

COVID-19 AstraZeneca Vaccine Analysis Print

All UK spontaneous reports received between 04/01/21 and 15/06/22 for COVID-19 vaccine Oxford University/AstraZeneca.

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

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 16-Jun-2022

Data Lock Date: 15-Jun-2022 18:30:06

MedDRA Version: MedDRA 25.0

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	197	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	10	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	143	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	31	0
Coagulopathy	90	0
Disseminated intravascular coagulation	19	2
Hypercoagulation	30	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	16	1
Bone marrow disorder	3	0
Bone marrow oedema	1	0
Mast cell activation syndrome	17	0
Mastocytosis	4	0
Methaemoglobinaemia	1	0
<i>Haemolyses NEC</i>		
Haemolysis	11	0
<i>Leukocytoses NEC</i>		
Leukocytosis	5	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	598	0
Lymphadenitis	36	0
Lymphadenopathy	5043	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	7	0
Cytopenia	1	0
Myelosuppression	5	0
Pancytopenia	20	1
Neutropenias		
Agranulocytosis	4	0
Autoimmune neutropenia	2	0
Febrile neutropenia	1	0
Neutropenia	84	0
Platelet disorders NEC		
Platelet anisocytosis	4	0
Platelet disorder	9	0
Polycythaemia (excl rubra vera)		
Polycythaemia	4	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
Red blood cell abnormality	1	0
Rouleaux formation	1	0
Sickle cell trait and disorders		
Sickle cell anaemia with crisis	7	0
Spleen disorders		
Spleen disorder	1	0
Splenic artery thrombosis	3	0
Splenic haemorrhage	1	0
Splenic infarction	19	0
Splenic thrombosis	1	0
Splenic varices	1	0
Splenic vein thrombosis	13	0

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Reaction Name	Total	Fatal
Blood disorders Blood disorders cont'd		
Splenomegaly	8	0
Spleno renal shunt	1	0
<i>Thrombocytopenias</i>		
Autoimmune heparin-induced thrombocytopenia	1	0
Heparin-induced thrombocytopenia	17	0
Immune thrombocytopenia	226	1
Thrombocytopenia	896	9
Thrombocytopenic purpura	11	0
Thrombosis with thrombocytopenia syndrome	34	2
Thrombotic thrombocytopenic purpura	11	0
<i>Thrombocytoses</i>		
Thrombocytosis	13	0
<i>White blood cell abnormal findings NEC</i>		
White blood cell disorder	4	0
Blood disorders SOC TOTAL	7870	17

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Aortic valvular disorders</i>		
Aortic valve incompetence	5	0
Aortic valve sclerosis	1	0
Aortic valve stenosis	1	0
<i>Cardiac conduction disorders</i>		
Atrioventricular block	35	2
Atrioventricular block complete	3	0
Atrioventricular block first degree	4	0
Atrioventricular block second degree	5	0
Bundle branch block	2	0
Bundle branch block left	10	0
Bundle branch block right	5	0
Long QT syndrome	2	0
Trifascicular block	2	0
<i>Cardiac disorders NEC</i>		
Acute cardiac event	4	2
Atrial thrombosis	5	0
Cardiac disorder	108	3
Cardiac dysfunction	2	0
Cardiac ventricular thrombosis	14	2
Cardiovascular disorder	10	0
Cardiovascular insufficiency	10	0
Intracardiac thrombus	20	3
<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	20	0
Cardiovascular symptom	3	0
Palpitations	6023	0
<i>Cardiac valve disorders NEC</i>		
Cardiac valve disease	4	1
Heart valve incompetence	4	0
<i>Cardiomyopathies</i>		
Cardiomyopathy	19	1
Cardiomyopathy acute	1	0
Congestive cardiomyopathy	13	1
Stress cardiomyopathy	6	0
<i>Coronary artery disorders NEC</i>		
Arteriosclerosis coronary artery	10	1
Coronary artery disease	12	0
Coronary artery dissection	5	1
Coronary artery embolism	1	0
Coronary artery occlusion	5	0
Coronary artery stenosis	1	0
Coronary artery thrombosis	28	4
<i>Heart failure signs and symptoms</i>		
Cardiac asthma	1	0
<i>Heart failures NEC</i>		
Cardiac failure	118	15
Cardiac failure acute	14	5
Cardiac failure chronic	3	1

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Reaction Name	Total	Fatal
Cardiac disorders Cardiac disorders cont'd		
Cardiac failure congestive	8	4
Cardiogenic shock	11	2
Cardiopulmonary failure	2	2
Ventricular failure	1	0
Ischaemic coronary artery disorders		
Acute coronary syndrome	9	0
Acute myocardial infarction	91	14
Angina pectoris	271	0
Angina unstable	19	0
Arteriospasm coronary	7	0
Microvascular coronary artery disease	2	0
Myocardial infarction	513	65
Myocardial ischaemia	36	14
Prinzmetal angina	2	0
Left ventricular failures		
Acute left ventricular failure	2	0
Left ventricular failure	10	1
Mitral valvular disorders		
Ischaemic mitral regurgitation	1	0
Mitral valve disease	1	0
Mitral valve incompetence	11	0
Mitral valve prolapse	5	0
Myocardial disorders NEC		
Cardiac aneurysm	1	0
Cardiac sarcoidosis	1	0
Cardiac ventricular scarring	1	0
Cardiomegaly	37	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	5	0
Myocardial fibrosis	3	0
Myocardial injury	21	0
Myocardial oedema	1	0
Myocardial rupture	2	0
Right atrial dilatation	2	0
Right ventricular dilatation	3	0
Right ventricular dysfunction	5	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	5
Myocarditis post infection	1	0
Myopericarditis	29	0
Noninfectious pericarditis		
Autoimmune pericarditis	1	0
Pericarditis	220	0
Pericardial disorders NEC		

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Cardiac disorders Cardiac disorders cont'd		
Cardiac tamponade	2	2
Pericardial disease	1	0
Pericardial effusion	43	0
Pericardial haemorrhage	10	4
Pericardial rub	3	0
Rate and rhythm disorders NEC		
Arrhythmia	165	4
Arrhythmia neonatal	1	0
Bradyarrhythmia	1	0
Bradycardia	95	1
Cardiac fibrillation	9	0
Cardiac flutter	318	0
Extrasystoles	170	0
Heart alternation	4	0
Paroxysmal arrhythmia	2	0
Postural orthostatic tachycardia syndrome	39	0
Tachyarrhythmia	11	0
Tachycardia	1707	0
Right ventricular failures		
Right ventricular failure	4	1
Supraventricular arrhythmias		
Arrhythmia supraventricular	20	0
Atrial fibrillation	370	1
Atrial flutter	53	0
Atrial tachycardia	4	0
Sinus arrest	1	0
Sinus arrhythmia	3	0
Sinus bradycardia	6	0
Sinus node dysfunction	2	0
Sinus tachycardia	72	0
Supraventricular extrasystoles	2	0
Supraventricular tachycardia	45	0
Tricuspid valvular disorders		
Tricuspid valve incompetence	9	0
Ventricular arrhythmias and cardiac arrest		
Cardiac arrest	198	43
Cardio-respiratory arrest	2	1
Pulseless electrical activity	7	0
Ventricular arrhythmia	2	0
Ventricular extrasystoles	25	0
Ventricular fibrillation	10	1
Ventricular tachycardia	19	0
Cardiac disorders SOC TOTAL	11554	209

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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>		
Brugada syndrome	1	0
Heart disease congenital	12	0
<i>Cardiac septal defects congenital</i>		
Atrial septal defect	1	0
Hypertrophic cardiomyopathy	3	0
<i>Cardiac valve disorders congenital</i>		
Bicuspid aortic valve	1	0
<i>Central nervous system disorders congenital NEC</i>		
Brain malformation	1	0
Neural tube defect	1	1
Spina bifida	2	0
Syringomyelia	1	0
<i>Cerebellar disorders congenital</i>		
Arnold-Chiari malformation	2	0
<i>Cerebral disorders congenital</i>		
Anencephaly	1	0
Cerebral palsy	2	0
<i>Coagulation disorders congenital</i>		
Factor VII deficiency	1	0
<i>Congenital disorders NEC</i>		
Congenital anomaly	5	0
Congenital midline defect	1	0
Heterotaxia	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>Gastrointestinal tract disorders congenital NEC</i>		
Gastrointestinal malformation	1	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 lipid metabolism</i>		
Type IIa hyperlipidaemia	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	3	0
Micropenis	2	0
Penoscrotal fusion	3	0

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Reaction Name	Total	Fatal
Congenital disorders Congenital disorders cont'd		
<i>Multiple cardiac abnormalities congenital</i>		
Multiple cardiac defects	1	0
<i>Musculoskeletal and connective tissue disorders of face, neck and jaw congenital</i>		
Branchial cyst	3	0
<i>Musculoskeletal and connective tissue disorders of limbs congenital</i>		
Limb reduction defect	2	0
Os trigonum	1	0
<i>Musculoskeletal disorders congenital NEC</i>		
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
Huntington's disease	1	1
Neurofibromatosis	1	0
Spinal muscular atrophy	1	0
Tourette's disorder	3	0
<i>Ocular disorders congenital NEC</i>		
Colour blindness	9	0
<i>Palate disorders congenital</i>		
Cleft lip and palate	1	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
Congenital disorders SOC TOTAL	112	2

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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	128	0
Ear disorder	23	0
Ear haemorrhage	20	0
Ear inflammation	2	0
Ear pain	2122	0
Ear pruritus	7	0
Ear swelling	79	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	42	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
Dysacusis	1	0
<i>Hearing losses</i>		
Conductive deafness	1	0
Deafness	433	1
Deafness bilateral	21	0
Deafness neurosensory	43	0
Deafness transitory	4	0
Deafness unilateral	59	0
Hypoacusis	255	0
Mixed deafness	3	0
Neurosensory hypoacusis	2	0
Sudden hearing loss	86	0
<i>Hyperacusia</i>		
Hyperacusis	182	0
<i>Inner ear disorders NEC</i>		
Endolymphatic hydrops	1	0
Inner ear disorder	8	0
Meniere's disease	30	0
Vestibular disorder	11	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	131	0
Phobic postural vertigo	2	0
Tinnitus	4526	0
Vertigo	2344	0

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Reaction Name	Total	Fatal
Ear disorders Ear disorders cont'd		
Vertigo labyrinthine	18	0
Vertigo positional	161	0
<i>Middle ear disorders NEC</i>		
Middle ear disorder	1	0
Middle ear effusion	6	0
<i>Tympanic membrane disorders (excl infections)</i>		
Tympanic membrane perforation	7	0
Ear disorders SOC TOTAL	10863	1

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Autoimmune thyroiditis	10	0
Thyroiditis	22	0
Thyroiditis acute	9	0
Thyroiditis chronic	2	0
Thyroiditis subacute	9	0
<i>Adrenal cortical hyperfunctions</i>		
Cushing's syndrome	2	0
Cushingoid	5	0
<i>Adrenal cortical hypofunctions</i>		
Addison's disease	4	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	2	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	3	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	18	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	9	0
Inappropriate antidiuretic hormone secretion	1	0
<i>Thyroid disorders NEC</i>		
Autoimmune thyroid disorder	1	0

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Endocrine disorders Endocrine disorders cont'd		
Euthyroid sick syndrome	1	0
Goitre	28	0
Thyroid disorder	29	0
Thyroid mass	9	0
Thyroid pain	20	0
Thyroid hyperfunction disorders		
Basedow's disease	28	0
Hyperthyroidism	70	0
Thyrotoxic crisis	6	0
Thyroid hypofunction disorders		
Hypothyroidism	70	0
Immune-mediated hypothyroidism	1	0
Thyroid neoplasms		
Thyroid cyst	1	0
Endocrine disorders SOC TOTAL	492	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Amblyopic vision impairment</i>		
Amblyopia	13	0
<i>Cataract conditions</i>		
Cataract	26	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	1	0
Vitreous detachment	60	0
Vitreous floaters	215	0
Vitreous opacities	1	0
<i>Colour blindness (incl acquired)</i>		
Dyschromatopsia	21	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	131	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	163	0
Excessive eye blinking	9	0
Eyelid function disorder	1	0
Eyelid myokymia	2	0
Eyelid ptosis	65	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	27	0
Iritis	15	0
Uveitis	54	0
<i>Lacrimation disorders</i>		
Dry eye	331	0
Lacrimal disorder	1	0
Lacrimation increased	267	0

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
<i>Lens structural change, deposit and degeneration (excl cataracts)</i>		
Anterior capsule contraction	2	0
<i>Lid bleeding and vascular disorders</i>		
Eyelid bleeding	3	0
Eyelid haematoma	3	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Blepharitis	33	0
Chalazion	2	0
Eczema eyelids	9	0
Erythema of eyelid	9	0
Eyelid cyst	20	0
Eyelid irritation	5	0
Eyelid margin crusting	1	0
Eyelid oedema	14	0
Eyelid rash	15	0
Meibomianitis	1	0
Swelling of eyelid	144	0
<i>Lid, lash and lacrimal structural disorders</i>		
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	5	0
<i>Ocular bleeding and vascular disorders NEC</i>		
Eye haematoma	4	0
Eye haemorrhage	116	0
Ocular retrobulbar haemorrhage	1	0
Ocular vascular disorder	2	0
Ophthalmic vein thrombosis	4	0
<i>Ocular cysts and polyps</i>		
Vitreous cyst	1	0
<i>Ocular disorders NEC</i>		
Dark circles under eyes	12	0
Eye disorder	51	0
Eye oedema	20	0
Eye pain	3426	0
Eye swelling	654	0
Eye symptom	11	0
Eye ulcer	11	0
Eyelid disorder	18	0
Eyelid pain	21	0
Eyelids pruritus	13	0
Ocular discomfort	90	0
Periorbital discomfort	1	0
Periorbital oedema	18	0
Periorbital pain	4	0
Periorbital swelling	111	0
Retinal disorder	2	0
Retinal fovea disorder	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		

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Report Run Date: 16-Jun-2022

Data Lock Date: 15-Jun-2022 18:30:06

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Autoimmune eye disorder	1	0
Eye allergy	32	0
Eye discharge	30	0
Eye inflammation	36	0
Eye irritation	210	0
Eye pruritus	309	0
Limbal swelling	8	0
Ocular hyperaemia	478	0
Ocular rosacea	1	0
Ocular nerve and muscle disorders		
Eye movement disorder	58	0
Gaze palsy	5	0
Ocular myasthenia	4	0
Ophthalmoplegia	15	0
Parinaud syndrome	1	0
Strabismus	5	0
Tolosa-Hunt syndrome	1	0
Ocular sensation disorders		
Abnormal sensation in eye	29	0
Asthenopia	365	0
Eye paraesthesia	5	0
Eyelid sensory disorder	5	0
Foreign body sensation in eyes	37	0
Hypoaesthesia eye	30	0
Photophobia	1099	0
Optic disc abnormalities NEC		
Optic atrophy	2	0
Optic discs blurred	3	0
Papilloedema	17	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	2	0
Pupil disorders		
Anisocoria	12	0
Holmes-Adie pupil	1	0
Miosis	16	0
Mydriasis	35	0
Pupil fixed	15	0
Pupillary deformity	1	0
Pupillary reflex impaired	4	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)		

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Retinal aneurysm	2	0
Retinal artery embolism	5	0
Retinal artery occlusion	29	0
Retinal haemorrhage	22	0
Retinal infarction	1	0
Retinal ischaemia	2	0
Retinal vascular occlusion	3	0
Retinal vascular thrombosis	4	0
Retinal vein occlusion	107	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	2	0
Macular cyst	1	0
Macular degeneration	9	0
Macular detachment	1	0
Macular hole	2	0
Macular rupture	2	0
Maculopathy	4	0
Neovascular age-related macular degeneration	13	0
Retinal degeneration	1	0
Retinal detachment	31	0
Retinal drusen	1	0
Retinal tear	21	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 occlusive vasculitis	1	0
Retinal oedema	3	0
Retinal vasculitis	1	0
<i>Retinopathies NEC</i>		
Acute macular neuroretinopathy	6	0
Central serous chorioretinopathy	1	0
Diabetic retinopathy	3	0
Retinal exudates	17	0
Retinal white dots syndrome	1	0
Retinopathy	8	0
Serous retinopathy	1	0
<i>Scleral infections, irritations and inflammations</i>		
Episcleritis	22	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	6	0
Exophthalmos	8	0
Eye opacity	1	0
<i>Visual colour distortions</i>		
Chloropsia	2	0

