

COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 18-Nov-2021
Data Lock Date: 17-Nov-2021 18:30:04

All UK spontaneous reports received between 04/01/21 and 17/11/21 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 24.1

Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemia deficiencies</i>		
Anaemia folate deficiency	2	0
Anaemia vitamin B12 deficiency	15	0
Deficiency anaemia	1	0
Iron deficiency anaemia	17	0
Pernicious anaemia	6	0
<i>Anaemias NEC</i>		
Anaemia	173	0
Autoimmune anaemia	1	0
Blood loss anaemia	4	0
Hypochromic anaemia	3	0
Microcytic anaemia	1	0
Normocytic anaemia	4	0
<i>Anaemias haemolytic NEC</i>		
Haemolytic anaemia	10	0
<i>Anaemias haemolytic immune</i>		
Autoimmune haemolytic anaemia	8	0
Cold type haemolytic anaemia	1	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	136	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	11	0
Antiphospholipid syndrome	29	0
Coagulopathy	78	0
Disseminated intravascular coagulation	19	2
Hypercoagulation	24	1
Hyperfibrinogenaemia	1	0
Hypocoagulable state	1	0
<i>Eosinophilic disorders</i>		
Eosinophilia	22	0
Hypereosinophilic syndrome	1	0
<i>Haematological cysts and polyps</i>		
Splenic cyst	1	0
<i>Haematological disorders</i>		
Blood disorder	14	1
Bone marrow disorder	2	0
Bone marrow oedema	1	0
Mast cell activation syndrome	10	0
Mastocytosis	3	0
Methaemoglobinaemia	1	0
<i>Haemolyses NEC</i>		
Haemolysis	11	0
<i>Leukocytoses NEC</i>		
Leukocytosis	4	0
Lymphocytosis	11	0

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Reaction Name	Total	Fatal
Blood disorders Blood disorders cont'd		
Monocytosis	2	0
Neutrophilia	14	0
Leukopenias NEC		
Leukopenia	14	0
Lymphopenia	9	0
Lymphatic system disorders NEC		
Abdominal lymphadenopathy	1	0
Hilar lymphadenopathy	1	0
Lymph node fibrosis	1	0
Lymph node pain	579	0
Lymphadenitis	32	0
Lymphadenopathy	4924	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	83	0
Platelet disorders NEC		
Platelet anisocytosis	4	0
Platelet disorder	6	0
Polycythaemia (excl rubra vera)		
Polycythaemia	3	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		

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Blood disorders Blood disorders cont'd		
Autoimmune heparin-induced thrombocytopenia	1	0
Heparin-induced thrombocytopenia	14	0
Immune thrombocytopenia	227	1
Thrombocytopenia	881	7
Thrombocytopenic purpura	11	0
Thrombosis with thrombocytopenia syndrome	1	0
Thrombotic thrombocytopenic purpura	9	0
<i>Thrombocytoses</i>		
Thrombocytosis	12	0
<i>White blood cell abnormal findings NEC</i>		
White blood cell disorder	3	0
Blood disorders SOC TOTAL	7586	12

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Aortic valvular disorders</i>		
Aortic valve incompetence	4	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	3	0
Atrioventricular block second degree	5	0
Bundle branch block	2	0
Bundle branch block left	10	0
Bundle branch block right	4	0
Long QT syndrome	1	0
Trifascicular block	2	0
<i>Cardiac disorders NEC</i>		
Acute cardiac event	4	2
Atrial thrombosis	5	0
Cardiac disorder	80	1
Cardiac dysfunction	2	0
Cardiac ventricular thrombosis	12	2
Cardiovascular disorder	10	0
Cardiovascular insufficiency	10	0
Intracardiac thrombus	17	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	17	0
Cardiovascular symptom	3	0
Palpitations	5424	1
<i>Cardiac valve disorders NEC</i>		
Cardiac valve disease	4	1
Heart valve incompetence	4	0
<i>Cardiomyopathies</i>		
Cardiomyopathy	15	1
Congestive cardiomyopathy	12	1
Stress cardiomyopathy	5	0
<i>Coronary artery disorders NEC</i>		
Arteriosclerosis coronary artery	6	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	96	12
Cardiac failure acute	13	4
Cardiac failure chronic	2	1
Cardiac failure congestive	5	2
Cardiogenic shock	10	2
Cardiopulmonary failure	1	1
Ventricular failure	1	0

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Cardiac disorders Cardiac disorders cont'd		
<i>Ischaemic coronary artery disorders</i>		
Acute coronary syndrome	9	0
Acute myocardial infarction	86	13
Angina pectoris	235	0
Angina unstable	17	0
Arteriospasm coronary	6	0
Microvascular coronary artery disease	2	0
Myocardial infarction	433	52
Myocardial ischaemia	27	12
Prinzmetal angina	2	0
<i>Left ventricular failures</i>		
Acute left ventricular failure	2	0
Left ventricular failure	8	1
<i>Mitral valvular disorders</i>		
Ischaemic mitral regurgitation	1	0
Mitral valve disease	1	0
Mitral valve incompetence	8	0
Mitral valve prolapse	4	0
<i>Myocardial disorders NEC</i>		
Cardiac aneurysm	1	0
Cardiac sarcoidosis	1	0
Cardiomegaly	32	1
Diastolic dysfunction	2	0
Dilatation ventricular	1	0
Left atrial dilatation	1	0
Left ventricular dilatation	2	0
Left ventricular dysfunction	21	0
Left ventricular hypertrophy	1	0
Myocardial fibrosis	1	0
Myocardial injury	12	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 dyskinesia	1	0
Ventricular hypertrophy	5	1
Ventricular hypokinesia	3	0
<i>Noninfectious myocarditis</i>		
Autoimmune myocarditis	1	0
Myocarditis	153	2
<i>Noninfectious pericarditis</i>		
Pericarditis	189	0
<i>Pericardial disorders NEC</i>		
Cardiac tamponade	2	2
Pericardial effusion	36	0
Pericardial haemorrhage	6	3
Pericardial rub	1	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	144	3
Arrhythmia neonatal	1	0
Bradycardia	84	0
Brugada syndrome	1	0

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Cardiac disorders Cardiac disorders cont'd		
Cardiac fibrillation	9	0
Cardiac flutter	278	0
Extrasystoles	156	0
Heart alternation	3	0
Paroxysmal arrhythmia	2	0
Postural orthostatic tachycardia syndrome	22	0
Tachyarrhythmia	11	0
Tachycardia	1343	0
<i>Right ventricular failures</i>		
Right ventricular failure	3	1
<i>Supraventricular arrhythmias</i>		
Arrhythmia supraventricular	16	0
Atrial fibrillation	331	1
Atrial flutter	44	0
Atrial tachycardia	3	0
Sinus arrest	1	0
Sinus arrhythmia	3	0
Sinus bradycardia	4	0
Sinus node dysfunction	2	0
Sinus tachycardia	71	1
Supraventricular extrasystoles	1	0
Supraventricular tachycardia	43	0
<i>Tricuspid valvular disorders</i>		
Tricuspid valve incompetence	7	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	175	36
Cardio-respiratory arrest	2	1
Pulseless electrical activity	7	0
Ventricular arrhythmia	2	0
Ventricular extrasystoles	19	0
Ventricular fibrillation	9	1
Ventricular tachycardia	17	0
Cardiac disorders SOC TOTAL	10002	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	10	0
<i>Cardiac septal defects congenital</i>		
Hypertrophic cardiomyopathy	3	0
<i>Central nervous system disorders congenital NEC</i>		
Brain malformation	1	0
Encephalocele	1	0
Neural tube defect	1	1
Spina bifida	2	0
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
<i>Congenital disorders NEC</i>		
Congenital anomaly	3	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>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	3	0
<i>Musculoskeletal and connective tissue disorders of limbs congenital</i>		
Limb reduction defect	2	0
Os trigonum	1	0
<i>Musculoskeletal disorders congenital NEC</i>		

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Reaction Name	Total	Fatal
Congenital disorders Congenital disorders cont'd		
Congenital multiplex arthrogryposis	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	9	0
Pancreatic disorders congenital		
Hereditary pancreatitis	1	0
Peripheral nervous system disorders congenital NEC		
Paroxysmal extreme pain disorder	13	0
Pulmonary and bronchial disorders congenital		
Cystic fibrosis	1	0
Sex chromosomal abnormalities		
Klinefelter's syndrome	1	0
Skin and subcutaneous tissue disorders congenital NEC		
Benign familial pemphigus	1	0
Tongue disorders congenital		
Ankyloglossia congenital	1	0
Macroglossia	1	0
Vascular anomalies congenital NEC		
Arteriovenous malformation	1	0
Congenital disorders SOC TOTAL	98	1

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Aural polyp	1	0
Ear canal erythema	1	0
Ear congestion	34	0
Ear discomfort	120	0
Ear disorder	22	0
Ear haemorrhage	18	0
Ear pain	2070	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	8	0
<i>External ear disorders NEC</i>		
Excessive cerumen production	39	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	389	1
Deafness bilateral	18	0
Deafness neurosensory	38	0
Deafness transitory	4	0
Deafness unilateral	57	0
Hypoacusis	241	0
Mixed deafness	3	0
Neurosensory hypoacusis	2	0
Sudden hearing loss	76	0
<i>Hyperacusia</i>		
Hyperacusis	173	0
<i>Inner ear disorders NEC</i>		
Endolymphatic hydrops	1	0
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	129	0
Phobic postural vertigo	2	0
Tinnitus	4192	0
Vertigo	2228	0
Vertigo labyrinthine	13	0
Vertigo positional	155	0

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Reaction Name	Total	Fatal
Ear disorders Ear disorders cont'd		
<i>Middle ear disorders NEC</i>		
Middle ear disorder	1	0
Middle ear effusion	6	0
<i>Tympanic membrane disorders (excl infections)</i>		
Tympanic membrane perforation	7	0
Ear disorders SOC TOTAL	10231	1

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Autoimmune thyroiditis	10	0
Thyroiditis	20	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
<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
Secondary adrenocortical insufficiency	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	25	0

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Reaction Name	Total	Fatal
Endocrine disorders Endocrine disorders cont'd		
Thyroid disorder	21	0
Thyroid mass	8	0
Thyroid pain	17	0
<i>Thyroid hyperfunction disorders</i>		
Basedow's disease	19	0
Hyperthyroidism	58	0
Thyrotoxic crisis	6	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	58	0
<i>Thyroid neoplasms</i>		
Thyroid cyst	1	0
Endocrine disorders SOC TOTAL	422	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	201	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	127	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	151	0
Excessive eye blinking	8	0
Eyelid function disorder	1	0
Eyelid myokymia	2	0
Eyelid ptosis	60	0
Paralytic lagophthalmos	1	0
<i>Glaucomas (excl congenital)</i>		
Angle closure glaucoma	5	0
Glaucoma	14	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	24	0
Iritis	13	0
Uveitis	49	0
<i>Lacrimation disorders</i>		
Dry eye	313	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
Lid bleeding and vascular disorders		
Eyelid bleeding	3	0
Eyelid haematoma	3	0
Lid, lash and lacrimal infections, irritations and inflammations		
Blepharitis	29	0
Chalazion	2	0
Eczema eyelids	6	0
Erythema of eyelid	7	0
Eyelid cyst	17	0
Eyelid irritation	4	0
Eyelid margin crusting	1	0
Eyelid oedema	12	0
Eyelid rash	15	0
Meibomianitis	1	0
Swelling of eyelid	132	0
Lid, lash and lacrimal structural disorders		
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
Ocular bleeding and vascular disorders NEC		
Eye haematoma	4	0
Eye haemorrhage	110	0
Ocular retrobulbar haemorrhage	1	0
Ocular vascular disorder	2	0
Ophthalmic vein thrombosis	3	0
Ocular cysts and polyps		
Vitreous cyst	1	0
Ocular disorders NEC		
Dark circles under eyes	11	0
Eye disorder	42	0
Eye oedema	18	0
Eye pain	3335	0
Eye swelling	625	0
Eye symptom	11	0
Eye ulcer	10	0
Eyelid disorder	17	0
Eyelid pain	20	0
Eyelids pruritus	12	0
Ocular discomfort	83	0
Periorbital discomfort	1	0
Periorbital oedema	18	0
Periorbital pain	4	0
Periorbital swelling	107	0
Retinal disorder	2	0
Retinal fovea disorder	1	0
Ocular infections, inflammations and associated manifestations		
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	33	0
Eye irritation	204	0
Eye pruritus	304	0
Limbal swelling	8	0
Ocular hyperaemia	457	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	3	0
Ophthalmoplegia	1	0
Parinaud syndrome	1	0
Strabismus	5	0
Ocular sensation disorders		
Abnormal sensation in eye	28	0
Asthenopia	360	0
Eye paraesthesia	5	0
Eyelid sensory disorder	5	0
Foreign body sensation in eyes	36	0
Hypoaesthesia eye	29	0
Photophobia	1069	0
Optic disc abnormalities NEC		
Optic atrophy	1	0
Optic discs blurred	3	0
Papilloedema	14	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
Orbital oedema	1	0
Pupil disorders		
Holmes-Adie pupil	1	0
Miosis	15	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	24	0

