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COVID-19 AstraZeneca Vaccine Analysis Print

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Report Run Date: 06-Jan-2022
Data Lock Date: 05-Jan-2022 18:30:04

All UK spontaneous reports received between 04/01/21 and 05/01/22 for COVID-19 vaccine Oxford University/AstraZeneca

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemia deficiencies</i>		
Anaemia folate deficiency	3	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	187	0
Autoimmune anaemia	2	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	9	0
<i>Anaemias haemolytic immune</i>		
Autoimmune haemolytic anaemia	10	0
Cold type haemolytic anaemia	1	0
Evans syndrome	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	140	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	12	0
Antiphospholipid syndrome	30	0
Coagulopathy	85	0
Disseminated intravascular coagulation	19	2
Hypercoagulation	25	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	15	1
Bone marrow disorder	3	0
Bone marrow oedema	1	0
Mast cell activation syndrome	12	0
Mastocytosis	3	0
Methaemoglobinaemia	1	0
<i>Haemolyses NEC</i>		
Haemolysis	11	0
<i>Leukocytoses NEC</i>		
Leukocytosis	4	0

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Reaction Name	Total	Fatal
Blood disorders Blood disorders cont'd		
Lymphocytosis	11	0
Monocytosis	2	0
Neutrophilia	14	0
Leukopenias NEC		
Leukopenia	15	0
Lymphopenia	9	0
Lymphatic system disorders NEC		
Abdominal lymphadenopathy	1	0
Hilar lymphadenopathy	1	0
Lymph node fibrosis	1	0
Lymph node pain	592	0
Lymphadenitis	33	0
Lymphadenopathy	4997	0
Lymphadenopathy mediastinal	1	0
Lymphatic disorder	2	0
Lymphatic insufficiency	1	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	19	1
Neutropenias		
Agranulocytosis	4	0
Autoimmune neutropenia	2	0
Febrile neutropenia	1	0
Neutropenia	83	0
Platelet disorders NEC		
Platelet anisocytosis	4	0
Platelet disorder	8	0
Polycythaemia (excl rubra vera)		
Polycythaemia	3	0
Stress polycythaemia	3	0
Purpuras (excl thrombocytopenic)		
Purpura non-thrombocytopenic	4	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	17	0
Splenic thrombosis	1	0
Splenic varices	1	0
Splenic vein thrombosis	12	0
Splenomegaly	7	0

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Reaction Name	Total	Fatal
Blood disorders Blood disorders cont'd		
Spleno renal shunt	1	0
<i>Thrombocytopenias</i>		
Autoimmune heparin-induced thrombocytopenia	1	0
Heparin-induced thrombocytopenia	14	0
Immune thrombocytopenia	218	1
Thrombocytopenia	889	7
Thrombocytopenic purpura	11	0
Thrombosis with thrombocytopenia syndrome	10	0
Thrombotic thrombocytopenic purpura	11	0
<i>Thrombocytoses</i>		
Thrombocytosis	12	0
<i>White blood cell abnormal findings NEC</i>		
White blood cell disorder	4	0
Blood disorders SOC TOTAL	7728	13

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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	31	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	88	2
Cardiac dysfunction	2	0
Cardiac ventricular thrombosis	12	2
Cardiovascular disorder	10	0
Cardiovascular insufficiency	10	0
Intracardiac thrombus	18	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	18	0
Cardiovascular symptom	3	0
Palpitations	5728	0
<i>Cardiac valve disorders NEC</i>		
Cardiac valve disease	4	1
Heart valve incompetence	4	0
<i>Cardiomyopathies</i>		
Cardiomyopathy	17	1
Cardiomyopathy acute	1	0
Congestive cardiomyopathy	12	1
Stress cardiomyopathy	5	0
<i>Coronary artery disorders NEC</i>		
Arteriosclerosis coronary artery	7	1
Coronary artery disease	9	0
Coronary artery dissection	5	1
Coronary artery embolism	1	0
Coronary artery occlusion	4	0
Coronary artery stenosis	1	0
Coronary artery thrombosis	24	3
<i>Heart failure signs and symptoms</i>		
Cardiac asthma	1	0
<i>Heart failures NEC</i>		
Cardiac failure	103	13
Cardiac failure acute	13	4
Cardiac failure chronic	2	1

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Reaction Name	Total	Fatal
Cardiac disorders Cardiac disorders cont'd		
Cardiac failure congestive	7	3
Cardiogenic shock	10	2
Cardiopulmonary failure	1	1
Ventricular failure	1	0
Ischaemic coronary artery disorders		
Acute coronary syndrome	9	0
Acute myocardial infarction	88	14
Angina pectoris	254	0
Angina unstable	18	0
Arteriospasm coronary	7	0
Microvascular coronary artery disease	2	0
Myocardial infarction	461	55
Myocardial ischaemia	28	12
Prinzmetal angina	2	0
Left ventricular failures		
Acute left ventricular failure	2	0
Left ventricular failure	9	1
Mitral valvular disorders		
Ischaemic mitral regurgitation	1	0
Mitral valve disease	1	0
Mitral valve incompetence	10	0
Mitral valve prolapse	4	0
Myocardial disorders NEC		
Cardiac aneurysm	1	0
Cardiac sarcoidosis	1	0
Cardiomegaly	34	1
Diastolic dysfunction	2	0
Dilatation ventricular	1	0
Left atrial dilatation	1	0
Left ventricular dilatation	2	0
Left ventricular dysfunction	23	0
Left ventricular hypertrophy	4	0
Myocardial fibrosis	2	0
Myocardial injury	14	0
Myocardial oedema	1	0
Myocardial rupture	1	0
Right atrial dilatation	2	0
Right ventricular dilatation	3	0
Right ventricular dysfunction	4	0
Systolic dysfunction	1	0
Ventricular dyskinesia	1	0
Ventricular hypertrophy	5	1
Ventricular hypokinesia	3	0
Noninfectious myocarditis		
Autoimmune myocarditis	1	0
Myocarditis	201	3
Myocarditis post infection	1	0
Noninfectious pericarditis		
Pericarditis	211	0
Pericardial disorders NEC		
Cardiac tamponade	2	2
Pericardial disease	1	0
Pericardial effusion	38	0

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Reaction Name	Total	Fatal
Cardiac disorders Cardiac disorders cont'd		
Pericardial haemorrhage	8	4
Pericardial rub	2	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	158	3
Arrhythmia neonatal	1	0
Bradyarrhythmia	1	0
Bradycardia	87	0
Brugada syndrome	1	0
Cardiac fibrillation	9	0
Cardiac flutter	300	0
Extrasystoles	164	0
Heart alternation	3	0
Paroxysmal arrhythmia	2	0
Postural orthostatic tachycardia syndrome	26	0
Tachyarrhythmia	11	0
Tachycardia	1538	0
<i>Right ventricular failures</i>		
Right ventricular failure	4	1
<i>Supraventricular arrhythmias</i>		
Arrhythmia supraventricular	17	0
Atrial fibrillation	344	1
Atrial flutter	50	0
Atrial tachycardia	3	0
Sinus arrest	1	0
Sinus arrhythmia	3	0
Sinus bradycardia	5	0
Sinus node dysfunction	2	0
Sinus tachycardia	71	0
Supraventricular extrasystoles	2	0
Supraventricular tachycardia	44	0
<i>Tricuspid valvular disorders</i>		
Tricuspid valve incompetence	8	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	182	37
Cardio-respiratory arrest	2	1
Pulseless electrical activity	7	0
Ventricular arrhythmia	2	0
Ventricular extrasystoles	23	0
Ventricular fibrillation	10	1
Ventricular tachycardia	17	0
Cardiac disorders SOC TOTAL	10766	178

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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>		
Atrial septal defect	1	0
Hypertrophic cardiomyopathy	3	0
<i>Central nervous system disorders congenital NEC</i>		
Brain malformation	1	0
Neural tube defect	1	1
Spina bifida	2	0
Syringomyelia	2	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
Heterotaxia	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>		
Mucopolipidosis	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

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Reaction Name	Total	Fatal
Congenital disorders Congenital disorders cont'd		
<i>Musculoskeletal disorders congenital NEC</i>		
Congenital multiplex arthrogryposis	1	0
Dysmorphism	2	0
<i>Neurological disorders congenital NEC</i>		
Epilepsy with myoclonic-atonic seizures	1	0
Familial hemiplegic migraine	1	0
Neurofibromatosis	1	0
Spinal muscular atrophy	1	0
Tourette's disorder	2	0
<i>Ocular disorders congenital NEC</i>		
Colour blindness	9	0
<i>Pancreatic disorders congenital</i>		
Hereditary pancreatitis	1	0
<i>Peripheral nervous system disorders congenital NEC</i>		
Paroxysmal extreme pain disorder	13	0
<i>Pulmonary and bronchial disorders congenital</i>		
Cystic fibrosis	1	0
<i>Sex chromosomal abnormalities</i>		
Klinefelter's syndrome	1	0
<i>Skin and subcutaneous tissue disorders congenital NEC</i>		
Benign familial pemphigus	1	0
<i>Tongue disorders congenital</i>		
Ankyloglossia congenital	1	0
Macroglossia	1	0
<i>Vascular anomalies congenital NEC</i>		
Arteriovenous malformation	1	0
Vascular malformation	1	0
Congenital disorders SOC TOTAL	102	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	122	0
Ear disorder	23	0
Ear haemorrhage	19	0
Ear inflammation	1	0
Ear pain	2092	0
Ear pruritus	7	0
Ear swelling	75	0
Otorrhoea	8	0
Paraesthesia ear	1	0
<i>Eustachian tube disorders</i>		
Eustachian tube disorder	7	0
Eustachian tube dysfunction	6	0
Eustachian tube obstruction	8	0
<i>External ear disorders NEC</i>		
Excessive cerumen production	40	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	418	1
Deafness bilateral	19	0
Deafness neurosensory	40	0
Deafness transitory	4	0
Deafness unilateral	57	0
Hypoacusis	250	0
Mixed deafness	3	0
Neurosensory hypoacusis	2	0
Sudden hearing loss	83	0
<i>Hyperacusia</i>		
Hyperacusis	176	0
<i>Inner ear disorders NEC</i>		
Endolymphatic hydrops	1	0
Inner ear disorder	8	0
Meniere's disease	30	0
Vestibular disorder	9	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	130	0
Phobic postural vertigo	2	0
Tinnitus	4335	0
Vertigo	2287	0
Vertigo labyrinthine	14	0

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Reaction Name	Total	Fatal
Ear disorders Ear disorders cont'd		
Vertigo positional	156	0
Middle ear disorders NEC		
Middle ear disorder	1	0
Middle ear effusion	6	0
Tympanic membrane disorders (excl infections)		
Tympanic membrane perforation	7	0
Ear disorders SOC TOTAL	10522	1

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Autoimmune thyroiditis	8	0
Thyroiditis	21	0
Thyroiditis acute	8	0
Thyroiditis chronic	2	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	3	0
Adrenal insufficiency	22	0
Adrenocortical insufficiency acute	31	0
Glucocorticoid deficiency	1	0
<i>Adrenal gland disorders NEC</i>		
Adrenal disorder	2	0
Adrenal haematoma	1	0
Adrenal haemorrhage	7	0
Adrenal mass	1	0
Adrenal thrombosis	1	0
Adrenomegaly	2	0
Haemorrhagic adrenal infarction	5	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	2	0
Premature menarche	17	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	23	0
Ovulation delayed	17	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>		
Empty sella syndrome	1	0
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

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Reaction Name	Total	Fatal
Endocrine disorders Endocrine disorders cont'd		
Euthyroid sick syndrome	1	0
Goitre	27	0
Thyroid disorder	21	0
Thyroid mass	8	0
Thyroid pain	18	0
<i>Thyroid hyperfunction disorders</i>		
Basedow's disease	23	0
Hyperthyroidism	63	0
Thyrotoxic crisis	6	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	63	0
<i>Thyroid neoplasms</i>		
Thyroid cyst	1	0
Endocrine disorders SOC TOTAL	450	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Amblyopic vision impairment</i>		
Amblyopia	12	0
<i>Cataract conditions</i>		
Cataract	24	0
Cataract cortical	2	0
Cataract subcapsular	4	0
<i>Choroid and vitreous haemorrhages and vascular disorders</i>		
Vitreous haematoma	1	0
Vitreous haemorrhage	9	0
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Chorioretinopathy	2	0
Vitreous detachment	58	0
Vitreous floaters	205	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	130	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	5	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	155	0
Excessive eye blinking	8	0
Eyelid function disorder	1	0
Eyelid myokymia	2	0
Eyelid ptosis	62	0
Paralytic lagophthalmos	1	0
<i>Glaucomas (excl congenital)</i>		
Angle closure glaucoma	6	0
Glaucoma	16	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	25	0
Iritis	15	0
Uveitis	54	0
<i>Lacrimation disorders</i>		
Dry eye	321	0
Lacrimation increased	262	0
<i>Lens structural change, deposit and degeneration (excl cataracts)</i>		

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Reaction Name	Total	Fatal
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	30	0
Chalazion	2	0
Eczema eyelids	7	0
Erythema of eyelid	8	0
Eyelid cyst	18	0
Eyelid irritation	5	0
Eyelid margin crusting	1	0
Eyelid oedema	12	0
Eyelid rash	15	0
Meibomianitis	1	0
Swelling of eyelid	139	0
Lid, lash and lacrimal structural disorders		
Blepharal pigmentation	1	0
Dermatochalasis	1	0
Ectropion	1	0
Eyelid exfoliation	3	0
Eyelid skin dryness	6	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	114	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	46	0
Eye oedema	19	0
Eye pain	3376	0
Eye swelling	638	0
Eye symptom	11	0
Eye ulcer	10	0
Eyelid disorder	17	0
Eyelid pain	20	0
Eyelids pruritus	13	0
Ocular discomfort	83	0
Periorbital discomfort	1	0
Periorbital oedema	18	0
Periorbital pain	4	0
Periorbital swelling	109	0
Retinal disorder	2	0
Retinal fovea disorder	1	0
Ocular infections, inflammations and associated manifestations		
Autoimmune eye disorder	1	0

