Joint effusion	9	0
Joint noise	51	0
Joint range of motion decreased	6	0
Joint stiffness	464	0
Joint swelling	1023	0
Joint vibration	6	0
Joint warmth	37	0
Loose body in joint	1	0
<i>Ligament disorders</i>		
Ligament pain	11	0
<i>Lupus erythematosus (incl subtypes)</i>		
Lupus-like syndrome	1	0
Systemic lupus erythematosus	37	0
<i>Metabolic bone disorders</i>		
Dwarfism	1	0
Osteopenia	2	0
Osteoporosis	12	0
<i>Muscle infections and inflammations</i>		
Autoimmune myositis	1	0
Myositis	49	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Myositis ossificans	1	0
Polymyositis	4	0
Muscle pains		
Fibromyalgia	292	0
Myalgia	26634	0
Myalgia intercostal	3	0
Myofascial pain syndrome	26	0
Muscle related signs and symptoms NEC		
Haematoma muscle	3	0
Muscle atrophy	36	0
Muscle discomfort	20	0
Muscle disorder	12	0
Muscle fatigue	1000	0
Muscle haemorrhage	4	0
Muscle hypertrophy	1	0
Muscle mass	12	0
Muscle oedema	2	0
Muscle spasms	3477	0
Muscle swelling	31	0
Muscle tightness	194	0
Muscle twitching	578	0
Muscle tone abnormalities		
Muscle rigidity	53	0
Nuchal rigidity	17	0
Torticollis	13	0
Trismus	55	0
Muscle weakness conditions		
Muscular weakness	2161	0
Musculoskeletal and connective tissue conditions NEC		
Back disorder	3	0
Extremity contracture	2	0
Infantile back arching	1	0
Limb mass	18	0
Mandibular mass	1	0
Mastication disorder	9	0
Mobility decreased	157	0
Muscle contracture	4	0
Musculoskeletal disorder	3	0
Musculoskeletal stiffness	2348	0
Posture abnormal	2	0
Somatic dysfunction	1	0
Weight bearing difficulty	13	0
Winged scapula	1	0
Musculoskeletal and connective tissue deformities of skull, face and buccal cavity		
Facial asymmetry	3	0
Head deformity	1	0
Musculoskeletal and connective tissue infections and inflammations NEC		
Connective tissue inflammation	3	0
Dactylitis	3	0
Dupuytren's contracture	2	0
Fasciitis	1	0
Plantar fasciitis	14	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Amplified musculoskeletal pain syndrome	1	0
Back pain	5824	0
Flank pain	91	0
Growing pains	8	0
Limb discomfort	2334	0
Musculoskeletal chest pain	416	0
Musculoskeletal discomfort	152	0
Musculoskeletal pain	76	0
Neck pain	3100	0
Pain in extremity	21962	0
Rheumatic disorder	27	0
<i>Myopathies</i>		
Compartment syndrome	4	0
Muscle necrosis	1	0
Myopathy	6	0
Rhabdomyolysis	9	1
<i>Osteoarthropathies</i>		
Nodal osteoarthritis	1	0
Osteoarthritis	92	0
Spinal osteoarthritis	8	0
<i>Psoriatic arthropathies</i>		
Psoriatic arthropathy	31	0
<i>Rheumatoid arthropathies</i>		
Felty's syndrome	1	0
Juvenile idiopathic arthritis	2	0
Rheumatoid arthritis	188	0
Rheumatoid nodule	1	0
Still's disease	6	0
<i>Soft tissue disorders NEC</i>		
Axillary mass	81	0
Clubbing	1	0
Fistula	3	0
Groin pain	227	0
Neck mass	25	0
Soft tissue disorder	3	0
Soft tissue mass	3	0
Soft tissue swelling	7	0
<i>Spine and neck deformities</i>		
Kyphosis	6	0
Scoliosis	4	0
Spinal stenosis	2	0
<i>Spondyloarthropathies</i>		
Ankylosing spondylitis	32	0
Arthritis reactive	61	0
Axial spondyloarthritis	2	0
Spondylitis	7	0
<i>Synovial disorders</i>		
Synovial cyst	12	0
Synovitis	19	0
<i>Tendon disorders</i>		
Enthesopathy	1	0
Tendon discomfort	4	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Muscle & tissue disorders cont'd		
Tendon disorder	8	0
Tendon pain	43	0
Tendon sheath disorder	1	0
Tendonitis	101	0
Tenosynovitis	3	0
Tenosynovitis stenosaurs	3	0
Trigger finger	33	0
Muscle & tissue disorders SOC TOTAL	100517	1

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Reaction Name	Total	Fatal
Neoplasms		
<i>Anal canal neoplasms malignant</i>		
Anal cancer	1	0
<i>Aural neoplasms benign</i>		
Benign ear neoplasm	1	0
<i>B-cell lymphomas NEC</i>		
B-cell lymphoma	2	0
Follicular lymphoma	2	0
<i>Bile duct neoplasms malignant</i>		
Bile duct cancer	1	0
Cholangiocarcinoma	1	0
<i>Bladder neoplasms malignant</i>		
Bladder cancer	1	0
<i>Bone neoplasms malignant (excl sarcomas)</i>		
Bone cancer	2	0
<i>Breast and nipple neoplasms benign</i>		
Benign breast neoplasm	3	0
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	55	0
Breast cancer female	1	0
Breast cancer in situ	1	0
Breast cancer male	3	0
Breast cancer metastatic	1	0
Breast cancer stage I	1	0
Breast cancer stage III	3	0
Breast cancer stage IV	1	0
Intraductal proliferative breast lesion	1	0
<i>Cardiovascular neoplasms benign</i>		
Haemangioma	6	0
<i>Central nervous system neoplasms malignant NEC</i>		
Brain cancer metastatic	2	0
Brain neoplasm malignant	2	0
<i>Cervix neoplasms benign</i>		
Cervix warts	1	0
<i>Cervix neoplasms malignant</i>		
Cervix carcinoma	3	0
<i>Colorectal neoplasms malignant</i>		
Colon cancer	1	0
Colorectal cancer	3	0
<i>Endocrine neoplasms benign NEC</i>		
Pituitary tumour benign	2	0
<i>Endocrine neoplasms malignant and unspecified NEC</i>		
Neuroendocrine tumour	1	0
<i>Endometrial neoplasms malignant</i>		
Clear cell endometrial carcinoma	1	0
Endometrial cancer	2	0
<i>Gastrointestinal neoplasms benign NEC</i>		
Gastrointestinal tract adenoma	1	0
<i>Gastrointestinal neoplasms malignant NEC</i>		
Gastrointestinal carcinoma	6	0
<i>Glial tumours malignant</i>		
Glioblastoma	4	0
Glioblastoma multiforme	1	0
<i>Haematologic neoplasms NEC</i>		

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
Benign lymph node neoplasm	1	0
Haematological malignancy	2	0
Systemic mastocytosis	1	0
Hepatic neoplasms malignant		
Hepatocellular carcinoma	4	0
Hepatobiliary neoplasms malignancy unspecified		
Hepatic neoplasm	1	0
Hepatoblastomas		
Hepatoblastoma	1	0
Hodgkin's disease NEC		
Hodgkin's disease	2	0
Leiomyosarcomas		
Pleomorphic leiomyosarcoma	1	0
Leukaemias NEC		
Leukaemia	3	0
Leukaemia recurrent	1	0
Leukaemias acute myeloid		
Acute myeloid leukaemia	3	1
Leukaemias chronic lymphocytic		
Chronic lymphocytic leukaemia	7	0
Leukaemias chronic myeloid		
Chronic myeloid leukaemia	1	0
Leukaemias myeloid NEC		
Myeloid leukaemia	1	0
Lip and oral cavity neoplasms benign		
Papillary cystadenoma lymphomatosum	1	0
Lip and oral cavity neoplasms malignant		
Lip and/or oral cavity cancer	1	0
Squamous cell carcinoma of the oral cavity	2	0
Lymphomas unspecified NEC		
Lymphoma	19	0
Lymphoproliferative disorders NEC (excl leukaemias and lymphomas)		
Epstein Barr virus positive mucocutaneous ulcer	1	0
Histiocytic necrotising lymphadenitis	1	0
Lymphoproliferative disorder	1	0
Lymphoproliferative disorder in remission	1	0
Mediastinal neoplasms malignancy unspecified NEC		
Good syndrome	4	0
Metastases to specified sites		
Metastases to bone	1	0
Metastases to central nervous system	1	1
Metastases to liver	1	0
Metastases to lung	1	1
Metastases to unknown and unspecified sites		
Metastasis	4	1
Myelodysplastic syndromes		
Myelodysplastic syndrome	1	0
Myeloproliferative disorders (excl leukaemias)		
Essential thrombocythaemia	2	0
Neoplasms benign site unspecified NEC		
Adenoma benign	1	0
Fibroma	1	0
Neoplasms malignant site unspecified NEC		

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
Adenocarcinoma	2	0
Malignant neoplasm progression	1	0
Metastatic neoplasm	3	0
Neoplasm malignant	12	2
Squamous cell carcinoma	4	0
Neoplasms unspecified malignancy and site unspecified NEC		
Neoplasm	1	0
Neoplasm recurrence	7	0
Nervous system neoplasms unspecified malignancy NEC		
Brain neoplasm	7	1
Meningioma	4	0
Schwannoma	1	0
Neuromas		
Acoustic neuroma	5	0
Non-Hodgkin's lymphomas NEC		
Cutaneous lymphoma	1	0
Non-Hodgkin's lymphoma	1	0
Non-small cell neoplasms malignant of the respiratory tract cell type specified		
Lung adenocarcinoma	1	1
Ocular neoplasms benign		
Eye naevus	4	0
Oesophageal neoplasms malignant		
Oesophageal cancer metastatic	6	0
Oesophageal carcinoma	4	0
Oesophageal squamous cell carcinoma	1	0
Oncologic complications and emergencies		
Cancer fatigue	4	0
Cancer pain	2	0
Intracranial tumour haemorrhage	1	0
Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified		
Tonsil cancer	3	0
Ovarian neoplasms malignant (excl germ cell)		
Ovarian cancer	10	0
Ovarian cancer recurrent	1	0
Ovarian cancer stage IV	1	0
Pancreatic neoplasms malignant (excl islet cell and carcinoid)		
Pancreatic carcinoma	5	0
Pancreatic carcinoma metastatic	1	0
Paranasal sinus and nasal cavity neoplasms malignant and unspecified		
Nasal cavity cancer	1	0
Penile neoplasms malignant		
Penile cancer	1	0
Plasma cell myelomas		
Plasma cell myeloma	3	0
Plasmacytoma	1	0
Plasma cell neoplasms NEC		
Hypergammaglobulinaemia benign monoclonal	2	0
Prostatic neoplasms malignant		
Prostate cancer	6	0
Renal neoplasms malignant		
Clear cell renal cell carcinoma	2	0