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Retinal haemorrhage	19	0
Retinal infarction	1	0
Retinal ischaemia	2	0
Retinal vascular occlusion	3	0
Retinal vascular thrombosis	4	0
Retinal vein occlusion	97	0
Retinal vein thrombosis	8	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	29	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	8	0
Retinal oedema	2	0
Retinal vasculitis	1	0
<i>Retinopathies NEC</i>		
Acute macular neuroretinopathy	5	0
Diabetic retinopathy	2	0
Retinal exudates	18	0
Retinopathy	8	0
<i>Scleral infections, irritations and inflammations</i>		
Episcleritis	20	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	336	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	333	0
Scintillating scotoma	10	0
Vision blurred	3045	0
Visual brightness	10	0
Visual snow syndrome	5	0
Visual field disorders		
Visual field defect	42	0
Visual impairment and blindness (excl colour blindness)		
Amaurosis fugax	9	0
Blindness	302	0
Blindness day	1	0
Blindness transient	26	0
Blindness unilateral	42	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	787	0
Visual pathway disorders		
Optic nerve compression	1	0
Optic nerve disorder	4	0
Optic neuropathy	9	0
Eye disorders SOC TOTAL	14320	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	39	2
Pancreatitis acute	19	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	28	0
<i>Anal and rectal signs and symptoms</i>		
Anal blister	2	0
Anal hypoaesthesia	7	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	107	0
Crohn's disease	108	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	6	0
Periodontal inflammation	1	0
<i>Dental developmental disorders and anomalies</i>		
Tooth impacted	1	0
<i>Dental disorders NEC</i>		
Diastema	1	0
Loose tooth	3	0
Malpositioned teeth	3	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Teething	21	0
Tooth disorder	5	0
Tooth socket haemorrhage	2	0
<i>Dental pain and sensation disorders</i>		
Dental discomfort	12	0
Dental paraesthesia	18	0
Hyperaesthesia teeth	66	0
Hypoaesthesia teeth	2	0
Toothache	342	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	21	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	8899	0
Diarrhoea haemorrhagic	34	0
<i>Diverticula</i>		
Diverticulum	11	0
Diverticulum intestinal	1	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	893	0
Epigastric discomfort	20	0
Eructation	106	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	24	0
Faecaloma	4	0
Faeces discoloured	54	0
Faeces hard	4	0
Faeces pale	7	0
Faeces soft	23	0
Mucous stools	16	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	708	1
Flatulence	399	0
<i>Gastric and oesophageal haemorrhages</i>		
Gastric haemorrhage	15	1
<i>Gastric ulcers and perforation</i>		
Gastric ulcer	13	0
Gastric ulcer haemorrhage	1	0
Gastric ulcer perforation	1	0
<i>Gastritis (excl infective)</i>		
Chronic gastritis	5	0
Gastritis	108	0
Reflux gastritis	16	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Abdominal migraine	3	0
Abdominal pain	4559	0
Abdominal pain lower	266	0
Abdominal pain upper	5255	0
Abdominal rigidity	63	0
Abdominal tenderness	22	0
Gastrointestinal pain	326	0
Oesophageal pain	9	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	489	0
Duodenogastric reflux	3	0
Gastric dilatation	18	0
Gastrooesophageal reflux disease	241	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	19	0
Gastric disorder	14	0
Gastrointestinal disorder	47	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	5	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	1595	0
Abdominal symptom	6	0
Acute abdomen	18	0
Anal incontinence	54	0
Breath odour	25	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Dysphagia	282	0
Intestinal congestion	1	0
Odynophagia	34	0
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	148	0
Oesophageal spasm	7	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Intestinal obstruction	5	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	4	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	7	0
Gingival disorder	17	0
Gingival hypertrophy	1	0
Gingival oedema	2	0
Gingival pain	236	0
Gingival pruritus	1	0
Gingival recession	3	0
Gingival swelling	53	0
Gingival ulceration	9	0
Gingivitis ulcerative	2	0
Noninfective gingivitis	24	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	175	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Anorectal varices	1	0
Haemorrhoidal haemorrhage	4	0
Haemorrhoids	68	0
Haemorrhoids thrombosed	13	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Inguinal hernias</i>		
Inguinal hernia	3	0
<i>Intestinal haemorrhages</i>		
Anal haemorrhage	45	0
Intestinal haemorrhage	1	0
Lower gastrointestinal haemorrhage	2	0
Mesenteric haemorrhage	5	0
Rectal haemorrhage	117	0
Small intestinal haemorrhage	27	0
<i>Intestinal ulcers and perforation NEC</i>		
Intestinal perforation	5	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	33396	0
Regurgitation	3	0
Retching	236	0
Vomiting	11352	0
Vomiting projectile	154	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Gastrointestinal haemorrhage	39	1
Haematemesis	79	0
Haematochezia	104	0
Intra-abdominal haematoma	2	0
Intra-abdominal haemorrhage	2	0
Melaena	10	0
Upper gastrointestinal haemorrhage	9	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	2	0
<i>Oesophagitis (excl infective)</i>		
Eosinophilic oesophagitis	3	0
Oesophagitis	20	0
<i>Oral dryness and saliva altered</i>		

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Aptyalism	4	0
Dry mouth	1147	0
Lip dry	78	0
Saliva altered	7	0
Saliva discolouration	1	0
Salivary hypersecretion	94	0
Oral soft tissue disorders NEC		
Angina bullosa haemorrhagica	4	0
Chapped lips	24	0
Cheilitis	39	0
Chronic cheek biting	1	0
Enlarged uvula	11	0
Leukoplakia oral	2	0
Lip blister	36	0
Lip disorder	5	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	56	0
Oral blood blister	54	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	662	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	105	0
Oral dysaesthesia	1	0
Oral mucosal blistering	34	0
Oral mucosal discolouration	1	0
Oral mucosal eruption	29	0
Oral mucosal erythema	4	0
Oral mucosal exfoliation	10	0
Oral mucosal roughening	3	0
Oral pain	362	0
Oral pruritus	21	0
Paraesthesia oral	857	0
Oral soft tissue swelling and oedema		
Lip oedema	10	0
Lip swelling	977	0
Mouth swelling	131	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Oedema mouth	1	0
Palatal oedema	1	0
Palatal swelling	14	0
<i>Pancreatic disorders NEC</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	8	0
Pneumoperitoneum	1	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	14	0
Salivary gland enlargement	6	0
<i>Salivary gland infections and inflammations</i>		
Noninfective sialoadenitis	2	0
<i>Stomatitis and ulceration</i>		
Aphthous ulcer	64	0
Lip ulceration	17	0
Mouth ulceration	765	0
Stomatitis	108	0
<i>Tongue disorders</i>		
Acquired macroglossia	1	0
Glossitis	18	0
Plicated tongue	4	0
Tongue disorder	32	0
Tongue geographic	5	0
Tongue haemorrhage	2	0
Tongue ulceration	32	0
Trichoglossia	7	0
<i>Tongue signs and symptoms</i>		
Glossodynia	263	0
Scalloped tongue	4	0
Stiff tongue	6	0
Strawberry tongue	1	0
Swollen tongue	623	0
Tongue blistering	28	0
Tongue coated	36	0
Tongue discolouration	40	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Tongue discomfort	57	0
Tongue dry	23	0
Tongue eruption	12	0
Tongue erythema	7	0
Tongue exfoliation	2	0
Tongue movement disturbance	9	0
Tongue oedema	17	0
Tongue pruritus	3	0
Tongue rough	2	0
Tongue spasm	5	0
<i>Tooth missing</i>		
Tooth loss	10	0
Gastrointestinal disorders SOC TOTAL	79729	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	45	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	61	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	2	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	14	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	5023	0
Chronic fatigue syndrome	161	0
Decreased activity	16	0
Fatigue	50253	0
Malaise	12601	0
Sluggishness	30	0
<i>Body temperature altered</i>		
Hyperthermia	13	0
Hypothermia	58	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
Death	311	311
Drowning	1	0
Hanging	1	1
Sudden death	40	40
Sudden unexplained death in epilepsy	1	1
<i>Febrile disorders</i>		
Hyperpyrexia	42	0
Masked fever	1	0
PFAPA syndrome	1	0
Pyrexia	55142	0
<i>Feelings and sensations NEC</i>		
Chills	43062	0
Early satiety	1	0
Feeling abnormal	3322	0
Feeling cold	5259	0
Feeling drunk	132	0
Feeling hot	2451	0
Feeling jittery	45	0
Feeling of body temperature change	962	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	53	0
Temperature intolerance	89	0
Thirst	1267	0
Thirst decreased	11	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
<i>Fibrosis NEC</i>		
Fibrosis	7	0
<i>Gait disturbances</i>		
Decreased gait velocity	3	0
Gait disturbance	473	0
Gait inability	225	0
Loss of control of legs	58	0
<i>General signs and symptoms NEC</i>		
Apparent death	1	0
Chronic disease	1	0
Condition aggravated	311	0
Crepitations	10	0
Crying	301	0
Deformity	1	0
Developmental delay	3	0
Discharge	11	0
Disease progression	3	1
Disease recurrence	2	0
Effusion	1	0
Energy increased	26	0
Exercise tolerance decreased	43	0
Foaming at mouth	6	0
General physical health deterioration	33	2
General symptom	11	0
Glassy eyes	7	0
High-pitched crying	8	0
Ill-defined disorder	11	0
Illness	5066	0
Impaired self-care	1	0
Induration	21	0
Influenza like illness	9605	0
Irritability postvaccinal	3	0
Local reaction	155	0
Moaning	9	0
Multiple organ dysfunction syndrome	23	12
Nonspecific reaction	3	0
Organ failure	2	0
Perforation	2	0
Performance status decreased	1	0
Peripheral swelling	5927	0
Pre-existing condition improved	17	0
Premature ageing	2	0
Prolapse	1	0
Screaming	31	0
Secretion discharge	36	0
Sensitivity to weather change	3	0
Stenosis	2	0
Swelling	2783	0
Swelling face	1087	0
Symptom masked	1	0
Symptom recurrence	4	0
Tissue discolouration	1	0
Tissue infiltration	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Unevaluable event	9	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	843	0
Papillitis	1	0
Systemic inflammatory response syndrome	7	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 mobility decreased	1	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	46	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	8	0
Injection site discomfort	21	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

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Injection site inflammation	67	0
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	1424	0
Injection site movement impairment	5	0
Injection site muscle weakness	2	0
Injection site necrosis	7	0
Injection site nerve damage	2	0
Injection site nodule	4	0
Injection site oedema	27	0
Injection site pain	4502	0
Injection site papule	2	0
Injection site paraesthesia	26	0
Injection site pruritus	300	0
Injection site rash	309	0
Injection site reaction	122	0
Injection site scab	4	0
Injection site scar	6	0
Injection site swelling	257	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	34	0
Food interaction	2	0
Inhibitory drug interaction	12	0
Mass conditions NEC		
Cyst	33	0
Mass	92	0
Nodule	25	0
Pelvic mass	1	0
Mucosal findings abnormal		
Mucosa vesicle	2	0
Mucosal disorder	2	0
Mucosal dryness	1	0
Mucosal haemorrhage	11	0
Mucosal inflammation	11	0
Mucosal pain	2	0
Mucosal ulceration	1	0
Oedema mucosal	3	0
Polyp	5	0
Necrosis NEC		
Fat necrosis	4	0
Necrosis	8	0
Oedema NEC		
Face oedema	35	0
Localised oedema	12	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Oedema	88	0
Oedema peripheral	164	0
<i>Pain and discomfort NEC</i>		
Axillary pain	755	0
Chest discomfort	2090	0
Chest pain	5625	0
Discomfort	639	0
Facial discomfort	21	0
Facial pain	288	0
Hernia pain	2	0
Inflammatory pain	31	0
Non-cardiac chest pain	46	0
Pain	17513	0
Suprapubic pain	1	0
Tenderness	1839	0
Visceral pain	2	0
<i>Therapeutic and nontherapeutic responses</i>		
Adverse drug reaction	32	0
Adverse event	7	0
Adverse food reaction	1	0
Adverse reaction	12	0
Diet failure	1	0
Drug effect less than expected	1	0
Drug ineffective	173	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	16	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 changed	1	0
Therapeutic response decreased	1	0
Therapeutic response delayed	1	0
Therapeutic response shortened	2	0
Therapeutic response unexpected	176	0
Therapy non-responder	3	0
Treatment failure	19	0
Treatment noncompliance	1	0
Vaccination failure	42	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>		