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Chromatopsia	1	0
Cyanopsia	3	0
Erythropsia	7	0
Xanthopsia	9	0
Visual disorders NEC		
Charles Bonnet syndrome	1	0
Delayed dark adaptation	1	0
Diplopia	372	0
Dysmetropsia	1	0
Halo vision	13	0
Metamorphopsia	42	0
Oscillopsia	1	0
Photopsia	349	0
Scintillating scotoma	10	0
Vision blurred	3164	0
Visual brightness	10	0
Visual snow syndrome	6	0
Visual field disorders		
Visual field defect	46	0
Visual impairment and blindness (excl colour blindness)		
Amaurosis	1	0
Amaurosis fugax	10	0
Blindness	329	0
Blindness cortical	1	0
Blindness day	1	0
Blindness transient	28	0
Blindness unilateral	49	0
Central vision loss	3	0
Night blindness	6	0
Sudden visual loss	6	0
Visual acuity reduced	40	0
Visual acuity reduced transiently	1	0
Visual impairment	846	0
Visual pathway disorders		
Optic nerve compression	2	0
Optic nerve disorder	5	0
Optic neuropathy	11	0
Eye disorders SOC TOTAL	15020	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Abdominal findings abnormal</i>		
Abdominal mass	4	0
Gastrointestinal sounds abnormal	27	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	42	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	29	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	8	0
Anal rash	1	0
Anal spasm	1	0
Anorectal discomfort	12	0
Anorectal swelling	1	0
Rectal discharge	2	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	15	0
Tongue cyst	5	0
Tongue polyp	2	0
<i>Colitis (excl infective)</i>		
Autoimmune colitis	5	0
Colitis	64	0
Colitis ischaemic	8	1
Colitis microscopic	6	0
Colitis ulcerative	115	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	8	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 Gastrointestinal disorders cont'd		
Loose tooth	3	0
Malpositioned teeth	3	0
Teething	22	0
Tooth disorder	5	0
Tooth erosion	1	0
Tooth socket haemorrhage	2	0
Dental pain and sensation disorders		
Dental discomfort	12	0
Dental paraesthesia	18	0
Hyperaesthesia teeth	68	0
Hypoaesthesia teeth	2	0
Toothache	347	0
Dental pulp disorders		
Dental pulp disorder	1	0
Dental surface disorders		
Tooth discolouration	19	0
Diaphragmatic hernias		
Hiatus hernia	21	0
Diarrhoea (excl infective)		
Diarrhoea	9041	0
Diarrhoea haemorrhagic	34	0
Diverticula		
Diverticulum	12	0
Diverticulum intestinal	1	0
Duodenal and small intestinal stenosis and obstruction		
Small intestinal obstruction	1	0
Superior mesenteric artery syndrome	1	0
Duodenal ulcers and perforation		
Duodenal ulcer	2	0
Duodenal ulcer haemorrhage	2	1
Dyspeptic signs and symptoms		
Dyspepsia	916	0
Epigastric discomfort	20	0
Eructation	111	0
Faecal abnormalities NEC		
Abnormal faeces	27	0
Faecaloma	5	0
Faeces discoloured	56	0
Faeces hard	4	0
Faeces pale	8	0
Faeces soft	23	0
Mucous stools	16	0
Flatulence, bloating and distension		
Abdominal distension	747	0
Aerophagia	1	0
Flatulence	409	0
Gastric and oesophageal haemorrhages		
Gastric haemorrhage	16	1
Gastric ulcers and perforation		
Gastric ulcer	13	0
Gastric ulcer haemorrhage	1	0
Gastric ulcer perforation	1	0
Gastritis (excl infective)		

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Reaction Name	Total	Fatal
Gastrointestinal disorders Gastrointestinal disorders cont'd		
Chronic gastritis	5	0
Gastritis	122	0
Reflux gastritis	19	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal migraine	3	0
Abdominal pain	4637	1
Abdominal pain lower	272	0
Abdominal pain upper	5366	0
Abdominal rigidity	64	0
Abdominal tenderness	25	0
Gastrointestinal pain	336	0
Oesophageal pain	10	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	520	0
Duodenogastric reflux	4	0
Gastric dilatation	18	0
Gastrooesophageal reflux disease	251	0
Impaired gastric emptying	9	0
Infrequent bowel movements	3	0
Intestinal dilatation	3	0
Oesophageal hypomotility	1	0
<i>Gastrointestinal disorders NEC</i>		
Appendix disorder	4	0
Food poisoning	13	0
Functional gastrointestinal disorder	25	0
Gastric disorder	20	0
Gastrointestinal disorder	54	0
Gastrointestinal oedema	3	0
Gastroptosis	1	0
Neurogenic bowel	3	0
Stomach mass	2	0
<i>Gastrointestinal dyskinetic disorders</i>		
Bowel movement irregularity	9	0
Change of bowel habit	24	0
Dyschezia	14	0
Gastrointestinal motility disorder	6	0
Oesophageal achalasia	5	0
<i>Gastrointestinal fistulae</i>		
Anal fistula	1	0
<i>Gastrointestinal inflammatory disorders NEC</i>		
Appendicitis noninfective	2	0
Duodenitis	1	0
Enteritis	1	0
Gastrointestinal inflammation	3	0
Gastrointestinal tract irritation	4	0
Intestinal angioedema	1	0
Ischaemic enteritis	1	0
<i>Gastrointestinal mucosal dystrophies and secretion disorders</i>		
Achlorhydria	1	0
Barrett's oesophagus	1	0
Hyperchlorhydria	4	0
<i>Gastrointestinal necrosis and gangrene (excl gangrenous hernia)</i>		
Gastrointestinal necrosis	2	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders Gastrointestinal disorders cont'd		
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	1623	0
Abdominal symptom	6	0
Acute abdomen	18	0
Anal incontinence	61	0
Breath odour	25	0
Dysphagia	308	0
Intestinal congestion	1	0
Odynophagia	35	0
Oesophageal discomfort	1	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Cardiospasm	2	1
Defaecation urgency	17	0
Frequent bowel movements	51	0
Irritable bowel syndrome	165	0
Oesophageal spasm	9	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Intestinal obstruction	8	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	39	1
Mesenteric arterial occlusion	1	0
Mesenteric artery embolism	1	0
Mesenteric artery stenosis	1	0
Mesenteric artery thrombosis	5	0
Mesenteric vein thrombosis	24	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	243	0
Gingival pruritus	1	0
Gingival recession	3	0
Gingival swelling	59	0
Gingival ulceration	10	0
Gingivitis ulcerative	2	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders Gastrointestinal disorders cont'd		
Noninfective gingivitis	24	0
Gingival haemorrhages		
Gingival bleeding	186	0
Haemorrhoids and gastrointestinal varices (excl oesophageal)		
Anorectal varices	1	0
Haemorrhoidal haemorrhage	4	0
Haemorrhoids	72	0
Haemorrhoids thrombosed	15	0
Inguinal hernias		
Inguinal hernia	5	0
Intestinal haemorrhages		
Anal haemorrhage	52	0
Intestinal haemorrhage	1	0
Lower gastrointestinal haemorrhage	3	0
Mesenteric haemorrhage	5	0
Rectal haemorrhage	123	0
Small intestinal haemorrhage	27	0
Intestinal ulcers and perforation NEC		
Intestinal perforation	5	0
Large intestine perforation	1	0
Large intestinal stenosis and obstruction		
Large intestinal obstruction	1	0
Large intestinal stenosis	1	0
Malabsorption syndromes		
Bile acid malabsorption	1	0
Coeliac disease	24	0
Steatorrhoea	2	0
Nausea and vomiting symptoms		
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	33664	0
Regurgitation	3	0
Retching	237	0
Vomiting	11504	0
Vomiting projectile	157	0
Non-site specific gastrointestinal haemorrhages		
Gastrointestinal haemorrhage	41	2
Haematemesis	82	0
Haematochezia	111	0
Intra-abdominal haematoma	2	0
Intra-abdominal haemorrhage	2	0
Melaena	10	0
Upper gastrointestinal haemorrhage	10	0
Oesophageal disorders NEC		
Oesophageal disorder	2	0
Oesophageal stenosis and obstruction		
Acquired oesophageal web	1	0
Oesophageal obstruction	1	0
Oesophageal ulcers and perforation		

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Reaction Name	Total	Fatal
Gastrointestinal disorders Gastrointestinal disorders cont'd		
Oesophageal rupture	1	1
Oesophageal ulcer	1	0
Oesophageal varices		
Varices oesophageal	3	0
Oesophagitis (excl infective)		
Eosinophilic oesophagitis	3	0
Oesophagitis	21	0
Oral dryness and saliva altered		
Aptyalism	5	0
Dry mouth	1172	0
Lip dry	81	0
Saliva altered	9	0
Saliva discolouration	1	0
Salivary hypersecretion	95	0
Oral soft tissue disorders NEC		
Angina bullosa haemorrhagica	4	0
Chapped lips	25	0
Cheilitis	41	0
Chronic cheek biting	1	0
Enlarged uvula	11	0
Leukoplakia oral	2	0
Lip blister	38	0
Lip disorder	6	0
Oral disorder	22	0
Oral lichen planus	18	0
Oral papule	2	0
Palatal disorder	2	0
Uvulitis	5	0
Oral soft tissue haemorrhages		
Lip haemorrhage	4	0
Mouth haemorrhage	60	0
Oral blood blister	55	0
Oral purpura	2	0
Oral soft tissue infections		
Angular cheilitis	12	0
Oral soft tissue signs and symptoms		
Anaesthesia oral	8	0
Burning mouth syndrome	17	0
Coating in mouth	4	0
Hypoaesthesia oral	684	0
Lip discolouration	5	0
Lip erythema	4	0
Lip exfoliation	9	0
Lip pain	61	0
Lip pruritus	16	0
Oral discharge	1	0
Oral discomfort	115	0
Oral dysaesthesia	1	0
Oral mucosal blistering	35	0
Oral mucosal discolouration	1	0
Oral mucosal eruption	33	0
Oral mucosal erythema	3	0
Oral mucosal exfoliation	11	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders Gastrointestinal disorders cont'd		
Oral mucosal roughening	3	0
Oral pain	373	0
Oral pruritus	21	0
Paraesthesia oral	881	0
Oral soft tissue swelling and oedema		
Lip oedema	10	0
Lip swelling	1019	0
Mouth swelling	141	0
Oedema mouth	1	0
Palatal oedema	1	0
Palatal swelling	14	0
Pancreatic disorders NEC		
Pancreatic disorder	1	0
Pancreatic failure	1	0
Pancreatic mass	1	0
Pancreatic steatosis	1	0
Peptic ulcers and perforation		
Peptic ulcer	2	0
Peptic ulcer haemorrhage	9	0
Peritoneal and retroperitoneal disorders		
Ascites	9	0
Pneumoperitoneum	1	0
Peritoneal and retroperitoneal fibrosis and adhesions		
Abdominal adhesions	2	0
Peritoneal and retroperitoneal haemorrhages		
Haemoperitoneum	2	0
Retroperitoneal haematoma	1	0
Retroperitoneal haemorrhage	1	0
Rectal inflammations NEC		
Proctitis	5	0
Salivary gland disorders NEC		
Salivary gland calculus	4	0
Salivary gland cyst	1	0
Salivary gland disorder	1	0
Salivary gland mass	2	0
Salivary gland pain	13	0
Salivary gland enlargements		
Parotid gland enlargement	14	0
Salivary gland enlargement	6	0
Salivary gland infections and inflammations		
Noninfective sialoadenitis	2	0
Stomatitis and ulceration		
Apthous ulcer	66	0
Lip ulceration	19	0
Mouth ulceration	780	0
Stomatitis	112	0
Tongue disorders		
Acquired macroglossia	1	0
Glossitis	19	0
Plicated tongue	4	0
Tongue disorder	37	0
Tongue geographic	6	0
Tongue haemorrhage	2	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders Gastrointestinal disorders cont'd		
Tongue ulceration	33	0
Trichoglossia	7	0
<i>Tongue signs and symptoms</i>		
Glossodynia	270	0
Scalloped tongue	4	0
Stiff tongue	6	0
Strawberry tongue	1	0
Swollen tongue	643	0
Tongue blistering	29	0
Tongue coated	37	0
Tongue discolouration	41	0
Tongue discomfort	58	0
Tongue dry	25	0
Tongue eruption	12	0
Tongue erythema	7	0
Tongue exfoliation	3	0
Tongue movement disturbance	9	0
Tongue oedema	17	0
Tongue pruritus	3	0
Tongue rough	4	0
Tongue spasm	6	0
<i>Tooth missing</i>		
Tooth loss	12	0
Gastrointestinal disorders SOC TOTAL	81151	15

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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	3	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	54	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	5210	2
Chronic fatigue syndrome	180	0
Decreased activity	16	0
Fatigue	51461	0
Malaise	12876	0
Sluggishness	32	0
<i>Body temperature altered</i>		
Hyperthermia	13	0
Hypothermia	59	0
Temperature regulation disorder	31	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
Medical device site papule	1	0
Phantom shocks	4	0
<i>Death and sudden death</i>		
Brain death	5	3
Cardiac death	8	7
Death	327	327
Drowning	1	0
Hanging	2	1
Sudden cardiac death	2	2
Sudden death	43	43
Sudden unexplained death in epilepsy	1	1
<i>Febrile disorders</i>		
Hyperpyrexia	42	0
Masked fever	1	0
PFAPA syndrome	1	0
Pyrexia	55713	0
<i>Feelings and sensations NEC</i>		
Chills	43270	0
Early satiety	1	0
Feeling abnormal	3456	0
Feeling cold	5306	0
Feeling drunk	132	0
Feeling hot	2503	0
Feeling jittery	50	0
Feeling of body temperature change	975	0
Feeling of relaxation	2	0
Hangover	200	0
Humidity intolerance	1	0
Hunger	84	0
Sensation of blood flow	17	0
Sensation of foreign body	59	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Temperature intolerance	94	0
Thirst	1276	0
Thirst decreased	11	0
Fibrosis NEC		
Fibrosis	8	0
Gait disturbances		
Decreased gait velocity	3	0
Gait disturbance	526	0
Gait inability	249	0
Loss of control of legs	63	0
General signs and symptoms NEC		
Apparent death	1	0
Chronic disease	1	0
Condition aggravated	358	0
Crepitations	10	0
Crying	306	0
Deformity	1	0
Developmental delay	3	0
Discharge	9	0
Disease prodromal stage	1	0
Disease progression	3	1
Disease recurrence	2	0
Effusion	2	0
Energy increased	26	0
Exercise tolerance decreased	48	0
Foaming at mouth	6	0
General physical health deterioration	35	2
General symptom	12	0
Glassy eyes	8	0
High-pitched crying	8	0
Idiopathic environmental intolerance	2	0
Ill-defined disorder	14	0
Illness	5172	1
Impaired self-care	2	0
Induration	23	0
Influenza like illness	9745	0
Irritability postvaccinal	3	0
Local reaction	157	0
Moaning	9	0
Multiple organ dysfunction syndrome	29	14
Nonspecific reaction	3	0
Organ failure	5	0
Perforation	2	0
Performance status decreased	1	0
Peripheral swelling	6091	0
Pre-existing condition improved	18	0
Premature ageing	3	0
Prolapse	1	0
Screaming	34	0
Secretion discharge	35	0
Sensitivity to weather change	3	0
Stenosis	3	0
Swelling	2868	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Swelling face	1137	0
Symptom masked	1	0
Symptom recurrence	4	0
Tissue discolouration	1	0
Tissue infiltration	1	0
Unevaluable event	9	0
Healing abnormal NEC		
Impaired healing	8	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	5	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
Inflammations		
Granuloma	2	0
Inflammation	920	0
Papillitis	1	0
Scar inflammation	1	0
Serositis	1	0
Systemic inflammatory response syndrome	9	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	50	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	24	0
Injection site dryness	1	0
Injection site erythema	606	0
Injection site exfoliation	1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Injection site extravasation	2	0
Injection site haematoma	3	0
Injection site haemorrhage	22	0
Injection site hypersensitivity	5	0
Injection site hypoaesthesia	17	0
Injection site indentation	22	0
Injection site induration	11	0
Injection site inflammation	67	0
Injection site injury	6	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	1430	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	5	0
Injection site oedema	28	0
Injection site pain	4549	0
Injection site papule	2	0
Injection site paraesthesia	26	0
Injection site pruritus	302	0
Injection site rash	311	0
Injection site reaction	124	0
Injection site scab	4	0
Injection site scar	6	0
Injection site swelling	267	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	37	0
Drug-device interaction	3	0
Food interaction	2	0
Inhibitory drug interaction	12	0
Mass conditions NEC		
Cyst	39	0
Cyst rupture	1	0
Mass	101	0
Nodule	28	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

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Mucosal ulceration	1	0
Oedema mucosal	3	0
Polyp	6	0
Necrosis NEC		
Fat necrosis	5	0
Necrosis	8	0
Oedema NEC		
Face oedema	36	0
Generalised oedema	1	0
Localised oedema	13	0
Oedema	97	0
Oedema peripheral	174	0
Pain and discomfort NEC		
Axillary pain	781	0
Chest discomfort	2187	0
Chest pain	6225	0
Discomfort	669	0
Facial discomfort	23	0
Facial pain	306	0
Hernia pain	4	0
Inflammatory pain	37	0
Non-cardiac chest pain	49	0
Pain	18020	0
Suprapubic pain	1	0
Tenderness	1850	0
Visceral pain	4	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	50	0
Adverse event	11	0
Adverse food reaction	2	0
Adverse reaction	12	0
Diet failure	1	0
Drug effect less than expected	1	0
Drug ineffective	228	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	11	0
Remission not achieved	1	0
Similar reaction on previous exposure to drug	1	0
Therapeutic product effect decreased	3	0
Therapeutic product effect delayed	1	0
Therapeutic product effect incomplete	2	0
Therapeutic product effect prolonged	1	0
Therapeutic product ineffective	9	0
Therapeutic reaction time decreased	1	0
Therapeutic response changed	1	0
Therapeutic response decreased	1	0
Therapeutic response delayed	1	0
Therapeutic response shortened	2	0
Therapeutic response unexpected	191	0
Therapy non-responder	3	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Treatment failure	20	0
Treatment noncompliance	1	0
Vaccination failure	45	0
Vaccine positive rechallenge	1	0
Trophic disorders		
Atrophy	4	0
Calcinosis	2	0
Dysplasia	3	0
Hyperplasia	2	0
Ulcers NEC		
Ulcer	49	0
Ulcer haemorrhage	4	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	19	0
Shoulder injury related to vaccine administration	119	0
Vaccination site atrophy	1	0
Vaccination site bruising	142	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	11	0
Vaccination site hyperaesthesia	1	0
Vaccination site hypersensitivity	4	0
Vaccination site hypoaesthesia	25	0
Vaccination site induration	71	0
Vaccination site inflammation	57	0
Vaccination site injury	4	0
Vaccination site irritation	14	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	58	0
Vaccination site joint swelling	4	0
Vaccination site joint warmth	2	0
Vaccination site lymphadenopathy	2	0
Vaccination site mass	571	0
Vaccination site movement impairment	114	0
Vaccination site nerve damage	2	0
Vaccination site nodule	1	0
Vaccination site oedema	3	0
Vaccination site pain	2153	0
Vaccination site papule	4	0
Vaccination site paraesthesia	13	0
Vaccination site pruritus	113	0
Vaccination site rash	195	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site reaction	26	0
Vaccination site scab	2	0
Vaccination site scar	8	0
Vaccination site swelling	519	0
Vaccination site urticaria	13	0
Vaccination site vesicles	11	0
Vaccination site warmth	386	0
<i>Vascular complications associated with device</i>		
Vascular stent occlusion	1	0
Vascular stent thrombosis	1	0
<i>Withdrawal and rebound effects</i>		
Drug withdrawal syndrome	8	0
Withdrawal syndrome	104	0
General disorders SOC TOTAL	257551	405

