

COVID-19 mRNA Pfizer- BioNTech Vaccine Analysis Print

Report Run Date: 13-Jan-2022
Data Lock Date: 12-Jan-2022 18:30:17

All UK spontaneous reports received between 09/12/20 and 12/01/22 for mRNA Pfizer/BioNTech vaccine

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

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemia deficiencies</i>		
Anaemia folate deficiency	1	0
Anaemia vitamin B12 deficiency	4	0
Deficiency anaemia	1	0
Iron deficiency anaemia	8	0
Pernicious anaemia	1	0
<i>Anaemias NEC</i>		
Anaemia	132	0
Anaemia macrocytic	2	0
Anaemia megaloblastic	1	0
Autoimmune anaemia	3	0
Blood loss anaemia	1	0
Microcytic anaemia	1	0
<i>Anaemias haemolytic NEC</i>		
Coombs negative haemolytic anaemia	1	0
Haemolytic anaemia	7	0
<i>Anaemias haemolytic immune</i>		
Autoimmune haemolytic anaemia	16	0
Cold type haemolytic anaemia	1	0
Evans syndrome	1	0
Warm type haemolytic anaemia	1	0
<i>Anaemias haemolytic mechanical factor</i>		
Microangiopathic haemolytic anaemia	1	0
<i>Bleeding tendencies</i>		
Haemorrhagic diathesis	1	0
Increased tendency to bruise	53	0
Spontaneous haematoma	2	0
<i>Coagulation factor deficiencies</i>		
Acquired haemophilia	3	0
<i>Coagulopathies</i>		
Abnormal clotting factor	4	0
Antiphospholipid syndrome	6	0
Coagulopathy	26	1
Disseminated intravascular coagulation	2	0
Hypercoagulation	3	0
Thrombotic microangiopathy	3	0
<i>Eosinophilic disorders</i>		
Eosinophilia	13	0
<i>Haematological disorders</i>		
Blood disorder	5	0
Bone marrow disorder	1	0
Hypergammaglobulinaemia	1	0
Hyperviscosity syndrome	1	0
Mast cell activation syndrome	10	0
Methaemoglobinaemia	1	0
<i>Haemolyses NEC</i>		
Haemolysis	6	0
Intravascular haemolysis	1	0
Jaundice acholuric	1	0
<i>Leukocytoses NEC</i>		
Leukocytosis	3	0
Lymphocytic infiltration	1	0
Lymphocytosis	6	0

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Reaction Name	Total	Fatal
Blood disorders Blood disorders cont'd		
Neutrophilia	12	0
Leukopenias NEC		
Leukopenia	4	1
Lymphopenia	4	0
Lymphatic system disorders NEC		
Abdominal lymphadenopathy	3	0
Hilar lymphadenopathy	2	0
Lymph node pain	2166	0
Lymph node ulcer	1	0
Lymphadenitis	173	0
Lymphadenopathy	13177	0
Lymphatic disorder	3	0
Lymphatic insufficiency	1	0
Necrotic lymphadenopathy	4	0
Pseudolymphoma	12	0
Retroperitoneal lymphadenopathy	1	0
Marrow depression and hypoplastic anaemias		
Aplasia pure red cell	2	0
Aplastic anaemia	1	1
Hypoplastic anaemia	2	0
Myelosuppression	1	0
Pancytopenia	8	0
Neutropenias		
Autoimmune neutropenia	2	0
Neutropenia	41	0
Platelet disorders NEC		
Platelet anisocytosis	1	0
Platelet disorder	3	0
Polycythaemia (excl rubra vera)		
Polycythaemia	3	0
Purpuras (excl thrombocytopenic)		
Purpura non-thrombocytopenic	1	0
Red blood cell abnormal findings NEC		
Macrocytosis	2	0
Polychromasia	2	0
Red blood cell abnormality	2	0
Spleen disorders		
Spleen atrophy	1	0
Splenic infarction	3	0
Splenic thrombosis	1	0
Splenic vein thrombosis	2	0
Splenomegaly	12	0
Thrombocytopenias		
Acquired amegakaryocytic thrombocytopenia	1	0
Immune thrombocytopenia	80	0
Thrombocytopenia	229	1
Thrombocytopenic purpura	8	0
Thrombotic thrombocytopenic purpura	6	0
Thrombocytoses		
Thrombocytosis	7	0
Blood disorders SOC TOTAL	16320	4

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Aortic valvular disorders</i>		
Aortic valve incompetence	1	0
<i>Cardiac conduction disorders</i>		
Atrioventricular block	26	1
Atrioventricular block complete	3	1
Atrioventricular block first degree	2	0
Atrioventricular block second degree	3	0
Bundle branch block	2	0
Bundle branch block left	4	0
Bundle branch block right	4	0
Trifascicular block	1	0
<i>Cardiac disorders NEC</i>		
Acute cardiac event	5	0
Cardiac disorder	75	2
Cardiac dysfunction	2	0
Cardiac ventricular thrombosis	1	0
Cardiovascular deconditioning	1	0
Cardiovascular disorder	8	0
Intracardiac thrombus	5	0
<i>Cardiac hypertensive complications</i>		
Hypertensive heart disease	2	1
<i>Cardiac infections and inflammations NEC</i>		
Cauditis	8	0
<i>Cardiac neoplasms NEC</i>		
Pericardial cyst	1	0
<i>Cardiac signs and symptoms NEC</i>		
Cardiac discomfort	33	0
Cardiovascular symptom	1	0
Palpitations	5301	1
<i>Cardiac valve disorders NEC</i>		
Cardiac valve disease	2	0
Heart valve incompetence	3	0
<i>Cardiomyopathies</i>		
Cardiomyopathy	11	0
Congestive cardiomyopathy	7	0
Stress cardiomyopathy	3	0
<i>Coronary artery disorders NEC</i>		
Arteriosclerosis coronary artery	1	0
Coronary artery disease	7	3
Coronary artery dissection	1	0
Coronary artery occlusion	3	0
Coronary artery thrombosis	5	2
<i>Endocarditis NEC</i>		
Endocarditis noninfective	1	1
<i>Heart failures NEC</i>		
Cardiac failure	77	9
Cardiac failure acute	6	1
Cardiac failure chronic	2	0
Cardiac failure congestive	4	1
Cardiogenic shock	4	1
Cardiopulmonary failure	1	1
<i>Ischaemic coronary artery disorders</i>		
Acute coronary syndrome	7	1

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Cardiac disorders Cardiac disorders cont'd		
Acute myocardial infarction	25	1
Angina pectoris	284	1
Angina unstable	4	0
Arteriospasm coronary	4	0
Microvascular coronary artery disease	2	0
Myocardial infarction	259	37
Myocardial ischaemia	10	6
Left ventricular failures		
Acute left ventricular failure	1	1
Left ventricular failure	7	2
Mitral valvular disorders		
Mitral valve incompetence	8	0
Mitral valve prolapse	1	0
Myocardial disorders NEC		
Cardiac amyloidosis	1	0
Cardiac aneurysm	1	1
Cardiac ventricular scarring	1	0
Cardiomegaly	43	3
Left atrial dilatation	1	0
Left ventricular dysfunction	13	0
Left ventricular enlargement	2	0
Left ventricular hypertrophy	2	0
Myocardial fibrosis	6	0
Myocardial haemorrhage	1	0
Myocardial injury	14	0
Myocardial necrosis	1	0
Myocardial oedema	6	0
Myocardial rupture	1	0
Right atrial enlargement	1	0
Right ventricular dysfunction	2	0
Right ventricular enlargement	1	0
Ventricular dysfunction	2	0
Ventricular hypertrophy	1	0
Ventricular hypokinesia	2	0
Noninfectious myocarditis		
Eosinophilic myocarditis	1	0
Hypersensitivity myocarditis	1	0
Myocarditis	644	1
Myocarditis post infection	1	0
Noninfectious pericarditis		
Pericarditis	442	2
Pericarditis constrictive	1	0
Pleuropericarditis	1	0
Pericardial disorders NEC		
Cardiac tamponade	1	1
Pericardial effusion	40	2
Pericardial fibrosis	1	0
Pericardial haemorrhage	4	3
Pericardial rub	2	0
Rate and rhythm disorders NEC		
Arrhythmia	171	1
Arrhythmia neonatal	1	0
Bradycardia	69	0

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Cardiac disorders Cardiac disorders cont'd		
Bradycardia foetal	2	1
Cardiac flutter	555	0
Extrasystoles	194	0
Heart alternation	3	0
Paroxysmal arrhythmia	1	0
Postural orthostatic tachycardia syndrome	24	0
Tachyarrhythmia	8	0
Tachycardia	1967	0
Tachycardia foetal	1	0
Tachycardia paroxysmal	1	0
Right ventricular failures		
Cor pulmonale	1	0
Right ventricular failure	1	0
Supraventricular arrhythmias		
Arrhythmia supraventricular	16	0
Atrial fibrillation	265	1
Atrial flutter	39	0
Atrial tachycardia	10	0
Nodal arrhythmia	1	0
Sinus arrest	1	0
Sinus arrhythmia	7	0
Sinus bradycardia	13	0
Sinus node dysfunction	1	0
Sinus tachycardia	70	0
Supraventricular extrasystoles	4	0
Supraventricular tachycardia	44	0
Tricuspid valvular disorders		
Tricuspid valve incompetence	6	0
Ventricular arrhythmias and cardiac arrest		
Cardiac arrest	119	44
Cardio-respiratory arrest	1	1
Pulseless electrical activity	5	0
Ventricular arrhythmia	5	0
Ventricular extrasystoles	31	0
Ventricular fibrillation	9	1
Ventricular tachycardia	15	0
Cardiac disorders SOC TOTAL	11141	136

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Autosomal chromosomal abnormalities</i>		
Trisomy 8	1	0
<i>Cardiac disorders congenital NEC</i>		
Heart disease congenital	17	0
<i>Cardiac hypoplasias congenital</i>		
Ventricular hypoplasia	1	0
<i>Cardiac septal defects congenital</i>		
Atrial septal defect	2	0
Hypertrophic cardiomyopathy	1	0
Ventricular septal defect	1	0
<i>Cardiac valve disorders congenital</i>		
Bicuspid aortic valve	1	0
<i>Central nervous system disorders congenital NEC</i>		
Spina bifida	2	1
Syringomyelia	1	0
<i>Cerebellar disorders congenital</i>		
Arnold-Chiari malformation	1	0
Hereditary ataxia	1	0
<i>Cerebral disorders congenital</i>		
Anencephaly	2	0
Cerebral palsy	3	0
Congenital hydrocephalus	1	0
<i>Chromosomal abnormalities NEC</i>		
Cytogenetic abnormality	1	0
<i>Coagulation disorders congenital</i>		
Factor IX deficiency	1	0
Haemophilia	2	0
<i>Congenital disorders NEC</i>		
Foetal malformation	1	0
Heterotaxia	1	0
<i>Connective tissue disorders congenital</i>		
Ehlers-Danlos syndrome	4	0
<i>Gastrointestinal tract disorders congenital NEC</i>		
Gastroschisis	3	0
<i>Genetic polymorphisms</i>		
Genetic polymorphism	1	0
<i>Great vessel disorders congenital</i>		
Congenital great vessel anomaly	1	0
Transposition of the great vessels	1	0
<i>Haematological disorders congenital NEC</i>		
Amegakaryocytic thrombocytopenia	1	0
Neonatal alloimmune thrombocytopenia	1	0
<i>Haemoglobinopathies congenital</i>		
Congenital methaemoglobinaemia	1	0
<i>Immune system abnormalities congenital</i>		
Combined immunodeficiency	1	0
<i>Inborn errors of lipid metabolism</i>		
Short-chain acyl-coenzyme A dehydrogenase deficiency	1	0
<i>Inborn errors of metabolism NEC</i>		
Alpha-1 antitrypsin deficiency	1	0
<i>Inborn errors of porphyrin metabolism</i>		
Porphyria	1	0
<i>Laryngeal and tracheal disorders congenital</i>		

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Reaction Name	Total	Fatal
Congenital disorders Congenital disorders cont'd		
Laryngomalacia	1	0
Lymphatic system disorders congenital		
Cystic lymphangioma	3	0
Male reproductive tract disorders congenital		
Cryptorchism	1	0
Micropenis	4	0
Penoscrotal fusion	1	0
Phimosis	1	0
Musculoskeletal and connective tissue disorders of limbs congenital		
Developmental hip dysplasia	1	0
Limb malformation	1	0
Musculoskeletal and connective tissue disorders of skull congenital		
Platybasia	1	0
Musculoskeletal and connective tissue disorders of spine congenital		
Block vertebra	1	0
Brachyolmia	1	0
Musculoskeletal disorders congenital NEC		
Dysmorphism	1	0
Neurological disorders congenital NEC		
Familial hemiplegic migraine	2	0
Familial periodic paralysis	1	0
Moebius II syndrome	1	0
Neurofibromatosis	1	0
Tourette's disorder	3	0
Ocular disorders congenital NEC		
Colour blindness	4	0
Congenital eye disorder	1	0
Palate disorders congenital		
Cleft lip and palate	2	0
Peripheral nervous system disorders congenital NEC		
Hereditary neuropathy with liability to pressure palsies	1	0
Paroxysmal extreme pain disorder	1	0
Pulmonary and bronchial disorders congenital		
Congenital cystic lung	1	0
Retinal disorders congenital		
Retinitis pigmentosa	1	0
Sex chromosomal abnormalities		
Turner's syndrome	1	0
Skin and subcutaneous tissue disorders congenital NEC		
Acral peeling skin syndrome	1	0
Tongue disorders congenital		
Ankyloglossia congenital	1	0
Vascular anomalies congenital NEC		
Congenital LUMBAR syndrome	1	0
Venous disorders congenital		
Anomalous pulmonary venous connection	1	0
Congenital disorders SOC TOTAL	99	1

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear canal erythema	1	0
Ear congestion	35	0
Ear discomfort	99	0
Ear disorder	22	0
Ear haemorrhage	13	0
Ear inflammation	1	0
Ear pain	1108	0
Ear pruritus	12	0
Ear swelling	38	0
Otorrhoea	6	0
Paraesthesia ear	1	0
<i>Eustachian tube disorders</i>		
Eustachian tube disorder	4	0
Eustachian tube dysfunction	9	0
Eustachian tube obstruction	5	0
<i>External ear disorders NEC</i>		
Auricular swelling	2	0
Excessive cerumen production	12	0
External ear pain	6	0
Red ear syndrome	2	0
<i>External ear infections and inflammations</i>		
External ear inflammation	2	0
<i>Hearing disorders NEC</i>		
Auditory disorder	6	0
Diplacusic	2	0
<i>Hearing losses</i>		
Conductive deafness	1	0
Deafness	272	0
Deafness bilateral	11	0
Deafness neurosensory	20	0
Deafness transitory	9	0
Deafness unilateral	36	0
Hypoacusis	213	0
Sudden hearing loss	50	0
<i>Hyperacusia</i>		
Hyperacusis	67	0
Misophonia	3	0
<i>Inner ear disorders NEC</i>		
Acute vestibular syndrome	2	0
Inner ear disorder	13	0
Meniere's disease	12	0
Vestibular disorder	13	0
<i>Inner ear infections and inflammations</i>		
Inner ear inflammation	11	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	66	0
Tinnitus	2287	0
Vertigo	1564	0
Vertigo labyrinthine	12	0
Vertigo positional	80	0
<i>Mastoid disorders</i>		
Mastoid effusion	1	0

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Reaction Name	Total	Fatal
Ear disorders Ear disorders cont'd		
<i>Middle ear disorders NEC</i>		
Middle ear disorder	3	0
Middle ear effusion	1	0
<i>Middle ear infections and inflammations</i>		
Middle ear inflammation	1	0
<i>Tympanic membrane disorders (excl infections)</i>		
Tympanic membrane perforation	3	0
Ear disorders SOC TOTAL	6137	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Autoimmune thyroiditis	2	0
Thyroiditis	23	0
Thyroiditis acute	3	0
Thyroiditis subacute	3	0
<i>Adrenal cortical hypofunctions</i>		
Addison's disease	2	0
Adrenal insufficiency	3	0
Adrenocortical insufficiency acute	16	0
<i>Adrenal gland disorders NEC</i>		
Adrenal disorder	2	0
Adrenal haemorrhage	3	0
<i>Anterior pituitary hyperfunction</i>		
Pituitary-dependent Cushing's syndrome	1	0
<i>Anterior pituitary hypofunction</i>		
Hypopituitarism	1	0
<i>Endocrine abnormalities of gonadal function NEC</i>		
Oestrogen deficiency	1	0
<i>Endocrine abnormalities of puberty</i>		
Delayed menarche	4	0
Premature menarche	20	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	57	0
Ovulation delayed	34	0
<i>Male gonadal function disorders</i>		
Androgen deficiency	1	0
<i>Thyroid disorders NEC</i>		
Autoimmune thyroid disorder	1	0
Goitre	16	0
Thyroid disorder	10	0
Thyroid mass	2	0
Thyroid pain	11	0
<i>Thyroid hyperfunction disorders</i>		
Basedow's disease	11	0
Hyperthyroidism	47	0
Thyrotoxic crisis	4	0
<i>Thyroid hypofunction disorders</i>		
Autoimmune hypothyroidism	1	0
Hypothyroidism	37	0
Immune-mediated hypothyroidism	1	0
Myxoedema	1	0
Endocrine disorders SOC TOTAL	318	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Amblyopic vision impairment</i>		
Amblyopia	7	0
<i>Anterior chamber bleeding and vascular disorders</i>		
Spontaneous hyphaema	1	0
<i>Cataract conditions</i>		
Cataract	13	0
<i>Choroid and vitreous haemorrhages and vascular disorders</i>		
Choroidal haemorrhage	1	0
Choroidal neovascularisation	1	0
Vitreous haemorrhage	4	0
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Chorioretinopathy	8	0
Vitreous detachment	18	0
Vitreous floaters	106	0
<i>Colour blindness (incl acquired)</i>		
Colour blindness acquired	1	0
Dyschromatopsia	10	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	50	0
Scleral haemorrhage	1	0
<i>Conjunctival infections, irritations and inflammations</i>		
Conjunctival hyperaemia	2	0
Conjunctival irritation	1	0
Conjunctival oedema	3	0
Conjunctivitis allergic	2	0
<i>Corneal infections, oedemas and inflammations</i>		
Corneal oedema	2	0
Keratitis	7	0
Ulcerative keratitis	5	0
<i>Corneal structural change, deposit and degeneration</i>		
Corneal scar	1	0
<i>Eyelid movement disorders</i>		
Blepharospasm	159	0
Excessive eye blinking	6	0
Eyelid function disorder	3	0
Eyelid myokymia	4	0
Eyelid ptosis	47	0
Paralytic lagophthalmos	2	0
<i>Glaucomas (excl congenital)</i>		
Angle closure glaucoma	2	0
Glaucoma	7	0
Ocular hypertension	1	0
<i>Iris and ciliary body structural change, deposit and degeneration</i>		
Eye colour change	3	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Autoimmune uveitis	3	0
Iridocyclitis	17	0
Iritis	11	0
Uveitis	54	0
<i>Lacrimation disorders</i>		
Dry eye	167	0
Lacrimation increased	152	0
<i>Lid bleeding and vascular disorders</i>		

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Eye disorders Eye disorders cont'd		
Eyelid bleeding	1	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Blepharitis	18	0
Blepharitis allergic	1	0
Chalazion	7	0
Eczema eyelids	9	0
Erythema of eyelid	10	0
Eyelid cyst	6	0
Eyelid irritation	4	0
Eyelid margin crusting	5	0
Eyelid oedema	14	0
Eyelid rash	20	0
Meibomian gland dysfunction	1	0
Swelling of eyelid	138	0
Swollen tear duct	2	0
<i>Lid, lash and lacrimal structural disorders</i>		
Dacryostenosis acquired	1	0
Dermatochalasis	1	0
Ectropion	1	0
Eyelash changes	1	0
Eyelid exfoliation	3	0
Eyelid skin dryness	2	0
Eyelid thickening	1	0
Floppy eyelid syndrome	1	0
Growth of eyelashes	3	0
Lagophthalmos	3	0
<i>Ocular bleeding and vascular disorders NEC</i>		
Eye haematoma	4	0
Eye haemorrhage	35	0
Ocular vascular disorder	2	0
Ophthalmic vein thrombosis	1	0
<i>Ocular disorders NEC</i>		
Chorioretinal disorder	1	0
Dark circles under eyes	8	0
Eye disorder	40	0
Eye oedema	18	0
Eye pain	1228	0
Eye swelling	608	0
Eye symptom	9	0
Eye ulcer	5	0
Eyelid disorder	16	0
Eyelid pain	13	0
Eyelids pruritus	7	0
Ocular discomfort	29	0
Periorbital oedema	19	0
Periorbital pain	2	0
Periorbital swelling	123	0
Retinal disorder	2	0
Vitreous disorder	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye allergy	21	0
Eye discharge	32	0
Eye inflammation	34	0

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Eye disorders Eye disorders cont'd		
Eye irritation	102	0
Eye pruritus	269	0
Limbal swelling	4	0
Ocular hyperaemia	252	0
Ocular nerve and muscle disorders		
Binocular eye movement disorder	1	0
Extraocular muscle disorder	1	0
Extraocular muscle paresis	2	0
Eye movement disorder	39	0
Gaze palsy	1	0
Ocular myasthenia	1	0
Ophthalmoplegia	5	0
Strabismus	10	0
Ocular sensation disorders		
Abnormal sensation in eye	21	0
Asthenopia	167	0
Eye paraesthesia	2	0
Eyelid sensory disorder	3	0
Foreign body sensation in eyes	17	0
Hypoaesthesia eye	17	0
Photophobia	510	0
Optic disc abnormalities NEC		
Papilloedema	7	0
Optic nerve bleeding and vascular disorders		
Optic disc haemorrhage	1	0
Optic ischaemic neuropathy	2	0
Orbital infections, inflammations and irritations		
Parophthalmia	1	0
Orbital structural change, deposit and degeneration		
Orbital oedema	2	0
Pupil disorders		
Miosis	2	0
Mydriasis	23	0
Pupil fixed	3	0
Pupillary disorder	1	0
Pupils unequal	13	0
Refractive and accommodative disorders		
Accommodation disorder	1	0
Altered visual depth perception	5	0
Astigmatism	2	0
Hypermetropia	3	0
Myopia	1	0
Retinal bleeding and vascular disorders (excl retinopathy)		
Retinal artery occlusion	16	0
Retinal artery thrombosis	2	0
Retinal haemorrhage	10	0
Retinal vascular thrombosis	1	0
Retinal vein occlusion	39	0
Retinal vein thrombosis	2	0
Retinal structural change, deposit and degeneration		
Macular degeneration	4	0
Macular hole	3	0
Macular rupture	1	0