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Ulcer	48	0
Ulcer haemorrhage	3	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	19	0
Shoulder injury related to vaccine administration	79	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	49	0
Vaccination site dryness	1	0
Vaccination site erythema	714	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	56	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	17	0
Vaccination site joint pain	53	0
Vaccination site joint swelling	3	0
Vaccination site joint warmth	2	0
Vaccination site lymphadenopathy	2	0
Vaccination site mass	565	0
Vaccination site movement impairment	101	0
Vaccination site nodule	1	0
Vaccination site oedema	3	0
Vaccination site pain	2096	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	511	0
Vaccination site urticaria	12	0
Vaccination site vesicles	11	0
Vaccination site warmth	381	0
Vascular complications associated with device		
Vascular stent occlusion	1	0
Vascular stent thrombosis	1	0
Withdrawal and rebound effects		

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Drug withdrawal syndrome	8	0
Withdrawal syndrome	102	0
General disorders SOC TOTAL	252249	376

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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	19	0
<i>Hepatic enzymes and function abnormalities</i>		
Hepatic function abnormal	13	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	9	1
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 hypoperfusion	1	0
Hepatic infarction	2	1
Hepatic vascular thrombosis	2	0
Hepatic vein thrombosis	16	0
Portal hypertension	4	0
Portal vein phlebitis	1	0
Portal vein thrombosis	70	4
Portosplenomesenteric venous thrombosis	2	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	79	0
Hepatomegaly	5	0
Liver tenderness	6	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Acute yellow liver atrophy	1	0
Autoimmune hepatitis	8	0
Cholestatic liver injury	1	0
Drug-induced liver injury	1	0
Hepatic necrosis	1	0
Hepatic steatosis	12	0
Hepatitis	31	0
Hepatitis acute	7	1
Immune-mediated hepatitis	1	0

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Reaction Name	Total	Fatal
Hepatic disorders Hepatic disorders cont'd		
Ischaemic hepatitis	1	0
Liver injury	29	0
Nonalcoholic fatty liver disease	1	0
Reye's syndrome	1	0
Obstructive bile duct disorders (excl neoplasms)		
Biliary obstruction	1	0
Sphincter of Oddi dysfunction	3	0
Hepatic disorders SOC TOTAL	494	9

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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	21	0
Allergy to animal	1	0
Allergy to arthropod bite	1	0
Allergy to arthropod sting	5	0
Allergy to metals	1	0
Allergy to sting	1	0
Allergy to venom	1	0
Dust allergy	2	0
Hypersensitivity	1508	1
Infusion related hypersensitivity reaction	5	0
Mite allergy	2	0
Multiple allergies	22	0
Serum sickness	15	0
Serum sickness-like reaction	14	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	50	0
Milk allergy	1	0
Oral allergy syndrome	4	0
Polymers allergy	1	0
Reaction to colouring	2	0
Reaction to excipient	14	0
Reaction to preservatives	15	0
Rubber sensitivity	3	0
Smoke sensitivity	3	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	695	2
Anaphylactic shock	121	0
Anaphylactoid reaction	23	0
Anaphylactoid shock	4	0
<i>Atopic disorders</i>		
Atopy	3	0
Seasonal allergy	142	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	63	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

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Immune system disorders cont'd</i>		
Haemophagocytic lymphohistiocytosis	14	1
Hypocomplementaemia	1	0
Immune system disorder	50	0
Immune-mediated adverse reaction	10	0
Immunisation reaction	1	0
Multiple chemical sensitivity	2	0
Pre-engraftment immune reaction	1	0
Sensitisation	33	0
<i>Immunodeficiency disorders NEC</i>		
Immunodeficiency	10	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	3113	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	41	0
Appendicitis perforated	3	0
Diarrhoea infectious	4	0
Diverticulitis	32	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>		
Abscess bacterial	1	0
Administration site cellulitis	1	0
Arthritis bacterial	11	0
Bacterial infection	34	1
Bacterial vaginosis	4	0
Bacterial vulvovaginitis	1	0
Cellulitis	529	0
Cellulitis orbital	2	0
Ear infection bacterial	2	0
Endocarditis bacterial	2	0
Eye infection bacterial	1	0
Folliculitis	11	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	4	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

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
<i>Breast infections</i>		
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	80	0
Oral candidiasis	60	0
Skin candida	3	0
Vulvovaginal candidiasis	59	0
<i>Cardiac infections</i>		
Acute endocarditis	2	0
Cardiac infection	1	0
Endocarditis	7	0
Myocarditis infectious	1	0
<i>Central nervous system and spinal infections</i>		
Brain abscess	2	0
Cavernous sinus thrombosis	9	0
Central nervous system infection	2	0
Encephalitis	44	0
Encephalomyelitis	3	0
Extradural abscess	1	0
Meningitis	29	0
Myelitis	22	0
<i>Chlamydial infections</i>		
Chlamydial infection	1	0
<i>Clostridia infections</i>		
Clostridium difficile colitis	5	0
Clostridium difficile infection	2	0
Tetanus	3	0
<i>Coronavirus infections</i>		
Asymptomatic COVID-19	5	0
COVID-19	1092	29
COVID-19 pneumonia	70	10
Coronavirus infection	7	0
Post-acute COVID-19 syndrome	15	0
SARS-CoV-2 sepsis	1	0
Severe acute respiratory syndrome	5	0
Suspected COVID-19	45	0
Vaccine derived SARS-CoV-2 infection	1	0
<i>Corynebacteria infections</i>		
Diphtheria	3	0
<i>Coxiella infections</i>		
Q fever	113	0

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Reaction Name	Total	Fatal
Infections Infections cont'd		
<i>Coxsackie viral infections</i>		
Coxsackie bronchitis	1	0
<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	31	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	142	0
Labyrinthitis	187	0
Mastoiditis	5	0
Otitis externa	7	0
Otitis media	8	0
Otitis media chronic	14	0
Otosalpingitis	1	0
<i>Ectoparasitic infestations</i>		
Acarodermatitis	10	0
Infestation	1	0
Trombidiasis	3	0
<i>Epstein-Barr viral infections</i>		
Epstein-Barr virus infection	6	0
Epstein-Barr virus infection reactivation	2	0
Infectious mononucleosis	59	0
<i>Escherichia infections</i>		
Escherichia infection	2	0
Escherichia sepsis	2	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	85	0
Eye infection	46	0
Eyelid boil	3	0
Eyelid infection	4	0
Hordeolum	42	0
Keratouveitis	1	0
Retinitis	2	0
<i>Female reproductive tract infections</i>		
Endometritis	3	0
Fallopian tube abscess	1	0
Genital infection female	1	0
Ovarian abscess	1	0
Pelvic inflammatory disease	2	0
Pyometra	1	1

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Vaginal abscess	3	0
Vaginal infection	5	0
Vulval abscess	1	0
Flaviviral infections		
Dengue fever	1	0
Yellow fever	1	0
Yellow fever vaccine-associated neurotropic disease	1	0
Fungal infections NEC		
Ear infection fungal	2	0
Fungal infection	28	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
Helicobacter infections		
Helicobacter infection	1	0
Hepatitis virus infections		
Hepatitis E	1	0
Hepatobiliary and spleen infections		
Biliary sepsis	5	1
Liver abscess	1	0
Splenic infection	1	0
Herpes viral infections		
Eczema herpeticum	3	0
Genital herpes	79	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	47	0
Herpes simplex reactivation	4	0
Herpes virus infection	14	0
Herpes zoster	1606	0
Herpes zoster disseminated	1	0
Herpes zoster oticus	14	0
Herpes zoster reactivation	2	0
Meningoencephalitis herpetic	1	0
Nasal herpes	16	0
Ophthalmic herpes simplex	2	0
Ophthalmic herpes zoster	10	0
Oral herpes	711	0
Varicella	41	0
Varicella zoster virus infection	4	0
Infections NEC		
Abscess	52	0
Abscess limb	25	0
Abscess soft tissue	3	0
Catheter site infection	1	0
Coinfection	1	0

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Device related infection	3	0
Empyema	1	0
Genital abscess	1	0
Groin abscess	2	0
Groin infection	1	0
Infected bite	4	0
Infected cyst	4	0
Infection	529	4
Infection in an immunocompromised host	3	0
Infectious thyroiditis	1	0
Injection site abscess	3	0
Injection site infection	21	0
Localised infection	106	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	8	0
Toxic shock syndrome	1	0
Vaccination site abscess	7	0
Vaccination site infection	23	0
Vaccine breakthrough infection	3	0
Vestibulitis	4	0
Wound abscess	1	0
Infectious disorders carrier		
SARS-CoV-2 carrier	1	0
Infectious transmissions		
Secondary transmission	16	0
Vaccine virus shedding	1	0
Influenza viral infections		
H1N1 influenza	1	0
H2N2 influenza	3	0
Influenza	6795	0
Klebsiella infections		
Pneumonia klebsiella	1	0
Lower respiratory tract and lung infections		
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	313	4
Pleural infection	1	0
Pneumonia	267	28
Pneumonia aspiration	25	6
Sputum purulent	2	0
Male reproductive tract infections		
Epididymitis	8	0
Orchitis	5	0
Molluscum contagiosum viral infections		
Molluscum contagiosum	1	0

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Reaction Name	Total	Fatal
Infections Infections cont'd		
<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
<i>Neisseria infections</i>		
Gonorrhoea	1	0
<i>Orthopox viral infections</i>		
Cow pox	1	0
Vaccinia virus infection	2	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	7	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	3	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	6	0
<i>Salmonella infections</i>		
Typhoid fever	2	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Abdominal sepsis	2	0
Bacteraemia	1	0
Neutropenic sepsis	9	0
Pelvic sepsis	1	0
Pulmonary sepsis	1	0
Sepsis	115	13
Sepsis syndrome	1	0
Septic pulmonary embolism	1	0
Septic rash	13	0
Septic shock	5	1
Urosepsis	10	1
Viraemia	4	0
<i>Skin structures and soft tissue infections</i>		

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
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
Pilonidal cyst	2	0
Pustule	26	0
Rash pustular	19	0
Skin infection	73	0
Subcutaneous abscess	9	0
Vaccination site pustule	5	0
<i>Staphylococcal infections</i>		
Furuncle	56	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 bacteraemia	1	0
Streptococcal infection	3	0
Tonsillitis streptococcal	1	0
<i>Tinea infections</i>		
Body tinea	8	0
Tinea cruris	3	0
Tinea infection	3	0
Tinea pedis	4	0
Tinea versicolour	2	0
<i>Treponema infections</i>		
Neurosyphilis	1	0
Syphilis	4	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

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Chronic sinusitis	17	0
Croup infectious	1	0
Epiglottitis	1	0
Laryngitis	37	0
Nasal vestibulitis	1	0
Nasopharyngitis	1902	0
Peritonsillar abscess	1	0
Pharyngeal abscess	1	0
Pharyngitis	42	0
Rhinitis	53	0
Sinobronchitis	1	0
Sinusitis	390	0
Tonsillitis	88	0
Tracheitis	2	0
Upper respiratory tract infection	10	0
Urinary tract infections		
Cystitis	100	0
Genitourinary tract infection	1	0
Kidney infection	61	0
Pyelonephritis	7	0
Pyelonephritis acute	1	0
Pyelonephritis chronic	1	0
Renal abscess	2	0
Urethritis	1	0
Urinary tract infection	262	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	21	0
Pleurisy viral	1	0
Pneumonia viral	10	1
Post viral fatigue syndrome	143	0
Sweating fever	739	0
Vestibular neuronitis	41	0
Viral diarrhoea	4	0
Viral infection	87	0
Viral labyrinthitis	7	0
Viral myelitis	1	0
Viral myocarditis	2	0
Viral pericarditis	5	0

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Viral pharyngitis	31	0
Viral rash	81	0
Viral sepsis	1	0
Viral sinusitis	1	0
Viral tonsillitis	1	0
Viral upper respiratory tract infection	1	0
Infections SOC TOTAL	19058	105

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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
Pelvic bone injury	1	0
Splenic rupture	4	0
Tongue injury	3	0
Tooth fracture	2	0
Tooth injury	2	0
<i>Accidental exposures to product</i>		
Accidental exposure to product	23	0
Accidental exposure to product packaging	1	0
<i>Anaesthetic and allied procedural complications</i>		
Airway complication of anaesthesia	1	0
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	14	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>		
Vascular injury	11	0
Venous injury	1	0
<i>Cerebral injuries NEC</i>		
Brain contusion	16	0
Brain herniation	5	0
Concussion	9	0
Craniocerebral injury	1	0
Epidural haemorrhage	1	0
Extradural haematoma	2	0
Subarachnoid haematoma	3	0
Subdural haematoma	16	1
Subdural haemorrhage	5	0
Traumatic intracranial haemorrhage	1	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
<i>Chemical injuries</i>		
Chemical burn	2	0
Chemical burn of oral cavity	2	0
Chemical burn of skin	7	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	2	0
Traumatic haemothorax	1	0
Traumatic lung injury	1	0
<i>Conditions caused by cold</i>		
Chillblains	76	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	18	0
Exposure via breast milk	112	0
Foetal exposure during pregnancy	31	0
Maternal exposure before pregnancy	13	0
Maternal exposure during breast feeding	1377	0
Maternal exposure during pregnancy	368	0
Maternal exposure timing unspecified	2	0
Paternal exposure during pregnancy	2	0
<i>Exposures to agents or circumstances NEC</i>		
Exposure to SARS-CoV-2	7	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	57	0
Eye injury	49	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