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Eye allergy	31	0
Eye discharge	29	0
Eye inflammation	35	0
Eye irritation	206	0
Eye pruritus	309	0
Limbal swelling	8	0
Ocular hyperaemia	471	0
Ocular rosacea	1	0
Ocular nerve and muscle disorders		
Extraocular muscle paresis	13	0
Eye movement disorder	56	0
Gaze palsy	5	0
Ocular myasthenia	4	0
Ophthalmoplegia	2	0
Parinaud syndrome	1	0
Strabismus	5	0
Ocular sensation disorders		
Abnormal sensation in eye	28	0
Asthenopia	363	0
Eye paraesthesia	5	0
Eyelid sensory disorder	5	0
Foreign body sensation in eyes	37	0
Hypoaesthesia eye	29	0
Photophobia	1084	0
Optic disc abnormalities NEC		
Optic atrophy	1	0
Optic discs blurred	3	0
Papilloedema	15	0
Optic nerve bleeding and vascular disorders		
Optic disc haemorrhage	2	0
Optic ischaemic neuropathy	11	0
Optic nerve sheath haemorrhage	1	0
Orbital infections, inflammations and irritations		
Orbital myositis	1	0
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	12	0
Refractive and accommodative disorders		
Altered visual depth perception	5	0
Hypermetropia	3	0
Myopia	5	0
Refraction disorder	1	0
Retinal bleeding and vascular disorders (excl retinopathy)		
Retinal aneurysm	2	0

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Retinal artery embolism	5	0
Retinal artery occlusion	25	0
Retinal haemorrhage	20	0
Retinal infarction	1	0
Retinal ischaemia	2	0
Retinal vascular occlusion	3	0
Retinal vascular thrombosis	4	0
Retinal vein occlusion	99	0
Retinal vein thrombosis	8	0
Retinal vein varices	1	0
Retinal vessel avulsion	1	0
<i>Retinal structural change, deposit and degeneration</i>		
Epiretinal membrane	1	0
Macular cyst	1	0
Macular degeneration	9	0
Macular detachment	1	0
Macular hole	2	0
Macular rupture	2	0
Maculopathy	3	0
Neovascular age-related macular degeneration	12	0
Retinal detachment	30	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	3	0
Retinal exudates	18	0
Retinopathy	8	0
<i>Scleral infections, irritations and inflammations</i>		
Episcleritis	21	0
Scleritis	14	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	5	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

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Delayed dark adaptation	1	0
Diplopia	355	0
Dysmetropsia	1	0
Halo vision	13	0
Metamorphopsia	42	0
Oscillopsia	1	0
Photopsia	342	0
Scintillating scotoma	10	0
Vision blurred	3095	0
Visual brightness	10	0
Visual snow syndrome	6	0
Visual field disorders		
Visual field defect	45	0
Visual impairment and blindness (excl colour blindness)		
Amaurosis	1	0
Amaurosis fugax	10	0
Blindness	309	0
Blindness day	1	0
Blindness transient	27	0
Blindness unilateral	44	0
Central vision loss	3	0
Night blindness	6	0
Sudden visual loss	5	0
Visual acuity reduced	40	0
Visual acuity reduced transiently	1	0
Visual impairment	818	0
Visual pathway disorders		
Optic nerve compression	2	0
Optic nerve disorder	5	0
Optic neuropathy	9	0
Eye disorders SOC TOTAL	14641	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>		
Abdominal hernia	1	0
Internal hernia	1	0
<i>Acute and chronic pancreatitis</i>		
Obstructive pancreatitis	1	1
Pancreatitis	41	2
Pancreatitis acute	21	0
Pancreatitis chronic	1	0
Pancreatitis necrotising	2	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	7	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	63	0
Colitis ischaemic	7	1
Colitis microscopic	6	0
Colitis ulcerative	113	0
Crohn's disease	108	0
Inflammatory bowel disease	15	0
Terminal ileitis	1	0
<i>Cystic pancreatic disorders</i>		
Pancreatic cyst	1	0
Pancreatic pseudocyst	1	0
<i>Dental and periodontal infections and inflammations</i>		
Dental caries	7	0
Periodontal inflammation	1	0
<i>Dental developmental disorders and anomalies</i>		
Tooth impacted	1	0
<i>Dental disorders NEC</i>		
Diastema	1	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Loose tooth	3	0
Malpositioned teeth	3	0
Teething	22	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	67	0
Hypoaesthesia teeth	2	0
Toothache	344	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	8984	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	905	0
Epigastric discomfort	20	0
Eructation	110	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	26	0
Faecaloma	4	0
Faeces discoloured	56	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	725	0
Flatulence	404	0
<i>Gastric and oesophageal haemorrhages</i>		
Gastric haemorrhage	16	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	113	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Reflux gastritis	17	0
Gastrointestinal and abdominal pains (excl oral and throat)		
Abdominal migraine	3	0
Abdominal pain	4601	0
Abdominal pain lower	268	0
Abdominal pain upper	5324	0
Abdominal rigidity	64	0
Abdominal tenderness	22	0
Gastrointestinal pain	327	0
Oesophageal pain	9	0
Gastrointestinal atonic and hypomotility disorders NEC		
Constipation	500	0
Duodenogastric reflux	4	0
Gastric dilatation	18	0
Gastrooesophageal reflux disease	245	0
Impaired gastric emptying	7	0
Infrequent bowel movements	3	0
Intestinal dilatation	1	0
Oesophageal hypomotility	1	0
Gastrointestinal disorders NEC		
Appendix disorder	3	0
Food poisoning	13	0
Functional gastrointestinal disorder	21	0
Gastric disorder	15	0
Gastrointestinal disorder	49	0
Gastrointestinal oedema	3	0
Gastroptosis	1	0
Neurogenic bowel	3	0
Stomach mass	2	0
Gastrointestinal dyskinetic disorders		
Bowel movement irregularity	8	0
Change of bowel habit	21	0
Dyschezia	13	0
Gastrointestinal motility disorder	5	0
Oesophageal achalasia	5	0
Gastrointestinal fistulae		
Anal fistula	1	0
Gastrointestinal inflammatory disorders NEC		
Appendicitis noninfective	2	0
Duodenitis	1	0
Enteritis	1	0
Gastrointestinal inflammation	2	0
Gastrointestinal tract irritation	4	0
Intestinal angioedema	1	0
Ischaemic enteritis	1	0
Gastrointestinal mucosal dystrophies and secretion disorders		
Achlorhydria	1	0
Barrett's oesophagus	1	0
Hyperchlorhydria	4	0
Gastrointestinal necrosis and gangrene (excl gangrenous hernia)		
Gastrointestinal necrosis	1	0
Gastrointestinal signs and symptoms NEC		
Abdominal discomfort	1610	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Abdominal symptom	6	0
Acute abdomen	18	0
Anal incontinence	56	0
Breath odour	25	0
Dysphagia	293	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	50	0
Irritable bowel syndrome	160	0
Oesophageal spasm	8	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Intestinal obstruction	7	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	12	0
<i>Gastrointestinal vascular occlusion and infarction</i>		
Intestinal infarction	6	1
Intestinal ischaemia	35	1
Mesenteric artery embolism	1	0
Mesenteric artery stenosis	1	0
Mesenteric artery thrombosis	5	0
Mesenteric vein thrombosis	22	0
Mesenteric venous occlusion	1	0
Thrombosis mesenteric vessel	4	0
Visceral venous thrombosis	15	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 discolouration	1	0
Gingival discomfort	7	0
Gingival disorder	17	0
Gingival hypertrophy	1	0
Gingival oedema	2	0
Gingival pain	238	0
Gingival pruritus	1	0
Gingival recession	3	0
Gingival swelling	56	0
Gingival ulceration	10	0
Gingivitis ulcerative	2	0
Noninfective gingivitis	24	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	181	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Anorectal varices	1	0
Haemorrhoidal haemorrhage	4	0
Haemorrhoids	69	0
Haemorrhoids thrombosed	15	0
<i>Inguinal hernias</i>		
Inguinal hernia	4	0
<i>Intestinal haemorrhages</i>		
Anal haemorrhage	50	0
Intestinal haemorrhage	1	0
Lower gastrointestinal haemorrhage	2	0
Mesenteric haemorrhage	5	0
Rectal haemorrhage	120	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	24	0
Steatorrhoea	2	0
<i>Nausea and vomiting symptoms</i>		
Acetonaemic vomiting	1	0
Cyclic vomiting syndrome	2	0
Discoloured vomit	19	0
Faecal vomiting	3	0
Infantile spitting up	1	0
Infantile vomiting	6	0
Nausea	33549	0
Regurgitation	3	0
Retching	238	0
Vomiting	11438	0
Vomiting projectile	156	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Gastrointestinal haemorrhage	39	1
Haematemesis	81	0
Haematochezia	105	0
Intra-abdominal haematoma	2	0
Intra-abdominal haemorrhage	2	0
Melaena	10	0
Upper gastrointestinal haemorrhage	10	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>		

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Varices oesophageal	3	0
<i>Oesophagitis (excl infective)</i>		
Eosinophilic oesophagitis	3	0
Oesophagitis	21	0
<i>Oral dryness and saliva altered</i>		
Aptyalism	5	0
Dry mouth	1157	0
Lip dry	78	0
Saliva altered	8	0
Saliva discolouration	1	0
Salivary hypersecretion	94	0
<i>Oral soft tissue disorders NEC</i>		
Angina bullosa haemorrhagica	4	0
Chapped lips	25	0
Cheilitis	40	0
Chronic cheek biting	1	0
Enlarged uvula	11	0
Leukoplakia oral	2	0
Lip blister	37	0
Lip disorder	6	0
Oral disorder	20	0
Oral lichen planus	16	0
Oral papule	2	0
Palatal disorder	2	0
Uvulitis	5	0
<i>Oral soft tissue haemorrhages</i>		
Lip haemorrhage	4	0
Mouth haemorrhage	59	0
Oral blood blister	55	0
Oral purpura	2	0
<i>Oral soft tissue infections</i>		
Angular cheilitis	11	0
<i>Oral soft tissue signs and symptoms</i>		
Anaesthesia oral	8	0
Burning mouth syndrome	16	0
Coating in mouth	4	0
Hypoaesthesia oral	674	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	108	0
Oral dysaesthesia	1	0
Oral mucosal blistering	34	0
Oral mucosal discolouration	1	0
Oral mucosal eruption	31	0
Oral mucosal erythema	3	0
Oral mucosal exfoliation	10	0
Oral mucosal roughening	3	0
Oral pain	368	0
Oral pruritus	21	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Paraesthesia oral	862	0
<i>Oral soft tissue swelling and oedema</i>		
Lip oedema	10	0
Lip swelling	995	0
Mouth swelling	135	0
Oedema mouth	1	0
Palatal oedema	1	0
Palatal swelling	14	0
<i>Pancreatic disorders NEC</i>		
Pancreatic disorder	1	0
Pancreatic failure	2	0
Pancreatic mass	1	0
Pancreatic steatosis	1	0
<i>Peptic ulcers and perforation</i>		
Peptic ulcer	2	0
Peptic ulcer haemorrhage	9	0
<i>Peritoneal and retroperitoneal disorders</i>		
Ascites	9	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	65	0
Lip ulceration	17	0
Mouth ulceration	772	0
Stomatitis	108	0
<i>Tongue disorders</i>		
Acquired macroglossia	1	0
Glossitis	18	0
Plicated tongue	4	0
Tongue disorder	34	0
Tongue geographic	5	0
Tongue haemorrhage	2	0
Tongue ulceration	32	0
Trichoglossia	7	0
<i>Tongue signs and symptoms</i>		
Glossodynia	265	0
Scalloped tongue	4	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Stiff tongue	6	0
Strawberry tongue	1	0
Swollen tongue	631	0
Tongue blistering	28	0
Tongue coated	36	0
Tongue discolouration	40	0
Tongue discomfort	58	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	3	0
Tongue spasm	5	0
<i>Tooth missing</i>		
Tooth loss	10	0
Gastrointestinal disorders SOC TOTAL	80455	13

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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	4	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	5114	2
Chronic fatigue syndrome	167	0
Decreased activity	16	0
Fatigue	50875	0
Malaise	12742	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 dysaesthesia	1	0
Medical device site joint pain	1	0
Phantom shocks	4	0
<i>Death and sudden death</i>		
Brain death	4	3
Cardiac death	7	7
Death	323	323
Drowning	1	0
Hanging	1	1
Sudden death	42	42
Sudden unexplained death in epilepsy	1	1
<i>Febrile disorders</i>		
Hyperpyrexia	42	0
Masked fever	1	0
PFAPA syndrome	1	0
Pyrexia	55476	0
<i>Feelings and sensations NEC</i>		
Chills	43186	0
Early satiety	1	0
Feeling abnormal	3388	0
Feeling cold	5284	0
Feeling drunk	133	0
Feeling hot	2474	0
Feeling jittery	47	0
Feeling of body temperature change	970	0
Feeling of relaxation	2	0
Hangover	197	0
Humidity intolerance	1	0
Hunger	83	0
Sensation of blood flow	17	0
Sensation of foreign body	55	0
Temperature intolerance	90	0
Thirst	1273	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Thirst decreased	11	0
Fibrosis NEC		
Fibrosis	7	0
Gait disturbances		
Decreased gait velocity	3	0
Gait disturbance	496	0
Gait inability	235	0
Loss of control of legs	61	0
General signs and symptoms NEC		
Apparent death	1	0
Chronic disease	1	0
Condition aggravated	336	0
Crepitations	10	0
Crying	303	0
Deformity	1	0
Developmental delay	3	0
Discharge	10	0
Disease prodromal stage	1	0
Disease progression	3	1
Disease recurrence	2	0
Effusion	2	0
Energy increased	26	0
Exercise tolerance decreased	44	0
Foaming at mouth	6	0
General physical health deterioration	31	2
General symptom	11	0
Glassy eyes	8	0
High-pitched crying	8	0
Ill-defined disorder	12	0
Illness	5129	1
Impaired self-care	1	0
Induration	22	0
Influenza like illness	9682	0
Irritability postvaccinal	3	0
Local reaction	155	0
Moaning	9	0
Multiple organ dysfunction syndrome	24	12
Nonspecific reaction	3	0
Organ failure	4	1
Perforation	2	0
Performance status decreased	1	0
Peripheral swelling	6014	0
Pre-existing condition improved	19	0
Premature ageing	3	0
Prolapse	1	0
Screaming	32	0
Secretion discharge	36	0
Sensitivity to weather change	3	0
Stenosis	2	0
Swelling	2831	0
Swelling face	1105	0
Symptom masked	1	0
Symptom recurrence	4	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Tissue discolouration	1	0
Tissue infiltration	1	0
Unevaluable event	9	0
Healing abnormal NEC		
Impaired healing	7	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	878	0
Papillitis	1	0
Scar inflammation	1	0
Systemic inflammatory response syndrome	8	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	597	0
Injection site exfoliation	1	0
Injection site extravasation	2	0
Injection site haematoma	3	0
Injection site haemorrhage	20	0
Injection site hypersensitivity	5	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Injection site hypoaesthesia	16	0
Injection site indentation	22	0
Injection site induration	10	0
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	1429	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	28	0
Injection site pain	4528	0
Injection site papule	2	0
Injection site paraesthesia	26	0
Injection site pruritus	300	0
Injection site rash	309	0
Injection site reaction	123	0
Injection site scab	4	0
Injection site scar	6	0
Injection site swelling	264	0
Injection site thrombosis	1	0
Injection site ulcer	1	0
Injection site urticaria	41	0
Injection site vesicles	16	0
Injection site warmth	356	0
Interactions		
Drug interaction	35	0
Food interaction	2	0
Inhibitory drug interaction	12	0
Mass conditions NEC		
Cyst	38	0
Mass	91	0
Nodule	26	0
Pelvic mass	1	0
Mucosal findings abnormal		
Mucosa vesicle	2	0
Mucosal disorder	2	0
Mucosal dryness	1	0
Mucosal haemorrhage	12	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

