

COVID-19 mRNA Pfizer-BioNTech Vaccine Analysis Print

Report Run Date: 07-Oct-2021
Data Lock Date: 06-Oct-2021 18:31:55

All UK spontaneous reports received between 09/12/20 and 06/10/21 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.

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemia deficiencies</i>		
Anaemia folate deficiency	1	0
Anaemia vitamin B12 deficiency	2	0
Deficiency anaemia	1	0
Iron deficiency anaemia	7	0
<i>Anaemias NEC</i>		
Anaemia	100	0
Anaemia macrocytic	1	0
Anaemia megaloblastic	1	0
Autoimmune anaemia	2	0
Blood loss anaemia	1	0
Microcytic anaemia	1	0
<i>Anaemias haemolytic NEC</i>		
Coombs negative haemolytic anaemia	1	0
Haemolytic anaemia	6	0
<i>Anaemias haemolytic immune</i>		
Autoimmune haemolytic anaemia	9	0
<i>Anaemias haemolytic mechanical factor</i>		
Microangiopathic haemolytic anaemia	1	0
<i>Bleeding tendencies</i>		
Haemorrhagic diathesis	1	0
Increased tendency to bruise	37	0
Spontaneous haematoma	2	0
<i>Coagulation factor deficiencies</i>		
Acquired haemophilia	2	0
<i>Coagulopathies</i>		
Abnormal clotting factor	5	0
Antiphospholipid syndrome	5	0
Coagulopathy	22	1
Disseminated intravascular coagulation	2	0
Hypercoagulation	3	0
Thrombotic microangiopathy	2	0
<i>Eosinophilic disorders</i>		
Eosinophilia	12	0
<i>Haematological disorders</i>		
Blood disorder	3	0
Hypergammaglobulinaemia	1	0
Hyperviscosity syndrome	1	0
Mast cell activation syndrome	6	0
Methaemoglobinaemia	1	0
<i>Haemolyses NEC</i>		
Haemolysis	6	0
Intravascular haemolysis	1	0
<i>Leukocytoses NEC</i>		
Leukocytosis	1	0
Lymphocytosis	6	0
Neutrophilia	9	0
<i>Leukopenias NEC</i>		
Leukopenia	4	1
Lymphopenia	4	0
<i>Lymphatic system disorders NEC</i>		
Abdominal lymphadenopathy	3	0
Hilar lymphadenopathy	2	0

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Reaction Name	Total	Fatal
Blood disorders Blood disorders cont'd		
Lymph node pain	1471	0
Lymph node ulcer	1	0
Lymphadenitis	122	0
Lymphadenopathy	9311	0
Lymphatic disorder	1	0
Lymphatic insufficiency	1	0
Necrotic lymphadenopathy	3	0
Pseudolymphoma	10	0
Retroperitoneal lymphadenopathy	1	0
<i>Marrow depression and hypoplastic anaemias</i>		
Aplasia pure red cell	2	0
Hypoplastic anaemia	1	0
Myelosuppression	2	0
Pancytopenia	7	0
<i>Neutropenias</i>		
Autoimmune neutropenia	2	0
Neutropenia	36	0
<i>Platelet disorders NEC</i>		
Platelet anisocytosis	1	0
Platelet disorder	2	0
<i>Polycythaemia (excl rubra vera)</i>		
Polycythaemia	1	0
<i>Purpuras (excl thrombocytopenic)</i>		
Purpura non-thrombocytopenic	1	0
<i>Red blood cell abnormal findings NEC</i>		
Polychromasia	2	0
Red blood cell abnormality	2	0
<i>Spleen disorders</i>		
Spleen atrophy	1	0
Splenic infarction	2	0
Splenic thrombosis	1	0
Splenic vein thrombosis	1	0
Splenomegaly	11	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	67	0
Thrombocytopenia	182	1
Thrombocytopenic purpura	6	0
Thrombotic thrombocytopenic purpura	6	0
<i>Thrombocytoses</i>		
Thrombocytosis	6	0
Blood disorders SOC TOTAL	11538	3

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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	11	1
Atrioventricular block complete	2	1
Atrioventricular block first degree	1	0
Atrioventricular block second degree	2	0
Bundle branch block	2	0
Bundle branch block left	1	0
Bundle branch block right	1	0
<i>Cardiac disorders NEC</i>		
Acute cardiac event	3	0
Cardiac disorder	45	0
Cardiac dysfunction	1	0
Cardiovascular deconditioning	1	0
Cardiovascular disorder	5	0
Intracardiac thrombus	5	0
<i>Cardiac hypertensive complications</i>		
Hypertensive heart disease	1	0
<i>Cardiac infections and inflammations NEC</i>		
Carditis	3	0
<i>Cardiac neoplasms NEC</i>		
Pericardial cyst	1	0
<i>Cardiac signs and symptoms NEC</i>		
Cardiac discomfort	16	0
Cardiovascular symptom	1	0
Palpitations	2831	1
<i>Cardiac valve disorders NEC</i>		
Cardiac valve disease	2	0
Heart valve incompetence	1	0
<i>Cardiomyopathies</i>		
Cardiomyopathy	4	0
Congestive cardiomyopathy	4	0
Stress cardiomyopathy	2	0
<i>Coronary artery disorders NEC</i>		
Coronary artery disease	6	3
Coronary artery occlusion	2	0
Coronary artery thrombosis	1	1
<i>Endocarditis NEC</i>		
Endocarditis noninfective	1	1
<i>Heart failures NEC</i>		
Cardiac failure	60	8
Cardiac failure acute	2	0
Cardiac failure chronic	2	0
Cardiac failure congestive	3	1
Cardiogenic shock	4	1
Cardiopulmonary failure	1	1
<i>Ischaemic coronary artery disorders</i>		
Acute coronary syndrome	3	0
Acute myocardial infarction	18	1
Angina pectoris	168	0
Angina unstable	2	0
Arteriospasm coronary	2	0

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Reaction Name	Total	Fatal
Cardiac disorders Cardiac disorders cont'd		
Microvascular coronary artery disease	2	0
Myocardial infarction	180	31
Myocardial ischaemia	7	3
Left ventricular failures		
Acute left ventricular failure	1	1
Left ventricular failure	7	2
Mitral valvular disorders		
Mitral valve incompetence	4	0
Mitral valve prolapse	1	0
Myocardial disorders NEC		
Cardiac amyloidosis	1	0
Cardiomegaly	26	2
Left atrial dilatation	1	0
Left ventricular dysfunction	5	0
Left ventricular enlargement	1	0
Left ventricular hypertrophy	1	0
Myocardial fibrosis	3	0
Myocardial haemorrhage	1	0
Myocardial oedema	4	0
Myocardial rupture	1	0
Right ventricular enlargement	1	0
Ventricular hypertrophy	1	0
Noninfectious myocarditis		
Myocarditis	324	1
Noninfectious pericarditis		
Pericarditis	253	1
Pericardial disorders NEC		
Pericardial effusion	27	0
Pericardial haemorrhage	3	3
Pericardial rub	1	0
Rate and rhythm disorders NEC		
Arrhythmia	109	0
Bradycardia	54	0
Bradycardia foetal	2	1
Cardiac flutter	361	0
Extrasystoles	128	0
Paroxysmal arrhythmia	1	0
Postural orthostatic tachycardia syndrome	16	0
Tachyarrhythmia	1	0
Tachycardia	652	0
Tachycardia foetal	1	0
Tachycardia paroxysmal	1	0
Right ventricular failures		
Cor pulmonale	1	0
Supraventricular arrhythmias		
Arrhythmia supraventricular	10	0
Atrial fibrillation	168	0
Atrial flutter	19	0
Atrial tachycardia	6	0
Nodal arrhythmia	1	0
Sinus arrest	1	0
Sinus arrhythmia	2	0
Sinus bradycardia	9	0

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Cardiac disorders Cardiac disorders cont'd		
Sinus node dysfunction	1	0
Sinus tachycardia	47	0
Supraventricular extrasystoles	2	0
Supraventricular tachycardia	35	0
<i>Tricuspid valvular disorders</i>		
Tricuspid valve incompetence	3	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	88	33
Cardio-respiratory arrest	1	1
Pulseless electrical activity	3	0
Ventricular arrhythmia	5	0
Ventricular extrasystoles	18	0
Ventricular fibrillation	6	1
Ventricular tachycardia	10	0
Cardiac disorders SOC TOTAL	5840	100

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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	12	0
<i>Cardiac septal defects congenital</i>		
Atrial septal defect	1	0
Hypertrophic cardiomyopathy	1	0
<i>Cardiac valve disorders congenital</i>		
Bicuspid aortic valve	1	0
<i>Central nervous system disorders congenital NEC</i>		
Spina bifida	1	0
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
<i>Coagulation disorders congenital</i>		
Haemophilia	2	0
<i>Congenital disorders NEC</i>		
Foetal malformation	1	0
Young's syndrome	1	0
<i>Connective tissue disorders congenital</i>		
Ehlers-Danlos syndrome	2	0
<i>Gastrointestinal tract disorders congenital NEC</i>		
Gastroschisis	2	0
<i>Great vessel disorders congenital</i>		
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>Inborn errors of metabolism NEC</i>		
Alpha-1 antitrypsin deficiency	1	0
<i>Lymphatic system disorders congenital</i>		
Cystic lymphangioma	3	0
<i>Male reproductive tract disorders congenital</i>		
Cryptorchism	1	0
Micropenis	3	0
Phimosis	1	0
<i>Musculoskeletal and connective tissue disorders of limbs congenital</i>		
Developmental hip dysplasia	1	0
<i>Musculoskeletal and connective tissue disorders of spine congenital</i>		
Brachyolmia	1	0
<i>Neurological disorders congenital NEC</i>		
Familial hemiplegic migraine	2	0
Familial periodic paralysis	1	0
Moebius II syndrome	1	0
Tourette's disorder	2	0
<i>Ocular disorders congenital NEC</i>		
Colour blindness	4	0

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Reaction Name	Total	Fatal
Congenital disorders Congenital disorders cont'd		
<i>Palate disorders congenital</i>		
Cleft lip and palate	1	0
<i>Peripheral nervous system disorders congenital NEC</i>		
Hereditary neuropathy with liability to pressure palsies	1	0
Paroxysmal extreme pain disorder	1	0
<i>Pulmonary and bronchial disorders congenital</i>		
Congenital cystic lung	1	0
<i>Retinal disorders congenital</i>		
Retinitis pigmentosa	1	0
<i>Skin and subcutaneous tissue disorders congenital NEC</i>		
Acral peeling skin syndrome	1	0
<i>Tongue disorders congenital</i>		
Ankyloglossia congenital	1	0
Congenital disorders SOC TOTAL	65	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear canal erythema	1	0
Ear congestion	28	0
Ear discomfort	85	0
Ear disorder	14	0
Ear haemorrhage	9	0
Ear pain	856	0
Ear pruritus	9	0
Ear swelling	31	0
Otorrhoea	4	0
<i>Eustachian tube disorders</i>		
Eustachian tube disorder	4	0
Eustachian tube dysfunction	8	0
Eustachian tube obstruction	4	0
<i>External ear disorders NEC</i>		
Auricular swelling	1	0
Excessive cerumen production	8	0
External ear pain	2	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	7	0
Diplacusis	2	0
<i>Hearing losses</i>		
Conductive deafness	1	0
Deafness	207	0
Deafness bilateral	6	0
Deafness neurosensory	17	0
Deafness transitory	6	0
Deafness unilateral	29	0
Hypoacusis	161	0
Sudden hearing loss	38	0
<i>Hyperacusia</i>		
Hyperacusis	49	0
Misophonia	3	0
<i>Inner ear disorders NEC</i>		
Acute vestibular syndrome	1	0
Inner ear disorder	12	0
Meniere's disease	11	0
Vestibular disorder	10	0
<i>Inner ear infections and inflammations</i>		
Inner ear inflammation	8	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	52	0
Tinnitus	1697	0
Vertigo	1201	0
Vertigo labyrinthine	9	0
Vertigo positional	64	0
<i>Mastoid disorders</i>		
Mastoid effusion	1	0
<i>Middle ear disorders NEC</i>		
Middle ear disorder	3	0

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Reaction Name	Total	Fatal
Ear disorders Ear disorders cont'd		
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	4668	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Autoimmune thyroiditis	2	0
Thyroiditis	15	0
Thyroiditis acute	2	0
Thyroiditis subacute	3	0
<i>Adrenal cortical hypofunctions</i>		
Addison's disease	2	0
Adrenal insufficiency	2	0
Adrenocortical insufficiency acute	11	0
<i>Adrenal gland disorders NEC</i>		
Adrenal haemorrhage	2	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	16	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	40	0
Ovulation delayed	29	0
<i>Thyroid disorders NEC</i>		
Autoimmune thyroid disorder	1	0
Goitre	12	0
Thyroid disorder	7	0
Thyroid mass	1	0
Thyroid pain	6	0
<i>Thyroid hyperfunction disorders</i>		
Basedow's disease	8	0
Hyperthyroidism	29	0
Thyrotoxic crisis	3	0
<i>Thyroid hypofunction disorders</i>		
Autoimmune hypothyroidism	1	0
Hypothyroidism	24	0
Myxoedema	1	0
Endocrine disorders SOC TOTAL	224	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Amblyopic vision impairment</i>		
Amblyopia	6	0
<i>Cataract conditions</i>		
Cataract	10	0
<i>Choroid and vitreous haemorrhages and vascular disorders</i>		
Choroidal haemorrhage	1	0
Choroidal neovascularisation	1	0
Vitreous haemorrhage	3	0
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Chorioretinopathy	5	0
Vitreous detachment	17	0
Vitreous floaters	73	0
<i>Colour blindness (incl acquired)</i>		
Dyschromatopsia	8	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	34	0
<i>Conjunctival infections, irritations and inflammations</i>		
Conjunctival hyperaemia	2	0
Conjunctival irritation	1	0
Conjunctival oedema	3	0
Conjunctivitis allergic	1	0
<i>Corneal infections, oedemas and inflammations</i>		
Corneal oedema	2	0
Keratitis	6	0
Ulcerative keratitis	5	0
<i>Eyelid movement disorders</i>		
Blepharospasm	132	0
Excessive eye blinking	5	0
Eyelid function disorder	3	0
Eyelid myokymia	4	0
Eyelid ptosis	40	0
Paralytic lagophthalmos	2	0
<i>Glaucomas (excl congenital)</i>		
Angle closure glaucoma	2	0
Glaucoma	6	0
<i>Iris and ciliary body structural change, deposit and degeneration</i>		
Eye colour change	2	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Autoimmune uveitis	1	0
Iridocyclitis	14	0
Iritis	6	0
Uveitis	43	0
<i>Lacrimation disorders</i>		
Dry eye	127	0
Lacrimation increased	115	0
<i>Lid bleeding and vascular disorders</i>		
Eyelid bleeding	1	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Blepharitis	12	0
Chalazion	7	0
Eczema eyelids	6	0
Erythema of eyelid	8	0
Eyelid cyst	4	0

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Eye disorders Eye disorders cont'd		
Eyelid irritation	2	0
Eyelid margin crusting	4	0
Eyelid oedema	4	0
Eyelid rash	16	0
Swelling of eyelid	111	0
Swollen tear duct	1	0
Lid, lash and lacrimal structural disorders		
Dermatochalasis	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
Ocular bleeding and vascular disorders NEC		
Eye haematoma	4	0
Eye haemorrhage	24	0
Ocular vascular disorder	1	0
Ophthalmic vein thrombosis	1	0
Ocular disorders NEC		
Dark circles under eyes	6	0
Eye disorder	31	0
Eye oedema	14	0
Eye pain	925	0
Eye swelling	438	0
Eye symptom	9	0
Eye ulcer	3	0
Eyelid disorder	11	0
Eyelid pain	11	0
Eyelids pruritus	6	0
Ocular discomfort	25	0
Periorbital oedema	17	0
Periorbital pain	1	0
Periorbital swelling	107	0
Retinal disorder	2	0
Vitreous disorder	1	0
Ocular infections, inflammations and associated manifestations		
Eye allergy	12	0
Eye discharge	24	0
Eye inflammation	22	0
Eye irritation	82	0
Eye pruritus	208	0
Limbal swelling	2	0
Ocular hyperaemia	188	0
Ocular nerve and muscle disorders		
Binocular eye movement disorder	1	0
Extraocular muscle disorder	1	0
Extraocular muscle paresis	1	0
Eye movement disorder	29	0
Gaze palsy	1	0
Ocular myasthenia	1	0
Ophthalmoplegia	4	0