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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	16	0
<i>Cholestasis and jaundice</i>		
Cholestasis	7	0
Cholestasis of pregnancy	1	0
Jaundice	58	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
Hypertransaminasaemia	10	0
<i>Hepatic failure and associated disorders</i>		
Acute hepatic failure	2	0
Hepatic failure	13	1
Hepatorenal syndrome	1	0
Subacute hepatic failure	3	0
<i>Hepatic fibrosis and cirrhosis</i>		
Hepatic cirrhosis	9	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	75	3
Portosplenomesenteric venous thrombosis	2	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	81	0
Hepatomegaly	5	0
Liver tenderness	6	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Acute yellow liver atrophy	1	0
Allergic hepatitis	1	0
Autoimmune hepatitis	14	0
Cholestatic liver injury	1	0
Drug-induced liver injury	2	0
Hepatic necrosis	2	1
Hepatic steatosis	13	0

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Reaction Name	Total	Fatal
Hepatic disorders Hepatic disorders cont'd		
Hepatitis	35	0
Hepatitis acute	8	1
Immune-mediated hepatitis	1	0
Ischaemic hepatitis	1	0
Liver injury	31	0
Non-alcoholic fatty liver	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	543	9

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	31	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	4	0
Allergy to metals	1	0
Allergy to sting	1	0
Allergy to venom	1	0
Dust allergy	3	0
Hypersensitivity	1593	2
Infusion related hypersensitivity reaction	5	0
Mite allergy	2	0
Multiple allergies	27	0
Serum sickness	15	0
Serum sickness-like reaction	13	0
Type I hypersensitivity	1	0
Type III immune complex mediated reaction	8	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	10	0
Allergy to vaccine	62	0
Contrast media reaction	4	0
Drug hypersensitivity	73	0
Food allergy	63	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 flavouring	1	0
Reaction to preservatives	16	0
Rubber sensitivity	3	0
Smoke sensitivity	3	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	728	2
Anaphylactic shock	129	0
Anaphylactoid reaction	24	0
Anaphylactoid shock	4	0
<i>Atopic disorders</i>		
Atopy	5	0
Seasonal allergy	149	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	80	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	38	0
Cytokine release syndrome	2	0

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Reaction Name	Total	Fatal
Immune system disorders Immune system disorders cont'd		
Cytokine storm	6	0
Decreased immune responsiveness	3	0
Haemophagocytic lymphohistiocytosis	16	1
Hypocomplementaemia	1	0
Immune system disorder	64	0
Immune-mediated adverse reaction	11	0
Immunisation reaction	114	0
Multisystem inflammatory syndrome	1	0
Pre-engraftment immune reaction	1	0
Sensitisation	34	0
Systemic immune activation	1	0
Immunodeficiency disorders NEC		
Immunodeficiency	17	0
Immunosuppression	7	0
Transplant rejections		
Corneal graft rejection	3	0
Transplant rejection	7	0
Vasculitides		
Anti-neutrophil cytoplasmic antibody positive vasculitis	5	1
Eosinophilic granulomatosis with polyangiitis	2	0
Immune system disorders SOC TOTAL	3448	6

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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	43	0
Appendicitis perforated	5	0
Diarrhoea infectious	4	0
Diverticulitis	33	0
Dysentery	5	0
Gastric infection	1	0
Gastroenteritis	46	0
Gastrointestinal infection	6	0
Large intestine infection	2	0
Peritonitis	5	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	38	1
Bacterial sepsis	1	0
Bacterial vaginosis	5	0
Bacterial vulvovaginitis	1	0
Cellulitis	546	0
Cellulitis orbital	4	0
Ear infection bacterial	2	0
Endocarditis bacterial	2	0
Eye infection bacterial	1	0
Folliculitis	13	0
Gangrene	3	0
Injection site cellulitis	8	0
Janeway lesion	1	0
Meningitis bacterial	1	0
Perichondritis	1	0
Periorbital cellulitis	5	0
Pneumonia bacterial	7	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>		

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Erythema migrans	2	0
Lyme disease	8	0
Relapsing fever	1	0
Breast infections		
Breast abscess	3	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	83	0
Oral candidiasis	64	0
Skin candida	3	0
Vulvovaginal candidiasis	63	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	3	0
Cavernous sinus thrombosis	9	0
Central nervous system infection	2	0
Encephalitis	50	1
Encephalomyelitis	4	0
Extradural abscess	1	0
Meningitis	30	0
Myelitis	32	0
Chlamydial infections		
Chlamydial infection	1	0
Clostridia infections		
Clostridium difficile colitis	5	0
Clostridium difficile infection	3	0
Tetanus	5	0
Coronavirus infections		
Asymptomatic COVID-19	5	0
COVID-19	1962	31
COVID-19 pneumonia	73	10
Coronavirus infection	7	0
Post-acute COVID-19 syndrome	23	0
SARS-CoV-2 sepsis	1	0
Severe acute respiratory syndrome	5	0
Suspected COVID-19	54	0
Vaccine derived SARS-CoV-2 infection	1	0
Corynebacteria infections		

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Diphtheria	3	0
<i>Coxiella infections</i>		
Q fever	114	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	152	0
Labyrinthitis	193	0
Mastoiditis	5	0
Otitis externa	7	0
Otitis media	9	0
Otitis media chronic	15	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	3	0
Infectious mononucleosis	60	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	87	0
Eye infection	48	0
Eyelid boil	3	0
Eyelid infection	6	0
Hordeolum	42	0
Keratouveitis	1	0
Retinitis	4	0
<i>Female reproductive tract infections</i>		
Endometritis	3	0
Fallopian tube abscess	1	0

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Genital infection female	1	0
Ovarian abscess	1	0
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	32	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	4	0
Genital herpes	84	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	50	0
Herpes simplex reactivation	4	0
Herpes virus infection	17	0
Herpes zoster	1702	0
Herpes zoster disseminated	1	0
Herpes zoster oticus	17	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	727	0
Varicella	44	0
Varicella zoster virus infection	4	0
Infections NEC		

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Abscess	55	0
Abscess limb	25	0
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	554	4
Infection in an immunocompromised host	3	0
Infectious thyroiditis	1	0
Injection site abscess	3	0
Injection site infection	22	0
Localised infection	110	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	10	1
Toxic shock syndrome	1	0
Vaccination site abscess	7	0
Vaccination site infection	25	0
Vaccine breakthrough infection	3	0
Vestibulitis	4	0
Wound abscess	1	0
<i>Infectious disorders carrier</i>		
SARS-CoV-2 carrier	1	0
<i>Infectious transmissions</i>		
Secondary transmission	16	0
Vaccine virus shedding	1	0
<i>Influenza viral infections</i>		
H1N1 influenza	1	0
H2N2 influenza	3	0
Influenza	6851	0
<i>Klebsiella infections</i>		
Cystitis klebsiella	1	0
Pneumonia klebsiella	1	0
<i>Lower respiratory tract and lung infections</i>		
Atypical pneumonia	2	0
Bronchitis	29	0
Infectious pleural effusion	4	0
Infective exacerbation of bronchiectasis	1	0
Infective pulmonary exacerbation of cystic fibrosis	1	1
Lower respiratory tract infection	351	3
Pleural infection	1	0
Pneumonia	293	31
Pneumonia aspiration	31	6

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 16-Jun-2022

Data Lock Date: 15-Jun-2022 18:30:06

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Infections Infections cont'd		
Sputum purulent	3	0
Male reproductive tract infections		
Epididymitis	10	0
Orchitis	7	0
Molluscum contagiosum viral infections		
Molluscum contagiosum	1	0
Mumps viral infections		
Mumps	13	0
Muscle and soft tissue infections		
Muscle abscess	1	0
Necrotising fasciitis	1	0
Soft tissue infection	5	0
Neisseria infections		
Gonorrhoea	1	0
Prostatitis gonococcal	1	0
Orthopox viral infections		
Cow pox	1	0
Vaccinia virus infection	2	0
Papilloma viral infections		
Papilloma viral infection	1	0
Paravaccinia infections		
Paravaccinia	1	0
Phleboviral infections		
Severe fever with thrombocytopenia syndrome	2	0
Plasmodia infections		
Malaria	7	0
Pneumocystis infections		
Pneumocystis jirovecii pneumonia	1	0
Prion-associated disorders		
Creutzfeldt-Jakob disease	3	0
Pseudomonal infections		
Pseudomonas infection	1	0
Retroviral infections		
Acquired immunodeficiency syndrome	2	0
HIV infection	3	0
HIV-associated neurocognitive disorder	1	0
Persistent generalised lymphadenopathy	1	0
Rotaviral infections		
Gastroenteritis rotavirus	1	0
Rotavirus infection	1	0
Rubella viral infections		
Rubella	1	0
Rubeola viral infections		
Measles	6	0
Measles post vaccine	1	0
Salmonella infections		
Typhoid fever	2	0
Sepsis, bacteraemia, viraemia and fungaemia NEC		
Abdominal sepsis	2	0
Bacteraemia	1	0
Neutropenic sepsis	9	0
Pelvic sepsis	1	0
Pulmonary sepsis	1	0

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 16-Jun-2022

Data Lock Date: 15-Jun-2022 18:30:06

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Sepsis	125	16
Sepsis syndrome	1	0
Septic pulmonary embolism	1	0
Septic rash	13	0
Septic shock	5	1
Urosepsis	11	1
Viraemia	4	0
<i>Skin structures and soft tissue infections</i>		
Blister infected	2	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 disease	2	0
Pustule	27	0
Pyoderma	1	0
Rash pustular	19	0
Skin infection	75	0
Subcutaneous abscess	10	0
Vaccination site pustule	5	0
<i>Staphylococcal infections</i>		
Furuncle	58	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	5	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

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Syphilis	4	0
<i>Trypanosomal infections</i>		
African trypanosomiasis	6	0
<i>Tuberculous infections</i>		
Disseminated Bacillus Calmette-Guerin infection	1	0
Erythema induratum	1	0
Lymph node tuberculosis	3	0
Meningitis tuberculous	1	0
Pulmonary tuberculosis	2	0
Tuberculosis	6	2
<i>Upper respiratory tract infections</i>		
Acute sinusitis	6	0
Chronic sinusitis	18	0
Chronic tonsillitis	1	0
Croup infectious	1	0
Epiglottitis	1	0
Laryngitis	42	0
Nasal vestibulitis	1	0
Nasopharyngitis	1953	0
Peritonsillar abscess	1	0
Pharyngeal abscess	1	0
Pharyngitis	44	0
Rhinitis	58	0
Sinobronchitis	1	0
Sinusitis	412	0
Tonsillitis	90	0
Tracheitis	2	0
Upper respiratory tract infection	12	0
<i>Urinary tract infections</i>		
Cystitis	104	0
Genitourinary tract infection	1	0
Kidney infection	64	0
Pyelonephritis	9	0
Pyelonephritis acute	1	0
Pyelonephritis chronic	1	0
Renal abscess	2	0
Urethritis	1	0
Urinary tract infection	283	0
<i>Vascular infections</i>		
Haematoma infection	2	0
Infected lymphocele	1	0
Infected varicose vein	1	0
Lymphangitis	6	0
<i>Viral infections NEC</i>		
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	70	0
Gastrointestinal viral infection	1	0

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MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Hepatitis viral	3	0
Meningitis viral	22	0
Pleurisy viral	1	0
Pneumonia viral	13	1
Post viral fatigue syndrome	158	0
Sweating fever	742	0
Vestibular neuronitis	44	0
Viral diarrhoea	4	0
Viral infection	90	0
Viral labyrinthitis	7	0
Viral myelitis	1	0
Viral myocarditis	3	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	20550	116

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MedDRA Version: MedDRA 25.0

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	27	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
<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	3	0
Joint injury	20	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	14	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	20	1
Subdural haemorrhage	6	0
Traumatic intracranial haemorrhage	1	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
<i>Chemical injuries</i>		
Chemical burn	2	0
Chemical burn of oral cavity	2	0
Chemical burn of skin	7	0
Chemical phlebitis	2	0
<i>Chest and respiratory tract injuries NEC</i>		
Asbestosis	1	0
Chest crushing	16	0
Chest injury	2	0
Foreign body in throat	2	0
Traumatic haemothorax	1	0
Traumatic lung injury	1	0
<i>Conditions caused by cold</i>		
Chillblains	77	0
Frostbite	1	0
<i>Cranial nerve injuries</i>		
Cranial nerve injury	1	0
Optic nerve injury	9	0
VIIIth nerve injury	1	0
Vth nerve injury	1	0
<i>Ear injuries NEC</i>		
Deafness traumatic	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Drug exposure before pregnancy	1	0
Exposure during pregnancy	19	0
Exposure via breast milk	112	0
Foetal exposure during pregnancy	40	0
Maternal exposure before pregnancy	18	0
Maternal exposure during breast feeding	1397	0
Maternal exposure during pregnancy	403	0
Maternal exposure timing unspecified	2	0
Paternal exposure during pregnancy	2	0
<i>Exposures to agents or circumstances NEC</i>		
Exposure to SARS-CoV-2	8	0
Exposure to household chemicals	1	0
Exposure to toxic agent	1	0
Exposure to vaccinated person	4	0
<i>Eye injuries NEC</i>		
Cataract traumatic	1	0
Eye contusion	59	0
Eye injury	56	0
Eyelid contusion	5	0
Foreign body in eye	2	0
Hyphaema	1	0
Injury corneal	1	0
Periorbital haematoma	1	0
Periorbital haemorrhage	2	0
Retinal injury	4	0
Superficial injury of eye	1	0
Traumatic iritis	1	0
<i>Foetal and neonatal conditions associated with product exposure</i>		
Intoxication by breast feeding	1	0
<i>Fractures and dislocations NEC</i>		

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Fracture	2	0
Joint dislocation	15	1
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	16	0
<i>Intentional product use issues</i>		
Intentional dose omission	21	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	4	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	17	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	148	0
Prescription drug used without a prescription	2	0
Product use in unapproved indication	1	0
Product use issue	9	0
Vaccination error	11	0
Wrong device used	1	0
Wrong drug	5	0
Wrong route	1	0
Wrong schedule	2	0
Wrong technique in product usage process	13	0
<i>Muscle, tendon and ligament injuries</i>		
Epicondylitis	33	0

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Reaction Name	Total	Fatal
Injuries		
Injuries cont'd		
Ligament injury	4	0
Ligament rupture	2	0
Ligament sprain	25	0
Muscle injury	72	0
Muscle rupture	20	0
Muscle strain	59	0
Post-traumatic neck syndrome	4	0
Repetitive strain injury	3	0
Tendon injury	8	0
Tendon rupture	32	0
<i>Nerve injuries NEC</i>		
Nerve injury	227	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	7	0
Arthropod sting	13	0
Bite	1	0
Child maltreatment syndrome	1	0
Electric shock	37	0
Extraskeletal ossification	1	0
Fall	318	0
Foreign body	3	0
Inflammation of wound	5	0
Injury	25	0
Internal injury	1	0
Nervous system injury	5	0
Post concussion syndrome	2	0
Road traffic accident	2	0
Skeletal injury	1	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

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Infusion related reaction	19	0
Injection related reaction	613	0
Needle fatigue	1	0
Post procedural complication	35	0
Post procedural contusion	2	0
Post procedural discomfort	2	0
Post procedural haematoma	1	0
Post procedural haemorrhage	1	0
Procedural complication	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	118	0
Overdoses NEC		
Intentional overdose	14	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
Peripheral nerve injury	1	0
Radial nerve injury	2	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	27	0
Extra dose administered	10	0
Inappropriate schedule of product administration	153	0
Incomplete course of vaccination	79	0
Incorrect dose administered	13	0
Incorrect product administration duration	2	0
Incorrect product formulation administered	1	0

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Reaction Name	Total	Fatal
Injuries		
Injuries cont'd		
Incorrect route of product administration	58	0
Intercepted product administration error	2	0
Lack of vaccination site rotation	1	0
Poor quality product administered	3	0
Product administered at inappropriate site	33	0
Product administered to patient of inappropriate age	31	0
Product administration error	31	0
Product dose omission in error	2	0
Product dose omission issue	44	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	55	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	45	0
Limb crushing injury	11	0
Limb injury	380	0

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MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Nasal injury	2	0
Neck crushing	1	0
Neck injury	3	0
Pharyngeal contusion	3	0
Site specific procedural complications NEC		
Axillary web syndrome	3	0
Head and neck procedural complication	1	0
Skin injuries NEC		
Contusion	3429	0
Hair injury	4	0
Nail injury	1	0
Scar	50	0
Scratch	6	0
Skin abrasion	6	0
Skin injury	28	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
Skin procedural complication	1	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	3	0
Cold burn	3	0
Thermal burn	57	0
Thermal burns of eye	47	0
Thoracic cage fractures and dislocations		
Rib fracture	1	0
Transplantation complications		
Transplant failure	1	0
Underdoses NEC		

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Intentional underdose	1	0
Underdose	11	0
<i>Vaccination related complications</i>		
Adverse event following immunisation	5	0
Post vaccination syndrome	5	0
Reaction to previous exposure to any vaccine	1	0
Vaccination complication	3	0
Injuries SOC TOTAL	9661	2