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
<i>Oedema NEC</i>		
Face oedema	36	0
Generalised oedema	1	0
Localised oedema	13	0
Oedema	94	0
Oedema peripheral	167	0
<i>Pain and discomfort NEC</i>		
Axillary pain	772	0
Chest discomfort	2148	0
Chest pain	5927	0
Discomfort	653	0
Facial discomfort	22	0
Facial pain	298	0
Hernia pain	4	0
Inflammatory pain	36	0
Non-cardiac chest pain	47	0
Pain	17759	0
Suprapubic pain	1	0
Tenderness	1848	0
Visceral pain	2	0
<i>Therapeutic and nontherapeutic responses</i>		
Adverse drug reaction	49	0
Adverse event	10	0
Adverse food reaction	1	0
Adverse reaction	12	0
Diet failure	1	0
Drug effect less than expected	1	0
Drug ineffective	178	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	10	0
Remission not achieved	1	0
Similar reaction on previous exposure to drug	1	0
Therapeutic product effect decreased	4	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	181	0
Therapy non-responder	3	0
Treatment failure	21	0
Treatment noncompliance	1	0
Vaccination failure	42	0
Vaccine positive rechallenge	1	0
<i>Trophic disorders</i>		
Atrophy	4	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Calcinosis	2	0
Dysplasia	3	0
Hyperplasia	2	0
Ulcers NEC		
Ulcer	48	0
Ulcer haemorrhage	3	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	19	0
Shoulder injury related to vaccine administration	101	0
Vaccination site atrophy	1	0
Vaccination site bruising	139	0
Vaccination site coldness	1	0
Vaccination site cyst	3	0
Vaccination site discharge	1	0
Vaccination site discolouration	18	0
Vaccination site discomfort	50	0
Vaccination site dryness	1	0
Vaccination site erythema	720	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	18	0
Vaccination site joint pain	54	0
Vaccination site joint swelling	3	0
Vaccination site joint warmth	2	0
Vaccination site lymphadenopathy	2	0
Vaccination site mass	568	0
Vaccination site movement impairment	106	0
Vaccination site nodule	1	0
Vaccination site oedema	3	0
Vaccination site pain	2126	0
Vaccination site papule	4	0
Vaccination site paraesthesia	12	0
Vaccination site pruritus	112	0
Vaccination site rash	194	0
Vaccination site reaction	26	0
Vaccination site scab	2	0
Vaccination site scar	7	0
Vaccination site swelling	516	0
Vaccination site urticaria	12	0
Vaccination site vesicles	11	0
Vaccination site warmth	382	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
<i>Vascular complications associated with device</i>		
Vascular stent occlusion	1	0
Vascular stent thrombosis	1	0
<i>Withdrawal and rebound effects</i>		
Drug withdrawal syndrome	8	0
Withdrawal syndrome	104	0
General disorders SOC TOTAL	254979	397

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	33	0
Cholangitis	3	0
<i>Cholecystitis and cholelithiasis</i>		
Cholecystitis	16	0
Cholecystitis acute	3	0
Cholelithiasis	17	0
<i>Cholestasis and jaundice</i>		
Cholestasis	6	0
Jaundice	57	0
Jaundice cholestatic	12	0
Ocular icterus	1	0
<i>Gallbladder disorders NEC</i>		
Gallbladder disorder	4	0
Gallbladder oedema	1	0
Gallbladder polyp	1	0
<i>Hepatic and hepatobiliary disorders NEC</i>		
Liver disorder	21	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
Hepatorenal syndrome	1	0
Subacute hepatic failure	3	0
<i>Hepatic fibrosis and cirrhosis</i>		
Hepatic cirrhosis	10	1
<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	71	4
Portosplenomesenteric venous thrombosis	2	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	80	0
Hepatomegaly	5	0
Liver tenderness	6	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Acute yellow liver atrophy	1	0
Autoimmune hepatitis	11	0
Cholestatic liver injury	1	0
Drug-induced liver injury	2	0
Hepatic necrosis	1	0
Hepatic steatosis	12	0
Hepatitis	32	0
Hepatitis acute	8	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	30	0
Nonalcoholic fatty liver disease	1	0
Reye's syndrome	1	0
<i>Obstructive bile duct disorders (excl neoplasms)</i>		
Biliary obstruction	1	0
Sphincter of Oddi dysfunction	3	0
Hepatic disorders SOC TOTAL	516	9

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	28	0
<i>Allergic conditions NEC</i>		
Allergic oedema	22	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	3	0
Hypersensitivity	1550	1
Infusion related hypersensitivity reaction	5	0
Mite allergy	2	0
Multiple allergies	23	0
Serum sickness	15	0
Serum sickness-like reaction	13	0
Type I hypersensitivity	1	0
Type III immune complex mediated reaction	7	0
Type IV hypersensitivity reaction	4	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergic reaction to excipient	3	0
Allergy to chemicals	9	0
Allergy to vaccine	61	0
Contrast media reaction	4	0
Drug hypersensitivity	71	0
Food allergy	55	0
Milk allergy	1	0
Oral allergy syndrome	5	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	711	2
Anaphylactic shock	125	0
Anaphylactoid reaction	23	0
Anaphylactoid shock	4	0
<i>Atopic disorders</i>		
Atopy	5	0
Seasonal allergy	149	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	67	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	36	0
Cytokine release syndrome	2	0
Cytokine storm	5	0

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Reaction Name	Total	Fatal
Immune system disorders		
Immune system disorders cont'd		
Decreased immune responsiveness	1	0
Haemophagocytic lymphohistiocytosis	13	1
Hypocomplementaemia	1	0
Immune system disorder	54	0
Immune-mediated adverse reaction	10	0
Immunisation reaction	1	0
Multiple chemical sensitivity	2	0
Pre-engraftment immune reaction	1	0
Sensitisation	34	0
Immunodeficiency disorders NEC		
Immunodeficiency	14	0
Immunosuppression	7	0
Transplant rejections		
Corneal graft rejection	3	0
Transplant rejection	7	0
Vasculitides		
Anti-neutrophil cytoplasmic antibody positive vasculitis	4	1
Eosinophilic granulomatosis with polyangiitis	2	0
Immune system disorders SOC TOTAL	3213	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	42	0
Appendicitis perforated	4	0
Diarrhoea infectious	4	0
Diverticulitis	33	0
Dysentery	5	0
Gastric infection	1	0
Gastroenteritis	46	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
Gastroenteritis bacillus	1	0
<i>Bacterial infections NEC</i>		
Abscess bacterial	1	0
Administration site cellulitis	1	0
Arthritis bacterial	10	0
Bacterial infection	34	1
Bacterial vaginosis	4	0
Bacterial vulvovaginitis	1	0
Cellulitis	540	0
Cellulitis orbital	2	0
Ear infection bacterial	2	0
Endocarditis bacterial	2	0
Eye infection bacterial	1	0
Folliculitis	12	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	3	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

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Relapsing fever	1	0
Breast infections		
Breast abscess	2	0
Mastitis	47	0
Brucella infections		
Brucellosis	1	0
Caliciviral infections		
Gastroenteritis norovirus	1	0
Norovirus infection	1	0
Campylobacter infections		
Campylobacter colitis	1	0
Campylobacter gastroenteritis	1	0
Campylobacter infection	1	0
Candida infections		
Anal candidiasis	2	0
Balanitis candida	1	0
Candida infection	82	0
Oral candidiasis	62	0
Skin candida	3	0
Vulvovaginal candidiasis	59	0
Cardiac infections		
Acute endocarditis	2	0
Cardiac infection	1	0
Endocarditis	8	0
Myocarditis infectious	1	0
Central nervous system and spinal infections		
Brain abscess	2	0
Cavernous sinus thrombosis	9	0
Central nervous system infection	2	0
Encephalitis	48	0
Encephalomyelitis	3	0
Extradural abscess	1	0
Meningitis	30	0
Myelitis	26	0
Chlamydial infections		
Chlamydial infection	1	0
Clostridia infections		
Clostridium difficile colitis	5	0
Clostridium difficile infection	3	0
Tetanus	4	0
Coronavirus infections		
Asymptomatic COVID-19	5	0
COVID-19	1415	29
COVID-19 pneumonia	73	10
Coronavirus infection	7	0
Post-acute COVID-19 syndrome	19	0
SARS-CoV-2 sepsis	1	0
Severe acute respiratory syndrome	5	0
Suspected COVID-19	48	0
Vaccine derived SARS-CoV-2 infection	1	0
Corynebacteria infections		
Diphtheria	3	0
Coxiella infections		

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Q fever	113	0
<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	5	0
Tooth abscess	16	0
Tooth infection	15	0
<i>Ear infections</i>		
Ear infection	148	0
Labyrinthitis	192	0
Mastoiditis	5	0
Otitis externa	7	0
Otitis media	9	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
Gastroenteritis Escherichia coli	1	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	86	0
Eye infection	46	0
Eyelid boil	3	0
Eyelid infection	4	0
Hordeolum	42	0
Keratouveitis	1	0
Retinitis	3	0
<i>Female reproductive tract infections</i>		
Endometritis	3	0
Fallopian tube abscess	1	0
Genital infection female	1	0
Ovarian abscess	1	0

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Pelvic inflammatory disease	2	0
Pyometra	2	1
Vaginal abscess	3	0
Vaginal infection	6	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	31	0
Fungal skin infection	10	0
Oral fungal infection	1	0
Overgrowth fungal	1	0
Pneumonia 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	82	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	49	0
Herpes simplex reactivation	4	0
Herpes virus infection	16	0
Herpes zoster	1649	0
Herpes zoster disseminated	1	0
Herpes zoster oticus	15	0
Herpes zoster reactivation	2	0
Meningoencephalitis herpetic	2	0
Nasal herpes	16	0
Ophthalmic herpes simplex	2	0
Ophthalmic herpes zoster	10	0
Oral herpes	720	0
Varicella	42	0
Varicella zoster virus infection	4	0
Infections NEC		
Abscess	52	0
Abscess limb	25	0

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Abscess soft tissue	2	0
Catheter site infection	1	0
Coinfection	1	0
Device related infection	3	0
Empyema	1	0
Genital abscess	1	0
Groin abscess	2	0
Groin infection	1	0
Infected bite	5	0
Infected cyst	4	0
Infection	543	4
Infection in an immunocompromised host	3	0
Infectious thyroiditis	1	0
Injection site abscess	3	0
Injection site infection	21	0
Localised infection	107	0
Lymph gland infection	9	0
Lymph node abscess	2	0
Omphalitis	1	0
Pathogen resistance	3	0
Pelvic infection	1	0
Pyuria	1	0
Respiratory tract infection	9	0
Toxic shock syndrome	1	0
Vaccination site abscess	7	0
Vaccination site infection	24	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	6829	0
Klebsiella infections		
Cystitis klebsiella	1	0
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	328	4
Pleural infection	1	0
Pneumonia	278	30
Pneumonia aspiration	26	5
Sputum purulent	3	0
Male reproductive tract infections		

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Epididymitis	9	0
Orchitis	6	0
<i>Molluscum contagiosum viral infections</i>		
Molluscum contagiosum	1	0
<i>Mumps viral infections</i>		
Mumps	13	0
<i>Muscle and soft tissue infections</i>		
Muscle abscess	1	0
Necrotising fasciitis	1	0
Soft tissue infection	5	0
<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	119	14
Sepsis syndrome	1	0
Septic pulmonary embolism	1	0
Septic rash	13	0

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Septic shock	5	1
Urosepsis	10	1
Viraemia	4	0
<i>Skin structures and soft tissue infections</i>		
Blister infected	1	0
Carbuncle	1	0
Dermatitis infected	10	0
Dermo-hypodermatitis	1	0
Eczema infected	3	0
Impetigo	13	0
Infected dermal cyst	3	0
Pilonidal cyst	2	0
Pustule	27	0
Pyoderma	1	0
Rash pustular	19	0
Skin infection	75	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	3	0
Staphylococcal scalded skin syndrome	1	0
Staphylococcal sepsis	4	1
Toxic shock syndrome staphylococcal	1	0
Vulvovaginitis staphylococcal	1	0
Wound infection 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
Streptococcal sepsis	1	0
Tonsillitis streptococcal	1	0
<i>Tinea infections</i>		
Body tinea	9	0
Tinea cruris	3	0
Tinea infection	3	0
Tinea pedis	4	0
Tinea versicolour	2	0
<i>Treponema infections</i>		
Neurosyphilis	1	0
Pinta	1	0
Syphilis	4	0
<i>Trypanosomal infections</i>		
African trypanosomiasis	6	0
<i>Tuberculous infections</i>		

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
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
Upper respiratory tract infections		
Acute sinusitis	6	0
Chronic sinusitis	17	0
Chronic tonsillitis	1	0
Croup infectious	1	0
Epiglottitis	1	0
Laryngitis	38	0
Nasal vestibulitis	1	0
Nasopharyngitis	1929	0
Peritonsillar abscess	1	0
Pharyngeal abscess	1	0
Pharyngitis	42	0
Rhinitis	56	0
Sinobronchitis	1	0
Sinusitis	401	0
Tonsillitis	89	0
Tracheitis	2	0
Upper respiratory tract infection	11	0
Urinary tract infections		
Cystitis	103	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	272	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	69	0
Gastrointestinal viral infection	1	0
Hepatitis viral	3	0
Meningitis viral	21	0
Pleurisy viral	1	0
Pneumonia viral	11	1

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Post viral fatigue syndrome	149	0
Sweating fever	740	0
Vestibular neuronitis	43	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
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	19679	107

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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	2	0
Anaesthetic complication	3	0
Anaesthetic complication neurological	1	0
Delayed recovery from anaesthesia	6	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	18	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>		
Arterial injury	1	0
Vascular injury	13	0
Venous injury	1	0
<i>Cerebral injuries NEC</i>		
Brain contusion	16	0
Brain herniation	6	0
Concussion	10	0
Craniocerebral injury	1	0
Epidural haemorrhage	1	0
Extradural haematoma	2	0
Subarachnoid haematoma	3	0
Subdural haematoma	19	1
Subdural haemorrhage	6	0