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Strabismus	5	0
Ocular sensation disorders		
Abnormal sensation in eye	17	0
Asthenopia	133	0
Eye paraesthesia	2	0
Eyelid sensory disorder	1	0
Foreign body sensation in eyes	16	0
Hypoaesthesia eye	14	0
Photophobia	398	0
Optic disc abnormalities NEC		
Papilloedema	5	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	20	0
Pupil fixed	2	0
Pupils unequal	12	0
Refractive and accommodative disorders		
Accommodation disorder	1	0
Altered visual depth perception	2	0
Astigmatism	1	0
Hypermetropia	1	0
Myopia	1	0
Retinal bleeding and vascular disorders (excl retinopathy)		
Retinal artery occlusion	9	0
Retinal artery thrombosis	1	0
Retinal haemorrhage	7	0
Retinal vascular thrombosis	1	0
Retinal vein occlusion	30	0
Retinal vein thrombosis	2	0
Retinal structural change, deposit and degeneration		
Macular degeneration	4	0
Macular hole	2	0
Macular rupture	1	0
Maculopathy	1	0
Neovascular age-related macular degeneration	2	0
Retinal degeneration	1	0
Retinal detachment	4	0
Retinal tear	2	0
Retinal toxicity	3	0
Retinal, choroid and vitreous infections and inflammations		
Birdshot chorioretinopathy	2	0
Cystoid macular oedema	1	0
Macular oedema	4	0
Retinal vasculitis	3	0
Retinopathies NEC		
Acute macular outer retinopathy	1	0

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Eye disorders Eye disorders cont'd		
Retinal exudates	2	0
Retinopathy	2	0
<i>Scleral infections, irritations and inflammations</i>		
Episcleritis	7	0
Scleritis	3	0
<i>Scleral structural change, deposit and degeneration</i>		
Scleral discolouration	2	0
<i>Structural change, deposit and degeneration of eye NEC</i>		
Exophthalmos	1	0
<i>Visual colour distortions</i>		
Chloropsia	2	0
Chromatopsia	1	0
Cyanopsia	2	0
Erythropsia	2	0
Xanthopsia	1	0
<i>Visual disorders NEC</i>		
Charles Bonnet syndrome	1	0
Diplopia	139	0
Glare	1	0
Halo vision	7	0
Heteronymous diplopia	1	0
Metamorphopsia	16	0
Oscillopsia	2	0
Photopsia	114	0
Scintillating scotoma	4	0
Vision blurred	1040	0
Visual brightness	3	0
Visual snow syndrome	7	0
<i>Visual field disorders</i>		
Visual field defect	23	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Amaurosis fugax	2	0
Blindness	110	0
Blindness cortical	1	0
Blindness transient	11	0
Blindness unilateral	12	0
Central vision loss	3	0
Sudden visual loss	3	0
Visual acuity reduced	20	0
Visual acuity reduced transiently	1	0
Visual impairment	302	0
<i>Visual pathway disorders</i>		
Optic nerve disorder	1	0
Eye disorders SOC TOTAL	5653	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Abdominal findings abnormal</i>		
Abdominal mass	2	0
Gastrointestinal sounds abnormal	16	0
<i>Abdominal hernias NEC</i>		
Abdominal hernia	2	0
<i>Abdominal wall conditions NEC</i>		
Abdominal wall haematoma	1	0
<i>Acute and chronic pancreatitis</i>		
Alcoholic pancreatitis	1	0
Obstructive pancreatitis	1	0
Pancreatitis	13	0
Pancreatitis acute	13	1
Pancreatitis necrotising	1	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	9	0
<i>Anal and rectal signs and symptoms</i>		
Anal hypoaesthesia	1	0
Anal spasm	1	0
Anorectal discomfort	4	0
Anorectal swelling	1	0
Rectal discharge	1	0
Rectal tenesmus	1	0
<i>Benign oral cavity neoplasms</i>		
Mouth cyst	5	0
Tongue cyst	4	0
<i>Colitis (excl infective)</i>		
Autoimmune colitis	1	0
Colitis	37	1
Colitis ischaemic	1	0
Colitis microscopic	1	0
Colitis ulcerative	61	0
Crohn's disease	36	0
Eosinophilic colitis	1	0
Inflammatory bowel disease	4	0
<i>Dental and periodontal infections and inflammations</i>		
Dental caries	1	0
<i>Dental disorders NEC</i>		
Loose tooth	1	0
Malpositioned teeth	2	0
Periodontal disease	1	0
Teeth brittle	3	0
Teething	6	0
Tooth disorder	2	0
Tooth socket haemorrhage	1	0
<i>Dental pain and sensation disorders</i>		
Dental discomfort	6	0
Dental paraesthesia	10	0
Hyperaesthesia teeth	34	0
Toothache	137	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Gastrointestinal disorders Gastrointestinal disorders cont'd		
<i>Dental surface disorders</i>		
Tooth discolouration	9	0
<i>Diaphragmatic hernias</i>		
Hiatus hernia	5	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	4514	2
Diarrhoea haemorrhagic	19	0
<i>Diverticula</i>		
Diverticulum	4	0
Diverticulum intestinal	1	0
<i>Duodenal and small intestinal stenosis and obstruction</i>		
Small intestinal obstruction	1	0
<i>Duodenal ulcers and perforation</i>		
Duodenal ulcer haemorrhage	1	0
Duodenal ulcer perforation	3	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	361	0
Epigastric discomfort	14	0
Eructation	43	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	19	0
Faecaloma	4	0
Faeces discoloured	54	0
Faeces hard	2	0
Faeces pale	3	0
Faeces soft	10	0
Mucous stools	9	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	456	0
Aerophagia	3	0
Flatulence	159	0
<i>Gastric and oesophageal haemorrhages</i>		
Gastric haemorrhage	5	1
Mallory-Weiss syndrome	1	0
Oesophageal varices haemorrhage	1	0
<i>Gastric ulcers and perforation</i>		
Gastric ulcer	6	0
<i>Gastritis (excl infective)</i>		
Chronic gastritis	2	0
Gastritis	46	0
Reflux gastritis	5	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal migraine	2	0
Abdominal pain	1221	0
Abdominal pain lower	114	0
Abdominal pain upper	2020	0
Abdominal rigidity	22	0
Abdominal tenderness	9	0
Gastrointestinal pain	112	0
Oesophageal pain	7	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	218	0
Duodenogastric reflux	3	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders Gastrointestinal disorders cont'd		
Gastric dilatation	7	0
Gastroesophageal reflux disease	125	0
Impaired gastric emptying	7	0
Infrequent bowel movements	3	0
Intestinal dilatation	1	0
Intestinal pseudo-obstruction	2	0
Gastrointestinal disorders NEC		
Appendix disorder	1	0
Food poisoning	7	0
Functional gastrointestinal disorder	9	0
Gastric disorder	6	0
Gastrointestinal disorder	18	0
Stomach mass	4	0
Gastrointestinal dyskinetic disorders		
Bowel movement irregularity	5	0
Change of bowel habit	5	0
Dyschezia	2	0
Gastrointestinal motility disorder	2	0
Oesophageal achalasia	1	0
Gastrointestinal fistulae		
Diverticular fistula	2	0
Gastrointestinal inflammatory disorders NEC		
Duodenitis	1	0
Enteritis	6	0
Epiploic appendagitis	2	0
Gastrointestinal inflammation	3	0
Intestinal angioedema	2	0
Gastrointestinal mucosal dystrophies and secretion disorders		
Hyperchlorhydria	4	0
Gastrointestinal signs and symptoms NEC		
Abdominal discomfort	522	0
Abdominal symptom	1	0
Acute abdomen	4	0
Anal incontinence	19	0
Breath odour	16	0
Dysphagia	179	1
Odynophagia	29	0
Gastrointestinal spastic and hypermotility disorders		
Cardiospasm	1	0
Defaecation urgency	8	0
Frequent bowel movements	22	0
Gastrointestinal hypermotility	1	0
Irritable bowel syndrome	75	0
Oesophageal spasm	3	0
Pylorospasm	1	0
Gastrointestinal stenosis and obstruction NEC		
Intestinal obstruction	2	0
Neonatal intestinal obstruction	1	0
Gastrointestinal vascular malformations		
Gastric antral vascular ectasia	8	0
Gastrointestinal vascular occlusion and infarction		
Intestinal ischaemia	5	2
Mesenteric vein thrombosis	6	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders Gastrointestinal disorders cont'd		
Omental infarction	1	0
Thrombosis mesenteric vessel	2	0
Visceral venous thrombosis	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival blister	11	0
Gingival discomfort	5	0
Gingival disorder	3	0
Gingival erythema	2	0
Gingival hypertrophy	1	0
Gingival oedema	1	0
Gingival pain	93	0
Gingival pruritus	1	0
Gingival swelling	31	0
Gingival ulceration	1	0
Gingivitis ulcerative	1	0
Noninfective gingivitis	7	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	55	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Gastric varices	1	0
Haemorrhoidal haemorrhage	1	0
Haemorrhoids	27	0
Haemorrhoids thrombosed	1	0
<i>Inguinal hernias</i>		
Inguinal hernia	1	0
<i>Intestinal haemorrhages</i>		
Anal haemorrhage	17	1
Intestinal haemorrhage	1	0
Rectal haemorrhage	61	0
Small intestinal haemorrhage	5	0
<i>Intestinal ulcers and perforation NEC</i>		
Intestinal perforation	5	2
Large intestinal ulcer	1	0
Large intestine perforation	1	0
<i>Malabsorption syndromes</i>		
Bile acid malabsorption	2	0
Coeliac disease	9	0
Malabsorption	1	0
Steatorrhoea	4	0
<i>Nausea and vomiting symptoms</i>		
Discoloured vomit	12	0
Infantile vomiting	7	0
Nausea	11762	0
Regurgitation	1	0
Retching	88	0
Vomiting	3612	1
Vomiting projectile	53	0
<i>Non-mechanical ileus</i>		
Ileus paralytic	1	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Gastrointestinal haemorrhage	14	1
Haematemesis	26	2
Haematochezia	48	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders Gastrointestinal disorders cont'd		
Melaena	8	0
Upper gastrointestinal haemorrhage	6	0
<i>Oesophageal stenosis and obstruction</i>		
Oesophageal stenosis	3	0
<i>Oesophagitis (excl infective)</i>		
Eosinophilic oesophagitis	1	0
Oesophagitis	3	0
<i>Oral dryness and saliva altered</i>		
Aptyalism	3	0
Dry mouth	430	0
Lip dry	36	0
Saliva altered	5	0
Salivary hypersecretion	44	0
<i>Oral soft tissue disorders NEC</i>		
Angina bullosa haemorrhagica	1	0
Chapped lips	19	0
Cheilitis	23	0
Enlarged uvula	14	0
Leukoplakia oral	2	0
Lip blister	26	0
Lip disorder	4	0
Oral disorder	15	0
Oral lichen planus	10	0
Oral mucosal hypertrophy	1	0
Oral papule	1	0
Uvulitis	2	0
<i>Oral soft tissue haemorrhages</i>		
Mouth haemorrhage	12	0
Oral blood blister	10	0
Oral purpura	2	0
<i>Oral soft tissue infections</i>		
Angular cheilitis	2	0
<i>Oral soft tissue signs and symptoms</i>		
Anaesthesia oral	2	0
Burning mouth syndrome	6	0
Coating in mouth	1	0
Hypoaesthesia oral	420	0
Lip discolouration	7	0
Lip erythema	2	0
Lip exfoliation	5	0
Lip pain	47	0
Lip pruritus	14	0
Lip scab	1	0
Oral discomfort	72	0
Oral dysaesthesia	1	0
Oral mucosal blistering	13	0
Oral mucosal discolouration	1	0
Oral mucosal eruption	12	0
Oral mucosal erythema	5	0
Oral mucosal exfoliation	8	0
Oral mucosal roughening	3	0
Oral mucosal scab	1	0
Oral pain	146	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders Gastrointestinal disorders cont'd		
Oral pruritus	20	0
Paraesthesia oral	817	0
Pigmentation lip	1	0
Oral soft tissue swelling and oedema		
Lip oedema	4	0
Lip swelling	625	0
Mouth swelling	78	0
Oedema mouth	4	0
Palatal oedema	3	0
Palatal swelling	2	0
Pancreatic disorders NEC		
Pancreatic mass	1	0
Peptic ulcers and perforation		
Peptic ulcer	1	0
Peptic ulcer haemorrhage	11	0
Peritoneal and retroperitoneal disorders		
Ascites	1	0
Peritoneal and retroperitoneal fibrosis and adhesions		
Abdominal adhesions	1	0
Peritoneal and retroperitoneal haemorrhages		
Haemoperitoneum	1	0
Retroperitoneal haemorrhage	1	1
Rectal inflammations NEC		
Proctitis	2	0
Proctitis ulcerative	1	0
Salivary gland disorders NEC		
Salivary gland disorder	1	0
Salivary gland pain	12	0
Salivary gland enlargements		
Parotid gland enlargement	9	0
Salivary gland enlargement	5	0
Submaxillary gland enlargement	7	0
Salivary gland infections and inflammations		
Noninfective sialoadenitis	1	0
Stomatitis and ulceration		
Aphthous ulcer	43	0
Lip ulceration	16	0
Mouth ulceration	381	0
Oral mucosa erosion	1	0
Palatal ulcer	1	0
Stomatitis	57	0
Tongue disorders		
Glossitis	16	0
Hypertrophy of tongue papillae	1	0
Plicated tongue	3	0
Tongue disorder	34	0
Tongue geographic	1	0
Tongue haemorrhage	3	0
Tongue ulceration	29	0
Trichoglossia	4	0
Tongue signs and symptoms		
Glossodynia	177	0
Scalloped tongue	5	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders Gastrointestinal disorders cont'd		
Stiff tongue	3	0
Swollen tongue	422	0
Tongue blistering	16	0
Tongue coated	16	0
Tongue discolouration	33	0
Tongue discomfort	38	0
Tongue dry	13	0
Tongue eruption	9	0
Tongue erythema	8	0
Tongue exfoliation	1	0
Tongue movement disturbance	6	0
Tongue oedema	20	0
Tongue pruritus	2	0
Tongue rough	4	0
Tongue spasm	8	0
<i>Tooth missing</i>		
Tooth loss	6	0
Gastrointestinal disorders SOC TOTAL	31457	16

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site bruise	5	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	1	0
Administration site nerve damage	1	0
Administration site pain	15	0
Administration site rash	4	0
Administration site reaction	1	0
Administration site swelling	3	0
Administration site urticaria	1	0
Administration site warmth	2	0
Puncture site bruise	32	0
Puncture site pain	6	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	4	0
<i>Application and instillation site reactions</i>		
Application site acne	2	0
Application site bruise	8	0
Application site burn	1	0
Application site erythema	13	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	6	0
Application site warmth	1	0
Instillation site warmth	5	0
<i>Asthenic conditions</i>		
Asthenia	1562	0
Chronic fatigue syndrome	65	0
Decreased activity	9	0
Fatigue	18816	0
Malaise	4226	0
Sluggishness	12	0
<i>Body temperature altered</i>		