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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	2	0
Antinuclear antibody increased	2	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	14	0
Full blood count decreased	3	0
Full blood count increased	1	0
Full blood count normal	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	6	0
Blood pH	18	0
Blood pH increased	15	0
Carbon dioxide increased	1	0
Oxygen consumption	2	0
Oxygen saturation	27	0
Oxygen saturation abnormal	3	0
Oxygen saturation decreased	201	0
Oxygen saturation normal	1	0
Venous oxygen saturation decreased	1	0
<i>Blood grouping and cross-matching analyses</i>		
Blood group O	2	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Blood grouping	1	0
Rhesus antigen negative	1	0
<i>Bone marrow and immune tissue histopathology procedures</i>		
Biopsy lymph gland	1	0
<i>Bone marrow and immune tissue imaging procedures</i>		
Scan lymph nodes	2	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose	20	0
Blood glucose abnormal	23	0
Blood glucose decreased	45	0
Blood glucose fluctuation	35	0
Blood glucose increased	193	0
Glycosylated haemoglobin increased	2	0
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	44	0
Heart sounds	19	0
Heart sounds abnormal	9	0
<i>Cardiac function diagnostic procedures</i>		
Cardiac monitoring	1	0
Central venous pressure	1	0
Echocardiogram	3	0
Ejection fraction decreased	6	0
Myocardial strain imaging	21	0
Stroke volume decreased	2	0
Stroke volume increased	3	0
Venous pressure jugular increased	1	0
<i>Cardiac imaging procedures</i>		
Magnetic resonance imaging heart	1	0
<i>Cell marker analyses</i>		
Carbohydrate antigen 15-3	1	0
Carcinoembryonic antigen increased	2	0
Prostatic specific antigen decreased	1	0
Prostatic specific antigen increased	5	0
Tumour marker increased	1	0
<i>Central nervous system histopathology procedures</i>		
Biopsy brain	1	0
<i>Central nervous system imaging procedures</i>		
Brain scan abnormal	2	0
Computerised tomogram head	28	0
Magnetic resonance imaging head	47	0
Magnetic resonance imaging head abnormal	1	0
Scan brain	1	0
<i>Cerebrospinal fluid tests (excl microbiology)</i>		
CSF cell count abnormal	1	0
CSF lymphocyte count abnormal	1	0
CSF oligoclonal band present	1	0
CSF pressure	4	0
CSF protein increased	1	0
CSF test abnormal	1	0
CSF white blood cell count increased	1	0
Xanthochromia	1	0
<i>Chemistry analyses NEC</i>		
Histamine abnormal	4	0

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Histamine level	4	0
Histamine level increased	1	0
Inflammatory marker decreased	1	0
Inflammatory marker increased	14	0
Serum serotonin increased	1	0
<i>Cholesterol analyses</i>		
Blood cholesterol increased	22	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	10	0
Coagulation time prolonged	14	0
Coagulation time shortened	5	0
Fibrin D dimer	1	0
Fibrin D dimer decreased	1	0
Fibrin D dimer increased	69	0
Heparin-induced thrombocytopenia test positive	1	0
International normalised ratio	4	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>		

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Cardiac telemetry	1	0
Electrocardiogram	8	0
Electrocardiogram P wave abnormal	1	0
Electrocardiogram QT prolonged	4	0
Electrocardiogram ST segment elevation	7	0
Electrocardiogram ST-T segment abnormal	6	0
Electrocardiogram T wave inversion	5	0
Electrocardiogram abnormal	22	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	67	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

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Red blood cell sedimentation rate abnormal	1	0
Red blood cell sedimentation rate increased	13	0
<i>Heart rate and pulse investigations</i>		
Brachial pulse decreased	1	0
Carotid pulse	1	0
Femoral pulse	1	0
Heart rate	1150	0
Heart rate abnormal	75	0
Heart rate decreased	144	0
Heart rate increased	2183	0
Heart rate irregular	284	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	31	0
Pulse absent	4	0
Pulse pressure decreased	1	0
Pulse pressure increased	3	0
Pulse waveform abnormal	1	0
Radial pulse	1	0
Sinus rhythm	9	0
<i>Hepatobiliary function diagnostic procedures</i>		
Alanine aminotransferase decreased	1	0
Alanine aminotransferase increased	32	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	2	0
Hepatic enzyme increased	17	0
Liver function test	3	0
Liver function test abnormal	57	0
Liver function test increased	17	0
Transaminases increased	3	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>		

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Blood immunoglobulin A increased	2	0
Blood immunoglobulin E	1	0
Blood immunoglobulin E increased	4	0
Blood immunoglobulin G	1	0
Blood immunoglobulin M	1	0
Blood immunoglobulin M increased	2	0
Immunoglobulins decreased	2	0
Immunology analyses NEC		
Antibody test	6	0
Antibody test abnormal	8	0
Antibody test negative	18	0
Antibody test positive	3	0
Immunology test	14	1
Immunology test normal	1	0
Mast cell degranulation present	1	0
Tryptase increased	1	0
Immunology skin tests NEC		
Allergy alert test	3	0
Skin test positive	7	0
Investigations NEC		
APACHE II score	1	0
Blood test	53	0
Blood test abnormal	95	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	5	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
N-terminal prohormone 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	37	0
Blood iron increased	6	0
Blood magnesium decreased	3	0
Blood phosphorus abnormal	1	0
Blood phosphorus decreased	7	0

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Blood phosphorus increased	4	0
Blood potassium decreased	12	0
Blood potassium increased	9	0
Blood sodium	2	0
Blood sodium decreased	6	0
Blood zinc increased	1	0
Iron binding capacity total decreased	1	0
Serum ferritin	1	0
Serum ferritin decreased	7	0
Serum ferritin increased	9	0
Sweat test	3	0
Transferrin decreased	1	0
Urine copper	2	0
Musculoskeletal and soft tissue imaging procedures		
Bone densitometry	1	0
Discogram abnormal	1	0
Magnetic resonance imaging neck	1	0
Skull X-ray	12	0
X-ray limb	2	0
X-ray limb abnormal	1	0
X-ray of pelvis and hip	2	0
Musculoskeletal and soft tissue tests NEC		
Muscle mass percentage	1	0
Swollen joint count	2	0
Swollen joint count increased	5	0
Tender joint count	4	0
Mycobacteria identification and serology		
Interferon gamma release assay positive	2	0
Neurologic diagnostic procedures		
Coma scale abnormal	19	0
Electroencephalogram abnormal	1	0
Electromyogram abnormal	2	0
Hoover's sign of leg paresis	1	0
Joint position sense decreased	2	0
Lumbar puncture	19	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
Ophthalmic function diagnostic procedures		
Corneal reflex decreased	2	0
Intraocular pressure increased	9	0
Intraocular pressure test	8	0
Pupillary light reflex tests abnormal	1	0
Retinal function test abnormal	1	0
Visual tracking test	1	0
Parathyroid analyses		
Blood parathyroid hormone decreased	1	0
Physical examination procedures and organ system status		
Body height decreased	1	0
Body surface area	3	0

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Body surface area decreased	1	0
Body temperature	1043	0
Body temperature abnormal	88	0
Body temperature decreased	142	0
Body temperature fluctuation	197	0
Body temperature increased	1176	0
Body temperature normal	3	0
Breath sounds	3	0
Breath sounds abnormal	8	0
Dermatologic examination abnormal	1	0
Emergency care examination	1	0
General physical condition abnormal	4	0
Grip strength	14	0
Grip strength decreased	45	0
Head lag	19	0
Lymph node palpable	6	0
Male genital examination abnormal	2	0
Menstruation normal	7	0
Muscle strength abnormal	6	0
Neurological examination	1	0
Neurological examination abnormal	1	0
Neurological examination normal	1	0
Ophthalmological examination	5	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	13	0
Respiratory rate decreased	32	0
Respiratory rate increased	86	0
Skin temperature	179	0
Temperature difference of extremities	9	0
Urological examination	1	0
Vital signs measurement	1	0
Weight decreased	260	0
Weight increased	80	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	7	0
<i>Platelet analyses</i>		
Platelet count	4	0
Platelet count abnormal	2	0
Platelet count decreased	359	1
Platelet count increased	8	0
Platelet count normal	1	0
Platelet morphology abnormal	1	0

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Plateletcrit	1	0
Protein analyses NEC		
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	47	0
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	22	0
Haemoglobin increased	2	0
Mean cell haemoglobin concentration	1	0
Mean cell volume abnormal	3	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	2	0
Blood testosterone decreased	2	0
Blood testosterone increased	1	0
Dihydrotestosterone decreased	1	0
False negative pregnancy test	5	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

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Reproductive hormone	1	0
Reproductive organ and breast histopathology procedures		
Biopsy breast	1	0
Biopsy vagina	1	0
Smear cervix	2	0
Reproductive organ and breast imaging procedures		
Mammogram	1	0
Ultrasound scan vagina normal	1	0
Respiratory and pulmonary function diagnostic procedures		
Forced expiratory volume	2	0
Forced expiratory volume decreased	1	0
Forced expiratory volume increased	14	0
Forced expiratory volume normal	1	0
Forced vital capacity decreased	2	0
Fractional exhaled nitric oxide normal	1	0
Maximal voluntary ventilation	2	0
Peak expiratory flow rate	1	0
Peak expiratory flow rate abnormal	1	0
Peak expiratory flow rate decreased	7	0
Pulmonary function test	5	0
Pulmonary function test decreased	7	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	21	0
Skin histopathology and skin investigations NEC		
Biopsy skin	2	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

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
<i>Thyroid analyses</i>		
Anti-thyroid antibody	1	0
Thyroid function test abnormal	4	0
Thyroxine	2	0
Thyroxine abnormal	1	0
Thyroxine free decreased	1	0
Thyroxine increased	2	0
Tri-iodothyronine decreased	7	0
<i>Tissue enzyme analyses NEC</i>		
Blood alkaline phosphatase	1	0
Blood alkaline phosphatase decreased	1	0
Blood alkaline phosphatase increased	3	0
Blood lactate dehydrogenase	1	0
Blood lactate dehydrogenase increased	1	0
Lactate dehydrogenase urine increased	1	0
<i>Toxicology laboratory analyses</i>		
Blood aluminium	1	0
Blood arsenic normal	1	0
Blood cannabinoids	1	0
Blood carbon monoxide increased	3	0
Blood lead	1	0
Drug screen positive	4	0
Heavy metal test	1	0
<i>Triglyceride analyses</i>		
Blood triglycerides	1	0
Blood triglycerides increased	1	0
<i>Urinalysis NEC</i>		
Blood urine	40	0
Blood urine present	97	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
<i>Urinary tract function analyses NEC</i>		
Urine output	50	0
Urine output decreased	18	0
Urine output increased	11	0
<i>Urinary tract histopathology procedures</i>		
Biopsy kidney	1	0
<i>Urinary tract imaging procedures</i>		
Cystoscopy	3	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
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
Vascular tests NEC (incl blood pressure)		
Blood pressure abnormal	20	0
Blood pressure decreased	108	0
Blood pressure diastolic	1	0
Blood pressure diastolic decreased	1	0
Blood pressure diastolic increased	5	0
Blood pressure difference of extremities	2	0
Blood pressure increased	365	0
Blood pressure measurement	117	0
Blood pressure normal	6	0
Blood pressure orthostatic decreased	1	0
Blood pressure systolic	1	0
Blood pressure systolic abnormal	1	0
Blood pressure systolic increased	5	0
Capillary nail refill test	1	0
Pulmonary arterial pressure abnormal	1	0
Virus identification and serology		
Blood HIV RNA increased	1	0
Coronavirus test	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 negative	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	12	0
SARS-CoV-2 antibody test negative	38	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	119	0
Varicella virus test positive	1	0
Viral load	1	0
Viral test	4	0
Viral test positive	1	0
Vitamin analyses		
Blood folate	3	0
Blood folate abnormal	1	0
Blood folate decreased	14	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Vitamin B12	2	0
Vitamin B12 abnormal	3	0
Vitamin B12 decreased	6	0
Vitamin B12 increased	1	0
Vitamin D	4	0
Vitamin D decreased	7	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
Volume blood	7	0
<i>White blood cell analyses</i>		
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	22	0
Neutrophil count increased	1	0
Neutrophil toxic granulation present	1	0
White blood cell count	21	0
White blood cell count decreased	38	0
White blood cell count increased	14	0
White blood cell count normal	1	0
Investigations SOC TOTAL	11802	2

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	38	0
Decreased appetite	6510	0
Diet refusal	2	0
Eating disorder symptom	1	0
Food craving	26	0
Food refusal	44	0
Hyperphagia	10	0
Hypophagia	40	0
Increased appetite	62	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	124	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	7	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	189	0
<i>Electrolyte imbalance NEC</i>		
Electrolyte imbalance	4	0
Fluid imbalance	1	0
Hyperosmolar state	1	0
<i>Elevated cholesterol</i>		
Hypercholesterolaemia	1	0
<i>Fat soluble vitamin deficiencies and disorders</i>		
Vitamin D deficiency	21	0
<i>Fluid intake decreased</i>		
Fluid intake reduced	11	0
<i>Fluid intake increased</i>		
Polydipsia	17	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Alcohol intolerance	15	0
Dairy intolerance	6	0
Food intolerance	28	0
Gluten sensitivity	6	0
Histamine intolerance	5	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	92	0

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Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
Abnormal weight gain	41	0
Cachexia	2	0
Feeding disorder	220	0
Food aversion	57	0
Malnutrition	1	0
Neonatal insufficient breast milk syndrome	4	0
Obesity	2	0
Overfeeding of infant	1	0
Overweight	2	0
Poor feeding infant	17	0
Protein deficiency	1	0
Starvation	1	0
Underweight	2	0
Weight gain poor	1	0
Weight loss poor	4	0
Hyperglycaemic conditions NEC		
Glucose tolerance impaired	5	0
Hyperglycaemia	135	0
Insulin resistance	10	0
Metabolic syndrome	1	0
Hyperlipidaemias NEC		
Hyperlipidaemia	4	0
Hypoglycaemic conditions NEC		
Hyperinsulinaemic hypoglycaemia	1	0
Hypoglycaemia	108	0
Hypoglycaemia unawareness	2	0
Postprandial hypoglycaemia	3	0
Iron deficiencies		
Iron deficiency	19	0
Iron excess		
Haemochromatosis	1	0
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	8	0
Hypokalaemia	6	0
Hypokalaemic syndrome	3	0

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Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
<i>Protein metabolism disorders NEC</i>		
Hypoalbuminaemia	1	0
<i>Sodium imbalance</i>		
Hypernatraemia	3	0
Hyponatraemia	30	0
Hyponatraemic syndrome	4	1
<i>Sugar intolerance (excl glucose intolerance)</i>		
Lactose intolerance	9	0
<i>Total fluid volume decreased</i>		
Dehydration	701	0
Hypovolaemia	2	0
<i>Total fluid volume increased</i>		
Fluid retention	100	0
Hypervolaemia	13	0
<i>Vitamin deficiencies NEC</i>		
Hypovitaminosis	4	0
<i>Water soluble vitamin deficiencies</i>		
Folate deficiency	13	0
Vitamin B complex deficiency	2	0
Vitamin B12 deficiency	18	0
Metabolic disorders SOC TOTAL	8985	3

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	653	0
Arthritis enteropathic	2	0
Arthropathy	43	0
Autoimmune arthritis	13	0
Haemarthrosis	9	0
Oligoarthritis	1	0
Palindromic rheumatism	9	0
Polyarthritis	22	0
Rheumatic fever	8	0
Sacroiliitis	4	0
Seronegative arthritis	4	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 cyst	1	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	3	0
<i>Bone related signs and symptoms</i>		
Bone pain	1126	0
Bone swelling	11	0
Coccydynia	8	0
Pain in jaw	639	0
Pubic pain	1	0
Spinal pain	284	0
<i>Bursal disorders</i>		
Bursitis	229	0
<i>Cartilage disorders</i>		
Chondritis	1	0
Chondropathy	2	0
Costochondritis	96	0
Osteochondrosis	1	0
Polychondritis	2	0
<i>Connective tissue disorders NEC</i>		
Collagen disorder	2	0
Connective tissue disorder	7	0
Eosinophilic fasciitis	1	0
Mixed connective tissue disease	1	0
Morphoea	4	0
Polymyalgia rheumatica	118	0
Reynold's syndrome	6	0
Scleroderma	4	0
Sjogren's syndrome	4	0
Systemic scleroderma	3	0
<i>Crystal arthropathic disorders</i>		

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Reaction Name	Total	Fatal
Muscle & tissue disorders Muscle & tissue disorders cont'd		
Chondrocalcinosis pyrophosphate	4	0
Gouty tophus	1	0
Epiphyseal disorders		
Epiphyses premature fusion	1	0
Extremity deformities		
Acquired claw toe	1	0
Elbow deformity	1	0
Finger deformity	5	0
Foot deformity	7	0
Hand deformity	4	0
Knee deformity	1	0
Limb deformity	9	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
Greater trochanteric pain syndrome	10	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	64	0
Ligament laxity	1	0
Patellofemoral pain syndrome	7	0
Periarthritis	562	0
Rotator cuff syndrome	109	0
Temporomandibular joint syndrome	23	0
Joint related signs and symptoms		
Arthralgia	23608	0
Jaw clicking	6	0
Joint effusion	12	0
Joint noise	53	0
Joint range of motion decreased	7	0
Joint stiffness	497	0
Joint swelling	1120	0
Joint vibration	6	0
Joint warmth	39	0
Loose body in joint	1	0
Ligament disorders		
Ligament pain	11	0
Lupus erythematosus (incl subtypes)		
Lupus-like syndrome	4	0
Systemic lupus erythematosus	41	0
Metabolic bone disorders		