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
Metastatic renal cell carcinoma	1	0
Renal cancer	1	0
Reproductive neoplasms female benign NEC		
Benign hydatidiform mole	1	0
Reproductive neoplasms male benign NEC		
Testicle adenoma	2	0
Respiratory tract and pleural neoplasms malignancy unspecified NEC		
Maxillofacial sinus neoplasm	1	0
Respiratory tract and pleural neoplasms malignant cell type unspecified NEC		
Bronchial carcinoma	5	0
Lung cancer metastatic	1	0
Lung neoplasm malignant	12	0
Throat cancer	1	0
Respiratory tract small cell carcinomas		
Small cell lung cancer	1	0
Salivary gland neoplasms malignant		
Salivary gland cancer stage 0	1	0
Salivary gland cancer stage III	1	0
Skin melanomas (excl ocular)		
Acral lentiginous melanoma stage III	1	0
Malignant melanoma	4	0
Malignant melanoma in situ	3	0
Metastatic malignant melanoma	1	0
Skin neoplasms benign		
Acrochordon	6	0
Anogenital warts	4	0
Haemangioma of skin	18	0
Melanocytic naevus	5	0
Seborrhoeic keratosis	2	0
Skin papilloma	29	0
Skin neoplasms malignant and unspecified (excl melanoma)		
Basal cell carcinoma	6	0
Bowen's disease	1	0
Neoplasm skin	1	0
Skin cancer	8	0
Squamous cell carcinoma of skin	1	0
Soft tissue neoplasms benign NEC		
Knuckle pads	1	0
Lipoma	10	0
Thyroid neoplasms benign		
Benign neoplasm of thyroid gland	1	0
Thyroid adenoma	1	0
Uterine neoplasms benign		
Uterine leiomyoma	16	0
Uterine neoplasms malignant NEC		
Uterine cancer	4	0
Vulval neoplasms malignant		
Vulval cancer	1	0
Neoplasms SOC TOTAL	451	8

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Areflexia	35	0
Extensor plantar response	2	0
Hyperreflexia	8	0
Hyporeflexia	22	0
Poor sucking reflex	4	0
Reflexes abnormal	1	0
<i>Abnormal sleep-related events</i>		
Sleep paralysis	24	0
<i>Absence seizures</i>		
Petit mal epilepsy	41	0
<i>Acute polyneuropathies</i>		
Acute motor axonal neuropathy	6	0
Acute polyneuropathy	2	0
Guillain-Barre syndrome	432	4
Miller Fisher syndrome	26	0
Subacute inflammatory demyelinating polyneuropathy	4	0
<i>Alzheimer's disease (incl subtypes)</i>		
Dementia Alzheimer's type	1	0
Mixed dementia	1	0
<i>Auditory nerve disorders</i>		
Acoustic neuritis	1	0
<i>Autonomic nervous system disorders</i>		
Autonomic nervous system imbalance	20	0
Autonomic neuropathy	1	0
Horner's syndrome	2	0
Orthostatic intolerance	7	0
<i>Central nervous system aneurysms and dissections</i>		
Carotid artery aneurysm	1	0
Carotid artery dissection	1	0
Intracranial aneurysm	3	1
Vertebral artery dissection	3	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Basal ganglia haemorrhage	3	0
Basal ganglia stroke	1	0
Basilar artery occlusion	1	0
Basilar artery thrombosis	4	1
Brain stem haemorrhage	5	1
Brain stem infarction	2	2
Brain stem stroke	8	2
Brain stem thrombosis	1	0
Carotid artery occlusion	2	0
Carotid artery thrombosis	10	0
Cerebellar haemorrhage	5	0
Cerebellar infarction	6	0
Cerebellar stroke	11	0
Cerebral artery embolism	11	0
Cerebral artery occlusion	4	0
Cerebral artery thrombosis	15	0
Cerebral haematoma	13	1
Cerebral haemorrhage	174	46
Cerebral infarction	95	5
Cerebral ischaemia	4	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Cerebral thrombosis	36	2
Cerebral vascular occlusion	2	0
Cerebrovascular accident	1222	45
Embolic stroke	20	0
Haemorrhage intracranial	56	14
Haemorrhagic cerebral infarction	3	1
Haemorrhagic stroke	46	7
Haemorrhagic transformation stroke	7	3
Internal capsule infarction	1	0
Intracranial haematoma	8	1
Intraventricular haemorrhage	6	0
Ischaemic cerebral infarction	2	0
Ischaemic stroke	150	7
Lacunar infarction	5	0
Lacunar stroke	24	0
Pseudostroke	1	0
Spinal cord haematoma	1	0
Spinal cord infarction	1	0
Spinal stroke	3	0
Stroke in evolution	1	0
Subarachnoid haemorrhage	112	7
Thalamic infarction	1	0
Thalamus haemorrhage	9	0
Thrombotic stroke	15	0
Vertebral artery occlusion	1	0
Vertebral artery thrombosis	1	0
Central nervous system inflammatory disorders NEC		
Arachnoiditis	4	0
Central nervous system inflammation	15	0
Neurosarcoidosis	3	0
Central nervous system vascular disorders NEC		
Brain hypoxia	1	0
Brain stem microhaemorrhage	1	0
Carotid arteriosclerosis	1	0
Carotid artery stenosis	4	0
Central nervous system vasculitis	3	0
Cerebral amyloid angiopathy	5	0
Cerebral arteriosclerosis	2	0
Cerebral arteritis	1	0
Cerebral congestion	3	0
Cerebral microangiopathy	1	0
Cerebral microhaemorrhage	4	0
Cerebral small vessel ischaemic disease	3	0
Cerebral vasoconstriction	2	0
Cerebrovascular disorder	4	0
Cerebrovascular insufficiency	1	0
Internal carotid artery deformity	1	0
Reversible cerebral vasoconstriction syndrome	4	0
Cerebrovascular venous and sinus thrombosis		
Cerebral venous sinus thrombosis	206	21
Cerebral venous thrombosis	51	5
Superior sagittal sinus thrombosis	29	3
Transverse sinus thrombosis	6	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
<i>Cervical spinal cord and nerve root disorders</i>		
Cervical radiculopathy	4	0
Cervicobrachial syndrome	6	0
<i>Choreiform movements</i>		
Chorea	3	0
Choreoathetosis	1	0
Sydenham's chorea	1	0
<i>Chronic polyneuropathies</i>		
Chronic inflammatory demyelinating polyradiculoneuropathy	7	0
Demyelinating polyneuropathy	11	0
Diabetic neuropathy	2	0
Polyneuropathy chronic	1	0
<i>Coma states</i>		
Coma	21	0
Diabetic coma	3	0
Hypoglycaemic coma	2	0
<i>Coordination and balance disturbances</i>		
Ataxia	49	0
Balance disorder	920	0
Cerebellar ataxia	2	0
Cerebellar syndrome	2	0
Coordination abnormal	130	0
Dysdiadochokinesis	1	0
Dysstasia	118	0
Hand-eye coordination impaired	1	0
Nystagmus	23	0
<i>Cortical dysfunction NEC</i>		
Agraphia	1	0
Alexia	7	0
Aphasia	170	0
Apraxia	2	0
Dysgraphia	7	0
Dyslexia	2	0
Dyspraxia	7	0
Neurologic neglect syndrome	3	0
Visuospatial deficit	2	0
<i>Cranial nerve disorders NEC</i>		
Cranial nerve disorder	2	0
Cranial nerve paralysis	1	0
Neurovascular conflict	1	0
Paresis cranial nerve	2	0
<i>Dementia (excl Alzheimer's type)</i>		
Dementia	32	0
Dementia with Lewy bodies	1	0
Frontotemporal dementia	1	0
Senile dementia	1	0
Vascular dementia	5	0
<i>Demyelinating disorders NEC</i>		
Acute disseminated encephalomyelitis	14	0
Clinically isolated syndrome	3	0
Demyelination	24	0
Neuromyelitis optica spectrum disorder	4	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>		
Altered state of consciousness	18	0
Consciousness fluctuating	4	0
Depressed level of consciousness	92	0
Hypoglycaemic unconsciousness	1	0
Lethargy	4928	0
Loss of consciousness	1075	0
Postictal state	1	0
Sedation	17	0
Somnolence	1939	0
Stupor	9	0
Syncope	2492	0
<i>Disturbances in sleep phase rhythm</i>		
Advanced sleep phase	1	0
Circadian rhythm sleep disorder	6	0
Delayed sleep phase	1	0
Irregular sleep phase	4	0
Irregular sleep wake rhythm disorder	1	0
Non-24-hour sleep-wake disorder	1	0
<i>Dyskinesias and movement disorders NEC</i>		
Akathisia	10	0
Akinesia	1	0
Ballismus	1	0
Bradykinesia	33	0
Clumsiness	53	0
Dyskinesia	116	0
Extrapyramidal disorder	18	0
Fine motor delay	3	0
Fine motor skill dysfunction	19	0
Hyperkinesia	27	0
Hypokinesia	94	0
Meige's syndrome	1	0
Motor dysfunction	21	0
Movement disorder	105	0
Psychomotor hyperactivity	40	0
Tardive dyskinesia	1	0
<i>Dystonias</i>		
Dystonia	21	0
Dystonic tremor	3	0
Opisthotonus	4	0
Writer's cramp	1	0
<i>Encephalitis NEC</i>		
Bickerstaff's encephalitis	1	0
Encephalitis autoimmune	3	0
Limbic encephalitis	1	0
Noninfective encephalitis	10	0
<i>Encephalopathies NEC</i>		
Autoimmune encephalopathy	4	1
Encephalopathy	9	0
Hypertensive encephalopathy	1	0
Hypoxic-ischaemic encephalopathy	1	0
Posterior reversible encephalopathy syndrome	3	0
<i>Encephalopathies toxic and metabolic</i>		
Hepatic encephalopathy	2	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
<i>Eye movement disorders</i>		
IIIrd nerve disorder	1	0
IIIrd nerve paralysis	6	0
IIIrd nerve paresis	1	0
Microvascular cranial nerve palsy	2	0
VIth nerve paralysis	9	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	578	0
Facial nerve disorder	8	0
Facial paralysis	343	0
Facial paresis	166	0
Facial spasm	43	0
Oculofacial paralysis	1	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	99	0
<i>Glossopharyngeal nerve disorders</i>		
Glossopharyngeal neuralgia	1	0
<i>Headaches NEC</i>		
Cervicogenic headache	6	0
Chronic paroxysmal hemicrania	1	0
Cluster headache	743	0
Cold-stimulus headache	89	0
Drug withdrawal headache	17	0
Exertional headache	12	0
External compression headache	5	0
Headache	80685	0
Medication overuse headache	19	0
New daily persistent headache	19	0
Occipital neuralgia	26	0
Ophthalmoplegic migraine	1	0
Post-traumatic headache	3	0
Primary cough headache	2	0
Primary headache associated with sexual activity	13	0
Sinus headache	956	0
Tension headache	1514	0
Thunderclap headache	49	0
Vascular headache	80	0
<i>Hydrocephalic conditions</i>		
Hydrocephalus	15	0
<i>Hypoglossal nerve disorders</i>		
Tongue paralysis	6	0
<i>Increased intracranial pressure disorders</i>		
Brain compression	4	0
Brain oedema	31	1
Cerebrospinal fluid circulation disorder	6	0
Cytotoxic oedema	1	0
Idiopathic intracranial hypertension	7	0
Intracranial pressure increased	26	0
<i>Intellectual disabilities</i>		
Intellectual disability	11	0
<i>Lumbar spinal cord and nerve root disorders</i>		
Lumbar radiculopathy	4	0
Sciatica	214	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
<i>Memory loss (excl dementia)</i>		
Amnesia	397	0
Memory impairment	361	0
Transient global amnesia	25	0
<i>Meningitis NEC</i>		
Meningitis noninfective	1	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	195	1
Disturbance in attention	725	0
Judgement impaired	4	0
Mental impairment	138	0
<i>Migraine headaches</i>		
Basilar migraine	5	0
Hemiplegic migraine	48	0
Migraine	7537	0
Migraine with aura	388	0
Migraine without aura	47	0
Ophthalmic migraine	13	0
Retinal migraine	87	0
Status migrainosus	5	0
Typical aura without headache	18	0
Vestibular migraine	40	0
<i>Mixed cranial nerve disorders</i>		
Bulbar palsy	3	0
<i>Mononeuropathies</i>		
Carpal tunnel syndrome	40	0
Cubital tunnel syndrome	1	0
Diabetic mononeuropathy	1	0
Meralgia paraesthetica	3	0
Mononeuritis	4	0
Mononeuropathy	3	0
Nerve compression	55	0
Peripheral nerve lesion	1	0
Peroneal nerve palsy	17	0
Piriformis syndrome	4	0
Radial nerve palsy	2	0
Sciatic nerve neuropathy	3	0
Ulnar nerve palsy	3	0
Ulnar neuritis	3	0
Ulnar tunnel syndrome	1	0
<i>Motor neurone diseases</i>		
Amyotrophic lateral sclerosis	1	0
Lower motor neurone lesion	1	0
Motor neurone disease	3	0
<i>Multiple sclerosis acute and progressive</i>		
Band sensation	6	0
Multiple sclerosis	60	0
Multiple sclerosis relapse	53	0
Progressive multiple sclerosis	1	0
Relapsing multiple sclerosis	1	0
Tumefactive multiple sclerosis	1	0
Uhthoff's phenomenon	4	0
<i>Muscle tone abnormal</i>		