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Reaction Name	Total	Fatal
Injuries		
Injuries cont'd		
Joint dislocation	13	0
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	27	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	13	0
<i>Intentional product use issues</i>		
Intentional dose omission	16	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	3	0
Humerus fracture	1	0
Lower limb fracture	3	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	14	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	93	0
Prescription drug used without a prescription	2	0
Product use in unapproved indication	1	0
Product use issue	8	0
Vaccination error	8	0
Wrong device used	1	0
Wrong drug	5	0
Wrong route	1	0
Wrong schedule	2	0
Wrong technique in product usage process	10	0
<i>Muscle, tendon and ligament injuries</i>		
Epicondylitis	27	0
Ligament injury	3	0

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Reaction Name	Total	Fatal
Injuries		
Injuries cont'd		
Ligament rupture	2	0
Ligament sprain	21	0
Muscle injury	62	0
Muscle rupture	19	0
Muscle strain	51	0
Post-traumatic neck syndrome	4	0
Repetitive strain injury	3	0
Tendon injury	6	0
Tendon rupture	28	0
<i>Nerve injuries NEC</i>		
Nerve injury	185	0
<i>Neurological and psychiatric procedural complications</i>		
Post lumbar puncture syndrome	8	0
Posterior fossa syndrome	1	0
Procedural dizziness	37	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
Extraskeletal ossification	1	0
Fall	286	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	4	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

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Injection related reaction	610	0
Needle fatigue	1	0
Post procedural complication	35	0
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	56	0
Overdoses NEC		
Intentional overdose	13	0
Overdose	56	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	109	0
Incomplete course of vaccination	53	0
Incorrect dose administered	12	0
Incorrect product administration duration	2	0
Incorrect product formulation administered	1	0
Incorrect route of product administration	54	0
Intercepted product administration error	2	0
Lack of vaccination site rotation	1	0
Poor quality product administered	3	0

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Reaction Name	Total	Fatal
Injuries		
Injuries cont'd		
Product administered at inappropriate site	23	0
Product administered to patient of inappropriate age	30	0
Product administration error	28	0
Product dose omission in error	1	0
Product dose omission issue	35	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	16	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	320	0
Nasal injury	2	0
Neck crushing	1	0
Neck injury	3	0
Pharyngeal contusion	3	0

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Reaction Name	Total	Fatal
Injuries		
Injuries cont'd		
Site specific procedural complications NEC		
Axillary web syndrome	3	0
Skin injuries NEC		
Contusion	3337	0
Hair injury	2	0
Nail injury	1	0
Scar	43	0
Scratch	6	0
Skin abrasion	5	0
Skin injury	23	0
Skin laceration	4	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
Skull fractures, facial bone fractures and dislocations		
Skull fracture	1	0
Spinal cord injuries NEC		
Prevertebral soft tissue swelling of cervical space	1	0
Spinal cord injury	5	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	52	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

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Vaccination complication	104	0
Injuries SOC TOTAL	9096	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	3	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
Helicobacter test positive	1	0
Staphylococcus test positive	1	0
Streptococcus test positive	1	0
Treponema test positive	1	0
<i>Blood counts NEC</i>		
Full blood count	21	0
Full blood count abnormal	12	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	17	0
Blood pH increased	14	0
Carbon dioxide increased	1	0
Oxygen consumption	2	0
Oxygen saturation	26	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	44	0
Blood glucose fluctuation	34	0
Blood glucose increased	191	0
Glycosylated haemoglobin increased	2	0
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	37	0
Heart sounds	18	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 imaging	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 oligoclonal band present	1	0
CSF pressure	4	0
CSF protein increased	1	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	13	0
Serum serotonin increased	1	0
<i>Cholesterol analyses</i>		

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Blood cholesterol increased	18	0
Low density lipoprotein	1	0
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	123	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	2	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	6	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	64	0
Heparin-induced thrombocytopenia test positive	1	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	89	0
Prothrombin level increased	1	0
Prothrombin time	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	4	0
Electrocardiogram ST segment elevation	7	0
Electrocardiogram ST-T segment abnormal	6	0
Electrocardiogram T wave inversion	5	0
Electrocardiogram abnormal	21	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Electrocardiogram change	2	0
Electrocardiogram normal	1	0
Exercise electrocardiogram	1	0
Endocrine analyses and imaging NEC		
Hormone level abnormal	59	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	1107	0
Heart rate abnormal	64	0
Heart rate decreased	137	0
Heart rate increased	2094	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Heart rate irregular	245	0
Heart rate variability decreased	1	0
Heart rate variability increased	2	0
Maximum heart rate	7	0
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	9	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	2	0
Immunoglobulins decreased	2	0
<i>Immunology analyses NEC</i>		
Antibody test	4	0
Antibody test abnormal	7	0
Antibody test negative	15	0
Antibody test positive	1	0
Immunology test	12	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

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Quality of life decreased	3	0
Liver function analyses		
Alanine aminotransferase decreased	1	0
Alanine aminotransferase increased	32	0
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	53	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
Brain natriuretic peptide increased	1	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
Serology test	1	0
Mineral and electrolyte analyses		
Blood calcium	2	0
Blood calcium increased	1	0
Blood cyanide	1	0
Blood iron	12	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
Iron binding capacity total decreased	1	0
Serum ferritin	1	0
Serum ferritin decreased	3	0
Serum ferritin increased	5	0
Sweat test	3	0
Transferrin decreased	1	0
Urine copper	2	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
<i>Musculoskeletal and soft tissue imaging procedures</i>		
Bone densitometry	1	0
Discogram abnormal	1	0
Magnetic resonance imaging neck	1	0
Skull X-ray	11	0
X-ray limb	3	0
X-ray limb abnormal	1	0
X-ray of pelvis and hip	2	0
<i>Musculoskeletal and soft tissue tests NEC</i>		
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	19	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	2	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	7	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	1035	0
Body temperature abnormal	89	0
Body temperature decreased	137	0
Body temperature fluctuation	190	0
Body temperature increased	1156	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	12	0
Grip strength decreased	36	0
Head lag	19	0
Lymph node palpable	6	0
Male genital examination abnormal	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
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
Respiratory rate	14	0
Respiratory rate decreased	32	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	228	0
Weight increased	68	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	5	0
Blood thyroid stimulating hormone increased	5	0
<i>Platelet analyses</i>		
Platelet count	3	0
Platelet count abnormal	3	0
Platelet count decreased	341	1
Platelet count increased	7	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	40	0
Protein total	2	0
Protein total abnormal	1	0
Protein total increased	2	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	20	0
Haemoglobin increased	2	0
Mean cell haemoglobin concentration	1	0
Mean cell volume abnormal	2	0
Red blood cell count	3	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
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
Renal function analyses		
Blood creatine increased	1	0
Blood creatinine abnormal	1	0
Blood creatinine decreased	2	0
Blood creatinine increased	3	0
Blood urea	7	0
Blood urea increased	1	0
Glomerular filtration rate decreased	6	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

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
<i>Respiratory tract and thoracic imaging procedures</i>		
Chest X-ray	21	0
Computerised tomogram thorax	4	0
Laryngoscopy	1	0
Ventilation/perfusion scan	1	0
<i>Skeletal and cardiac muscle analyses</i>		
Blood creatine phosphokinase increased	8	0
Muscle enzyme increased	1	0
Myocardial necrosis marker	1	0
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	9	0
<i>Skin histopathology procedures</i>		
Biopsy skin	1	0
<i>Special sense investigations NEC</i>		
Olfactory test	1	0
<i>Therapeutic drug monitoring analyses</i>		
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	2	0
<i>Thyroid analyses</i>		
Anti-thyroid antibody	1	0
Thyroid function test abnormal	5	0
Thyroxine	1	0
Thyroxine abnormal	1	0
Thyroxine increased	2	0
Tri-iodothyronine decreased	7	0
<i>Tissue enzyme analyses NEC</i>		
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
<i>Toxicology laboratory analyses</i>		
Blood aluminium	1	0
Blood arsenic normal	1	0
Blood cannabinoids	1	0
Blood carbon monoxide increased	3	0
Blood lead	1	0
Drug screen positive	4	0
Heavy metal test	1	0
<i>Triglyceride analyses</i>		
Blood triglycerides	1	0
Blood triglycerides increased	1	0
<i>Urinalysis NEC</i>		

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
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
Urine analysis	1	0
Urine analysis abnormal	16	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 histopathology procedures		
Biopsy kidney	1	0
Urinary tract imaging procedures		
Cystoscopy	3	0
Ultrasound kidney	1	0
Vascular auscultatory investigations		
Abdominal bruit	1	0
Aortic 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	16	0
Blood pressure decreased	102	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	337	0
Blood pressure measurement	115	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

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
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	34	0
SARS-CoV-2 antibody test positive	8	0
SARS-CoV-2 test	30	0
SARS-CoV-2 test false negative	5	0
SARS-CoV-2 test false positive	4	0
SARS-CoV-2 test negative	18	0
SARS-CoV-2 test positive	109	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	12	0
Vitamin B12	2	0
Vitamin B12 abnormal	1	0
Vitamin B12 decreased	6	0
Vitamin D	3	0
Vitamin D decreased	6	0
Vitamin D increased	1	0
Vitamin E decreased	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	35	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
White blood cell count increased	14	0
Investigations SOC TOTAL	11199	1

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	38	0
Decreased appetite	6446	0
Diet refusal	2	0
Eating disorder symptom	1	0
Food craving	25	0
Food refusal	42	0
Hyperphagia	10	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	113	0
Diabetes mellitus inadequate control	29	0
Increased insulin requirement	1	0
Insulin resistant diabetes	1	0
Steroid diabetes	1	0
Type 1 diabetes mellitus	25	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	183	0
<i>Electrolyte imbalance NEC</i>		
Electrolyte imbalance	4	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	14	0
Dairy intolerance	4	0
Food intolerance	21	0
Gluten sensitivity	4	0
Histamine intolerance	4	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	76	0
Abnormal weight gain	37	0
Cachexia	2	0

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Reaction Name	Total	Fatal
Metabolic disorders <small>Metabolic disorders cont'd</small>		
Feeding disorder	211	0
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	4	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	104	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	13	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	29	0
Hyponatraemic syndrome	4	1

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Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
<i>Sugar intolerance (excl glucose intolerance)</i>		
Lactose intolerance	6	0
<i>Total fluid volume decreased</i>		
Dehydration	690	0
Hypovolaemia	2	0
<i>Total fluid volume increased</i>		
Fluid retention	94	0
Hypervolaemia	12	0
<i>Vitamin deficiencies NEC</i>		
Hypovitaminosis	3	0
<i>Water soluble vitamin deficiencies</i>		
Folate deficiency	12	0
Vitamin B complex deficiency	1	0
Vitamin B12 deficiency	15	0
Metabolic disorders SOC TOTAL	8784	3

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	592	0
Arthritis enteropathic	2	0
Arthropathy	39	0
Autoimmune arthritis	11	0
Haemarthrosis	9	0
Oligoarthritis	1	0
Palindromic rheumatism	7	0
Polyarthritis	19	0
Rheumatic fever	8	0
Sacroiliitis	4	0
Seronegative arthritis	3	0
Sympathetic posterior cervical syndrome	1	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	3	0
Osteonecrosis of jaw	4	0
Osteosclerosis	2	0
Spinal disorder	2	0
<i>Bone related signs and symptoms</i>		
Bone pain	1084	0
Bone swelling	8	0
Coccydynia	8	0
Pain in jaw	620	0
Pubic pain	1	0
Spinal pain	265	0
<i>Bursal disorders</i>		
Bursitis	208	0
<i>Cartilage disorders</i>		
Chondritis	1	0
Chondropathy	2	0
Costochondritis	87	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	98	0
Reynold's syndrome	6	0
Scleroderma	4	0
Sjogren's syndrome	4	0
Systemic scleroderma	1	0
<i>Crystal arthropathic disorders</i>		
Chondrocalcinosis pyrophosphate	4	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Gouty tophus	1	0
<i>Epiphyseal disorders</i>		
Epiphyses premature fusion	1	0
<i>Extremity deformities</i>		
Acquired claw toe	1	0
Elbow deformity	1	0
Finger deformity	4	0
Foot deformity	5	0
Hand deformity	4	0
Knee deformity	1	0
Limb deformity	9	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	10	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	461	0
Rotator cuff syndrome	92	0
Temporomandibular joint syndrome	22	0
<i>Joint related signs and symptoms</i>		
Arthralgia	23021	0
Jaw clicking	5	0
Joint effusion	10	0
Joint noise	51	0
Joint range of motion decreased	6	0
Joint stiffness	468	0
Joint swelling	1051	0
Joint vibration	6	0
Joint warmth	38	0
Loose body in joint	1	0
<i>Ligament disorders</i>		
Ligament pain	11	0
<i>Lupus erythematosus (incl subtypes)</i>		
Lupus-like syndrome	2	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>		