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Hyperthermia	5	0
Hypothermia	21	0
Temperature regulation disorder	10	0
Breast complications associated with device		
Breast implant palpable	1	0
Capsular contracture associated with breast implant	1	0
Cardiac complications associated with device		
Prosthetic cardiac valve thrombosis	2	0
Complications associated with device NEC		
Capsular contracture associated with implant	1	0
Complication of device removal	3	0
Injury associated with device	3	0
Medical device pain	1	0
Medical device site pain	1	0
Medical device site swelling	1	0
Phantom shocks	1	0
Death and sudden death		
Brain death	3	3
Cardiac death	1	1
Clinical death	1	1
Death	149	149
Drowning	1	0
Sudden death	26	26
Febrile disorders		
Hyperpyrexia	9	0
Pyrexia	12207	0
Feelings and sensations NEC		
Chills	7735	0
Feeling abnormal	1336	0
Feeling cold	944	0
Feeling drunk	71	0
Feeling hot	966	0
Feeling jittery	20	0
Feeling of body temperature change	273	0
Feeling of relaxation	3	0
Hangover	74	0
Hunger	39	0
Sensation of blood flow	3	0
Sensation of foreign body	46	0
Temperature intolerance	37	0
Thirst	286	0
Fibrosis NEC		
Fibrosis	1	0
Gait disturbances		
Gait disturbance	190	0
Gait inability	63	0
Loss of control of legs	16	0
General signs and symptoms NEC		
Adhesion	1	0
Chronic disease	1	0
Condition aggravated	177	0
Crepitations	1	0
Crying	135	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Deformity	2	0
Discharge	10	0
Disease progression	2	0
Disease recurrence	25	0
Effusion	2	0
Energy increased	19	0
Exercise tolerance decreased	20	0
Foaming at mouth	1	0
General physical health deterioration	15	2
General symptom	2	0
Glassy eyes	4	0
High-pitched crying	2	0
Illness	1511	0
Induration	14	0
Influenza like illness	1919	0
Irritability postvaccinal	2	0
Local reaction	69	0
Moaning	3	0
Multiple organ dysfunction syndrome	9	4
Nonspecific reaction	1	0
Organ failure	1	1
Perforation	2	0
Peripheral swelling	2895	0
Physical deconditioning	2	0
Pre-existing condition improved	8	0
Prolapse	1	0
Screaming	19	0
Secretion discharge	18	0
Swelling	2360	0
Swelling face	679	0
Symptom recurrence	1	0
Terminal state	1	0
Tissue irritation	1	0
Implant and catheter site reactions		
Implant site discolouration	2	0
Implant site pain	2	0
Implant site rash	1	0
Implant site swelling	1	0
Implant site urticaria	1	0
Implant site warmth	3	0
Inflamations		
Granuloma	1	0
Inflammation	372	0
Papillitis	1	0
Serositis	1	0
Systemic inflammatory response syndrome	2	0
Infusion site reactions		
Infusion site coldness	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	1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Infusion site pruritus	1	0
Infusion site swelling	1	0
Infusion site urticaria	1	0
Infusion site warmth	1	0
Injection site reactions		
Injected limb mobility decreased	26	0
Injection site bruising	58	0
Injection site coldness	1	0
Injection site cyst	2	0
Injection site discolouration	5	0
Injection site discomfort	9	0
Injection site eczema	1	0
Injection site erythema	313	0
Injection site haemorrhage	6	0
Injection site hypersensitivity	2	0
Injection site hypoaesthesia	8	0
Injection site indentation	9	0
Injection site induration	3	0
Injection site inflammation	31	0
Injection site irritation	1	0
Injection site joint discomfort	2	0
Injection site joint erythema	2	0
Injection site joint movement impairment	1	0
Injection site joint pain	13	0
Injection site lymphadenopathy	1	0
Injection site macule	1	0
Injection site mass	429	0
Injection site movement impairment	1	0
Injection site necrosis	3	0
Injection site nerve damage	1	0
Injection site oedema	13	0
Injection site pain	2494	0
Injection site paraesthesia	11	0
Injection site pruritus	155	0
Injection site rash	138	0
Injection site reaction	21	0
Injection site scab	4	0
Injection site scar	5	0
Injection site swelling	251	0
Injection site urticaria	24	0
Injection site vesicles	9	0
Injection site warmth	162	0
Interactions		
Alcohol interaction	3	0
Drug interaction	25	0
Inhibitory drug interaction	3	0
Mass conditions NEC		
Cyst	36	0
Mass	60	0
Nodule	31	0
Mucosal findings abnormal		
Mucosa vesicle	1	0
Mucosal dryness	1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Mucosal haemorrhage	8	0
Mucosal inflammation	2	0
Oedema mucosal	1	0
Polyp	5	0
Necrosis NEC		
Fat necrosis	3	0
Necrosis	4	0
Oedema NEC		
Face oedema	26	0
Generalised oedema	3	0
Localised oedema	15	0
Oedema	58	0
Oedema peripheral	73	0
Pain and discomfort NEC		
Axillary pain	2492	0
Chest discomfort	1380	0
Chest pain	3285	0
Discomfort	393	0
Facial discomfort	17	0
Facial pain	179	0
Inflammatory pain	11	0
Non-cardiac chest pain	24	0
Pain	7256	0
Suprapubic pain	1	0
Tenderness	556	0
Visceral pain	1	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	33	0
Adverse event	1	0
Adverse food reaction	2	0
Adverse reaction	2	0
Drug ineffective	256	1
Drug intolerance	2	0
Immediate post-injection reaction	2	0
Inadequate analgesia	8	0
No reaction on previous exposure to drug	29	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	71	0
Therapy non-responder	1	0
Treatment failure	6	0
Vaccination failure	32	0
Trophic disorders		
Atrophy	2	0
Calcinosis	1	0
Hyperplasia	1	0
Ulcers NEC		
Ulcer	30	0
Ulcer haemorrhage	1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
<i>Vaccination site reactions</i>		
Extensive swelling of vaccinated limb	11	0
Shoulder injury related to vaccine administration	23	0
Vaccination site anaesthesia	1	0
Vaccination site bruising	107	0
Vaccination site coldness	2	0
Vaccination site cyst	5	0
Vaccination site dermatitis	1	0
Vaccination site discolouration	14	0
Vaccination site discomfort	42	0
Vaccination site dryness	1	0
Vaccination site eczema	1	0
Vaccination site erythema	523	0
Vaccination site granuloma	3	0
Vaccination site haematoma	2	0
Vaccination site haemorrhage	18	0
Vaccination site hypersensitivity	3	0
Vaccination site hypoaesthesia	14	0
Vaccination site induration	69	0
Vaccination site inflammation	50	0
Vaccination site irritation	12	0
Vaccination site joint discomfort	2	0
Vaccination site joint erythema	7	0
Vaccination site joint inflammation	1	0
Vaccination site joint movement impairment	17	0
Vaccination site joint pain	30	0
Vaccination site joint swelling	4	0
Vaccination site joint warmth	1	0
Vaccination site lymphadenopathy	5	0
Vaccination site macule	1	0
Vaccination site mass	228	0
Vaccination site movement impairment	73	0
Vaccination site nerve damage	1	0
Vaccination site nodule	2	0
Vaccination site oedema	3	0
Vaccination site pain	1905	0
Vaccination site paraesthesia	7	0
Vaccination site phlebitis	1	0
Vaccination site pruritus	140	0
Vaccination site rash	111	0
Vaccination site reaction	31	0
Vaccination site scab	2	0
Vaccination site scar	1	0
Vaccination site swelling	487	0
Vaccination site thrombosis	1	0
Vaccination site ulcer	1	0
Vaccination site urticaria	10	0
Vaccination site vesicles	9	0
Vaccination site warmth	240	0
<i>Vascular complications associated with device</i>		
Vascular stent thrombosis	1	0
<i>Withdrawal and rebound effects</i>		
Drug withdrawal syndrome	4	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Withdrawal syndrome	33	0
General disorders SOC TOTAL	84653	188

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	11	0
Cholangitis	1	0
<i>Cholecystitis and cholelithiasis</i>		
Cholecystitis	3	0
Cholecystitis acute	2	0
Cholelithiasis	9	0
<i>Cholestasis and jaundice</i>		
Cholestasis	2	0
Jaundice	20	0
Jaundice cholestatic	10	0
Ocular icterus	2	0
<i>Gallbladder disorders NEC</i>		
Gallbladder disorder	1	0
<i>Hepatic and hepatobiliary disorders NEC</i>		
Liver disorder	11	0
<i>Hepatic enzymes and function abnormalities</i>		
Hepatic function abnormal	4	0
<i>Hepatic failure and associated disorders</i>		
Acute hepatic failure	1	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	6	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	23	0
Hepatomegaly	2	0
Liver tenderness	3	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Autoimmune hepatitis	7	0
Drug-induced liver injury	2	0
Hepatic steatosis	1	0
Hepatitis	9	0
Immune-mediated hepatic disorder	1	0
Liver injury	12	0
Hepatic disorders SOC TOTAL	156	1

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	12	0
<i>Allergic conditions NEC</i>		
Allergic oedema	14	0
Allergy to animal	1	0
Allergy to arthropod bite	6	0
Allergy to arthropod sting	2	0
Allergy to metals	1	0
Allergy to sting	1	0
Hypersensitivity	813	0
Infusion related hypersensitivity reaction	2	0
Mite allergy	3	0
Multiple allergies	9	0
Serum sickness	2	0
Serum sickness-like reaction	4	0
Type I hypersensitivity	1	0
Type III immune complex mediated reaction	2	0
Type IV hypersensitivity reaction	6	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergic reaction to excipient	5	0
Allergy to chemicals	3	0
Allergy to vaccine	34	0
Contrast media reaction	2	0
Drug hypersensitivity	22	0
Food allergy	25	0
Milk allergy	2	0
Oral allergy syndrome	2	0
Reaction to colouring	1	0
Reaction to excipient	8	0
Reaction to preservatives	5	0
Rubber sensitivity	1	0
Smoke sensitivity	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	423	2
Anaphylactic shock	43	0
Anaphylactoid reaction	19	0
Anaphylactoid shock	4	0
<i>Atopic disorders</i>		
Atopy	1	0
Seasonal allergy	101	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	37	0
<i>Immune and associated conditions NEC</i>		
Anamnestic reaction	1	0
Bacille Calmette-Guerin scar reactivation	47	0
Cytokine storm	1	0
Decreased immune responsiveness	1	0
Graft versus host disease	1	0
Haemophagocytic lymphohistiocytosis	1	0
Immune reconstitution inflammatory syndrome	1	0
Immune system disorder	20	0
Immune-mediated adverse reaction	6	0
Immunisation reaction	1	0

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Reaction Name	Total	Fatal
Immune system disorders Immune system disorders cont'd		
Sensitisation	4	0
Systemic immune activation	2	0
<i>Immunodeficiency disorders NEC</i>		
Hypogammaglobulinaemia	1	0
Immunodeficiency	1	0
Immunosuppression	3	0
<i>Primary immunodeficiency syndromes</i>		
Selective IgA immunodeficiency	1	0
<i>Transplant rejections</i>		
Corneal graft rejection	6	0
Kidney transplant rejection	1	0
Solid organ transplant rejection	1	0
Transplant rejection	1	0
Immune system disorders SOC TOTAL	1719	2

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Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Abdominal abscess	1	0
Abdominal infection	1	0
Anal abscess	3	0
Appendicitis	35	0
Appendicitis perforated	7	0
Diverticulitis	10	0
Dysentery	1	0
Gastric infection	2	0
Gastroenteritis	24	0
Mesenteric abscess	1	0
Peritonitis	2	1
Rectal abscess	1	0
<i>Adenoviral infections</i>		
Adenoviral conjunctivitis	1	0
<i>Aspergillus infections</i>		
Bronchopulmonary aspergillosis	1	0
<i>Bacterial infections NEC</i>		
Abscess bacterial	1	0
Arthritis bacterial	3	0
Bacterial colitis	1	0
Bacterial diarrhoea	1	0
Bacterial infection	13	0
Bacterial sepsis	1	0
Cellulitis	147	0
Conjunctivitis bacterial	1	0
Ear infection bacterial	1	0
Folliculitis	15	0
Gangrene	1	0
Injection site cellulitis	2	0
Meningitis bacterial	3	0
Paronychia	3	0
Perichondritis	1	0
Periorbital cellulitis	1	0
Sinusitis bacterial	1	0
Skin bacterial infection	2	0
Tonsillitis bacterial	3	0
Urinary tract infection bacterial	1	0
Vaccination site cellulitis	19	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
Arthritis infective	1	0
Osteomyelitis	2	0
<i>Borrelial infections</i>		
Lyme disease	2	0
Relapsing fever	2	0
<i>Breast infections</i>		
Breast abscess	3	0
Mastitis	69	0
<i>Caliciviral infections</i>		

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
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	57	0
Oral candidiasis	36	0
Respiratory moniliasis	1	0
Skin candida	1	0
Systemic candida	1	0
Vulvovaginal candidiasis	42	0
<i>Cardiac infections</i>		
Pericarditis infective	2	0
<i>Central nervous system and spinal infections</i>		
Brain abscess	1	0
CNS ventriculitis	1	0
Cavernous sinus thrombosis	1	0
Encephalitis	17	0
Encephalomyelitis	1	0
Meningitis	7	0
Meningitis aseptic	3	0
Myelitis	6	0
Subdural abscess	1	0
<i>Clostridia infections</i>		
Clostridium difficile infection	2	0
<i>Coronavirus infections</i>		
Asymptomatic COVID-19	13	0
COVID-19	1181	39
COVID-19 pneumonia	46	13
Coronavirus infection	7	0
Post-acute COVID-19 syndrome	1	0
Severe acute respiratory syndrome	2	0
Suspected COVID-19	60	4
<i>Coxiella infections</i>		
Q fever	9	0
<i>Cytomegaloviral infections</i>		
Cytomegalovirus infection	2	0
Cytomegalovirus syndrome	1	0
<i>Dental and oral soft tissue infections</i>		
Abscess oral	5	0
Gingivitis	10	0
Oral infection	1	0
Parotitis	9	0
Pericoronitis	2	0
Pulpitis dental	1	0
Sialoadenitis	3	0
Tongue abscess	1	0
Tooth abscess	8	0
Tooth infection	8	0
<i>Ear infections</i>		
Ear infection	74	0

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Labyrinthitis	90	0
Mastoiditis	1	0
Otitis externa	2	0
Otitis media	6	0
Otitis media acute	1	0
Ectoparasitic infestations		
Acarodermatitis	4	0
Bed bug infestation	1	0
Epstein-Barr viral infections		
Epstein-Barr virus infection	3	0
Infectious mononucleosis	23	0
Eye and eyelid infections		
Conjunctivitis	61	0
Eye abscess	1	0
Eye infection	17	0
Eyelid boil	2	0
Eyelid infection	2	0
Hordeolum	24	0
Periorbital infection	2	0
Female reproductive tract infections		
Bartholin's abscess	1	0
Bartholinitis	1	0
Endometritis	3	0
Funisitis	1	0
Pelvic inflammatory disease	1	0
Vaginal infection	1	0
Vulval abscess	1	0
Vulvitis	1	0
Fungal infections NEC		
Fungal infection	15	0
Fungal skin infection	5	0
Onychomycosis	1	0
Oral fungal infection	2	0
Pneumonia fungal	2	0
Vulvovaginal mycotic infection	6	0
Hepatitis virus infections		
Hepatitis A	1	0
Hepatitis E	1	0
Hepatobiliary and spleen infections		
Biliary sepsis	2	0
Cholecystitis infective	1	0
Herpes viral infections		
Disseminated varicella zoster virus infection	1	0
Eczema herpeticum	2	0
Genital herpes	77	0
Genital herpes simplex	6	0
Herpes ophthalmic	3	0
Herpes simplex	24	0
Herpes simplex encephalitis	1	1
Herpes simplex reactivation	2	0
Herpes virus infection	9	0
Herpes zoster	1238	0
Herpes zoster meningoencephalitis	1	0