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Maculopathy	1	0
Neovascular age-related macular degeneration	4	0
Retinal degeneration	1	0
Retinal detachment	7	0
Retinal tear	3	0
Retinal toxicity	3	0
<i>Retinal, choroid and vitreous infections and inflammations</i>		
Birdshot chorioretinopathy	2	0
Choroiditis	1	0
Cystoid macular oedema	1	0
Macular oedema	5	0
Retinal oedema	1	0
Retinal vasculitis	3	0
<i>Retinopathies NEC</i>		
Acute macular neuroretinopathy	3	0
Retinal exudates	2	0
Retinopathy	4	0
<i>Scleral infections, irritations and inflammations</i>		
Episcleritis	9	0
Scleritis	6	0
<i>Scleral structural change, deposit and degeneration</i>		
Scleral discolouration	2	0
<i>Structural change, deposit and degeneration of eye NEC</i>		
Endocrine ophthalmopathy	1	0
Exophthalmos	4	0
<i>Visual colour distortions</i>		
Chloropsia	2	0
Chromatopsia	1	0
Cyanopsia	4	0
Erythropsia	2	0
Xanthopsia	1	0
<i>Visual disorders NEC</i>		
Charles Bonnet syndrome	2	0
Diplopia	172	0
Dysmetropsia	1	0
Glare	1	0
Halo vision	7	0
Heteronymous diplopia	1	0
Metamorphopsia	23	0
Oscillopsia	3	0
Photopsia	153	0
Scintillating scotoma	4	0
Vision blurred	1354	0
Visual brightness	3	0
Visual snow syndrome	8	0
<i>Visual field disorders</i>		
Visual field defect	36	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Amaurosis fugax	4	0
Blindness	144	0
Blindness cortical	1	0
Blindness transient	18	0
Blindness unilateral	17	0

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Central vision loss	6	0
Sudden visual loss	3	0
Visual acuity reduced	27	0
Visual acuity reduced transiently	1	0
Visual impairment	427	0
<i>Visual pathway disorders</i>		
Optic nerve disorder	1	0
Eye disorders SOC TOTAL	7452	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Abdominal findings abnormal</i>		
Abdominal mass	2	0
Gastrointestinal sounds abnormal	17	0
<i>Abdominal hernias NEC</i>		
Abdominal hernia	2	0
<i>Abdominal wall conditions NEC</i>		
Abdominal wall haematoma	2	0
<i>Acute and chronic pancreatitis</i>		
Alcoholic pancreatitis	1	0
Autoimmune pancreatitis	1	0
Obstructive pancreatitis	1	0
Pancreatitis	17	0
Pancreatitis acute	16	1
Pancreatitis chronic	1	0
Pancreatitis necrotising	2	0
<i>Anal and rectal disorders NEC</i>		
Anal fissure	2	0
Anal sphincter atony	1	0
Rectal prolapse	1	0
<i>Anal and rectal pains</i>		
Proctalgia	15	0
<i>Anal and rectal signs and symptoms</i>		
Anal blister	1	0
Anal erythema	1	0
Anal hypoaesthesia	1	0
Anal pruritus	2	0
Anal spasm	1	0
Anorectal discomfort	5	0
Anorectal swelling	1	0
Rectal discharge	2	0
Rectal tenesmus	1	0
<i>Anal and rectal ulcers and perforation</i>		
Anal ulcer	1	0
<i>Benign oral cavity neoplasms</i>		
Mouth cyst	6	0
Tongue cyst	4	0
Tongue polyp	2	0
<i>Colitis (excl infective)</i>		
Autoimmune colitis	2	0
Colitis	50	1
Colitis ischaemic	2	0
Colitis microscopic	2	0
Colitis ulcerative	75	0
Crohn's disease	44	0
Eosinophilic colitis	1	0
Inflammatory bowel disease	10	0
<i>Dental and periodontal infections and inflammations</i>		
Dental caries	2	0
Periodontal inflammation	1	0
<i>Dental developmental disorders and anomalies</i>		
Tooth impacted	1	0
<i>Dental disorders NEC</i>		
Loose tooth	5	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Malpositioned teeth	2	0
Periodontal disease	1	0
Teeth brittle	3	0
Teething	9	0
Tooth disorder	2	0
Tooth erosion	1	0
Tooth socket haemorrhage	1	0
Dental pain and sensation disorders		
Dental discomfort	7	0
Dental paraesthesia	14	0
Hyperaesthesia teeth	38	0
Toothache	189	0
Dental surface disorders		
Tooth discolouration	9	0
Diaphragmatic hernias		
Hiatus hernia	8	0
Diarrhoea (excl infective)		
Diarrhoea	5901	0
Diarrhoea haemorrhagic	26	0
Diverticula		
Diverticulum	6	0
Diverticulum intestinal	1	0
Duodenal and small intestinal stenosis and obstruction		
Small intestinal obstruction	2	0
Duodenal ulcers and perforation		
Duodenal ulcer haemorrhage	1	0
Duodenal ulcer perforation	3	0
Dyspeptic signs and symptoms		
Dyspepsia	511	0
Epigastric discomfort	14	0
Eructation	58	0
Faecal abnormalities NEC		
Abnormal faeces	20	0
Faecaloma	6	0
Faeces discoloured	62	0
Faeces hard	2	0
Faeces pale	4	0
Faeces soft	12	0
Mucous stools	10	0
Flatulence, bloating and distension		
Abdominal distension	559	0
Aerophagia	3	0
Flatulence	194	0
Gastric and oesophageal haemorrhages		
Gastric haemorrhage	5	1
Mallory-Weiss syndrome	1	0
Oesophageal varices haemorrhage	1	0
Gastric ulcers and perforation		
Gastric ulcer	7	0
Gastritis (excl infective)		
Chronic gastritis	4	0
Gastritis	63	0
Reflux gastritis	8	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal migraine	2	0
Abdominal pain	1597	0
Abdominal pain lower	144	0
Abdominal pain upper	2672	0
Abdominal rigidity	25	0
Abdominal tenderness	14	0
Gastrointestinal pain	155	0
Oesophageal pain	13	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	269	0
Duodenogastric reflux	4	0
Gastric dilatation	7	0
Gastrooesophageal reflux disease	178	0
Impaired gastric emptying	9	0
Infrequent bowel movements	3	0
Intestinal dilatation	1	0
Intestinal pseudo-obstruction	2	0
<i>Gastrointestinal disorders NEC</i>		
Appendicolith	1	0
Appendix disorder	2	0
Food poisoning	7	0
Functional gastrointestinal disorder	10	0
Gastric disorder	10	0
Gastrointestinal disorder	25	0
Stomach mass	4	0
<i>Gastrointestinal dyskinetic disorders</i>		
Bowel movement irregularity	7	0
Change of bowel habit	11	0
Dyschezia	4	0
Gastrointestinal motility disorder	3	0
Oesophageal achalasia	1	0
<i>Gastrointestinal fistulae</i>		
Diverticular fistula	2	0
<i>Gastrointestinal inflammatory disorders NEC</i>		
Duodenitis	1	0
Enteritis	6	0
Epiplonic appendagitis	2	0
Gastrointestinal inflammation	3	0
Gastrointestinal tract irritation	1	0
Intestinal angioedema	2	0
<i>Gastrointestinal mucosal dystrophies and secretion disorders</i>		
Barrett's oesophagus	1	0
Hyperchlorhydria	4	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	667	0
Abdominal symptom	1	0
Acute abdomen	7	0
Anal incontinence	19	0
Breath odour	22	0
Dysphagia	224	2
Gastrointestinal wall thickening	1	0
Odynophagia	42	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Cardiospasm	1	0
Defaecation urgency	11	0
Frequent bowel movements	30	0
Gastrointestinal hypermotility	1	0
Irritable bowel syndrome	92	0
Oesophageal spasm	5	0
Pylorospasm	1	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Ileus	1	0
Intestinal obstruction	6	0
Neonatal intestinal obstruction	1	0
<i>Gastrointestinal vascular malformations</i>		
Gastric antral vascular ectasia	11	0
<i>Gastrointestinal vascular occlusion and infarction</i>		
Intestinal ischaemia	7	2
Mesenteric vein thrombosis	9	0
Omental infarction	1	0
Thrombosis mesenteric vessel	2	0
Visceral venous thrombosis	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival blister	13	0
Gingival discomfort	8	0
Gingival disorder	4	0
Gingival erythema	2	0
Gingival hypertrophy	1	0
Gingival oedema	1	0
Gingival pain	127	0
Gingival pruritus	1	0
Gingival recession	1	0
Gingival swelling	41	0
Gingival ulceration	2	0
Gingivitis ulcerative	1	0
Noninfective gingivitis	10	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	78	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Gastric varices	1	0
Haemorrhoidal haemorrhage	1	0
Haemorrhoids	34	1
Haemorrhoids thrombosed	1	0
<i>Inguinal hernias</i>		
Inguinal hernia	1	0
<i>Intestinal haemorrhages</i>		
Anal haemorrhage	23	1
Intestinal haemorrhage	1	0
Rectal haemorrhage	78	0
Small intestinal haemorrhage	5	0
<i>Intestinal ulcers and perforation NEC</i>		
Intestinal perforation	5	2
Large intestinal ulcer	1	0
Large intestinal ulcer haemorrhage	1	0
Large intestine perforation	1	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Large intestinal stenosis and obstruction</i>		
Large intestinal obstruction	1	1
<i>Malabsorption syndromes</i>		
Bile acid malabsorption	4	0
Coeliac disease	14	0
Malabsorption	1	0
Steatorrhoea	4	0
<i>Nausea and vomiting symptoms</i>		
Discoloured vomit	13	0
Infantile vomiting	7	0
Nausea	14788	0
Regurgitation	1	0
Retching	109	0
Vomiting	4899	1
Vomiting projectile	67	0
<i>Non-mechanical ileus</i>		
Ileus paralytic	2	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Gastrointestinal haemorrhage	18	1
Haematemesis	37	2
Haematochezia	58	0
Melaena	9	0
Upper gastrointestinal haemorrhage	13	0
<i>Oesophageal stenosis and obstruction</i>		
Oesophageal stenosis	3	0
<i>Oesophagitis (excl infective)</i>		
Eosinophilic oesophagitis	1	0
Oesophagitis	5	0
<i>Oral dryness and saliva altered</i>		
Aptyalism	4	0
Dry mouth	525	0
Lip dry	48	0
Saliva altered	8	0
Salivary hypersecretion	50	0
<i>Oral soft tissue disorders NEC</i>		
Angina bullosa haemorrhagica	1	0
Chapped lips	26	0
Cheilitis	26	0
Enlarged uvula	15	0
Leukoplakia oral	2	0
Lip blister	32	0
Lip disorder	5	0
Oral disorder	21	0
Oral lichen planus	14	0
Oral mucosal hypertrophy	1	0
Oral papule	1	0
Uvulitis	7	0
<i>Oral soft tissue haemorrhages</i>		
Lip haemorrhage	1	0
Mouth haemorrhage	16	0
Oral blood blister	17	0
Oral purpura	2	0
<i>Oral soft tissue infections</i>		

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Angular cheilitis	4	0
Oral soft tissue signs and symptoms		
Anaesthesia oral	3	0
Burning mouth syndrome	6	0
Coating in mouth	1	0
Hypoaesthesia oral	498	0
Lip discolouration	9	0
Lip erythema	4	0
Lip exfoliation	6	0
Lip pain	60	0
Lip pruritus	17	0
Lip scab	1	0
Oral discomfort	86	0
Oral dysaesthesia	1	0
Oral mucosal blistering	16	0
Oral mucosal discolouration	1	0
Oral mucosal eruption	18	0
Oral mucosal erythema	7	0
Oral mucosal exfoliation	10	0
Oral mucosal roughening	3	0
Oral mucosal scab	1	0
Oral pain	180	0
Oral pruritus	23	0
Paraesthesia oral	928	0
Pigmentation lip	1	0
Oral soft tissue swelling and oedema		
Lip oedema	4	0
Lip swelling	841	0
Mouth swelling	112	0
Oedema mouth	4	0
Palatal oedema	4	0
Palatal swelling	3	0
Pancreatic disorders NEC		
Pancreatic disorder	1	0
Pancreatic failure	1	0
Pancreatic mass	1	0
Peptic ulcers and perforation		
Peptic ulcer	1	0
Peptic ulcer haemorrhage	14	0
Peritoneal and retroperitoneal disorders		
Ascites	2	0
Peritoneal and retroperitoneal fibrosis and adhesions		
Abdominal adhesions	2	0
Peritoneal and retroperitoneal haemorrhages		
Haemoperitoneum	1	0
Retroperitoneal haemorrhage	2	1
Rectal inflammations NEC		
Proctitis	3	0
Proctitis ulcerative	1	0
Salivary gland disorders NEC		
Salivary gland disorder	1	0
Salivary gland pain	12	0
Salivary gland enlargements		

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Parotid gland enlargement	10	0
Salivary gland enlargement	5	0
Submaxillary gland enlargement	7	0
<i>Salivary gland infections and inflammations</i>		
Noninfective sialoadenitis	1	0
<i>Stomatitis and ulceration</i>		
Aphthous ulcer	56	0
Lip ulceration	21	0
Mouth ulceration	468	0
Oral mucosa erosion	1	0
Palatal ulcer	1	0
Stomatitis	67	0
<i>Tongue disorders</i>		
Glossitis	21	0
Hypertrophy of tongue papillae	1	0
Plicated tongue	4	0
Tongue disorder	43	0
Tongue geographic	7	0
Tongue haemorrhage	3	0
Tongue ulceration	32	0
Trichoglossia	4	0
<i>Tongue signs and symptoms</i>		
Glossodynia	224	0
Scalloped tongue	5	0
Stiff tongue	4	0
Swollen tongue	526	0
Tongue blistering	19	0
Tongue coated	19	0
Tongue discolouration	39	0
Tongue discomfort	44	0
Tongue dry	16	0
Tongue eruption	10	0
Tongue erythema	13	0
Tongue exfoliation	2	0
Tongue movement disturbance	7	0
Tongue oedema	23	0
Tongue pruritus	2	0
Tongue rough	5	0
Tongue spasm	12	0
<i>Tooth missing</i>		
Tooth loss	6	0
Gastrointestinal disorders SOC TOTAL	40378	17

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site bruise	8	0
Administration site erythema	4	0
Administration site extravasation	3	0
Administration site haematoma	3	0
Administration site inflammation	1	0
Administration site irritation	1	0
Administration site joint discomfort	1	0
Administration site joint movement impairment	2	0
Administration site nerve damage	1	0
Administration site pain	20	0
Administration site rash	5	0
Administration site reaction	1	0
Administration site swelling	4	0
Administration site urticaria	2	0
Administration site warmth	2	0
Puncture site bruise	42	0
Puncture site pain	8	0
Puncture site reaction	1	0
Puncture site swelling	2	0
Vessel puncture site bruise	2	0
Vessel puncture site erythema	1	0
Vessel puncture site pain	1	0
<i>Adverse effect absent</i>		
No adverse event	9	0
<i>Application and instillation site reactions</i>		
Application site acne	2	0
Application site bruise	12	0
Application site burn	1	0
Application site dryness	1	0
Application site erythema	18	0
Application site haemorrhage	1	0
Application site hypoaesthesia	1	0
Application site irritation	1	0
Application site joint erythema	1	0
Application site joint pain	1	0
Application site mass	1	0
Application site odour	2	0
Application site pain	12	0
Application site pruritus	4	0
Application site rash	2	0
Application site reaction	1	0
Application site swelling	2	0
Application site vesicles	7	0
Application site warmth	1	0
Instillation site warmth	9	0
<i>Asthenic conditions</i>		
Asthenia	2197	0
Chronic fatigue syndrome	79	0
Decreased activity	10	0
Fatigue	24688	1
Malaise	5593	1
Sluggishness	19	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
<i>Body temperature altered</i>		
Hyperthermia	7	0
Hyperthermia malignant	1	0
Hypothermia	25	0
Temperature regulation disorder	14	0
<i>Breast complications associated with device</i>		
Breast implant palpable	1	0
Capsular contracture associated with breast implant	2	0
<i>Cardiac complications associated with device</i>		
Prosthetic cardiac valve thrombosis	2	0
<i>Complications associated with device NEC</i>		
Capsular contracture associated with implant	1	0
Complication of device removal	3	0
Injury associated with device	5	0
Medical device pain	1	0
Medical device site swelling	1	0
Phantom shocks	2	0
<i>Death and sudden death</i>		
Brain death	3	2
Cardiac death	3	2
Clinical death	1	1
Death	188	188
Sudden cardiac death	1	1
Sudden death	26	26
<i>Febrile disorders</i>		
Hyperpyrexia	9	0
Pyrexia	16111	0
<i>Feelings and sensations NEC</i>		
Chills	10152	0
Feeling abnormal	1733	0
Feeling cold	1311	0
Feeling drunk	81	0
Feeling hot	1231	0
Feeling jittery	34	0
Feeling of body temperature change	350	0
Feeling of relaxation	3	0
Hangover	84	0
Hunger	50	0
Sensation of blood flow	5	0
Sensation of foreign body	58	0
Temperature intolerance	50	0
Thirst	375	0
Thirst decreased	1	0
<i>Fibrosis NEC</i>		
Fibrosis	1	0
<i>Gait disturbances</i>		
Gait deviation	1	0
Gait disturbance	255	0
Gait inability	98	0
Loss of control of legs	25	0
<i>General signs and symptoms NEC</i>		
Adhesion	1	0
Chronic disease	1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Concomitant disease progression	1	1
Condition aggravated	280	0
Crepitations	4	0
Crying	163	0
Deformity	2	0
Developmental delay	1	0
Discharge	13	0
Disease progression	2	0
Disease recurrence	32	0
Effusion	3	0
Energy increased	25	0
Exercise tolerance decreased	27	0
Exercise tolerance increased	1	0
Fat tissue increased	1	0
Foaming at mouth	3	0
General physical health deterioration	17	2
General symptom	3	0
Glassy eyes	6	0
High-pitched crying	3	0
Illness	2133	0
Induration	16	0
Influenza like illness	2554	0
Irritability postvaccinal	2	0
Local reaction	92	0
Moaning	3	0
Multiple organ dysfunction syndrome	12	4
Nonspecific reaction	2	0
Organ failure	3	1
Perforation	2	0
Peripheral swelling	4203	0
Physical deconditioning	2	0
Pre-existing condition improved	9	0
Prolapse	1	0
Screaming	24	0
Secretion discharge	24	0
Swelling	3393	0
Swelling face	925	0
Symptom recurrence	1	0
Terminal state	1	0
Tissue irritation	1	0
Healing abnormal NEC		
Impaired healing	4	0
Implant and catheter site reactions		
Implant site discolouration	2	0
Implant site pain	3	0
Implant site rash	1	0
Implant site swelling	2	0
Implant site urticaria	1	0
Implant site warmth	3	0
Inflammations		
Foreign body reaction	1	0
Granuloma	1	0
Inflammation	579	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Papillitis	1	0
Scar inflammation	3	0
Serositis	1	0
Systemic inflammatory response syndrome	6	0
Infusion site reactions		
Infusion site coldness	1	0
Infusion site discolouration	1	0
Infusion site joint effusion	1	0
Infusion site joint pain	2	0
Infusion site mass	1	0
Infusion site nerve damage	1	0
Infusion site pain	4	0
Infusion site pruritus	3	0
Infusion site swelling	2	0
Infusion site urticaria	1	0
Infusion site warmth	2	0
Injection site reactions		
Injected limb mobility decreased	35	0
Injection site bruising	71	0
Injection site coldness	1	0
Injection site cyst	3	0
Injection site discolouration	5	0
Injection site discomfort	11	0
Injection site eczema	1	0
Injection site erythema	424	0
Injection site extravasation	1	0
Injection site haematoma	1	0
Injection site haemorrhage	8	0
Injection site hypersensitivity	2	0
Injection site hypoaesthesia	14	0
Injection site indentation	9	0
Injection site induration	4	0
Injection site inflammation	46	0
Injection site injury	2	0
Injection site irritation	2	0
Injection site joint discomfort	2	0
Injection site joint erythema	4	0
Injection site joint movement impairment	1	0
Injection site joint pain	15	0
Injection site lymphadenopathy	1	0
Injection site macule	1	0
Injection site mass	619	0
Injection site movement impairment	1	0
Injection site muscle weakness	1	0
Injection site necrosis	4	0
Injection site nerve damage	1	0
Injection site nodule	1	0
Injection site oedema	18	0
Injection site pain	3119	0
Injection site pallor	1	0
Injection site paraesthesia	13	0
Injection site pruritus	236	0
Injection site rash	198	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Injection site reaction	57	0
Injection site scab	4	0
Injection site scar	5	0
Injection site swelling	331	0
Injection site urticaria	35	0
Injection site vesicles	10	0
Injection site warmth	205	0
Interactions		
Alcohol interaction	5	0
Drug interaction	30	0
Inhibitory drug interaction	3	0
Mass conditions NEC		
Cyst	51	0
Mass	80	0
Nodule	40	0
Mucosal findings abnormal		
Mucosa vesicle	1	0
Mucosal dryness	1	0
Mucosal haemorrhage	10	0
Mucosal inflammation	3	0
Oedema mucosal	2	0
Polyp	5	0
Necrosis NEC		
Fat necrosis	4	0
Necrosis	5	0
Oedema NEC		
Face oedema	33	0
Generalised oedema	4	0
Localised oedema	21	0
Oedema	85	0
Oedema peripheral	92	0
Pain and discomfort NEC		
Axillary pain	3838	0
Breakthrough pain	1	0
Chest discomfort	1910	0
Chest pain	5898	0
Discomfort	523	0
Facial discomfort	21	0
Facial pain	224	0
Inflammatory pain	18	0
Non-cardiac chest pain	33	0
Pain	9493	0
Suprapubic pain	1	0
Tenderness	714	0
Visceral pain	2	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	66	0
Adverse food reaction	3	0
Adverse reaction	11	0
Drug ineffective	359	0
Drug intolerance	4	0
Drug resistance	1	0
Immediate post-injection reaction	4	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech Vaccine Analysis Print