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Muscle & tissue disorders cont'd		
Autoimmune myositis	1	0
Myositis	53	0
Polymyositis	4	0
Muscle pains		
Fibromyalgia	296	0
Myalgia	26770	0
Myalgia intercostal	3	0
Myofascial pain syndrome	26	0
Muscle related signs and symptoms NEC		
Haematoma muscle	3	0
Muscle atrophy	37	0
Muscle discomfort	20	0
Muscle disorder	12	0
Muscle fatigue	1005	0
Muscle haemorrhage	5	0
Muscle hypertrophy	1	0
Muscle mass	12	0
Muscle oedema	2	0
Muscle spasms	3529	0
Muscle swelling	33	0
Muscle tightness	196	0
Muscle twitching	589	0
Muscle tone abnormalities		
Muscle rigidity	53	0
Nuchal rigidity	18	0
Torticollis	13	0
Trismus	55	0
Muscle weakness conditions		
Muscular weakness	2209	0
Sarcopenia	1	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	164	0
Muscle contracture	4	0
Musculoskeletal disorder	3	0
Musculoskeletal stiffness	2382	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	4	0
Dactylitis	3	0
Dupuytren's contracture	4	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Fasciitis	1	0
Plantar fasciitis	14	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Amplified musculoskeletal pain syndrome	1	0
Back pain	5865	0
Flank pain	93	0
Growing pains	8	0
Limb discomfort	2365	0
Musculoskeletal chest pain	423	0
Musculoskeletal discomfort	156	0
Musculoskeletal pain	165	0
Neck pain	3129	0
Pain in extremity	22188	0
Rheumatic disorder	29	0
Sacral pain	6	0
<i>Myopathies</i>		
Compartment syndrome	6	0
Muscle necrosis	1	0
Myopathy	6	0
Rhabdomyolysis	9	1
<i>Osteoarthropathies</i>		
Nodal osteoarthritis	1	0
Osteoarthritis	97	0
Spinal osteoarthritis	9	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	196	0
Rheumatoid nodule	1	0
Still's disease	6	0
<i>Soft tissue disorders NEC</i>		
Axillary mass	83	0
Clubbing	1	0
Fistula	3	0
Groin pain	231	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	62	0
Axial spondyloarthritis	2	0
Spondylitis	7	0
<i>Synovial disorders</i>		
Synovial cyst	13	0
Synovitis	19	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
<i>Tendon disorders</i>		
Enthesopathy	1	0
Tendon discomfort	4	0
Tendon disorder	9	0
Tendon pain	45	0
Tendon sheath disorder	1	0
Tendonitis	104	0
Tenosynovitis	3	0
Tenosynovitis stenosaurs	3	0
Trigger finger	36	0
Muscle & tissue disorders SOC TOTAL	101666	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
Fibroadenoma of breast	1	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	7	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

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
<i>Haematologic neoplasms NEC</i>		
Benign lymph node neoplasm	1	0
Haematological malignancy	2	0
Systemic mastocytosis	1	0
<i>Hepatic neoplasms malignant</i>		
Hepatocellular carcinoma	4	0
<i>Hepatobiliary neoplasms malignancy unspecified</i>		
Hepatic neoplasm	1	0
<i>Hepatoblastomas</i>		
Hepatoblastoma	1	0
<i>Hodgkin's disease NEC</i>		
Hodgkin's disease	2	0
<i>Leiomyosarcomas</i>		
Pleomorphic leiomyosarcoma	1	0
<i>Leukaemias NEC</i>		
Leukaemia	4	0
Leukaemia recurrent	1	0
<i>Leukaemias acute myeloid</i>		
Acute myeloid leukaemia	4	1
<i>Leukaemias chronic lymphocytic</i>		
Chronic lymphocytic leukaemia	7	0
<i>Leukaemias chronic myeloid</i>		
Chronic myeloid leukaemia	1	0
<i>Leukaemias myeloid NEC</i>		
Myeloid leukaemia	1	0
<i>Lip and oral cavity neoplasms benign</i>		
Papillary cystadenoma lymphomatosum	1	0
<i>Lip and oral cavity neoplasms malignant</i>		
Lip and/or oral cavity cancer	1	0
Squamous cell carcinoma of the oral cavity	2	0
<i>Lymphomas unspecified NEC</i>		
Lymphoma	20	0
<i>Lymphoproliferative disorders NEC (excl leukaemias and lymphomas)</i>		
Epstein Barr virus positive mucocutaneous ulcer	1	0
Histiocytic necrotising lymphadenitis	1	0
Lymphoproliferative disorder	1	0
Lymphoproliferative disorder in remission	1	0
<i>Mediastinal neoplasms malignancy unspecified NEC</i>		
Good syndrome	4	0
<i>Metastases to specified sites</i>		
Metastases to bone	2	0
Metastases to central nervous system	1	1
Metastases to liver	1	0
Metastases to lung	1	1
<i>Metastases to unknown and unspecified sites</i>		
Metastasis	4	1
<i>Myelodysplastic syndromes</i>		
Myelodysplastic syndrome	1	0
<i>Myeloproliferative disorders (excl leukaemias)</i>		
Essential thrombocythaemia	2	0
<i>Neoplasms benign site unspecified NEC</i>		
Fibroma	1	0
<i>Neoplasms malignant site unspecified NEC</i>		

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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	8	0
Nervous system neoplasms unspecified malignancy NEC		
Brain neoplasm	7	1
Meningioma	5	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	8	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	2	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	15	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	7	0
Anogenital warts	4	0
Haemangioma of skin	18	0
Melanocytic naevus	5	0
Seborrhoeic keratosis	2	0
Skin papilloma	31	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	18	0
Uterine neoplasms malignant NEC		
Uterine cancer	4	0
Vulval neoplasms malignant		
Squamous cell carcinoma of the vulva	1	0
Vulval cancer	1	0
Neoplasms SOC TOTAL	470	8

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Areflexia	35	0
Extensor plantar response	3	0
Hyperreflexia	9	0
Hyporeflexia	22	0
Poor sucking reflex	4	0
Reflexes abnormal	1	0
<i>Abnormal sleep-related events</i>		
Sleep paralysis	25	0
<i>Absence seizures</i>		
Petit mal epilepsy	42	0
<i>Acute polyneuropathies</i>		
Acute motor axonal neuropathy	6	0
Acute polyneuropathy	3	0
Guillain-Barre syndrome	456	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>Autonomic nervous system disorders</i>		
Autonomic nervous system imbalance	21	0
Autonomic neuropathy	2	0
Horner's syndrome	2	0
Orthostatic intolerance	8	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	3	0
Carotid artery thrombosis	10	0
Cerebellar haemorrhage	5	0
Cerebellar infarction	6	0
Cerebellar stroke	11	0
Cerebral artery embolism	12	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
Cerebral thrombosis	38	4
Cerebral vascular occlusion	2	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Cerebrovascular accident	1240	46
Embolic stroke	20	0
Haemorrhage intracranial	56	14
Haemorrhagic cerebral infarction	3	1
Haemorrhagic stroke	46	7
Haemorrhagic transformation stroke	8	3
Internal capsule infarction	1	0
Intracranial haematoma	8	1
Intraventricular haemorrhage	6	0
Ischaemic cerebral infarction	2	0
Ischaemic stroke	153	7
Lacunar infarction	5	0
Lacunar stroke	25	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	113	7
Thalamic infarction	1	0
Thalamus haemorrhage	9	0
Thrombotic stroke	14	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	4	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
Dural arteriovenous fistula	1	0
Internal carotid artery deformity	1	0
Reversible cerebral vasoconstriction syndrome	4	0
Cerebrovascular venous and sinus thrombosis		
Cerebral venous sinus thrombosis	210	22
Cerebral venous thrombosis	51	5
Superior sagittal sinus thrombosis	31	3
Transverse sinus thrombosis	6	0
Cervical spinal cord and nerve root disorders		

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Cervical radiculopathy	4	0
Cervicobrachial syndrome	6	0
Choreiform movements		
Chorea	3	0
Choreoathetosis	1	0
Sydenham's chorea	1	0
Chronic polyneuropathies		
Chronic inflammatory demyelinating polyradiculoneuropathy	7	0
Demyelinating polyneuropathy	11	0
Diabetic neuropathy	2	0
Polyneuropathy chronic	2	0
Coma states		
Coma	22	0
Diabetic coma	3	0
Hypoglycaemic coma	2	0
Coordination and balance disturbances		
Ataxia	50	0
Balance disorder	947	0
Cerebellar ataxia	4	0
Cerebellar syndrome	2	0
Coordination abnormal	133	0
Dysdiadochokinesis	1	0
Dysstasia	118	0
Hand-eye coordination impaired	1	0
Nystagmus	23	0
Cortical dysfunction NEC		
Agraphia	1	0
Alexia	7	0
Aphasia	177	0
Apraxia	4	0
Dysgraphia	7	0
Dyslexia	2	0
Dyspraxia	8	0
Neurologic neglect syndrome	3	0
Visuospatial deficit	2	0
Cranial nerve disorders NEC		
Cranial nerve disorder	2	0
Cranial nerve paralysis	1	0
Neurovascular conflict	1	0
Paresis cranial nerve	2	0
Dementia (excl Alzheimer's type)		
Dementia	32	0
Dementia with Lewy bodies	1	0
Frontotemporal dementia	1	0
Senile dementia	1	0
Vascular dementia	5	0
Demyelinating disorders NEC		
Acute disseminated encephalomyelitis	15	0
Clinically isolated syndrome	3	0
Demyelination	26	0
Neuromyelitis optica spectrum disorder	5	0
Disturbances in consciousness NEC		
Altered state of consciousness	20	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Consciousness fluctuating	4	0
Depressed level of consciousness	91	0
Hypoglycaemic unconsciousness	1	0
Lethargy	4946	0
Loss of consciousness	1091	0
Postictal state	1	0
Sedation	17	0
Somnolence	1959	0
Stupor	9	0
Syncope	2529	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	119	0
Extrapyramidal disorder	18	0
Fine motor delay	3	0
Fine motor skill dysfunction	20	0
Hyperkinesia	27	0
Hypokinesia	97	0
Meige's syndrome	1	0
Motor dysfunction	20	0
Movement disorder	109	0
Psychomotor hyperactivity	41	0
Tardive dyskinesia	1	0
<i>Dystonias</i>		
Dystonia	22	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	11	0
<i>Encephalopathies NEC</i>		
Autoimmune encephalopathy	5	1
Encephalopathy	10	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
<i>Eye movement disorders</i>		