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Herpes zoster oticus	13	0
Herpes zoster reactivation	1	0
Nasal herpes	3	0
Ophthalmic herpes simplex	2	0
Ophthalmic herpes zoster	3	0
Oral herpes	269	0
Varicella	23	0
Varicella zoster virus infection	1	0
<i>Infections NEC</i>		
Abscess	35	0
Abscess limb	7	0
Abscess soft tissue	1	0
Catheter site infection	1	0
Genital abscess	2	0
Infected bite	3	0
Infected cyst	2	0
Infection	203	0
Infection susceptibility increased	1	0
Injection site abscess	1	0
Injection site infection	5	0
Localised infection	23	0
Lymph gland infection	7	0
Lymph node abscess	5	0
Opportunistic infection	1	0
Pathogen resistance	1	0
Purulent discharge	1	0
Respiratory tract infection	10	0
Vaccination site abscess	6	0
Vaccination site infection	13	0
Vaccine breakthrough infection	23	0
Vestibulitis	2	0
Wound infection	1	0
<i>Infectious transmissions</i>		
Secondary transmission	8	0
Vaccine virus shedding	1	0
<i>Influenza viral infections</i>		
Influenza	1288	0
<i>Klebsiella infections</i>		
Klebsiella infection	1	0
<i>Lower respiratory tract and lung infections</i>		
Bronchitis	20	0
Infectious pleural effusion	1	0
Lower respiratory tract infection	180	7
Pneumonia	113	12
Sputum purulent	1	0
<i>Male reproductive tract infections</i>		
Epididymitis	6	0
Orchitis	4	0
Prostate infection	2	0
<i>Molluscum contagiosum viral infections</i>		
Molluscum contagiosum	1	0
<i>Mumps viral infections</i>		
Mumps	6	0

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Reaction Name	Total	Fatal
Infections Infections cont'd		
<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	1	0
<i>Neisseria infections</i>		
Gonorrhoea	1	0
Meningococcal bacteraemia	1	0
<i>Plasmodia infections</i>		
Malaria	2	0
<i>Pneumocystis infections</i>		
Pneumocystis jirovecii pneumonia	2	0
<i>Prion-associated disorders</i>		
Creutzfeldt-Jakob disease	1	0
<i>Retroviral infections</i>		
Acquired immunodeficiency syndrome	1	0
HIV infection	1	0
<i>Rotaviral infections</i>		
Gastroenteritis rotavirus	1	0
<i>Rubeola viral infections</i>		
Measles	4	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Bacteraemia	1	0
Neutropenic sepsis	3	1
Sepsis	43	7
Sepsis syndrome	1	0
Septic rash	1	0
Septic shock	5	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	2	0
Impetigo	10	0
Infected skin ulcer	1	0
Injection site pustule	1	0
Nail infection	1	0
Pustule	14	0
Rash pustular	9	0
Skin infection	28	0
Subcutaneous abscess	8	0
Sweat gland infection	1	0
Vaccination site pustule	4	0
<i>Staphylococcal infections</i>		
Furuncle	36	1
Pneumonia staphylococcal	1	0
Staphylococcal abscess	1	0
Staphylococcal infection	3	0
Staphylococcal sepsis	1	0
<i>Streptococcal infections</i>		
Meningitis pneumococcal	1	0

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Pharyngitis streptococcal	5	0
Streptococcal abscess	1	0
Streptococcal endocarditis	1	0
Streptococcal infection	1	0
Streptococcal sepsis	1	0
<i>Tinea infections</i>		
Body tinea	3	0
Tinea infection	1	0
Tinea pedis	2	0
Tinea versicolour	3	0
<i>Treponema infections</i>		
Syphilis	2	0
<i>Trypanosomal infections</i>		
African trypanosomiasis	2	0
<i>Tuberculous infections</i>		
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	1	0
Croup infectious	1	0
Epiglottitis	1	0
Laryngitis	26	0
Nasopharyngitis	874	0
Peritonsillar abscess	3	0
Pharyngitis	29	0
Rhinitis	37	0
Sinusitis	134	0
Tonsillitis	99	0
Tracheitis	4	0
Tracheostomy infection	1	0
Upper respiratory tract infection	7	0
<i>Urinary tract infections</i>		
Cystitis	66	0
Kidney infection	41	0
Pyelonephritis	2	0
Urethritis	1	0
Urinary tract infection	167	0
<i>Vascular infections</i>		
Haematoma infection	1	0
Infected lymphocele	2	0
Infusion site infection	1	0
Lymphangitis	7	0
<i>Viral infections NEC</i>		
Arthritis viral	1	0
Conjunctivitis viral	2	0
Encephalitis viral	4	1
Eye infection viral	2	0
Gastroenteritis viral	24	0
Hepatitis viral	2	0
Meningitis viral	8	0

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Meningoencephalitis viral	1	0
Oral viral infection	1	0
Pleurisy viral	1	0
Pneumonia viral	2	1
Post viral fatigue syndrome	41	0
Sweating fever	87	0
Vestibular neuronitis	26	0
Viral diarrhoea	2	0
Viral infection	43	0
Viral labyrinthitis	4	0
Viral myocarditis	2	0
Viral pericarditis	4	0
Viral pharyngitis	15	0
Viral rash	48	0
Viral sinusitis	1	0
Viral tonsillitis	1	0
Infections SOC TOTAL	8038	90

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Reaction Name	Total	Fatal
Injuries		
<i>Abdominal and gastrointestinal injuries NEC</i>		
Mouth injury	3	0
Oral contusion	3	0
Palate injury	1	0
Rectal injury	1	0
Splenic rupture	6	0
Tongue injury	2	0
Tooth fracture	1	0
Tooth injury	1	0
<i>Accidental exposures to product</i>		
Accidental exposure to product	18	0
<i>Anaesthetic and allied procedural complications</i>		
Airway complication of anaesthesia	1	0
Delayed recovery from anaesthesia	2	0
Sedation complication	1	0
<i>Atmospheric pressure injuries</i>		
Barotitis media	1	0
Hypobarism	1	0
<i>Bone and joint injuries NEC</i>		
Bursa injury	2	0
Joint injury	7	0
<i>Cardiac and vascular procedural complications</i>		
Shunt blood flow excessive	1	0
<i>Cardiovascular injuries</i>		
Heart injury	8	0
Vascular injury	6	0
<i>Cerebral injuries NEC</i>		
Brain contusion	2	0
Brain herniation	1	0
Concussion	4	0
Cranio-cerebral injury	1	0
Subarachnoid haematoma	1	0
Subdural haematoma	5	0
Subdural haemorrhage	5	0
Traumatic intracranial haemorrhage	1	1
<i>Chemical injuries</i>		
Chemical burn of skin	3	0
Chemical cystitis	1	0
<i>Chest and respiratory tract injuries NEC</i>		
Chest crushing	8	0
Foreign body in throat	1	0
<i>Conditions caused by cold</i>		
Chillblains	50	0
Cold shock response	1	0
<i>Cranial nerve injuries</i>		
Vth nerve injury	1	0
<i>Ear injuries NEC</i>		
Ear injury	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	9	0
Exposure via breast milk	103	0
Foetal exposure during pregnancy	39	0
Maternal exposure before pregnancy	6	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Maternal exposure during breast feeding	1480	0
Maternal exposure during pregnancy	788	0
Maternal exposure timing unspecified	10	0
Paternal exposure before pregnancy	2	0
Exposures to agents or circumstances NEC		
Exposure to SARS-CoV-2	3	0
Exposure to vaccinated person	4	0
Eye and ear procedural complications		
Toxic anterior segment syndrome	1	0
Eye injuries NEC		
Corneal abrasion	1	0
Eye contusion	13	0
Eye injury	15	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
Foetal and neonatal conditions associated with product exposure		
Intoxication by breast feeding	1	0
Fractures and dislocations NEC		
Bone fragmentation	1	0
Fracture	2	0
Joint dislocation	3	0
Multiple fractures	1	0
Gastrointestinal and hepatobiliary procedural complications		
Post procedural constipation	1	0
Postoperative ileus	1	0
Procedural nausea	8	0
Procedural vomiting	1	0
Heat injuries (excl thermal burns)		
Heat cramps	2	0
Heat exhaustion	3	0
Heat illness	1	0
Heat oedema	8	0
Heat stroke	3	0
Intentional product use issues		
Intentional dose omission	1	0
Intentional product use issue	1	0
Limb fractures and dislocations		
Atypical femur fracture	1	0
Clavicle fracture	23	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	1	0
Dose calculation error	1	0
Inadequate aseptic technique in use of product	1	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Medication error	18	0
Prescription drug used without a prescription	2	0
Product use complaint	1	0
Product use issue	20	0
Vaccination error	5	0
Wrong dose	3	0
Wrong drug	11	0
Wrong technique in product usage process	4	0
Muscle, tendon and ligament injuries		
Epicondylitis	17	0
Ligament injury	2	0
Ligament sprain	9	0
Mallet finger	1	0
Muscle injury	16	0
Muscle rupture	7	0
Muscle strain	27	0
Post-traumatic neck syndrome	2	0
Tendon injury	5	0
Tendon rupture	16	0
Musculoskeletal procedural complications		
Periprosthetic osteolysis	1	0
Post laminectomy syndrome	1	0
Nerve injuries NEC		
Nerve injury	74	0
Neurological and psychiatric procedural complications		
Post procedural stroke	1	0
Procedural dizziness	11	0
Non-occupational environmental exposures		
Exposure to extreme temperature	1	0
Non-site specific injuries NEC		
Animal scratch	1	0
Arthropod bite	5	0
Arthropod sting	5	0
Bite	1	0
Electric shock	17	0
Fall	155	0
Foreign body	2	0
Injury	10	0
Multiple injuries	2	0
Nervous system injury	1	0
Post concussion syndrome	1	0
Traumatic haematoma	1	0
Wound	7	0
Wound complication	9	0
Wound haematoma	1	0
Wound haemorrhage	2	0
Wound secretion	5	0
Non-site specific procedural complications		
Incision site pain	3	0
Infusion related reaction	6	0
Injection related reaction	38	0
Post procedural complication	3	0
Post procedural erythema	1	0

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Reaction Name	Total	Fatal
Injuries		
Injuries cont'd		
Procedural pain	2	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	58	0
Overdoses NEC		
Overdose	42	0
Pathways and sources of exposure		
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
Ulnar nerve injury	4	0
Poisoning and toxicity		
Alcohol poisoning	1	0
Poisoning	11	0
Toxicity to various agents	2	0
Product administration errors and issues		
Accidental overdose	6	0
Contraindicated product administered	1	0
Expired product administered	12	0
Inappropriate schedule of product administration	478	0
Incomplete course of vaccination	1	0
Incorrect dose administered	52	0
Incorrect drug administration rate	1	0
Incorrect product formulation administered	2	0
Incorrect route of product administration	4	0
Poor quality product administered	3	0
Product administered at inappropriate site	14	0
Product administered to patient of inappropriate age	1	0
Product administration error	6	0
Product dose omission issue	5	0
Wrong product administered	19	0
Product confusion errors and issues		
Product label confusion	1	0
Product dispensing errors and issues		
Product dispensing error	3	0
Product monitoring errors and issues		
Drug monitoring procedure incorrectly performed	1	0
Product preparation errors and issues		
Product preparation error	2	0
Product preparation issue	4	0
Product prescribing errors and issues		
Contraindicated product prescribed	2	0
Product prescribing error	1	0
Product selection errors and issues		
Product selection error	2	0
Radiation injuries		
Radiation sickness syndrome	1	0

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

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Sunburn	20	0
Renal and urinary tract injuries NEC		
Foreign body in urogenital tract	1	0
Reproductive system and breast injuries		
Penis injury	1	0
Site specific injuries NEC		
Face crushing	2	0
Face injury	1	0
Head injury	33	0
Limb crushing injury	2	0
Limb injury	92	0
Nasal injury	1	0
Neck crushing	1	0
Neck injury	1	0
Skin injuries NEC		
Contusion	1017	0
Nail avulsion	1	0
Scar	19	0
Scratch	7	0
Skin abrasion	6	0
Skin injury	4	0
Skin laceration	2	0
Skin wound	3	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 fracture	3	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	2	0
Burn of internal organs	2	0
Burn oral cavity	4	0
Burns second degree	5	0
Burns third degree	1	0
Thermal burn	19	0
Thermal burns of eye	10	0
Underdoses NEC		
Underdose	6	0
Vaccination related complications		
Vaccination complication	45	0
Injuries SOC TOTAL	5311	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 abnormal	1	0
Epinephrine increased	1	0
<i>Auditory and vestibular diagnostic procedures</i>		
Acoustic stimulation tests	5	0
Audiogram abnormal	1	0
<i>Autoimmunity analyses</i>		
Antinuclear antibody	1	0
Antinuclear antibody increased	1	0
Antinuclear antibody positive	2	0
Rheumatoid factor	3	0
<i>Bacteria identification and serology (excl mycobacteria)</i>		
Bacterial test positive	1	0
Klebsiella test positive	1	0
<i>Blood counts NEC</i>		
Blood count	5	0
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	4	0
Blood pH	8	0
Blood pH increased	7	0
Oxygen consumption decreased	2	0
Oxygen saturation	8	0
Oxygen saturation decreased	56	0
PO2 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	7	0
Blood glucose abnormal	11	0
Blood glucose decreased	27	0
Blood glucose fluctuation	16	0
Blood glucose increased	88	0
Blood glucose normal	1	0
Glycosylated haemoglobin increased	1	0
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	31	0
Heart sounds	4	0
Heart sounds abnormal	4	0
<i>Cardiac function diagnostic procedures</i>		
Cardiac monitoring	1	0
Cardiac output	1	0
Central venous pressure	1	0
Echocardiogram	1	0