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Drop attacks	2	0
Hypertonia	5	0
Hypotonia	38	0
Serotonin syndrome	1	0
Stiff leg syndrome	10	0
Stiff person syndrome	1	0
Myelitis (incl infective)		
Myelitis transverse	91	0
Narcolepsy and hypersomnia		
Cataplexy	1	0
Hypersomnia	219	0
Narcolepsy	21	0
Nervous system cysts and polyps		
Pineal gland cyst	1	0
Nervous system disorders NEC		
Brain stem syndrome	2	0
Central nervous system lesion	6	0
Cerebral disorder	7	0
Microglial nodules	1	0
Nervous system disorder	68	0
Neurotoxicity	4	0
Psychomotor skills impaired	4	0
Neurologic visual problems NEC		
Hemianopia	9	0
Hemianopia homonymous	2	0
Quadrantanopia	1	0
Tunnel vision	22	0
Neurological signs and symptoms NEC		
Agitation neonatal	1	0
Clonus	2	0
Dizziness	22303	0
Dizziness exertional	101	0
Dizziness postural	2143	0
Drooling	25	0
Exaggerated startle response	4	0
Fontanelle bulging	4	0
Grimacing	1	0
Head discomfort	745	0
Hyporesponsive to stimuli	3	0
Inability to crawl	2	0
Infant irritability	6	0
Intracranial hypotension	3	0
Meningism	3	0
Myoclonus	32	0
Neurological decompensation	4	0
Neurological symptom	123	0
Patient elopement	3	0
Persistent postural-perceptual dizziness	38	0
Pleocytosis	3	0
Presyncope	604	0
Sensory overload	11	0
Slow response to stimuli	8	0
Spontaneous cerebrospinal fluid leak syndrome	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Tongue biting	10	0
Unresponsive to stimuli	105	0
Neuromuscular disorders NEC		
Hypotonic-hyporesponsive episode	1	0
Muscle contractions involuntary	37	0
Muscle spasticity	31	0
Neuromuscular pain	6	0
Neuromyopathy	3	0
Neuromyotonia	1	0
Sensorimotor disorder	1	0
Neuromuscular junction dysfunction		
Myasthenia gravis	17	0
Myasthenia gravis crisis	3	0
Olfactory nerve disorders		
Anosmia	325	0
Hyposmia	11	0
Parosmia	399	0
Optic nerve disorders NEC		
Optic neuritis	54	0
Paraesthesias and dysaesthesias		
Anaesthesia	3	0
Burning feet syndrome	30	0
Burning sensation	990	0
Burning sensation mucosal	3	0
Dysaesthesia	13	0
Formication	79	0
Hand-arm vibration syndrome	3	0
Hemianaesthesia	5	0
Hemiparaesthesia	3	0
Hyperaesthesia	272	0
Hypoaesthesia	5888	0
Lhermitte's sign	3	0
Paraesthesia	9570	0
Reversed hot-cold sensation	1	0
Paralysis and paresis (excl cranial nerve)		
Diplegia	35	0
Gait spastic	1	0
Hemiparesis	114	0
Hemiplegia	44	0
Monoparesis	107	0
Monoplegia	138	0
Paralysis	326	1
Paraparesis	6	0
Paraplegia	3	0
Paresis	8	0
Peripheral nerve palsy	1	0
Postictal paralysis	3	0
Quadriparesis	1	0
Quadriplegia	3	0
Parkinson's disease and parkinsonism		
Freezing phenomenon	158	0
Parkinson's disease	17	0
Parkinsonism	12	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Reduced facial expression	8	0
Vascular parkinsonism	1	0
Partial complex seizures		
Dreamy state	21	0
Focal dyscognitive seizures	7	0
Temporal lobe epilepsy	5	0
Partial simple seizures NEC		
Autonomic seizure	1	0
Simple partial seizures	7	0
Peripheral neuropathies NEC		
Autoimmune neuropathy	2	0
Axonal neuropathy	2	0
Ischaemic neuropathy	2	0
Neuralgic amyotrophy	7	0
Neuritis	17	0
Neuropathy peripheral	249	0
Peripheral motor neuropathy	2	0
Peripheral sensorimotor neuropathy	2	0
Peripheral sensory neuropathy	18	0
Polyneuropathy	13	0
Small fibre neuropathy	3	0
Thoracic outlet syndrome	2	0
Seizures and seizure disorders NEC		
Acute encephalitis with refractory, repetitive partial seizures	1	0
Alcoholic seizure	1	0
Atonic seizures	12	0
Change in seizure presentation	7	0
Clonic convulsion	10	0
Convulsive threshold lowered	1	0
Drug withdrawal convulsions	2	0
Epilepsy	327	1
Epileptic aura	2	0
Febrile convulsion	92	0
Hypoglycaemic seizure	1	0
Migraine-triggered seizure	2	0
Myoclonic epilepsy	5	0
Partial seizures	58	0
Psychogenic seizure	5	0
Seizure	1326	3
Seizure anoxic	3	0
Seizure cluster	9	0
Seizure like phenomena	2	0
Status epilepticus	27	2
Tonic clonic movements	3	0
Tonic convulsion	36	0
Sensory abnormalities NEC		
Ageusia	1076	0
Allodynia	62	0
Aura	25	0
Central pain syndrome	2	0
Complex regional pain syndrome	13	0
Decreased vibratory sense	1	0
Dysgeusia	2010	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Electric shock sensation	102	0
Hypogeusia	7	0
Intercostal neuralgia	2	0
Loss of proprioception	6	0
Neuralgia	1408	0
Persistent genital arousal disorder	2	0
Phantom limb syndrome	18	0
Post herpetic neuralgia	11	0
Restless arm syndrome	15	0
Restless legs syndrome	397	0
Sensory disturbance	153	0
Sensory loss	237	0
Taste disorder	510	0
Vibratory sense increased	5	0
Visual perseveration	1	0
Sleep disturbances NEC		
Microsleep	3	0
Periodic limb movement disorder	1	0
Sleep deficit	52	0
Sudden onset of sleep	1	0
Speech and language abnormalities		
Dysarthria	444	0
Incoherent	18	0
Language disorder	3	0
Muscle tension dysphonia	1	0
Repetitive speech	1	0
Slow speech	39	0
Speech disorder	120	0
Speech disorder developmental	1	0
Spinal cord and nerve root disorders NEC		
Cauda equina syndrome	6	0
Myelopathy	5	0
Radicular pain	1	0
Radiculitis brachial	27	0
Radiculopathy	3	0
Spinal cord disorder	6	0
Spinal cord ischaemia	1	0
Spinal cord oedema	1	0
Subacute combined cord degeneration	1	0
Structural brain disorders NEC		
Brain injury	37	3
Cerebral mass effect	10	0
Encephalomalacia	1	0
Intracranial mass	4	0
White matter lesion	4	0
Transient cerebrovascular events		
Transient ischaemic attack	482	1
Tremor (excl congenital)		
Action tremor	4	0
Asterixis	1	0
Essential tremor	7	0
Head titubation	24	0
Intention tremor	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Postural tremor	2	0
Resting tremor	8	0
Tremor	9728	1
Trigeminal disorders		
Facial neuralgia	39	0
Numb chin syndrome	3	0
Trigeminal nerve disorder	6	0
Trigeminal neuralgia	110	0
Trigeminal neuritis	2	0
Trigeminal palsy	1	0
Vagus nerve disorders		
Vagus nerve paralysis	1	0
Vocal cord paralysis	4	0
Vertigos NEC		
Vertigo CNS origin	2	0
Nervous system disorders SOC TOTAL	177154	194

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortion related conditions and complications</i>		
Anembryonic gestation	1	0
<i>Abortions not specified as induced or spontaneous</i>		
Abortion missed	1	0
<i>Abortions spontaneous</i>		
Abortion spontaneous	212	3
<i>Foetal complications NEC</i>		
Haemorrhage foetal	1	0
<i>Foetal position and presentation abnormalities</i>		
Face presentation	1	0
<i>Gestational age and weight conditions</i>		
Low birth weight baby	1	0
Premature baby	1	0
<i>Haemorrhagic complications of pregnancy</i>		
Haemorrhage in pregnancy	1	0
<i>Hypertension associated disorders of pregnancy</i>		
Pre-eclampsia	2	0
<i>Labour onset and length abnormalities</i>		
Precipitate labour	1	0
Premature labour	3	0
Premature rupture of membranes	1	0
Prolonged labour	1	0
<i>Maternal complications of delivery NEC</i>		
Traumatic delivery	1	0
<i>Maternal complications of labour NEC</i>		
Uterine contractions abnormal	2	0
<i>Maternal complications of pregnancy NEC</i>		
Biochemical pregnancy	3	0
Decidual cast	3	0
Ectopic pregnancy	7	0
Hyperemesis gravidarum	2	0
Morning sickness	2	0
Pelvic girdle pain	2	0
Somatic symptom disorder of pregnancy	1	0
<i>Multiple pregnancies</i>		
Twin pregnancy	2	0
<i>Normal pregnancy, labour and delivery</i>		
Labour pain	1	0
Pregnancy	26	0
Uterine contractions during pregnancy	1	0
<i>Pregnancy complicated by maternal disorders</i>		
Gestational diabetes	6	0
Peripartum cardiomyopathy	1	0
<i>Stillbirth and foetal death</i>		
Stillbirth	3	3
<i>Umbilical cord complications</i>		
Umbilical cord around neck	1	0
<i>Unintended pregnancies</i>		
Pregnancy after post coital contraception	2	0
Pregnancy on contraceptive	4	0
Pregnancy with implant contraceptive	2	0
Unintended pregnancy	2	0
Pregnancy conditions SOC TOTAL	301	6