Report Run Date: 13-Jan-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Inadequate analgesia	9	0
No reaction on previous exposure to drug	22	0
Product intolerance	1	0
Therapeutic product effect decreased	1	0
Therapeutic product effect delayed	2	0
Therapeutic product effect increased	1	0
Therapeutic product ineffective	2	0
Therapeutic response decreased	2	0
Therapeutic response unexpected	77	0
Therapy non-responder	1	0
Treatment failure	10	0
Vaccination failure	52	0
Trophic disorders		
Abnormal organ growth	1	0
Atrophy	2	0
Calcinosis	2	0
Hyperplasia	1	0
Hypertrophy	1	0
Ulcers NEC		
Ulcer	37	0
Ulcer haemorrhage	1	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	18	0
Shoulder injury related to vaccine administration	49	0
Vaccination site anaesthesia	1	0
Vaccination site bruising	139	0
Vaccination site coldness	3	0
Vaccination site cyst	6	0
Vaccination site dermatitis	1	0
Vaccination site discolouration	17	0
Vaccination site discomfort	51	0
Vaccination site dryness	1	0
Vaccination site eczema	1	0
Vaccination site erythema	671	0
Vaccination site granuloma	5	0
Vaccination site haematoma	2	0
Vaccination site haemorrhage	26	0
Vaccination site hypersensitivity	5	0
Vaccination site hypoaesthesia	18	0
Vaccination site induration	78	0
Vaccination site inflammation	62	0
Vaccination site irritation	15	0
Vaccination site joint discomfort	3	0
Vaccination site joint erythema	12	0
Vaccination site joint inflammation	1	0
Vaccination site joint movement impairment	20	0
Vaccination site joint pain	34	0
Vaccination site joint swelling	4	0
Vaccination site joint warmth	1	0
Vaccination site lymphadenopathy	8	0
Vaccination site macule	1	0
Vaccination site mass	314	0
Vaccination site movement impairment	92	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site nerve damage	1	0
Vaccination site nodule	4	0
Vaccination site oedema	3	0
Vaccination site pain	2286	0
Vaccination site paraesthesia	9	0
Vaccination site phlebitis	1	0
Vaccination site photosensitivity reaction	1	0
Vaccination site pruritus	179	0
Vaccination site rash	150	0
Vaccination site reaction	36	0
Vaccination site scab	2	0
Vaccination site scar	1	0
Vaccination site swelling	627	0
Vaccination site thrombosis	1	0
Vaccination site ulcer	2	0
Vaccination site urticaria	10	0
Vaccination site vesicles	12	0
Vaccination site warmth	292	0
<i>Vascular complications associated with device</i>		
Vascular stent thrombosis	1	0
<i>Withdrawal and rebound effects</i>		
Drug withdrawal syndrome	4	0
Withdrawal syndrome	48	0
General disorders SOC TOTAL	114390	230

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech Vaccine Analysis Print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	17	0
Cholangitis	1	0
<i>Cholecystitis and cholelithiasis</i>		
Cholecystitis	4	0
Cholecystitis acute	2	0
Cholelithiasis	11	0
<i>Cholestasis and jaundice</i>		
Cholestasis	2	0
Jaundice	25	0
Jaundice cholestatic	10	0
Ocular icterus	2	0
<i>Gallbladder disorders NEC</i>		
Gallbladder disorder	2	0
Gallbladder enlargement	1	0
<i>Hepatic and hepatobiliary disorders NEC</i>		
Hepatic cyst	1	0
Liver disorder	14	0
<i>Hepatic enzymes and function abnormalities</i>		
Hepatic function abnormal	7	0
<i>Hepatic failure and associated disorders</i>		
Acute hepatic failure	2	0
Hepatic failure	2	1
<i>Hepatic fibrosis and cirrhosis</i>		
Hepatic cirrhosis	1	0
<i>Hepatic vascular disorders</i>		
Congestive hepatopathy	2	0
Hepatic artery embolism	1	0
Hepatic haemorrhage	2	0
Hepatic vein thrombosis	5	0
Portal vein thrombosis	8	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	32	0
Hepatomegaly	6	0
Liver tenderness	3	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Autoimmune hepatitis	12	0
Drug-induced liver injury	3	0
Hepatic steatosis	5	0
Hepatitis	14	0
Hepatitis acute	3	0
Hepatitis toxic	1	0
Immune-mediated hepatic disorder	1	0
Liver injury	24	0
Hepatic disorders SOC TOTAL	226	1

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Immune system disorders		
<i>Acute and chronic sarcoidosis</i>		
Loefgren syndrome	1	0
Sarcoidosis	18	0
<i>Allergic conditions NEC</i>		
Allergic oedema	18	0
Allergy to animal	2	0
Allergy to arthropod bite	6	0
Allergy to arthropod sting	2	0
Allergy to metals	3	0
Allergy to sting	1	0
Hypersensitivity	1088	0
Infusion related hypersensitivity reaction	3	0
Mite allergy	2	0
Multiple allergies	16	0
Serum sickness	3	0
Serum sickness-like reaction	6	0
Type I hypersensitivity	1	0
Type III immune complex mediated reaction	4	0
Type IV hypersensitivity reaction	6	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergic reaction to excipient	6	0
Allergy to chemicals	5	0
Allergy to vaccine	44	0
Contrast media reaction	2	0
Drug hypersensitivity	36	0
Food allergy	36	0
Milk allergy	2	0
Oral allergy syndrome	3	0
Polymers allergy	1	0
Reaction to colouring	1	0
Reaction to excipient	10	0
Reaction to preservatives	5	0
Rubber sensitivity	1	0
Smoke sensitivity	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	536	1
Anaphylactic shock	60	0
Anaphylactoid reaction	24	0
Anaphylactoid shock	4	0
<i>Atopic disorders</i>		
Atopy	3	0
Seasonal allergy	107	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	52	0
<i>Immune and associated conditions NEC</i>		
Anamnestic reaction	1	0
Bacille Calmette-Guerin scar reactivation	63	0
Cytokine storm	1	0
Decreased immune responsiveness	3	0
Graft versus host disease	2	0
Haemophagocytic lymphohistiocytosis	3	0
Immune reconstitution inflammatory syndrome	1	0
Immune system disorder	31	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Immune system disorders cont'd</i>		
Immune-mediated adverse reaction	7	0
Immunisation reaction	2	0
Multisystem inflammatory syndrome in children	4	0
Sensitisation	9	0
Systemic immune activation	2	0
<i>Immunodeficiency disorders NEC</i>		
Hypogammaglobulinaemia	1	0
Immunodeficiency	4	0
Immunosuppression	4	0
<i>Transplant rejections</i>		
Corneal graft rejection	10	0
Kidney transplant rejection	1	0
Solid organ transplant rejection	1	0
Transplant rejection	2	0
Immune system disorders SOC TOTAL	2271	1

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Abdominal abscess	2	0
Abdominal infection	1	0
Anal abscess	3	0
Anorectal infection	1	0
Appendicitis	45	0
Appendicitis perforated	7	0
Diverticulitis	15	0
Dysentery	1	0
Gastric infection	2	0
Gastroenteritis	30	0
Mesenteric abscess	1	0
Peritonitis	3	1
Rectal abscess	1	0
<i>Adenoviral infections</i>		
Adenoviral conjunctivitis	1	0
Adenovirus infection	1	0
<i>Aspergillus infections</i>		
Bronchopulmonary aspergillosis	1	0
<i>Bacterial infections NEC</i>		
Abscess bacterial	2	0
Administration site cellulitis	1	0
Arthritis bacterial	4	0
Bacterial colitis	1	0
Bacterial diarrhoea	1	0
Bacterial infection	16	0
Bacterial sepsis	1	0
Bacterial vaginosis	2	0
Cellulitis	196	0
Cellulitis orbital	1	0
Conjunctivitis bacterial	1	0
Ear infection bacterial	1	0
External ear cellulitis	1	0
Folliculitis	18	0
Gangrene	1	0
Gastrointestinal bacterial overgrowth	1	0
Injection site cellulitis	2	0
Meningitis bacterial	3	0
Myocarditis bacterial	1	0
Paronychia	3	0
Perichondritis	3	0
Periorbital cellulitis	3	0
Pneumonia bacterial	1	0
Sinusitis bacterial	2	0
Skin bacterial infection	4	0
Tonsillitis bacterial	3	0
Urinary tract infection bacterial	1	0
Vaccination site cellulitis	20	0
Zoonotic bacterial infection	1	1
<i>Bartonella infections</i>		
Cat scratch disease	1	0
<i>Bone and joint infections</i>		
Abscess jaw	1	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Infections Infections cont'd		
Arthritis infective	2	0
Osteomyelitis	2	0
<i>Bordetella infections</i>		
Pertussis	1	0
<i>Borrelial infections</i>		
Lyme disease	3	0
Relapsing fever	1	0
<i>Breast infections</i>		
Breast abscess	3	0
Mastitis	82	0
<i>Caliciviral infections</i>		
Gastroenteritis norovirus	3	0
<i>Campylobacter infections</i>		
Campylobacter gastroenteritis	1	0
Campylobacter infection	1	0
<i>Candida infections</i>		
Anal candidiasis	3	0
Balanitis candida	1	0
Candida infection	71	0
Oral candidiasis	39	0
Respiratory moniliasis	1	0
Skin candida	2	0
Systemic candida	1	0
Urinary tract candidiasis	1	0
Vulvovaginal candidiasis	53	0
<i>Cardiac infections</i>		
Cardiac infection	1	0
Cardiac valve vegetation	1	0
Endocarditis	1	0
Myocarditis infectious	1	0
Pericarditis infective	2	0
<i>Central nervous system and spinal infections</i>		
Brain abscess	2	0
CNS ventriculitis	1	0
Cavernous sinus thrombosis	1	0
Encephalitis	21	0
Encephalomyelitis	1	0
Meningitis	12	0
Meningitis aseptic	3	0
Myelitis	9	0
Subdural abscess	1	0
<i>Clostridia infections</i>		
Clostridium difficile infection	2	0
<i>Coronavirus infections</i>		
Asymptomatic COVID-19	19	0
COVID-19	1913	44
COVID-19 pneumonia	51	14
Coronavirus infection	7	0
Post-acute COVID-19 syndrome	5	0
Severe acute respiratory syndrome	4	0
Suspected COVID-19	75	4
<i>Corynebacteria infections</i>		
Diphtheria	2	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
<i>Coxiella infections</i>		
Q fever	13	0
<i>Cytomegaloviral infections</i>		
Cytomegalovirus infection	2	0
Cytomegalovirus syndrome	1	0
<i>Dental and oral soft tissue infections</i>		
Abscess oral	6	0
Gingival abscess	1	0
Gingivitis	13	0
Oral infection	1	0
Parotitis	12	0
Pericoronitis	3	0
Periodontitis	1	0
Pulpitis dental	2	0
Sialoadenitis	3	0
Tongue abscess	1	0
Tooth abscess	8	0
Tooth infection	9	0
<i>Ear infections</i>		
Ear infection	98	0
Labyrinthitis	109	0
Mastoiditis	3	0
Otitis externa	3	0
Otitis media	3	0
Otitis media acute	1	0
Otitis media chronic	5	0
<i>Ectoparasitic infestations</i>		
Acarodermatitis	5	0
Bed bug infestation	1	0
Demodicidosis	1	0
<i>Epstein-Barr viral infections</i>		
Epstein-Barr virus infection	5	0
Epstein-Barr virus infection reactivation	1	0
Infectious mononucleosis	29	0
<i>Escherichia infections</i>		
Escherichia bacteraemia	1	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	81	0
Eye abscess	1	0
Eye infection	28	0
Eye infection intraocular	1	0
Eyelid boil	2	0
Eyelid infection	2	0
Hordeolum	29	0
Keratouveitis	1	0
Periorbital infection	2	0
<i>Female reproductive tract infections</i>		
Bartholin's abscess	1	0
Bartholinitis	1	0
Endometritis	3	0
Funisitis	1	0
Pelvic inflammatory disease	2	0
Vaginal infection	2	0

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Vulval abscess	1	0
Vulvitis	1	0
<i>Fungal infections NEC</i>		
Fungal infection	19	0
Fungal skin infection	5	0
Myocarditis mycotic	1	0
Onychomycosis	2	0
Oral fungal infection	2	0
Pneumonia fungal	2	0
Severe asthma with fungal sensitisation	1	0
Vulvovaginal mycotic infection	8	0
<i>Hepatitis virus infections</i>		
Hepatitis A	1	0
Hepatitis E	1	0
<i>Hepatobiliary and spleen infections</i>		
Biliary sepsis	3	0
Cholecystitis infective	2	0
Hepatic infection	1	0
<i>Herpes viral infections</i>		
Eczema herpeticum	3	0
Genital herpes	94	0
Genital herpes simplex	6	0
Genital herpes zoster	1	0
Herpes ophthalmic	3	0
Herpes simplex	33	0
Herpes simplex encephalitis	1	1
Herpes simplex reactivation	2	0
Herpes virus infection	13	0
Herpes zoster	1533	0
Herpes zoster disseminated	1	0
Herpes zoster meningoencephalitis	1	0
Herpes zoster oticus	15	0
Herpes zoster reactivation	2	0
Meningitis herpes	1	0
Nasal herpes	5	0
Ophthalmic herpes simplex	3	0
Ophthalmic herpes zoster	4	0
Oral herpes	327	0
Varicella	30	0
Varicella zoster virus infection	3	0
<i>Infections NEC</i>		
Abscess	39	0
Abscess limb	9	0
Abscess soft tissue	1	0
Catheter site infection	1	0
Genital abscess	2	0
Groin abscess	1	0
Infected bite	3	0
Infected cyst	2	0
Infection	261	0
Infection susceptibility increased	2	0
Injection site abscess	1	0
Injection site infection	5	0

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Localised infection	35	0
Lymph gland infection	18	0
Lymph node abscess	6	0
Opportunistic infection	1	0
Pathogen resistance	1	0
Purulence	1	0
Purulent discharge	1	0
Respiratory tract infection	12	0
Vaccination site abscess	11	0
Vaccination site infection	13	0
Vaccine breakthrough infection	23	0
Vestibulitis	2	0
Wound infection	2	0
<i>Infectious transmissions</i>		
Nosocomial infection	1	0
Secondary transmission	8	0
Vaccine virus shedding	1	0
<i>Influenza viral infections</i>		
H1N1 influenza	1	0
Influenza	1745	0
<i>Klebsiella infections</i>		
Klebsiella infection	1	0
<i>Lower respiratory tract and lung infections</i>		
Bronchitis	24	0
Infectious pleural effusion	1	0
Lower respiratory tract infection	269	8
Pneumonia	159	13
Pneumonia aspiration	10	6
Sputum purulent	1	0
<i>Male reproductive tract infections</i>		
Epididymitis	10	0
Orchitis	6	0
Prostate infection	2	0
<i>Molluscum contagiosum viral infections</i>		
Molluscum contagiosum	1	0
<i>Mumps viral infections</i>		
Mumps	8	0
<i>Muscle and soft tissue infections</i>		
Abscess neck	1	0
Infective tenosynovitis	1	0
Necrotising fasciitis	2	0
Psoas abscess	1	0
Soft tissue infection	2	0
<i>Neisseria infections</i>		
Gonorrhoea	1	0
Meningococcal bacteraemia	1	0
Meningococcal infection	1	0
<i>Orthopox viral infections</i>		
Smallpox	1	0
Vaccinia virus infection	2	0
<i>Plasmodia infections</i>		
Malaria	2	0
<i>Pneumocystis infections</i>		

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Pneumocystis jirovecii pneumonia	2	0
<i>Pseudomonal infections</i>		
Pseudomonas infection	1	0
<i>Retroviral infections</i>		
Acquired immunodeficiency syndrome	1	0
HIV infection	2	0
Persistent generalised lymphadenopathy	1	0
<i>Rhinoviral infections</i>		
Rhinovirus infection	1	0
<i>Rotaviral infections</i>		
Gastroenteritis rotavirus	1	0
<i>Rubeola viral infections</i>		
Measles	5	0
<i>Salmonella infections</i>		
Typhoid fever	1	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Neutropenic sepsis	4	1
Sepsis	57	8
Sepsis syndrome	2	0
Septic rash	2	0
Septic shock	6	1
Urosepsis	5	0
<i>Skin structures and soft tissue infections</i>		
Abscess sweat gland	1	0
Acne pustular	1	0
Blister infected	1	0
Dermatitis infected	3	0
Impetigo	11	0
Infected skin ulcer	2	0
Injection site pustule	3	0
Nail infection	2	0
Pustule	19	0
Pyoderma	1	0
Rash pustular	12	0
Skin infection	32	0
Subcutaneous abscess	12	0
Sweat gland infection	1	0
Vaccination site pustule	4	0
<i>Staphylococcal infections</i>		
Furuncle	43	1
Pneumonia staphylococcal	1	0
Staphylococcal abscess	1	0
Staphylococcal infection	5	0
Staphylococcal sepsis	1	0
<i>Streptococcal infections</i>		
Meningitis pneumococcal	1	0
Pharyngitis streptococcal	7	0
Pneumonia pneumococcal	1	0
Streptococcal abscess	1	0
Streptococcal endocarditis	1	0
Streptococcal infection	1	0
Streptococcal sepsis	1	0
<i>Tinea infections</i>		

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Body tinea	4	0
Tinea capitis	1	0
Tinea infection	1	0
Tinea pedis	3	0
Tinea versicolour	4	0
<i>Treponema infections</i>		
Syphilis	2	0
<i>Trypanosomal infections</i>		
African trypanosomiasis	3	0
<i>Tuberculous infections</i>		
Disseminated Bacillus Calmette-Guerin infection	1	0
Lymph node tuberculosis	1	0
Pulmonary tuberculosis	1	0
Tuberculosis	1	0
Tuberculosis of central nervous system	1	0
<i>Upper respiratory tract infections</i>		
Acute sinusitis	4	0
Chronic sinusitis	3	0
Croup infectious	1	0
Epiglottitis	1	0
Laryngitis	33	0
Nasopharyngitis	1122	1
Peritonsillar abscess	4	0
Pharyngitis	34	0
Rhinitis	53	0
Sinusitis	186	0
Tonsillitis	132	0
Tracheitis	5	0
Tracheostomy infection	1	0
Upper respiratory tract infection	12	0
<i>Urinary tract infections</i>		
Cystitis	84	0
Kidney infection	51	0
Pyelonephritis	3	0
Urethritis	1	0
Urinary tract infection	211	0
<i>Vascular infections</i>		
Haematoma infection	1	0
Infected lymphocele	2	0
Infusion site infection	1	0
Lymphangitis	10	0
<i>Viral infections NEC</i>		
Arthritis viral	1	0
Conjunctivitis viral	2	0
Ear infection viral	1	0
Encephalitis viral	6	1
Eye infection viral	2	0
Gastroenteritis viral	32	0
Hepatitis viral	3	0
Meningitis viral	8	0
Meningoencephalitis viral	1	0
Oral viral infection	1	0
Pleurisy viral	2	0

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Pneumonia viral	4	2
Post viral fatigue syndrome	49	0
Sweating fever	123	0
Vestibular neuronitis	34	0
Viral diarrhoea	2	0
Viral infection	61	0
Viral labyrinthitis	4	0
Viral myocarditis	3	0
Viral pericarditis	3	0
Viral pharyngitis	22	0
Viral rash	66	0
Viral sinusitis	1	0
Viral tonsillitis	2	0
Infections SOC TOTAL	10834	107