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Ejection fraction decreased	1	0
Myocardial strain	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		
HLA-B*27 positive	1	0
Prostatic specific antigen increased	2	0
Central nervous system imaging procedures		
Computerised tomogram head	5	0
Magnetic resonance imaging head	12	0
Magnetic resonance imaging head abnormal	1	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 increased	3	0
Renin	1	0
Cholesterol analyses		
Blood cholesterol increased	7	0
Remnant-like lipoprotein particles	3	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	7	0
Blood thromboplastin	1	0
Clot retraction	2	1
Coagulation factor VIII level decreased	1	0
Coagulation time prolonged	9	0
Coagulation time shortened	4	0
Fibrin D dimer increased	9	0
International normalised ratio abnormal	6	0
International normalised ratio decreased	20	0
International normalised ratio fluctuation	2	0
International normalised ratio increased	49	0
Prothrombin time shortened	1	0
Digestive enzymes		
Amylase increased	1	0
ECG investigations		
Electrocardiogram	3	0
Electrocardiogram QRS complex prolonged	1	0
Electrocardiogram QT prolonged	6	0
Electrocardiogram ST segment depression	1	0
Electrocardiogram ST segment elevation	7	0
Electrocardiogram ST-T segment abnormal	1	0
Electrocardiogram T wave inversion	4	0
Electrocardiogram abnormal	16	0
Electrocardiogram change	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Electrocardiogram normal	2	0
Electrocardiogram repolarisation abnormality	1	0
QRS axis abnormal	1	0
Endocrine analyses and imaging NEC		
Hormone level abnormal	46	0
Faecal analyses NEC		
Faecal calprotectin	2	0
Faecal calprotectin increased	4	0
Fertility analyses		
Infertility tests	1	0
Semen analysis abnormal	1	0
Sperm concentration	2	0
Foetal and neonatal diagnostic procedures		
Foetal heart rate abnormal	3	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	1	0
Gastrointestinal, pancreatic and APUD hormone analyses		
Blood insulin	1	0
Blood insulin decreased	1	0
Haematological analyses NEC		
Blood viscosity abnormal	1	0
Plasma viscosity	1	0
Red blood cell sedimentation rate increased	6	0
Heart rate and pulse investigations		
Carotid pulse	1	0
Heart rate	381	0
Heart rate abnormal	51	0
Heart rate decreased	66	0
Heart rate increased	722	0
Heart rate irregular	156	0
Heart rate normal	1	0
Maximum heart rate	2	0
Pulse abnormal	17	0
Pulse pressure increased	1	0
Radial pulse abnormal	1	0
Sinus rhythm	6	0
Imaging procedures NEC		
Computerised tomogram	3	0
Magnetic resonance imaging	4	0
Magnetic resonance imaging abnormal	1	0
Scan	2	0
X-ray	1	0
Immune response protein analyses NEC		
Cytokine test	1	0
Immunoglobulin analyses		
Blood immunoglobulin G increased	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Blood immunoglobulin M	1	0
Blood immunoglobulin M increased	1	0
Immunology analyses NEC		
Antibody test	4	0
Immunology test	10	0
Immunology skin tests NEC		
Skin test positive	1	0
Investigations NEC		
Blood test	20	0
Blood test abnormal	45	0
False positive investigation result	1	0
Laboratory test	1	0
Polymerase chain reaction positive	33	0
Quality of life decreased	2	0
Systemic lupus erythematosus disease activity index increased	1	0
Liver function analyses		
Alanine aminotransferase increased	20	0
Aspartate aminotransferase	1	0
Aspartate aminotransferase abnormal	1	0
Aspartate aminotransferase increased	2	0
Blood bilirubin increased	3	0
Gamma-glutamyltransferase increased	4	0
Hepatic enzyme increased	6	0
Liver function test	1	0
Liver function test abnormal	26	0
Liver function test increased	23	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
Mineral and electrolyte analyses		
Blood copper increased	1	0
Blood iron	1	0
Blood iron decreased	9	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	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
<i>Musculoskeletal and soft tissue imaging procedures</i>		
Skull X-ray	6	0
<i>Musculoskeletal and soft tissue tests NEC</i>		
Swollen joint count increased	1	0
<i>Mycobacteria identification and serology</i>		
Tuberculin test positive	1	0
<i>Neurologic diagnostic procedures</i>		
Coma scale abnormal	4	0
Hoover's sign of leg paresis	1	0
Joint position sense decreased	1	0
Lumbar puncture	7	0
Temperature perception test abnormal	1	0
Temperature perception test increased	1	0
<i>Ophthalmic function diagnostic procedures</i>		
Corneal reflex decreased	1	0
Intraocular pressure increased	7	0
Intraocular pressure test	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature	220	0
Body temperature abnormal	39	0
Body temperature decreased	36	0
Body temperature fluctuation	40	0
Body temperature increased	353	0
Body temperature normal	1	0
Breath sounds abnormal	2	0
General physical condition abnormal	1	0
Grip strength	2	0
Grip strength decreased	20	0
Head lag	6	0
Lymph node palpable	36	0
Menstruation normal	2	0
Muscle strength abnormal	1	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
Respiratory rate	9	0
Respiratory rate decreased	16	0
Respiratory rate increased	33	0
Skin temperature	35	0
Temperature difference of extremities	9	0
Weight	1	0
Weight decreased	90	0
Weight increased	32	0
<i>Pituitary analyses anterior</i>		
Blood corticotrophin	1	0
Blood follicle stimulating hormone increased	1	0
Blood growth hormone	3	0
Blood prolactin	2	0
Blood prolactin increased	2	0
Blood thyroid stimulating hormone decreased	1	0
Blood thyroid stimulating hormone increased	4	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
<i>Platelet analyses</i>		
Mean platelet volume decreased	1	0
Mean platelet volume increased	1	0
Platelet count	3	0
Platelet count decreased	63	0
Platelet count increased	2	0
<i>Protein analyses NEC</i>		
Alpha 1 globulin decreased	1	0
Alpha 2 globulin decreased	1	0
C-reactive protein increased	17	0
<i>Red blood cell analyses</i>		
Haematocrit	1	0
Haematocrit increased	1	0
Haemoglobin	1	0
Haemoglobin decreased	10	0
Haemoglobin increased	1	0
Red blood cell count decreased	1	0
<i>Renal function analyses</i>		
Blood creatinine increased	1	0
Glomerular filtration rate decreased	3	0
<i>Reproductive hormone analyses</i>		
Blood oestrogen decreased	1	0
Blood testosterone decreased	1	0
Blood testosterone increased	1	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
<i>Reproductive organ and breast histopathology procedures</i>		
Biopsy endometrium	1	0
Smear cervix	1	0
<i>Reproductive organ and breast imaging procedures</i>		
Breast scan	1	0
Hysteroscopy	2	0
<i>Respiratory and pulmonary function diagnostic procedures</i>		
Forced expiratory volume increased	2	0
Fractional exhaled nitric oxide normal	1	0
Maximal voluntary ventilation	1	0
Peak expiratory flow rate	1	0
Peak expiratory flow rate decreased	4	0
Pulmonary function test	3	0
Total lung capacity decreased	3	0
Vital capacity	1	0
<i>Respiratory tract and thoracic histopathology procedures</i>		
Sputum abnormal	3	0
<i>Respiratory tract and thoracic imaging procedures</i>		
Chest X-ray	18	0
Chest X-ray abnormal	1	0
Chest X-ray normal	2	0
Chest scan	2	0
Computerised tomogram thorax	1	0

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
<i>Skeletal and cardiac muscle analyses</i>		
Blood creatine phosphokinase increased	4	0
Muscle enzyme	1	0
Myocardial necrosis marker	1	0
Myocardial necrosis marker increased	1	0
Troponin	1	0
Troponin T increased	1	0
Troponin increased	13	0
<i>Therapeutic drug monitoring analyses</i>		
Analgesic drug level	4	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	4	0
Thyroxine free increased	2	0
Tri-iodothyronine	1	0
Tri-iodothyronine decreased	5	0
<i>Tissue enzyme analyses NEC</i>		
Blood alkaline phosphatase increased	3	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	14	0
Blood urine present	44	0
Cells in urine	1	0
Glucose urine present	1	0
Protein urine absent	1	0
Urine analysis abnormal	6	0
Urine uric acid increased	1	0
pH urine	5	0
pH urine increased	2	0
<i>Urinary tract function analyses NEC</i>		
Urine output	12	0
Urine output decreased	11	0
Urine output increased	6	0
<i>Urinary tract histopathology procedures</i>		
Urine cytology	1	0
<i>Urinary tract imaging procedures</i>		
Cystoscopy	2	0
Ultrasound kidney normal	1	0
<i>Vascular imaging procedures NEC</i>		
Venogram	2	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure abnormal	6	0
Blood pressure decreased	63	0
Blood pressure diastolic	2	0

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Blood pressure diastolic decreased	1	0
Blood pressure diastolic increased	2	0
Blood pressure increased	196	0
Blood pressure measurement	33	0
Blood pressure normal	2	0
Blood pressure systolic	1	0
Blood pressure systolic decreased	3	0
Blood pressure systolic increased	1	0
<i>Virus identification and serology</i>		
Coronavirus test	11	0
Coronavirus test positive	4	0
HIV test	1	0
SARS-CoV-1 test	1	0
SARS-CoV-1 test positive	1	0
SARS-CoV-2 antibody test	11	0
SARS-CoV-2 antibody test negative	13	0
SARS-CoV-2 antibody test positive	3	0
SARS-CoV-2 test	26	0
SARS-CoV-2 test false negative	2	0
SARS-CoV-2 test false positive	3	0
SARS-CoV-2 test negative	7	0
SARS-CoV-2 test positive	94	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	2	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 increased	3	0
Lymphocyte count	2	0
Lymphocyte count decreased	2	0
Neutrophil count	3	0
Neutrophil count decreased	8	0
White blood cell count	2	0
White blood cell count decreased	10	0
White blood cell count increased	6	0
Investigations SOC TOTAL	4238	3

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	14	0
Decreased appetite	1003	0
Diet refusal	1	0
Eating disorder symptom	2	0
Food craving	10	0
Food refusal	11	0
Hyperphagia	12	0
Hypophagia	16	0
Increased appetite	28	0
Salt craving	2	0
<i>Calcium metabolism disorders</i>		
Hypocalcaemia	3	0
Tetany	3	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	42	0
Diabetes mellitus inadequate control	12	1
Increased insulin requirement	1	0
Insulin resistant diabetes	1	0
Latent autoimmune diabetes in adults	2	0
Type 1 diabetes mellitus	15	0
Type 2 diabetes mellitus	4	0
<i>Diabetic complications NEC</i>		
Diabetic complication	2	0
Diabetic ketoacidosis	11	0
Diabetic ketosis	1	0
<i>Disorders of purine metabolism</i>		
Gout	81	0
<i>Electrolyte imbalance NEC</i>		
Electrolyte imbalance	1	0
Fluid imbalance	1	0
<i>Fat soluble vitamin deficiencies and disorders</i>		
Vitamin D deficiency	4	0
<i>Fluid intake increased</i>		
Polydipsia	6	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Alcohol intolerance	3	0
Dairy intolerance	2	0
Food intolerance	12	0
Gluten sensitivity	6	0
Histamine intolerance	4	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	15	0
Abnormal weight gain	18	0
Cachexia	1	0
Feeding disorder	65	0
Food aversion	8	0
Malnutrition	1	0
Neonatal insufficient breast milk syndrome	2	0
Obesity	1	0
Overweight	1	0
Poor feeding infant	15	0
Weight loss poor	3	0

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Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
<i>Hyperglycaemic conditions NEC</i>		
Glucose tolerance impaired	1	0
Hyperglycaemia	62	0
Insulin resistance	4	0
<i>Hypoglycaemic conditions NEC</i>		
Glycopenia	1	0
Hypoglycaemia	71	0
Hypoglycaemia unawareness	1	0
Postprandial hypoglycaemia	1	0
<i>Iron deficiencies</i>		
Iron deficiency	11	0
<i>Iron excess</i>		
Haemochromatosis	1	0
Iron overload	1	0
<i>Lipid metabolism and deposit disorders NEC</i>		
Body fat disorder	1	0
<i>Metabolic acidoses (excl diabetic acidoses)</i>		
Ketoacidosis	5	1
Lactic acidosis	2	0
Metabolic acidosis	2	0
<i>Metabolic disorders NEC</i>		
Metabolic disorder	1	0
<i>Mixed acid-base disorders</i>		
Acidosis	3	0
<i>Potassium imbalance</i>		
Hyperkalaemia	3	0
Hypokalaemia	3	0
Hypokalaemic syndrome	1	0
<i>Sodium imbalance</i>		
Hyponatraemia	7	0
Hyponatraemic syndrome	3	0
Salt intoxication	1	0
<i>Sugar intolerance (excl glucose intolerance)</i>		
Lactose intolerance	1	0
<i>Total fluid volume decreased</i>		
Dehydration	173	0
<i>Total fluid volume increased</i>		
Fluid overload	1	0
Fluid retention	46	0
Hypervolaemia	1	0
<i>Vitamin deficiencies NEC</i>		
Hypovitaminosis	5	0
<i>Water soluble vitamin deficiencies</i>		
Folate deficiency	3	0
Vitamin B12 deficiency	4	0
Metabolic disorders SOC TOTAL	1866	2

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	236	0
Arthropathy	23	0
Autoimmune arthritis	6	0
Haemarthrosis	5	0
Joint microhaemorrhage	1	0
Palindromic rheumatism	1	0
Polyarthritis	15	0
Rheumatic fever	1	0
Sacroiliitis	4	0
Seronegative arthritis	2	0
<i>Bone disorders NEC</i>		
Bone cyst	1	0
Exostosis	1	0
Jaw disorder	3	0
Medial tibial stress syndrome	4	0
Osteitis	6	0
Osteonecrosis	1	0
Osteonecrosis of jaw	3	0
Spinal disorder	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	308	0
Bone swelling	7	0
Coccydynia	3	0
Metatarsalgia	1	0
Pain in jaw	305	0
Pubic pain	2	0
Spinal pain	63	0
<i>Bursal disorders</i>		
Bursitis	57	0
<i>Cartilage disorders</i>		
Chondritis	1	0
Costochondritis	72	0
Osteochondritis	1	0
Polychondritis	3	0
<i>Connective tissue disorders NEC</i>		
Connective tissue disorder	1	0
Polymyalgia rheumatica	51	0
Reynold's syndrome	1	0
Sjogren's syndrome	5	0
<i>Crystal arthropathic disorders</i>		
Chondrocalcinosis pyrophosphate	2	0
Crystal arthropathy	1	0
<i>Epiphyseal disorders</i>		
Epiphyses premature fusion	1	0
<i>Extremity deformities</i>		
Bone deformity	1	0
Finger deformity	1	0
Foot deformity	1	0
Hand deformity	2	0
Knee deformity	1	0
Limb deformity	4	0
Musculoskeletal deformity	1	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders Muscle & tissue disorders cont'd		
Fractures NEC		
Osteoporotic fracture	1	0
Intervertebral disc disorders NEC		
Intervertebral disc protrusion	3	0
Joint related disorders NEC		
Chondromalacia	1	0
Hypermobility syndrome	1	0
Joint deposit	1	0
Joint destruction	1	0
Joint instability	1	0
Joint laxity	3	0
Joint lock	23	0
Patellofemoral pain syndrome	1	0
Periarthritis	139	0
Rotator cuff syndrome	25	0
Temporomandibular joint syndrome	8	0
Joint related signs and symptoms		
Arthralgia	7521	0
Jaw clicking	6	0
Joint effusion	14	0
Joint noise	32	0
Joint range of motion decreased	29	0
Joint stiffness	205	0
Joint swelling	446	0
Joint vibration	3	0
Joint warmth	13	0
Loose body in joint	1	0
Ligament disorders		
Ligament pain	2	0
Symphysiolysis	1	0
Lupus erythematosus (incl subtypes)		
Lupus-like syndrome	1	0
Systemic lupus erythematosus	18	0
Metabolic bone disorders		
Osteopenia	3	0
Osteoporosis	2	0
Muscle infections and inflammations		
Antisynthetase syndrome	3	0
Immune-mediated myositis	1	0
Myositis	26	0
Polymyositis	7	0
Muscle pains		
Fibromyalgia	87	0
Myalgia	9212	0
Myalgia intercostal	1	0
Myofascial pain syndrome	11	0
Muscle related signs and symptoms NEC		
Haematoma muscle	1	0
Muscle atrophy	18	0
Muscle discomfort	4	0
Muscle disorder	6	0
Muscle fatigue	298	0
Muscle haemorrhage	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Muscle & tissue disorders Muscle & tissue disorders cont'd		
Muscle mass	4	0
Muscle oedema	1	0
Muscle spasms	1798	0
Muscle swelling	27	0
Muscle tightness	79	0
Muscle twitching	413	0
Muscle tone abnormalities		
Muscle rigidity	14	0
Nuchal rigidity	10	0
Torticollis	4	0
Trismus	30	0
Muscle weakness conditions		
Muscular weakness	767	0
Musculoskeletal and connective tissue conditions NEC		
Back disorder	2	0
Growth disorder	2	0
Limb mass	20	0
Mandibular mass	2	0
Mastication disorder	3	0
Mobility decreased	91	0
Musculoskeletal disorder	10	0
Musculoskeletal stiffness	1075	0
Posture abnormal	1	0
Sacroiliac joint dysfunction	1	0
Weight bearing difficulty	2	0
Musculoskeletal and connective tissue deformities of skull, face and buccal cavity		
Head deformity	2	0
Musculoskeletal and connective tissue infections and inflammations NEC		
Dactylitis	2	0
Dupuytren's contracture	1	0
Fasciitis	1	0
Plantar fasciitis	8	0
Musculoskeletal and connective tissue pain and discomfort		
Back pain	2011	0
Flank pain	55	0
Limb discomfort	1302	0
Musculoskeletal chest pain	183	0
Musculoskeletal discomfort	79	0
Musculoskeletal pain	38	0
Neck pain	1581	0
Pain in extremity	10780	0
Rheumatic disorder	13	0
Myopathies		
Myopathy	6	0
Rhabdomyolysis	11	0
Osteoarthropathies		
Nodal osteoarthritis	1	0
Osteoarthritis	37	0
Spinal osteoarthritis	1	0
Psoriatic arthropathies		
Psoriatic arthropathy	16	0
Rheumatoid arthropathies		