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
IIIrd nerve disorder	1	0
IIIrd nerve paralysis	6	0
IIIrd nerve paresis	1	0
IVth nerve paralysis	1	0
Microvascular cranial nerve palsy	2	0
VIth nerve paralysis	9	0
Facial cranial nerve disorders		
Bell's palsy	594	0
Facial nerve disorder	8	0
Facial paralysis	350	0
Facial paresis	169	0
Facial spasm	45	0
Oculofacial paralysis	1	0
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	101	0
Glossopharyngeal nerve disorders		
Glossopharyngeal neuralgia	1	0
Headaches NEC		
Cervicogenic headache	6	0
Chronic paroxysmal hemicrania	1	0
Cluster headache	751	0
Cold-stimulus headache	90	0
Drug withdrawal headache	17	0
Exertional headache	12	0
External compression headache	5	0
Headache	80998	0
Medication overuse headache	19	0
New daily persistent headache	19	0
Occipital neuralgia	27	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	1521	0
Thunderclap headache	49	0
Vascular headache	80	0
Hydrocephalic conditions		
Hydrocephalus	17	1
Hypoglossal nerve disorders		
Tongue paralysis	6	0
Increased intracranial pressure disorders		
Brain compression	4	0
Brain oedema	33	2
Cerebrospinal fluid circulation disorder	6	0
Cytotoxic oedema	1	0
Idiopathic intracranial hypertension	7	0
Intracranial pressure increased	27	0
Vasogenic cerebral oedema	1	0
Intellectual disabilities		
Intellectual disability	11	0
Lumbar spinal cord and nerve root disorders		
Lumbar radiculopathy	4	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Sciatica	226	0
Memory loss (excl dementia)		
Amnesia	410	0
Memory impairment	376	0
Retrograde amnesia	1	0
Transient global amnesia	25	0
Meningitis NEC		
Meningitis noninfective	1	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	197	1
Disturbance in attention	741	0
Judgement impaired	5	0
Mental impairment	140	0
Migraine headaches		
Basilar migraine	5	0
Hemiplegic migraine	49	0
Migraine	7606	0
Migraine with aura	393	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
Mixed cranial nerve disorders		
Bulbar palsy	3	0
Mononeuropathies		
Carpal tunnel syndrome	42	0
Cubital tunnel syndrome	1	0
Diabetic mononeuropathy	1	0
Long thoracic nerve palsy	1	0
Meralgia paraesthetica	3	0
Mononeuritis	4	0
Mononeuropathy	3	0
Nerve compression	55	0
Peripheral nerve lesion	1	0
Peroneal nerve palsy	18	0
Piriformis syndrome	4	0
Radial nerve palsy	2	0
Sciatic nerve neuropathy	3	0
Ulnar nerve palsy	3	0
Ulnar neuritis	4	0
Ulnar tunnel syndrome	1	0
Motor neurone diseases		
Amyotrophic lateral sclerosis	1	0
Lower motor neurone lesion	1	0
Motor neurone disease	4	0
Multiple sclerosis acute and progressive		
Band sensation	6	0
Multiple sclerosis	55	0
Multiple sclerosis pseudo relapse	2	0
Multiple sclerosis relapse	61	0
Progressive multiple sclerosis	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Relapsing multiple sclerosis	1	0
Tumefactive multiple sclerosis	1	0
Uhthoff's phenomenon	2	0
Muscle tone abnormal		
Drop attacks	2	0
Hypertonia	5	0
Hypotonia	41	0
Serotonin syndrome	1	0
Stiff leg syndrome	10	0
Stiff person syndrome	1	0
Myelitis (incl infective)		
Myelitis transverse	95	0
Narcolepsy and hypersomnia		
Cataplexy	1	0
Hypersomnia	222	0
Narcolepsy	21	0
Nervous system cysts and polyps		
Arachnoid cyst	1	0
Pineal gland cyst	1	0
Nervous system disorders NEC		
Brain stem syndrome	2	0
Central nervous system lesion	7	0
Cerebral disorder	8	0
Microglial nodules	1	0
Nervous system disorder	75	0
Neurotoxicity	4	0
Psychomotor skills impaired	4	0
Neurologic visual problems NEC		
Hemianopia	9	0
Hemianopia homonymous	3	0
Quadrantanopia	1	0
Tunnel vision	23	0
Neurological signs and symptoms NEC		
Agitation neonatal	1	0
Clonus	2	0
Dizziness	22435	0
Dizziness exertional	100	0
Dizziness postural	2150	0
Drooling	25	0
Exaggerated startle response	4	0
Fontanelle bulging	4	0
Head discomfort	753	0
Hyporesponsive to stimuli	4	0
Inability to crawl	2	0
Infant irritability	6	0
Intracranial hypotension	3	0
Meningism	3	0
Myoclonus	34	0
Neurological decompensation	4	0
Neurological symptom	136	0
Patient elopement	3	0
Persistent postural-perceptual dizziness	41	0
Pleocytosis	4	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Presyncope	608	0
Sensory overload	11	0
Slow response to stimuli	8	0
Spontaneous cerebrospinal fluid leak syndrome	1	0
Tongue biting	10	0
Unresponsive to stimuli	106	0
Neuromuscular disorders NEC		
Hypotonic-hyporesponsive episode	1	0
Muscle contractions involuntary	38	0
Muscle spasticity	33	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	341	0
Hyposmia	11	0
Parosmia	402	0
Optic nerve disorders NEC		
Optic neuritis	61	0
Paraesthesias and dysaesthesias		
Anaesthesia	3	0
Burning feet syndrome	30	0
Burning sensation	1022	0
Burning sensation mucosal	3	0
Dysaesthesia	17	0
Formication	83	0
Hand-arm vibration syndrome	3	0
Hemianaesthesia	5	0
Hemiparaesthesia	3	0
Hyperaesthesia	275	0
Hypoaesthesia	5992	0
Lhermitte's sign	4	0
Paraesthesia	9697	0
Reversed hot-cold sensation	1	0
Paralysis and paresis (excl cranial nerve)		
Diplegia	36	0
Gait spastic	1	0
Hemiparesis	115	0
Hemiplegia	45	0
Monoparesis	113	0
Monoplegia	140	0
Paralysis	339	1
Paraparesis	6	0
Paraplegia	3	0
Paresis	8	0
Peripheral nerve palsy	1	0
Peripheral paralysis	1	0
Postictal paralysis	3	0
Quadriparesis	3	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Quadriplegia	3	0
<i>Parkinson's disease and parkinsonism</i>		
Freezing phenomenon	159	0
Parkinson's disease	17	0
Parkinsonism	13	0
Reduced facial expression	8	0
Vascular parkinsonism	1	0
<i>Partial complex seizures</i>		
Dreamy state	21	0
Focal dyscognitive seizures	7	0
Temporal lobe epilepsy	5	0
<i>Partial simple seizures NEC</i>		
Autonomic seizure	1	0
Simple partial seizures	7	0
<i>Peripheral neuropathies NEC</i>		
Autoimmune neuropathy	2	0
Axonal and demyelinating polyneuropathy	1	0
Axonal neuropathy	2	0
Brachial plexopathy	1	0
Ischaemic neuropathy	2	0
Neuralgic amyotrophy	9	0
Neuritis	19	0
Neuropathy peripheral	269	0
Peripheral motor neuropathy	2	0
Peripheral sensorimotor neuropathy	3	0
Peripheral sensory neuropathy	18	0
Polyneuropathy	15	0
Small fibre neuropathy	3	0
Thoracic outlet syndrome	2	0
<i>Seizures and seizure disorders NEC</i>		
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	342	1
Epileptic aura	3	0
Febrile convulsion	91	0
Hypoglycaemic seizure	1	0
Migraine-triggered seizure	2	0
Myoclonic epilepsy	5	0
Partial seizures	58	0
Psychogenic seizure	5	0
Seizure	1351	3
Seizure anoxic	3	0
Seizure cluster	9	0
Seizure like phenomena	3	0
Status epilepticus	29	2
Tonic clonic movements	3	0
Tonic convulsion	38	0
<i>Sensory abnormalities NEC</i>		

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Ageusia	1093	0
Allodynia	63	0
Aura	25	0
Central pain syndrome	2	0
Complex regional pain syndrome	14	0
Decreased vibratory sense	1	0
Dysgeusia	2011	0
Electric shock sensation	107	0
Hypogeusia	7	0
Intercostal neuralgia	2	0
Loss of proprioception	6	0
Neuralgia	1451	0
Persistent genital arousal disorder	2	0
Phantom limb syndrome	18	0
Post herpetic neuralgia	12	0
Restless arm syndrome	15	0
Restless legs syndrome	400	0
Sensory disturbance	160	0
Sensory loss	242	0
Taste disorder	514	0
Vibratory sense increased	5	0
Visual perseveration	1	0
Sleep disturbances NEC		
Microsleep	3	0
Periodic limb movement disorder	1	0
Sleep deficit	53	0
Sudden onset of sleep	1	0
Speech and language abnormalities		
Dysarthria	451	0
Incoherent	20	0
Language disorder	3	0
Muscle tension dysphonia	1	0
Repetitive speech	1	0
Slow speech	40	0
Speech disorder	124	0
Speech disorder developmental	1	0
Spinal cord and nerve root disorders NEC		
Cauda equina syndrome	6	0
Myelopathy	6	0
Radicular pain	1	0
Radiculitis brachial	27	0
Radiculopathy	3	0
Spinal cord disorder	7	0
Spinal cord ischaemia	1	0
Spinal cord oedema	1	0
Subacute combined cord degeneration	1	0
Structural brain disorders NEC		
Brain injury	39	3
Cerebral mass effect	10	0
Encephalomalacia	1	0
Intracranial mass	4	0
White matter lesion	5	0
Transient cerebrovascular events		

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Transient ischaemic attack	497	2
Tremor (excl congenital)		
Action tremor	4	0
Asterixis	1	0
Essential tremor	7	0
Head titubation	25	0
Intention tremor	1	0
Postural tremor	2	0
Resting tremor	8	0
Tremor	9780	1
Trigeminal disorders		
Numb chin syndrome	3	0
Trigeminal nerve disorder	6	0
Trigeminal neuralgia	146	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	3	0
Nervous system disorders SOC TOTAL	178662	201

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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	214	0
<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	2	0
<i>Haemorrhagic complications of pregnancy</i>		
Haemorrhage in pregnancy	1	0
<i>High risk pregnancies</i>		
Pregnancy of unknown location	1	0
<i>Hypertension associated disorders of pregnancy</i>		
Pre-eclampsia	3	0
<i>Labour onset and length abnormalities</i>		
Precipitate labour	1	0
Premature labour	3	0
Premature rupture of membranes	2	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	1	0
<i>Maternal complications of pregnancy NEC</i>		
Biochemical pregnancy	3	0
Decidual cast	3	0
Ectopic pregnancy	8	0
Hyperemesis gravidarum	2	0
Morning sickness	1	0
Pelvic girdle pain	2	0
Preterm premature rupture of membranes	1	0
Somatic symptom disorder of pregnancy	1	0
<i>Multiple pregnancies</i>		
Twin pregnancy	2	0
<i>Normal pregnancy, labour and delivery</i>		
Delivery	1	0
Labour pain	1	0
Live birth	2	0
Pregnancy	24	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	4	4
<i>Umbilical cord complications</i>		
Umbilical cord around neck	1	0
<i>Unintended pregnancies</i>		

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Reaction Name	Total	Fatal
Pregnancy conditions <small>Pregnancy conditions cont'd</small>		
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	309	4

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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
Electromagnetic interference	1	0
<i>Device incompatibility issues</i>		
Patient-device incompatibility	2	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	67	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 after taste	8	0
Product colour issue	4	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	2	0
null SOC TOTAL	186	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	13	0
Flat affect	10	0
Inappropriate affect	18	0
<i>Amnesic symptoms</i>		
Paramnesia	6	0
<i>Anxiety disorders NEC</i>		
Anxiety disorder	4	0
Generalised anxiety disorder	4	0
Neurosis	1	0
<i>Anxiety symptoms</i>		
Agitation	204	0
Anxiety	1268	0
Immunisation anxiety related reaction	1	0
Nervousness	599	0
Procedural anxiety	1	0
Stress	160	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	17	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	42	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	485	0
Communications disorders		
Communication disorder	6	0
Mutism	6	0
Speech sound disorder	2	0
Confusion and disorientation		
Confusional state	2147	0
Disorientation	731	0
Decreased physical activity levels		
Catatonia	3	0
Deliria		
Delirium	481	0
Delirium febrile	3	0
Delusional disorders		
Alice in wonderland syndrome	3	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	676	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	77	0
Dissociative amnesia	1	0
Dissociative disorder	2	0
Disturbances in initiating and maintaining sleep		
Initial insomnia	42	0
Insomnia	3108	0
Middle insomnia	72	0
Terminal insomnia	27	0
Dyssomnias		
Dyssomnia	5	0
Poor quality sleep	666	0
Eating disorders NEC		
Binge eating	1	0
Eating disorder	17	0
Pica	1	0
Selective eating disorder	2	0
Emotional and mood disturbances NEC		
Anger	90	0