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Injuries		
<i>Abdominal and gastrointestinal injuries NEC</i>		
Gallbladder injury	1	0
Liver contusion	1	0
Mouth injury	3	0
Oral contusion	5	0
Oral mucosal scar	1	0
Palate injury	1	0
Rectal injury	1	0
Splenic rupture	7	0
Tongue injury	2	0
Tooth fracture	1	0
Tooth injury	1	0
<i>Accidental exposures to product</i>		
Accidental exposure to product	21	0
<i>Anaesthetic and allied procedural complications</i>		
Airway complication of anaesthesia	2	0
Delayed recovery from anaesthesia	3	0
Sedation complication	1	0
<i>Atmospheric pressure injuries</i>		
Barotitis media	1	0
Barotrauma	2	0
Hypobarism	1	0
<i>Bone and joint injuries NEC</i>		
Bursa injury	2	0
Joint injury	11	0
Meniscus injury	2	0
<i>Cardiac and vascular procedural complications</i>		
Ischaemic contracture of the left ventricle	1	0
Shunt blood flow excessive	1	0
Vascular pseudoaneurysm	1	0
<i>Cardiovascular injuries</i>		
Vascular injury	8	0
<i>Cerebral injuries NEC</i>		
Brain contusion	4	0
Brain herniation	2	0
Concussion	4	0
Craniocerebral injury	1	0
Subarachnoid haematoma	1	0
Subdural haematoma	6	0
Subdural haemorrhage	7	0
Traumatic intracranial haemorrhage	1	1
<i>Chemical injuries</i>		
Chemical burn of skin	9	0
Chemical cystitis	2	0
<i>Chest and respiratory tract injuries NEC</i>		
Bronchial injury	1	0
Chest crushing	12	0
Foreign body in throat	1	0
Traumatic lung injury	1	0
<i>Conditions caused by cold</i>		
Chillblains	68	0
Cold shock response	1	0
Frostbite	1	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech Vaccine Analysis Print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
<i>Cranial nerve injuries</i>		
Vth nerve injury	1	0
<i>Ear injuries NEC</i>		
Deafness traumatic	1	0
Ear injury	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	11	0
Exposure via breast milk	155	0
Foetal exposure during pregnancy	60	0
Foetal exposure timing unspecified	1	0
Maternal exposure before pregnancy	19	0
Maternal exposure during breast feeding	1899	0
Maternal exposure during delivery	1	0
Maternal exposure during pregnancy	1014	0
Maternal exposure timing unspecified	12	0
Paternal exposure before pregnancy	3	0
<i>Exposures to agents or circumstances NEC</i>		
Exposure to SARS-CoV-2	3	0
Exposure to vaccinated person	4	0
<i>Eye and ear procedural complications</i>		
Toxic anterior segment syndrome	1	0
<i>Eye injuries NEC</i>		
Corneal abrasion	1	0
Eye contusion	16	0
Eye injury	27	0
Foreign body in eye	3	0
Injury corneal	1	0
Periorbital haematoma	1	0
Retinal injury	2	0
Superficial injury of eye	1	0
<i>Foetal and neonatal conditions associated with product exposure</i>		
Intoxication by breast feeding	1	0
<i>Fractures and dislocations NEC</i>		
Bone fragmentation	1	0
Fracture	3	0
Joint dislocation	3	0
Multiple fractures	1	0
<i>Gastrointestinal and hepatobiliary procedural complications</i>		
Post procedural constipation	1	0
Postoperative ileus	1	0
Procedural nausea	11	0
Procedural vomiting	2	0
<i>Heat injuries (excl thermal burns)</i>		
Heat cramps	2	0
Heat exhaustion	3	0
Heat illness	2	0
Heat oedema	14	0
Heat stroke	3	0
<i>Intentional product use issues</i>		
Intentional dose omission	1	0
Intentional product use issue	1	0
<i>Limb fractures and dislocations</i>		
Atypical femur fracture	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Injuries		
Injuries cont'd		
Clavicle fracture	28	0
Femoral neck fracture	1	0
Femur fracture	1	0
Fibula fracture	1	0
Hip fracture	2	0
Tibia fracture	1	0
Upper limb fracture	1	0
Wrist fracture	1	0
Medication errors, product use errors and issues NEC		
Circumstance or information capable of leading to medication error	2	0
Dose calculation error	1	0
Inadequate aseptic technique in use of product	1	0
Medication error	25	0
Prescription drug used without a prescription	3	0
Product use complaint	2	0
Product use issue	29	0
Vaccination error	5	0
Wrong dose	4	0
Wrong drug	11	0
Wrong schedule	1	0
Wrong technique in product usage process	6	0
Muscle, tendon and ligament injuries		
Epicondylitis	21	0
Ligament injury	2	0
Ligament sprain	9	0
Mallet finger	1	0
Muscle hernia	1	0
Muscle injury	36	0
Muscle rupture	9	0
Muscle strain	35	0
Post-traumatic neck syndrome	2	0
Tendon injury	7	0
Tendon rupture	23	0
Musculoskeletal procedural complications		
Periprosthetic osteolysis	1	0
Post laminectomy syndrome	1	0
Nerve injuries NEC		
Nerve injury	102	0
Neurological and psychiatric procedural complications		
Post lumbar puncture syndrome	1	0
Post procedural stroke	1	0
Procedural dizziness	12	0
Non-occupational environmental exposures		
Exposure to extreme temperature	2	0
Non-site specific injuries NEC		
Animal scratch	1	0
Arthropod bite	9	0
Arthropod sting	6	0
Bite	1	0
Bone contusion	1	0
Crush injury	1	0
Electric shock	19	0
Fall	204	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Foreign body	2	0
Injury	14	0
Multiple injuries	2	0
Nervous system injury	2	0
Post concussion syndrome	2	0
Traumatic haematoma	1	0
Wound	7	0
Wound complication	12	0
Wound haematoma	1	0
Wound haemorrhage	2	0
Wound secretion	6	0
Non-site specific procedural complications		
Administration related reaction	2	0
Incision site pain	3	0
Infusion related reaction	8	0
Injection related reaction	66	0
Post procedural complication	5	0
Post procedural erythema	1	0
Post procedural inflammation	1	0
Post procedural pruritus	1	0
Procedural pain	3	0
Seroma	1	0
Occupational exposures		
Occupational exposure to SARS-CoV-2	1	0
Occupational exposure to product	1	0
Off label uses		
Off label use	389	0
Overdoses NEC		
Intentional overdose	1	0
Overdose	51	0
Pathways and sources of exposure		
Exposure via contaminated device	1	0
Exposure via unknown route	1	0
Pelvic fractures and dislocations		
Pelvic fracture	1	0
Peripheral nerve injuries		
Axillary nerve injury	1	0
Brachial plexus injury	1	0
Radial nerve injury	1	0
Sciatic nerve injury	2	0
Ulnar nerve injury	4	0
Poisoning and toxicity		
Alcohol poisoning	1	0
Poisoning	14	0
Toxicity to various agents	4	0
Product administration errors and issues		
Accidental overdose	8	0
Contraindicated product administered	1	0
Duplicate therapy error	1	0
Expired product administered	12	0
Inappropriate schedule of product administration	656	0
Incomplete course of vaccination	2	0
Incorrect dose administered	54	0

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Reaction Name	Total	Fatal
Injuries		
Injuries cont'd		
Incorrect drug administration rate	1	0
Incorrect product formulation administered	2	0
Incorrect route of product administration	7	0
Lack of vaccination site rotation	1	0
Poor quality product administered	3	0
Product administered at inappropriate site	21	0
Product administered to patient of inappropriate age	1	0
Product administration error	9	0
Product dose omission issue	6	0
Wrong product administered	20	0
Product confusion errors and issues		
Product dosage form confusion	1	0
Product label confusion	5	0
Product packaging confusion	1	0
Product dispensing errors and issues		
Product dispensing error	4	0
Product monitoring errors and issues		
Drug monitoring procedure incorrectly performed	1	0
Product preparation errors and issues		
Product preparation error	3	0
Product preparation issue	6	0
Product prescribing errors and issues		
Contraindicated product prescribed	2	0
Product prescribing error	2	0
Product selection errors and issues		
Product selection error	2	0
Radiation injuries		
Sunburn	23	0
Renal and urinary tract injuries NEC		
Bladder injury	1	0
Foreign body in urogenital tract	1	0
Reproductive system and breast injuries		
Breast injury	1	0
Cervix injury	1	0
Penile contusion	1	0
Penis injury	2	0
Reproductive tract and breast procedural complications		
Failed in vitro fertilisation	1	0
Site specific injuries NEC		
Back injury	3	0
Face crushing	3	0
Face injury	1	0
Head injury	36	0
Limb crushing injury	4	0
Limb injury	171	0
Nasal injury	1	0
Neck crushing	1	0
Neck injury	1	0
Pharyngeal contusion	1	0
Site specific procedural complications NEC		
Axillary web syndrome	3	0
Skin injuries NEC		
Contusion	1311	0

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Reaction Name	Total	Fatal
Injuries		
Injuries cont'd		
Hair injury	1	0
Nail avulsion	1	0
Scar	31	0
Scratch	7	0
Skin abrasion	7	0
Skin injury	4	0
Skin laceration	4	0
Skin wound	3	0
Splinter	1	0
Subcutaneous haematoma	2	0
Skin procedural complications		
Dermal filler overcorrection	1	0
Recall phenomenon	1	0
Skull fractures, facial bone fractures and dislocations		
Facial bones fracture	1	0
Fractured skull depressed	1	0
Spinal cord injuries NEC		
Spinal cord injury cervical	1	0
Spinal fractures and dislocations		
Spinal compression fracture	1	0
Spinal fracture	5	0
Stoma complications		
Gastrointestinal stoma complication	2	0
Stoma site discharge	1	0
Stoma site extravasation	1	0
Stoma site haemorrhage	1	0
Thermal burns		
Airway burns	1	0
Burn oesophageal	4	0
Burn of internal organs	4	0
Burn oral cavity	5	0
Burns second degree	3	0
Burns third degree	1	0
Cold burn	1	0
Thermal burn	25	0
Thermal burns of eye	17	0
Underdoses NEC		
Underdose	6	0
Vaccination related complications		
Adverse event following immunisation	1	0
Post vaccination syndrome	1	0
Vaccination complication	52	0
Injuries SOC TOTAL	7339	1

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Reaction Name	Total	Fatal
Investigations		
<i>Adrenal cortex tests</i>		
Cortisol decreased	4	0
<i>Adrenal medulla tests</i>		
Epinephrine	1	0
Epinephrine abnormal	1	0
Epinephrine increased	1	0
<i>Auditory and vestibular diagnostic procedures</i>		
Acoustic stimulation tests	5	0
Audiogram abnormal	1	0
Weber tuning fork test abnormal	1	0
<i>Autoimmunity analyses</i>		
Antinuclear antibody	2	0
Antinuclear antibody increased	1	0
Antinuclear antibody positive	1	0
Beta-2 glycoprotein antibody positive	1	0
Cardiolipin antibody positive	1	0
Rheumatoid factor	3	0
<i>Bacteria identification and serology (excl mycobacteria)</i>		
Bacterial test positive	1	0
<i>Blood counts NEC</i>		
Full blood count	5	0
Full blood count abnormal	2	0
<i>Blood gas and acid base analyses</i>		
Acid base balance abnormal	1	0
Blood lactic acid	4	0
Blood lactic acid decreased	1	0
Blood lactic acid increased	5	0
Blood pH	7	0
Blood pH abnormal	1	0
Blood pH increased	12	0
Oxygen consumption	1	0
Oxygen consumption decreased	2	0
Oxygen saturation	10	0
Oxygen saturation abnormal	2	0
Oxygen saturation decreased	87	0
PO2 decreased	1	0
Venous oxygen saturation decreased	1	0
<i>Bone marrow and immune tissue histopathology procedures</i>		
Aspiration bone marrow	1	0
Biopsy lymph gland	1	0
<i>Bone marrow and immune tissue imaging procedures</i>		
Lymph nodes scan abnormal	1	0
Scan lymph nodes	4	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose	11	0
Blood glucose abnormal	14	0
Blood glucose decreased	38	0
Blood glucose fluctuation	17	0
Blood glucose increased	107	0
Blood glucose normal	1	0
Glycosylated haemoglobin increased	1	0
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	45	0

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Heart sounds	8	0
Heart sounds abnormal	5	0
Cardiac function diagnostic procedures		
Cardiac monitoring	1	0
Cardiac output	1	0
Central venous pressure	1	0
Echocardiogram	1	0
Ejection fraction decreased	2	0
Myocardial strain imaging	1	0
Right atrial volume abnormal	1	0
Stroke volume decreased	1	0
Cardiac imaging procedures		
Magnetic resonance imaging heart	1	0
Scan myocardial perfusion abnormal	1	0
Cell marker analyses		
Carcinoembryonic antigen increased	1	0
HLA-B*27 positive	1	0
Prostatic specific antigen increased	2	0
Central nervous system imaging procedures		
Computerised tomogram head	10	0
Magnetic resonance imaging head	12	0
Magnetic resonance imaging head abnormal	2	0
Cerebrospinal fluid tests (excl microbiology)		
CSF pressure	1	0
Chemistry analyses NEC		
Histamine abnormal	1	0
Histamine level	1	0
Histamine level increased	1	0
Inflammatory marker decreased	1	0
Inflammatory marker increased	4	0
Inflammatory marker test	1	0
Renin	1	0
Cholesterol analyses		
Blood cholesterol increased	12	0
Remnant-like lipoprotein particles	4	0
Coagulation and bleeding analyses		
Activated partial thromboplastin time prolonged	15	0
Activated partial thromboplastin time shortened	1	0
Bleeding time	1	0
Bleeding time abnormal	1	0
Bleeding time prolonged	10	0
Blood thromboplastin	1	0
Clot retraction	1	1
Coagulation factor VIII level decreased	1	0
Coagulation time prolonged	9	0
Coagulation time shortened	4	0
Fibrin D dimer increased	24	0
International normalised ratio abnormal	8	0
International normalised ratio decreased	22	0
International normalised ratio fluctuation	3	0
International normalised ratio increased	53	0
Platelet factor 4	1	0
Prothrombin time prolonged	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Prothrombin time shortened	1	0
Digestive enzymes		
Amylase increased	1	0
ECG investigations		
Electrocardiogram	5	0
Electrocardiogram QRS complex prolonged	1	0
Electrocardiogram QT prolonged	11	0
Electrocardiogram ST segment depression	2	0
Electrocardiogram ST segment elevation	10	0
Electrocardiogram ST-T segment abnormal	2	0
Electrocardiogram T wave inversion	5	0
Electrocardiogram abnormal	20	0
Electrocardiogram change	1	0
Electrocardiogram normal	3	0
Electrocardiogram repolarisation abnormality	1	0
QRS axis abnormal	1	0
Endocrine analyses and imaging NEC		
Hormone level abnormal	75	0
Faecal analyses NEC		
Faecal calprotectin	2	0
Faecal calprotectin increased	4	0
Fertility analyses		
Infertility tests	1	0
Semen analysis abnormal	1	0
Semen volume increased	1	0
Sperm concentration	2	0
Sperm concentration decreased	1	0
Spermatozoa abnormal	1	0
Foetal and neonatal diagnostic procedures		
Foetal heart rate abnormal	5	2
Foetal heart rate increased	1	0
Foetal monitoring	1	0
Foetal non-stress test	1	0
Gastrointestinal and abdominal imaging procedures		
Computerised tomogram abdomen	1	0
Sigmoidoscopy abnormal	1	0
X-ray with contrast upper gastrointestinal tract	1	0
Gastrointestinal function diagnostic procedures		
Gastric pH decreased	4	0
Gastrointestinal, pancreatic and APUD hormone analyses		
Blood insulin	2	0
Blood insulin decreased	1	0
Haematological analyses NEC		
Blood viscosity abnormal	1	0
Blood viscosity decreased	1	0
Blood viscosity increased	1	0
Plasma viscosity	1	0
Plasma viscosity abnormal	1	0
Red blood cell sedimentation rate increased	7	0
Heart rate and pulse investigations		
Carotid pulse	1	0
Heart rate	531	0
Heart rate abnormal	68	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Heart rate decreased	99	0
Heart rate increased	1090	0
Heart rate irregular	264	0
Heart rate normal	1	0
Heart rate variability decreased	1	0
Maximum heart rate	2	0
Maximum heart rate increased	2	0
Pulse abnormal	21	0
Pulse absent	1	0
Pulse pressure increased	1	0
Radial pulse abnormal	1	0
Sinus rhythm	7	0
Hepatobiliary imaging procedures		
Liver scan	1	0
Imaging procedures NEC		
Computerised tomogram	4	0
Magnetic resonance imaging	4	0
Magnetic resonance imaging abnormal	2	0
Scan	2	0
X-ray	1	0
Immune response protein analyses NEC		
Cytokine test	1	0
Immunoglobulin analyses		
Blood immunoglobulin E increased	2	0
Blood immunoglobulin G increased	1	0
Blood immunoglobulin M	1	0
Blood immunoglobulin M increased	2	0
Immunology analyses NEC		
Antibody test	4	0
Antibody test positive	1	0
Immunology test	12	0
Immunology skin tests NEC		
Allergy alert test	1	0
Skin test positive	2	0
Investigations NEC		
Blood test	27	0
Blood test abnormal	47	0
False positive investigation result	1	0
Laboratory test	1	0
Polymerase chain reaction	1	0
Polymerase chain reaction positive	33	0
Quality of life decreased	1	0
Systemic lupus erythematosus disease activity index increased	1	0
Liver function analyses		
Alanine aminotransferase increased	27	0
Aspartate aminotransferase	1	0
Aspartate aminotransferase abnormal	1	0
Aspartate aminotransferase increased	2	0
Blood bilirubin increased	5	0
Gamma-glutamyltransferase increased	5	0
Hepatic enzyme increased	9	0
Liver function test	1	0
Liver function test abnormal	31	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Liver function test increased	28	0
Transaminases	1	0
Transaminases increased	5	0
Metabolism tests NEC		
Blood ketone body	3	0
Blood ketone body increased	1	0
Blood ketone body present	1	0
Blood uric acid increased	2	0
Brain natriuretic peptide increased	1	0
Ubiquinone	1	0
Urine ketone body present	1	0
Microbiology and serology tests NEC		
Culture negative	1	0
Culture throat	1	0
Culture urine	1	0
Vaccine induced antibody absent	1	0
Mineral and electrolyte analyses		
Blood calcium increased	1	0
Blood copper increased	1	0
Blood iron	1	0
Blood iron decreased	9	0
Blood iron increased	1	0
Blood magnesium decreased	1	0
Blood phosphorus decreased	1	0
Blood phosphorus increased	1	0
Blood potassium abnormal	1	0
Blood potassium decreased	4	0
Blood potassium increased	3	0
Blood sodium decreased	10	0
Serum ferritin	1	0
Serum ferritin decreased	4	0
Serum ferritin increased	1	0
Sweat test	1	0
Urine copper	2	0
Musculoskeletal and soft tissue imaging procedures		
Skull X-ray	6	0
Musculoskeletal and soft tissue tests NEC		
Swollen joint count	1	0
Swollen joint count increased	1	0
Mycobacteria identification and serology		
Tuberculin test positive	1	0
Neurologic diagnostic procedures		
Coma scale abnormal	5	0
Hoover's sign of leg paresis	1	0
Joint position sense decreased	1	0
Lumbar puncture	6	0
Magnetic resonance neurography	1	0
Pain threshold decreased	1	0
Temperature perception test abnormal	1	0
Temperature perception test increased	1	0
Ophthalmic function diagnostic procedures		
Corneal reflex decreased	1	0
Intraocular pressure increased	7	0

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Intraocular pressure test	3	0
Pupil dilation procedure	1	0
Visual acuity tests	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature	281	0
Body temperature abnormal	52	0
Body temperature decreased	44	0
Body temperature fluctuation	61	0
Body temperature increased	483	0
Body temperature normal	1	0
Breath sounds abnormal	2	0
General physical condition abnormal	1	0
Grip strength	3	0
Grip strength decreased	22	0
Gynaecological examination	1	0
Head lag	8	0
Lymph node palpable	44	0
Male genital examination abnormal	1	0
Menstruation normal	3	0
Muscle strength abnormal	3	0
Ophthalmological examination	2	0
Orthopaedic examination	1	0
Palpatory finding abnormal	2	0
Product residue present	2	0
Psoriasis area severity index decreased	2	0
Psoriasis area severity index increased	1	0
Respiratory rate	9	0
Respiratory rate decreased	26	0
Respiratory rate increased	44	0
Skin temperature	43	0
Temperature difference of extremities	13	0
Weight	1	0
Weight abnormal	1	0
Weight decreased	121	0
Weight increased	44	0
<i>Pituitary analyses anterior</i>		
Blood corticotrophin	1	0
Blood follicle stimulating hormone increased	3	0
Blood growth hormone	3	0
Blood prolactin	3	0
Blood prolactin increased	3	0
Blood thyroid stimulating hormone decreased	1	0
Blood thyroid stimulating hormone increased	8	0
<i>Platelet analyses</i>		
Mean platelet volume decreased	1	0
Mean platelet volume increased	1	0
Platelet count	3	0
Platelet count abnormal	1	0
Platelet count decreased	78	0
Platelet count increased	6	0
<i>Protein analyses NEC</i>		
Alpha 1 globulin decreased	1	0
Alpha 2 globulin decreased	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
C-reactive protein increased	26	0
Red blood cell analyses		
Haematocrit	1	0
Haematocrit decreased	1	0
Haematocrit increased	1	0
Haemoglobin decreased	14	0
Haemoglobin increased	2	0
Red blood cell count decreased	1	0
Red blood cell rouleaux formation present	1	0
Renal function analyses		
Blood creatinine	1	0
Blood creatinine decreased	1	0
Blood creatinine increased	4	0
Glomerular filtration rate decreased	4	0
Glomerular filtration rate increased	1	0
Reproductive hormone analyses		
Blood oestrogen	1	0
Blood oestrogen decreased	2	0
Blood testosterone decreased	1	0
Blood testosterone increased	2	0
False negative pregnancy test	7	0
Female sex hormone level	3	0
Human chorionic gonadotropin increased	1	0
Pregnancy test	18	0
Pregnancy test false positive	1	0
Pregnancy test positive	1	0
Reproductive organ and breast histopathology procedures		
Biopsy breast	2	0
Biopsy endometrium	1	0
Smear cervix	3	0
Reproductive organ and breast imaging procedures		
Breast scan	1	0
Hysteroscopy	2	0
Respiratory and pulmonary function diagnostic procedures		
Forced expiratory volume increased	2	0
Fractional exhaled nitric oxide normal	1	0
Maximal voluntary ventilation	2	0
Peak expiratory flow rate	2	0
Peak expiratory flow rate decreased	5	0
Pulmonary function test	3	0
Total lung capacity decreased	3	0
Vital capacity	1	0
Respiratory tract and thoracic histopathology procedures		
Sputum abnormal	3	0
Respiratory tract and thoracic imaging procedures		
Chest X-ray	19	0
Chest X-ray abnormal	1	0
Chest X-ray normal	2	0
Chest scan	2	0
Computerised tomogram thorax	2	0
Ventilation/perfusion scan	1	0
Skeletal and cardiac muscle analyses		
Blood creatine phosphokinase increased	9	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Muscle enzyme	1	0
Myocardial necrosis marker	1	0
Myocardial necrosis marker increased	3	0
Troponin I increased	2	0
Troponin T increased	1	0
Troponin increased	18	0
<i>Therapeutic drug monitoring analyses</i>		
Analgesic drug level	8	0
Anticoagulation drug level above therapeutic	1	0
Anticoagulation drug level below therapeutic	5	0
Anticoagulation drug level increased	1	0
Drug level decreased	1	0
<i>Thyroid analyses</i>		
Anti-thyroid antibody	1	0
Thyroid function test abnormal	5	0
Thyroxine	1	0
Thyroxine free increased	2	0
Tri-iodothyronine	1	0
Tri-iodothyronine decreased	5	0
<i>Tissue enzyme analyses NEC</i>		
Blood alkaline phosphatase abnormal	1	0
Blood alkaline phosphatase increased	5	0
Enzyme level increased	1	0
<i>Toxicology laboratory analyses</i>		
Blood caffeine decreased	1	0
Blood lead	1	0
Drug screen positive	2	0
Opiates	1	0
<i>Urinalysis NEC</i>		
Blood urine	15	0
Blood urine present	69	0
Cells in urine	1	0
Glucose urine present	1	0
Protein urine absent	1	0
Protein urine present	1	0
Red blood cells urine	1	0
Urine analysis abnormal	6	0
Urine leukocyte esterase positive	1	0
Urine uric acid increased	1	0
pH urine	6	0
pH urine increased	2	0
<i>Urinary tract function analyses NEC</i>		
Urine output	13	0
Urine output decreased	14	0
Urine output increased	7	0
<i>Urinary tract histopathology procedures</i>		
Urine cytology	1	0
<i>Urinary tract imaging procedures</i>		
Bladder scan	1	0
Cystoscopy	2	0
Ultrasound kidney normal	1	0
<i>Vascular imaging procedures NEC</i>		
Venogram	2	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure abnormal	9	0
Blood pressure ambulatory increased	1	0
Blood pressure decreased	87	0
Blood pressure diastolic	1	0
Blood pressure diastolic decreased	1	0
Blood pressure diastolic increased	4	0
Blood pressure difference of extremities	1	0
Blood pressure increased	280	0
Blood pressure measurement	45	0
Blood pressure normal	2	0
Blood pressure systolic	1	0
Blood pressure systolic decreased	4	0
Blood pressure systolic increased	1	0
<i>Virus identification and serology</i>		
Coronavirus test	11	0
Coronavirus test positive	4	0
Cytomegalovirus test positive	1	0
HIV antibody positive	1	0
HIV test	1	0
SARS-CoV-1 test	1	0
SARS-CoV-1 test positive	1	0
SARS-CoV-2 antibody test	10	0
SARS-CoV-2 antibody test negative	15	0
SARS-CoV-2 antibody test positive	6	0
SARS-CoV-2 test	35	0
SARS-CoV-2 test false negative	2	0
SARS-CoV-2 test false positive	4	0
SARS-CoV-2 test negative	10	0
SARS-CoV-2 test positive	103	0
Viral load	2	0
Viral test	4	0
Viral test positive	1	0
<i>Vitamin analyses</i>		
Blood folate decreased	6	0
Vitamin B12	1	0
Vitamin B12 abnormal	2	0
Vitamin B12 decreased	2	0
Vitamin D	3	0
Vitamin D decreased	3	0
<i>Water and electrolyte analyses NEC</i>		
Urine osmolarity	1	0
Volume blood	1	0
<i>White blood cell analyses</i>		
Eosinophil count	1	0
Eosinophil count decreased	1	0
Eosinophil count increased	3	0
Lymphocyte count	1	0
Lymphocyte count decreased	3	0
Lymphocyte count increased	1	0
Monocyte count increased	2	0
Neutrophil count	3	0
Neutrophil count decreased	10	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Neutrophil count increased	4	0
White blood cell count	4	0
White blood cell count decreased	13	0
White blood cell count increased	11	0
Investigations SOC TOTAL	5817	3