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Reaction Name	Total	Fatal
<i>Counterfeit, falsified and substandard products</i>		
Suspected counterfeit product	2	0
<i>Device electrical issues</i>		
Device electrical impedance issue	1	0
<i>Device incompatibility issues</i>		
Patient-device incompatibility	1	0
<i>Device issues NEC</i>		
Device expulsion	3	0
Device issue	4	0
Device leakage	2	0
<i>Device malfunction events NEC</i>		
Device occlusion	1	0
Oversensing	34	0
Stent malfunction	1	0
Thrombosis in device	65	1
Undersensing	7	0
<i>Device physical property and chemical issues</i>		
Needle issue	11	0
Syringe issue	1	0
<i>Manufacturing facilities and equipment issues</i>		
Manufacturing equipment issue	1	0
<i>Product contamination and sterility issues</i>		
Product contamination	1	0
Suspected product contamination	1	0
<i>Product distribution and storage issues</i>		
Product temperature excursion issue	5	0
<i>Product label issues</i>		
Product barcode issue	1	0
Product label issue	2	0
<i>Product packaging issues</i>		
Product container issue	2	0
<i>Product physical issues</i>		
Liquid product physical issue	1	0
Product colour issue	3	0
Product leakage	1	0
Product odour abnormal	3	0
Product physical issue	2	0
Product taste abnormal	8	0
<i>Product quality issues NEC</i>		
Product formulation issue	1	0
Product origin unknown	3	0
Product quality issue	1	0
Suspected product quality issue	2	0
<i>Product supply and availability issues</i>		
Product availability issue	1	0
null SOC TOTAL	172	1

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	25	0
Behaviour disorder	1	0
Breath holding	5	0
Sexually inappropriate behaviour	1	0
Staring	13	0
<i>Abnormal food elimination</i>		
Self-induced vomiting	1	0
<i>Adjustment disorders</i>		
Adjustment disorder	1	0
Adjustment disorder with depressed mood	6	0
Adjustment disorder with mixed anxiety and depressed mood	2	0
<i>Affect alterations NEC</i>		
Affect lability	13	0
Blunted affect	1	0
Constricted affect	11	0
Flat affect	10	0
Inappropriate affect	18	0
<i>Amnesic symptoms</i>		
Paramnesia	6	0
<i>Anxiety disorders NEC</i>		
Anxiety disorder	3	0
Generalised anxiety disorder	4	0
Neurosis	1	0
<i>Anxiety symptoms</i>		
Agitation	202	0
Anxiety	1243	0
Immunisation anxiety related reaction	1	0
Nervousness	595	0
Procedural anxiety	1	0
Stress	157	0
Tension	72	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	20	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	16	0
Antisocial behaviour	2	0
Asocial behaviour	1	0
Attention-seeking behaviour	1	0
Aversion	1	0
Disinhibition	2	0
Homicidal ideation	1	0
Impatience	2	0
Indifference	10	0
Paranoia	41	0
Personality change	10	0
Social avoidant behaviour	6	0
Soliloquy	3	0
Violence-related symptom	3	0
<i>Bipolar disorders</i>		
Bipolar I disorder	8	0
Bipolar disorder	6	0
<i>Cognitive and attention disorders and disturbances NEC</i>		

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Change in sustained attention	1	0
Daydreaming	15	0
Distractibility	2	0
Mental fatigue	481	0
Communications disorders		
Communication disorder	6	0
Mutism	6	0
Speech sound disorder	2	0
Confusion and disorientation		
Confusional state	2115	0
Disorientation	726	0
Decreased physical activity levels		
Catatonia	3	0
Deliria		
Delirium	479	0
Delirium febrile	3	0
Delusional disorders		
Alice in wonderland syndrome	4	0
Delusional symptoms		
Delusion	55	0
Delusion of parasitosis	3	0
Mixed delusion	1	0
Thought withdrawal	1	0
Dementia NEC		
Pseudodementia	1	0
Depressive disorders		
Agitated depression	3	0
Childhood depression	1	0
Depression	650	0
Depression suicidal	16	0
Major depression	24	0
Menopausal depression	2	0
Mixed anxiety and depressive disorder	2	0
Dissociative states		
Depersonalisation/derealisation disorder	20	0
Dissociation	75	0
Dissociative amnesia	1	0
Dissociative disorder	2	0
Disturbances in initiating and maintaining sleep		
Initial insomnia	42	0
Insomnia	3080	0
Middle insomnia	72	0
Terminal insomnia	26	0
Dyssomnias		
Dyssomnia	5	0
Poor quality sleep	661	0
Eating disorders NEC		
Binge eating	1	0
Eating disorder	16	0
Pica	1	0
Selective eating disorder	2	0
Emotional and mood disturbances NEC		
Anger	88	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Dysphoria	2	0
Emotional disorder	101	0
Emotional distress	83	0
Emotional poverty	2	0
Euphoric mood	68	0
Frustration tolerance decreased	15	0
Irritability	316	0
Mood altered	86	0
Factitious disorders		
Factitious disorder	4	0
Fear symptoms and phobic disorders (incl social phobia)		
Acrophobia	2	0
Agoraphobia	4	0
Fear	63	0
Fear of death	18	0
Fear of disease	2	0
Fear of eating	1	0
Fear of falling	4	0
Fear of injection	2	0
Fear of open spaces	1	0
Fear-related avoidance of activities	2	0
Performance fear	1	0
Phobia	3	0
Phonophobia	3	0
Social anxiety disorder	1	0
Social fear	1	0
Thanatophobia	1	0
Fluctuating mood symptoms		
Mood swings	129	0
Hallucinations (excl sleep-related)		
Hallucination	933	0
Hallucination, auditory	48	0
Hallucination, olfactory	14	0
Hallucination, tactile	1	0
Hallucination, visual	57	0
Hallucinations, mixed	9	0
Somatic hallucination	1	0
Impulse control disorders		
Clinomania	1	0
Impulse-control disorder	2	0
Impulsive behaviour	2	0
Intermittent explosive disorder	1	0
Increased physical activity levels		
Restlessness	489	0
Infancy, childhood and adolescence psychiatric disorders NEC		
Emotional disorder of childhood	1	0
Learning disorders		
Reading disorder	1	0
Mental disorders NEC		
Mental disorder	28	0
Mental status changes	4	0
Mental disorders due to a general medical condition NEC		
Mental disorder due to a general medical condition	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Neuropsychiatric symptoms	2	0
<i>Mood alterations with depressive symptoms</i>		
Anhedonia	4	0
Decreased interest	17	0
Depressed mood	679	0
Depressive symptom	2	0
Feeling guilty	1	0
Feeling of despair	19	0
Negative thoughts	9	0
Sense of a foreshortened future	3	0
Tearfulness	104	0
<i>Mood alterations with manic symptoms</i>		
Hypomania	1	0
Mania	31	0
<i>Mood disorders NEC</i>		
Affective disorder	4	0
Apathy	74	0
Laziness	1	0
Listless	123	0
Mood disorder due to a general medical condition	1	0
Substance-induced mood disorder	1	0
<i>Narcolepsy and associated conditions</i>		
Hypnagogic hallucination	4	0
Sleep attacks	2	0
<i>Obsessive-compulsive disorders and symptoms</i>		
Body dysmorphic disorder	2	0
Compulsive shopping	2	0
Dermatillomania	2	0
Obsessive thoughts	3	0
Obsessive-compulsive disorder	2	0
Obsessive-compulsive symptom	1	0
<i>Orgasmic disorders and disturbances</i>		
Anorgasmia	6	0
Female orgasmic disorder	1	0
Orgasm abnormal	1	0
Orgasmic sensation decreased	4	0
Premature ejaculation	3	0
<i>Panic attacks and disorders</i>		
Limited symptom panic attack	1	0
Panic attack	334	0
Panic disorder	8	0
Panic reaction	40	0
<i>Paraphilias and paraphilic disorders</i>		
Fetishism	2	0
<i>Parasomnias</i>		
Abnormal dreams	368	0
Abnormal sleep-related event	2	0
Confusional arousal	3	0
Exploding head syndrome	6	0
Nightmare	453	0
Parasomnia	1	0
Rapid eye movements sleep abnormal	4	0
Sleep inertia	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Sleep talking	16	0
Sleep terror	59	0
Sleep-related eating disorder	2	0
Somnambulism	11	0
Perception disturbances NEC		
Autoscopy	28	0
Deja vu	4	0
Delusional perception	2	0
Derealisation	15	0
Flashback	2	0
Illusion	11	0
Imperception	1	0
Near death experience	1	0
Pseudohallucination	1	0
Time perception altered	5	0
Personality disorders NEC		
Personality disorder	1	0
Pervasive developmental disorders NEC		
Autism spectrum disorder	4	0
Psychiatric elimination disorders		
Enuresis	58	0
Psychiatric symptoms NEC		
Decreased eye contact	2	0
Helplessness	3	0
Hypervigilance	13	0
Psychiatric symptom	11	0
Psychological trauma	5	0
Psychotic disorder NEC		
Acute psychosis	5	0
Psychotic behaviour	2	0
Psychotic disorder	44	0
Psychotic symptom	1	0
Rebound psychosis	1	0
Schizoaffective and schizophreniform disorders		
Schizoaffective disorder	1	0
Schizophrenia NEC		
Schizophrenia	1	0
Sexual arousal disorders		
Disturbance in sexual arousal	5	0
Sexual desire disorders		
Excessive masturbation	1	0
Hypersexuality	1	0
Libido decreased	24	0
Libido disorder	1	0
Libido increased	9	0
Loss of libido	49	0
Sexual dysfunction NEC		
Genito-pelvic pain/penetration disorder	1	0
Sleep disorders NEC		
Sleep disorder	421	1
Sleep disorder due to a general medical condition	1	0
Sleep disorder due to general medical condition, insomnia type	3	0
Somatic symptom disorders		

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Conversion disorder	32	0
Habit cough	39	0
Illness anxiety disorder	1	0
Psychogenic tremor	2	0
Somatic symptom disorder	1	0
Speech and language usage disturbances		
Disorganised speech	21	0
Logorrhoea	3	0
Pedantic speech	1	0
Poverty of speech	1	0
Verbigeration	1	0
Speech articulation and rhythm disturbances		
Dysphemia	33	0
Lack of spontaneous speech	3	0
Stereotypies and automatisms		
Bruxism	35	0
Head banging	47	0
Waxy flexibility	2	0
Stress disorders		
Acute stress disorder	2	0
Burnout syndrome	13	0
Hyperarousal	3	0
Post-traumatic stress disorder	14	0
Substance related and addictive disorders		
Alcohol abuse	2	0
Alcohol use disorder	3	0
Alcoholic hangover	1	0
Alcoholism	3	0
Dependence	2	0
Drug abuse	1	0
Drug dependence	1	0
Nicotine dependence	1	0
Substance abuse	2	0
Suicidal and self-injurious behaviour		
Completed suicide	5	5
Intentional self-injury	9	0
Self-injurious ideation	3	0
Suicidal behaviour	3	0
Suicidal ideation	116	0
Suicide attempt	30	0
Suicide threat	1	0
Thinking disturbances		
Bradyphrenia	91	0
Confabulation	1	0
Illogical thinking	1	0
Impaired reasoning	3	0
Intrusive thoughts	6	0
Morbid thoughts	5	0
Tachyphrenia	23	0
Thinking abnormal	29	0
Thought blocking	6	0
Tic disorders		
Secondary tic	2	0

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Reaction Name	Total	Fatal
Psychiatric disorders ^{Psychiatric disorders cont'd}		
Tic	20	0
Psychiatric disorders SOC TOTAL	17510	6