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Reaction Name	Total	Fatal
Psychiatric disorders ^{Psychiatric disorders cont'd}		
Dysphoria	2	0
Emotional disorder	102	0
Emotional distress	84	0
Emotional poverty	2	0
Euphoric mood	70	0
Frustration tolerance decreased	15	0
Irritability	319	0
Mood altered	88	0
Factitious disorders		
Factitious disorder	4	0
Fear symptoms and phobic disorders (incl social phobia)		
Acrophobia	2	0
Agoraphobia	4	0
Fear	65	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	4	0
Social anxiety disorder	1	0
Social fear	1	0
Thanatophobia	1	0
Fluctuating mood symptoms		
Mood swings	135	0
Hallucinations (excl sleep-related)		
Hallucination	936	0
Hallucination, auditory	49	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	30	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	686	0
Depressive symptom	2	0
Feeling guilty	1	0
Feeling of despair	19	0
Negative thoughts	10	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	75	0
Laziness	2	0
Listless	124	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	343	0
Panic disorder	9	0
Panic reaction	41	0
<i>Paraphilias and paraphilic disorders</i>		
Fetishism	2	0
<i>Parasomnias</i>		
Abnormal dreams	369	0
Abnormal sleep-related event	2	0
Confusional arousal	3	0
Exploding head syndrome	7	0
Nightmare	458	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	60	0
Sleep-related eating disorder	2	0
Somnambulism	11	0
Perception disturbances NEC		
Autoscopy	27	0
Deja vu	4	0
Delusional perception	2	0
Derealisation	16	0
Flashback	2	0
Illusion	12	0
Imperception	1	0
Near death experience	1	0
Pseudohallucination	1	0
Time perception altered	5	0
Pervasive developmental disorders NEC		
Autism spectrum disorder	4	0
Psychiatric elimination disorders		
Enuresis	59	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	6	0
Psychotic behaviour	2	0
Psychotic disorder	45	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	25	0
Libido disorder	1	0
Libido increased	9	0
Loss of libido	51	0
Sexual dysfunction NEC		
Genito-pelvic pain/penetration disorder	1	0
Sleep disorders NEC		
Sleep disorder	434	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		
Conversion disorder	32	0
Habit cough	39	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Illness anxiety disorder	1	0
Psychogenic tremor	2	0
Somatic symptom disorder	1	0
<i>Speech and language usage disturbances</i>		
Disorganised speech	21	0
Logorrhoea	3	0
Pedantic speech	1	0
Poverty of speech	1	0
Verbigeration	1	0
<i>Speech articulation and rhythm disturbances</i>		
Dysphemia	34	0
Lack of spontaneous speech	3	0
<i>Stereotypies and automatisms</i>		
Bruxism	35	0
Head banging	47	0
Waxy flexibility	2	0
<i>Stress disorders</i>		
Acute stress disorder	2	0
Burnout syndrome	14	0
Hyperarousal	3	0
Post-traumatic stress disorder	14	0
<i>Substance related and addictive disorders</i>		
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
<i>Suicidal and self-injurious behaviour</i>		
Completed suicide	5	5
Intentional self-injury	9	0
Self-injurious ideation	3	0
Suicidal behaviour	3	0
Suicidal ideation	119	0
Suicide attempt	31	0
Suicide threat	1	0
<i>Thinking disturbances</i>		
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	32	0
Thought blocking	6	0
<i>Tic disorders</i>		
Secondary tic	2	0
Tic	20	0
Psychiatric disorders SOC TOTAL	17738	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	86	0
Micturition disorder	4	0
Micturition frequency decreased	1	0
Micturition urgency	102	0
Mixed incontinence	1	0
Pollakiuria	296	0
Stress urinary incontinence	1	0
Urethral pain	6	0
Urge incontinence	2	0
Urinary hesitation	7	0
Urinary incontinence	128	0
Urinary retention	96	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	16	1
Urinary bladder rupture	1	0
<i>Bladder infections and inflammations</i>		
Cystitis haemorrhagic	1	0
Cystitis interstitial	10	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	6	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	14	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	45	2
Renal impairment	26	0
Renal injury	7	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 cortical necrosis	1	0
Renal embolism	1	0
Renal infarct	17	1
Renal ischaemia	1	0
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	106	0
Glycosuria	1	0
Haematuria	1	0
Haematuria	62	0
Microalbuminuria	1	0
Proteinuria	11	0
Urine abnormality	21	0
Urine odour abnormal	21	0
<i>Urinary tract signs and symptoms NEC</i>		
Costovertebral angle tenderness	1	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
Renal & urinary disorders cont'd		
Haemorrhage urinary tract	58	0
Nocturia	22	0
Polyuria	33	0
Renal colic	4	0
Renal pain	937	0
Urinary tract discomfort	2	0
Urinary tract pain	15	0
Renal & urinary disorders SOC TOTAL	2640	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	69	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	487	0
Breast swelling	70	0
Breast tenderness	77	0
Nipple exudate bloody	1	0
Nipple pain	38	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	4	0
Ejaculation failure	5	0
Erectile dysfunction	90	0
Erection increased	6	0
Organic erectile dysfunction	20	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
Galactostasis	2	0
Lactation disorder	2	0
Lactation puerperal increased	6	0
Suppressed lactation	27	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
<i>Menopausal effects NEC</i>		
Artificial menopause	2	0
Menopausal disorder	3	0
Menopausal symptoms	59	0
Menopause delayed	5	0
Premature menopause	45	0
<i>Menopausal effects on the genitourinary tract</i>		
Atrophic vulvovaginitis	1	0
Postmenopausal haemorrhage	299	0
<i>Menstruation and uterine bleeding NEC</i>		
Abnormal uterine bleeding	7	0
Abnormal withdrawal bleeding	5	0
Dysmenorrhoea	1367	0
Intermenstrual bleeding	673	0
Menstrual discomfort	14	0
Menstrual disorder	1461	0
Menstruation irregular	2213	0
Premenstrual dysphoric disorder	6	0
Premenstrual headache	8	0
Premenstrual pain	80	0
Premenstrual syndrome	53	0
Retrograde menstruation	4	0
Withdrawal bleed	13	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	577	0
Hypomenorrhoea	419	0
Menstruation delayed	3130	0
Oligomenorrhoea	114	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	4529	0
Menometrorrhagia	17	0
Polymenorrhoea	658	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>		
Ovarian cyst	28	0
Ovarian cyst ruptured	2	0
Polycystic ovaries	41	0
<i>Ovarian and fallopian tube disorders NEC</i>		
Fallopian tube spasm	1	0
Ovarian adhesion	1	0
Ovarian enlargement	2	0
Ovarian failure	2	0
Ovarian haemorrhage	5	0
Ovarian hyperstimulation syndrome	1	0
Ovarian necrosis	1	0
Ovarian oedema	1	0
Ovarian vein thrombosis	2	0
Ovulation pain	54	0
Premature ovulation	8	0
<i>Pelvic prolapse conditions</i>		
Vaginal prolapse	2	0
<i>Pelvis and broad ligament disorders NEC</i>		
Adnexa uteri pain	42	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
Pelvic organ prolapse	1	0
<i>Penile and scrotal infections and inflammations</i>		
Balanoposthitis	4	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 dysaesthesia	1	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	3	0
Genital erythema	1	0
Genital pain	3	0
Genital rash	6	0
Genital swelling	2	0
Pelvic discomfort	4	0
Pelvic pain	172	0
Perineal pain	2	0
Pruritus genital	9	0
<i>Scrotal disorders NEC</i>		

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Scrotal dermatitis	1	0
Scrotal oedema	1	0
Scrotal pain	19	0
Scrotal swelling	6	0
Varicocele	1	0
<i>Sexual function and fertility disorders NEC</i>		
Dyspareunia	7	0
Female sexual dysfunction	1	0
Infertility	11	0
Infertility female	6	0
Infertility male	3	0
Male sexual dysfunction	2	0
Sexual dysfunction	14	0
<i>Spermatogenesis and semen disorders</i>		
Aspermia	2	0
Haemospermia	17	0
Semen discolouration	2	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular atrophy	1	0
Testicular disorder	8	0
Testicular mass	1	0
Testicular oedema	2	0
Testicular pain	109	0
Testicular retraction	3	0
Testicular swelling	24	0
Testis discomfort	6	0
<i>Testicular and epididymal infections and inflammations</i>		
Orchitis noninfective	1	0
<i>Testicular and epididymal neoplasms</i>		
Epididymal cyst	1	0
Testicular cyst	1	0
<i>Uterine disorders NEC</i>		
Adenomyosis	14	0
Endometrial hyperplasia	1	0
Endometrial thickening	2	0
Endometriosis	83	0
Metrorrhoea	1	0
Uterine enlargement	2	0
Uterine haemorrhage	70	0
Uterine pain	10	0
<i>Uterine neoplasms</i>		
Uterine cyst	1	0
Uterine polyp	4	0
<i>Uterine tone disorders</i>		
Uterine spasm	23	0
<i>Vaginal and vulval infections and inflammations</i>		
Vulvovaginal inflammation	2	0
<i>Vulvovaginal cysts and neoplasms</i>		
Bartholin's cyst	2	0
Vaginal cyst	15	0
Vulva cyst	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal disorder	1	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Vaginal haemorrhage	1276	0
Vaginal ulceration	7	0
Vulval disorder	3	0
Vulval haemorrhage	33	0
Vulval ulceration	7	0
Vulvovaginal disorder	1	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	88	0
Vaginal lesion	7	0
Vaginal odour	5	0
Vulval oedema	1	0
Vulvovaginal burning sensation	10	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	19340	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	7499	0
Dyspnoea at rest	15	0
Dyspnoea exertional	59	0
Dyspnoea paroxysmal nocturnal	1	0
Grunting	2	0
Hyperventilation	99	0
Hypopnoea	230	0
Hypoventilation	1	0
Irregular breathing	26	0
Mouth breathing	8	0
Orthopnoea	3	0
Respiration abnormal	107	0
Respiratory arrest	27	0
Respiratory distress	11	0
Respiratory fatigue	7	0
Sleep apnoea syndrome	32	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	620	0
Asthma exercise induced	4	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	2	0
Bronchospasm	18	0
Chronic obstructive pulmonary disease	51	4
Cough variant asthma	9	0
Obstructive airways disorder	2	0
Reversible airways obstruction	1	0
Wheezing	631	0
<i>Conditions associated with abnormal gas exchange</i>		
Asphyxia	3	0
Hypercapnia	1	0
Hypoxia	70	1
<i>Coughing and associated symptoms</i>		
Allergic cough	8	0
Cough	3945	0
Haemoptysis	142	0
Productive cough	203	0
Sputum discoloured	14	0
Sputum increased	3	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 paralysis	1	0
Diaphragmatic spasm	2	0
<i>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</i>		
Reflux laryngitis	3	0
Vocal cord disorder	5	0
Vocal cord dysfunction	5	0
Vocal cord thickening	2	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Epiglottic oedema	1	0
Laryngeal oedema	3	0
Laryngospasm	3	0
Stridor	21	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Alveolitis	2	0
Autoimmune lung disease	1	0
Eosinophilic pneumonia	2	0
Hypersensitivity pneumonitis	1	0
Pneumonitis	34	1
Pulmonary sarcoidosis	2	0
Pulmonary vasculitis	1	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	47	0
Lower respiratory tract congestion	4	0
Lung opacity	7	0
Pleuritic pain	48	0
Pulmonary haemorrhage	7	1
Pulmonary pain	230	0
Rales	2	0
<i>Mediastinal disorders</i>		
Pulmonary hilum mass	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	470	0
Nasal inflammation	8	0
Rhinitis allergic	27	0
Rhinitis perennial	1	0
<i>Nasal disorders NEC</i>		
Epistaxis	2260	0
Intranasal hypoaesthesia	1	0
Nasal crusting	6	0
Nasal cyst	2	0
Nasal disorder	7	0
Nasal dryness	68	0
Nasal mucosal discolouration	1	0
Nasal odour	2	0
Nasal oedema	16	0
Nasal polyps	1	0
Nasal pruritus	12	0
Nasal septum deviation	1	0
Nasal septum perforation	1	0
Nasal ulcer	4	0
<i>Neonatal hypoxic conditions</i>		
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	2	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	17	0
Sinus polyp	3	0
<i>Parenchymal lung disorders NEC</i>		
Atelectasis	8	0
Cystic lung disease	1	0
Emphysema	5	0
Idiopathic pulmonary fibrosis	3	0
Interstitial lung disease	8	2
Lung consolidation	9	0
Lung cyst	1	0
Lung induration	1	0
Lung infiltration	2	0
Pulmonary alveolar haemorrhage	1	0
Pulmonary calcification	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	14	0
Pharyngeal paraesthesia	36	0
Pharyngeal swelling	293	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
Tonsillolith	1	0
<i>Pleural conditions NEC</i>		
Pleural thickening	1	0
<i>Pleural infections and inflammations</i>		
Lupus pleurisy	2	0
Pleurisy	53	0
<i>Pneumothorax and pleural effusions NEC</i>		
Haemothorax	1	0
Pleural effusion	47	1
Pneumothorax	11	0
Pneumothorax spontaneous	1	0
<i>Pulmonary hypertension</i>		
Pulmonary hypertension	6	1
<i>Pulmonary oedemas</i>		

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Acute lung injury	1	0
Acute pulmonary oedema	3	0
Acute respiratory distress syndrome	1	0
Pulmonary congestion	22	0
Pulmonary oedema	40	1
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary artery thrombosis	2	0
Pulmonary embolism	1653	107
Pulmonary infarction	15	1
Pulmonary thrombosis	25	4
Pulmonary venous thrombosis	4	0
<i>Respiratory failures (excl neonatal)</i>		
Acute respiratory failure	3	1
Respiratory failure	27	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	114	0
Catarrh	66	0
Choking	21	0
Choking sensation	11	0
Dry throat	259	0
Dysphonia	170	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	113	0
Nasal obstruction	2	0
Oropharyngeal blistering	27	0
Oropharyngeal discomfort	38	0

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Oropharyngeal pain	4202	0
Oropharyngeal plaque	1	0
Paranasal sinus discomfort	76	0
Rhinalgia	34	0
Rhinorrhoea	1670	0
Sinus pain	602	0
Sneezing	515	0
Snoring	5	0
Throat clearing	7	0
Throat irritation	214	0
Throat lesion	1	0
Throat tightness	226	0
Upper airway obstruction	1	0
Upper respiratory tract congestion	1	0
Upper-airway cough syndrome	26	0
Yawning	71	0
<i>Vascular pulmonary disorders NEC</i>		
Pulmonary artery occlusion	1	0
Pulmonary vascular disorder	1	0
Respiratory disorders SOC TOTAL	28493	131