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	19	0
Decreased appetite	1419	0
Diet refusal	1	0
Eating disorder symptom	3	0
Food craving	12	0
Food refusal	16	0
Hyperphagia	15	0
Hypophagia	18	0
Increased appetite	35	0
Salt craving	2	0
<i>Calcium metabolism disorders</i>		
Hypocalcaemia	3	0
Tetany	3	0
<i>Copper metabolism disorders</i>		
Copper deficiency	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	52	0
Diabetes mellitus inadequate control	16	1
Increased insulin requirement	2	0
Insulin resistant diabetes	1	0
Latent autoimmune diabetes in adults	2	0
Type 1 diabetes mellitus	16	0
Type 2 diabetes mellitus	4	0
<i>Diabetic complications NEC</i>		
Diabetic complication	2	0
Diabetic ketoacidosis	12	0
Diabetic ketosis	1	0
<i>Disorders of purine metabolism</i>		
Gout	104	0
<i>Electrolyte imbalance NEC</i>		
Electrolyte imbalance	1	0
Fluid imbalance	2	0
<i>Fat soluble vitamin deficiencies and disorders</i>		
Vitamin D deficiency	8	0
<i>Fluid intake decreased</i>		
Fluid intake reduced	2	0
<i>Fluid intake increased</i>		
Polydipsia	7	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Alcohol intolerance	6	0
Breast milk substitute intolerance	1	0
Dairy intolerance	3	0
Food intolerance	18	0
Gluten sensitivity	7	0
Histamine intolerance	4	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	34	0
Abnormal weight gain	20	0
Cachexia	1	0
Feeding disorder	97	0
Food aversion	10	0
Malnutrition	2	0

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Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
Neonatal insufficient breast milk syndrome	6	0
Obesity	1	0
Overweight	1	0
Poor feeding infant	16	0
Weight loss poor	3	0
Hyperglycaemic conditions NEC		
Glucose tolerance impaired	1	0
Hyperglycaemia	68	0
Insulin resistance	5	0
Hyperlipidaemias NEC		
Hyperlipidaemia	1	0
Hypoglycaemic conditions NEC		
Glycopenia	1	0
Hypoglycaemia	79	0
Hypoglycaemia unawareness	1	0
Postprandial hypoglycaemia	1	0
Iron deficiencies		
Iron deficiency	12	0
Iron excess		
Haemochromatosis	1	0
Iron overload	1	0
Lipid metabolism and deposit disorders NEC		
Body fat disorder	1	0
Magnesium metabolism disorders		
Hypomagnesaemia	1	0
Magnesium deficiency	1	0
Metabolic acidoses (excl diabetic acidoses)		
Ketoacidosis	5	1
Lactic acidosis	2	0
Metabolic acidosis	2	0
Metabolic disorders NEC		
Hypercatabolism	1	0
Metabolic disorder	1	0
Mixed acid-base disorders		
Acidosis	4	0
Phosphorus metabolism disorders		
Hypophosphataemia	1	0
Potassium imbalance		
Hyperkalaemia	6	0
Hypokalaemia	5	0
Hypokalaemic syndrome	1	0
Sodium imbalance		
Hypernatraemia	1	1
Hyponatraemia	12	0
Hyponatraemic syndrome	3	0
Salt intoxication	1	0
Sugar intolerance (excl glucose intolerance)		
Lactose intolerance	3	0
Total fluid volume decreased		
Dehydration	227	0
Total fluid volume increased		
Fluid retention	60	0
Hypervolaemia	5	0

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Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
<i>Vitamin deficiencies NEC</i>		
Hypovitaminosis	6	0
<i>Water soluble vitamin deficiencies</i>		
Folate deficiency	6	0
Vitamin B complex deficiency	1	0
Vitamin B12 deficiency	6	0
Metabolic disorders SOC TOTAL	2542	3

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	357	0
Arthropathy	31	0
Autoimmune arthritis	9	0
Haemarthrosis	5	0
Joint microhaemorrhage	1	0
Palindromic rheumatism	2	0
Polyarthritis	15	0
Rheumatic fever	2	0
Sacroiliitis	5	0
Seronegative arthritis	2	0
<i>Bone disorders NEC</i>		
Bone cyst	1	0
Exostosis	1	0
Jaw disorder	4	0
Medial tibial stress syndrome	6	0
Osteitis	9	0
Osteonecrosis	1	0
Osteonecrosis of jaw	3	0
Spinal disorder	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	424	0
Bone swelling	10	0
Coccydynia	3	0
Metatarsalgia	1	0
Pain in jaw	411	0
Pubic pain	2	0
Spinal pain	88	0
<i>Bursal disorders</i>		
Bursitis	91	0
<i>Cartilage disorders</i>		
Chondritis	1	0
Costochondritis	121	0
Osteochondritis	1	0
Polychondritis	3	0
<i>Connective tissue disorders NEC</i>		
Connective tissue disorder	2	0
Polymyalgia rheumatica	70	0
Reynold's syndrome	1	0
Sjogren's syndrome	6	0
Systemic scleroderma	1	0
<i>Crystal arthropathic disorders</i>		
Chondrocalcinosis pyrophosphate	3	0
Crystal arthropathy	2	0
Gouty arthritis	1	0
<i>Epiphyseal disorders</i>		
Epiphyses premature fusion	1	0
<i>Extremity deformities</i>		
Bone deformity	1	0
Finger deformity	2	0
Foot deformity	2	0
Hand deformity	2	0
Knee deformity	1	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Muscle & tissue disorders cont'd		
Limb deformity	5	0
Musculoskeletal deformity	1	0
Fractures NEC		
Osteoporotic fracture	1	0
Intervertebral disc disorders NEC		
Intervertebral disc protrusion	3	0
Joint related disorders NEC		
Carpal collapse	1	0
Chondromalacia	1	0
Hypermobility syndrome	1	0
Joint deposit	1	0
Joint destruction	1	0
Joint instability	2	0
Joint laxity	3	0
Joint lock	30	0
Ligament laxity	1	0
Patellofemoral pain syndrome	2	0
Periarthritis	221	0
Rotator cuff syndrome	35	0
Temporomandibular joint syndrome	13	0
Joint related signs and symptoms		
Arthralgia	9955	0
Jaw clicking	6	0
Joint effusion	16	0
Joint noise	39	0
Joint range of motion decreased	32	0
Joint stiffness	274	0
Joint swelling	620	0
Joint vibration	3	0
Joint warmth	16	0
Loose body in joint	1	0
Ligament disorders		
Ligament pain	4	0
Ligamentitis	1	0
Symphysiolysis	1	0
Lupus erythematosus (incl subtypes)		
Lupus-like syndrome	1	0
Systemic lupus erythematosus	25	0
Metabolic bone disorders		
Osteopenia	3	0
Osteoporosis	7	0
Muscle infections and inflammations		
Antisynthetase syndrome	3	0
Immune-mediated myositis	1	0
Myositis	42	0
Polymyositis	8	0
Muscle pains		
Fibromyalgia	135	0
Myalgia	11416	0
Myalgia intercostal	2	0
Myofascial pain syndrome	12	0
Muscle related signs and symptoms NEC		
Haematoma muscle	1	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Muscle atrophy	24	0
Muscle discomfort	8	0
Muscle disorder	10	0
Muscle fatigue	382	0
Muscle haemorrhage	1	0
Muscle mass	5	0
Muscle oedema	4	0
Muscle spasms	2220	0
Muscle swelling	42	0
Muscle tightness	95	0
Muscle twitching	526	0
Muscle tone abnormalities		
Muscle rigidity	17	0
Nuchal rigidity	12	0
Torticollis	7	0
Trismus	39	0
Muscle weakness conditions		
Muscular weakness	1043	0
Musculoskeletal and connective tissue conditions NEC		
Back disorder	3	0
Chest wall mass	1	0
Growth disorder	2	0
Limb mass	21	0
Mandibular mass	2	0
Mastication disorder	7	0
Mobility decreased	130	0
Muscle contracture	1	0
Musculoskeletal disorder	11	0
Musculoskeletal stiffness	1417	0
Pelvic misalignment	1	0
Posture abnormal	2	0
Sacroiliac joint dysfunction	1	0
Weight bearing difficulty	4	0
Musculoskeletal and connective tissue deformities of skull, face and buccal cavity		
Facial asymmetry	1	0
Head deformity	2	0
Nose deformity	1	0
Musculoskeletal and connective tissue infections and inflammations NEC		
Connective tissue inflammation	1	0
Dactylitis	3	0
Dupuytren's contracture	1	0
Fasciitis	1	0
Plantar fasciitis	13	0
Musculoskeletal and connective tissue pain and discomfort		
Back pain	2686	0
Flank pain	84	0
Growing pains	1	0
Limb discomfort	1601	0
Musculoskeletal chest pain	293	0
Musculoskeletal discomfort	116	0
Musculoskeletal pain	129	0
Neck pain	2090	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Muscle & tissue disorders cont'd		
Pain in extremity	13857	1
Rheumatic disorder	15	0
Sacral pain	4	0
Myopathies		
Mitochondrial myopathy acquired	1	0
Myopathy	6	0
Rhabdomyolysis	14	0
Osteoarthropathies		
Nodal osteoarthritis	1	0
Osteoarthritis	54	0
Spinal osteoarthritis	2	0
Psoriatic arthropathies		
Psoriatic arthropathy	19	0
Rheumatoid arthropathies		
Juvenile idiopathic arthritis	1	0
Rheumatoid arthritis	128	0
Rheumatoid nodule	1	0
Still's disease	2	0
Soft tissue disorders NEC		
Axillary mass	292	0
Fluctuance	1	0
Groin pain	122	0
Neck mass	43	0
Purple glove syndrome	1	0
Soft tissue disorder	3	0
Soft tissue swelling	7	0
Spine and neck deformities		
Kyphosis	2	0
Lordosis	1	0
Neck deformity	1	0
Scoliosis	1	0
Spinal stenosis	2	0
Spondyloarthropathies		
Ankylosing spondylitis	10	0
Arthritis reactive	65	0
Spondylitis	4	0
Spondyloarthropathy	1	0
Synovial disorders		
Synovial cyst	22	0
Synovitis	11	0
Tendon disorders		
Enthesopathy	2	0
Posterior tibial tendon dysfunction	1	0
Tendon disorder	6	0
Tendon pain	27	0
Tendonitis	55	0
Tenosynovitis	4	0
Tenosynovitis stenosaurs	2	0
Trigger finger	30	0
Trunk deformities		
Deformity thorax	1	0
Drooping shoulder syndrome	2	0
Shoulder deformity	3	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders cont'd		
Muscle & tissue disorders SOC TOTAL	52540	1

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Reaction Name	Total	Fatal
Neoplasms		
<i>Angioimmunoblastic T-cell lymphomas</i>		
Angioimmunoblastic T-cell lymphoma	1	0
<i>B-cell lymphomas NEC</i>		
B-cell lymphoma	2	1
Follicular lymphoma	4	0
<i>Bone neoplasms malignant (excl sarcomas)</i>		
Bone cancer	1	1
<i>Bone neoplasms unspecified malignancy</i>		
Bone neoplasm	1	0
<i>Breast and nipple neoplasms benign</i>		
Benign breast neoplasm	2	0
Fibroadenoma of breast	1	0
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	41	0
Breast cancer female	1	0
Breast cancer male	2	0
Breast cancer stage I	1	0
Breast cancer stage III	3	0
Invasive ductal breast carcinoma	1	0
Triple negative breast cancer	2	0
<i>Cardiovascular neoplasms benign</i>		
Haemangioma	2	0
Pericardial lipoma	1	0
<i>Cartilage sarcomas</i>		
Chondrosarcoma	1	0
<i>Cervix neoplasms malignant</i>		
Cervix carcinoma	2	0
<i>Colorectal neoplasms malignant</i>		
Colon cancer	2	0
Colorectal cancer	1	0
Rectal cancer	2	0
<i>Endocrine neoplasms malignant and unspecified NEC</i>		
Neuroendocrine tumour	1	0
Thyroid neoplasm	1	0
<i>Endometrial neoplasms malignant</i>		
Endometrial cancer	2	0
<i>Follicular lymphomas</i>		
Primary gastrointestinal follicular lymphoma	1	0
<i>Gastric neoplasms malignant</i>		
Gastric cancer	1	1
<i>Gastrointestinal neoplasms malignant NEC</i>		
Gastrointestinal carcinoma	3	0
<i>Hepatic neoplasms malignant</i>		
Hepatocellular carcinoma	1	0
<i>Hepatobiliary neoplasms malignancy unspecified</i>		
Hepatic neoplasm	1	0
<i>Hodgkin's disease NEC</i>		
Hodgkin's disease	4	0
<i>Islet cell neoplasms and APUDoma NEC</i>		
Pancreatic neuroendocrine tumour	1	0
<i>Kaposi's sarcomas</i>		
Kaposi's sarcoma	1	0
<i>Leukaemias NEC</i>		

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
Leukaemia	5	1
Leukaemias acute NEC		
Acute leukaemia	2	0
Leukaemias chronic NEC		
Chronic leukaemia	1	0
Leukaemias chronic lymphocytic		
Chronic lymphocytic leukaemia	3	0
Leukaemias chronic myeloid		
Chronic myeloid leukaemia	1	0
Lip and oral cavity neoplasms malignant		
Lip and/or oral cavity cancer recurrent	1	0
Lymphomas unspecified NEC		
Lymphoma	44	1
Metastases to specified sites		
Metastases to bone	1	0
Metastases to liver	1	0
Metastases to lymph nodes	5	0
Metastases to unknown and unspecified sites		
Metastasis	1	0
Myelodysplastic syndromes		
Myelodysplastic syndrome	3	0
Myeloproliferative disorders (excl leukaemias)		
Essential thrombocythaemia	2	0
Neoplasms malignant site unspecified NEC		
Adenocarcinoma metastatic	1	0
Metastatic neoplasm	2	0
Neoplasm malignant	9	0
Second primary malignancy	1	0
Squamous cell carcinoma	5	0
Neoplasms unspecified malignancy and site unspecified NEC		
Neoplasm	2	0
Neoplasm recurrence	1	0
Nervous system neoplasms benign NEC		
Cranial nerve neoplasm benign	1	0
Neurilemmoma benign	1	0
Nervous system neoplasms unspecified malignancy NEC		
Brain neoplasm	2	0
Meningioma	1	0
Spinal cord neoplasm	1	0
Neuromas		
Acoustic neuroma	2	0
Neuroma	1	0
Non-Hodgkin's lymphomas NEC		
Non-Hodgkin's lymphoma	2	0
Ocular neoplasms benign		
Eye naevus	1	0
Oesophageal neoplasms malignant		
Oesophageal cancer metastatic	4	0
Oncologic complications and emergencies		
Cancer pain	1	0
Tumour haemorrhage	1	0
Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified		

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
Tonsil cancer	4	0
<i>Ovarian neoplasms malignant (excl germ cell)</i>		
Ovarian cancer	1	0
<i>Pancreatic neoplasms malignant (excl islet cell and carcinoid)</i>		
Pancreatic carcinoma	4	0
<i>Plasma cell myelomas</i>		
POEMS syndrome	1	0
Plasma cell myeloma	2	0
<i>Plasma cell neoplasms NEC</i>		
Hypergammaglobulinaemia benign monoclonal	1	0
TEMPI syndrome	2	0
<i>Prostatic neoplasms malignant</i>		
Prostate cancer	4	0
<i>Renal neoplasms malignant</i>		
Clear cell renal cell carcinoma	1	0
Renal cancer	3	0
<i>Reproductive neoplasms female benign NEC</i>		
Benign hydatidiform mole	2	0
<i>Respiratory tract and pleural neoplasms malignant cell type unspecified NEC</i>		
Bronchial carcinoma	1	0
Lung neoplasm malignant	13	1
<i>Salivary gland neoplasms unspecified malignancy</i>		
Salivary gland neoplasm	2	0
<i>Skin melanomas (excl ocular)</i>		
Malignant melanoma	2	0
<i>Skin neoplasms benign</i>		
Acrochordon	5	0
Anogenital warts	7	0
Fibrous histiocytoma	1	0
Haemangioma of skin	5	0
Melanocytic naevus	7	0
Pyogenic granuloma	1	0
Seborrhoeic keratosis	1	0
Skin papilloma	21	0
<i>Skin neoplasms malignant and unspecified (excl melanoma)</i>		
Basal cell carcinoma	3	0
Bowen's disease	1	0
Neoplasm skin	3	0
Skin cancer	1	0
Squamous cell carcinoma of skin	1	0
<i>Soft tissue neoplasms benign NEC</i>		
Lipoma	7	0
Lymphangioma	1	0
<i>Soft tissue sarcomas histology unspecified</i>		
Sarcoma	1	0
<i>Thyroid neoplasms malignant</i>		
Papillary thyroid cancer	2	0
Thyroid cancer	1	0
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	12	0
Neoplasms SOC TOTAL	324	6