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder discomfort	8	0
Bladder irritation	7	0
Bladder pain	63	0
Bladder spasm	1	0
Dysuria	87	0
Incontinence	85	0
Micturition disorder	4	0
Micturition frequency decreased	1	0
Micturition urgency	102	0
Mixed incontinence	1	0
Pollakiuria	291	0
Stress urinary incontinence	1	0
Urethral pain	6	0
Urge incontinence	2	0
Urinary hesitation	7	0
Urinary incontinence	125	0
Urinary retention	94	0
Urine flow decreased	22	0
<i>Bladder disorders NEC</i>		
Bladder dilatation	1	0
Bladder disorder	22	0
Bladder prolapse	1	0
Urinary bladder haemorrhage	15	1
Urinary bladder rupture	1	0
<i>Bladder infections and inflammations</i>		
Cystitis haemorrhagic	1	0
Cystitis interstitial	8	0
Cystitis noninfective	3	0
Lupus cystitis	1	0
<i>Genital and urinary tract disorders NEC</i>		
Urinary tract disorder	11	0
Urogenital haemorrhage	1	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
Anti-glomerular basement membrane disease	1	0
Focal segmental glomerulosclerosis	2	0
Glomerulonephritis	1	0
Glomerulonephritis membranoproliferative	1	0
Glomerulonephritis membranous	2	0
Glomerulonephritis minimal lesion	5	0
IgA nephropathy	4	0
Nephrotic syndrome	17	0
<i>Myoneurogenic bladder disorders</i>		
Atonic urinary bladder	1	0
Automatic bladder	1	0
Bladder dysfunction	13	0
Hypertonic bladder	15	0
Loss of bladder sensation	12	0
Neurogenic bladder	4	0
<i>Nephritis NEC</i>		
Lupus nephritis	2	0
Nephritis	7	0
Tubulointerstitial nephritis	6	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Renal & urinary disorders cont'd</i>		
<i>Nephropathies and tubular disorders NEC</i>		
Nephropathy	2	0
<i>Renal disorders NEC</i>		
Oedematous kidney	1	0
Renal disorder	13	0
Renal haemorrhage	3	0
<i>Renal failure and impairment</i>		
Acute kidney injury	69	1
Anuria	5	0
Chronic kidney disease	10	0
End stage renal disease	1	0
Oliguria	11	0
Renal failure	43	2
Renal impairment	23	0
Renal injury	6	0
<i>Renal hypertension and related conditions</i>		
Hypertensive nephropathy	1	0
<i>Renal lithiasis</i>		
Nephrolithiasis	21	0
<i>Renal obstructive disorders</i>		
Hydronephrosis	1	0
<i>Renal structural abnormalities and trauma</i>		
Kidney enlargement	1	0
Renal atrophy	2	0
<i>Renal vascular and ischaemic conditions</i>		
Renal artery occlusion	1	0
Renal artery thrombosis	1	0
Renal embolism	1	0
Renal infarct	17	1
Renal tubular injury	1	0
Renal vascular thrombosis	2	0
Renal vasculitis	1	0
Renal vein embolism	1	0
Renal vein occlusion	3	0
Renal vein thrombosis	9	0
<i>Structural and obstructive urethral disorders (excl congenital)</i>		
Urethral spasm	1	0
Urethral stenosis	1	0
<i>Ureteric disorders NEC</i>		
Ureteral disorder	2	0
<i>Urinary abnormalities</i>		
Chromaturia	104	0
Glycosuria	1	0
Haematuria	1	0
Haematuria	62	0
Microalbuminuria	1	0
Proteinuria	11	0
Urine abnormality	20	0
Urine odour abnormal	21	0
<i>Urinary tract signs and symptoms NEC</i>		
Costovertebral angle tenderness	1	0
Haemorrhage urinary tract	58	0
Nocturia	22	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
Renal & urinary disorders cont'd		
Pneumaturia	1	0
Polyuria	33	0
Renal colic	4	0
Renal pain	933	0
Urinary tract discomfort	2	0
Urinary tract pain	15	0
Renal & urinary disorders SOC TOTAL	2610	5

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Benign and malignant breast neoplasms</i>		
Breast cyst	12	0
<i>Breast disorders NEC</i>		
Anisomastia	1	0
Breast disorder	4	0
Breast enlargement	11	0
Breast mass	66	0
Gynaecomastia	9	0
Mammary duct ectasia	1	0
Nipple disorder	1	0
<i>Breast infections and inflammations</i>		
Breast inflammation	4	0
Nipple inflammation	1	0
<i>Breast signs and symptoms</i>		
Breast discharge	9	0
Breast discolouration	1	0
Breast discomfort	12	0
Breast engorgement	6	0
Breast haemorrhage	1	0
Breast induration	1	0
Breast oedema	1	0
Breast pain	475	0
Breast swelling	68	0
Breast tenderness	74	0
Nipple exudate bloody	1	0
Nipple pain	37	0
Nipple swelling	4	0
<i>Cervix disorders NEC</i>		
Cervical friability	1	0
Cervix haemorrhage uterine	1	0
Ectropion of cervix	1	0
<i>Cervix neoplasms</i>		
Cervical polyp	1	0
<i>Erection and ejaculation conditions and disorders</i>		
Ejaculation delayed	2	0
Ejaculation disorder	3	0
Ejaculation failure	5	0
Erectile dysfunction	88	0
Erection increased	6	0
Organic erectile dysfunction	19	0
Painful ejaculation	1	0
Painful erection	2	0
Priapism	3	0
Retrograde ejaculation	4	0
Spontaneous penile erection	2	0
<i>Fallopian tube and ovary infections and inflammations</i>		
Noninfective oophoritis	1	0
<i>Lactation disorders</i>		
Galactorrhoea	3	0
Lactation disorder	2	0
Lactation puerperal increased	6	0
Suppressed lactation	27	0
<i>Menopausal effects NEC</i>		

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Artificial menopause	2	0
Menopausal disorder	3	0
Menopausal symptoms	58	0
Menopause delayed	5	0
Premature menopause	43	0
Menopausal effects on the genitourinary tract		
Atrophic vulvovaginitis	1	0
Postmenopausal haemorrhage	292	0
Menstruation and uterine bleeding NEC		
Abnormal uterine bleeding	7	0
Abnormal withdrawal bleeding	5	0
Dysmenorrhoea	1330	0
Intermenstrual bleeding	663	0
Menstrual discomfort	13	0
Menstrual disorder	1424	0
Menstruation irregular	2136	0
Premenstrual dysphoric disorder	6	0
Premenstrual headache	8	0
Premenstrual pain	76	0
Premenstrual syndrome	51	0
Retrograde menstruation	4	0
Withdrawal bleed	13	0
Menstruation with decreased bleeding		
Amenorrhoea	568	0
Hypomenorrhoea	412	0
Menstruation delayed	3069	0
Oligomenorrhoea	107	0
Menstruation with increased bleeding		
Heavy menstrual bleeding	4418	0
Menometrorrhagia	17	0
Polymenorrhoea	635	0
Ovarian and fallopian tube cysts and neoplasms		
Ovarian cyst	27	0
Ovarian cyst ruptured	2	0
Polycystic ovaries	39	0
Ovarian and fallopian tube disorders NEC		
Fallopian tube spasm	1	0
Ovarian adhesion	1	0
Ovarian enlargement	2	0
Ovarian failure	2	0
Ovarian haemorrhage	4	0
Ovarian hyperstimulation syndrome	1	0
Ovarian necrosis	1	0
Ovarian oedema	1	0
Ovarian vein thrombosis	2	0
Ovulation pain	53	0
Premature ovulation	7	0
Pelvic prolapse conditions		
Pelvic prolapse	1	0
Vaginal prolapse	2	0
Pelvis and broad ligament disorders NEC		
Adnexa uteri pain	40	0
Pelvic haematoma	1	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Pelvic haemorrhage	27	0
<i>Penile and scrotal infections and inflammations</i>		
Balanoposthitis	3	0
<i>Penile disorders NEC (excl erection and ejaculation)</i>		
Penile blister	6	0
Penile burning sensation	1	0
Penile curvature	4	0
Penile discharge	4	0
Penile erosion	1	0
Penile exfoliation	1	0
Penile haemorrhage	7	0
Penile oedema	3	0
Penile pain	2	0
Penile size reduced	2	0
Penis disorder	10	0
Peyronie's disease	4	0
<i>Prostate and seminal vesicles infections and inflammations</i>		
Prostatitis	6	0
<i>Prostatic neoplasms and hypertrophy</i>		
Benign prostatic hyperplasia	2	0
<i>Prostatic signs, symptoms and disorders NEC</i>		
Prostatic pain	1	0
Prostatism	1	0
Prostatomegaly	3	0
<i>Reproductive tract disorders NEC (excl neoplasms)</i>		
Female genital tract fistula	1	0
Genital blister	5	0
Genital haemorrhage	31	0
Genital hyperaesthesia	1	0
Genital hypoaesthesia	2	0
Genital lesion	2	0
Genital paraesthesia	5	0
Genital ulceration	13	0
Perineal disorder	2	0
Varicose veins pelvic	1	0
<i>Reproductive tract infections and inflammations NEC</i>		
Genital tract inflammation	2	0
<i>Reproductive tract neoplasms NEC</i>		
Genital cyst	2	0
<i>Reproductive tract signs and symptoms NEC</i>		
Genital burning sensation	8	0
Genital discomfort	4	0
Genital erythema	1	0
Genital pain	3	0
Genital rash	6	0
Genital swelling	2	0
Pelvic discomfort	4	0
Pelvic pain	167	0
Perineal pain	2	0
Pruritus genital	9	0
<i>Scrotal disorders NEC</i>		
Scrotal dermatitis	1	0
Scrotal oedema	1	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Scrotal pain	19	0
Scrotal swelling	5	0
Varicocele	1	0
Sexual function and fertility disorders NEC		
Dyspareunia	7	0
Female sexual dysfunction	1	0
Infertility	11	0
Infertility female	5	0
Infertility male	3	0
Male sexual dysfunction	2	0
Sexual dysfunction	14	0
Spermatogenesis and semen disorders		
Aspermia	2	0
Haematospermia	17	0
Semen discolouration	2	0
Testicular and epididymal disorders NEC		
Testicular atrophy	1	0
Testicular disorder	8	0
Testicular mass	1	0
Testicular oedema	2	0
Testicular pain	107	0
Testicular retraction	3	0
Testicular swelling	23	0
Testis discomfort	6	0
Testicular and epididymal infections and inflammations		
Orchitis noninfective	1	0
Testicular and epididymal neoplasms		
Epididymal cyst	1	0
Testicular cyst	1	0
Uterine disorders NEC		
Adenomyosis	13	0
Endometrial hyperplasia	1	0
Endometrial thickening	2	0
Endometriosis	82	0
Metrorrhoea	1	0
Uterine enlargement	2	0
Uterine haemorrhage	68	0
Uterine pain	9	0
Uterine neoplasms		
Uterine cyst	1	0
Uterine polyp	4	0
Uterine tone disorders		
Uterine spasm	23	0
Vaginal and vulval infections and inflammations		
Vulvovaginal inflammation	2	0
Vulvovaginal cysts and neoplasms		
Bartholin's cyst	2	0
Vaginal cyst	14	0
Vulva cyst	1	0
Vulvovaginal disorders NEC		
Vaginal disorder	1	0
Vaginal haemorrhage	1257	0
Vaginal ulceration	7	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Vulval disorder	3	0
Vulval haemorrhage	32	0
Vulval ulceration	6	0
Vulvovaginal ulceration	2	0
<i>Vulvovaginal signs and symptoms</i>		
Clitoral engorgement	1	0
Coital bleeding	7	0
Enlarged clitoris	1	0
Labia enlarged	2	0
Vaginal discharge	85	0
Vaginal lesion	7	0
Vaginal odour	4	0
Vulval oedema	1	0
Vulvovaginal burning sensation	9	0
Vulvovaginal discomfort	8	0
Vulvovaginal dryness	12	0
Vulvovaginal erythema	1	0
Vulvovaginal pain	36	0
Vulvovaginal pruritus	12	0
Vulvovaginal rash	2	0
Vulvovaginal swelling	7	0
Reproductive & breast disorders SOC TOTAL	18865	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	13	0
Apnoeic attack	1	0
Cheyne-Stokes respiration	2	0
Dyspnoea	7330	0
Dyspnoea at rest	15	0
Dyspnoea exertional	57	0
Dyspnoea paroxysmal nocturnal	1	0
Grunting	2	0
Hyperventilation	98	0
Hypopnoea	225	0
Hypoventilation	1	0
Irregular breathing	26	0
Mouth breathing	8	0
Orthopnoea	3	0
Respiration abnormal	107	0
Respiratory arrest	25	0
Respiratory distress	11	0
Respiratory fatigue	7	0
Sleep apnoea syndrome	31	0
Tachypnoea	36	0
<i>Bronchial conditions NEC</i>		
Bronchial haemorrhage	1	0
Bronchial secretion retention	1	0
Bronchiectasis	16	0
<i>Bronchospasm and obstruction</i>		
Aspirin-exacerbated respiratory disease	1	0
Asthma	606	0
Asthma exercise induced	3	0
Asthma late onset	3	0
Asthma-chronic obstructive pulmonary disease overlap syndrome	2	0
Asthmatic crisis	5	0
Bronchial oedema	1	0
Bronchitis chronic	1	0
Bronchospasm	18	0
Chronic obstructive pulmonary disease	48	4
Cough variant asthma	9	0
Obstructive airways disorder	2	0
Reversible airways obstruction	1	0
Wheezing	622	0
<i>Conditions associated with abnormal gas exchange</i>		
Asphyxia	2	0
Hypercapnia	1	0
Hypoxia	70	1
<i>Coughing and associated symptoms</i>		
Allergic cough	8	0
Cough	3910	0
Haemoptysis	141	0
Productive cough	200	0
Sputum discoloured	14	0
Sputum increased	2	0
Sputum retention	1	0
<i>Diaphragmatic disorders</i>		