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Reaction Name	Total	Fatal
Muscle & tissue disorders Muscle & tissue disorders cont'd		
Dwarfism	1	0
Low turnover osteopathy	1	0
Osteopenia	2	0
Osteoporosis	12	0
Muscle infections and inflammations		
Autoimmune myositis	1	0
Myositis	58	0
Polymyositis	6	0
Muscle pains		
Fibromyalgia	328	0
Myalgia	27120	0
Myalgia intercostal	3	0
Myofascial pain syndrome	30	0
Muscle related signs and symptoms NEC		
Haematoma muscle	4	0
Muscle atrophy	45	0
Muscle discomfort	22	0
Muscle disorder	16	0
Muscle fatigue	1031	0
Muscle haemorrhage	5	0
Muscle hypertrophy	1	0
Muscle mass	13	0
Muscle oedema	4	0
Muscle spasms	3664	0
Muscle swelling	35	0
Muscle tightness	202	0
Muscle twitching	633	0
Muscle tone abnormalities		
Muscle rigidity	55	0
Nuchal rigidity	19	0
Torticollis	14	0
Trismus	60	0
Muscle weakness conditions		
Muscular weakness	2364	0
Sarcopenia	1	0
Musculoskeletal and connective tissue conditions NEC		
Back disorder	4	0
Camptocormia	1	0
Extremity contracture	2	0
Infantile back arching	1	0
Limb mass	21	0
Mandibular mass	1	0
Mastication disorder	9	0
Mobility decreased	206	0
Muscle contracture	5	0
Musculoskeletal disorder	3	0
Musculoskeletal stiffness	2468	0
Pelvic misalignment	1	0
Posture abnormal	3	0
Somatic dysfunction	1	0
Weight bearing difficulty	14	0
Winged scapula	2	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders Muscle & tissue disorders cont'd		
<i>Musculoskeletal and connective tissue deformities of skull, face and buccal cavity</i>		
Facial asymmetry	3	0
Head deformity	1	0
<i>Musculoskeletal and connective tissue infections and inflammations NEC</i>		
Connective tissue inflammation	4	0
Dactylitis	3	0
Dupuytren's contracture	6	0
Fasciitis	1	0
Plantar fasciitis	18	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Amplified musculoskeletal pain syndrome	1	0
Back pain	6029	0
Flank pain	98	0
Growing pains	8	0
Limb discomfort	2452	0
Musculoskeletal chest pain	438	0
Musculoskeletal discomfort	171	0
Musculoskeletal pain	176	0
Neck pain	3222	0
Pain in extremity	22832	0
Rheumatic disorder	33	0
Sacral pain	7	0
<i>Myopathies</i>		
Compartment syndrome	6	0
Muscle necrosis	2	0
Myopathy	6	0
Rhabdomyolysis	10	1
<i>Osteoarthropathies</i>		
Nodal osteoarthritis	1	0
Osteoarthritis	110	0
Spinal osteoarthritis	11	0
<i>Psoriatic arthropathies</i>		
Psoriatic arthropathy	36	0
<i>Rheumatoid arthropathies</i>		
Felty's syndrome	1	0
Juvenile idiopathic arthritis	2	0
Rheumatoid arthritis	230	0
Rheumatoid nodule	1	0
Still's disease	6	0
<i>Soft tissue disorders NEC</i>		
Axillary mass	87	0
Clubbing	1	0
Fistula	3	0
Groin pain	241	0
Neck mass	27	0
Soft tissue disorder	3	0
Soft tissue mass	3	0
Soft tissue swelling	7	0
<i>Spine and neck deformities</i>		
Kyphosis	6	0
Scoliosis	5	0
Spinal stenosis	3	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders Muscle & tissue disorders cont'd		
Thoracic spinal stenosis	1	0
<i>Spondyloarthropathies</i>		
Ankylosing spondylitis	34	0
Arthritis reactive	73	0
Axial spondyloarthritis	2	0
Spondylitis	9	0
Spondyloarthropathy	3	0
<i>Synovial disorders</i>		
Synovial cyst	18	0
Synovitis	22	0
<i>Tendon disorders</i>		
Enthesopathy	2	0
Tendon discomfort	4	0
Tendon disorder	10	0
Tendon pain	51	0
Tendon sheath disorder	1	0
Tendonitis	112	0
Tenosynovitis	3	0
Tenosynovitis stenosaurs	4	0
Trigger finger	36	0
Muscle & tissue disorders SOC TOTAL	104810	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
Cholesterol granuloma	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	2	0
<i>Bone neoplasms malignant (excl sarcomas)</i>		
Bone cancer	2	0
<i>Breast and nipple neoplasms benign</i>		
Benign breast neoplasm	4	0
Fibroadenoma of breast	1	0
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	55	0
Breast cancer female	1	0
Breast cancer in situ	1	0
Breast cancer male	3	0
Breast cancer metastatic	1	0
Breast cancer stage I	1	0
Breast cancer stage III	3	0
Breast cancer stage IV	1	0
Inflammatory carcinoma of breast stage III	1	0
Intraductal proliferative breast lesion	1	0
Triple negative breast cancer	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>Diffuse large B-cell lymphomas</i>		
Diffuse large B-cell lymphoma	1	0
Diffuse large B-cell lymphoma stage IV	1	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>		

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
Clear cell endometrial carcinoma	1	0
Endometrial cancer	2	0
<i>Gastric neoplasms malignant</i>		
Gastric cancer	2	0
<i>Gastrointestinal neoplasms benign NEC</i>		
Gastrointestinal tract adenoma	1	0
<i>Gastrointestinal neoplasms malignant NEC</i>		
Gastrointestinal carcinoma	8	0
<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>		
Hepatic cancer	1	0
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	5	1
Leukaemia recurrent	1	0
<i>Leukaemias acute myeloid</i>		
Acute myeloid leukaemia	6	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	2	0
Lymphoproliferative disorder	1	0
Lymphoproliferative disorder in remission	1	0
<i>Mediastinal neoplasms malignancy unspecified NEC</i>		
Good syndrome	4	0
<i>Mesotheliomas malignant and unspecified</i>		

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
Mesothelioma	1	0
Metastases to specified sites		
Metastases to bone	2	0
Metastases to central nervous system	1	1
Metastases to liver	1	0
Metastases to lung	1	1
Metastases to unknown and unspecified sites		
Metastasis	4	1
Myelodysplastic syndromes		
Myelodysplastic syndrome	1	0
Myeloproliferative disorders (excl leukaemias)		
Essential thrombocythaemia	2	0
Myeloproliferative neoplasm	1	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	14	3
Recurrent cancer	1	0
Squamous cell carcinoma	4	0
Neoplasms unspecified malignancy and site unspecified NEC		
Neoplasm	3	0
Neoplasm progression	1	0
Neoplasm recurrence	9	0
Nervous system neoplasms unspecified malignancy NEC		
Brain neoplasm	12	3
Meningioma	6	0
Schwannoma	1	0
Neuromas		
Acoustic neuroma	7	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
Tumour pain	1	0
Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified		
Tonsil cancer	4	0
Ovarian neoplasms malignant (excl germ cell)		

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
Ovarian cancer	10	0
Ovarian cancer recurrent	2	0
Ovarian cancer stage IV	1	0
<i>Pancreatic neoplasms malignant (excl islet cell and carcinoid)</i>		
Pancreatic carcinoma	6	0
Pancreatic carcinoma metastatic	1	0
<i>Paranasal sinus and nasal cavity neoplasms malignant and unspecified</i>		
Nasal cavity cancer	1	0
<i>Paraneoplastic syndromes NEC</i>		
Paraneoplastic syndrome	3	0
<i>Penile neoplasms malignant</i>		
Penile cancer	1	0
<i>Plasma cell myelomas</i>		
Plasma cell myeloma	3	0
Plasmacytoma	1	0
<i>Plasma cell neoplasms NEC</i>		
Hypergammaglobulinaemia benign monoclonal	4	0
<i>Prostatic neoplasms malignant</i>		
Prostate cancer	10	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	2	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	17	1
Throat cancer	2	0
<i>Respiratory tract small cell carcinomas</i>		
Small cell lung cancer	1	0
Small cell lung cancer metastatic	1	1
<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	6	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	19	0
Melanocytic naevus	5	0
Seborrhoeic keratosis	2	0
Skin papilloma	33	0

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
<i>Skin neoplasms malignant and unspecified (excl melanoma)</i>		
Basal cell carcinoma	6	0
Bowen's disease	1	0
Neoplasm skin	3	0
Skin cancer	9	0
Squamous cell carcinoma of skin	1	0
<i>Soft tissue neoplasms benign NEC</i>		
Knuckle pads	1	0
Leiomyoma	1	0
Lipoma	11	0
<i>Thyroid neoplasms benign</i>		
Benign neoplasm of thyroid gland	1	0
Thyroid adenoma	1	0
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	24	0
<i>Uterine neoplasms malignant NEC</i>		
Uterine cancer	5	0
<i>Vulval neoplasms malignant</i>		
Squamous cell carcinoma of the vulva	1	0
Vulval cancer	1	0
Neoplasms SOC TOTAL	541	16

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Areflexia	34	0
Extensor plantar response	3	0
Hyperreflexia	10	0
Hyporeflexia	25	0
Poor sucking reflex	4	0
Reflexes abnormal	2	0
<i>Abnormal sleep-related events</i>		
Sleep paralysis	27	0
<i>Absence seizures</i>		
Petit mal epilepsy	43	0
<i>Acute polyneuropathies</i>		
Acute motor axonal neuropathy	9	0
Acute polyneuropathy	3	0
Guillain-Barre syndrome	500	5
Miller Fisher syndrome	29	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	27	0
Autonomic neuropathy	2	0
Horner's syndrome	2	0
Orthostatic intolerance	9	0
<i>Central nervous system aneurysms and dissections</i>		
Carotid artery aneurysm	2	0
Carotid artery dissection	1	0
Intracranial aneurysm	8	1
Vertebral artery dissection	3	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Basal ganglia haemorrhage	3	0
Basal ganglia infarction	1	0
Basal ganglia stroke	2	1
Basilar artery occlusion	1	0
Basilar artery thrombosis	5	1
Brain stem embolism	1	1
Brain stem haemorrhage	5	1
Brain stem infarction	2	2
Brain stem stroke	9	2
Brain stem thrombosis	2	1
Carotid artery occlusion	3	0
Carotid artery thrombosis	11	0
Cerebellar haemorrhage	5	0
Cerebellar infarction	6	0
Cerebellar stroke	13	0
Cerebral artery embolism	12	0
Cerebral artery occlusion	5	1
Cerebral artery thrombosis	17	0
Cerebral haematoma	14	1
Cerebral haemorrhage	206	57
Cerebral infarction	99	6
Cerebral ischaemia	4	0

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Reaction Name	Total	Fatal
Nervous system disorders Nervous system disorders cont'd		
Cerebral thrombosis	47	5
Cerebral vascular occlusion	2	0
Cerebrovascular accident	1380	54
Embolic cerebral infarction	1	0
Embolic stroke	21	1
Haemorrhage intracranial	57	14
Haemorrhagic cerebellar infarction	1	0
Haemorrhagic cerebral infarction	3	1
Haemorrhagic stroke	50	9
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	169	8
Lacunar infarction	6	0
Lacunar stroke	30	0
Perinatal stroke	1	0
Pseudostroke	3	0
Ruptured cerebral aneurysm	1	0
Spinal cord haematoma	1	0
Spinal cord infarction	1	0
Spinal stroke	5	0
Stroke in evolution	1	0
Subarachnoid haemorrhage	120	8
Thalamic infarction	2	0
Thalamus haemorrhage	11	0
Thrombotic stroke	17	0
Vertebral artery occlusion	1	0
Vertebral artery thrombosis	2	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	5	0
Central nervous system vasculitis	3	0
Cerebral amyloid angiopathy	5	0
Cerebral arteriosclerosis	2	0
Cerebral arteritis	1	0
Cerebral artery stenosis	1	0
Cerebral congestion	4	0
Cerebral microangiopathy	1	0
Cerebral microhaemorrhage	4	0
Cerebral small vessel ischaemic disease	3	0
Cerebral vasoconstriction	3	0
Cerebrovascular disorder	4	0
Cerebrovascular insufficiency	1	0
Dural arteriovenous fistula	1	0
Internal carotid artery deformity	1	0

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Reaction Name	Total	Fatal
Nervous system disorders Nervous system disorders cont'd		
Reversible cerebral vasoconstriction syndrome	4	0
Cerebrovascular venous and sinus thrombosis		
Cerebral venous sinus thrombosis	220	26
Cerebral venous thrombosis	53	6
Superior sagittal sinus thrombosis	34	3
Transverse sinus thrombosis	10	0
Cervical spinal cord and nerve root disorders		
Cervical radiculopathy	4	0
Cervicobrachial syndrome	9	0
Choreiform movements		
Chorea	3	0
Choreoathetosis	1	0
Sydenham's chorea	1	0
Chronic polyneuropathies		
Chronic inflammatory demyelinating polyradiculoneuropathy	11	0
Demyelinating polyneuropathy	11	0
Diabetic neuropathy	3	0
Polyneuropathy chronic	2	0
Coma states		
Coma	27	0
Diabetic coma	3	0
Hypoglycaemic coma	2	0
Coordination and balance disturbances		
Ataxia	55	0
Balance disorder	1029	0
Cerebellar ataxia	5	0
Cerebellar syndrome	2	0
Cerebral ataxia	1	0
Coordination abnormal	143	0
Dysdiadochokinesis	1	0
Dysstasia	129	0
Hand-eye coordination impaired	3	0
Nystagmus	24	0
Cortical dysfunction NEC		
Agraphia	1	0
Alexia	7	0
Aphasia	204	0
Apraxia	4	0
Dysgraphia	8	0
Dyslexia	2	0
Dyspraxia	8	0
Neurologic neglect syndrome	3	0
Sensory processing disorder	1	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	36	0
Dementia with Lewy bodies	3	0
Frontotemporal dementia	1	0

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Reaction Name	Total	Fatal
Nervous system disorders Nervous system disorders cont'd		
Senile dementia	1	0
Vascular dementia	5	0
<i>Demyelinating disorders NEC</i>		
Acute disseminated encephalomyelitis	16	0
Autoimmune demyelinating disease	1	0
Clinically isolated syndrome	3	0
Demyelination	28	0
Neuromyelitis optica spectrum disorder	6	0
<i>Disturbances in consciousness NEC</i>		
Altered state of consciousness	20	0
Consciousness fluctuating	4	0
Depressed level of consciousness	94	0
Hypoglycaemic unconsciousness	1	0
Lethargy	5014	0
Loss of consciousness	1140	0
Postictal state	1	0
Sedation	19	0
Sedation complication	4	0
Somnolence	2005	0
Stupor	10	0
Syncope	2695	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	2	0
<i>Dyskinesias and movement disorders NEC</i>		
Akathisia	10	0
Akinesia	1	0
Ballismus	1	0
Bradykinesia	40	0
Clumsiness	56	0
Dyskinesia	130	0
Extrapyramidal disorder	18	0
Fine motor delay	3	0
Fine motor skill dysfunction	23	0
Hyperkinesia	27	0
Hypokinesia	117	0
Meige's syndrome	1	0
Micrographia	1	0
Motor dysfunction	22	0
Movement disorder	123	0
Psychomotor hyperactivity	41	0
Tardive dyskinesia	1	0
<i>Dystonias</i>		
Dystonia	23	0
Dystonic tremor	4	0
Opisthotonus	4	0
Writer's cramp	1	0
<i>Encephalitis NEC</i>		
Bickerstaff's encephalitis	1	0

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Reaction Name	Total	Fatal
Nervous system disorders Nervous system disorders cont'd		
Encephalitis autoimmune	4	0
Limbic encephalitis	1	0
Noninfective encephalitis	16	0
<i>Encephalopathies NEC</i>		
Autoimmune encephalopathy	6	1
Encephalopathy	12	0
Hypertensive encephalopathy	1	0
Hypoxic-ischaemic encephalopathy	1	0
Posterior reversible encephalopathy syndrome	4	0
<i>Encephalopathies toxic and metabolic</i>		
Hepatic encephalopathy	2	0
<i>Eye movement disorders</i>		
IIIrd nerve disorder	1	0
IIIrd nerve paralysis	8	0
IIIrd nerve paresis	1	0
IVth nerve paralysis	1	0
Microvascular cranial nerve palsy	2	0
VIth nerve paralysis	10	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	644	0
Facial nerve disorder	9	0
Facial paralysis	377	0
Facial paresis	179	0
Facial spasm	47	0
Oculofacial paralysis	1	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	106	0
<i>Glossopharyngeal nerve disorders</i>		
Glossopharyngeal neuralgia	1	0
<i>Headaches NEC</i>		
Cervicogenic headache	6	0
Chronic paroxysmal hemicrania	1	0
Cluster headache	775	0
Cold-stimulus headache	92	0
Drug withdrawal headache	17	0
Exertional headache	12	0
External compression headache	5	0
Headache	81957	0
Medication overuse headache	19	0
New daily persistent headache	20	0
Occipital neuralgia	28	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	963	0
Tension headache	1547	0
Thunderclap headache	53	1
Vascular headache	87	0
<i>Hydrocephalic conditions</i>		
Hydrocephalus	17	1
<i>Hypoglossal nerve disorders</i>		
Tongue paralysis	6	0