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	147	0
Acne cystic	11	0
Dermatitis acneiform	11	0
<i>Alopecias</i>		
Alopecia	419	0
Alopecia areata	40	0
Alopecia scarring	2	0
Alopecia totalis	2	0
Alopecia universalis	3	0
Androgenetic alopecia	2	0
Diffuse alopecia	5	0
Hypotrichosis	1	0
Madarosis	5	0
<i>Angioedemas</i>		
Angioedema	352	0
Circumoral oedema	2	0
Idiopathic angioedema	3	0
<i>Apocrine and eccrine gland disorders</i>		
Anhidrosis	2	0
Cold sweat	1718	0
Hidradenitis	3	0
Hyperhidrosis	9216	0
Hypohidrosis	6	0
Miliaria	220	0
Night sweats	1907	0
Sweat discolouration	3	0
Sweat gland disorder	1	0
<i>Bullous conditions</i>		
Autoimmune blistering disease	1	0
Blister	624	0
Blister rupture	7	0
Blood blister	112	0
Bullous haemorrhagic dermatosis	1	0
Dermatitis bullous	17	0
Dermatitis herpetiformis	2	0
Erythema multiforme	39	0
Linear IgA disease	1	0
Oedema blister	1	0
Pemphigoid	35	0
Pemphigus	8	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	4	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	453	0
Koebner phenomenon	1	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Macule	13	0
Myxoid cyst	1	0
Neutrophilic dermatosis	1	0
Pain of skin	935	0
Papule	126	0
Scab	28	0
Scar pain	18	0
Sensitive skin	594	0
Skin burning sensation	578	0
Skin discolouration	211	0
Skin discomfort	6	0
Skin disorder	41	0
Skin fissures	15	0
Skin fragility	2	0
Skin indentation	17	0
Skin induration	16	0
Skin laxity	1	0
Skin lesion	59	0
Skin necrosis	6	0
Skin odour abnormal	51	0
Skin plaque	3	0
Skin reaction	273	0
Skin sensitisation	89	0
Skin swelling	100	0
Skin texture abnormal	2	0
Skin tightness	41	0
Skin warm	582	0
Skin weeping	8	0
Sticky skin	9	0
Target skin lesion	2	0
Transient acantholytic dermatosis	2	0
Yellow skin	33	0
<i>Dermatitis and eczema</i>		
Autoimmune dermatitis	2	0
Dermatitis	190	0
Dermatitis allergic	318	0
Dermatitis atopic	40	0
Dermatitis contact	34	0
Dermatitis diaper	3	0
Dyshidrotic eczema	21	0
Eczema	360	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	157	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	12	0
Fixed eruption	8	0
Palmar-plantar erythrodysesthesia syndrome	3	0
<i>Erythemas</i>		
Erythema	3380	0
Erythema ab igne	1	0
Palmar erythema	7	0
Plantar erythema	3	0
<i>Exfoliative conditions</i>		
Dermatitis exfoliative	2	0
Dermatitis exfoliative generalised	9	0
Exfoliative rash	19	0
Skin exfoliation	178	0
<i>Granulomatous and deep cutaneous inflammatory conditions</i>		
Granuloma annulare	7	0
Granuloma skin	1	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	33	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	2	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

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Onychoclasia	9	0
Onycholysis	4	0
Onychomadesis	5	0
Splinter haemorrhages	6	0
<i>Panniculitides</i>		
Erythema nodosum	37	0
Panniculitis	4	0
<i>Papulosquamous conditions</i>		
Erythema annulare	2	0
Lichen planus	33	0
Lichen sclerosus	8	0
Lichen striatus	1	0
Parapsoriasis	2	0
Pityriasis lichenoides et varioliformis acuta	1	0
Pityriasis rosea	67	0
Pityriasis rubra pilaris	2	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photodermatosis	2	0
Photosensitivity reaction	169	0
Polymorphic light eruption	6	0
Solar dermatitis	1	0
<i>Pigmentation changes NEC</i>		
Pigmentation disorder	17	0
<i>Pilar disorders NEC</i>		
Hair colour changes	14	0
Hair disorder	1	0
Hair growth abnormal	7	0
Hair texture abnormal	10	0
Piloerection	101	0
Pseudofolliculitis	1	0
Trichodynia	6	0
Trichorrhexis	5	0
<i>Pruritus NEC</i>		
Itching scar	5	0
Pruritus	8255	0
Pruritus allergic	1	0
Senile pruritus	1	0
<i>Psoriatic conditions</i>		
Dermatitis psoriasiform	2	0
Erythrodermic psoriasis	1	0
Guttate psoriasis	29	0
Nail psoriasis	1	0
Palmoplantar pustulosis	2	0
Psoriasis	236	0
Pustular psoriasis	6	0
<i>Purpura and related conditions</i>		
Ecchymosis	5	0
Henoch-Schonlein purpura	18	0
Petechiae	372	0
Purpura	144	0
<i>Pustular conditions</i>		
Acute generalised exanthematous pustulosis	1	0
Rash follicular	4	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
<i>Rashes, eruptions and exanthems NEC</i>		
Butterfly rash	8	0
Rash	9061	0
Rash erythematous	2250	0
Rash macular	766	0
Rash maculo-papular	69	0
Rash morbilliform	48	0
Rash papular	571	0
Rash pruritic	1949	0
Rash rubelliform	1	0
Rash scarlatiniform	2	0
Rash vesicular	104	0
Systemic lupus erythematosus rash	9	0
<i>Rosaceas</i>		
Erythematotelangiectatic rosacea	3	0
Granulomatous rosacea	1	0
Papulopustular rosacea	1	0
Rosacea	48	0
<i>Scaly conditions</i>		
Dandruff	1	0
Pityriasis	13	0
<i>Sebaceous gland disorders</i>		
Sebaceous glands overactivity	1	0
Seborrhoea	15	0
<i>Skin and subcutaneous conditions NEC</i>		
Cellulite	3	0
Cutaneous symptom	11	0
Skin discharge	1	0
Skin mass	43	0
<i>Skin and subcutaneous tissue ulcerations</i>		
Diabetic foot	2	0
Diabetic ulcer	1	0
Ischaemic skin ulcer	1	0
Pyoderma gangrenosum	3	0
Skin erosion	57	0
Skin ulcer	32	0
Vasculitic ulcer	1	0
<i>Skin cysts and polyps</i>		
Dermal cyst	23	0
<i>Skin dystrophies</i>		
Keloid scar	3	0
Skin wrinkling	4	0
<i>Skin haemorrhages</i>		
Haemorrhage subcutaneous	21	0
Mucocutaneous haemorrhage	3	0
Skin haemorrhage	50	0
<i>Skin hyperplasias and hypertrophies</i>		
Skin hypertrophy	3	0
<i>Skin hypoplasias and atrophies</i>		
Skin atrophy	11	0
Skin striae	13	0
<i>Skin injuries and mechanical dermatoses</i>		
Decubitus ulcer	5	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Needle track marks	3	0
<i>Skin preneoplastic conditions NEC</i>		
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	60	0
<i>Telangiectasia and related conditions</i>		
Spider naevus	5	0
Telangiectasia	5	0
<i>Urticarias</i>		
Chronic spontaneous urticaria	5	0
Cold urticaria	10	0
Idiopathic urticaria	10	0
Mechanical urticaria	7	0
Solar urticaria	1	0
Urticaria	2561	0
Urticaria chronic	46	0
Urticaria contact	3	0
Urticaria papular	3	0
Urticaria pigmentosa	1	0
Urticaria thermal	7	0
Urticularial vasculitis	5	0
Skin disorders SOC TOTAL	51853	0

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Reaction Name	Total	Fatal
Social circumstances		
<i>Age related issues</i>		
Childhood	1	0
Menarche	3	0
Menopause	70	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	98	0
Breast prosthesis user	2	0
Dependence on oxygen therapy	1	0
Disability	7	0
Hearing aid user	2	0
Hearing disability	1	0
Housebound	2	0
Immobile	56	0
Immobilisation prolonged	4	0
Impaired driving ability	4	0
Impaired work ability	28	0
Loss of personal independence in daily activities	11	0
Paralytic disability	1	0
Physical disability	3	0
Sight disability	23	0
Sitting disability	3	0
Walking aid user	2	0
Walking disability	7	0
Wheelchair user	2	0
<i>Educational issues</i>		
Educational problem	1	0
Illiteracy	3	0
<i>Employment issues</i>		
Job dissatisfaction	2	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	5	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	414	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	2	0
Tooth restoration	4	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	8	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>Fascial and bursal therapeutic procedures</i>		
Bursa removal	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	4	0
<i>Haematological therapeutic procedures NEC</i>		
Anticoagulant therapy	2	0
Haemofiltration	1	0
Thrombosis prophylaxis	2	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	221	0
Immunisation	112	0
Influenza immunisation	1	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	6	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	5	0
Limb immobilisation	27	0
Limb operation	13	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Surgical & medical procedures cont'd</i>		
Limb reattachment surgery	1	0
Toe amputation	5	0
Mastectomies		
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	3	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

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Surgical & medical procedures cont'd</i>		
Heat therapy	3	0
Hospitalisation	31	0
Immobilisation bandage	1	0
Injection	53	0
Interchange of vaccine products	30	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	2	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
Vascular graft	1	0
<i>Venous therapeutic procedures</i>		
Phlebotomy	2	0
Surgical & medical procedures SOC TOTAL	811	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	13	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	59	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	126	2
Distributive shock	2	0
Hypoperfusion	2	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	113	0
Haemorrhage	1427	2
Internal haemorrhage	31	0
Venous haemorrhage	8	0
<i>Lymphangiopathies</i>		
Lymphangiopathy	1	0

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Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
Lymphocele	2	0
Lymphorrhoea	1	0
Lymphoedemas		
Lymphoedema	74	0
Non-site specific embolism and thrombosis		
Air embolism	1	0
Arterial thrombosis	30	1
Atheroembolism	1	0
Embolism	255	3
Embolism arterial	3	0
Embolism venous	13	1
Microembolism	3	0
Paradoxical embolism	1	0
Post thrombotic syndrome	3	0
Thrombophlebitis migrans	2	0
Thrombosis	1814	38
Venous thrombosis	36	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	11	0
Vascular compression	2	0
Vascular occlusion	3	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	7	0
Vascular fragility	1	0
Vascular pain	135	0
Vascular rupture	2	0
Vascular wall discolouration	1	0
Vasodilatation	123	0
Vein collapse	2	0
Vein discolouration	8	0
Vein disorder	25	0
Vein rupture	17	0
Peripheral aneurysms and dissections		
Peripheral artery aneurysm	2	0
Peripheral embolism and thrombosis		
Axillary vein thrombosis	1	0
Blue toe syndrome	39	0

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Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
Deep vein thrombosis	1239	9
Femoral artery embolism	2	0
Iliac artery embolism	2	0
Jugular vein thrombosis	25	0
Pelvic venous thrombosis	24	1
Peripheral artery thrombosis	18	0
Peripheral embolism	10	0
Peripheral vein thrombus extension	1	0
Subclavian artery embolism	2	0
Subclavian artery thrombosis	1	0
Subclavian vein thrombosis	4	0
Superficial vein thrombosis	69	0
Thrombophlebitis	142	0
Venous thrombosis limb	5	0
Peripheral vascular disorders NEC		
Cyanosis	110	0
Erythromelalgia	7	0
Flushing	703	0
Hot flush	2193	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	1302	0
Peripheral ischaemia	34	2
Poor peripheral circulation	57	0
Raynaud's phenomenon	149	0
Phlebitis NEC		
Phlebitis	62	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 dilatation	1	0
Aortic rupture	1	0
Pallor	421	0
Plethoric face	1	0
Varicose veins NEC		
Bleeding varicose vein	2	0
Spider vein	21	0
Varicophlebitis	10	0
Varicose ulceration	1	0
Varicose vein	153	0
Varicose vein ruptured	1	0
Vascular hypertensive disorders NEC		

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Reaction Name	Total	Fatal
Vascular disorders <small>Vascular disorders cont'd</small>		
Diastolic hypertension	5	0
Hypertension	998	0
Labile hypertension	1	0
Systolic hypertension	3	0
Venous hypertension	3	0
White coat hypertension	12	0
<i>Vascular hypotensive disorders</i>		
Capillary leak syndrome	14	0
Diastolic hypotension	1	0
Hypotension	544	0
Orthostatic hypotension	48	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	108	3
<i>Vena caval embolism and thrombosis</i>		
Vena cava thrombosis	6	1
Vascular disorders SOC TOTAL	13307	72
TOTAL REACTIONS FOR DRUG	842270	1127
TOTAL REPORTS	237487	
TOTAL FATAL OUTCOME REPORTS		1127