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Diaphragmatic spasm	1	0
Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)		
Reflux laryngitis	3	0
Vocal cord disorder	5	0
Vocal cord dysfunction	4	0
Vocal cord thickening	2	0
Laryngeal spasm, oedema and obstruction		
Epiglottic oedema	1	0
Laryngeal oedema	3	0
Laryngospasm	3	0
Stridor	20	0
Lower respiratory tract inflammatory and immunologic conditions		
Alveolitis	2	0
Autoimmune lung disease	1	0
Eosinophilic pneumonia	2	0
Hypersensitivity pneumonitis	1	0
Pneumonia aspiration	25	6
Pneumonitis	33	1
Pulmonary sarcoidosis	2	0
Pulmonary vasculitis	1	0
Lower respiratory tract signs and symptoms		
Hiccups	47	0
Lower respiratory tract congestion	4	0
Lung opacity	7	0
Pleuritic pain	48	0
Pulmonary haemorrhage	7	1
Pulmonary pain	226	0
Rales	2	0
Mediastinal disorders		
Pulmonary hilum mass	1	0
Nasal congestion and inflammations		
Nasal congestion	466	0
Nasal inflammation	8	0
Rhinitis allergic	27	0
Rhinitis perennial	1	0
Nasal disorders NEC		
Epistaxis	2247	0
Intranasal hypoaesthesia	1	0
Nasal crusting	6	0
Nasal cyst	2	0
Nasal disorder	7	0
Nasal dryness	64	0
Nasal mucosal discolouration	1	0
Nasal odour	2	0
Nasal oedema	15	0
Nasal polyps	1	0
Nasal pruritus	12	0
Nasal septum deviation	1	0
Nasal septum perforation	1	0
Nasal ulcer	3	0
Neonatal hypoxic conditions		
Gasping syndrome	2	0

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Allergic sinusitis	1	0
Paranasal sinus haemorrhage	5	0
Paranasal sinus hypersecretion	1	0
Paranasal sinus inflammation	4	0
Sinonasal obstruction	10	0
Sinus congestion	90	0
Sinus disorder	16	0
Sinus polyp	3	0
<i>Parenchymal lung disorders NEC</i>		
Atelectasis	7	0
Cystic lung disease	1	0
Emphysema	3	0
Idiopathic pulmonary fibrosis	3	0
Interstitial lung disease	23	2
Lung consolidation	9	0
Lung cyst	1	0
Lung induration	1	0
Lung infiltration	2	0
Pulmonary alveolar haemorrhage	1	0
Pulmonary cavitation	3	0
Pulmonary fibrosis	10	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Oropharyngeal swelling	2	0
Pharyngeal erythema	5	0
Pharyngeal haemorrhage	1	0
Pharyngeal hypoaesthesia	40	0
Pharyngeal inflammation	1	0
Pharyngeal oedema	12	0
Pharyngeal paraesthesia	36	0
Pharyngeal swelling	288	0
Pharyngeal ulceration	15	0
Tonsillar disorder	1	0
Tonsillar erythema	7	0
Tonsillar haemorrhage	1	0
Tonsillar hypertrophy	64	0
Tonsillar inflammation	4	0
Tonsillar ulcer	2	0
Tonsilloolith	1	0
<i>Pleural conditions NEC</i>		
Pleural thickening	1	0
<i>Pleural infections and inflammations</i>		
Lupus pleurisy	2	0
Pleurisy	51	0
<i>Pneumothorax and pleural effusions NEC</i>		
Haemothorax	1	0
Pleural effusion	42	1
Pneumothorax	11	0
Pneumothorax spontaneous	1	0
<i>Pulmonary hypertension</i>		
Pulmonary hypertension	5	1
<i>Pulmonary oedemas</i>		
Acute lung injury	1	0

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Acute pulmonary oedema	3	0
Acute respiratory distress syndrome	1	0
Pulmonary congestion	22	0
Pulmonary oedema	36	1
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary artery thrombosis	1	0
Pulmonary embolism	1617	104
Pulmonary infarction	15	1
Pulmonary thrombosis	23	4
Pulmonary venous thrombosis	4	0
<i>Respiratory failures (excl neonatal)</i>		
Acute respiratory failure	3	1
Respiratory failure	26	3
<i>Respiratory signs and symptoms NEC</i>		
Allergic respiratory symptom	11	0
Diaphragmalgia	15	0
Nasal flaring	1	0
Painful respiration	9	0
Pleural rub	1	0
Respiratory symptom	22	0
Suffocation feeling	5	0
Use of accessory respiratory muscles	2	0
<i>Respiratory tract disorders NEC</i>		
Aspiration	10	2
Chronic respiratory disease	2	1
Lung disorder	10	0
Pulmonary mass	9	0
Respiratory disorder	9	0
Respiratory tract congestion	10	0
Respiratory tract haemorrhage	2	0
Respiratory tract irritation	10	0
Respiratory tract oedema	3	0
<i>Thoracic musculoskeletal disorders</i>		
Respiratory muscle weakness	2	0
<i>Tracheal disorders (excl infections and neoplasms)</i>		
Tracheal fistula	1	0
Tracheal pain	4	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	112	0
Catarrh	65	0
Choking	21	0
Choking sensation	11	0
Dry throat	256	0
Dysphonia	167	0
Increased upper airway secretion	4	0
Increased viscosity of upper respiratory secretion	21	0
Laryngeal pain	1	0
Nasal discharge discolouration	2	0
Nasal discomfort	114	0
Nasal obstruction	2	0
Oropharyngeal blistering	27	0
Oropharyngeal discomfort	38	0
Oropharyngeal pain	4185	0

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Oropharyngeal plaque	1	0
Paranasal sinus discomfort	75	0
Rhinalgia	34	0
Rhinorrhoea	1661	0
Sinus pain	598	0
Sneezing	501	0
Snoring	5	0
Throat clearing	7	0
Throat irritation	211	0
Throat lesion	1	0
Throat tightness	224	0
Upper airway obstruction	1	0
Upper respiratory tract congestion	1	0
Upper-airway cough syndrome	25	0
Yawning	70	0
<i>Vascular pulmonary disorders NEC</i>		
Pulmonary artery occlusion	1	0
Pulmonary vascular disorder	1	0
Respiratory disorders SOC TOTAL	28127	134