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Reaction Name	Total	Fatal
Nervous system disorders Nervous system disorders cont'd		
<i>Increased intracranial pressure disorders</i>		
Brain compression	4	0
Brain oedema	41	2
Cerebrospinal fluid circulation disorder	6	0
Idiopathic intracranial hypertension	7	0
Intracranial pressure increased	36	0
Vasogenic cerebral oedema	1	0
<i>Intellectual disabilities</i>		
Intellectual disability	12	0
<i>Lumbar spinal cord and nerve root disorders</i>		
Cauda equina syndrome	7	0
Lumbar radiculopathy	5	0
Sciatica	246	0
<i>Memory loss (excl dementia)</i>		
Amnesia	466	0
Memory impairment	424	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	223	0
Disturbance in attention	789	0
Judgement impaired	5	0
Mental impairment	153	0
<i>Migraine headaches</i>		
Basilar migraine	5	0
Hemiplegic migraine	55	0
Migraine	7816	0
Migraine with aura	405	0
Migraine without aura	49	0
Ophthalmic migraine	15	0
Retinal migraine	90	0
Status migrainosus	5	0
Typical aura without headache	19	0
Vestibular migraine	41	0
<i>Mixed cranial nerve disorders</i>		
Bulbar palsy	4	0
<i>Mononeuropathies</i>		
Carpal tunnel syndrome	46	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	58	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

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Reaction Name	Total	Fatal
Nervous system disorders Nervous system disorders cont'd		
Ulnar neuritis	4	0
Ulnar tunnel syndrome	1	0
Motor neurone diseases		
Amyotrophic lateral sclerosis	2	0
Lower motor neurone lesion	1	0
Motor neurone disease	7	0
Multiple sclerosis acute and progressive		
Band sensation	6	0
Multiple sclerosis	65	0
Multiple sclerosis pseudo relapse	2	0
Multiple sclerosis relapse	62	0
Progressive multiple sclerosis	1	0
Relapsing multiple sclerosis	1	0
Relapsing-remitting 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)		
Acute flaccid myelitis	1	0
Myelitis transverse	125	0
Narcolepsy and hypersomnia		
Cataplexy	1	0
Hypersomnia	233	0
Narcolepsy	22	0
Nervous system cysts and polyps		
Arachnoid cyst	1	0
Cerebral cyst	1	0
Pineal gland cyst	1	0
Nervous system disorders NEC		
Brain stem syndrome	2	0
Central nervous system lesion	12	0
Cerebral disorder	10	0
Microglial nodules	1	0
Nerve degeneration	1	0
Nervous system disorder	93	0
Neurotoxicity	5	0
Psychomotor skills impaired	5	0
Neurologic visual problems NEC		
Hemianopia	9	0
Hemianopia homonymous	3	0
Quadrantanopia	1	0
Tunnel vision	24	0
Neurological signs and symptoms NEC		
Agitation neonatal	1	0
Cerebrospinal fluid leakage	1	0
Clonus	2	0
Dizziness	22853	0

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Reaction Name	Total	Fatal
Nervous system disorders Nervous system disorders cont'd		
Dizziness exertional	104	0
Dizziness postural	2187	1
Drooling	27	0
Exaggerated startle response	4	0
Fontanelle bulging	4	0
Head discomfort	791	0
Hyporesponsive to stimuli	5	0
Inability to crawl	2	0
Infant irritability	6	0
Intracranial hypotension	4	0
Meningism	3	0
Myoclonus	35	0
Neurological decompensation	4	0
Neurological symptom	154	0
Patient elopement	3	0
Persistent postural-perceptual dizziness	43	0
Pleocytosis	4	0
Presyncope	627	0
Sensory overload	12	0
Slow response to stimuli	10	0
Spontaneous cerebrospinal fluid leak syndrome	2	0
Tongue biting	10	0
Unresponsive to stimuli	113	0
Neuromuscular disorders NEC		
Hypotonic-hyporesponsive episode	1	0
Muscle contractions involuntary	45	0
Muscle spasticity	35	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	4	0
Olfactory nerve disorders		
Anosmia	370	0
Hyposmia	11	0
Parosmia	420	0
Optic nerve disorders NEC		
Optic neuritis	67	0
Paraesthesias and dysaesthesias		
Anaesthesia	3	0
Burning feet syndrome	36	0
Burning sensation	1076	0
Burning sensation mucosal	3	0
Dysaesthesia	17	0
Formication	87	0
Hemianaesthesia	2	0
Hemihypoaesthesia	2	0
Hemiparaesthesia	5	0
Hyperaesthesia	277	0
Hypoaesthesia	6273	0
Lhermitte's sign	4	0

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Reaction Name	Total	Fatal
Nervous system disorders Nervous system disorders cont'd		
Paraesthesia	10056	0
Reversed hot-cold sensation	1	0
Vibration syndrome	3	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Diplegia	39	0
Gait spastic	1	0
Hemiparesis	128	0
Hemiplegia	58	0
Locked-in syndrome	1	0
Monoparesis	124	0
Monoplegia	152	0
Paralysis	366	0
Paraparesis	6	0
Paraplegia	4	0
Paresis	12	0
Peripheral nerve palsy	1	0
Peripheral paralysis	1	0
Postictal paralysis	3	0
Quadriparesis	3	0
Quadriplegia	4	0
<i>Parkinson's disease and parkinsonism</i>		
Freezing phenomenon	163	0
Parkinson's disease	19	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	6	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
Lumbosacral plexopathy	1	0
Neuralgic amyotrophy	11	0
Neuritis	19	0
Neuropathy peripheral	310	0
Peripheral motor neuropathy	2	0
Peripheral sensorimotor neuropathy	3	0
Peripheral sensory neuropathy	21	0
Polyneuropathy	16	0
Small fibre neuropathy	6	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

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Reaction Name	Total	Fatal
Nervous system disorders Nervous system disorders cont'd		
Change in seizure presentation	7	0
Clonic convulsion	10	0
Convulsive threshold lowered	1	0
Drug withdrawal convulsions	2	0
Epilepsy	362	1
Epileptic aura	3	0
Febrile convulsion	93	0
Hypoglycaemic seizure	1	0
Migraine-triggered seizure	3	0
Myoclonic epilepsy	5	0
Partial seizures	61	0
Psychogenic seizure	5	0
Seizure	1436	3
Seizure anoxic	4	0
Seizure cluster	9	0
Seizure like phenomena	3	0
Status epilepticus	30	2
Tonic clonic movements	3	0
Tonic convulsion	39	0
Sensory abnormalities NEC		
Ageusia	1117	0
Allodynia	63	0
Aura	27	0
Central pain syndrome	2	0
Complex regional pain syndrome	15	0
Decreased vibratory sense	1	0
Dysgeusia	2035	0
Electric shock sensation	119	0
Hypogeusia	8	0
Intercostal neuralgia	3	0
Loss of proprioception	8	0
Neuralgia	1568	0
Persistent genital arousal disorder	2	0
Phantom limb syndrome	19	0
Post herpetic neuralgia	15	0
Restless arm syndrome	15	0
Restless legs syndrome	414	0
Sensory disturbance	178	0
Sensory loss	257	0
Taste disorder	531	0
Vibratory sense increased	5	0
Visual perseveration	1	0
Sleep disturbances NEC		
Microsleep	3	0
Periodic limb movement disorder	2	0
Sleep deficit	54	0
Sudden onset of sleep	1	0
Speech and language abnormalities		
Dysarthria	476	0
Incoherent	21	0
Language disorder	3	0
Muscle tension dysphonia	1	0
Repetitive speech	4	0

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Reaction Name	Total	Fatal
Nervous system disorders Nervous system disorders cont'd		
Slow speech	44	0
Speech disorder	149	0
Speech disorder developmental	2	0
Spinal cord and nerve root disorders NEC		
Acquired syringomyelia	1	0
Myelopathy	8	0
Radicular pain	1	0
Radiculitis brachial	32	0
Radiculopathy	5	0
Spinal cord disorder	8	0
Spinal cord ischaemia	1	0
Spinal cord oedema	1	0
Subacute combined cord degeneration	1	0
Structural brain disorders NEC		
Brain injury	48	3
Cerebral mass effect	10	0
Encephalomalacia	1	0
Intracranial mass	4	0
White matter lesion	5	0
Transient cerebrovascular events		
Transient ischaemic attack	534	2
Tremor (excl congenital)		
Action tremor	4	0
Asterixis	1	0
Essential tremor	10	0
Head titubation	27	0
Intention tremor	1	0
Postural tremor	2	0
Resting tremor	8	0
Tremor	9925	1
Trigeminal disorders		
Numb chin syndrome	3	0
Trigeminal nerve disorder	7	0
Trigeminal neuralgia	153	0
Trigeminal neuritis	2	0
Trigeminal palsy	1	0
Vagus nerve disorders		
Vagus nerve paralysis	1	0
Vocal cord paralysis	6	0
Vertigos NEC		
Vertigo CNS origin	3	0
Nervous system disorders SOC TOTAL	183398	237

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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	236	0
<i>Foetal complications NEC</i>		
Haemorrhage foetal	1	0
<i>Foetal position and presentation abnormalities</i>		
Face presentation	1	0
<i>Gestational age and weight conditions</i>		
Low birth weight baby	1	0
Premature baby	2	0
<i>Haemorrhagic complications of pregnancy</i>		
Haemorrhage in pregnancy	1	0
Subchorionic haemorrhage	1	0
<i>High risk pregnancies</i>		
Pregnancy of unknown location	1	0
<i>Hypertension associated disorders of pregnancy</i>		
Pre-eclampsia	4	0
<i>Labour onset and length abnormalities</i>		
Precipitate labour	1	0
Premature labour	4	0
Premature rupture of membranes	3	0
Prolonged labour	1	0
<i>Maternal complications of delivery NEC</i>		
Traumatic delivery	1	0
<i>Maternal complications of labour NEC</i>		
Uterine contractions abnormal	2	0
<i>Maternal complications of pregnancy NEC</i>		
Biochemical pregnancy	3	0
Decidual cast	3	0
Ectopic pregnancy	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	23	0
Uterine contractions during pregnancy	1	0
<i>Placental abnormalities (excl neoplasms)</i>		
Foetal vascular malperfusion	1	0
Placental calcification	1	0
Placental disorder	1	0
<i>Pregnancy complicated by maternal disorders</i>		
Gestational diabetes	6	0
Peripartum cardiomyopathy	1	0

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Reaction Name	Total	Fatal
Pregnancy conditions Pregnancy conditions cont'd		
<i>Stillbirth and foetal death</i>		
Stillbirth	5	5
<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	5	0
Pregnancy with implant contraceptive	2	0
Unintended pregnancy	2	0
Pregnancy conditions SOC TOTAL	340	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 dislocation	2	0
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	194	1

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	28	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	12	0
Inappropriate affect	18	0
<i>Amnesic symptoms</i>		
Paramnesia	9	0
<i>Anxiety disorders NEC</i>		
Anxiety disorder	7	0
Generalised anxiety disorder	5	0
Neurosis	1	0
<i>Anxiety symptoms</i>		
Agitation	216	0
Anxiety	1386	0
Immunisation stress-related response	2	0
Nervousness	614	0
Procedural anxiety	1	0
Stress	174	0
Tension	74	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	21	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	19	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	12	0
Social avoidant behaviour	8	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 Psychiatric disorders cont'd		
Change in sustained attention	1	0
Daydreaming	17	0
Distractibility	2	0
Mental fatigue	504	0
Communications disorders		
Communication disorder	11	0
Mutism	6	0
Speech sound disorder	2	0
Confusion and disorientation		
Confusional state	2241	0
Disorientation	749	0
Decreased physical activity levels		
Catatonia	3	0
Deliria		
Delirium	494	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	732	0
Depression suicidal	18	0
Major depression	25	0
Menopausal depression	2	0
Mixed anxiety and depressive disorder	3	0
Dissociative states		
Depersonalisation/derealisation disorder	21	0
Dissociation	82	0
Dissociative amnesia	1	0
Dissociative disorder	3	0
Disturbances in initiating and maintaining sleep		
Initial insomnia	44	0
Insomnia	3195	0
Middle insomnia	74	0
Terminal insomnia	27	0
Dyssomnias		
Dyssomnia	5	0
Poor quality sleep	681	0
Eating disorders NEC		
Binge eating	1	0
Eating disorder	21	0
Pica	1	0
Selective eating disorder	2	0
Emotional and mood disturbances NEC		
Anger	91	0

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Reaction Name	Total	Fatal
Psychiatric disorders Psychiatric disorders cont'd		
Dysphoria	2	0
Emotional disorder	104	0
Emotional distress	92	0
Emotional poverty	2	0
Euphoric mood	69	0
Frustration tolerance decreased	16	0
Irritability	327	0
Mood altered	90	0
Factitious disorders		
Factitious disorder	4	0
Fear symptoms and phobic disorders (incl social phobia)		
Acrophobia	2	0
Agoraphobia	5	0
Claustrophobia	1	0
Fear	79	0
Fear of death	20	0
Fear of disease	2	0
Fear of eating	1	0
Fear of falling	6	0
Fear of injection	3	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	2	0
Thanatophobia	1	0
Fluctuating mood symptoms		
Mood swings	152	0
Hallucinations (excl sleep-related)		
Hallucination	948	0
Hallucination, auditory	49	0
Hallucination, olfactory	15	0
Hallucination, tactile	1	0
Hallucination, visual	61	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
Pyromania	1	0
Increased physical activity levels		
Restlessness	495	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	36	0
Mental status changes	6	0

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Reaction Name	Total	Fatal
Psychiatric disorders Psychiatric disorders cont'd		
<i>Mental disorders due to a general medical condition NEC</i>		
Mental disorder due to a general medical condition	1	0
Neuropsychiatric symptoms	2	0
<i>Mood alterations with depressive symptoms</i>		
Anhedonia	4	0
Decreased interest	20	0
Depressed mood	720	0
Depressive symptom	2	0
Feeling guilty	2	0
Feeling of despair	21	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	80	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	363	0
Panic disorder	10	0
Panic reaction	43	0
<i>Paraphilias and paraphilic disorders</i>		
Fetishism	2	0
<i>Parasomnias</i>		
Abnormal dreams	372	0
Abnormal sleep-related event	2	0
Confusional arousal	3	0
Exploding head syndrome	7	0
Nightmare	471	0
Parasomnia	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders Psychiatric disorders cont'd		
Rapid eye movements sleep abnormal	4	0
Sleep inertia	1	0
Sleep talking	17	0
Sleep terror	63	0
Sleep-related eating disorder	2	0
Somnambulism	11	0
Perception disturbances NEC		
Autoscopy	29	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
Personality disorders NEC		
Personality disorder	1	0
Pervasive developmental disorders NEC		
Autism spectrum disorder	4	0
Psychiatric elimination disorders		
Enuresis	62	0
Psychiatric symptoms NEC		
Abulia	1	0
Decreased eye contact	2	0
Helplessness	3	0
Hypervigilance	12	0
Psychiatric symptom	16	0
Psychological trauma	5	0
Psychotic disorder NEC		
Acute psychosis	6	0
Psychotic behaviour	2	0
Psychotic disorder	48	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	7	0
Sexual desire disorders		
Excessive masturbation	1	0
Hypersexuality	2	0
Libido decreased	25	0
Libido disorder	1	0
Libido increased	9	0
Loss of libido	59	0
Sexual dysfunction NEC		
Genito-pelvic pain/penetration disorder	1	0
Sleep disorders NEC		

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Reaction Name	Total	Fatal
Psychiatric disorders Psychiatric disorders cont'd		
Sleep disorder	459	0
Sleep disorder due to a general medical condition	1	0
Sleep disorder due to general medical condition, insomnia type	3	0
<i>Somatic symptom disorders</i>		
Conversion disorder	44	0
Habit cough	39	0
Illness anxiety disorder	1	0
Psychogenic tremor	2	0
Somatic symptom disorder	2	0
<i>Speech and language usage disturbances</i>		
Disorganised speech	23	0
Logorrhoea	3	0
Pedantic speech	1	0
Poverty of speech	1	0
Verbigeration	1	0
<i>Speech articulation and rhythm disturbances</i>		
Dysphemia	38	0
Lack of spontaneous speech	3	0
<i>Stereotypies and automatisms</i>		
Bruxism	35	0
Head banging	49	0
Waxy flexibility	2	0
<i>Stress disorders</i>		
Acute stress disorder	4	0
Burnout syndrome	16	0
Catastrophic reaction	2	1
Hyperarousal	3	0
Post-traumatic stress disorder	16	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	7	0
Suicidal ideation	122	0
Suicide attempt	31	0
Suicide threat	1	0
<i>Thinking disturbances</i>		
Bradyphrenia	99	0
Confabulation	1	0
Illogical thinking	1	0
Impaired reasoning	3	0
Intrusive thoughts	6	0
Morbid thoughts	5	0

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Reaction Name	Total	Fatal
Psychiatric disorders Psychiatric disorders cont'd		
Tachyphrenia	23	0
Thinking abnormal	30	0
Thought blocking	8	0
<i>Tic disorders</i>		
Secondary tic	2	0
Tic	23	0
Psychiatric disorders SOC TOTAL	18540	5

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder discomfort	10	0
Bladder irritation	9	0
Bladder pain	68	0
Bladder spasm	1	0
Dysuria	96	0
Incontinence	101	0
Micturition disorder	4	0
Micturition frequency decreased	1	0
Micturition urgency	103	0
Mixed incontinence	1	0
Pollakiuria	309	0
Stress urinary incontinence	2	0
Urethral pain	6	0
Urge incontinence	2	0
Urinary hesitation	7	0
Urinary incontinence	138	0
Urinary retention	104	0
Urine flow decreased	23	0
<i>Bladder disorders NEC</i>		
Bladder dilatation	1	0
Bladder disorder	25	0
Bladder prolapse	1	0
Urinary bladder haemorrhage	18	1
Urinary bladder rupture	1	0
<i>Bladder infections and inflammations</i>		
Cystitis haemorrhagic	1	0
Cystitis interstitial	12	0
Cystitis noninfective	3	0
<i>Bladder neoplasms</i>		
Bladder cyst	1	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	6	0
IgA nephropathy	4	0
Nephrotic syndrome	20	0
<i>Myoneurogenic bladder disorders</i>		
Atonic urinary bladder	1	0
Automatic bladder	1	0
Bladder dysfunction	14	0
Hypertonic bladder	17	0
Loss of bladder sensation	13	0
Neurogenic bladder	4	0
<i>Nephritis NEC</i>		
Lupus nephritis	2	0
Nephritis	7	0