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Reaction Name	Total	Fatal
Injuries		
Injuries cont'd		
Traumatic intracranial haemorrhage	1	0
Chemical injuries		
Chemical burn	2	0
Chemical burn of oral cavity	2	0
Chemical burn of skin	7	0
Chemical phlebitis	2	0
Chest and respiratory tract injuries NEC		
Asbestosis	1	0
Chest crushing	15	0
Chest injury	2	0
Foreign body in throat	2	0
Traumatic haemothorax	1	0
Traumatic lung injury	1	0
Conditions caused by cold		
Chillblains	76	0
Frostbite	1	0
Cranial nerve injuries		
Cranial nerve injury	1	0
Optic nerve injury	8	0
Vth nerve injury	1	0
Ear injuries NEC		
Deafness traumatic	1	0
Exposures associated with pregnancy, delivery and lactation		
Drug exposure before pregnancy	1	0
Exposure during pregnancy	21	0
Exposure via breast milk	112	0
Foetal exposure during pregnancy	34	0
Maternal exposure before pregnancy	13	0
Maternal exposure during breast feeding	1386	0
Maternal exposure during pregnancy	391	0
Maternal exposure timing unspecified	2	0
Paternal exposure during pregnancy	2	0
Exposures to agents or circumstances NEC		
Exposure to SARS-CoV-2	8	0
Exposure to household chemicals	1	0
Exposure to toxic agent	1	0
Exposure to vaccinated person	3	0
Eye injuries NEC		
Cataract traumatic	1	0
Eye contusion	58	0
Eye injury	53	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
Foetal and neonatal conditions associated with product exposure		
Intoxication by breast feeding	1	0
Fractures and dislocations NEC		

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Fracture	2	0
Joint dislocation	14	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	14	0
<i>Intentional product use issues</i>		
Intentional dose omission	20	0
Intentional product use issue	2	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	15	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	6	0
Medication error	100	0
Prescription drug used without a prescription	2	0
Product use in unapproved indication	1	0
Product use issue	8	0
Vaccination error	10	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	30	0

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Reaction Name	Total	Fatal
Injuries		
Injuries cont'd		
Ligament injury	3	0
Ligament rupture	2	0
Ligament sprain	23	0
Muscle injury	66	0
Muscle rupture	19	0
Muscle strain	56	0
Post-traumatic neck syndrome	4	0
Repetitive strain injury	3	0
Tendon injury	7	0
Tendon rupture	29	0
<i>Nerve injuries NEC</i>		
Nerve injury	201	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>		
Animal bite	1	0
Arthropod bite	8	0
Arthropod sting	13	0
Bite	1	0
Child maltreatment syndrome	1	0
Electric shock	35	0
Extraskeletal ossification	1	0
Fall	298	0
Foreign body	2	0
Inflammation of wound	4	0
Injury	21	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	15	0
Wound haemorrhage	11	0
Wound secretion	4	0
<i>Non-site specific procedural complications</i>		
Administration related reaction	2	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	611	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	86	0
Overdoses NEC		
Intentional overdose	13	0
Overdose	58	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	7	0
Systemic toxicity	2	0
Toxicity to various agents	10	0
Product administration errors and issues		
Accidental overdose	4	0
Accidental underdose	2	0
Booster dose missed	1	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	134	0
Incomplete course of vaccination	64	0
Incorrect dose administered	13	0
Incorrect product administration duration	2	0
Incorrect product formulation administered	1	0
Incorrect route of product administration	57	0
Intercepted product administration error	2	0
Lack of vaccination site rotation	1	0

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Reaction Name	Total	Fatal
Injuries		
Injuries cont'd		
Poor quality product administered	3	0
Product administered at inappropriate site	25	0
Product administered to patient of inappropriate age	31	0
Product administration error	29	0
Product dose omission in error	2	0
Product dose omission issue	40	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	2	0
Radiation injuries		
Sunburn	54	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	2	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	44	0
Limb crushing injury	9	0
Limb injury	355	0
Nasal injury	2	0
Neck crushing	1	0
Neck injury	3	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Pharyngeal contusion	3	0
Site specific procedural complications NEC		
Axillary web syndrome	3	0
Skin injuries NEC		
Contusion	3384	0
Hair injury	3	0
Nail injury	1	0
Scar	46	0
Scratch	6	0
Skin abrasion	6	0
Skin injury	24	0
Skin laceration	7	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	4	0
Spinal fracture	9	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	2	0
Cold burn	3	0
Thermal burn	55	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	5	0
Post vaccination syndrome	5	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Reaction to previous exposure to any vaccine	1	0
Vaccination complication	109	0
Injuries SOC TOTAL	9407	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	4	0
Cold agglutinins positive	2	0
DNA antibody negative	1	0
DNA antibody positive	1	0
Rheumatoid factor	4	0
Rheumatoid factor increased	3	0
Rheumatoid factor negative	1	0
Smooth muscle antibody	1	0
<i>Bacteria identification and serology (excl mycobacteria)</i>		
Bacterial test	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	18	0
Blood pH increased	15	0
Carbon dioxide increased	1	0
Oxygen consumption	2	0
Oxygen saturation	26	0
Oxygen saturation abnormal	3	0
Oxygen saturation decreased	194	0
Oxygen saturation normal	1	0
PO2 decreased	1	0
Venous oxygen saturation decreased	1	0
<i>Blood grouping and cross-matching analyses</i>		
Blood group O	2	0
Blood grouping	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Rhesus antigen negative	1	0
Bone marrow and immune tissue imaging procedures		
Scan lymph nodes	2	0
Carbohydrate tolerance analyses (incl diabetes)		
Blood glucose	20	0
Blood glucose abnormal	22	0
Blood glucose decreased	45	0
Blood glucose fluctuation	35	0
Blood glucose increased	191	0
Glycosylated haemoglobin increased	2	0
Cardiac auscultatory investigations		
Cardiac murmur	39	0
Heart sounds	18	0
Heart sounds abnormal	8	0
Cardiac function diagnostic procedures		
Cardiac monitoring	1	0
Central venous pressure	1	0
Echocardiogram	3	0
Ejection fraction decreased	4	0
Myocardial strain imaging	21	0
Stroke volume decreased	2	0
Stroke volume increased	1	0
Venous pressure jugular increased	1	0
Cardiac imaging procedures		
Magnetic resonance imaging heart	1	0
Cell marker analyses		
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
Central nervous system histopathology procedures		
Biopsy brain	1	0
Central nervous system imaging procedures		
Brain scan abnormal	1	0
Computerised tomogram head	28	0
Magnetic resonance imaging head	47	0
Magnetic resonance imaging head abnormal	1	0
Scan brain	1	0
Cerebrospinal fluid tests (excl microbiology)		
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
Chemistry analyses NEC		
Histamine abnormal	4	0
Histamine level	3	0
Histamine level increased	1	0
Inflammatory marker decreased	1	0
Inflammatory marker increased	13	0

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Serum serotonin increased	1	0
<i>Cholesterol analyses</i>		
Blood cholesterol increased	20	0
Low density lipoprotein	1	0
Low density lipoprotein increased	1	0
Very low density lipoprotein decreased	1	0
<i>Coagulation and bleeding analyses</i>		
ADAMTS13 activity abnormal	1	0
ADAMTS13 activity decreased	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
Anti-platelet factor 4 antibody positive	1	0
Bleeding time	11	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	90	0
Prothrombin level increased	1	0
Prothrombin time	1	0
Prothrombin time prolonged	1	0
Thrombin time	1	0
Thrombin time abnormal	2	0
<i>Digestive enzymes</i>		
Amylase increased	1	0
Lipase increased	1	0
Pancreatic enzymes increased	1	0
<i>ECG investigations</i>		
Cardiac telemetry	1	0
Electrocardiogram	8	0
Electrocardiogram P wave abnormal	1	0
Electrocardiogram QT prolonged	4	0

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Electrocardiogram ST segment elevation	7	0
Electrocardiogram ST-T segment abnormal	6	0
Electrocardiogram T wave inversion	5	0
Electrocardiogram abnormal	21	0
Electrocardiogram change	2	0
Electrocardiogram normal	1	0
Electrocardiogram pacemaker spike	1	0
Exercise electrocardiogram	1	0
Endocrine analyses and imaging NEC		
Hormone level abnormal	63	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
Magnetic resonance imaging abdominal	1	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	4	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	12	0
Heart rate and pulse investigations		
Brachial pulse decreased	1	0

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Carotid pulse	1	0
Femoral pulse	1	0
Heart rate	1133	0
Heart rate abnormal	67	0
Heart rate decreased	142	0
Heart rate increased	2134	0
Heart rate irregular	270	0
Heart rate variability decreased	1	0
Heart rate variability increased	3	0
Maximum heart rate	8	0
Maximum heart rate decreased	1	0
Maximum heart rate increased	2	0
Orthostatic heart rate response increased	1	0
Popliteal pulse	1	0
Pulse abnormal	30	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	3	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	5	0
Antibody test abnormal	7	0
Antibody test negative	17	0
Antibody test positive	2	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>		

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
APACHE II score	1	0
Blood test	53	0
Blood test abnormal	94	0
Blood test normal	1	0
Laboratory test	1	0
Laboratory test abnormal	1	0
Polymerase chain reaction positive	3	0
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	7	0
Gamma-glutamyltransferase increased	5	0
Hepatic enzyme abnormal	1	0
Hepatic enzyme increased	16	0
Liver function test	3	0
Liver function test abnormal	56	0
Liver function test increased	17	0
Transaminases increased	12	0
Metabolism tests NEC		
Blood ketone body	10	0
Blood ketone body increased	1	0
Blood ketone body present	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	14	0
Blood iron decreased	33	0
Blood iron increased	5	0
Blood magnesium decreased	3	0
Blood phosphorus abnormal	1	0
Blood phosphorus decreased	7	0
Blood phosphorus increased	4	0
Blood potassium decreased	12	0
Blood potassium increased	9	0
Blood sodium	2	0
Blood sodium decreased	6	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Blood zinc increased	1	0
Iron binding capacity total decreased	1	0
Serum ferritin	1	0
Serum ferritin decreased	5	0
Serum ferritin increased	7	0
Sweat test	3	0
Transferrin decreased	1	0
Urine copper	2	0
<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	12	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	20	0
Nerve conduction studies	1	0
Nerve conduction studies abnormal	2	0
Nerve stimulation test abnormal	1	0
Neurotransmitter level altered	1	0
Sensory level abnormal	1	0
Sleep study normal	1	0
<i>Ophthalmic function diagnostic procedures</i>		
Corneal reflex decreased	2	0
Intraocular pressure increased	8	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	1041	0
Body temperature abnormal	88	0
Body temperature decreased	140	0
Body temperature fluctuation	193	0
Body temperature increased	1165	0

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
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	38	0
Head lag	19	0
Lymph node palpable	6	0
Male genital examination abnormal	1	0
Menstruation normal	5	0
Muscle strength abnormal	6	0
Neurological examination	1	0
Neurological examination abnormal	1	0
Neurological examination normal	1	0
Ophthalmological examination	3	0
Ophthalmological examination abnormal	1	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	81	0
Skin temperature	178	0
Temperature difference of extremities	9	0
Urological examination	1	0
Vital signs measurement	1	0
Weight decreased	244	0
Weight increased	74	0
<i>Pituitary analyses anterior</i>		
Blood corticotrophin	1	0
Blood follicle stimulating hormone increased	2	0
Blood growth hormone increased	1	0
Blood prolactin increased	1	0
Blood thyroid stimulating hormone	1	0
Blood thyroid stimulating hormone abnormal	1	0
Blood thyroid stimulating hormone decreased	4	0
Blood thyroid stimulating hormone increased	5	0
<i>Platelet analyses</i>		
Platelet count	4	0
Platelet count abnormal	2	0
Platelet count decreased	347	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	44	0

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Protein total	2	0
Protein total abnormal	1	0
Protein total increased	2	0
Zinc sulphate turbidity increased	1	0
Red blood cell analyses		
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
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	2	0
Blood oestrogen decreased	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
Progesterone decreased	1	0
Reproductive hormone	1	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

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
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 abnormal	1	0
Peak expiratory flow rate decreased	7	0
Pulmonary function test	4	0
Pulmonary function test decreased	6	0
Slow vital capacity	1	0
Total lung capacity decreased	6	0
Respiratory tract and thoracic histopathology procedures		
Sputum abnormal	3	0
Respiratory tract and thoracic imaging procedures		
Chest X-ray	21	0
Computerised tomogram thorax	4	0
Laryngoscopy	1	0
Ventilation/perfusion scan	1	0
Skeletal and cardiac muscle analyses		
Blood creatine phosphokinase increased	8	0
Muscle enzyme increased	1	0
Myocardial necrosis marker	1	0
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	19	0
Skin histopathology procedures		
Biopsy skin	1	0
Special sense investigations NEC		
Olfactory test	1	0
Therapeutic drug monitoring analyses		
Analgesic drug level	17	0
Analgesic drug level increased	1	0
Analgesic drug level therapeutic	1	0
Anticoagulation drug level above therapeutic	3	0
Anticoagulation drug level below therapeutic	4	0
Anticoagulation drug level increased	1	0
Antidepressant drug level decreased	1	0
Drug level increased	3	0
Thyroid analyses		
Anti-thyroid antibody	1	0
Thyroid function test abnormal	5	0
Thyroid hormones decreased	1	0
Thyroxine	1	0
Thyroxine abnormal	1	0
Thyroxine increased	2	0

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Tri-iodothyronine decreased	7	0
Tissue enzyme analyses NEC		
Blood alkaline phosphatase decreased	1	0
Blood alkaline phosphatase increased	3	0
Blood lactate dehydrogenase	1	0
Blood lactate dehydrogenase increased	1	0
Lactate dehydrogenase urine increased	1	0
Toxicology laboratory analyses		
Blood aluminium	1	0
Blood arsenic normal	1	0
Blood cannabinoids	1	0
Blood carbon monoxide increased	3	0
Blood lead	1	0
Drug screen positive	4	0
Heavy metal test	1	0
Triglyceride analyses		
Blood triglycerides	1	0
Blood triglycerides increased	1	0
Urinalysis NEC		
Blood urine	39	0
Blood urine present	92	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	2	0
Red blood cells urine	1	0
Urea urine increased	1	0
Urine analysis	1	0
Urine analysis abnormal	17	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	49	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	2	0