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Areflexia	7	0
Extensor plantar response	2	0
Hoffmann's sign	1	0
Hyperreflexia	4	0
Hyporeflexia	10	0
Reflexes abnormal	2	0
<i>Abnormal sleep-related events</i>		
Sleep paralysis	29	0
<i>Absence seizures</i>		
Petit mal epilepsy	28	0
<i>Acute polyneuropathies</i>		
Acute motor axonal neuropathy	1	0
Acute motor-sensory axonal neuropathy	1	0
Guillain-Barre syndrome	84	2
Miller Fisher syndrome	3	0
Subacute inflammatory demyelinating polyneuropathy	1	0
<i>Autonomic nervous system disorders</i>		
Anticholinergic syndrome	1	0
Autonomic nervous system imbalance	11	0
Autonomic neuropathy	2	0
Horner's syndrome	2	0
Orthostatic intolerance	2	0
<i>Central nervous system aneurysms and dissections</i>		
Carotid artery dissection	1	0
Intracranial aneurysm	2	1
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Basal ganglia haemorrhage	1	0
Brain stem haemorrhage	2	2
Brain stem infarction	1	1
Brain stem stroke	1	0
Carotid artery occlusion	1	0
Carotid artery thrombosis	4	0
Cerebellar artery thrombosis	1	0
Cerebellar haemorrhage	3	0
Cerebellar infarction	3	0
Cerebellar ischaemia	1	0
Cerebellar stroke	8	1
Cerebral artery embolism	3	1
Cerebral artery occlusion	2	0
Cerebral artery thrombosis	4	0
Cerebral haemorrhage	53	12
Cerebral infarction	30	2
Cerebral ischaemia	1	0
Cerebral thrombosis	14	0
Cerebrovascular accident	453	20
Embolic stroke	7	0
Haemorrhage intracranial	12	3
Haemorrhagic cerebral infarction	1	0
Haemorrhagic stroke	11	4
Internal capsule infarction	1	0
Intracranial haematoma	1	0
Ischaemic cerebral infarction	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Ischaemic stroke	54	2
Lacunar infarction	4	0
Lacunar stroke	5	0
Lateral medullary syndrome	2	0
Pseudostroke	2	0
Ruptured cerebral aneurysm	1	0
Stroke in evolution	1	0
Subarachnoid haemorrhage	18	7
Thalamic infarction	1	0
Thrombotic stroke	5	1
Central nervous system inflammatory disorders NEC		
Arachnoiditis	1	0
Gliosis	1	0
Central nervous system vascular disorders NEC		
Brain hypoxia	5	1
Carotid arteriosclerosis	1	0
Central nervous system vasculitis	1	0
Cerebral amyloid angiopathy	1	0
Cerebral congestion	5	0
Cerebral small vessel ischaemic disease	3	0
Cerebrovascular disorder	3	0
Post cardiac arrest syndrome	1	0
Reversible cerebral vasoconstriction syndrome	1	0
Cerebrovascular venous and sinus thrombosis		
Cerebral venous sinus thrombosis	52	5
Cerebral venous thrombosis	6	0
Superior sagittal sinus thrombosis	6	0
Transverse sinus thrombosis	2	0
Cervical spinal cord and nerve root disorders		
Cervical radiculopathy	2	0
Cervicobrachial syndrome	6	0
Choreiform movements		
Chorea	3	0
Chronic polyneuropathies		
Chronic inflammatory demyelinating polyradiculoneuropathy	2	0
Demyelinating polyneuropathy	1	0
Diabetic neuropathy	1	0
Coma states		
Coma	15	0
Diabetic coma	1	0
Hypoglycaemic coma	1	0
Coordination and balance disturbances		
Ataxia	20	0
Balance disorder	471	0
Cerebellar ataxia	1	0
Coordination abnormal	65	0
Dysdiadochokinesis	1	0
Dysstasia	65	0
Nystagmus	16	0
Cortical dysfunction NEC		
Alexia	2	0
Aphasia	94	0
Apraxia	1	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Dysgraphia	2	0
Dyslexia	1	0
Dyspraxia	1	0
Neurologic neglect syndrome	1	0
Sensory processing disorder	3	0
Visuospatial deficit	1	0
Cranial nerve disorders NEC		
Cranial nerve disorder	2	0
Cranial nerve paralysis	1	0
Dementia (excl Alzheimer's type)		
Dementia	18	0
Dementia with Lewy bodies	1	0
Senile dementia	1	0
Demyelinating disorders NEC		
Acute disseminated encephalomyelitis	6	0
Clinically isolated syndrome	1	0
Demyelination	10	0
Neuromyelitis optica spectrum disorder	2	0
Disturbances in consciousness NEC		
Altered state of consciousness	12	0
Consciousness fluctuating	3	0
Depressed level of consciousness	50	0
Infant sedation	1	0
Lethargy	2439	0
Loss of consciousness	760	1
Postictal state	5	0
Sedation	8	0
Somnolence	1155	0
Stupor	5	0
Syncope	2600	0
Disturbances in sleep phase rhythm		
Circadian rhythm sleep disorder	1	0
Irregular sleep phase	2	0
Irregular sleep wake rhythm disorder	2	0
Non-24-hour sleep-wake disorder	1	0
Dyskinesias and movement disorders NEC		
Akathisia	6	0
Ballismus	1	0
Bradykinesia	22	0
Clumsiness	23	0
Dyskinesia	75	0
Extrapyramidal disorder	3	0
Fine motor skill dysfunction	13	0
Foetal movement disorder	4	0
Hyperkinesia	3	0
Hypokinesia	94	0
Motor dysfunction	4	0
Movement disorder	61	0
Psychomotor hyperactivity	28	0
Synkinesis	2	0
Tardive dyskinesia	2	0
Dystonias		
Dystonia	16	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Writer's cramp	1	0
Encephalitis NEC		
Encephalitis autoimmune	1	0
Limbic encephalitis	1	0
Noninfective encephalitis	6	0
Encephalopathies NEC		
Autoimmune encephalopathy	1	1
Encephalopathy	5	0
Hashimoto's encephalopathy	1	0
Posterior reversible encephalopathy syndrome	1	0
Eye movement disorders		
IIIrd nerve disorder	1	0
IIIrd nerve paralysis	7	0
IVth nerve paralysis	1	0
Microvascular cranial nerve palsy	1	0
VIth nerve disorder	1	0
VIth nerve paralysis	11	0
Facial cranial nerve disorders		
Bell's palsy	586	0
Facial nerve disorder	9	0
Facial paralysis	443	0
Facial paresis	101	0
Facial spasm	52	0
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	66	0
Headaches NEC		
Cervicogenic headache	3	0
Cluster headache	274	0
Cold-stimulus headache	32	0
Drug withdrawal headache	3	0
Exertional headache	9	0
External compression headache	2	0
Headache	29000	1
Medication overuse headache	2	0
New daily persistent headache	8	0
Occipital neuralgia	15	0
Ophthalmoplegic migraine	1	0
Primary cough headache	4	0
Primary headache associated with sexual activity	9	0
Sinus headache	388	0
Tension headache	607	0
Thunderclap headache	19	0
Vascular headache	20	0
Hydrocephalic conditions		
Hydrocephalus	4	0
Hypoglossal nerve disorders		
Tongue paralysis	1	0
Increased intracranial pressure disorders		
Brain compression	2	0
Brain oedema	12	2
Idiopathic intracranial hypertension	11	0
Intracranial pressure increased	3	0
Intellectual disabilities		

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Intellectual disability	4	0
Lumbar spinal cord and nerve root disorders		
Sciatica	123	0
Memory loss (excl dementia)		
Amnesia	208	0
Memory impairment	229	0
Transient global amnesia	9	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	99	0
Cognitive linguistic deficit	1	0
Disturbance in attention	370	0
Mental impairment	55	0
Migraine headaches		
Basilar migraine	1	0
Hemiplegic migraine	35	0
Migraine	3332	0
Migraine with aura	220	0
Migraine without aura	22	0
Ophthalmic migraine	7	0
Retinal migraine	36	0
Typical aura without headache	8	0
Vestibular migraine	26	0
Mixed cranial nerve disorders		
Bulbar palsy	2	0
Mononeuropathies		
Carpal tunnel syndrome	27	0
Cubital tunnel syndrome	4	0
Meralgia paraesthetica	2	0
Mononeuritis	2	0
Mononeuropathy	4	0
Nerve compression	29	0
Peripheral nerve lesion	2	0
Peroneal nerve palsy	20	0
Piriformis syndrome	1	0
Pudendal canal syndrome	2	0
Sciatic nerve neuropathy	2	0
Ulnar nerve palsy	2	0
Ulnar neuritis	3	0
Ulnar tunnel syndrome	2	0
Motor neurone diseases		
Lower motor neurone lesion	1	0
Motor neurone disease	6	2
Upper motor neurone lesion	1	0
Multiple sclerosis acute and progressive		
Band sensation	1	0
Multiple sclerosis	36	0
Multiple sclerosis relapse	25	0
Tumefactive multiple sclerosis	1	1
Muscle tone abnormal		
Drop attacks	2	0
Hypertonia	2	0
Hypotonia	35	0
Morvan syndrome	1	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Muscle tone disorder	1	0
Serotonin syndrome	1	0
Stiff leg syndrome	1	0
Myelitis (incl infective)		
Myelitis transverse	30	0
Narcolepsy and hypersomnia		
Cataplexy	3	0
Hypersomnia	121	0
Narcolepsy	6	0
Nervous system disorders NEC		
Central nervous system lesion	2	0
Cerebral disorder	1	0
Nervous system disorder	21	0
Neurotoxicity	4	0
Psychomotor skills impaired	1	0
Neurologic visual problems NEC		
Hemianopia	1	0
Hemianopia homonymous	2	0
Quadrantanopia	2	0
Tunnel vision	22	0
Neurological signs and symptoms NEC		
Agitation neonatal	1	0
Cerebrospinal fluid leakage	1	0
Clonus	5	0
Decerebrate posture	1	0
Decorticate posture	1	0
Dizziness	10808	0
Dizziness exertional	48	0
Dizziness postural	819	0
Drooling	23	0
Fontanelle bulging	2	0
Head discomfort	379	0
Hyporesponsive to stimuli	2	0
Inability to crawl	3	0
Infant irritability	10	0
Meningism	2	0
Myoclonus	32	0
Neurological symptom	61	0
Patient elopement	1	0
Persistent postural-perceptual dizziness	17	0
Presyncope	685	0
Sensory overload	5	0
Slow response to stimuli	4	0
Tongue biting	8	0
Unresponsive to stimuli	59	0
Neuromuscular disorders NEC		
Muscle contractions involuntary	29	0
Muscle spasticity	18	0
Neuromuscular pain	3	0
Neuromuscular junction dysfunction		
Myasthenia gravis	8	0
Myasthenia gravis crisis	2	0
Olfactory nerve disorders		

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Anosmia	313	0
Hyposmia	18	0
Parosmia	299	0
<i>Optic nerve disorders NEC</i>		
Optic neuritis	34	0
<i>Paraesthesias and dysaesthesias</i>		
Burning feet syndrome	13	0
Burning sensation	618	0
Burning sensation mucosal	2	0
Dysaesthesia	8	0
Formication	44	0
Hand-arm vibration syndrome	3	0
Hemianaesthesia	4	0
Hemiparaesthesia	5	0
Hyperaesthesia	119	0
Hypoaesthesia	3303	0
Lhermitte's sign	1	0
Paraesthesia	4543	0
Reversed hot-cold sensation	4	0
Synaesthesia	1	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Diplegia	19	0
Hemiparesis	62	0
Hemiplegia	46	0
Locked-in syndrome	1	0
Monoparesis	85	0
Monoplegia	96	0
Paralysis	145	0
Paraparesis	3	0
Paraplegia	3	0
Paresis	8	0
Quadriparesis	1	0
Quadriplegia	1	0
<i>Parkinson's disease and parkinsonism</i>		
Freezing phenomenon	15	0
Hypokinetic dysarthria	1	0
Parkinson's disease	4	0
Parkinsonian gait	1	0
Parkinsonian rest tremor	1	0
Parkinsonism	4	0
Reduced facial expression	11	0
<i>Partial complex seizures</i>		
Dreamy state	6	0
Focal dyscognitive seizures	4	0
Temporal lobe epilepsy	2	0
<i>Partial simple seizures NEC</i>		
Autonomic seizure	1	0
<i>Peripheral neuropathies NEC</i>		
Axonal neuropathy	2	0
Brachial plexopathy	1	0
Neuralgic amyotrophy	4	0
Neuritis	7	0
Neuropathy peripheral	139	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Peripheral sensorimotor neuropathy	1	0
Peripheral sensory neuropathy	12	0
Polyneuropathy	3	0
Small fibre neuropathy	3	0
Thoracic outlet syndrome	2	0
Seizures and seizure disorders NEC		
Atonic seizures	8	0
Change in seizure presentation	2	0
Clonic convulsion	4	0
Convulsions local	1	0
Convulsive threshold lowered	1	0
Epilepsy	164	0
Epileptic aura	2	0
Epileptic encephalopathy	2	0
Febrile convulsion	17	0
Idiopathic generalised epilepsy	1	0
Neonatal epileptic seizure	1	0
Partial seizures	28	0
Partial seizures with secondary generalisation	1	0
Post stroke seizure	1	0
Psychogenic seizure	11	0
Seizure	694	1
Seizure anoxic	3	0
Seizure cluster	6	0
Seizure like phenomena	3	0
Status epilepticus	39	0
Tonic clonic movements	5	0
Tonic convulsion	35	0
Tonic posturing	1	0
Sensory abnormalities NEC		
Ageusia	582	0
Allodynia	30	0
Aura	27	0
Central pain syndrome	1	0
Complex regional pain syndrome	6	0
Dysgeusia	1263	0
Electric shock sensation	47	0
Hypergeusia	1	0
Hypogeusia	8	0
Intercostal neuralgia	1	0
Loss of proprioception	3	0
Morton's neuralgia	3	0
Neuralgia	655	0
Persistent genital arousal disorder	2	0
Phantom limb syndrome	7	0
Post herpetic neuralgia	15	0
Restless arm syndrome	3	0
Restless legs syndrome	154	0
Sensory disturbance	119	0
Sensory loss	93	0
Taste disorder	292	0
Visual perseveration	3	0
Sleep disturbances NEC		

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Microsleep	1	0
Sleep deficit	13	0
Sudden onset of sleep	1	0
Speech and language abnormalities		
Dysarthria	223	0
Incoherent	14	0
Language disorder	2	0
Repetitive speech	5	0
Slow speech	22	0
Speech disorder	79	0
Speech disorder developmental	1	0
Spinal cord and nerve root disorders NEC		
Acquired syringomyelia	1	0
Cauda equina syndrome	1	0
Myelopathy	1	0
Radiculitis brachial	16	0
Radiculopathy	8	0
Structural brain disorders NEC		
Brain injury	9	2
Cerebral ventricle dilatation	2	0
Hyperintensity in brain deep nuclei	1	0
Transient cerebrovascular events		
Transient ischaemic attack	180	3
Tremor (excl congenital)		
Essential tremor	5	0
Head titubation	13	0
Resting tremor	4	0
Tremor	2030	0
Trigeminal disorders		
Numb chin syndrome	2	0
Trigeminal nerve disorder	3	0
Trigeminal neuralgia	80	0
Trigeminal neuritis	3	0
Vagus nerve disorders		
Vocal cord paralysis	2	0
Vertigos NEC		
Cervicogenic vertigo	1	0
Vertigo CNS origin	3	0
Nervous system disorders SOC TOTAL	76294	79

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortion related conditions and complications</i>		
Anembryonic gestation	3	0
<i>Abortions not specified as induced or spontaneous</i>		
Abortion	1	0
Abortion missed	7	0
<i>Abortions spontaneous</i>		
Abortion spontaneous	438	4
Abortion threatened	2	0
<i>Amniotic fluid and cavity disorders of pregnancy NEC</i>		
Amniorrhoea	2	0
<i>Foetal complications NEC</i>		
Foetal cardiac disorder	1	0
Foetal distress syndrome	1	0
Foetal hypokinesia	14	0
<i>Foetal conditions due to maternal conditions</i>		
Maternal condition affecting foetus	1	0
<i>Foetal growth complications</i>		
Foetal growth restriction	5	0
<i>Gestational age and weight conditions</i>		
Low birth weight baby	1	0
Premature baby	6	1
<i>Haemorrhagic complications of pregnancy</i>		
Haemorrhage in pregnancy	3	0
Premature separation of placenta	3	0
Subchorionic haematoma	3	0
Subchorionic haemorrhage	1	0
<i>High risk pregnancies</i>		
High risk pregnancy	1	0
<i>Hypertension associated disorders of pregnancy</i>		
Pre-eclampsia	1	0
<i>Labour onset and length abnormalities</i>		
Induced labour	1	0
Premature delivery	1	0
Premature labour	8	0
Premature rupture of membranes	3	0
Threatened labour	1	0
<i>Maternal complications of delivery NEC</i>		
Retained placenta or membranes	2	0
<i>Maternal complications of labour NEC</i>		
Uterine contractions abnormal	1	0
Uterine hypertonus	9	0
<i>Maternal complications of pregnancy NEC</i>		
Biochemical pregnancy	2	0
Complication of pregnancy	1	0
Decidual cast	5	0
Ectopic pregnancy	12	0
Hyperemesis gravidarum	1	0
Morning sickness	15	0
Preterm premature rupture of membranes	3	0
Ruptured ectopic pregnancy	1	0
Somatic symptom disorder of pregnancy	3	0
<i>Normal newborn status</i>		
Normal newborn	1	0

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Reaction Name	Total	Fatal
Pregnancy conditions <small>Pregnancy conditions cont'd</small>		
<i>Normal pregnancy, labour and delivery</i>		
Labour pain	1	0
Live birth	7	0
Pregnancy	33	0
Uterine contractions during pregnancy	6	0
<i>Placental abnormalities (excl neoplasms)</i>		
Foetal vascular malperfusion	2	0
Placental disorder	1	0
Placental insufficiency	1	0
Small size placenta	1	0
<i>Postpartum complications NEC</i>		
Postpartum haemorrhage	5	0
<i>Pregnancy complicated by maternal disorders</i>		
Gestational diabetes	2	0
Peripartum cardiomyopathy	1	0
<i>Stillbirth and foetal death</i>		
Foetal death	4	2
Stillbirth	11	9
<i>Umbilical cord complications</i>		
Umbilical cord thrombosis	1	0
<i>Unintended pregnancies</i>		
Pregnancy after post coital contraception	2	0
Pregnancy on contraceptive	2	0
Pregnancy on oral contraceptive	2	0
Pregnancy with contraceptive device	1	0
Pregnancy with implant contraceptive	1	0
Unintended pregnancy	4	0
Unwanted pregnancy	1	0
Pregnancy conditions SOC TOTAL	653	16

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Reaction Name	Total	Fatal
<i>Device electrical issues</i>		
Electromagnetic interference	1	0
<i>Device issues NEC</i>		
Device connection issue	1	0
Device failure	1	0
Device issue	2	0
<i>Device malfunction events NEC</i>		
Device infusion issue	1	0
Device malfunction	1	0
Device pacing issue	1	0
Device stimulation issue	1	0
Oversensing	19	0
Thrombosis in device	14	0
Undersensing	1	0
<i>Device physical property and chemical issues</i>		
Device breakage	1	0
Device defective	9	0
Device kink	1	0
Needle issue	3	0
<i>Manufacturing materials issues</i>		
Manufacturing materials contamination	1	0
<i>Product contamination and sterility issues</i>		
Product contamination	13	0
Product contamination physical	8	0
<i>Product packaging issues</i>		
Packaging design issue	1	0
Product closure issue	1	0
<i>Product physical issues</i>		
Liquid product physical issue	11	0
Product after taste	2	0
Product deposit	1	0
Product odour abnormal	3	0
Product physical issue	2	0
Product taste abnormal	9	0
<i>Product quality issues NEC</i>		
Product complaint	1	0
Product origin unknown	5	0
<i>Product supply and availability issues</i>		
Product availability issue	1	0
null SOC TOTAL	116	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	28	0
Behaviour disorder	2	0
Breath holding	6	0
Staring	7	0
<i>Adjustment disorders</i>		
Adjustment disorder	1	0
Adjustment disorder with depressed mood	4	0
<i>Affect alterations NEC</i>		
Affect lability	15	0
Constricted affect	3	0
Flat affect	13	0
Inappropriate affect	23	0
<i>Amnesic symptoms</i>		
Paramnesia	7	0
<i>Anxiety disorders NEC</i>		
Anxiety disorder	2	0
Generalised anxiety disorder	3	0
Neurosis	1	0
<i>Anxiety symptoms</i>		
Agitation	90	0
Anxiety	1007	0
Immunisation anxiety related reaction	3	0
Nervousness	204	0
Stress	121	0
Tension	40	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	7	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	16	0
Attention-seeking behaviour	1	0
Aversion	1	0
Disinhibition	3	0
Indifference	7	0
Paranoia	27	0
Personality change	5	0
Social avoidant behaviour	5	0
Soliloquy	2	0
Suspiciousness	1	0
<i>Bipolar disorders</i>		
Bipolar I disorder	2	0
Bipolar disorder	5	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Daydreaming	8	0
Distractibility	4	0
Mental fatigue	239	0
<i>Communications disorders</i>		
Communication disorder	5	0
Mutism	4	0
<i>Confusion and disorientation</i>		
Confusional state	1005	0
Disorientation	317	0
<i>Decreased physical activity levels</i>		