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Reaction Name	Total	Fatal
Renal & urinary disorders Renal & urinary disorders cont'd		
Tubulointerstitial nephritis	8	0
<i>Nephropathies and tubular disorders NEC</i>		
Nephropathy	2	0
Nephrosclerosis	1	0
<i>Renal disorders NEC</i>		
Oedematous kidney	1	0
Renal disorder	16	0
Renal haemorrhage	3	0
<i>Renal failure and impairment</i>		
Acute kidney injury	75	1
Anuria	5	0
Chronic kidney disease	15	1
End stage renal disease	1	0
Oliguria	11	0
Renal failure	51	2
Renal impairment	26	0
Renal injury	9	1
<i>Renal failure complications</i>		
Malnutrition-inflammation-atherosclerosis syndrome	1	0
<i>Renal hypertension and related conditions</i>		
Hypertensive nephropathy	1	0
<i>Renal lithiasis</i>		
Nephrolithiasis	24	0
<i>Renal obstructive disorders</i>		
Hydronephrosis	1	0
<i>Renal structural abnormalities and trauma</i>		
Acquired cystic kidney disease	1	0
Kidney enlargement	1	0
Renal atrophy	2	0
<i>Renal vascular and ischaemic conditions</i>		
Renal artery occlusion	3	0
Renal artery thrombosis	2	0
Renal cortical necrosis	1	0
Renal embolism	1	0
Renal infarct	17	1
Renal ischaemia	2	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
<i>Structural and obstructive urethral disorders (excl congenital)</i>		
Urethral spasm	1	0
Urethral stenosis	1	0
<i>Ureteric disorders NEC</i>		
Ureteral disorder	2	0
<i>Urinary abnormalities</i>		
Chromaturia	111	0
Glycosuria	1	0
Haematuria	1	0
Haematuria	70	0
Microalbuminuria	1	0

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Reaction Name	Total	Fatal
Renal & urinary disorders Renal & urinary disorders cont'd		
Proteinuria	12	0
Urine abnormality	21	0
Urine odour abnormal	23	0
<i>Urinary tract signs and symptoms NEC</i>		
Costovertebral angle tenderness	1	0
Haemorrhage urinary tract	60	0
Nocturia	23	0
Polyuria	34	0
Renal colic	4	0
Renal pain	953	0
Urinary tract discomfort	2	0
Urinary tract pain	16	0
Renal & urinary disorders SOC TOTAL	2792	7

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Benign and malignant breast neoplasms</i>		
Breast cyst	14	0
<i>Breast disorders NEC</i>		
Anisomastia	1	0
Breast disorder	4	0
Breast enlargement	11	0
Breast mass	77	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	507	0
Breast swelling	75	0
Breast tenderness	79	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	4	0
Erectile dysfunction	104	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	28	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders Reproductive & breast disorders cont'd		
<i>Menopausal effects NEC</i>		
Artificial menopause	2	0
Menopausal disorder	3	0
Menopausal symptoms	69	0
Menopause delayed	5	0
Premature menopause	53	0
<i>Menopausal effects on the genitourinary tract</i>		
Atrophic vulvovaginitis	1	0
Postmenopausal haemorrhage	312	0
<i>Menstruation and uterine bleeding NEC</i>		
Abnormal uterine bleeding	9	0
Abnormal withdrawal bleeding	6	0
Dysmenorrhoea	1498	0
Intermenstrual bleeding	721	0
Menstrual discomfort	18	0
Menstrual disorder	1617	0
Menstruation irregular	2448	0
Premenstrual dysphoric disorder	7	0
Premenstrual headache	12	0
Premenstrual pain	86	0
Premenstrual syndrome	61	0
Retrograde menstruation	4	0
Withdrawal bleed	14	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	635	0
Hypomenorrhoea	446	0
Menstruation delayed	3351	0
Oligomenorrhoea	127	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	4854	0
Menometrorrhagia	18	0
Polymenorrhoea	727	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>		
Ovarian cyst	35	0
Ovarian cyst ruptured	2	0
Polycystic ovaries	45	0
<i>Ovarian and fallopian tube disorders NEC</i>		
Fallopian tube spasm	1	0
Ovarian adhesion	1	0
Ovarian enlargement	3	0
Ovarian failure	4	0
Ovarian haemorrhage	5	0
Ovarian hyperstimulation syndrome	1	0
Ovarian mass	1	0
Ovarian necrosis	1	0
Ovarian oedema	1	0
Ovarian vein thrombosis	2	0
Ovulation pain	63	0
Premature ovulation	8	0
<i>Pelvic prolapse conditions</i>		
Cystocele	1	0
Vaginal prolapse	2	0
<i>Pelvis and broad ligament disorders NEC</i>		

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Reaction Name	Total	Fatal
Reproductive & breast disorders Reproductive & breast disorders cont'd		
Adnexa uteri pain	47	0
Pelvic haematoma	1	0
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	5	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	11	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	4	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	34	0
Genital hyperaesthesia	1	0
Genital hypoaesthesia	2	0
Genital lesion	2	0
Genital paraesthesia	5	0
Genital ulceration	14	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	5	0
Genital rash	6	0
Genital swelling	2	0
Pelvic discomfort	4	0
Pelvic pain	182	0
Perineal pain	2	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders Reproductive & breast disorders cont'd		
Pruritus genital	9	0
Scrotal disorders NEC		
Scrotal dermatitis	1	0
Scrotal oedema	1	0
Scrotal pain	20	0
Scrotal swelling	7	0
Varicocele	2	0
Sexual function and fertility disorders NEC		
Dyspareunia	7	0
Female sexual dysfunction	1	0
Infertility	15	0
Infertility female	7	0
Infertility male	3	0
Male sexual dysfunction	2	0
Sexual dysfunction	15	0
Spermatogenesis and semen disorders		
Aspermia	2	0
Haemospermia	19	0
Semen discolouration	2	0
Testicular and epididymal disorders NEC		
Testicular atrophy	1	0
Testicular disorder	9	0
Testicular mass	1	0
Testicular oedema	2	0
Testicular pain	116	0
Testicular retraction	3	0
Testicular swelling	25	0
Testis discomfort	6	0
Testicular and epididymal infections and inflammations		
Orchitis noninfective	1	0
Testicular and epididymal neoplasms		
Epididymal cyst	1	0
Testicular cyst	1	0
Uterine disorders NEC		
Adenomyosis	15	0
Endometrial hyperplasia	2	0
Endometrial thickening	3	0
Endometriosis	91	0
Metrorrhoea	1	0
Uterine enlargement	2	0
Uterine haemorrhage	73	0
Uterine pain	10	0
Uterine neoplasms		
Uterine cyst	1	0
Uterine polyp	5	0
Uterine tone disorders		
Uterine spasm	25	0
Vaginal and vulval infections and inflammations		
Vulvovaginal inflammation	3	0
Vulvovaginal cysts and neoplasms		
Bartholin's cyst	3	0
Vaginal cyst	15	0
Vulva cyst	1	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders Reproductive & breast disorders cont'd		
<i>Vulvovaginal disorders NEC</i>		
Vaginal disorder	2	0
Vaginal haemorrhage	1340	0
Vaginal mucosal blistering	1	0
Vaginal ulceration	7	0
Vulval disorder	3	0
Vulval haemorrhage	34	0
Vulval ulceration	7	0
Vulvovaginal disorder	1	0
Vulvovaginal ulceration	3	0
<i>Vulvovaginal signs and symptoms</i>		
Clitoral engorgement	1	0
Coital bleeding	8	0
Enlarged clitoris	1	0
Labia enlarged	2	0
Vaginal discharge	92	0
Vaginal lesion	7	0
Vaginal odour	7	0
Vulval oedema	1	0
Vulvovaginal burning sensation	11	0
Vulvovaginal discomfort	10	0
Vulvovaginal dryness	13	0
Vulvovaginal erythema	1	0
Vulvovaginal pain	40	0
Vulvovaginal pruritus	12	0
Vulvovaginal rash	3	0
Vulvovaginal swelling	7	0
Reproductive & breast disorders SOC TOTAL	20910	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Agonal respiration	1	0
Apnoea	13	0
Apnoeic attack	1	0
Cheyne-Stokes respiration	2	0
Dyspnoea	8177	0
Dyspnoea at rest	15	0
Dyspnoea exertional	66	0
Dyspnoea paroxysmal nocturnal	1	0
Grunting	2	0
Hyperventilation	102	0
Hypopnoea	239	0
Hypoventilation	1	0
Irregular breathing	28	0
Mouth breathing	8	0
Orthopnoea	3	0
Respiration abnormal	120	0
Respiratory arrest	29	0
Respiratory distress	13	0
Respiratory fatigue	8	0
Sleep apnoea syndrome	35	0
Tachypnoea	41	0
<i>Bronchial conditions NEC</i>		
Bronchial haemorrhage	1	0
Bronchial secretion retention	2	0
Bronchiectasis	16	0
<i>Bronchospasm and obstruction</i>		
Aspirin-exacerbated respiratory disease	1	0
Asthma	660	0
Asthma exercise induced	4	0
Asthma late onset	3	0
Asthma-chronic obstructive pulmonary disease overlap syndrome	2	0
Asthmatic crisis	6	0
Bronchial oedema	1	0
Bronchitis chronic	2	0
Bronchospasm	19	0
Chronic obstructive pulmonary disease	57	4
Cough variant asthma	9	0
Obstructive airways disorder	2	0
Reversible airways obstruction	1	0
Wheezing	653	0
<i>Conditions associated with abnormal gas exchange</i>		
Asphyxia	4	1
Hypercapnia	1	0
Hypoxia	73	1
<i>Coughing and associated symptoms</i>		
Allergic cough	8	0
Cough	4087	0
Haemoptysis	150	0
Productive cough	219	0
Sputum discoloured	15	0
Sputum increased	3	0
Sputum retention	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
<i>Diaphragmatic disorders</i>		
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	8	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	23	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Alveolitis	2	0
Autoimmune lung disease	1	0
Eosinophilic pneumonia	2	0
Hypersensitivity pneumonitis	2	0
Pneumonitis	38	1
Pulmonary sarcoidosis	3	0
Pulmonary vasculitis	1	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	49	0
Lower respiratory tract congestion	4	0
Lung hyperinflation	1	0
Lung opacity	8	0
Pleuritic pain	49	0
Pulmonary haemorrhage	8	1
Pulmonary pain	238	0
Rales	2	0
<i>Mediastinal disorders</i>		
Pulmonary hilum mass	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	479	0
Nasal inflammation	10	0
Rhinitis allergic	28	0
Rhinitis perennial	1	0
<i>Nasal disorders NEC</i>		
Epistaxis	2302	0
Intranasal hypoaesthesia	1	0
Nasal crusting	6	0
Nasal cyst	2	0
Nasal disorder	8	0
Nasal dryness	71	0
Nasal mucosal blistering	1	0
Nasal mucosal discolouration	1	0
Nasal odour	2	0
Nasal oedema	17	0
Nasal polyps	1	0
Nasal pruritus	12	0
Nasal septum deviation	1	0
Nasal septum perforation	1	0

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Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Nasal ulcer	4	0
Neonatal hypoxic conditions		
Brief resolved unexplained event	1	0
Gasping syndrome	2	0
Paranasal sinus disorders (excl infections and neoplasms)		
Allergic sinusitis	2	0
Paranasal sinus haemorrhage	5	0
Paranasal sinus hypersecretion	1	0
Paranasal sinus inflammation	4	0
Sinonasal obstruction	14	0
Sinus congestion	92	0
Sinus disorder	21	0
Sinus polyp	3	0
Parenchymal lung disorders NEC		
Alveolar proteinosis	1	0
Atelectasis	8	0
Cystic lung disease	1	0
Emphysema	6	0
Idiopathic pulmonary fibrosis	4	1
Interstitial lung disease	9	2
Lung consolidation	10	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	12	0
Pharyngeal disorders (excl infections and neoplasms)		
Oropharyngeal swelling	2	0
Pharyngeal erythema	5	0
Pharyngeal haemorrhage	1	0
Pharyngeal hypoaesthesia	41	0
Pharyngeal inflammation	1	0
Pharyngeal oedema	14	0
Pharyngeal paraesthesia	37	0
Pharyngeal swelling	317	0
Pharyngeal ulceration	17	0
Tonsillar disorder	1	0
Tonsillar erythema	7	0
Tonsillar haemorrhage	1	0
Tonsillar hypertrophy	65	0
Tonsillar inflammation	5	0
Tonsillar ulcer	2	0
Tonsillolith	1	0
Pleural conditions NEC		
Pleural thickening	1	0
Pleural infections and inflammations		
Lupus pleurisy	2	0
Pleurisy	55	0
Pneumothorax and pleural effusions NEC		
Haemothorax	1	0
Pleural effusion	56	1

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Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Pneumothorax	14	0
Pneumothorax spontaneous	2	0
<i>Pulmonary hypertensions</i>		
Pulmonary hypertension	6	1
<i>Pulmonary oedemas</i>		
Acute lung injury	1	0
Acute pulmonary oedema	3	0
Acute respiratory distress syndrome	2	0
Pulmonary congestion	23	0
Pulmonary oedema	44	1
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary artery thrombosis	3	0
Pulmonary embolism	1771	120
Pulmonary infarction	15	1
Pulmonary thrombosis	35	7
Pulmonary venous thrombosis	4	0
<i>Respiratory failures (excl neonatal)</i>		
Acute respiratory failure	3	1
Respiratory failure	30	3
<i>Respiratory signs and symptoms NEC</i>		
Allergic respiratory symptom	11	0
Diaphragmalgia	16	0
Nasal flaring	1	0
Painful respiration	12	0
Pleural rub	1	0
Respiratory symptom	26	0
Suffocation feeling	5	0
Use of accessory respiratory muscles	3	0
<i>Respiratory tract disorders NEC</i>		
Allergic respiratory disease	1	0
Aspiration	11	2
Chronic respiratory disease	2	1
Lung disorder	19	0
Pulmonary mass	10	0
Respiratory disorder	9	0
Respiratory tract congestion	10	0
Respiratory tract haemorrhage	2	0
Respiratory tract irritation	10	0
Respiratory tract oedema	4	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
Tracheomalacia	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	124	0
Catarrh	70	0
Choking	24	0
Choking sensation	14	0
Dry throat	263	0
Dysphonia	182	0
Increased upper airway secretion	4	0

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Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Increased viscosity of upper respiratory secretion	24	0
Laryngeal pain	1	0
Nasal discharge discolouration	2	0
Nasal discomfort	116	0
Nasal obstruction	2	0
Oropharyngeal blistering	27	0
Oropharyngeal discolouration	1	0
Oropharyngeal discomfort	45	0
Oropharyngeal pain	4261	0
Oropharyngeal plaque	1	0
Paranasal sinus discomfort	80	0
Rhinalgia	35	0
Rhinorrhoea	1706	0
Sinus pain	614	0
Sneezing	534	0
Snoring	6	0
Throat clearing	8	0
Throat irritation	223	0
Throat lesion	1	0
Throat tightness	247	0
Upper airway obstruction	1	0
Upper respiratory tract congestion	1	0
Upper-airway cough syndrome	30	0
Yawning	73	0
<i>Vascular pulmonary disorders NEC</i>		
Pulmonary artery occlusion	1	0
Pulmonary vascular disorder	1	0
Respiratory disorders SOC TOTAL	29990	149