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure abnormal	17	0
Blood pressure decreased	104	0
Blood pressure diastolic	1	0
Blood pressure diastolic decreased	1	0
Blood pressure diastolic increased	5	0
Blood pressure difference of extremities	1	0
Blood pressure increased	347	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
<i>Virus identification and serology</i>		
Blood HIV RNA increased	1	0
Coronavirus test	43	0
Cytomegalovirus test	1	0
Epstein-Barr virus antibody positive	1	0
HIV antibody negative	2	0
Hepatitis B core antibody positive	1	0
Hepatitis B surface antibody positive	1	0
Herpes virus test	1	0
Human papilloma virus test positive	1	0
SARS-CoV-1 test positive	1	0
SARS-CoV-2 RNA	1	0
SARS-CoV-2 antibody test	9	0
SARS-CoV-2 antibody test negative	34	0
SARS-CoV-2 antibody test positive	11	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	19	0
SARS-CoV-2 test positive	115	0
Varicella virus test positive	1	0
Viral load	1	0
Viral test	4	0
Viral test positive	1	0
<i>Vitamin analyses</i>		
Blood folate	3	0
Blood folate abnormal	1	0
Blood folate decreased	14	0
Vitamin B12	2	0
Vitamin B12 abnormal	3	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
<i>Water and electrolyte analyses NEC</i>		
Blood electrolytes decreased	2	0
Blood osmolarity	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Volume blood	7	0
White blood cell analyses		
CD4 lymphocytes decreased	1	0
Eosinophil count	1	0
Eosinophil count abnormal	2	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
Natural killer cell count increased	1	0
Neutrophil count	4	0
Neutrophil count abnormal	1	0
Neutrophil count decreased	20	0
Neutrophil count increased	1	0
Neutrophil toxic granulation present	1	0
White blood cell count	21	0
White blood cell count decreased	36	0
White blood cell count increased	14	0
White blood cell count normal	1	0
Investigations SOC TOTAL	11497	1

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	38	0
Decreased appetite	6473	0
Diet refusal	2	0
Eating disorder symptom	1	0
Food craving	26	0
Food refusal	42	0
Hyperphagia	10	0
Hypophagia	38	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	121	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	26	0
Type 2 diabetes mellitus	5	0
<i>Diabetic complications NEC</i>		
Diabetic ketoacidosis	42	2
Diabetic ketosis	5	0
Euglycaemic diabetic ketoacidosis	1	0
<i>Diabetic complications neurological</i>		
Hyperglycaemic hyperosmolar nonketotic syndrome	2	0
<i>Disorders of purine metabolism</i>		
Gout	186	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	17	0
<i>Fluid intake decreased</i>		
Fluid intake reduced	10	0
<i>Fluid intake increased</i>		
Polydipsia	16	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Alcohol intolerance	14	0
Dairy intolerance	6	0
Food intolerance	26	0
Gluten sensitivity	5	0
Histamine intolerance	4	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	82	0
Abnormal weight gain	39	0
Cachexia	2	0

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Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
Feeding disorder	216	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	17	0
Starvation	1	0
Underweight	2	0
Weight loss poor	4	0
Hyperglycaemic conditions NEC		
Glucose tolerance impaired	4	0
Hyperglycaemia	133	0
Insulin resistance	9	0
Metabolic syndrome	1	0
Hyperlipidaemias NEC		
Hyperlipidaemia	4	0
Hypoglycaemic conditions NEC		
Hyperinsulinaemic hypoglycaemia	1	0
Hypoglycaemia	105	0
Hypoglycaemia unawareness	2	0
Postprandial hypoglycaemia	3	0
Iron deficiencies		
Iron deficiency	17	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	6	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	3	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	9	0
<i>Total fluid volume decreased</i>		
Dehydration	696	0
Hypovolaemia	2	0
<i>Total fluid volume increased</i>		
Fluid retention	97	0
Hypervolaemia	13	0
<i>Vitamin deficiencies NEC</i>		
Hypovitaminosis	4	0
<i>Water soluble vitamin deficiencies</i>		
Folate deficiency	12	0
Vitamin B complex deficiency	1	0
Vitamin B12 deficiency	17	0
Metabolic disorders SOC TOTAL	8878	3

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	622	0
Arthritis enteropathic	2	0
Arthropathy	42	0
Autoimmune arthritis	12	0
Haemarthrosis	9	0
Oligoarthritis	1	0
Palindromic rheumatism	7	0
Polyarthritis	20	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	4	0
Osteonecrosis of jaw	4	0
Osteosclerosis	2	0
Spinal disorder	2	0
<i>Bone related signs and symptoms</i>		
Bone pain	1098	0
Bone swelling	9	0
Coccydynia	8	0
Pain in jaw	630	0
Pubic pain	1	0
Spinal pain	271	0
<i>Bursal disorders</i>		
Bursitis	224	0
<i>Cartilage disorders</i>		
Chondritis	1	0
Chondropathy	2	0
Costochondritis	92	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	104	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		
Muscle & tissue disorders cont'd		
Gouty tophus	1	0
Epiphyseal disorders		
Epiphyses premature fusion	1	0
Extremity deformities		
Acquired claw toe	1	0
Elbow deformity	1	0
Finger deformity	4	0
Foot deformity	7	0
Hand deformity	4	0
Knee deformity	1	0
Limb deformity	10	0
Wrist deformity	2	0
Fractures NEC		
Osteoporotic fracture	3	0
Pathological fracture	1	0
Intervertebral disc disorders NEC		
Intervertebral disc degeneration	3	0
Intervertebral disc disorder	1	0
Intervertebral disc protrusion	11	0
Joint related disorders NEC		
Ankle impingement	1	0
Femoroacetabular impingement	2	0
Hypermobility syndrome	3	0
Joint adhesion	1	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	515	0
Rotator cuff syndrome	97	0
Temporomandibular joint syndrome	22	0
Joint related signs and symptoms		
Arthralgia	23336	0
Jaw clicking	5	0
Joint effusion	11	0
Joint noise	52	0
Joint range of motion decreased	6	0
Joint stiffness	484	0
Joint swelling	1091	0
Joint vibration	6	0
Joint warmth	38	0
Loose body in joint	1	0
Ligament disorders		
Ligament pain	11	0
Lupus erythematosus (incl subtypes)		
Lupus-like syndrome	2	0
Systemic lupus erythematosus	40	0
Metabolic bone disorders		
Dwarfism	1	0
Osteopenia	2	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Muscle & tissue disorders cont'd		
Osteoporosis	12	0
Muscle infections and inflammations		
Autoimmune myositis	1	0
Myositis	55	0
Polymyositis	5	0
Muscle pains		
Fibromyalgia	310	0
Myalgia	26956	0
Myalgia intercostal	3	0
Myofascial pain syndrome	27	0
Muscle related signs and symptoms NEC		
Haematoma muscle	4	0
Muscle atrophy	38	0
Muscle discomfort	22	0
Muscle disorder	13	0
Muscle fatigue	1017	0
Muscle haemorrhage	5	0
Muscle hypertrophy	1	0
Muscle mass	12	0
Muscle oedema	3	0
Muscle spasms	3600	0
Muscle swelling	34	0
Muscle tightness	198	0
Muscle twitching	616	0
Muscle tone abnormalities		
Muscle rigidity	53	0
Nuchal rigidity	18	0
Torticollis	14	0
Trismus	57	0
Muscle weakness conditions		
Muscular weakness	2281	0
Sarcopenia	1	0
Musculoskeletal and connective tissue conditions NEC		
Back disorder	4	0
Extremity contracture	2	0
Infantile back arching	1	0
Limb mass	20	0
Mandibular mass	1	0
Mastication disorder	9	0
Mobility decreased	177	0
Muscle contracture	6	0
Musculoskeletal disorder	3	0
Musculoskeletal stiffness	2424	0
Posture abnormal	3	0
Somatic dysfunction	1	0
Weight bearing difficulty	13	0
Winged scapula	2	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

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Dactylitis	3	0
Dupuytren's contracture	5	0
Fasciitis	1	0
Plantar fasciitis	14	0
Musculoskeletal and connective tissue pain and discomfort		
Amplified musculoskeletal pain syndrome	1	0
Back pain	5946	0
Flank pain	96	0
Growing pains	8	0
Limb discomfort	2401	0
Musculoskeletal chest pain	427	0
Musculoskeletal discomfort	160	0
Musculoskeletal pain	168	0
Neck pain	3174	0
Pain in extremity	22511	0
Rheumatic disorder	32	0
Sacral pain	7	0
Myopathies		
Compartment syndrome	6	0
Muscle necrosis	1	0
Myopathy	6	0
Rhabdomyolysis	10	1
Osteoarthropathies		
Nodal osteoarthritis	1	0
Osteoarthritis	104	0
Spinal osteoarthritis	10	0
Psoriatic arthropathies		
Psoriatic arthropathy	31	0
Rheumatoid arthropathies		
Felty's syndrome	1	0
Juvenile idiopathic arthritis	2	0
Rheumatoid arthritis	210	0
Rheumatoid nodule	1	0
Still's disease	6	0
Soft tissue disorders NEC		
Axillary mass	86	0
Clubbing	1	0
Fistula	3	0
Groin pain	235	0
Neck mass	26	0
Soft tissue disorder	3	0
Soft tissue mass	3	0
Soft tissue swelling	7	0
Spine and neck deformities		
Kyphosis	6	0
Scoliosis	4	0
Spinal stenosis	3	0
Spondyloarthropathies		
Ankylosing spondylitis	33	0
Arthritis reactive	66	0
Axial spondyloarthritis	2	0
Spondylitis	7	0
Spondyloarthropathy	3	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
<i>Synovial disorders</i>		
Synovial cyst	16	0
Synovitis	20	0
<i>Tendon disorders</i>		
Enthesopathy	1	0
Tendon discomfort	4	0
Tendon disorder	10	0
Tendon pain	49	0
Tendon sheath disorder	1	0
Tendonitis	108	0
Tenosynovitis	3	0
Tenosynovitis stenosaurs	4	0
Trigger finger	36	0
Muscle & tissue disorders SOC TOTAL	103219	1

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Reaction Name	Total	Fatal
Neoplasms		
<i>Anal canal neoplasms malignant</i>		
Anal cancer	1	0
<i>Anaplastic large cell lymphomas T- and null-cell types</i>		
T-cell lymphoma	1	1
<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
Cholangiosarcoma	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	56	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	3	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	2	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	7	0

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
<i>Glial tumours malignant</i>		
Glioblastoma	4	0
Glioblastoma multiforme	1	0
<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	6	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
Lip neoplasm malignant stage unspecified	1	0
Squamous cell carcinoma of the oral cavity	2	0
<i>Lymphomas unspecified NEC</i>		
Lymphoma	21	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>		

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
Essential thrombocythaemia	2	0
Neoplasms benign site unspecified NEC		
Fibroma	1	0
Neoplasms malignant site unspecified NEC		
Adenocarcinoma	2	0
Malignant neoplasm progression	1	0
Metastatic neoplasm	3	0
Neoplasm malignant	13	2
Recurrent cancer	1	0
Squamous cell carcinoma	4	0
Neoplasms unspecified malignancy and site unspecified NEC		
Neoplasm	1	0
Neoplasm progression	1	0
Neoplasm recurrence	9	0
Nervous system neoplasms unspecified malignancy NEC		
Brain neoplasm	10	3
Meningioma	6	0
Schwannoma	1	0
Neuromas		
Acoustic neuroma	6	0
Non-Hodgkin's lymphomas NEC		
Cutaneous lymphoma	1	0
Non-Hodgkin's lymphoma	2	1
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	4	0
Ovarian neoplasms malignant (excl germ cell)		
Ovarian cancer	10	0
Ovarian cancer recurrent	2	0
Ovarian cancer stage IV	1	0
Pancreatic neoplasms malignant (excl islet cell and carcinoid)		
Pancreatic carcinoma	6	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

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
<i>Plasma cell neoplasms NEC</i>		
Hypergammaglobulinaemia benign monoclonal	2	0
<i>Prostatic neoplasms malignant</i>		
Prostate cancer	8	0
<i>Renal neoplasms malignant</i>		
Clear cell renal cell carcinoma	2	0
Metastatic renal cell carcinoma	1	0
Renal cancer	2	0
<i>Reproductive neoplasms female benign NEC</i>		
Benign hydatidiform mole	1	0
<i>Reproductive neoplasms male benign NEC</i>		
Testicle adenoma	2	0
<i>Respiratory tract and pleural neoplasms malignancy unspecified NEC</i>		
Maxillofacial sinus neoplasm	1	0
<i>Respiratory tract and pleural neoplasms malignant cell type unspecified NEC</i>		
Bronchial carcinoma	4	0
Lung cancer metastatic	1	0
Lung neoplasm malignant	15	0
Throat cancer	1	0
<i>Respiratory tract small cell carcinomas</i>		
Small cell lung cancer	1	0
<i>Salivary gland neoplasms malignant</i>		
Salivary gland cancer stage 0	1	0
Salivary gland cancer stage III	1	0
<i>Skin melanomas (excl ocular)</i>		
Acral lentiginous melanoma stage III	1	0
Malignant melanoma	4	0
Malignant melanoma in situ	3	0
Metastatic malignant melanoma	1	0
<i>Skin neoplasms benign</i>		
Acrochordon	7	0
Anogenital warts	4	0
Haemangioma of skin	18	0
Melanocytic naevus	5	0
Seborrhoeic keratosis	2	0
Skin papilloma	31	0
<i>Skin neoplasms malignant and unspecified (excl melanoma)</i>		
Basal cell carcinoma	6	0
Bowen's disease	1	0
Neoplasm skin	1	0
Skin cancer	9	0
Squamous cell carcinoma of skin	1	0
<i>Soft tissue neoplasms benign NEC</i>		
Knuckle pads	1	0
Lipoma	10	0
<i>Thyroid neoplasms benign</i>		
Benign neoplasm of thyroid gland	1	0
Thyroid adenoma	1	0
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	19	0
<i>Uterine neoplasms malignant NEC</i>		
Uterine cancer	4	0

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
<i>Vulval neoplasms malignant</i>		
Squamous cell carcinoma of the vulva	1	0
Vulval cancer	1	0
Neoplasms SOC TOTAL	491	12

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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	23	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	483	5
Miller Fisher syndrome	28	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	24	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	5	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 embolism	1	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	16	0
Cerebral haematoma	13	1
Cerebral haemorrhage	188	50
Cerebral infarction	97	5
Cerebral ischaemia	4	0
Cerebral thrombosis	41	4