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Reaction Name	Total	Fatal
Muscle & tissue disorders Muscle & tissue disorders cont'd		
Juvenile idiopathic arthritis	1	0
Rheumatoid arthritis	100	0
<i>Soft tissue disorders NEC</i>		
Axillary mass	205	0
Fluctuance	1	0
Groin pain	95	0
Neck mass	27	0
Purple glove syndrome	1	0
Soft tissue disorder	3	0
Soft tissue swelling	6	0
<i>Spine and neck deformities</i>		
Kyphosis	2	0
Lordosis	1	0
Neck deformity	1	0
Scoliosis	1	0
Spinal stenosis	1	0
<i>Spondyloarthropathies</i>		
Ankylosing spondylitis	6	0
Arthritis reactive	39	0
Spondylitis	2	0
Spondyloarthropathy	1	0
<i>Synovial disorders</i>		
Synovial cyst	18	0
Synovitis	7	0
<i>Tendon disorders</i>		
Enthesopathy	2	0
Tendon disorder	5	0
Tendon pain	19	0
Tendonitis	35	0
Tenosynovitis	2	0
Tenosynovitis stenosaurs	2	0
Trigger finger	25	0
<i>Trunk deformities</i>		
Drooping shoulder syndrome	1	0
Shoulder deformity	2	0
Muscle & tissue disorders SOC TOTAL	40486	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>B-cell lymphomas NEC</i>		
B-cell lymphoma	1	1
Follicular lymphoma	3	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	1	0
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	31	0
Breast cancer female	1	0
Breast cancer male	1	0
Breast cancer stage I	1	0
Breast cancer stage III	2	0
Invasive ductal breast carcinoma	1	0
Triple negative breast cancer	2	0
<i>Cardiovascular neoplasms benign</i>		
Pericardial lipoma	1	0
<i>Cervix neoplasms malignant</i>		
Cervix carcinoma	1	0
<i>Colorectal neoplasms malignant</i>		
Colon cancer	1	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	1	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>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>Leukaemias NEC</i>		
Leukaemia	4	1
<i>Leukaemias acute NEC</i>		
Acute leukaemia	2	0
<i>Leukaemias chronic NEC</i>		
Chronic leukaemia	1	0
<i>Leukaemias chronic lymphocytic</i>		
Chronic lymphocytic leukaemia	3	0
<i>Leukaemias chronic myeloid</i>		
Chronic myeloid leukaemia	1	0
<i>Lip and oral cavity neoplasms malignant</i>		

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
Lip and/or oral cavity cancer recurrent	1	0
Lymphomas unspecified NEC		
Lymphoma	29	1
Metastases to specified sites		
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	1	0
Neoplasms benign site unspecified NEC		
Adenoma benign	1	0
Neoplasms malignant site unspecified NEC		
Adenocarcinoma metastatic	1	0
Metastatic neoplasm	1	0
Neoplasm malignant	7	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
Spinal cord neoplasm	1	0
Neuromas		
Acoustic neuroma	2	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
Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified		
Tonsil cancer	3	0
Ovarian neoplasms malignant (excl germ cell)		
Ovarian cancer	1	0
Pancreatic neoplasms malignant (excl islet cell and carcinoid)		
Pancreatic carcinoma	4	0
Plasma cell myelomas		
POEMS syndrome	1	0
Plasma cell myeloma	1	0
Plasma cell neoplasms NEC		
TEMPI syndrome	1	0
Prostatic neoplasms malignant		
Prostate cancer	3	0

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
<i>Renal neoplasms malignant</i>		
Renal cancer	2	0
<i>Reproductive neoplasms female benign NEC</i>		
Benign hydatidiform mole	1	0
<i>Respiratory tract and pleural neoplasms malignant cell type unspecified NEC</i>		
Bronchial carcinoma	1	0
Lung neoplasm malignant	9	0
<i>Skin melanomas (excl ocular)</i>		
Malignant melanoma	1	0
<i>Skin neoplasms benign</i>		
Acrochordon	3	0
Anogenital warts	7	0
Haemangioma of skin	4	0
Melanocytic naevus	6	0
Pyogenic granuloma	1	0
Skin papilloma	15	0
<i>Skin neoplasms malignant and unspecified (excl melanoma)</i>		
Basal cell carcinoma	2	0
Bowen's disease	1	0
Neoplasm skin	2	0
Squamous cell carcinoma of skin	1	0
<i>Soft tissue neoplasms benign NEC</i>		
Lipoma	6	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	9	0
Neoplasms SOC TOTAL	242	5

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Areflexia	6	0
Extensor plantar response	2	0
Hyperreflexia	4	0
Hyporeflexia	7	0
Reflexes abnormal	1	0
<i>Abnormal sleep-related events</i>		
Sleep paralysis	23	0
<i>Absence seizures</i>		
Petit mal epilepsy	22	0
<i>Acute polyneuropathies</i>		
Acute motor axonal neuropathy	1	0
Guillain-Barre syndrome	55	1
Miller Fisher syndrome	1	0
Subacute inflammatory demyelinating polyneuropathy	1	0
<i>Autonomic nervous system disorders</i>		
Anticholinergic syndrome	1	0
Autonomic nervous system imbalance	8	0
Autonomic neuropathy	2	0
Horner's syndrome	1	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>		
Brain stem infarction	1	1
Brain stem stroke	1	0
Carotid artery occlusion	1	0
Carotid artery thrombosis	3	0
Cerebellar haemorrhage	2	0
Cerebellar infarction	2	0
Cerebellar ischaemia	1	0
Cerebellar stroke	8	1
Cerebral artery embolism	3	1
Cerebral artery occlusion	1	0
Cerebral artery thrombosis	3	0
Cerebral haemorrhage	42	8
Cerebral infarction	25	1
Cerebral thrombosis	12	0
Cerebrovascular accident	334	14
Embolic stroke	6	0
Haemorrhage intracranial	9	2
Haemorrhagic cerebral infarction	1	0
Haemorrhagic stroke	9	3
Internal capsule infarction	1	0
Intracranial haematoma	1	0
Ischaemic cerebral infarction	1	0
Ischaemic stroke	39	2
Lacunar infarction	2	0
Lacunar stroke	3	0
Lateral medullary syndrome	1	0
Pseudostroke	1	0
Subarachnoid haemorrhage	14	6
Thalamic infarction	1	0

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Reaction Name	Total	Fatal
Nervous system disorders Nervous system disorders cont'd		
Thrombotic stroke	3	1
Central nervous system inflammatory disorders NEC		
Arachnoiditis	1	0
Gliositis	1	0
Central nervous system vascular disorders NEC		
Brain hypoxia	2	1
Central nervous system vasculitis	1	0
Cerebral amyloid angiopathy	1	0
Cerebral congestion	3	0
Cerebral small vessel ischaemic disease	1	0
Cerebrovascular disorder	1	0
Post cardiac arrest syndrome	1	0
Reversible cerebral vasoconstriction syndrome	1	0
Cerebrovascular venous and sinus thrombosis		
Cerebral venous sinus thrombosis	42	3
Cerebral venous thrombosis	6	0
Superior sagittal sinus thrombosis	4	0
Transverse sinus thrombosis	1	0
Cervical spinal cord and nerve root disorders		
Cervical radiculopathy	1	0
Cervicobrachial syndrome	3	0
Choreiform movements		
Chorea	2	0
Chronic polyneuropathies		
Demyelinating polyneuropathy	1	0
Coma states		
Coma	10	0
Diabetic coma	1	0
Hypoglycaemic coma	1	0
Coordination and balance disturbances		
Ataxia	12	0
Balance disorder	322	0
Cerebellar ataxia	1	0
Coordination abnormal	47	0
Dysdiadochokinesis	1	0
Dysstasia	51	0
Nystagmus	10	0
Cortical dysfunction NEC		
Alexia	2	0
Aphasia	72	0
Apraxia	1	0
Dyslexia	1	0
Dyspraxia	1	0
Neurologic neglect syndrome	1	0
Sensory processing disorder	2	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	14	0
Dementia with Lewy bodies	1	0
Senile dementia	1	0

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Reaction Name	Total	Fatal
Nervous system disorders Nervous system disorders cont'd		
<i>Demyelinating disorders NEC</i>		
Acute disseminated encephalomyelitis	5	0
Clinically isolated syndrome	1	0
Demyelination	8	0
Neuromyelitis optica spectrum disorder	2	0
<i>Disturbances in consciousness NEC</i>		
Altered state of consciousness	11	0
Consciousness fluctuating	2	0
Depressed level of consciousness	41	0
Infant sedation	1	0
Lethargy	1919	0
Loss of consciousness	542	0
Postictal state	4	0
Sedation	8	0
Somnolence	875	0
Stupor	4	0
Syncope	1806	0
<i>Disturbances in sleep phase rhythm</i>		
Circadian rhythm sleep disorder	1	0
Irregular sleep phase	2	0
Irregular sleep wake rhythm disorder	1	0
<i>Dyskinesias and movement disorders NEC</i>		
Akathisia	5	0
Bradykinesia	18	0
Clumsiness	17	0
Dyskinesia	57	0
Extrapyramidal disorder	2	0
Fine motor skill dysfunction	11	0
Foetal movement disorder	3	0
Hyperkinesia	3	0
Hypokinesia	61	0
Motor dysfunction	2	0
Movement disorder	49	0
Psychomotor hyperactivity	21	0
Synkinesis	2	0
Tardive dyskinesia	2	0
<i>Dystonias</i>		
Dystonia	15	0
Writer's cramp	1	0
<i>Encephalitis NEC</i>		
Encephalitis autoimmune	1	0
Limbic encephalitis	1	0
Noninfective encephalitis	5	0
<i>Encephalopathies NEC</i>		
Autoimmune encephalopathy	1	1
Encephalopathy	3	0
Hashimoto's encephalopathy	1	0
Posterior reversible encephalopathy syndrome	1	0
<i>Eye movement disorders</i>		
IIIrd nerve disorder	1	0
IIIrd nerve paralysis	6	0
IVth nerve paralysis	1	0
Microvascular cranial nerve palsy	1	0

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Reaction Name	Total	Fatal
Nervous system disorders Nervous system disorders cont'd		
Vlth nerve disorder	1	0
Vlth nerve paralysis	10	0
Facial cranial nerve disorders		
Bell's palsy	432	0
Facial nerve disorder	8	0
Facial paralysis	336	0
Facial paresis	84	0
Facial spasm	43	0
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	45	0
Headaches NEC		
Cervicogenic headache	3	0
Cluster headache	193	0
Cold-stimulus headache	19	0
Drug withdrawal headache	2	0
Exertional headache	8	0
External compression headache	2	0
Headache	22539	0
Medication overuse headache	2	0
New daily persistent headache	4	0
Occipital neuralgia	10	0
Ophthalmoplegic migraine	1	0
Primary cough headache	4	0
Primary headache associated with sexual activity	5	0
Sinus headache	310	0
Tension headache	488	0
Thunderclap headache	9	0
Vascular headache	14	0
Hydrocephalic conditions		
Hydrocephalus	2	0
Hypoglossal nerve disorders		
Tongue paralysis	1	0
Increased intracranial pressure disorders		
Brain compression	1	0
Brain oedema	6	2
Idiopathic intracranial hypertension	6	0
Intracranial pressure increased	1	0
Intellectual disabilities		
Intellectual disability	3	0
Lumbar spinal cord and nerve root disorders		
Sciatica	73	0
Memory loss (excl dementia)		
Amnesia	152	0
Memory impairment	162	0
Transient global amnesia	7	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	74	0
Cognitive linguistic deficit	1	0
Disturbance in attention	277	0
Mental impairment	44	0
Migraine headaches		
Hemiplegic migraine	29	0
Migraine	2565	0

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Reaction Name	Total	Fatal
Nervous system disorders Nervous system disorders cont'd		
Migraine with aura	167	0
Migraine without aura	17	0
Ophthalmic migraine	5	0
Retinal migraine	30	0
Typical aura without headache	7	0
Vestibular migraine	18	0
Mixed cranial nerve disorders		
Bulbar palsy	2	0
Mononeuropathies		
Carpal tunnel syndrome	20	0
Cubital tunnel syndrome	2	0
Meralgia paraesthetica	1	0
Mononeuritis	2	0
Mononeuropathy	3	0
Nerve compression	20	0
Peripheral nerve lesion	1	0
Peroneal nerve palsy	14	0
Sciatic nerve neuropathy	2	0
Ulnar nerve palsy	2	0
Ulnar neuritis	1	0
Ulnar tunnel syndrome	1	0
Motor neurone diseases		
Lower motor neurone lesion	1	0
Motor neurone disease	1	0
Multiple sclerosis acute and progressive		
Band sensation	1	0
Multiple sclerosis	28	0
Multiple sclerosis relapse	20	0
Tumefactive multiple sclerosis	1	1
Muscle tone abnormal		
Drop attacks	1	0
Hypertonia	2	0
Hypotonia	25	0
Morvan syndrome	1	0
Muscle tone disorder	1	0
Serotonin syndrome	1	0
Stiff leg syndrome	1	0
Myelitis (incl infective)		
Myelitis transverse	26	0
Narcolepsy and hypersomnia		
Cataplexy	2	0
Hypersomnia	101	0
Narcolepsy	6	0
Nervous system disorders NEC		
Central nervous system lesion	2	0
Cerebral disorder	1	0
Nervous system disorder	14	0
Neurotoxicity	3	0
Neurologic visual problems NEC		
Hemianopia	1	0
Hemianopia homonymous	2	0
Quadrantanopia	1	0
Tunnel vision	17	0

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Reaction Name	Total	Fatal
Nervous system disorders Nervous system disorders cont'd		
<i>Neurological signs and symptoms NEC</i>		
Agitation neonatal	1	0
Clonus	3	0
Decerebrate posture	1	0
Decorticate posture	1	0
Dizziness	8558	0
Dizziness exertional	39	0
Dizziness postural	635	0
Drooling	21	0
Fontanelle bulging	2	0
Head discomfort	299	0
Hyporesponsive to stimuli	2	0
Inability to crawl	2	0
Infant irritability	9	0
Myoclonus	25	0
Neurological symptom	40	0
Patient elopement	1	0
Persistent postural-perceptual dizziness	12	0
Presyncope	553	0
Sensory overload	4	0
Slow response to stimuli	4	0
Tongue biting	5	0
Unresponsive to stimuli	39	0
<i>Neuromuscular disorders NEC</i>		
Muscle contractions involuntary	17	0
Muscle spasticity	10	0
Neuromuscular pain	3	0
<i>Neuromuscular junction dysfunction</i>		
Myasthenia gravis	7	0
Myasthenia gravis crisis	2	0
<i>Olfactory nerve disorders</i>		
Anosmia	227	0
Hyposmia	16	0
Parosmia	220	0
<i>Optic nerve disorders NEC</i>		
Optic neuritis	26	0
<i>Paraesthesias and dysaesthesias</i>		
Burning feet syndrome	7	0
Burning sensation	464	0
Burning sensation mucosal	2	0
Dysaesthesia	7	0
Formication	37	0
Hand-arm vibration syndrome	3	0
Hemianaesthesia	1	0
Hemiparaesthesia	3	0
Hyperaesthesia	79	0
Hypoaesthesia	2570	0
Paraesthesia	3518	0
Reversed hot-cold sensation	4	0
Synaesthesia	1	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Diplegia	12	0
Hemiparesis	42	0

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Reaction Name	Total	Fatal
Nervous system disorders Nervous system disorders cont'd		
Hemiplegia	37	0
Locked-in syndrome	1	0
Monoparesis	48	0
Monoplegia	67	0
Paralysis	115	0
Paraparesis	3	0
Paraplegia	1	0
Paresis	6	0
Quadriparesis	1	0
Quadriplegia	1	0
Parkinson's disease and parkinsonism		
Freezing phenomenon	8	0
Hypokinetic dysarthria	1	0
Parkinson's disease	3	0
Parkinsonian gait	1	0
Parkinsonian rest tremor	1	0
Parkinsonism	4	0
Reduced facial expression	10	0
Partial complex seizures		
Dreamy state	6	0
Focal dyscognitive seizures	3	0
Temporal lobe epilepsy	2	0
Partial simple seizures NEC		
Autonomic seizure	1	0
Peripheral neuropathies NEC		
Axonal neuropathy	2	0
Neuralgic amyotrophy	3	0
Neuritis	7	0
Neuropathy peripheral	95	0
Peripheral sensorimotor neuropathy	1	0
Peripheral sensory neuropathy	11	0
Polyneuropathy	3	0
Thoracic outlet syndrome	1	0
Seizures and seizure disorders NEC		
Atonic seizures	4	0
Change in seizure presentation	2	0
Clonic convulsion	3	0
Convulsions local	1	0
Epilepsy	143	0
Epileptic aura	2	0
Epileptic encephalopathy	1	0
Febrile convulsion	14	0
Partial seizures	17	0
Post stroke seizure	1	0
Psychogenic seizure	7	0
Seizure	516	0
Seizure anoxic	2	0
Seizure cluster	6	0
Seizure like phenomena	2	0
Status epilepticus	40	0
Tonic clonic movements	2	0
Tonic convulsion	24	0
Tonic posturing	1	0