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Catatonia	1	0
Deliria		
Delirium	145	0
Delusional symptoms		
Delusion	16	0
Depressive disorders		
Agitated depression	6	0
Depression	393	0
Depression suicidal	19	0
Major depression	14	0
Mixed anxiety and depressive disorder	4	0
Dissociative states		
Depersonalisation/derealisation disorder	12	0
Dissociation	36	0
Dissociative amnesia	4	0
Dissociative disorder	2	0
Disturbances in initiating and maintaining sleep		
Initial insomnia	29	0
Insomnia	1835	0
Middle insomnia	34	0
Terminal insomnia	32	0
Dyssomnias		
Breathing-related sleep disorder	1	0
Dyssomnia	1	0
Poor quality sleep	260	0
Eating disorders NEC		
Bulimia nervosa	1	0
Eating disorder	12	0
Selective eating disorder	1	0
Emotional and mood disturbances NEC		
Anger	42	0
Dysphoria	2	0
Emotional disorder	65	0
Emotional distress	57	0
Emotional poverty	2	0
Euphoric mood	49	0
Frustration tolerance decreased	2	0
Irritability	226	0
Mood altered	63	0
Factitious disorders		
Factitious disorder	4	0
Fear symptoms and phobic disorders (incl social phobia)		
Agoraphobia	2	0
Claustrophobia	1	0
Fear	26	0
Fear of death	2	0
Fear of eating	1	0
Fear of falling	3	0
Fear of injection	6	0
Osmophobia	1	0
Performance fear	1	0
Phobia	3	0
Phonophobia	3	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Social anxiety disorder	2	0
Social fear	1	0
Fluctuating mood symptoms		
Mood swings	157	0
Hallucinations (excl sleep-related)		
Hallucination	245	0
Hallucination, auditory	21	0
Hallucination, olfactory	15	0
Hallucination, tactile	1	0
Hallucination, visual	31	0
Hallucinations, mixed	3	0
Increased physical activity levels		
Restlessness	173	0
Infancy, childhood and adolescence psychiatric disorders NEC		
Social (pragmatic) communication disorder	1	0
Learning disorders		
Learning disability	1	0
Learning disorder	1	0
Mental disorders NEC		
Mental disorder	19	0
Mental status changes	1	0
Psychological factor affecting medical condition	1	0
Mood alterations with depressive symptoms		
Anhedonia	3	0
Decreased interest	10	0
Depressed mood	436	0
Depressive symptom	2	0
Feeling guilty	1	0
Feeling of despair	5	0
Feelings of worthlessness	2	0
Negative thoughts	3	0
Psychomotor retardation	2	0
Sense of a foreshortened future	3	0
Tearfulness	47	0
Mood alterations with manic symptoms		
Hypomania	2	0
Mania	11	0
Mood disorders NEC		
Affective disorder	4	0
Apathy	38	0
Boredom	1	0
Laziness	3	0
Listless	25	0
Mood disorder due to a general medical condition	1	0
Narcolepsy and associated conditions		
Hypnagogic hallucination	4	0
Hypnopompic hallucination	2	0
Sleep attacks	3	0
Obsessive-compulsive disorders and symptoms		
Obsessive-compulsive symptom	1	0
Orgasmic disorders and disturbances		
Anorgasmia	5	0
Female orgasmic disorder	2	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Orgasm abnormal	4	0
Orgasmic sensation decreased	1	0
Premature ejaculation	1	0
Panic attacks and disorders		
Limited symptom panic attack	1	0
Panic attack	245	0
Panic disorder	8	0
Panic reaction	31	0
Paraphilias and paraphilic disorders		
Transvestism	1	0
Parasomnias		
Abnormal dreams	208	0
Abnormal sleep-related event	1	0
Confusional arousal	1	0
Exploding head syndrome	2	0
Nightmare	223	0
Parasomnia	4	0
Sleep inertia	1	0
Sleep talking	6	0
Sleep terror	29	0
Somnambulism	8	0
Perception disturbances NEC		
Autoscopy	20	0
Deja vu	2	0
Derealisation	13	0
Flashback	4	0
Illusion	6	0
Near death experience	1	0
Time perception altered	2	0
Personality disorders NEC		
Personality disorder	1	0
Self esteem decreased	1	0
Pervasive developmental disorders NEC		
Autism spectrum disorder	3	0
Psychiatric elimination disorders		
Enuresis	31	0
Psychiatric symptoms NEC		
Helplessness	1	0
Hypervigilance	9	0
Psychiatric symptom	11	0
Psychological trauma	4	0
Trance	1	0
Psychotic disorder NEC		
Acute psychosis	1	0
Psychotic behaviour	1	0
Psychotic disorder	29	0
Schizophrenia NEC		
Schizophrenia	2	0
Sexual and gender identity disorders NEC		
Gender dysphoria	1	0
Sexual arousal disorders		
Disturbance in sexual arousal	4	0
Sexual inhibition	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Sexual desire disorders</i>		
Hypersexuality	1	0
Libido decreased	19	0
Libido disorder	1	0
Libido increased	8	0
Loss of libido	20	0
<i>Sexual dysfunction NEC</i>		
Genito-pelvic pain/penetration disorder	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	264	0
Sleep disorder due to general medical condition, insomnia type	5	0
<i>Somatic symptom disorders</i>		
Conversion disorder	25	0
Habit cough	22	0
Somatic symptom disorder	2	0
Vomiting psychogenic	1	0
<i>Speech and language usage disturbances</i>		
Disorganised speech	9	0
Logorrhoea	2	0
<i>Speech articulation and rhythm disturbances</i>		
Dysphemia	27	0
Lack of spontaneous speech	1	0
Pressure of speech	1	0
<i>Stereotypies and automatisms</i>		
Automatism	1	0
Bruxism	14	0
Head banging	12	0
Stereotypy	1	0
<i>Stress disorders</i>		
Burnout syndrome	2	0
Post-traumatic stress disorder	4	0
<i>Substance related and addictive disorders</i>		
Alcohol problem	1	0
Alcoholic hangover	1	0
Alcoholism	5	0
Nicotine dependence	2	0
<i>Suicidal and self-injurious behaviour</i>		
Completed suicide	2	2
Intentional self-injury	6	0
Self-injurious ideation	2	0
Suicidal ideation	47	0
Suicide attempt	8	0
Suicide threat	2	0
<i>Thinking disturbances</i>		
Bradyphrenia	44	0
Flight of ideas	1	0
Intrusive thoughts	7	0
Morbid thoughts	1	0
Tachyphrenia	8	0
Thinking abnormal	21	0
Thought blocking	1	0
<i>Tic disorders</i>		
Tic	15	0

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Reaction Name	Total	Fatal
Psychiatric disorders ^{Psychiatric disorders cont'd}		
Psychiatric disorders SOC TOTAL	9493	2

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder discomfort	3	0
Bladder irritation	10	0
Bladder pain	34	0
Bladder spasm	2	0
Dysuria	55	0
Incontinence	39	0
Lower urinary tract symptoms	3	0
Micturition disorder	2	0
Micturition urgency	50	0
Pollakiuria	150	0
Stress urinary incontinence	2	0
Urethral pain	7	0
Urge incontinence	3	0
Urinary hesitation	2	0
Urinary incontinence	69	0
Urinary retention	51	0
Urine flow decreased	18	0
<i>Bladder disorders NEC</i>		
Bladder disorder	11	0
Bladder fibrosis	1	0
Bladder prolapse	1	0
Urinary bladder haemorrhage	4	0
<i>Bladder infections and inflammations</i>		
Cystitis haemorrhagic	1	0
Cystitis interstitial	6	0
Cystitis noninfective	1	0
<i>Genital and urinary tract disorders NEC</i>		
Genitourinary symptom	2	0
Urinary tract disorder	4	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
Glomerulonephritis minimal lesion	5	0
Glomerulonephritis rapidly progressive	2	0
IgA nephropathy	4	0
Nephrotic syndrome	18	0
<i>Myoneurogenic bladder disorders</i>		
Bladder dysfunction	6	0
Hypertonic bladder	4	0
Hypotonic urinary bladder	1	0
Loss of bladder sensation	3	0
Neurogenic bladder	2	0
<i>Nephritis NEC</i>		
Lupus nephritis	1	0
Nephritis	3	0
Tubulointerstitial nephritis	2	0
<i>Nephropathies and tubular disorders NEC</i>		
Nephropathy	1	0
<i>Renal disorders NEC</i>		
Renal disorder	7	1
Renal haemorrhage	1	0
Renal mass	1	0
<i>Renal failure and impairment</i>		
Acute kidney injury	50	4

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Renal & urinary disorders cont'd</i>		
Anuria	3	0
Chronic kidney disease	4	0
Oliguria	1	0
Renal failure	24	1
Renal impairment	27	0
Renal injury	2	0
<i>Renal failure complications</i>		
Azotaemia	1	0
<i>Renal lithiasis</i>		
Nephrolithiasis	11	0
<i>Renal neoplasms</i>		
Renal cyst	1	0
<i>Renal obstructive disorders</i>		
Hydronephrosis	2	0
<i>Renal structural abnormalities and trauma</i>		
Kidney enlargement	1	0
Kidney small	2	0
<i>Renal vascular and ischaemic conditions</i>		
Renal aneurysm	1	0
Renal infarct	4	0
Renal tubular necrosis	2	0
Renal vasculitis	1	1
<i>Structural and obstructive urethral disorders (excl congenital)</i>		
Urethral stenosis	1	0
<i>Ureteric disorders NEC</i>		
Ureteric stenosis	1	0
<i>Urinary abnormalities</i>		
Albuminuria	1	0
Chromaturia	65	0
Haematuria	48	0
Ketonuria	1	0
Myoglobinuria	1	0
Proteinuria	12	0
Urine abnormality	12	0
Urine odour abnormal	10	0
<i>Urinary tract lithiasis (excl renal)</i>		
Calculus bladder	1	0
Calculus urinary	1	0
<i>Urinary tract signs and symptoms NEC</i>		
Costovertebral angle tenderness	1	0
Cystitis-like symptom	1	0
Haemorrhage urinary tract	28	1
Nocturia	3	0
Polyuria	9	0
Renal colic	4	0
Renal pain	351	0
Urinary tract discomfort	2	0
Urinary tract pain	6	0
Renal & urinary disorders SOC TOTAL	1288	8

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Benign and malignant breast neoplasms</i>		
Breast cyst	16	0
<i>Breast disorders NEC</i>		
Breast atrophy	1	0
Breast disorder	3	0
Breast enlargement	30	0
Breast mass	134	0
Fibrocystic breast disease	1	0
Gynaecomastia	5	0
Mastoptosis	1	0
Nipple disorder	1	0
<i>Breast infections and inflammations</i>		
Breast inflammation	6	0
Nipple inflammation	2	0
<i>Breast signs and symptoms</i>		
Breast discharge	4	0
Breast discomfort	13	0
Breast engorgement	11	0
Breast haematoma	1	0
Breast oedema	8	0
Breast pain	812	0
Breast swelling	182	0
Breast tenderness	93	0
Nipple pain	46	1
Nipple swelling	4	0
<i>Cervix disorders NEC</i>		
Cervical dysplasia	2	0
Cervix disorder	1	0
Cervix haemorrhage uterine	5	0
Ectropion of cervix	4	0
<i>Cervix infections and inflammations</i>		
Cervix inflammation	1	0
<i>Cervix neoplasms</i>		
Cervical polyp	1	0
<i>Erection and ejaculation conditions and disorders</i>		
Ejaculation disorder	3	0
Ejaculation failure	3	0
Erectile dysfunction	71	0
Erection increased	4	0
Organic erectile dysfunction	14	0
Painful ejaculation	1	0
Spontaneous ejaculation	2	0
Spontaneous penile erection	2	0
<i>Fallopian tube and ovary infections and inflammations</i>		
Noninfective oophoritis	5	0
<i>Lactation disorders</i>		
Breast milk discolouration	3	0
Breast milk odour abnormal	2	0
Galactorrhoea	5	0
Galactostasis	1	0
Lactation disorder	10	0
Lactation puerperal increased	5	0
Suppressed lactation	47	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
<i>Menopausal effects NEC</i>		
Artificial menopause	1	0
Menopausal disorder	1	0
Menopausal symptoms	39	0
Menopause delayed	1	0
Premature menopause	23	0
<i>Menopausal effects on the genitourinary tract</i>		
Atrophic vulvovaginitis	2	0
Postmenopausal haemorrhage	106	0
<i>Menstruation and uterine bleeding NEC</i>		
Abnormal uterine bleeding	6	0
Abnormal withdrawal bleeding	3	0
Bleeding anovulatory	1	0
Dysmenorrhoea	3085	0
Intermenstrual bleeding	1224	0
Menstrual discomfort	30	0
Menstrual disorder	2079	0
Menstruation irregular	3660	0
Premenstrual dysphoric disorder	12	0
Premenstrual headache	11	0
Premenstrual pain	135	0
Premenstrual syndrome	122	0
Retrograde menstruation	1	0
Withdrawal bleed	16	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	654	0
Hypomenorrhoea	700	0
Menstruation delayed	5239	0
Oligomenorrhoea	194	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	5845	0
Menometrorrhagia	19	0
Polymenorrhoea	934	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>		
Haemorrhagic ovarian cyst	3	0
Ovarian cyst	28	0
Ovarian cyst ruptured	1	0
Polycystic ovaries	49	0
<i>Ovarian and fallopian tube disorders NEC</i>		
Adnexal torsion	1	0
Hydrosalpinx	2	0
Ovarian enlargement	1	0
Ovarian haemorrhage	7	0
Ovarian mass	1	0
Ovulation disorder	2	0
Ovulation pain	75	0
Premature ovulation	4	0
<i>Pelvic prolapse conditions</i>		
Vaginal prolapse	1	0
<i>Pelvis and broad ligament disorders NEC</i>		
Adnexa uteri mass	1	0
Adnexa uteri pain	66	0
Pelvic congestion	1	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Pelvic floor muscle weakness	1	0
Pelvic haemorrhage	22	0
<i>Penile and scrotal infections and inflammations</i>		
Balanoposthitis	4	0
<i>Penile disorders NEC (excl erection and ejaculation)</i>		
Penile blister	1	0
Penile discharge	1	0
Penile discomfort	1	0
Penile erythema	1	0
Penile haemorrhage	3	0
Penile oedema	1	0
Penile pain	1	0
Penile size reduced	1	0
Penile swelling	6	0
Penis disorder	12	0
<i>Prostate and seminal vesicles infections and inflammations</i>		
Prostatitis	4	0
<i>Prostatic neoplasms and hypertrophy</i>		
Benign prostatic hyperplasia	2	0
<i>Prostatic signs, symptoms and disorders NEC</i>		
Prostatic pain	1	0
Prostatomegaly	3	0
<i>Reproductive tract disorders NEC (excl neoplasms)</i>		
Genital erosion	1	0
Genital haemorrhage	25	0
Genital hypoaesthesia	1	0
Genital lesion	2	0
Genital paraesthesia	1	0
Genital ulceration	8	0
Perineal ulceration	1	0
<i>Reproductive tract infections and inflammations NEC</i>		
Genital tract inflammation	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Genital burning sensation	2	0
Genital erythema	1	0
Genital pain	6	0
Genital rash	5	0
Genital swelling	4	0
Pelvic discomfort	6	0
Pelvic pain	120	0
Perineal pain	2	0
Perineal rash	1	0
Pruritus genital	6	0
<i>Scrotal disorders NEC</i>		
Acquired hydrocele	1	0
Scrotal angiokeratoma	1	0
Scrotal discomfort	1	0
Scrotal erythema	2	0
Scrotal exfoliation	2	0
Scrotal pain	22	0
Scrotal swelling	5	0
Scrotum erosion	1	0
Varicocele	2	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
<i>Sexual function and fertility disorders NEC</i>		
Dyspareunia	6	0
Infertility	14	0
Infertility female	4	0
Sexual dysfunction	9	0
<i>Spermatogenesis and semen disorders</i>		
Aspermia	1	0
Haematospermia	8	0
Semen discolouration	1	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular atrophy	1	0
Testicular disorder	4	0
Testicular oedema	1	0
Testicular pain	68	0
Testicular swelling	13	0
Testicular torsion	1	0
Testis discomfort	3	0
<i>Testicular and epididymal neoplasms</i>		
Testicular cyst	1	0
<i>Uterine disorders NEC</i>		
Adenomyosis	10	0
Endometrial thickening	4	0
Endometriosis	90	0
Uterine haemorrhage	43	0
Uterine pain	17	0
<i>Uterine infections and inflammations (excl cervix)</i>		
Uterine inflammation	1	0
<i>Uterine neoplasms</i>		
Uterine polyp	5	0
<i>Uterine tone disorders</i>		
Uterine spasm	35	0
<i>Vulvovaginal cysts and neoplasms</i>		
Bartholin's cyst	2	0
Vaginal cyst	7	0
Vaginal polyp	1	0
Vulva cyst	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	1689	0
Vaginal mucosal blistering	1	0
Vaginal ulceration	3	0
Vulval disorder	2	0
Vulval haemorrhage	34	0
Vulval ulceration	7	0
Vulvovaginal ulceration	5	0
<i>Vulvovaginal signs and symptoms</i>		
Clitoral engorgement	1	0
Coital bleeding	6	0
Labia enlarged	2	0
Vaginal discharge	85	0
Vaginal lesion	1	0
Vaginal odour	3	0
Vulval oedema	2	0
Vulvovaginal burning sensation	8	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
Reproductive & breast disorders cont'd		
Vulvovaginal discomfort	2	0
Vulvovaginal dryness	5	0
Vulvovaginal erythema	2	0
Vulvovaginal pain	30	0
Vulvovaginal pruritus	10	0
Vulvovaginal rash	2	0
Vulvovaginal swelling	5	0
Reproductive & breast disorders SOC TOTAL	28503	1

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	6	0
Apnoeic attack	1	0
Dyspnoea	6114	5
Dyspnoea at rest	11	0
Dyspnoea exertional	39	1
Grunting	1	0
Hyperventilation	59	0
Hypopnoea	123	0
Hypoventilation	1	0
Irregular breathing	24	0
Mouth breathing	7	0
Nocturnal dyspnoea	2	0
Orthopnoea	3	0
Respiration abnormal	67	0
Respiratory arrest	18	0
Respiratory depression	1	0
Respiratory distress	20	0
Sleep apnoea syndrome	15	0
Tachypnoea	31	0
<i>Bronchial conditions NEC</i>		
Bronchial secretion retention	4	0
Bronchiectasis	15	0
<i>Bronchospasm and obstruction</i>		
Asthma	397	0
Asthma late onset	3	0
Bronchospasm	18	0
Chronic obstructive pulmonary disease	24	1
Cough variant asthma	7	0
Obstructive airways disorder	9	0
Reversible airways obstruction	1	0
Wheezing	457	0
<i>Conditions associated with abnormal gas exchange</i>		
Asphyxia	2	0
Cyanosis central	1	0
Hyperoxia	1	0
Hypoxia	32	2
Respiratory acidosis	2	0
<i>Coughing and associated symptoms</i>		
Allergic cough	8	0
Cough	2828	1
Cough decreased	2	0
Haemoptysis	68	0
Productive cough	188	0
Sputum discoloured	11	0
Sputum increased	4	0
<i>Diaphragmatic disorders</i>		
Acquired diaphragmatic eventration	1	0
Diaphragm muscle weakness	1	0
Diaphragmatic disorder	1	0
<i>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</i>		
Laryngeal disorder	1	0

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Reflux laryngitis	2	0
Vocal cord disorder	1	0
Vocal cord dysfunction	3	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Epiglottic oedema	1	0
Laryngeal obstruction	1	0
Laryngeal oedema	4	0
Laryngospasm	3	0
Stridor	27	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Alveolitis	1	0
Autoimmune lung disease	1	0
Hypersensitivity pneumonitis	1	0
Lower respiratory tract inflammation	1	0
Pneumonitis	33	2
Pulmonary sarcoidosis	2	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	36	0
Increased bronchial secretion	3	0
Increased viscosity of bronchial secretion	1	0
Lung hyperinflation	2	0
Lung opacity	3	0
Pleuritic pain	24	0
Pulmonary haemorrhage	1	0
Pulmonary pain	112	0
Rales	5	0
Respiratory fremitus	1	0
<i>Mediastinal disorders</i>		
Mediastinal mass	1	0
Pulmonary hilum mass	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	321	0
Nasal inflammation	4	0
Rhinitis allergic	25	0
<i>Nasal disorders NEC</i>		
Epistaxis	1033	0
Intranasal hyposaesthesia	2	0
Intranasal paraesthesia	1	0
Nasal crusting	2	0
Nasal disorder	3	0
Nasal dryness	36	0
Nasal mucosal discolouration	1	0
Nasal odour	6	0
Nasal oedema	8	0
Nasal polyps	1	0
Nasal pruritus	12	0
Nasal ulcer	1	0
<i>Neonatal hypoxic conditions</i>		
Dry lung syndrome	1	0
Gasping syndrome	1	0
Infantile apnoea	2	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Allergic sinusitis	1	0

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Paranasal sinus inflammation	4	0
Sinonasal obstruction	14	0
Sinus congestion	69	0
Sinus disorder	6	0
<i>Parenchymal lung disorders NEC</i>		
Atelectasis	3	0
Combined pulmonary fibrosis and emphysema	1	0
Emphysema	3	0
Interstitial lung disease	11	0
Lung consolidation	5	0
Lung infiltration	2	1
Organising pneumonia	2	0
Pulmonary alveolar haemorrhage	1	0
Pulmonary cavitation	1	0
Pulmonary fibrosis	9	0
Pulmonary toxicity	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Hyperactive pharyngeal reflex	1	0
Pharyngeal enanthema	1	0
Pharyngeal erythema	9	0
Pharyngeal haemorrhage	2	0
Pharyngeal hypoaesthesia	40	0
Pharyngeal inflammation	4	0
Pharyngeal lesion	1	0
Pharyngeal mass	1	0
Pharyngeal oedema	14	0
Pharyngeal paraesthesia	55	0
Pharyngeal swelling	281	0
Pharyngeal ulceration	15	0
Tonsillar erythema	13	0
Tonsillar haemorrhage	1	0
Tonsillar hypertrophy	93	0
Tonsillar inflammation	3	0
Tonsillar ulcer	1	0
Tonsilloolith	1	0
<i>Pleural infections and inflammations</i>		
Pleurisy	37	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	36	0
Pneumothorax	10	0
Pneumothorax spontaneous	4	0
<i>Pulmonary hypertensions</i>		
Pulmonary hypertension	3	0
<i>Pulmonary oedemas</i>		
Acute respiratory distress syndrome	2	1
Pulmonary congestion	19	0
Pulmonary oedema	22	2
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary artery thrombosis	2	0
Pulmonary embolism	503	36
Pulmonary infarction	6	0
Pulmonary thrombosis	10	1
<i>Respiratory failures (excl neonatal)</i>		

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Acute respiratory failure	3	1
Respiratory failure	13	2
<i>Respiratory signs and symptoms NEC</i>		
Allergic respiratory symptom	6	0
Diaphragmalgia	8	0
Nasal flaring	1	0
Painful respiration	16	1
Pleural rub	1	0
Respiratory symptom	21	0
Suffocation feeling	2	0
Use of accessory respiratory muscles	2	0
<i>Respiratory tract disorders NEC</i>		
Allergic respiratory disease	1	0
Aspiration	3	0
Lung disorder	8	1
Pulmonary mass	5	0
Respiratory disorder	15	1
Respiratory tract congestion	4	0
Respiratory tract haemorrhage	2	0
Respiratory tract inflammation	2	0
Respiratory tract irritation	9	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 disorder	1	0
Tracheal pain	2	0
<i>Upper respiratory tract neoplasms</i>		
Tonsillar cyst	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	137	0
Catarrh	31	0
Choking	18	0
Choking sensation	5	0
Dry throat	184	0
Dysphonia	177	0
Increased upper airway secretion	6	0
Increased viscosity of upper respiratory secretion	35	0
Laryngeal pain	1	0
Nasal discharge discolouration	3	0
Nasal discomfort	55	0
Nasal obstruction	2	0
Oropharyngeal blistering	11	0
Oropharyngeal discolouration	1	0
Oropharyngeal discomfort	69	0
Oropharyngeal pain	3129	0
Oropharyngeal plaque	2	0
Paranasal sinus discomfort	51	0
Rhinalgia	14	0
Rhinorrhoea	1021	0
Sinus pain	241	0
Sneezing	437	0
Snoring	8	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Throat clearing	8	0
Throat irritation	254	0
Throat lesion	1	0
Throat tightness	277	0
Upper airway obstruction	3	0
Upper respiratory tract congestion	2	0
Upper respiratory tract irritation	1	0
Upper-airway cough syndrome	14	0
Yawning	28	0
<i>Vascular pulmonary disorders NEC</i>		
Acute chest syndrome	1	0
Respiratory disorders SOC TOTAL	20042	59