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Cerebral vascular occlusion	2	0
Cerebrovascular accident	1303	52
Embolic stroke	21	1
Haemorrhage intracranial	58	15
Haemorrhagic cerebral infarction	3	1
Haemorrhagic stroke	47	7
Haemorrhagic transformation stroke	8	3
Internal capsule infarction	1	0
Intracranial haematoma	8	1
Intraventricular haemorrhage	6	0
Ischaemic cerebral infarction	3	0
Ischaemic stroke	161	7
Lacunar infarction	5	0
Lacunar stroke	28	0
Perinatal stroke	1	0
Pseudostroke	2	0
Spinal cord haematoma	1	0
Spinal cord infarction	1	0
Spinal stroke	4	0
Stroke in evolution	1	0
Subarachnoid haemorrhage	118	7
Thalamic infarction	1	0
Thalamus haemorrhage	9	0
Thrombotic stroke	15	0
Vertebral artery occlusion	1	0
Vertebral artery thrombosis	1	0
Central nervous system inflammatory disorders NEC		
Arachnoiditis	4	0
Central nervous system inflammation	15	0
Neurosarcoidosis	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	4	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	213	23
Cerebral venous thrombosis	51	5
Superior sagittal sinus thrombosis	32	3

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Transverse sinus thrombosis	8	0
Cervical spinal cord and nerve root disorders		
Cervical radiculopathy	4	0
Cervicobrachial syndrome	7	0
Choreiform movements		
Chorea	3	0
Choreoathetosis	1	0
Sydenham's chorea	1	0
Chronic polyneuropathies		
Chronic inflammatory demyelinating polyradiculoneuropathy	10	0
Demyelinating polyneuropathy	12	0
Diabetic neuropathy	2	0
Polyneuropathy chronic	2	0
Coma states		
Coma	24	0
Diabetic coma	3	0
Hypoglycaemic coma	2	0
Coordination and balance disturbances		
Ataxia	53	0
Balance disorder	984	0
Cerebellar ataxia	5	0
Cerebellar syndrome	2	0
Coordination abnormal	139	0
Dysdiadochokinesis	1	0
Dysstasia	123	0
Hand-eye coordination impaired	2	0
Nystagmus	23	0
Cortical dysfunction NEC		
Agraphia	1	0
Alexia	7	0
Aphasia	184	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	34	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	16	0
Clinically isolated syndrome	3	0
Demyelination	28	0
Neuromyelitis optica spectrum disorder	5	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
<i>Disturbances in consciousness NEC</i>		
Altered state of consciousness	21	0
Consciousness fluctuating	4	0
Depressed level of consciousness	93	0
Hypoglycaemic unconsciousness	1	0
Lethargy	4981	0
Loss of consciousness	1118	0
Postictal state	1	0
Sedation	18	0
Somnolence	1980	0
Stupor	9	0
Syncope	2603	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	35	0
Clumsiness	54	0
Dyskinesia	123	0
Extrapyramidal disorder	18	0
Fine motor delay	3	0
Fine motor skill dysfunction	22	0
Hyperkinesia	27	0
Hypokinesia	105	0
Meige's syndrome	1	0
Motor dysfunction	21	0
Movement disorder	115	0
Psychomotor hyperactivity	40	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	5	0
Limbic encephalitis	1	0
Noninfective encephalitis	13	0
<i>Encephalopathies NEC</i>		
Autoimmune encephalopathy	6	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>		

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Hepatic encephalopathy	2	0
Eye movement disorders		
IIIrd nerve disorder	1	0
IIIrd nerve paralysis	7	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	615	0
Facial nerve disorder	9	0
Facial paralysis	363	0
Facial paresis	177	0
Facial spasm	46	0
Oculofacial paralysis	1	0
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	105	0
Glossopharyngeal nerve disorders		
Glossopharyngeal neuralgia	1	0
Headaches NEC		
Cervicogenic headache	6	0
Chronic paroxysmal hemicrania	1	0
Cluster headache	761	0
Cold-stimulus headache	91	0
Drug withdrawal headache	17	0
Exertional headache	12	0
External compression headache	5	0
Headache	81545	0
Medication overuse headache	19	0
New daily persistent headache	20	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	961	0
Tension headache	1534	0
Thunderclap headache	50	0
Vascular headache	85	0
Hydrocephalic conditions		
Hydrocephalus	18	1
Hypoglossal nerve disorders		
Tongue paralysis	6	0
Increased intracranial pressure disorders		
Brain compression	4	0
Brain oedema	37	2
Cerebrospinal fluid circulation disorder	6	0
Cytotoxic oedema	1	0
Idiopathic intracranial hypertension	7	0
Intracranial pressure increased	31	0
Vasogenic cerebral oedema	1	0
Intellectual disabilities		
Intellectual disability	11	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
<i>Lumbar spinal cord and nerve root disorders</i>		
Lumbar radiculopathy	5	0
Sciatica	234	0
<i>Memory loss (excl dementia)</i>		
Amnesia	433	0
Memory impairment	401	0
Retrograde amnesia	1	0
Transient global amnesia	25	0
<i>Meningitis NEC</i>		
Meningitis noninfective	1	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	212	0
Disturbance in attention	762	0
Judgement impaired	5	0
Mental impairment	143	0
<i>Migraine headaches</i>		
Basilar migraine	5	0
Hemiplegic migraine	51	0
Migraine	7721	0
Migraine with aura	400	0
Migraine without aura	48	0
Ophthalmic migraine	14	0
Retinal migraine	89	0
Status migrainosus	5	0
Typical aura without headache	19	0
Vestibular migraine	40	0
<i>Mixed cranial nerve disorders</i>		
Bulbar palsy	3	0
<i>Mononeuropathies</i>		
Carpal tunnel syndrome	44	0
Cubital tunnel syndrome	1	0
Diabetic mononeuropathy	1	0
Long thoracic nerve palsy	2	0
Meralgia paraesthetica	3	0
Mononeuritis	4	0
Mononeuropathy	3	0
Nerve compression	57	0
Peripheral nerve lesion	1	0
Peroneal nerve palsy	19	0
Piriformis syndrome	4	0
Radial nerve palsy	2	0
Sciatic nerve neuropathy	5	0
Ulnar nerve palsy	3	0
Ulnar neuritis	4	0
Ulnar tunnel syndrome	1	0
<i>Motor neurone diseases</i>		
Amyotrophic lateral sclerosis	1	0
Lower motor neurone lesion	1	0
Motor neurone disease	6	0
<i>Multiple sclerosis acute and progressive</i>		
Band sensation	6	0
Multiple sclerosis	60	0
Multiple sclerosis pseudo relapse	2	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Multiple sclerosis relapse	61	0
Progressive multiple sclerosis	1	0
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	43	0
Serotonin syndrome	1	0
Stiff leg syndrome	10	0
Stiff person syndrome	1	0
Myelitis (incl infective)		
Myelitis transverse	106	0
Narcolepsy and hypersomnia		
Cataplexy	1	0
Hypersomnia	228	0
Narcolepsy	22	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	10	0
Cerebral disorder	9	0
Microglial nodules	1	0
Nervous system disorder	83	0
Neurotoxicity	5	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	22637	0
Dizziness exertional	101	0
Dizziness postural	2171	0
Drooling	27	0
Exaggerated startle response	4	0
Fontanelle bulging	4	0
Head discomfort	767	0
Hyporesponsive to stimuli	4	0
Inability to crawl	2	0
Infant irritability	6	0
Intracranial hypotension	4	0
Meningism	3	0
Myoclonus	34	0
Neurological decompensation	4	0
Neurological symptom	144	0
Patient elopement	3	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Persistent postural-perceptual dizziness	43	0
Pleocytosis	4	0
Presyncope	619	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	108	0
Neuromuscular disorders NEC		
Hypotonic-hyporesponsive episode	1	0
Muscle contractions involuntary	40	0
Muscle spasticity	34	0
Neuromuscular pain	6	0
Neuromyopathy	3	0
Neuromyotonia	1	0
Sensorimotor disorder	1	0
Neuromuscular junction dysfunction		
Myasthenia gravis	20	0
Myasthenia gravis crisis	3	0
Olfactory nerve disorders		
Anosmia	362	0
Hyposmia	11	0
Parosmia	410	0
Optic nerve disorders NEC		
Optic neuritis	63	0
Paraesthesias and dysaesthesias		
Anaesthesia	3	0
Burning feet syndrome	33	0
Burning sensation	1043	0
Burning sensation mucosal	3	0
Dysaesthesia	17	0
Formication	85	0
Hand-arm vibration syndrome	3	0
Hemianaesthesia	5	0
Hemiparaesthesia	5	0
Hyperaesthesia	276	0
Hypoaesthesia	6129	0
Lhermitte's sign	4	0
Paraesthesia	9867	0
Reversed hot-cold sensation	1	0
Paralysis and paresis (excl cranial nerve)		
Diplegia	37	0
Gait spastic	1	0
Hemiparesis	118	0
Hemiplegia	53	0
Monoparesis	119	0
Monoplegia	144	0
Paralysis	353	0
Paraparesis	6	0
Paraplegia	3	0
Paresis	9	0
Peripheral nerve palsy	1	0
Peripheral paralysis	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Postictal paralysis	3	0
Quadriparesis	3	0
Quadriplegia	4	0
<i>Parkinson's disease and parkinsonism</i>		
Freezing phenomenon	161	0
Parkinson's disease	18	0
Parkinsonism	13	0
Reduced facial expression	9	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	3	0
Axonal and demyelinating polyneuropathy	1	0
Axonal neuropathy	2	0
Brachial plexopathy	1	0
Ischaemic neuropathy	2	0
Neuralgic amyotrophy	11	0
Neuritis	19	0
Neuropathy peripheral	284	0
Peripheral motor neuropathy	2	0
Peripheral sensorimotor neuropathy	3	0
Peripheral sensory neuropathy	18	0
Polyneuropathy	16	0
Small fibre neuropathy	4	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	351	1
Epileptic aura	3	0
Febrile convulsion	91	0
Hypoglycaemic seizure	1	0
Migraine-triggered seizure	2	0
Myoclonic epilepsy	5	0
Partial seizures	60	0
Psychogenic seizure	5	0
Seizure	1389	3
Seizure anoxic	4	0
Seizure cluster	9	0
Seizure like phenomena	3	0
Status epilepticus	29	2
Tonic clonic movements	3	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Tonic convulsion	39	0
Sensory abnormalities NEC		
Ageusia	1115	0
Allodynia	63	0
Aura	26	0
Central pain syndrome	2	0
Complex regional pain syndrome	15	0
Decreased vibratory sense	1	0
Dysgeusia	2024	0
Electric shock sensation	113	0
Hypogeusia	7	0
Intercostal neuralgia	2	0
Loss of proprioception	6	0
Neuralgia	1512	0
Persistent genital arousal disorder	2	0
Phantom limb syndrome	19	0
Post herpetic neuralgia	14	0
Restless arm syndrome	15	0
Restless legs syndrome	408	0
Sensory disturbance	163	0
Sensory loss	250	0
Taste disorder	525	0
Vibratory sense increased	5	0
Visual perseveration	1	0
Sleep disturbances NEC		
Microsleep	3	0
Periodic limb movement disorder	2	0
Sleep deficit	53	0
Sudden onset of sleep	1	0
Speech and language abnormalities		
Dysarthria	461	0
Incoherent	20	0
Language disorder	3	0
Muscle tension dysphonia	1	0
Repetitive speech	4	0
Slow speech	42	0
Speech disorder	135	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	29	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	43	3
Cerebral mass effect	10	0
Encephalomalacia	1	0
Intracranial mass	4	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
White matter lesion	5	0
Transient cerebrovascular events		
Transient ischaemic attack	514	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	9849	1
Trigeminal disorders		
Numb chin syndrome	3	0
Trigeminal nerve disorder	6	0
Trigeminal neuralgia	148	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	180996	214

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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	229	€
<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	4	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
Uterine hypertonus	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>Placental abnormalities (excl neoplasms)</i>		
Foetal vascular malperfusion	1	0
<i>Pregnancy complicated by maternal disorders</i>		
Gestational diabetes	6	0
Peripartum cardiomyopathy	1	0
<i>Stillbirth and foetal death</i>		
Stillbirth	5	5

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Reaction Name	Total	Fatal
Pregnancy conditions <small>Pregnancy conditions cont'd</small>		
<i>Umbilical cord complications</i>		
Umbilical cord around neck	1	0
<i>Unintended pregnancies</i>		
Pregnancy after post coital contraception	2	0
Pregnancy on contraceptive	4	0
Pregnancy with implant contraceptive	2	0
Unintended pregnancy	2	0
Pregnancy conditions SOC TOTAL	328	5

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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	36	0
Stent malfunction	1	0
Thrombosis in device	69	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	4	0
null SOC TOTAL	192	1