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Reaction Name	Total	Fatal
Nervous system disorders Nervous system disorders cont'd		
<i>Sensory abnormalities NEC</i>		
Ageusia	457	0
Allodynia	24	0
Aura	19	0
Complex regional pain syndrome	5	0
Dysgeusia	1041	0
Electric shock sensation	35	0
Hypergeusia	1	0
Hypogeusia	7	0
Intercostal neuralgia	1	0
Loss of proprioception	3	0
Morton's neuralgia	1	0
Neuralgia	458	0
Persistent genital arousal disorder	1	0
Phantom limb syndrome	4	0
Post herpetic neuralgia	14	0
Restless arm syndrome	2	0
Restless legs syndrome	118	0
Sensory disturbance	92	0
Sensory loss	66	0
Taste disorder	230	0
Visual perseveration	3	0
<i>Sleep disturbances NEC</i>		
Sleep deficit	9	0
Sudden onset of sleep	1	0
<i>Speech and language abnormalities</i>		
Dysarthria	165	0
Incoherent	9	0
Language disorder	2	0
Repetitive speech	3	0
Slow speech	17	0
Speech disorder	59	0
<i>Spinal cord and nerve root disorders NEC</i>		
Cauda equina syndrome	1	0
Myelopathy	1	0
Radiculitis brachial	8	0
Radiculopathy	5	0
<i>Structural brain disorders NEC</i>		
Brain injury	6	2
Hyperintensity in brain deep nuclei	1	0
<i>Transient cerebrovascular events</i>		
Transient ischaemic attack	131	3
<i>Tremor (excl congenital)</i>		
Essential tremor	3	0
Head titubation	12	0
Resting tremor	4	0
Tremor	1444	0
<i>Trigeminal disorders</i>		
Facial neuralgia	16	0
Numb chin syndrome	2	0
Trigeminal nerve disorder	3	0
Trigeminal neuralgia	40	0
Trigeminal neuritis	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Nervous system disorders Nervous system disorders cont'd		
<i>Vagus nerve disorders</i>		
Vocal cord paralysis	1	0
<i>Vertigos NEC</i>		
Cervicogenic vertigo	1	0
Vertigo CNS origin	3	0
Nervous system disorders SOC TOTAL	58668	55

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortion related conditions and complications</i>		
Anembryonic gestation	2	0
<i>Abortions not specified as induced or spontaneous</i>		
Abortion	1	0
Abortion missed	4	1
<i>Abortions spontaneous</i>		
Abortion spontaneous	349	8
Abortion threatened	2	0
<i>Amniotic fluid and cavity disorders of pregnancy NEC</i>		
Amniorrhoea	1	0
<i>Foetal complications NEC</i>		
Foetal cardiac disorder	1	0
Foetal disorder	1	0
Foetal distress syndrome	1	0
Foetal hypokinesia	10	0
<i>Foetal growth complications</i>		
Foetal growth restriction	6	0
<i>Gestational age and weight conditions</i>		
Premature baby	3	1
<i>Haemorrhagic complications of pregnancy</i>		
Haemorrhage in pregnancy	2	0
Premature separation of placenta	2	0
Subchorionic haematoma	2	0
Subchorionic haemorrhage	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	5	0
Premature rupture of membranes	2	0
Threatened labour	1	0
<i>Maternal complications of labour NEC</i>		
Uterine contractions abnormal	1	0
Uterine hypertonus	8	0
<i>Maternal complications of pregnancy NEC</i>		
Biochemical pregnancy	1	0
Complication of pregnancy	1	0
Decidual cast	4	0
Ectopic pregnancy	6	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>Newborn complications NEC</i>		
Neonatal disorder	1	0
<i>Normal newborn status</i>		
Normal newborn	1	0
<i>Normal pregnancy, labour and delivery</i>		
Labour pain	1	0
Live birth	3	0
Pregnancy	34	0

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Reaction Name	Total	Fatal
Pregnancy conditions Pregnancy conditions cont'd		
Uterine contractions during pregnancy	4	0
<i>Placental abnormalities (excl neoplasms)</i>		
Placental disorder	1	0
Placental insufficiency	1	0
<i>Postpartum complications NEC</i>		
Postpartum haemorrhage	3	0
<i>Pregnancy complicated by maternal disorders</i>		
Gestational diabetes	2	0
Peripartum cardiomyopathy	1	0
<i>Stillbirth and foetal death</i>		
Foetal death	3	3
Stillbirth	6	6
<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	2	0
Unwanted pregnancy	1	0
Pregnancy conditions SOC TOTAL	515	19

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Reaction Name	Total	Fatal
<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	15	0
Thrombosis in device	9	0
<i>Device physical property and chemical issues</i>		
Device breakage	1	0
Device defective	7	0
Device kink	1	0
Needle issue	2	0
<i>Product contamination and sterility issues</i>		
Product contamination	11	0
Product contamination physical	6	0
<i>Product packaging issues</i>		
Product closure issue	1	0
<i>Product physical issues</i>		
Liquid product physical issue	9	0
Product deposit	1	0
Product odour abnormal	2	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
total SOC TOTAL	91	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	24	0
Behaviour disorder	1	0
Breath holding	6	0
Staring	7	0
<i>Adjustment disorders</i>		
Adjustment disorder with depressed mood	4	0
<i>Affect alterations NEC</i>		
Affect lability	12	0
Constricted affect	3	0
Flat affect	7	0
Inappropriate affect	19	0
<i>Amnesic symptoms</i>		
Paramnesia	5	0
<i>Anxiety disorders NEC</i>		
Anxiety disorder	1	0
Generalised anxiety disorder	1	0
Neurosis	1	0
<i>Anxiety symptoms</i>		
Agitation	69	0
Anxiety	735	0
Immunisation anxiety related reaction	2	0
Nervousness	154	0
Stress	90	0
Tension	36	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	5	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	12	0
Attention-seeking behaviour	1	0
Aversion	1	0
Disinhibition	2	0
Indifference	6	0
Paranoia	23	0
Personality change	4	0
Social avoidant behaviour	5	0
Soliloquy	2	0
Suspiciousness	1	0
<i>Bipolar disorders</i>		
Bipolar I disorder	2	0
Bipolar disorder	4	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Daydreaming	7	0
Distractibility	1	0
Mental fatigue	192	0
<i>Communications disorders</i>		
Communication disorder	5	0
Mutism	3	0
<i>Confusion and disorientation</i>		
Confusional state	776	0
Disorientation	251	0
<i>Decreased physical activity levels</i>		
Catatonia	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders Psychiatric disorders cont'd		
<i>Deliria</i>		
Delirium	93	0
<i>Delusional symptoms</i>		
Delusion	11	0
<i>Depressive disorders</i>		
Agitated depression	4	0
Depression	300	0
Depression suicidal	13	0
Major depression	8	0
Mixed anxiety and depressive disorder	3	0
<i>Dissociative states</i>		
Depersonalisation/derealisation disorder	9	0
Dissociation	23	0
Dissociative amnesia	2	0
Dissociative disorder	2	0
<i>Disturbances in initiating and maintaining sleep</i>		
Initial insomnia	19	0
Insomnia	1234	0
Middle insomnia	24	0
Terminal insomnia	31	0
<i>Dyssomnias</i>		
Breathing-related sleep disorder	1	0
Dyssomnia	1	0
Poor quality sleep	192	0
<i>Eating disorders NEC</i>		
Bulimia nervosa	1	0
Eating disorder	10	0
Selective eating disorder	1	0
<i>Emotional and mood disturbances NEC</i>		
Anger	34	0
Dysphoria	2	0
Emotional disorder	52	0
Emotional distress	36	0
Emotional poverty	1	0
Euphoric mood	42	0
Frustration tolerance decreased	2	0
Irritability	188	0
Mood altered	53	0
<i>Factitious disorders</i>		
Factitious disorder	4	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Agoraphobia	2	0
Fear	18	0
Fear of death	1	0
Fear of eating	1	0
Fear of falling	3	0
Fear of injection	6	0
Osmophobia	1	0
Phobia	3	0
Phonophobia	2	0
Social anxiety disorder	1	0
Social fear	1	0
<i>Fluctuating mood symptoms</i>		

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Reaction Name	Total	Fatal
Psychiatric disorders Psychiatric disorders cont'd		
Mood swings	127	0
Hallucinations (excl sleep-related)		
Hallucination	170	0
Hallucination, auditory	13	0
Hallucination, olfactory	10	0
Hallucination, tactile	1	0
Hallucination, visual	23	0
Hallucinations, mixed	2	0
Increased physical activity levels		
Restlessness	137	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	15	0
Mental status changes	1	0
Psychological factor affecting medical condition	1	0
Mood alterations with depressive symptoms		
Anhedonia	3	0
Decreased interest	9	0
Depressed mood	339	0
Depressive symptom	2	0
Feeling guilty	1	0
Feeling of despair	5	0
Feelings of worthlessness	1	0
Negative thoughts	1	0
Psychomotor retardation	2	0
Sense of a foreshortened future	2	0
Tearfulness	34	0
Mood alterations with manic symptoms		
Hypomania	2	0
Mania	11	0
Mood disorders NEC		
Affective disorder	3	0
Apathy	28	0
Boredom	1	0
Laziness	3	0
Listless	17	0
Mood disorder due to a general medical condition	1	0
Narcolepsy and associated conditions		
Hypnagogic hallucination	3	0
Hypnopompic hallucination	2	0
Sleep attacks	3	0
Obsessive-compulsive disorders and symptoms		
Obsessive-compulsive symptom	1	0
Orgasmic disorders and disturbances		
Anorgasmia	4	0
Female orgasmic disorder	2	0
Orgasm abnormal	4	0
Orgasmic sensation decreased	1	0
Premature ejaculation	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders Psychiatric disorders cont'd		
<i>Panic attacks and disorders</i>		
Panic attack	173	0
Panic disorder	3	0
Panic reaction	25	0
<i>Paraphilias and paraphilic disorders</i>		
Transvestism	1	0
<i>Parasomnias</i>		
Abnormal dreams	159	0
Abnormal sleep-related event	1	0
Confusional arousal	1	0
Exploding head syndrome	2	0
Nightmare	177	0
Parasomnia	1	0
Sleep inertia	1	0
Sleep talking	6	0
Sleep terror	20	0
Somnambulism	5	0
<i>Perception disturbances NEC</i>		
Autoscopy	16	0
Deja vu	2	0
Derealisation	8	0
Flashback	3	0
Illusion	2	0
Near death experience	1	0
Time perception altered	2	0
<i>Personality disorders NEC</i>		
Personality disorder	1	0
<i>Pervasive developmental disorders NEC</i>		
Autism spectrum disorder	3	0
<i>Psychiatric elimination disorders</i>		
Enuresis	19	0
<i>Psychiatric symptoms NEC</i>		
Hypervigilance	9	0
Psychiatric symptom	4	0
Psychological trauma	2	0
Trance	1	0
<i>Psychotic disorder NEC</i>		
Acute psychosis	1	0
Psychotic behaviour	1	0
Psychotic disorder	22	0
<i>Schizophrenia NEC</i>		
Schizophrenia	1	0
<i>Sexual arousal disorders</i>		
Disturbance in sexual arousal	3	0
Sexual inhibition	1	0
<i>Sexual desire disorders</i>		
Hypersexuality	1	0
Libido decreased	13	0
Libido increased	6	0
Loss of libido	15	0
<i>Sexual dysfunction NEC</i>		
Genito-pelvic pain/penetration disorder	1	0
<i>Sleep disorders NEC</i>		

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Reaction Name	Total	Fatal
Psychiatric disorders Psychiatric disorders cont'd		
Sleep disorder	181	0
Sleep disorder due to general medical condition, insomnia type	3	0
<i>Somatic symptom disorders</i>		
Conversion disorder	20	0
Habit cough	16	0
Somatic symptom disorder	1	0
Vomiting psychogenic	1	0
<i>Speech and language usage disturbances</i>		
Disorganised speech	7	0
Logorrhoea	2	0
<i>Speech articulation and rhythm disturbances</i>		
Dysphemia	24	0
Lack of spontaneous speech	1	0
Pressure of speech	1	0
<i>Stereotypies and automatisms</i>		
Bruxism	10	0
Head banging	8	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	3	0
Nicotine dependence	2	0
<i>Suicidal and self-injurious behaviour</i>		
Completed suicide	1	1
Intentional self-injury	6	0
Self-injurious ideation	2	0
Suicidal ideation	35	0
Suicide attempt	8	0
Suicide threat	1	0
<i>Thinking disturbances</i>		
Bradyphrenia	38	0
Intrusive thoughts	6	0
Morbid thoughts	1	0
Tachyphrenia	5	0
Thinking abnormal	19	0
Thought blocking	1	0
<i>Tic disorders</i>		
Tic	9	0
Psychiatric disorders SOC TOTAL	7039	1

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder discomfort	2	0
Bladder irritation	7	0
Bladder pain	26	0
Dysuria	44	0
Incontinence	22	0
Lower urinary tract symptoms	2	0
Micturition disorder	2	0
Micturition urgency	38	0
Pollakiuria	110	0
Stress urinary incontinence	1	0
Urethral pain	7	0
Urge incontinence	1	0
Urinary hesitation	1	0
Urinary incontinence	45	0
Urinary retention	33	0
Urine flow decreased	11	0
<i>Bladder disorders NEC</i>		
Bladder disorder	7	0
Bladder fibrosis	1	0
Bladder prolapse	1	0
Urinary bladder haemorrhage	2	0
<i>Bladder infections and inflammations</i>		
Cystitis interstitial	5	0
Cystitis noninfective	1	0
<i>Genital and urinary tract disorders NEC</i>		
Genitourinary symptom	1	0
Urinary tract disorder	4	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
Glomerulonephritis minimal lesion	5	0
Glomerulonephritis rapidly progressive	2	0
IgA nephropathy	3	0
Nephrotic syndrome	17	0
<i>Myoneurogenic bladder disorders</i>		
Bladder dysfunction	5	0
Hypertonic bladder	1	0
Hypotonic urinary bladder	1	0
Loss of bladder sensation	2	0
Neurogenic bladder	2	0
<i>Nephritis NEC</i>		
Lupus nephritis	1	0
Nephritis	2	0
Tubulointerstitial nephritis	2	0
<i>Nephropathies and tubular disorders NEC</i>		
Nephropathy	1	0
<i>Renal disorders NEC</i>		
Renal disorder	4	1
Renal haemorrhage	1	0
Renal mass	1	0
<i>Renal failure and impairment</i>		
Acute kidney injury	41	4
Anuria	3	0
Chronic kidney disease	4	0

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Reaction Name	Total	Fatal
Renal & urinary disorders Renal & urinary disorders cont'd		
Oliguria	1	0
Renal failure	17	1
Renal impairment	21	0
Renal injury	1	0
Renal lithiasis		
Nephrolithiasis	9	0
Renal neoplasms		
Renal cyst	1	0
Renal obstructive disorders		
Hydronephrosis	2	0
Renal structural abnormalities and trauma		
Kidney small	1	0
Renal vascular and ischaemic conditions		
Renal infarct	1	0
Renal tubular necrosis	1	0
Renal vasculitis	1	1
Structural and obstructive urethral disorders (excl congenital)		
Urethral stenosis	1	0
Ureteric disorders NEC		
Ureteric stenosis	1	0
Urinary abnormalities		
Albuminuria	1	0
Chromaturia	44	0
Haematuria	31	0
Ketonuria	1	0
Myoglobinuria	1	0
Proteinuria	11	0
Urine abnormality	9	0
Urine odour abnormal	8	0
Urinary tract lithiasis (excl renal)		
Calculus urinary	1	0
Urinary tract signs and symptoms NEC		
Costovertebral angle tenderness	1	0
Cystitis-like symptom	1	0
Haemorrhage urinary tract	20	0
Nocturia	3	0
Polyuria	7	0
Renal colic	4	0
Renal pain	244	0
Urinary tract discomfort	1	0
Urinary tract pain	4	0
Renal & urinary disorders SOC TOTAL	922	7