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	208	0
Acne cystic	26	0
Dermatitis acneiform	13	0
<i>Alopecias</i>		
Alopecia	366	0
Alopecia areata	57	0
Alopecia totalis	3	0
Alopecia universalis	2	0
Androgenetic alopecia	2	0
Diffuse alopecia	3	0
Hypotrichosis	3	0
Lichen planopilaris	1	0
Madarosis	9	0
<i>Angioedemas</i>		
Angioedema	261	0
Circumoral oedema	1	0
Circumoral swelling	1	0
Idiopathic angioedema	1	0
<i>Apocrine and eccrine gland disorders</i>		
Anhidrosis	1	0
Bromhidrosis	1	0
Cold sweat	858	0
Hidradenitis	5	0
Hyperhidrosis	2593	0
Hypohidrosis	2	0
Milia	2	0
Miliaria	113	0
Night sweats	888	0
Sweat discolouration	1	0
<i>Bullous conditions</i>		
Blister	510	0
Blister rupture	1	0
Blood blister	35	0
Dermatitis bullous	14	0
Erythema multiforme	43	0
Fracture blisters	1	0
Herpes gestationis	1	0
Pemphigoid	28	0
Pemphigus	9	0
Stevens-Johnson syndrome	6	0
Toxic epidermal necrolysis	2	1
<i>Connective tissue disorders</i>		
Cutaneous lupus erythematosus	2	0
Dermatomyositis	9	0
Subacute cutaneous lupus erythematosus	2	0
<i>Dermal and epidermal conditions NEC</i>		
Acute febrile neutrophilic dermatosis	1	0
Dermatosis	1	0
Dry skin	268	0
Koebner phenomenon	1	0
Macule	5	0
Neutrophilic dermatosis	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Pain of skin	319	0
Papule	116	0
Pathergy reaction	1	0
Scab	24	0
Scar discomfort	1	0
Scar pain	18	0
Sensitive skin	219	0
Shagreen skin	1	0
Skin burning sensation	253	0
Skin degenerative disorder	1	0
Skin discolouration	148	0
Skin discomfort	4	0
Skin disorder	33	0
Skin fissures	8	0
Skin indentation	3	0
Skin induration	5	0
Skin lesion	49	0
Skin lesion inflammation	1	0
Skin necrosis	2	0
Skin odour abnormal	22	0
Skin plaque	4	0
Skin reaction	165	0
Skin sensitisation	44	0
Skin swelling	113	0
Skin texture abnormal	2	0
Skin tightness	29	0
Skin warm	357	0
Skin weeping	12	0
Sticky skin	3	0
Target skin lesion	3	0
Transient acantholytic dermatosis	1	0
Yellow skin	27	0
<i>Dermatitis and eczema</i>		
Dermatitis	154	0
Dermatitis allergic	288	0
Dermatitis atopic	48	0
Dermatitis contact	25	0
Dermatitis diaper	4	0
Dyshidrotic eczema	29	0
Eczema	375	0
Eczema asteatotic	13	0
Eczema infantile	1	0
Eczema nummular	5	0
Eczema weeping	5	0
Hand dermatitis	2	0
Intertrigo	1	0
Neurodermatitis	3	0
Perioral dermatitis	3	0
Seborrhoeic dermatitis	7	0
Skin irritation	143	0
Stasis dermatitis	2	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	35	0

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Reaction Name	Total	Fatal
Skin disorders <i>Skin disorders cont'd</i>		
Drug reaction with eosinophilia and systemic symptoms	1	0
Fixed eruption	2	0
Palmar-plantar erythrodysesthesia syndrome	2	0
Toxic skin eruption	2	0
<i>Erythemas</i>		
Erythema	2397	0
Palmar erythema	4	0
Pernio-like erythema	1	0
Red man syndrome	2	0
<i>Exfoliative conditions</i>		
Dermatitis exfoliative	2	0
Dermatitis exfoliative generalised	5	0
Exfoliative rash	25	0
Keratolysis exfoliativa acquired	2	0
Skin exfoliation	131	0
<i>Granulomatous and deep cutaneous inflammatory conditions</i>		
Cutaneous sarcoidosis	1	0
Granuloma annulare	7	0
Necrobiosis lipoidica diabetorum	1	0
<i>Hyperkeratoses</i>		
Hyperkeratosis	2	0
Keratosis pilaris	3	0
Lichenoid keratosis	4	0
<i>Hyperpigmentation disorders</i>		
Argyria	1	0
Chloasma	1	0
Ephelides	1	0
Skin hyperpigmentation	6	0
Solar lentigo	4	0
<i>Hypertrichoses</i>		
Hirsutism	2	0
Hypertrichosis	1	0
<i>Hypopigmentation disorders</i>		
Skin depigmentation	4	0
Skin hypopigmentation	1	0
Vitiligo	22	0
<i>Lipodystrophies</i>		
Lipoatrophy	4	0
Lipodystrophy acquired	1	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
Ingrowing nail	1	0
Nail discolouration	11	0
Nail disorder	7	0
Nail growth abnormal	1	0
Nail pigmentation	2	0
Nail ridging	3	0
Onychalgia	9	0
Onychoclasia	6	0
Onychomadesis	2	0
Splinter haemorrhages	3	0
<i>Panniculitides</i>		
Erythema nodosum	30	0
Panniculitis	1	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
<i>Papulosquamous conditions</i>		
Erythema annulare	2	0
Lichen planus	23	0
Lichen sclerosus	9	0
Parapsoriasis	4	0
Pityriasis alba	1	0
Pityriasis rosea	132	0
Pityriasis rubra pilaris	1	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	69	0
Polymorphic light eruption	3	0
Solar dermatitis	2	0
<i>Pigmentation changes NEC</i>		
Haemosiderin stain	1	0
Pigmentation disorder	15	0
<i>Pilar disorders NEC</i>		
Hair colour changes	11	0
Hair disorder	1	0
Hair growth abnormal	8	0
Hair texture abnormal	6	0
Piloerection	28	0
Pseudofolliculitis	3	0
Trichorrhexis	3	0
<i>Pruritus NEC</i>		
Itching scar	10	0
Pruritus	6103	0
<i>Psoriatic conditions</i>		
Dermatitis psoriasiform	5	0
Guttate psoriasis	19	0
Nail psoriasis	2	0
Palmoplantar pustulosis	2	0
Psoriasis	217	0
Pustular psoriasis	3	0
Rebound psoriasis	1	0
<i>Purpura and related conditions</i>		
Ecchymosis	1	0
Henoch-Schonlein purpura	12	0
Petechiae	152	0
Purpura	60	0
<i>Pustular conditions</i>		
Acute generalised exanthematous pustulosis	2	0
<i>Rashes, eruptions and exanthems NEC</i>		
Butterfly rash	6	0
Rash	6355	1
Rash erythematous	1377	0
Rash macular	551	0
Rash maculo-papular	67	0
Rash morbilliform	47	0
Rash papular	391	0
Rash pruritic	1342	0
Rash scarlatiniform	1	0
Rash vesicular	81	0
Systemic lupus erythematosus rash	7	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
<i>Rosaceas</i>		
Rosacea	36	0
<i>Scaly conditions</i>		
Dandruff	5	0
Pityriasis	26	0
<i>Sebaceous gland disorders</i>		
Sebaceous glands overactivity	1	0
Seborrhoea	12	0
<i>Skin and subcutaneous conditions NEC</i>		
Cellulite	2	0
Cutaneous symptom	6	0
Reactive perforating collagenosis	1	0
Skin mass	25	0
<i>Skin and subcutaneous tissue ulcerations</i>		
Ischaemic skin ulcer	1	0
Mucocutaneous ulceration	1	0
Pyoderma gangrenosum	1	0
Scleroderma associated digital ulcer	1	0
Skin erosion	27	0
Skin ulcer	23	0
<i>Skin cysts and polyps</i>		
Dermal cyst	16	0
<i>Skin dystrophies</i>		
Keloid scar	3	0
Skin wrinkling	3	0
<i>Skin haemorrhages</i>		
Haemorrhage subcutaneous	15	0
Skin haemorrhage	20	0
<i>Skin hyperplasias and hypertrophies</i>		
Skin hypertrophy	2	0
<i>Skin hypoplasias and atrophies</i>		
Skin atrophy	3	0
Skin striae	8	0
<i>Skin injuries and mechanical dermatoses</i>		
Decubitus ulcer	3	0
Needle track marks	5	0
<i>Skin preneoplastic conditions NEC</i>		
Actinic keratosis	1	0
<i>Skin vascular conditions NEC</i>		
Angiodermatitis	1	0
Skin oedema	4	0
<i>Skin vasculitides</i>		
Capillaritis	3	0
Cutaneous vasculitis	15	0
Hypersensitivity vasculitis	1	0
Vasculitic rash	22	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	26	0
<i>Telangiectasia and related conditions</i>		
Spider naevus	1	0
Telangiectasia	1	0
<i>Urticarias</i>		
Chronic spontaneous urticaria	13	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Cold urticaria	8	0
Idiopathic urticaria	2	0
Mechanical urticaria	11	0
Solar urticaria	2	0
Urticaria	2164	0
Urticaria cholinergic	2	0
Urticaria chronic	35	0
Urticaria contact	1	0
Urticaria papular	6	0
Urticaria thermal	8	0
Urticularial vasculitis	6	0
Skin disorders SOC TOTAL	31925	2

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Reaction Name	Total	Fatal
Social circumstances		
<i>Age related issues</i>		
Infant	2	0
Menarche	3	0
Menopause	46	0
Postmenopause	3	0
<i>Criminal activity</i>		
Verbal abuse	1	0
<i>Dependents</i>		
Sick relative	6	0
<i>Dietary and nutritional issues</i>		
Feeding tube user	1	0
<i>Disability issues</i>		
Bedridden	31	0
Breast prosthesis user	3	0
Disability	2	0
Hearing disability	3	0
Housebound	1	0
Immobile	13	0
Impaired driving ability	5	0
Impaired work ability	19	0
Loss of personal independence in daily activities	44	0
Physical disability	5	0
Sight disability	12	0
Sitting disability	4	0
Walking disability	1	0
Wheelchair user	1	0
<i>Economic circumstances</i>		
High income	1	0
Low income	1	0
<i>Educational issues</i>		
Educational problem	1	0
Illiteracy	2	0
<i>Employment issues</i>		
Job dissatisfaction	1	0
Retirement	4	0
Sick leave	1	0
Stress at work	3	0
<i>Family and partner issues</i>		
Bed sharing	1	0
<i>Non-occupational and unspecified environmental problems</i>		
Flooding	2	0
Water pollution	2	0
<i>Pregnancy related circumstances</i>		
Breast feeding	17	0
Multigravida	1	0
Parity	1	0
<i>Social issues NEC</i>		
Exercise adequate	2	0
Hair dye user	2	0
Impaired quality of life	3	0
<i>Tobacco use</i>		
Ex-tobacco user	1	0
Non-tobacco user	4	0

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Reaction Name	Total	Fatal
Social circumstances Social circumstances cont'd		
Tobacco user	1	0
Social circumstances SOC TOTAL	257	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Anaesthesia and allied procedures</i>		
Local anaesthesia	2	0
Nerve block	5	0
<i>Analgesia supportive care</i>		
Analgesic therapy	1	0
<i>Antiinfective therapies</i>		
Antiviral prophylaxis	1	0
COVID-19 prophylaxis	2	0
COVID-19 treatment	4	0
<i>Arterial therapeutic procedures (excl aortic)</i>		
Splenic artery embolisation	1	0
<i>Blood and blood product treatment</i>		
Transfusion	2	0
<i>Breast therapeutic procedures NEC</i>		
Axillary lymphadenectomy	3	0
Mammoplasty	1	0
<i>Bronchial and pulmonary therapeutic procedures</i>		
Airway secretion clearance therapy	1	0
<i>Cardiac device therapeutic procedures</i>		
Cardiac pacemaker insertion	1	0
<i>Cardiac therapeutic procedures NEC</i>		
Cardiac operation	1	0
<i>Contraceptive methods female</i>		
Contraception	1	0
Contraceptive implant	3	0
Oral contraception	1	0
<i>Contraceptive methods male</i>		
Condom	1	0
<i>Dietary and nutritional therapies</i>		
Medical diet	8	0
Nothing by mouth order	13	0
Wheat-free diet	1	0
<i>External ear therapeutic procedures</i>		
Ear irrigation	1	0
<i>Facial therapeutic procedures</i>		
Face lift	1	0
<i>Fertility and fertilisation interventions female</i>		
Endometrial scratching	1	0
<i>Gastrointestinal therapeutic procedures NEC</i>		
Intestinal anastomosis	1	0
Prophylaxis of nausea and vomiting	17	0
<i>Gynaecological therapeutic procedures NEC</i>		
Menstrual cycle management	16	0
<i>Haematological therapeutic procedures NEC</i>		
Anticoagulant therapy	1	0
<i>Head, neck and oral cavity therapeutic procedures NEC</i>		
Neck lift	1	0
<i>Hernia repairs</i>		
Hernia repair	1	0
<i>Hormonal therapeutic procedures NEC</i>		
Hormone replacement therapy	1	0
Hormone therapy	8	0
<i>Immunisations</i>		

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Reaction Name	Total	Fatal
Surgical & medical procedures		
COVID-19 immunisation	113	0
Immunisation	581	1
Induced abortions		
Abortion induced	2	0
Joint therapeutic procedures		
Joint injection	5	0
Joint surgery	1	0
Knee arthroplasty	1	0
Large intestine therapeutic procedures		
Appendectomy	4	0
Limb therapeutic procedures		
Arm amputation	1	0
Leg amputation	1	0
Limb immobilisation	15	0
Limb operation	9	0
Lip therapeutic procedures		
Lip lesion excision	1	0
Lymphoid tissue therapeutic procedures		
Lymphadenectomy	3	0
Splenectomy	1	0
Mastectomies		
Breast conserving surgery	4	0
Nail therapeutic procedures		
Nail operation	3	0
Nervous system therapeutic procedures NEC		
Multiple sclerosis relapse prophylaxis	2	0
Obstetric therapeutic procedures		
Caesarean section	2	0
Labour stimulation	1	0
Orbit and globe therapeutic procedures		
Strabismus correction	1	0
Ovarian therapeutic procedures		
Ovarian operation	1	0
Peripheral nerve therapeutic procedures		
Neurolysis	1	0
Peripheral nerve neurostimulation	1	0
Phototherapies		
UV light therapy	1	0
Prophylactic procedures NEC		
Anaphylaxis prophylaxis	2	0
Immune tolerance induction	1	0
Prophylaxis against transplant rejection	1	0
Reproductive system disorder prophylaxis	1	0
Psychiatric therapies		
Electroconvulsive therapy	1	0
Renal therapeutic procedures		
Dialysis	1	0
Respiratory tract therapeutic procedures NEC		
Asthma prophylaxis	3	0
Retinal therapeutic procedures		
Retinopexy	1	0
Skin and subcutaneous tissue therapeutic procedures NEC		
Dermal filler injection	4	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<small>Surgical & medical procedures cont'd</small>		
Therapeutic skin care topical	1	0
Skull and brain therapeutic procedures		
Cerebrovascular operation	1	0
Posterior fossa decompression	1	0
Small intestine therapeutic procedures		
Ileostomy	1	0
Therapeutic bladder catheterisation		
Bladder catheterisation	2	0
Therapeutic procedures NEC		
Abscess drainage	1	0
Anaphylaxis treatment	7	0
Bed rest	5	0
Emergency care	1	0
Fatigue management	1	0
Hospitalisation	16	0
Injection	64	0
Interchange of vaccine products	203	0
Localised alternating hot and cold therapy	2	0
Magnetic therapy	1	0
Mass excision	4	0
Medical procedure	1	0
Medication dilution	2	0
Physical fitness training	1	0
Product used for unknown indication	3	0
Promotion of wound healing	1	0
Specialist consultation	1	0
Sterilisation	1	0
Stoma care	1	0
Therapeutic procedure	1	0
Therapy change	1	0
Vehicle solution use	1	0
Tracheal therapeutic procedures		
Tracheostomy	1	0
Uterine therapeutic procedures		
Endometrial ablation	2	0
Vascular therapeutic procedures NEC		
Thrombolysis	1	0
Vasodilation procedure	1	0
Surgical & medical procedures SOC TOTAL	1202	1

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Accelerated and malignant hypertension</i>		
Hypertensive crisis	12	0
Hypertensive urgency	2	0
Malignant hypertension	4	0
<i>Aneurysms and dissections non-site specific</i>		
Aneurysm	3	0
Artery dissection	2	0
<i>Aortic aneurysms and dissections</i>		
Acute aortic syndrome	1	0
Aortic aneurysm rupture	1	1
Aortic dissection	1	0
<i>Aortic embolism and thrombosis</i>		
Aortic embolus	5	0
Aortic thrombosis	4	0
<i>Aortic infections and inflammations</i>		
Aortitis	1	0
<i>Aortic necrosis and vascular insufficiency</i>		
Aortic occlusion	1	0
<i>Arterial infections and inflammations</i>		
Arteritis	1	0
Giant cell arteritis	17	0
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	14	0
Labile blood pressure	3	0
<i>Bruising, ecchymosis and purpura</i>		
Achenbach syndrome	4	0
<i>Circulatory collapse and shock</i>		
CT hypotension complex	2	0
Circulatory collapse	80	0
Hypoperfusion	2	0
Hypovolaemic shock	1	1
Neurogenic shock	24	0
Peripheral circulatory failure	6	0
Shock	23	0
Shock symptom	2	0
<i>Haemorrhages NEC</i>		
Arterial haemorrhage	1	0
Bloody discharge	24	0
Haematoma	52	0
Haemorrhage	1319	2
Internal haemorrhage	10	0
Venous haemorrhage	2	0
<i>Lymphangiopathies</i>		
Lymphangiopathy	1	0
Lymphocele	6	0
Lymphorrhoea	2	0
Lymphostasis	1	0
<i>Lymphoedemas</i>		
Lymphoedema	237	0
<i>Non-site specific embolism and thrombosis</i>		
Arterial thrombosis	4	0
Embolism	64	0
Embolism arterial	1	0

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Reaction Name	Total	Fatal
Vascular disorders <small>Vascular disorders cont'd</small>		
Embolism venous	8	1
Microembolism	2	0
Thrombosis	478	9
Venous thrombosis	7	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Arterial occlusive disease	2	0
Arterial spasm	1	0
Arteriosclerosis	3	0
Haemorrhagic infarction	1	0
Infarction	3	0
Ischaemia	11	0
Peripheral venous disease	1	0
Vascular occlusion	1	0
Vasospasm	1	0
<i>Non-site specific vascular disorders NEC</i>		
Capillary disorder	1	0
Capillary fragility	4	0
Haemodynamic instability	1	0
Superficial vein prominence	2	0
Vascular pain	38	0
Vascular wall hypertrophy	1	0
Vasodilatation	42	0
Vein discolouration	7	0
Vein disorder	7	0
Vein rupture	7	0
<i>Peripheral aneurysms and dissections</i>		
Peripheral artery aneurysm	1	0
<i>Peripheral embolism and thrombosis</i>		
Axillary vein thrombosis	1	0
Blue toe syndrome	33	0
Deep vein thrombosis	329	1
Femoral artery embolism	1	0
Jugular vein thrombosis	3	0
Pelvic venous thrombosis	4	0
Peripheral artery thrombosis	2	0
Peripheral embolism	2	0
Subclavian vein thrombosis	4	0
Superficial vein thrombosis	28	0
Thrombophlebitis	26	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	49	0
Erythromelalgia	2	0
Flushing	460	0
Hot flush	1224	0
Peripheral vascular disorder	1	0
Vein wall hypertrophy	1	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Claudication of jaw muscles	1	0
Extremity necrosis	3	0
Iliac artery occlusion	1	0
Intermittent claudication	3	0
Ischaemic limb pain	2	0
Jugular vein occlusion	2	0

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Name: COVID-19 mRNA Pfizer- BioNTech Vaccine Analysis Print

Report Run Date: 13-Jan-2022

Data Lock Date: 12-Jan-2022 18:30:17

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Vascular disorders <small>Vascular disorders cont'd</small>		
Peripheral arterial occlusive disease	2	0
Peripheral artery occlusion	1	0
Peripheral coldness	367	0
Peripheral ischaemia	12	0
Poor peripheral circulation	21	0
Raynaud's phenomenon	63	0
Subclavian vein occlusion	1	0
Vasoconstriction	2	0
Phlebitis NEC		
Phlebitis	35	0
Phlebitis superficial	9	0
Site specific vascular disorders NEC		
Aortic disorder	1	0
Aortic rupture	1	1
Inferior vena cava dilatation	1	0
Pallor	418	0
Varicose veins NEC		
Spider vein	6	0
Varicophlebitis	4	0
Varicose vein	37	0
Vascular hypertensive disorders NEC		
Diastolic hypertension	6	0
Essential hypertension	4	0
Hypertension	692	0
Labile hypertension	2	0
Orthostatic hypertension	1	0
Secondary hypertension	1	0
Systolic hypertension	7	0
White coat hypertension	1	0
Vascular hypotensive disorders		
Capillary leak syndrome	1	0
Diastolic hypotension	1	0
Hypotension	436	1
Orthostatic hypotension	32	0
Vasculitides NEC		
Behcet's syndrome	5	0
Diffuse vasculitis	1	0
Granulomatosis with polyangiitis	2	0
MAGIC syndrome	1	0
Thromboangiitis obliterans	1	0
Vasculitis	51	0
Vena caval embolism and thrombosis		
Vena cava embolism	1	0
Vena cava thrombosis	1	0
Vascular disorders SOC TOTAL	6980	17
TOTAL REACTIONS FOR DRUG	454881	696
TOTAL REPORTS	158933	
TOTAL FATAL OUTCOME REPORTS		696