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	143	0
Acne cystic	11	0
Dermatitis acneiform	10	0
<i>Alopecias</i>		
Alopecia	393	0
Alopecia areata	35	0
Alopecia scarring	2	0
Alopecia totalis	2	0
Alopecia universalis	3	0
Androgenetic alopecia	2	0
Diffuse alopecia	4	0
Hypotrichosis	1	0
Madarosis	4	0
<i>Angioedemas</i>		
Angioedema	346	0
Circumoral oedema	2	0
Idiopathic angioedema	3	0
<i>Apocrine and eccrine gland disorders</i>		
Anhidrosis	2	0
Cold sweat	1713	0
Hidradenitis	3	0
Hyperhidrosis	9193	0
Hypohidrosis	6	0
Miliaria	219	0
Night sweats	1894	0
Sweat discolouration	3	0
Sweat gland disorder	1	0
<i>Bullous conditions</i>		
Autoimmune blistering disease	1	0
Blister	614	0
Blister rupture	7	0
Blood blister	110	0
Bullous haemorrhagic dermatosis	1	0
Dermatitis bullous	15	0
Dermatitis herpetiformis	2	0
Erythema multiforme	39	0
Linear IgA disease	1	0
Oedema blister	1	0
Pemphigoid	32	0
Pemphigus	5	0
Stevens-Johnson syndrome	7	0
Toxic epidermal necrolysis	2	0
<i>Connective tissue disorders</i>		
Chronic cutaneous lupus erythematosus	1	0
Cutaneous lupus erythematosus	1	0
Dermatomyositis	3	0
Subacute cutaneous lupus erythematosus	1	0
<i>Dermal and epidermal conditions NEC</i>		
Acute febrile neutrophilic dermatosis	3	0
Dermatosis	1	0
Dry skin	445	0
Macule	13	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Myxoid cyst	1	0
Neutrophilic dermatosis	1	0
Pain of skin	930	0
Papule	122	0
Peau d'orange	3	0
Scab	28	0
Scar pain	18	0
Sensitive skin	589	0
Skin burning sensation	574	0
Skin discolouration	203	0
Skin discomfort	6	0
Skin disorder	41	0
Skin fissures	15	0
Skin fragility	2	0
Skin indentation	16	0
Skin induration	16	0
Skin laxity	1	0
Skin lesion	57	0
Skin necrosis	6	0
Skin odour abnormal	51	0
Skin plaque	3	0
Skin reaction	269	0
Skin sensitisation	89	0
Skin swelling	100	0
Skin texture abnormal	2	0
Skin tightness	39	0
Skin warm	579	0
Skin weeping	8	0
Sticky skin	9	0
Target skin lesion	2	0
Transient acantholytic dermatosis	2	0
Yellow skin	32	0
<i>Dermatitis and eczema</i>		
Autoimmune dermatitis	2	0
Dermatitis	188	0
Dermatitis allergic	314	0
Dermatitis atopic	35	0
Dermatitis contact	32	0
Dermatitis diaper	3	0
Dyshidrotic eczema	19	0
Eczema	355	0
Eczema asteatotic	19	0
Eczema nummular	5	0
Eczema weeping	2	0
Hand dermatitis	7	0
Intertrigo	3	0
Neurodermatitis	2	0
Perioral dermatitis	5	0
Prurigo	1	0
Rebound eczema	1	0
Seborrhoeic dermatitis	11	0
Skin irritation	155	0
Stasis dermatitis	7	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Urticarial dermatitis	1	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	37	0
Drug reaction with eosinophilia and systemic symptoms	18	0
Fixed eruption	7	0
Palmar-plantar erythrodysesthesia syndrome	2	0
<i>Erythemas</i>		
Erythema	3357	0
Erythema ab igne	1	0
Palmar erythema	6	0
Plantar erythema	3	0
<i>Exfoliative conditions</i>		
Dermatitis exfoliative	2	0
Dermatitis exfoliative generalised	9	0
Exfoliative rash	17	0
Skin exfoliation	174	0
<i>Granulomatous and deep cutaneous inflammatory conditions</i>		
Granuloma annulare	7	0
<i>Hyperkeratoses</i>		
Hyperkeratosis	2	0
<i>Hyperpigmentation disorders</i>		
Chloasma	2	0
Ephelides	1	0
Melanoderma	2	0
Skin hyperpigmentation	10	0
Solar lentigo	7	0
<i>Hypertrichoses</i>		
Hypertrichosis	4	0
<i>Hypopigmentation disorders</i>		
Skin depigmentation	10	0
Skin hypopigmentation	3	0
Vitiligo	31	0
<i>Lipodystrophies</i>		
Lipoatrophy	2	0
Lipohypertrophy	2	0
Progressive facial hemiatrophy	1	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
Anonychia	1	0
Ingrowing nail	2	0
Nail bed bleeding	1	0
Nail bed disorder	2	0
Nail bed inflammation	1	0
Nail bed tenderness	2	0
Nail discolouration	14	0
Nail disorder	3	0
Nail growth abnormal	2	0
Nail hypertrophy	1	0
Nail necrosis	1	0
Nail pigmentation	2	0
Nail pitting	1	0
Nail ridging	8	0
Onychalgia	6	0
Onychoclasia	9	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Onycholysis	3	0
Onychomadesis	4	0
Splinter haemorrhages	5	0
<i>Panniculitides</i>		
Erythema nodosum	37	0
Panniculitis	4	0
<i>Papulosquamous conditions</i>		
Erythema annulare	2	0
Lichen planus	30	0
Lichen sclerosus	5	0
Lichen striatus	1	0
Parapsoriasis	2	0
Pityriasis lichenoides et varioliformis acuta	1	0
Pityriasis rosea	66	0
Pityriasis rubra pilaris	2	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photodermatosis	2	0
Photosensitivity reaction	164	0
Polymorphic light eruption	6	0
Solar dermatitis	1	0
<i>Pigmentation changes NEC</i>		
Pigmentation disorder	16	0
<i>Pilar disorders NEC</i>		
Hair colour changes	13	0
Hair disorder	1	0
Hair growth abnormal	7	0
Hair texture abnormal	10	0
Piloerection	99	0
Pseudofolliculitis	1	0
Trichodynia	6	0
Trichorrhexis	5	0
<i>Pruritus NEC</i>		
Itching scar	5	0
Pruritus	8181	0
Pruritus allergic	1	0
Senile pruritus	1	0
<i>Psoriatic conditions</i>		
Dermatitis psoriasiform	2	0
Erythrodermic psoriasis	1	0
Guttate psoriasis	28	0
Nail psoriasis	1	0
Palmoplantar pustulosis	2	0
Psoriasis	224	0
Pustular psoriasis	5	0
<i>Purpura and related conditions</i>		
Ecchymosis	5	0
Henoch-Schonlein purpura	17	0
Petechiae	369	0
Purpura	143	0
<i>Pustular conditions</i>		
Acute generalised exanthematous pustulosis	1	0
Rash follicular	4	0
<i>Rashes, eruptions and exanthems NEC</i>		

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Butterfly rash	8	0
Rash	8955	0
Rash erythematous	2235	0
Rash macular	759	0
Rash maculo-papular	69	0
Rash morbilliform	47	0
Rash papular	567	0
Rash pruritic	1930	0
Rash rubelliform	1	0
Rash scarlatiniform	2	0
Rash vesicular	101	0
Systemic lupus erythematosus rash	9	0
Rosaceas		
Erythematotelangiectatic rosacea	3	0
Granulomatous rosacea	1	0
Papulopustular rosacea	1	0
Rosacea	48	0
Scaly conditions		
Dandruff	1	0
Pityriasis	12	0
Sebaceous gland disorders		
Sebaceous glands overactivity	1	0
Seborrhoea	15	0
Skin and subcutaneous conditions NEC		
Cutaneous symptom	11	0
Skin discharge	1	0
Skin mass	43	0
Skin and subcutaneous tissue ulcerations		
Diabetic foot	2	0
Diabetic ulcer	1	0
Ischaemic skin ulcer	1	0
Pyoderma gangrenosum	3	0
Skin erosion	54	0
Skin ulcer	30	0
Vasculitic ulcer	1	0
Skin cysts and polyps		
Dermal cyst	23	0
Skin dystrophies		
Keloid scar	1	0
Skin wrinkling	4	0
Skin haemorrhages		
Haemorrhage subcutaneous	21	0
Mucocutaneous haemorrhage	3	0
Skin haemorrhage	50	0
Skin hyperplasias and hypertrophies		
Skin hypertrophy	3	0
Skin hypoplasias and atrophies		
Skin atrophy	11	0
Skin striae	13	0
Skin injuries and mechanical dermatoses		
Decubitus ulcer	5	0
Needle track marks	3	0
Skin preneoplastic conditions NEC		

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Actinic keratosis	3	0
Leukoplakia	1	0
<i>Skin vascular conditions NEC</i>		
Angiodermatitis	1	0
Haemangioma-thrombocytopenia syndrome	1	0
Skin oedema	3	0
<i>Skin vasculitides</i>		
Capillaritis	1	0
Cutaneous vasculitis	13	0
Hypersensitivity vasculitis	4	0
Nodular vasculitis	1	0
Vasculitic rash	28	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	58	0
<i>Telangiectasia and related conditions</i>		
Spider naevus	5	0
Telangiectasia	4	0
<i>Urticarias</i>		
Chronic spontaneous urticaria	5	0
Cold urticaria	8	0
Idiopathic urticaria	10	0
Mechanical urticaria	6	0
Solar urticaria	1	0
Urticaria	2517	0
Urticaria chronic	42	0
Urticaria contact	3	0
Urticaria papular	3	0
Urticaria pigmentosa	1	0
Urticaria thermal	6	0
Urticularial vasculitis	5	0
Skin disorders SOC TOTAL	51316	0

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Reaction Name	Total	Fatal
Social circumstances		
<i>Age related issues</i>		
Childhood	1	0
Menarche	3	0
Menopause	66	0
Postmenopause	18	0
<i>Alcohol product use</i>		
Alcoholic	4	0
<i>Crime victims</i>		
Victim of abuse	1	0
<i>Criminal activity</i>		
Chemical submission	1	0
Verbal abuse	1	0
<i>Dependents</i>		
Sick relative	1	0
<i>Dietary and nutritional issues</i>		
Inadequate diet	1	0
Kosher diet	1	0
<i>Disability issues</i>		
Bedridden	96	0
Breast prosthesis user	2	0
Dependence on oxygen therapy	1	0
Disability	10	0
Hearing aid user	2	0
Hearing disability	1	0
Housebound	2	0
Immobile	55	0
Immobilisation prolonged	4	0
Impaired driving ability	4	0
Impaired work ability	29	0
Loss of personal independence in daily activities	11	0
Paralytic disability	1	0
Physical disability	3	0
Sight disability	22	0
Sitting disability	3	0
Walking aid user	2	0
Walking disability	5	0
Wheelchair user	1	0
<i>Educational issues</i>		
Educational problem	1	0
Illiteracy	3	0
<i>Employment issues</i>		
Job dissatisfaction	1	0
Retirement	5	0
Stress at work	1	0
Unemployment	1	0
<i>Family and partner issues</i>		
Homosexual parent	1	0
Partner stress	1	0
<i>Non-occupational and unspecified environmental problems</i>		
Food contamination	1	0
Water pollution	4	0
<i>Pregnancy related circumstances</i>		
Breast feeding	8	0

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Reaction Name	Total	Fatal
Social circumstances <small>Social circumstances cont'd</small>		
<i>Sexuality issues</i>		
Anal sex	1	0
Homosexuality	1	0
<i>Social issues NEC</i>		
Blood donor	2	0
Contraindication to medical treatment	1	0
Contraindication to vaccination	2	0
Convalescent	1	0
Hair dye user	1	0
Impaired quality of life	6	0
Refusal of vaccination	3	0
Tanning	2	0
Tattoo	1	0
<i>Tobacco use</i>		
Non-tobacco user	5	0
Tobacco user	2	0
Social circumstances SOC TOTAL	407	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Anaesthesia and allied procedures</i>		
Local anaesthesia	3	0
Nerve block	5	0
<i>Analgesia supportive care</i>		
Analgesic therapy	1	0
<i>Antiinfective therapies</i>		
Antibiotic therapy	2	0
COVID-19 treatment	7	0
<i>Arterial therapeutic procedures (excl aortic)</i>		
Cerebral revascularisation	1	0
Coronary artery bypass	2	0
<i>Autonomic nerve therapeutic procedures</i>		
Vagotomy	3	0
<i>Biliary tract and gallbladder therapeutic procedures</i>		
Cholecystectomy	1	0
Cholelithotomy	1	0
<i>Blood and blood product treatment</i>		
Photopheresis	1	0
Transfusion	1	0
<i>Breast therapeutic procedures NEC</i>		
Axillary lymphadenectomy	1	0
<i>Bronchial and pulmonary therapeutic procedures</i>		
Airway secretion clearance therapy	1	0
Antitussive therapy	1	0
<i>Cardiac device therapeutic procedures</i>		
Cardiac pacemaker insertion	2	0
Pacemaker generated rhythm	1	0
<i>Cardiac therapeutic procedures NEC</i>		
Pericardial excision	2	0
<i>Cardiac valve therapeutic procedures</i>		
Aortic valve replacement	1	0
Heart valve replacement	1	0
<i>Chemotherapies</i>		
Chemotherapy toxicity attenuation	1	0
<i>Contraceptive methods female</i>		
Contraception	3	0
Contraceptive diaphragm	3	0
Intrauterine contraception	1	0
Oral contraception	2	0
<i>Corneal and scleral therapeutic procedures</i>		
Corneal transplant	1	0
<i>Dental and gingival therapeutic procedures</i>		
Dental care	1	0
Tooth extraction	1	0
Tooth repair	3	0
<i>Dietary and nutritional therapies</i>		
Fluid replacement	1	0
Gluten free diet	1	0
Medical diet	6	0
Mineral supplementation	1	0
Nothing by mouth order	7	0
<i>External ear therapeutic procedures</i>		
Cerumen removal	2	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Surgical & medical procedures cont'd</i>		
<i>Eye therapeutic procedures NEC</i>		
Eye irrigation	3	0
<i>Facial therapeutic procedures</i>		
Face lift	3	0
<i>Fallopian tube therapeutic procedures</i>		
Fallopian tube operation	1	0
<i>Fertility and fertilisation interventions female</i>		
Ovulation induction	2	0
<i>Gastric therapeutic procedures</i>		
Antacid therapy	1	0
<i>Gastrointestinal therapeutic procedures NEC</i>		
Intestinal resection	1	0
Prophylaxis against gastrointestinal ulcer	1	0
Prophylaxis of nausea and vomiting	28	0
<i>Gynaecological therapeutic procedures NEC</i>		
Gynaecological disorder prophylaxis	1	0
Menstrual cycle management	3	0
<i>Haematological therapeutic procedures NEC</i>		
Anticoagulant therapy	2	0
Haemofiltration	1	0
Thrombosis prophylaxis	1	0
<i>Head, neck and oral cavity therapeutic procedures NEC</i>		
Neck lift	1	0
<i>Hormonal therapeutic procedures NEC</i>		
Hormone replacement therapy	6	0
Hormone therapy	9	0
Steroid therapy	1	0
<i>Immunisations</i>		
COVID-19 immunisation	216	0
Immunisation	110	0
Tuberculosis immunisation	1	0
<i>Induced abortions</i>		
Abortion induced	5	0
<i>Iris and ciliary body therapeutic procedures</i>		
Pupil constriction procedure	1	0
<i>Joint therapeutic procedures</i>		
Hip surgery	1	0
Joint injection	5	0
Joint stabilisation	2	0
Knee operation	2	0
Shoulder operation	2	0
<i>Large intestine therapeutic procedures</i>		
Appendectomy	8	0
Colectomy	1	0
<i>Limb therapeutic procedures</i>		
Arm amputation	1	0
Foot amputation	1	0
Leg amputation	4	0
Limb immobilisation	27	0
Limb operation	12	0
Limb reattachment surgery	1	0
Toe amputation	5	0
<i>Mastectomies</i>		