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	26	0
Behaviour disorder	1	0
Breath holding	5	0
Sexually inappropriate behaviour	1	0
Staring	14	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	14	0
Blunted affect	1	0
Constricted affect	16	0
Flat affect	11	0
Inappropriate affect	18	0
<i>Amnesic symptoms</i>		
Paramnesia	6	0
<i>Anxiety disorders NEC</i>		
Anxiety disorder	5	0
Generalised anxiety disorder	5	0
Neurosis	1	0
<i>Anxiety symptoms</i>		
Agitation	210	0
Anxiety	1328	0
Immunisation anxiety related reaction	2	0
Nervousness	609	0
Procedural anxiety	1	0
Stress	167	0
Tension	73	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	20	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	18	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	43	0
Personality change	10	0
Social avoidant behaviour	7	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	17	0
Distractibility	2	0
Mental fatigue	495	0
Communications disorders		
Communication disorder	9	0
Mutism	6	0
Speech sound disorder	2	0
Confusion and disorientation		
Confusional state	2189	0
Disorientation	743	0
Decreased physical activity levels		
Catatonia	3	0
Deliria		
Delirium	487	0
Delirium febrile	3	0
Delusional disorders		
Alice in wonderland syndrome	3	0
Delusional symptoms		
Delusion	54	0
Delusion of parasitosis	3	0
Mixed delusion	1	0
Thought withdrawal	1	0
Dementia NEC		
Pseudodementia	1	0
Depressive disorders		
Agitated depression	4	0
Childhood depression	1	0
Depression	697	0
Depression suicidal	16	0
Major depression	24	0
Menopausal depression	2	0
Mixed anxiety and depressive disorder	3	0
Dissociative states		
Depersonalisation/derealisation disorder	20	0
Dissociation	79	0
Dissociative amnesia	1	0
Dissociative disorder	2	0
Disturbances in initiating and maintaining sleep		
Initial insomnia	44	0
Insomnia	3153	0
Middle insomnia	73	0
Terminal insomnia	27	0
Dyssomnias		
Dyssomnia	5	0
Poor quality sleep	672	0
Eating disorders NEC		
Binge eating	1	0
Eating disorder	19	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 <small>Psychiatric disorders cont'd</small>		
Dysphoria	2	0
Emotional disorder	102	0
Emotional distress	88	0
Emotional poverty	2	0
Euphoric mood	69	0
Frustration tolerance decreased	15	0
Irritability	321	0
Mood altered	89	0
Factitious disorders		
Factitious disorder	4	0
Fear symptoms and phobic disorders (incl social phobia)		
Acrophobia	2	0
Agoraphobia	5	0
Fear	70	0
Fear of death	18	0
Fear of disease	2	0
Fear of eating	1	0
Fear of falling	5	0
Fear of injection	2	0
Fear of open spaces	1	0
Fear-related avoidance of activities	3	0
Performance fear	1	0
Phobia	3	0
Phonophobia	5	0
Social anxiety disorder	1	0
Social fear	1	0
Thanatophobia	1	0
Fluctuating mood symptoms		
Mood swings	145	0
Hallucinations (excl sleep-related)		
Hallucination	944	0
Hallucination, auditory	49	0
Hallucination, olfactory	14	0
Hallucination, tactile	1	0
Hallucination, visual	59	0
Hallucinations, mixed	9	0
Somatic hallucination	1	0
Impulse control disorders		
Clinomania	1	0
Impulse-control disorder	3	0
Impulsive behaviour	2	0
Intermittent explosive disorder	1	0
Increased physical activity levels		
Restlessness	491	0
Infancy, childhood and adolescence psychiatric disorders NEC		
Emotional disorder of childhood	1	0
Learning disorders		
Reading disorder	2	0
Mental disorders NEC		
Mental disorder	30	0
Mental status changes	5	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	705	0
Depressive symptom	2	0
Feeling guilty	1	0
Feeling of despair	19	0
Negative thoughts	11	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	79	0
Laziness	2	0
Listless	125	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	352	0
Panic disorder	9	0
Panic reaction	42	0
<i>Paraphilias and paraphilic disorders</i>		
Fetishism	2	0
<i>Parasomnias</i>		
Abnormal dreams	370	0
Abnormal sleep-related event	2	0
Confusional arousal	3	0
Exploding head syndrome	7	0
Nightmare	466	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	62	0
Sleep-related eating disorder	2	0
Somnambulism	11	0
Perception disturbances NEC		
Autoscopy	28	0
Deja vu	4	0
Delusional perception	2	0
Derealisation	18	0
Flashback	3	0
Illusion	12	0
Imperception	1	0
Jamais vu	1	0
Near death experience	1	0
Pseudohallucination	1	0
Time perception altered	6	0
Pervasive developmental disorders NEC		
Autism spectrum disorder	4	0
Psychiatric elimination disorders		
Enuresis	62	0
Psychiatric symptoms NEC		
Decreased eye contact	2	0
Helplessness	3	0
Hypervigilance	12	0
Psychiatric symptom	13	0
Psychological trauma	5	0
Psychotic disorder NEC		
Acute psychosis	6	0
Psychotic behaviour	2	0
Psychotic disorder	47	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	54	0
Sexual dysfunction NEC		
Genito-pelvic pain/penetration disorder	1	0
Sleep disorders NEC		
Sleep disorder	443	0
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	35	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Habit cough	39	0
Illness anxiety disorder	1	0
Psychogenic tremor	2	0
Somatic symptom disorder	1	0
<i>Speech and language usage disturbances</i>		
Disorganised speech	22	0
Logorrhoea	3	0
Pedantic speech	1	0
Poverty of speech	1	0
Verbigeration	1	0
<i>Speech articulation and rhythm disturbances</i>		
Dysphemia	36	0
Lack of spontaneous speech	3	0
<i>Stereotypies and automatisms</i>		
Bruxism	35	0
Head banging	48	0
Waxy flexibility	2	0
<i>Stress disorders</i>		
Acute stress disorder	4	0
Burnout syndrome	15	0
Catastrophic reaction	1	0
Hyperarousal	3	0
Post-traumatic stress disorder	15	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	4	4
Intentional self-injury	9	0
Self-injurious ideation	3	0
Suicidal behaviour	4	0
Suicidal ideation	119	0
Suicide attempt	31	0
Suicide threat	1	0
<i>Thinking disturbances</i>		
Bradyphrenia	95	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	31	0
Thought blocking	7	0
<i>Tic disorders</i>		
Secondary tic	2	0

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Reaction Name	Total	Fatal
Psychiatric disorders ^{Psychiatric disorders cont'd}		
Tic	21	0
Psychiatric disorders SOC TOTAL	18117	4

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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	65	0
Bladder spasm	1	0
Dysuria	89	0
Incontinence	93	0
Micturition disorder	4	0
Micturition frequency decreased	1	0
Micturition urgency	102	0
Mixed incontinence	1	0
Pollakiuria	302	0
Stress urinary incontinence	1	0
Urethral pain	6	0
Urge incontinence	2	0
Urinary hesitation	7	0
Urinary incontinence	130	0
Urinary retention	100	0
Urine flow decreased	22	0
<i>Bladder disorders NEC</i>		
Bladder dilatation	1	0
Bladder disorder	23	0
Bladder prolapse	1	0
Urinary bladder haemorrhage	17	1
Urinary bladder rupture	1	0
<i>Bladder infections and inflammations</i>		
Cystitis haemorrhagic	1	0
Cystitis interstitial	11	0
Cystitis noninfective	3	0
<i>Genital and urinary tract disorders NEC</i>		
Urinary tract disorder	12	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	1	0
Glomerulonephritis minimal lesion	5	0
IgA nephropathy	4	0
Nephrotic syndrome	19	0
<i>Myoneurogenic bladder disorders</i>		
Atonic urinary bladder	1	0
Automatic bladder	1	0
Bladder dysfunction	13	0
Hypertonic bladder	16	0
Loss of bladder sensation	13	0
Neurogenic bladder	4	0
<i>Nephritis NEC</i>		
Lupus nephritis	2	0
Nephritis	7	0
Tubulointerstitial nephritis	7	0
<i>Nephropathies and tubular disorders NEC</i>		

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Reaction Name	Total	Fatal
Renal & urinary disorders		
Renal & urinary disorders cont'd		
Nephropathy	2	0
Renal disorders NEC		
Oedematous kidney	1	0
Renal disorder	15	0
Renal haemorrhage	3	0
Renal failure and impairment		
Acute kidney injury	70	1
Anuria	5	0
Chronic kidney disease	11	0
End stage renal disease	1	0
Oliguria	11	0
Renal failure	48	2
Renal impairment	29	0
Renal injury	9	1
Renal hypertension and related conditions		
Hypertensive nephropathy	1	0
Renal lithiasis		
Nephrolithiasis	22	0
Renal obstructive disorders		
Hydronephrosis	1	0
Renal structural abnormalities and trauma		
Kidney enlargement	1	0
Renal atrophy	2	0
Renal vascular and ischaemic conditions		
Renal artery occlusion	2	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	2	0
Renal vein embolism	1	0
Renal vein occlusion	3	0
Renal vein thrombosis	9	0
Structural and obstructive urethral disorders (excl congenital)		
Urethral spasm	1	0
Urethral stenosis	1	0
Ureteric disorders NEC		
Ureteral disorder	2	0
Urinary abnormalities		
Chromaturia	109	0
Glycosuria	1	0
Haematuria	1	0
Haematuria	65	0
Microalbuminuria	1	0
Proteinuria	12	0
Urine abnormality	21	0
Urine odour abnormal	21	0
Urinary tract signs and symptoms NEC		
Costovertebral angle tenderness	1	0
Haemorrhage urinary tract	60	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
Renal & urinary disorders cont'd		
Nocturia	23	0
Polyuria	34	0
Renal colic	4	0
Renal pain	946	0
Urinary tract discomfort	2	0
Urinary tract pain	16	0
Renal & urinary disorders SOC TOTAL	2704	6

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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	76	0
Gynaecomastia	10	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	500	0
Breast swelling	73	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	2	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	98	0
Erection increased	7	0
Organic erectile dysfunction	20	0
Painful ejaculation	1	0
Painful erection	2	0
Priapism	3	0
Retrograde ejaculation	4	0
Spontaneous penile erection	4	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	63	0
Menopause delayed	5	0
Premature menopause	49	0
<i>Menopausal effects on the genitourinary tract</i>		
Atrophic vulvovaginitis	1	0
Postmenopausal haemorrhage	303	0
<i>Menstruation and uterine bleeding NEC</i>		
Abnormal uterine bleeding	9	0
Abnormal withdrawal bleeding	5	0
Dysmenorrhoea	1444	0
Intermenstrual bleeding	700	0
Menstrual discomfort	15	0
Menstrual disorder	1542	0
Menstruation irregular	2349	0
Premenstrual dysphoric disorder	6	0
Premenstrual headache	12	0
Premenstrual pain	86	0
Premenstrual syndrome	58	0
Retrograde menstruation	4	0
Withdrawal bleed	14	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	604	0
Hypomenorrhoea	437	0
Menstruation delayed	3246	0
Oligomenorrhoea	118	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	4699	0
Menometrorrhagia	17	0
Polymenorrhoea	696	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>		
Ovarian cyst	31	0
Ovarian cyst ruptured	2	0
Polycystic ovaries	43	0
<i>Ovarian and fallopian tube disorders NEC</i>		
Fallopian tube spasm	1	0
Ovarian adhesion	1	0
Ovarian enlargement	3	0
Ovarian failure	3	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	61	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	44	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	33	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	4	0
Genital rash	6	0
Genital swelling	2	0
Pelvic discomfort	4	0
Pelvic pain	179	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	14	0
Infertility female	7	0
Infertility male	3	0
Male sexual dysfunction	2	0
Sexual dysfunction	15	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	9	0
Testicular mass	1	0
Testicular oedema	2	0
Testicular pain	112	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	3	0
Endometriosis	90	0
Metrorrhoea	1	0
Uterine enlargement	2	0
Uterine haemorrhage	71	0
Uterine pain	10	0
<i>Uterine neoplasms</i>		
Uterine cyst	1	0
Uterine polyp	4	0
<i>Uterine tone disorders</i>		
Uterine spasm	24	0
<i>Vaginal and vulval infections and inflammations</i>		
Vulvovaginal inflammation	2	0
<i>Vulvovaginal cysts and neoplasms</i>		
Bartholin's cyst	3	0
Vaginal cyst	15	0
Vulva cyst	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal disorder	1	0

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Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Vaginal haemorrhage	1313	0
Vaginal ulceration	7	0
Vulval disorder	3	0
Vulval haemorrhage	34	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	90	0
Vaginal lesion	7	0
Vaginal odour	7	0
Vulval oedema	1	0
Vulvovaginal burning sensation	11	0
Vulvovaginal discomfort	10	0
Vulvovaginal dryness	12	0
Vulvovaginal erythema	1	0
Vulvovaginal pain	39	0
Vulvovaginal pruritus	12	0
Vulvovaginal rash	3	0
Vulvovaginal swelling	7	0
Reproductive & breast disorders SOC TOTAL	20196	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	7839	0
Dyspnoea at rest	15	0
Dyspnoea exertional	59	0
Dyspnoea paroxysmal nocturnal	1	0
Grunting	2	0
Hyperventilation	101	0
Hypopnoea	234	0
Hypoventilation	1	0
Irregular breathing	28	0
Mouth breathing	8	0
Orthopnoea	3	0
Respiration abnormal	110	0
Respiratory arrest	28	0
Respiratory distress	13	0
Respiratory fatigue	7	0
Sleep apnoea syndrome	32	0
Tachypnoea	39	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	640	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	643	0
<i>Conditions associated with abnormal gas exchange</i>		
Asphyxia	3	0
Hypercapnia	1	0
Hypoxia	71	1
<i>Coughing and associated symptoms</i>		
Allergic cough	8	0
Cough	4011	0
Haemoptysis	144	0
Productive cough	211	0
Sputum discoloured	15	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	4	0
Vocal cord disorder	5	0
Vocal cord dysfunction	7	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	8	1
Pulmonary pain	233	0
Rales	2	0
<i>Mediastinal disorders</i>		
Pulmonary hilum mass	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	475	0
Nasal inflammation	8	0
Rhinitis allergic	28	0
Rhinitis perennial	1	0
<i>Nasal disorders NEC</i>		
Epistaxis	2288	0
Intranasal hypoaesthesia	1	0
Nasal crusting	6	0
Nasal cyst	2	0
Nasal disorder	7	0
Nasal dryness	70	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	12	0
Sinus congestion	90	0
Sinus disorder	19	0
Sinus polyp	3	0
<i>Parenchymal lung disorders NEC</i>		
Atelectasis	7	0
Cystic lung disease	1	0
Emphysema	5	0
Idiopathic pulmonary fibrosis	3	0
Interstitial lung disease	9	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	11	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	303	0
Pharyngeal ulceration	15	0
Tonsillar disorder	1	0
Tonsillar erythema	7	0
Tonsillar haemorrhage	1	0
Tonsillar hypertrophy	65	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	54	0
<i>Pneumothorax and pleural effusions NEC</i>		
Haemothorax	1	0
Pleural effusion	50	1
Pneumothorax	14	0
Pneumothorax spontaneous	2	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	1710	112
Pulmonary infarction	15	1
Pulmonary thrombosis	31	5
Pulmonary venous thrombosis	4	0
<i>Respiratory failures (excl neonatal)</i>		
Acute respiratory failure	3	1
Respiratory failure	28	3
<i>Respiratory signs and symptoms NEC</i>		
Allergic respiratory symptom	11	0
Diaphragmalgia	16	0
Nasal flaring	1	0
Painful respiration	11	0
Pleural rub	1	0
Respiratory symptom	25	0
Suffocation feeling	5	0
Use of accessory respiratory muscles	3	0
<i>Respiratory tract disorders NEC</i>		
Allergic respiratory disease	1	0
Aspiration	10	2
Chronic respiratory disease	2	1
Lung disorder	12	0
Pulmonary mass	9	0
Respiratory disorder	8	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	123	0
Catarrh	67	0
Choking	22	0
Choking sensation	13	0
Dry throat	261	0
Dysphonia	177	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

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Oropharyngeal discomfort	42	0
Oropharyngeal pain	4234	0
Oropharyngeal plaque	1	0
Paranasal sinus discomfort	78	0
Rhinalgia	35	0
Rhinorrhoea	1691	0
Sinus pain	608	0
Sneezing	525	0
Snoring	5	0
Throat clearing	7	0
Throat irritation	216	0
Throat lesion	1	0
Throat tightness	234	0
Upper airway obstruction	1	0
Upper respiratory tract congestion	1	0
Upper-airway cough syndrome	28	0
Yawning	72	0
<i>Vascular pulmonary disorders NEC</i>		
Pulmonary artery occlusion	1	0
Pulmonary vascular disorder	1	0
Respiratory disorders SOC TOTAL	29211	137