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	153	0
Acne cystic	12	0
Acne varioliformis	1	0
Dermatitis acneiform	13	0
<i>Alopecias</i>		
Alopecia	512	0
Alopecia areata	56	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	2	0
Madarosis	6	0
<i>Angioedemas</i>		
Angioedema	367	0
Circumoral oedema	2	0
Idiopathic angioedema	3	0
<i>Apocrine and eccrine gland disorders</i>		
Anhidrosis	2	0
Cold sweat	1740	0
Hidradenitis	4	0
Hyperhidrosis	9316	0
Hypohidrosis	6	0
Miliaria	225	0
Night sweats	1955	0
Sweat discolouration	3	0
Sweat gland disorder	1	0
<i>Bullous conditions</i>		
Autoimmune blistering disease	1	0
Blister	669	0
Blister rupture	7	0
Blood blister	115	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	39	0
Pemphigus	9	0
Stevens-Johnson syndrome	7	0
Toxic epidermal necrolysis	2	0
<i>Connective tissue disorders</i>		
Chronic cutaneous lupus erythematosus	4	0
Dermatomyositis	7	0
Subacute cutaneous lupus erythematosus	1	0
<i>Dermal and epidermal conditions NEC</i>		
Acute febrile neutrophilic dermatosis	4	0
Dermatosis	1	0
Dry skin	476	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Macule	13	0
Myxoid cyst	2	0
Neutrophilic dermatosis	1	0
Pain of skin	952	0
Papule	127	0
Parakeratosis	1	0
Scab	33	0
Scar discomfort	1	0
Scar pain	20	0
Sensitive skin	605	0
Skin burning sensation	600	0
Skin discolouration	235	0
Skin discomfort	6	0
Skin disorder	53	0
Skin fissures	18	0
Skin fragility	3	0
Skin indentation	18	0
Skin induration	18	0
Skin laxity	1	0
Skin lesion	67	0
Skin necrosis	9	0
Skin odour abnormal	52	0
Skin plaque	3	0
Skin reaction	279	0
Skin sensitisation	90	0
Skin swelling	101	0
Skin texture abnormal	2	0
Skin tightness	44	0
Skin warm	592	0
Skin weeping	11	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	206	0
Dermatitis allergic	335	0
Dermatitis atopic	47	0
Dermatitis contact	37	0
Dermatitis diaper	3	0
Dyshidrotic eczema	21	0
Eczema	404	0
Eczema asteatotic	22	0
Eczema nummular	5	0
Eczema weeping	3	0
Hand dermatitis	8	0
Intertrigo	3	0
Neurodermatitis	3	0
Perioral dermatitis	5	0
Prurigo	2	0
Rebound eczema	1	0
Seborrhoeic dermatitis	15	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Skin irritation	168	0
Stasis dermatitis	7	0
Urticarial dermatitis	2	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	38	0
Drug reaction with eosinophilia and systemic symptoms	14	0
Fixed eruption	9	0
Palmar-plantar erythrodysesthesia syndrome	3	0
<i>Erythemas</i>		
Erythema	3459	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	20	0
Skin exfoliation	202	0
<i>Granulomatous and deep cutaneous inflammatory conditions</i>		
Cutaneous sarcoidosis	1	0
Granuloma annulare	10	0
Granuloma skin	1	0
<i>Hyperkeratoses</i>		
Hyperkeratosis	3	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	5	0
<i>Hypopigmentation disorders</i>		
Skin depigmentation	10	0
Skin hypopigmentation	3	0
Vitiligo	38	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	17	0
Nail disorder	5	0
Nail growth abnormal	3	0
Nail hypertrophy	1	0
Nail necrosis	1	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Nail pigmentation	2	0
Nail pitting	1	0
Nail ridging	9	0
Onychalgia	7	0
Onychoclasia	12	0
Onycholysis	4	0
Onychomadesis	5	0
Splinter haemorrhages	6	0
<i>Panniculitides</i>		
Erythema nodosum	42	0
Panniculitis	5	0
<i>Papulosquamous conditions</i>		
Erythema annulare	2	0
Lichen planus	47	0
Lichen sclerosus	10	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	171	0
Polymorphic light eruption	6	0
Solar dermatitis	1	0
<i>Pigmentation changes NEC</i>		
Pigmentation disorder	18	0
<i>Pilar disorders NEC</i>		
Hair colour changes	16	0
Hair disorder	2	0
Hair growth abnormal	9	0
Hair texture abnormal	15	0
Piloerection	102	0
Pseudofolliculitis	2	0
Trichodynia	7	0
Trichorrhexis	7	0
<i>Pruritus NEC</i>		
Itching scar	5	0
Pruritus	8463	0
Pruritus allergic	1	0
Senile pruritus	1	0
<i>Psoriatic conditions</i>		
Dermatitis psoriasiform	3	0
Erythrodermic psoriasis	4	0
Guttate psoriasis	31	0
Nail psoriasis	1	0
Palmoplantar pustulosis	4	0
Psoriasis	281	0
Pustular psoriasis	10	0
<i>Purpura and related conditions</i>		
Ecchymosis	6	0
Henoch-Schonlein purpura	18	0
Petechiae	384	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Purpura	152	0
Pustular conditions		
Acute generalised exanthematous pustulosis	1	0
Rash follicular	4	0
Rashes, eruptions and exanthems NEC		
Butterfly rash	8	0
Nodular rash	1	0
Rash	9317	0
Rash erythematous	2307	0
Rash macular	790	0
Rash maculo-papular	71	0
Rash morbilliform	50	0
Rash papular	584	0
Rash pruritic	2002	0
Rash rubelliform	1	0
Rash scarlatiniform	2	0
Rash vesicular	108	0
Systemic lupus erythematosus rash	9	0
Rosaceas		
Erythematotelangiectatic rosacea	3	0
Granulomatous rosacea	1	0
Papulopustular rosacea	1	0
Rosacea	49	0
Scaly conditions		
Dandruff	3	0
Pityriasis	16	0
Sebaceous gland disorders		
Sebaceous glands overactivity	1	0
Seborrhoea	16	0
Skin and subcutaneous conditions NEC		
Cellulite	3	0
Cutaneous symptom	11	0
Skin discharge	1	0
Skin mass	49	0
Skin and subcutaneous tissue ulcerations		
Diabetic foot	2	0
Diabetic ulcer	1	0
Ischaemic skin ulcer	1	0
Pyoderma gangrenosum	3	0
Skin erosion	61	0
Skin ulcer	37	0
Vasculitic ulcer	1	0
Skin cysts and polyps		
Dermal cyst	28	0
Skin dystrophies		
Keloid scar	3	0
Skin wrinkling	6	0
Skin haemorrhages		
Haemorrhage subcutaneous	23	0
Mucocutaneous haemorrhage	3	0
Skin haemorrhage	54	0
Skin hyperplasias and hypertrophies		
Acanthosis	1	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Skin hypertrophy	4	0
Skin hypoplasias and atrophies		
Skin atrophy	13	0
Skin striae	13	0
Skin injuries and mechanical dermatoses		
Decubitus ulcer	7	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	30	0
Skin vasomotor conditions		
Livedo reticularis	60	0
Telangiectasia and related conditions		
Spider naevus	5	0
Telangiectasia	5	0
Urticarias		
Chronic spontaneous urticaria	10	0
Cold urticaria	12	0
Idiopathic urticaria	11	0
Mechanical urticaria	10	0
Solar urticaria	1	0
Urticaria	2670	0
Urticaria cholinergic	2	0
Urticaria chronic	55	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	53548	0

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Reaction Name	Total	Fatal
Social circumstances		
<i>Age related issues</i>		
Childhood	1	0
Life expectancy shortened	2	0
Menarche	3	0
Menopause	82	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	103	0
Breast prosthesis user	2	0
Corrective lens user	1	0
Dependence on oxygen therapy	1	0
Disability	11	0
Hearing aid user	3	0
Hearing disability	2	0
Housebound	4	0
Immobile	59	0
Immobilisation prolonged	4	0
Impaired driving ability	9	0
Impaired work ability	44	0
Loss of personal independence in daily activities	15	0
Mental disability	1	0
Paralytic disability	1	0
Physical disability	5	0
Sight disability	27	0
Sitting disability	4	0
Walking aid user	1	0
Walking disability	11	0
Wheelchair user	3	0
<i>Educational issues</i>		
Educational problem	1	0
Illiteracy	4	0
<i>Employment issues</i>		
Job dissatisfaction	4	0
Retirement	5	0
Stress at work	2	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

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Reaction Name	Total	Fatal
Social circumstances Social circumstances cont'd		
Water pollution	4	0
Pregnancy related circumstances		
Breast feeding	9	0
Sexuality issues		
Anal sex	1	0
Homosexuality	1	0
Social issues NEC		
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	8	0
Refusal of treatment by patient	1	0
Refusal of vaccination	3	0
Tanning	2	0
Tattoo	1	0
Unhealthy lifestyle	1	0
Tobacco use		
Non-tobacco user	7	0
Tobacco user	2	0
Social circumstances SOC TOTAL	494	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Adrenal gland therapeutic procedures</i>		
Adrenalectomy	1	0
<i>Anaesthesia and allied procedures</i>		
Local anaesthesia	3	0
Nerve block	5	0
<i>Analgesia supportive care</i>		
Analgesic therapy	1	0
<i>Antiinfective therapies</i>		
Antibiotic therapy	2	0
COVID-19 treatment	7	0
<i>Arterial therapeutic procedures (excl aortic)</i>		
Cerebral revascularisation	1	0
Coronary artery bypass	2	0
<i>Autonomic nerve therapeutic procedures</i>		
Vagotomy	3	0
<i>Biliary tract and gallbladder therapeutic procedures</i>		
Cholecystectomy	1	0
Cholelithotomy	1	0
<i>Blood and blood product treatment</i>		
Photopheresis	1	0
Transfusion	1	0
<i>Breast therapeutic procedures NEC</i>		
Axillary lymphadenectomy	1	0
<i>Bronchial and pulmonary therapeutic procedures</i>		
Airway secretion clearance therapy	1	0
Antitussive therapy	1	0
<i>Cardiac device therapeutic procedures</i>		
Cardiac pacemaker insertion	3	0
Pacemaker generated rhythm	1	0
<i>Cardiac therapeutic procedures NEC</i>		
Cardiac operation	1	0
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	4	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

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Reaction Name	Total	Fatal
Surgical & medical procedures Surgical & medical procedures cont'd		
Nothing by mouth order	8	0
External ear therapeutic procedures		
Cerumen removal	2	0
Eye therapeutic procedures NEC		
Eye irrigation	4	0
Facial therapeutic procedures		
Face lift	3	0
Fallopian tube therapeutic procedures		
Fallopian tube operation	1	0
Fascial and bursal therapeutic procedures		
Bursa removal	1	0
Fertility and fertilisation interventions female		
Ovulation induction	2	0
Gastric therapeutic procedures		
Antacid therapy	1	0
Gastrointestinal therapeutic procedures NEC		
Intestinal resection	1	0
Prophylaxis against gastrointestinal ulcer	1	0
Prophylaxis of nausea and vomiting	28	0
Gynaecological therapeutic procedures NEC		
Gynaecological disorder prophylaxis	1	0
Menstrual cycle management	4	0
Haematological therapeutic procedures NEC		
Anticoagulant therapy	2	0
Haemofiltration	1	0
Thrombosis prophylaxis	2	0
Head, neck and oral cavity therapeutic procedures NEC		
Neck lift	1	0
Hormonal therapeutic procedures NEC		
Hormone replacement therapy	6	0
Hormone therapy	9	0
Steroid therapy	2	0
Immunisations		
COVID-19 immunisation	221	0
Immunisation	118	0
Influenza immunisation	1	0
Tuberculosis immunisation	1	0
Vaccine coadministration	1	0
Induced abortions		
Abortion induced	1	0
Iris and ciliary body therapeutic procedures		
Pupil constriction procedure	1	0
Joint therapeutic procedures		
Hip surgery	1	0
Joint injection	6	0
Joint stabilisation	2	0
Knee operation	2	0
Shoulder operation	3	0
Large intestine therapeutic procedures		
Appendectomy	8	0
Colectomy	2	0
Limb therapeutic procedures		
Arm amputation	1	0

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Reaction Name	Total	Fatal
Surgical & medical procedures Surgical & medical procedures cont'd		
Foot amputation	2	0
Leg amputation	6	0
Limb immobilisation	28	0
Limb operation	16	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	2	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 grafts		
Skin graft	1	0
Skin lesion excisions		
Skin neoplasm excision	1	0
Tattoo excision	1	0
Skull and brain therapeutic procedures		
Brain operation	1	0
Small intestine therapeutic procedures		
Ileostomy	3	0
Spine and spinal cord therapeutic procedures		
Spinal operation	1	0
Spinal rod insertion	1	0
Testicular and scrotal therapeutic procedures		
Testes exploration	1	0

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Reaction Name	Total	Fatal
Surgical & medical procedures Surgical & medical procedures cont'd		
<i>Therapeutic bladder catheterisation</i>		
Bladder catheterisation	1	0
<i>Therapeutic procedures NEC</i>		
Anaphylaxis treatment	4	0
Antiallergic therapy	1	0
Bed rest	26	0
Catheter management	4	0
Catheter placement	2	0
Continuous passive motion machine therapy	1	0
Fatigue management	1	0
Heat therapy	3	0
Hospitalisation	30	0
Immobilisation bandage	1	0
Injection	54	0
Interchange of vaccine products	106	0
Localised alternating hot and cold therapy	6	0
Magnetic therapy	1	0
Manipulation	1	0
Mass excision	10	0
Medication dilution	3	0
Occupational therapy	1	0
Physical fitness training	4	0
Physiotherapy	1	0
Product used for unknown indication	2	0
Promotion of wound healing	1	0
Self-medication	1	0
Smoking cessation therapy	1	0
Specialist consultation	1	0
Stent placement	2	0
Stoma care	1	0
Surgery	2	0
Therapeutic hypothermia	2	0
Therapy change	3	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
Uterine dilation and evacuation	1	0
<i>Vascular therapeutic procedures NEC</i>		
Clamping of blood vessel	1	0
Thrombectomy	3	0
Thromboembolectomy	1	0
Thrombolysis	2	0
Vascular graft	1	0
<i>Venous therapeutic procedures</i>		

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Reaction Name	Total	Fatal
Surgical & medical procedures Surgical & medical procedures cont'd		
Phlebotomy	2	0
Surgical & medical procedures SOC TOTAL	917	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Accelerated and malignant hypertension</i>		
Accelerated hypertension	1	0
Hypertensive crisis	16	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	18	1
Aneurysm ruptured	2	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	24	1
Aortic thrombosis	14	3
<i>Aortic infections and inflammations</i>		
Aortitis	3	0
<i>Aortic necrosis and vascular insufficiency</i>		
Aortic arteriosclerosis	2	0
Aortic occlusion	1	0
Aortic stenosis	5	0
<i>Arterial infections and inflammations</i>		
Arteritis	6	0
Giant cell arteritis	65	0
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	28	0
Labile blood pressure	5	0
<i>Bruising, ecchymosis and purpura</i>		
Achenbach syndrome	10	0
<i>Circulatory collapse and shock</i>		
CT hypotension complex	1	0
Circulatory collapse	141	2
Distributive shock	2	0
Hypoperfusion	2	0
Hypovolaemic shock	1	0
Neurogenic shock	10	0
Peripheral circulatory failure	4	0
Shock	60	1
Shock haemorrhagic	1	0
Shock symptom	6	0
<i>Haemorrhages NEC</i>		
Bloody discharge	17	0
Haematoma	119	0
Haemorrhage	1493	2
Internal haemorrhage	31	0
Venous haemorrhage	10	0

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Reaction Name	Total	Fatal
Vascular disorders <small>Vascular disorders cont'd</small>		
<i>Lymphangiopathies</i>		
Lymphangiopathy	2	0
Lymphocele	2	0
Lymphorrhoea	1	0
<i>Lymphoedemas</i>		
Lymphoedema	81	0
<i>Non-site specific embolism and thrombosis</i>		
Air embolism	1	0
Arterial thrombosis	33	1
Atheroembolism	1	0
Embolism	257	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	1976	43
Venous thrombosis	40	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Arterial occlusive disease	17	0
Arterial spasm	2	0
Arterial stenosis	2	0
Arteriosclerosis	10	0
Haemorrhagic infarction	1	0
Infarction	15	0
Ischaemia	17	0
Peripheral venous disease	11	0
Vascular compression	2	0
Vascular occlusion	3	0
Vasospasm	13	0
Venous occlusion	1	0
<i>Non-site specific vascular disorders NEC</i>		
Angiopathy	7	0
Arterial rupture	1	0
Capillary disorder	2	0
Capillary fragility	12	0
Collateral circulation	1	0
Haemodynamic instability	4	0
Hyperaemia	2	0
Neovascularisation	1	0
Superficial vein prominence	10	0
Vascular fragility	1	0
Vascular pain	140	0
Vascular rupture	2	0
Vascular wall discolouration	1	0
Vasodilatation	129	0
Vein collapse	2	0
Vein discolouration	10	0
Vein disorder	26	0
Vein rupture	17	0
<i>Peripheral aneurysms and dissections</i>		
Peripheral artery aneurysm	2	0

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Reaction Name	Total	Fatal
Vascular disorders <small>Vascular disorders cont'd</small>		
<i>Peripheral embolism and thrombosis</i>		
Axillary vein thrombosis	2	0
Blue toe syndrome	42	0
Deep vein thrombosis	1308	10
Femoral artery embolism	2	0
Iliac artery embolism	2	0
Jugular vein thrombosis	31	0
Pelvic venous thrombosis	24	1
Peripheral artery thrombosis	21	0
Peripheral embolism	11	0
Peripheral vein thrombus extension	1	0
Subclavian artery embolism	3	0
Subclavian artery thrombosis	1	0
Subclavian vein thrombosis	5	0
Superficial vein thrombosis	73	0
Thrombophlebitis	147	0
Venous thrombosis limb	7	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	121	0
Erythromelalgia	8	0
Flushing	722	0
Hot flush	2216	0
Peripheral vascular disorder	7	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
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
May-Thurner syndrome	1	0
Peripheral arterial occlusive disease	5	0
Peripheral artery occlusion	10	0
Peripheral coldness	1353	0
Peripheral ischaemia	37	2
Poor peripheral circulation	61	0
Raynaud's phenomenon	159	0
<i>Phlebitis NEC</i>		
Phlebitis	68	0
Phlebitis superficial	13	0
<i>Site specific embolism and thrombosis NEC</i>		
Brachiocephalic vein thrombosis	1	0
<i>Site specific necrosis and vascular insufficiency NEC</i>		
Superior vena cava syndrome	1	0
<i>Site specific vascular disorders NEC</i>		
Aortic dilatation	1	0
Aortic rupture	1	0
Pallor	436	0
Plethoric face	1	0
<i>Varicose veins NEC</i>		
Bleeding varicose vein	2	0
Spider vein	21	0
Varicophlebitis	11	0

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Reaction Name	Total	Fatal
Vascular disorders <small>Vascular disorders cont'd</small>		
Varicose ulceration	1	0
Varicose vein	157	0
Varicose vein ruptured	1	0
<i>Vascular hypertensive disorders NEC</i>		
Diastolic hypertension	5	0
Essential hypertension	1	0
Hypertension	1078	1
Labile hypertension	2	0
Neurogenic hypertension	1	0
Systolic hypertension	3	0
Venous hypertension	4	0
White coat hypertension	12	0
<i>Vascular hypotensive disorders</i>		
Capillary leak syndrome	17	0
Diastolic hypotension	1	0
Hypotension	571	0
Orthostatic hypotension	50	0
<i>Vascular malformations and acquired anomalies</i>		
Arteriovenous fistula	1	0
<i>Vasculitides NEC</i>		
Behcet's syndrome	4	0
Diffuse vasculitis	2	1
Granulomatosis with polyangiitis	3	0
MAGIC syndrome	3	1
Vasculitis	117	2
<i>Vena caval embolism and thrombosis</i>		
Vena cava thrombosis	9	1
Vascular disorders SOC TOTAL	14017	79
TOTAL REACTIONS FOR DRUG	870093	1287
TOTAL REPORTS	245614	
TOTAL FATAL OUTCOME REPORTS		1287