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Reaction Name	Total	Fatal
Surgical & medical procedures		
Breast conserving surgery	2	0
Muscle therapeutic procedures		
Muscle relaxant therapy	3	0
Nail therapeutic procedures		
Nail operation	2	0
Nasal therapeutic procedures		
Nasal irrigation	1	0
Nervous system therapeutic procedures NEC		
Central nervous system stimulation	3	0
Multiple sclerosis relapse prophylaxis	1	0
Neurological rehabilitation	1	0
Orbit and globe therapeutic procedures		
Eye muscle operation	1	0
Patient positioning		
Prone position	1	0
Peripheral nerve therapeutic procedures		
Carpal tunnel decompression	1	0
Phototherapies		
UV light therapy	1	0
Prophylactic procedures NEC		
Anaphylaxis prophylaxis	3	0
Reproductive system disorder prophylaxis	1	0
Psychiatric therapies		
Antidepressant therapy	1	0
Psychotherapy	1	0
Renal therapeutic procedures		
Dialysis	1	0
Respiratory tract therapeutic procedures NEC		
Respiratory therapy	1	0
Skin and subcutaneous tissue therapeutic procedures NEC		
Dermal filler injection	1	0
Skin lesion excisions		
Skin neoplasm excision	1	0
Tattoo excision	1	0
Skull and brain therapeutic procedures		
Brain operation	1	0
Small intestine therapeutic procedures		
Ileostomy	2	0
Spine and spinal cord therapeutic procedures		
Spinal operation	1	0
Testicular and scrotal therapeutic procedures		
Testes exploration	1	0
Therapeutic procedures NEC		
Anaphylaxis treatment	4	0
Antiallergic therapy	1	0
Bed rest	24	0
Catheter management	4	0
Catheter placement	2	0
Continuous passive motion machine therapy	1	0
Fatigue management	1	0
Heat therapy	3	0
Hospitalisation	32	0
Immobilisation bandage	1	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
Surgical & medical procedures cont'd		
Injection	52	0
Interchange of vaccine products	25	0
Localised alternating hot and cold therapy	6	0
Magnetic therapy	1	0
Manipulation	1	0
Mass excision	10	0
Medication dilution	3	0
Occupational therapy	1	0
Physical fitness training	4	0
Physiotherapy	1	0
Product used for unknown indication	2	0
Promotion of wound healing	1	0
Self-medication	1	0
Smoking cessation therapy	1	0
Specialist consultation	1	0
Stoma care	1	0
Surgery	1	0
Therapeutic hypothermia	2	0
Therapy change	2	0
Transgender operation	1	0
Tumour excision	1	0
Wound treatment	1	0
<i>Tonsillar therapeutic procedures</i>		
Tonsillectomy	1	0
<i>Tracheal therapeutic procedures</i>		
Tracheostomy	1	0
<i>Tumour vaccine therapies</i>		
Tumour vaccine therapy	1	0
<i>Uterine therapeutic procedures</i>		
Endometrial ablation	6	0
Hysterectomy	1	0
<i>Vascular therapeutic procedures NEC</i>		
Clamping of blood vessel	1	0
Thrombectomy	3	0
Thromboembolectomy	1	0
Thrombolysis	2	0
<i>Venous therapeutic procedures</i>		
Phlebotomy	2	0
Surgical & medical procedures SOC TOTAL	786	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Accelerated and malignant hypertension</i>		
Accelerated hypertension	1	0
Hypertensive crisis	15	0
Hypertensive emergency	2	0
Hypertensive urgency	4	0
Malignant hypertension	4	0
Tyramine reaction	1	0
<i>Aneurysms and dissections non-site specific</i>		
Aneurysm	12	1
Aneurysm ruptured	1	0
Artery dissection	4	0
Venous aneurysm	1	0
<i>Aortic aneurysms and dissections</i>		
Acute aortic syndrome	1	0
Aortic aneurysm	7	0
Aortic aneurysm rupture	1	1
Aortic dissection	4	1
Aortic intramural haematoma	1	0
Penetrating aortic ulcer	1	0
<i>Aortic embolism and thrombosis</i>		
Aortic embolus	25	1
Aortic thrombosis	12	2
<i>Aortic infections and inflammations</i>		
Aortitis	2	0
<i>Aortic necrosis and vascular insufficiency</i>		
Aortic occlusion	1	0
Aortic stenosis	4	0
<i>Arterial infections and inflammations</i>		
Arteritis	5	0
Giant cell arteritis	58	0
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	24	0
Labile blood pressure	4	0
<i>Bruising, ecchymosis and purpura</i>		
Achenbach syndrome	10	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	124	2
Distributive shock	2	0
Hypoperfusion	3	0
Hypovolaemic shock	1	0
Neurogenic shock	10	0
Peripheral circulatory failure	4	0
Shock	57	1
Shock haemorrhagic	1	0
Shock symptom	6	0
<i>Haemorrhages NEC</i>		
Bloody discharge	16	0
Haematoma	112	0
Haemorrhage	1407	2
Internal haemorrhage	31	0
Venous haemorrhage	7	0
<i>Lymphangiopathies</i>		
Lymphocele	2	0

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Reaction Name	Total	Fatal
Vascular disorders <small>Vascular disorders cont'd</small>		
Lymphorrhoea	1	0
Lymphoedemas		
Lymphoedema	72	0
Non-site specific embolism and thrombosis		
Air embolism	1	0
Arterial thrombosis	29	1
Atheroembolism	1	0
Embolism	256	3
Embolism arterial	3	0
Embolism venous	13	1
Microembolism	3	0
Paradoxical embolism	1	0
Post thrombotic syndrome	2	0
Thrombophlebitis migrans	2	0
Thrombosis	1766	36
Venous thrombosis	35	0
Non-site specific necrosis and vascular insufficiency NEC		
Arterial occlusive disease	16	0
Arterial spasm	2	0
Arterial stenosis	1	0
Arteriosclerosis	7	0
Haemorrhagic infarction	1	0
Infarction	13	0
Ischaemia	15	0
Peripheral venous disease	9	0
Vascular compression	2	0
Vascular occlusion	2	0
Vasospasm	13	0
Non-site specific vascular disorders NEC		
Angiopathy	5	0
Arterial rupture	1	0
Capillary disorder	1	0
Capillary fragility	11	0
Collateral circulation	1	0
Haemodynamic instability	4	0
Hyperaemia	2	0
Neovascularisation	1	0
Superficial vein prominence	6	0
Vascular pain	132	0
Vascular rupture	2	0
Vascular wall discolouration	1	0
Vasodilatation	118	0
Vein collapse	2	0
Vein discolouration	8	0
Vein disorder	25	0
Vein rupture	15	0
Peripheral aneurysms and dissections		
Peripheral artery aneurysm	2	0
Peripheral embolism and thrombosis		
Axillary vein thrombosis	1	0
Blue toe syndrome	39	0
Deep vein thrombosis	1220	9
Femoral artery embolism	2	0

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Reaction Name	Total	Fatal
Vascular disorders <small>Vascular disorders cont'd</small>		
Iliac artery embolism	2	0
Jugular vein thrombosis	24	0
Pelvic venous thrombosis	23	1
Peripheral artery thrombosis	18	0
Peripheral embolism	9	0
Peripheral vein thrombus extension	1	0
Subclavian artery embolism	2	0
Subclavian artery thrombosis	1	0
Subclavian vein thrombosis	3	0
Thrombophlebitis	137	0
Thrombophlebitis superficial	69	0
Venous thrombosis limb	4	0
Peripheral vascular disorders NEC		
Cyanosis	110	0
Erythromelalgia	7	0
Flushing	694	0
Hot flush	2179	0
Peripheral vascular disorder	7	0
Peripheral vasoconstriction, necrosis and vascular insufficiency		
Dry gangrene	2	0
Extremity necrosis	3	0
Iliac artery occlusion	2	0
Intermittent claudication	7	0
Ischaemic limb pain	5	0
Jugular vein occlusion	2	0
Peripheral arterial occlusive disease	5	0
Peripheral artery occlusion	9	0
Peripheral coldness	1293	0
Peripheral ischaemia	33	2
Poor peripheral circulation	55	0
Raynaud's phenomenon	144	0
Phlebitis NEC		
Phlebitis	61	0
Phlebitis superficial	13	0
Site specific embolism and thrombosis NEC		
Brachiocephalic vein thrombosis	1	0
Site specific necrosis and vascular insufficiency NEC		
Superior vena cava syndrome	1	0
Site specific vascular disorders NEC		
Aortic rupture	1	0
Pallor	418	0
Plethoric face	1	0
Varicose veins NEC		
Bleeding varicose vein	2	0
Spider vein	20	0
Varicophlebitis	10	0
Varicose ulceration	1	0
Varicose vein	152	0
Varicose vein ruptured	1	0
Vascular hypertensive disorders NEC		
Diastolic hypertension	5	0
Hypertension	966	0
Labile hypertension	1	0

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 14-Oct-2021

Data Lock Date: 13-Oct-2021 18:30:20

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Vascular disorders <i>Vascular disorders cont'd</i>		
Systolic hypertension	3	0
Venous hypertension	3	0
White coat hypertension	12	0
<i>Vascular hypotensive disorders</i>		
Capillary leak syndrome	13	0
Diastolic hypotension	1	0
Hypotension	540	0
Orthostatic hypotension	47	0
<i>Vascular malformations and acquired anomalies</i>		
Arteriovenous fistula	1	0
<i>Vasculitides NEC</i>		
Behcet's syndrome	3	0
Diffuse vasculitis	2	1
Granulomatosis with polyangiitis	1	0
MAGIC syndrome	3	1
Vasculitis	107	3
<i>Vena caval embolism and thrombosis</i>		
Vena cava thrombosis	5	1
Vascular disorders SOC TOTAL	13098	70
TOTAL REACTIONS FOR DRUG	833735	1101
TOTAL REPORTS	234882	
TOTAL FATAL OUTCOME REPORTS		1101