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	150	0
Acne cystic	11	0
Acne varioliformis	1	0
Dermatitis acneiform	12	0
<i>Alopecias</i>		
Alopecia	467	0
Alopecia areata	50	0
Alopecia scarring	2	0
Alopecia totalis	3	0
Alopecia universalis	3	0
Androgenetic alopecia	2	0
Diffuse alopecia	5	0
Hypotrichosis	1	0
Lichen planopilaris	1	0
Madarosis	6	0
<i>Angioedemas</i>		
Angioedema	363	0
Circumoral oedema	2	0
Idiopathic angioedema	3	0
<i>Apocrine and eccrine gland disorders</i>		
Anhidrosis	2	0
Cold sweat	1728	0
Hidradenitis	4	0
Hyperhidrosis	9270	0
Hypohidrosis	6	0
Miliaria	222	0
Night sweats	1931	0
Sweat discolouration	3	0
Sweat gland disorder	1	0
<i>Bullous conditions</i>		
Autoimmune blistering disease	1	0
Blister	651	0
Blister rupture	7	0
Blood blister	114	0
Bullous haemorrhagic dermatosis	1	0
Dermatitis bullous	19	0
Dermatitis herpetiformis	2	0
Erythema multiforme	40	0
Linear IgA disease	1	0
Oedema blister	1	0
Pemphigoid	35	0
Pemphigus	9	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	3	0
Dermatomyositis	5	0
Subacute cutaneous lupus erythematosus	1	0
<i>Dermal and epidermal conditions NEC</i>		
Acute febrile neutrophilic dermatosis	4	0
Dermatosis	1	0

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Reaction Name	Total	Fatal
Skin disorders		
Skin disorders cont'd		
Dry skin	466	0
Macule	13	0
Myxoid cyst	1	0
Neutrophilic dermatosis	1	0
Pain of skin	945	0
Papule	127	0
Scab	32	0
Scar discomfort	1	0
Scar pain	19	0
Sensitive skin	598	0
Skin burning sensation	588	0
Skin discolouration	226	0
Skin discomfort	6	0
Skin disorder	48	0
Skin fissures	16	0
Skin fragility	3	0
Skin indentation	18	0
Skin induration	18	0
Skin laxity	1	0
Skin lesion	62	0
Skin necrosis	7	0
Skin odour abnormal	51	0
Skin plaque	3	0
Skin reaction	276	0
Skin sensitisation	90	0
Skin swelling	101	0
Skin texture abnormal	2	0
Skin tightness	43	0
Skin warm	584	0
Skin weeping	10	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	196	0
Dermatitis allergic	329	0
Dermatitis atopic	42	0
Dermatitis contact	36	0
Dermatitis diaper	3	0
Dyshidrotic eczema	21	0
Eczema	385	0
Eczema asteatotic	21	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	13	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Skin irritation	161	0
Stasis dermatitis	7	0
Urticarial dermatitis	1	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	38	0
Drug reaction with eosinophilia and systemic symptoms	13	0
Fixed eruption	8	0
Palmar-plantar erythrodysesthesia syndrome	3	0
<i>Erythemas</i>		
Erythema	3420	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	193	0
<i>Granulomatous and deep cutaneous inflammatory conditions</i>		
Granuloma annulare	9	0
Granuloma skin	1	0
<i>Hyperkeratoses</i>		
Hyperkeratosis	2	0
Lichenoid keratosis	1	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	35	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	16	0
Nail disorder	3	0
Nail growth abnormal	2	0
Nail hypertrophy	1	0
Nail necrosis	1	0
Nail pigmentation	2	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Nail pitting	1	0
Nail ridging	9	0
Onychalgia	7	0
Onychoclasia	11	0
Onycholysis	4	0
Onychomadesis	5	0
Splinter haemorrhages	6	0
<i>Panniculitides</i>		
Erythema nodosum	38	0
Panniculitis	4	0
<i>Papulosquamous conditions</i>		
Erythema annulare	2	0
Lichen planus	41	0
Lichen sclerosus	8	0
Lichen striatus	1	0
Parapsoriasis	2	0
Pityriasis lichenoides et varioliformis acuta	1	0
Pityriasis rosea	69	0
Pityriasis rubra pilaris	2	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photodermatosis	2	0
Photosensitivity reaction	172	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	2	0
Hair growth abnormal	8	0
Hair texture abnormal	14	0
Piloerection	101	0
Pseudofolliculitis	2	0
Trichodynia	7	0
Trichorrhexis	6	0
<i>Pruritus NEC</i>		
Itching scar	5	0
Pruritus	8372	0
Pruritus allergic	1	0
Senile pruritus	1	0
<i>Psoriatic conditions</i>		
Dermatitis psoriasiform	2	0
Erythrodermic psoriasis	2	0
Guttate psoriasis	30	0
Nail psoriasis	1	0
Palmoplantar pustulosis	3	0
Psoriasis	254	0
Pustular psoriasis	7	0
<i>Purpura and related conditions</i>		
Ecchymosis	5	0
Henoch-Schonlein purpura	18	0
Petechiae	380	0
Purpura	149	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
<i>Pustular conditions</i>		
Acute generalised exanthematous pustulosis	1	0
Rash follicular	4	0
<i>Rashes, eruptions and exanthems NEC</i>		
Butterfly rash	8	0
Nodular rash	1	0
Rash	9192	0
Rash erythematous	2275	0
Rash macular	779	0
Rash maculo-papular	69	0
Rash morbilliform	50	0
Rash papular	575	0
Rash pruritic	1983	0
Rash rubelliform	1	0
Rash scarlatiniform	2	0
Rash vesicular	107	0
Systemic lupus erythematosus rash	9	0
<i>Rosaceas</i>		
Erythematotelangiectatic rosacea	3	0
Granulomatous rosacea	1	0
Papulopustular rosacea	1	0
Rosacea	49	0
<i>Scaly conditions</i>		
Dandruff	1	0
Pityriasis	13	0
<i>Sebaceous gland disorders</i>		
Sebaceous glands overactivity	1	0
Seborrhoea	16	0
<i>Skin and subcutaneous conditions NEC</i>		
Cellulite	3	0
Cutaneous symptom	11	0
Skin discharge	1	0
Skin mass	45	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	58	0
Skin ulcer	35	0
Vasculitic ulcer	1	0
<i>Skin cysts and polyps</i>		
Dermal cyst	27	0
<i>Skin dystrophies</i>		
Keloid scar	3	0
Skin wrinkling	5	0
<i>Skin haemorrhages</i>		
Haemorrhage subcutaneous	21	0
Mucocutaneous haemorrhage	3	0
Skin haemorrhage	52	0
<i>Skin hyperplasias and hypertrophies</i>		
Skin hypertrophy	3	0
<i>Skin hypoplasias and atrophies</i>		

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Skin atrophy	12	0
Skin striae	13	0
Skin injuries and mechanical dermatoses		
Decubitus ulcer	5	0
Needle track marks	3	0
Skin preneoplastic conditions NEC		
Actinic keratosis	3	0
Leukoplakia	1	0
Skin vascular conditions NEC		
Angiodermatitis	1	0
Haemangioma-thrombocytopenia syndrome	1	0
Skin oedema	3	0
Skin vasculitides		
Capillaritis	1	0
Cutaneous vasculitis	15	0
Hypersensitivity vasculitis	4	0
Nodular vasculitis	1	0
Vasculitic rash	29	0
Skin vasomotor conditions		
Livedo reticularis	59	0
Telangiectasia and related conditions		
Spider naevus	5	0
Telangiectasia	5	0
Urticarias		
Chronic spontaneous urticaria	7	0
Cold urticaria	10	0
Idiopathic urticaria	10	0
Mechanical urticaria	9	0
Solar urticaria	1	0
Urticaria	2628	0
Urticaria cholinergic	1	0
Urticaria chronic	52	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	52749	0

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Reaction Name	Total	Fatal
Social circumstances		
<i>Age related issues</i>		
Childhood	1	0
Menarche	3	0
Menopause	77	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	99	0
Breast prosthesis user	2	0
Corrective lens user	1	0
Dependence on oxygen therapy	1	0
Disability	9	0
Hearing aid user	3	0
Hearing disability	1	0
Housebound	2	0
Immobile	57	0
Immobilisation prolonged	4	0
Impaired driving ability	6	0
Impaired work ability	33	0
Loss of personal independence in daily activities	15	0
Mental disability	1	0
Paralytic disability	1	0
Physical disability	3	0
Sight disability	26	0
Sitting disability	3	0
Walking aid user	2	0
Walking disability	9	0
Wheelchair user	3	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

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Reaction Name	Total	Fatal
Social circumstances <small>Social circumstances cont'd</small>		
<i>Pregnancy related circumstances</i>		
Breast feeding	9	0
<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 treatment by patient	1	0
Refusal of vaccination	3	0
Tanning	2	0
Tattoo	1	0
<i>Tobacco use</i>		
Non-tobacco user	6	0
Tobacco user	2	0
Social circumstances SOC TOTAL	448	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	2	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	2	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	2	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	5	0
<i>Haematological therapeutic procedures NEC</i>		
Anticoagulant therapy	2	0
Haemofiltration	1	0
Thrombosis prophylaxis	1	0
<i>Head, neck and oral cavity therapeutic procedures NEC</i>		
Neck lift	1	0
<i>Hormonal therapeutic procedures NEC</i>		
Hormone replacement therapy	7	0
Hormone therapy	9	0
Steroid therapy	1	0
<i>Immunisations</i>		
COVID-19 immunisation	222	0
Immunisation	117	0
Influenza immunisation	1	0
Tuberculosis immunisation	1	0
<i>Induced abortions</i>		
Abortion induced	4	0
<i>Iris and ciliary body therapeutic procedures</i>		
Pupil constriction procedure	1	0
<i>Joint therapeutic procedures</i>		
Hip surgery	1	0
Joint dislocation reduction	1	0
Joint injection	6	0
Joint stabilisation	2	0
Knee operation	2	0
Shoulder operation	3	0
<i>Large intestine therapeutic procedures</i>		
Appendectomy	8	0
Colectomy	2	0
<i>Limb therapeutic procedures</i>		
Arm amputation	1	0
Foot amputation	1	0
Leg amputation	6	0
Limb immobilisation	28	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Surgical & medical procedures cont'd</i>		
Limb operation	13	0
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		
Asthma prophylaxis	1	0
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	2	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	25	0
Catheter management	4	0
Catheter placement	2	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Surgical & medical procedures cont'd</i>		
Continuous passive motion machine therapy	1	0
Fatigue management	1	0
Heat therapy	3	0
Hospitalisation	30	0
Immobilisation bandage	1	0
Injection	55	0
Interchange of vaccine products	54	0
Localised alternating hot and cold therapy	6	0
Magnetic therapy	2	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
Rehabilitation therapy	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	4	0
Thromboembolectomy	1	0
Thrombolysis	2	0
Vascular graft	1	0
<i>Venous therapeutic procedures</i>		
Phlebotomy	2	0
Surgical & medical procedures SOC TOTAL	856	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	7	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	13	2
<i>Aortic infections and inflammations</i>		
Aortitis	2	0
<i>Aortic necrosis and vascular insufficiency</i>		
Aortic occlusion	1	0
Aortic stenosis	3	0
<i>Arterial infections and inflammations</i>		
Arteritis	5	0
Giant cell arteritis	61	0
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	25	0
Labile blood pressure	5	0
<i>Bruising, ecchymosis and purpura</i>		
Achenbach syndrome	10	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	132	2
Distributive shock	2	0
Hypoperfusion	2	0
Hypovolaemic shock	1	0
Neurogenic shock	10	0
Peripheral circulatory failure	4	0
Shock	59	1
Shock haemorrhagic	1	0
Shock symptom	6	0
<i>Haemorrhages NEC</i>		
Bloody discharge	16	0
Haematoma	115	0
Haemorrhage	1467	2
Internal haemorrhage	31	0
Venous haemorrhage	9	0
<i>Lymphangiopathies</i>		
Lymphangiopathy	2	0

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Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
Lymphocele	2	0
Lymphorrhoea	1	0
Lymphoedemas		
Lymphoedema	77	0
Non-site specific embolism and thrombosis		
Air embolism	1	0
Arterial thrombosis	31	1
Atheroembolism	1	0
Embolism	255	3
Embolism arterial	4	0
Embolism venous	13	1
Microembolism	3	0
Paradoxical embolism	1	0
Post thrombotic syndrome	4	0
Thrombophlebitis migrans	2	0
Thrombosis	1885	40
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	9	0
Haemorrhagic infarction	1	0
Infarction	14	0
Ischaemia	15	0
Peripheral venous disease	11	0
Vascular compression	2	0
Vascular occlusion	3	0
Vasospasm	13	0
Venous occlusion	1	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	8	0
Vascular fragility	1	0
Vascular pain	136	0
Vascular rupture	2	0
Vascular wall discolouration	1	0
Vasodilatation	124	0
Vein collapse	2	0
Vein discolouration	8	0
Vein disorder	26	0
Vein rupture	17	0
Peripheral aneurysms and dissections		
Peripheral artery aneurysm	2	0
Peripheral embolism and thrombosis		
Axillary vein thrombosis	1	0

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Reaction Name	Total	Fatal
Vascular disorders <small>Vascular disorders cont'd</small>		
Blue toe syndrome	41	0
Deep vein thrombosis	1281	9
Femoral artery embolism	2	0
Iliac artery embolism	2	0
Jugular vein thrombosis	28	0
Pelvic venous thrombosis	24	1
Peripheral artery thrombosis	20	0
Peripheral embolism	11	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	72	0
Thrombophlebitis	143	0
Venous thrombosis limb	7	0
Peripheral vascular disorders NEC		
Cyanosis	112	0
Erythromelalgia	7	0
Flushing	711	0
Hot flush	2207	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	1328	0
Peripheral ischaemia	35	2
Poor peripheral circulation	58	0
Raynaud's phenomenon	155	0
Phlebitis NEC		
Phlebitis	64	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	427	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	155	0
Varicose vein ruptured	1	0

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Reaction Name	Total	Fatal
Vascular disorders <small>Vascular disorders cont'd</small>		
<i>Vascular hypertensive disorders NEC</i>		
Diastolic hypertension	5	0
Essential hypertension	1	0
Hypertension	1030	0
Labile hypertension	2	0
Systolic hypertension	3	0
Venous hypertension	4	0
White coat hypertension	12	0
<i>Vascular hypotensive disorders</i>		
Capillary leak syndrome	16	0
Diastolic hypotension	1	0
Hypotension	556	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	2	0
MAGIC syndrome	3	1
Vasculitis	111	2
<i>Vena caval embolism and thrombosis</i>		
Vena cava thrombosis	6	1
Vascular disorders SOC TOTAL	13628	73
TOTAL REACTIONS FOR DRUG	855968	1182
TOTAL REPORTS	241657	
TOTAL FATAL OUTCOME REPORTS		1182