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Benign and malignant breast neoplasms</i>		
Breast cyst	9	0
<i>Breast disorders NEC</i>		
Breast disorder	1	0
Breast enlargement	25	0
Breast mass	101	0
Gynaecomastia	3	0
Mastoptosis	1	0
Nipple disorder	1	0
<i>Breast infections and inflammations</i>		
Breast inflammation	1	0
Nipple inflammation	2	0
<i>Breast signs and symptoms</i>		
Breast discharge	3	0
Breast discomfort	9	0
Breast engorgement	8	0
Breast haematoma	1	0
Breast oedema	5	0
Breast pain	557	0
Breast swelling	124	0
Breast tenderness	65	0
Nipple pain	36	1
Nipple swelling	4	0
<i>Cervix disorders NEC</i>		
Cervical dysplasia	2	0
Cervix disorder	1	0
Cervix haemorrhage uterine	4	0
Ectropion of cervix	2	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	2	0
Ejaculation failure	3	0
Erectile dysfunction	49	0
Erection increased	2	0
Organic erectile dysfunction	12	0
Painful ejaculation	1	0
Spontaneous ejaculation	1	0
<i>Fallopian tube and ovary infections and inflammations</i>		
Noninfective oophoritis	2	0
<i>Lactation disorders</i>		
Breast milk discolouration	3	0
Breast milk odour abnormal	1	0
Galactorrhoea	5	0
Galactostasis	1	0
Lactation disorder	7	0
Lactation puerperal increased	4	0
Suppressed lactation	38	0
<i>Menopausal effects NEC</i>		
Artificial menopause	1	0
Menopausal disorder	1	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders Reproductive & breast disorders cont'd		
Menopausal symptoms	21	0
Menopause delayed	1	0
Premature menopause	12	0
Menopausal effects on the genitourinary tract		
Atrophic vulvovaginitis	1	0
Postmenopausal haemorrhage	82	0
Menstruation and uterine bleeding NEC		
Abnormal uterine bleeding	6	0
Abnormal withdrawal bleeding	1	0
Dysmenorrhoea	2489	0
Intermenstrual bleeding	935	0
Menstrual discomfort	23	0
Menstrual disorder	1529	0
Menstruation irregular	2744	0
Premenstrual dysphoric disorder	9	0
Premenstrual headache	7	0
Premenstrual pain	97	0
Premenstrual syndrome	101	0
Retrograde menstruation	1	0
Withdrawal bleed	15	0
Menstruation with decreased bleeding		
Amenorrhoea	492	0
Hypomenorrhoea	561	0
Menstruation delayed	4237	0
Oligomenorrhoea	133	0
Menstruation with increased bleeding		
Heavy menstrual bleeding	4710	0
Menometrorrhagia	17	0
Polymenorrhoea	721	0
Ovarian and fallopian tube cysts and neoplasms		
Ovarian cyst	16	0
Ovarian cyst ruptured	1	0
Polycystic ovaries	41	0
Ovarian and fallopian tube disorders NEC		
Adnexal torsion	1	0
Hydrosalpinx	2	0
Ovarian enlargement	1	0
Ovarian haemorrhage	5	0
Ovulation disorder	2	0
Ovulation pain	57	0
Premature ovulation	4	0
Pelvis and broad ligament disorders NEC		
Adnexa uteri mass	1	0
Adnexa uteri pain	44	0
Pelvic congestion	1	0
Pelvic floor muscle weakness	1	0
Pelvic haemorrhage	17	0
Penile and scrotal infections and inflammations		
Balanoposthitis	2	0
Penile disorders NEC (excl erection and ejaculation)		
Penile blister	1	0
Penile discharge	1	0
Penile discomfort	1	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders Reproductive & breast disorders cont'd		
Penile erythema	1	0
Penile haemorrhage	2	0
Penile pain	1	0
Penile swelling	4	0
Penis disorder	8	0
Prostate and seminal vesicles infections and inflammations		
Prostatitis	3	0
Prostatic signs, symptoms and disorders NEC		
Prostatic pain	1	0
Prostatomegaly	3	0
Reproductive tract disorders NEC (excl neoplasms)		
Genital haemorrhage	22	0
Genital hypoaesthesia	1	0
Genital lesion	1	0
Genital paraesthesia	1	0
Genital ulceration	5	0
Perineal ulceration	1	0
Reproductive tract infections and inflammations NEC		
Genital tract inflammation	1	0
Reproductive tract signs and symptoms NEC		
Genital burning sensation	2	0
Genital erythema	1	0
Genital pain	4	0
Genital rash	4	0
Genital swelling	3	0
Pelvic discomfort	5	0
Pelvic pain	87	0
Perineal pain	2	0
Perineal rash	1	0
Pruritus genital	3	0
Scrotal disorders NEC		
Acquired hydrocele	1	0
Scrotal angiokeratoma	1	0
Scrotal discomfort	1	0
Scrotal erythema	1	0
Scrotal exfoliation	1	0
Scrotal pain	18	0
Scrotal swelling	4	0
Varicocele	1	0
Sexual function and fertility disorders NEC		
Dyspareunia	5	0
Infertility	7	0
Infertility female	1	0
Sexual dysfunction	6	0
Spermatogenesis and semen disorders		
Aspermia	1	0
Haemospermia	6	0
Semen discolouration	1	0
Testicular and epididymal disorders NEC		
Testicular disorder	3	0
Testicular pain	50	0
Testicular swelling	8	0
Testis discomfort	1	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders Reproductive & breast disorders cont'd		
<i>Uterine disorders NEC</i>		
Adenomyosis	7	0
Endometrial thickening	3	0
Endometriosis	72	0
Uterine haemorrhage	28	0
Uterine pain	13	0
<i>Uterine infections and inflammations (excl cervix)</i>		
Uterine inflammation	1	0
<i>Uterine neoplasms</i>		
Uterine polyp	4	0
<i>Uterine tone disorders</i>		
Uterine spasm	29	0
<i>Vulvovaginal cysts and neoplasms</i>		
Bartholin's cyst	1	0
Vaginal cyst	6	0
Vaginal polyp	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	1293	0
Vaginal mucosal blistering	1	0
Vaginal ulceration	1	0
Vulval disorder	1	0
Vulval haemorrhage	23	0
Vulval ulceration	7	0
Vulvovaginal ulceration	3	0
<i>Vulvovaginal signs and symptoms</i>		
Clitoral engorgement	1	0
Coital bleeding	4	0
Labia enlarged	1	0
Vaginal discharge	67	0
Vaginal lesion	1	0
Vaginal odour	2	0
Vulval oedema	1	0
Vulvovaginal burning sensation	4	0
Vulvovaginal dryness	3	0
Vulvovaginal erythema	1	0
Vulvovaginal pain	23	0
Vulvovaginal pruritus	7	0
Vulvovaginal rash	2	0
Vulvovaginal swelling	3	0
Reproductive & breast disorders SOC TOTAL	22142	1

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	5	0
Apnoeic attack	1	0
Dyspnoea	3821	5
Dyspnoea at rest	11	0
Dyspnoea exertional	33	1
Hyperventilation	42	0
Hypopnoea	93	0
Hypoventilation	1	0
Irregular breathing	18	0
Mouth breathing	3	0
Nocturnal dyspnoea	2	0
Orthopnoea	3	0
Respiration abnormal	47	0
Respiratory arrest	12	0
Respiratory depression	1	0
Respiratory distress	17	0
Sleep apnoea syndrome	11	0
Tachypnoea	23	0
<i>Bronchial conditions NEC</i>		
Bronchial secretion retention	4	0
Bronchiectasis	12	0
<i>Bronchospasm and obstruction</i>		
Asthma	299	0
Asthma late onset	2	0
Bronchospasm	15	0
Chronic obstructive pulmonary disease	16	1
Cough variant asthma	4	0
Obstructive airways disorder	9	0
Reversible airways obstruction	1	0
Wheezing	349	0
<i>Conditions associated with abnormal gas exchange</i>		
Asphyxia	1	0
Cyanosis central	1	0
Hyperoxia	1	0
Hypoxia	22	1
Respiratory acidosis	2	0
<i>Coughing and associated symptoms</i>		
Allergic cough	6	0
Cough	2102	3
Cough decreased	2	0
Haemoptysis	50	0
Productive cough	141	0
Sputum discoloured	7	0
Sputum increased	2	0
<i>Diaphragmatic disorders</i>		
Acquired diaphragmatic eventration	1	0
Diaphragm muscle weakness	1	0
<i>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</i>		
Laryngeal disorder	1	0
Reflux laryngitis	1	0
Vocal cord disorder	1	0

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Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Vocal cord dysfunction	1	0
Laryngeal spasm, oedema and obstruction		
Epiglottic oedema	1	0
Laryngeal obstruction	1	0
Laryngeal oedema	2	0
Laryngospasm	1	0
Stridor	21	0
Lower respiratory tract inflammatory and immunologic conditions		
Alveolitis	1	0
Hypersensitivity pneumonitis	1	0
Lower respiratory tract inflammation	1	0
Pneumonia aspiration	8	5
Pneumonitis	27	1
Pulmonary sarcoidosis	2	0
Lower respiratory tract signs and symptoms		
Hiccups	27	0
Increased bronchial secretion	2	0
Increased viscosity of bronchial secretion	1	0
Lung hyperinflation	1	0
Lung opacity	2	0
Pleuritic pain	18	0
Pulmonary haemorrhage	1	0
Pulmonary pain	77	0
Rales	4	0
Respiratory fremitus	1	0
Mediastinal disorders		
Mediastinal mass	1	0
Pulmonary hilum mass	1	0
Nasal congestion and inflammations		
Nasal congestion	249	0
Nasal inflammation	2	0
Rhinitis allergic	18	0
Nasal disorders NEC		
Epistaxis	785	0
Intranasal hyposaesthesia	1	0
Intranasal paraesthesia	1	0
Nasal crusting	1	0
Nasal disorder	3	0
Nasal dryness	32	0
Nasal mucosal discolouration	1	0
Nasal odour	6	0
Nasal oedema	6	0
Nasal polyps	1	0
Nasal pruritus	9	0
Neonatal hypoxic conditions		
Dry lung syndrome	1	0
Gasping syndrome	1	0
Infantile apnoea	1	0
Paranasal sinus disorders (excl infections and neoplasms)		
Allergic sinusitis	1	0
Paranasal sinus inflammation	3	0
Sinonasal obstruction	9	0
Sinus congestion	53	0

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Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Sinus disorder	6	0
<i>Parenchymal lung disorders NEC</i>		
Atelectasis	3	0
Combined pulmonary fibrosis and emphysema	1	0
Emphysema	2	0
Interstitial lung disease	9	0
Lung consolidation	1	0
Lung infiltration	1	0
Pulmonary alveolar haemorrhage	1	0
Pulmonary cavitation	1	0
Pulmonary fibrosis	5	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal enanthema	1	0
Pharyngeal erythema	6	0
Pharyngeal haemorrhage	2	0
Pharyngeal hypoaesthesia	31	0
Pharyngeal inflammation	4	0
Pharyngeal mass	1	0
Pharyngeal oedema	13	0
Pharyngeal paraesthesia	51	0
Pharyngeal swelling	222	0
Pharyngeal ulceration	14	0
Tonsillar erythema	9	0
Tonsillar haemorrhage	1	0
Tonsillar hypertrophy	68	0
Tonsillar inflammation	3	0
Tonsillar ulcer	1	0
Tonsillolith	1	0
<i>Pleural infections and inflammations</i>		
Pleurisy	30	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	21	0
Pneumothorax	8	0
Pneumothorax spontaneous	2	0
<i>Pulmonary hypertensions</i>		
Pulmonary hypertension	2	0
<i>Pulmonary oedemas</i>		
Acute respiratory distress syndrome	2	1
Pulmonary congestion	11	0
Pulmonary oedema	18	1
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	380	27
Pulmonary infarction	6	0
Pulmonary thrombosis	6	1
<i>Respiratory failures (excl neonatal)</i>		
Acute respiratory failure	2	1
Respiratory failure	11	2
<i>Respiratory signs and symptoms NEC</i>		
Allergic respiratory symptom	5	0
Diaphragmalgia	5	0
Nasal flaring	1	0
Painful respiration	8	1
Pleural rub	1	0

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Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Respiratory symptom	17	0
Suffocation feeling	2	0
<i>Respiratory tract disorders NEC</i>		
Aspiration	3	0
Lung disorder	5	0
Pulmonary mass	4	0
Respiratory disorder	11	0
Respiratory tract congestion	3	0
Respiratory tract haemorrhage	1	0
Respiratory tract inflammation	2	0
Respiratory tract irritation	8	0
Respiratory tract oedema	3	0
<i>Thoracic musculoskeletal disorders</i>		
Respiratory muscle weakness	2	0
<i>Tracheal disorders (excl infections and neoplasms)</i>		
Tracheal disorder	1	0
Tracheal pain	1	0
<i>Upper respiratory tract neoplasms</i>		
Tonsillar cyst	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	98	0
Catarrh	19	0
Choking	13	0
Choking sensation	3	0
Dry throat	150	0
Dysphonia	143	0
Increased upper airway secretion	5	0
Increased viscosity of upper respiratory secretion	28	0
Nasal discharge discolouration	3	0
Nasal discomfort	44	0
Nasal obstruction	2	0
Oropharyngeal blistering	10	0
Oropharyngeal discomfort	55	0
Oropharyngeal pain	2513	0
Oropharyngeal plaque	2	0
Paranasal sinus discomfort	41	0
Rhinalgia	11	0
Rhinorrhoea	796	0
Sinus pain	183	0
Sneezing	321	0
Snoring	7	0
Throat clearing	8	0
Throat irritation	211	0
Throat tightness	232	0
Upper airway obstruction	2	0
Upper respiratory tract congestion	2	0
Upper respiratory tract irritation	1	0
Upper-airway cough syndrome	7	0
Yawning	24	0
<i>Vascular pulmonary disorders NEC</i>		
Acute chest syndrome	1	0
Respiratory disorders SOC TOTAL	14560	51

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	171	0
Acne cystic	15	0
Dermatitis acneiform	9	0
<i>Alopecias</i>		
Alopecia	215	0
Alopecia areata	35	0
Alopecia totalis	2	0
Androgenetic alopecia	1	0
Diffuse alopecia	4	0
Hypotrichosis	1	0
Madarosis	3	0
<i>Angioedemas</i>		
Angioedema	179	0
Circumoral swelling	1	0
<i>Apocrine and eccrine gland disorders</i>		
Anhidrosis	1	0
Bromhidrosis	1	0
Cold sweat	653	0
Hidradenitis	3	0
Hyperhidrosis	1892	0
Hypohidrosis	2	0
Milia	2	0
Miliaria	77	0
Night sweats	526	0
<i>Bullous conditions</i>		
Blister	401	0
Blister rupture	1	0
Blood blister	23	0
Dermatitis bullous	10	0
Erythema multiforme	37	0
Fracture blisters	1	0
Herpes gestationis	1	0
Pemphigoid	22	0
Pemphigus	7	0
Stevens-Johnson syndrome	5	0
Toxic epidermal necrolysis	2	1
<i>Connective tissue disorders</i>		
Cutaneous lupus erythematosus	1	0
Dermatomyositis	5	0
Subacute cutaneous lupus erythematosus	1	0
<i>Dermal and epidermal conditions NEC</i>		
Acute febrile neutrophilic dermatosis	1	0
Dermatosis	1	0
Dry skin	191	0
Macule	4	0
Neutrophilic dermatosis	1	0
Pain of skin	230	0
Papule	97	0
Pathergy reaction	1	0
Peau d'orange	2	0
Scab	19	0
Scar pain	12	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Sensitive skin	146	0
Shagreen skin	1	0
Skin burning sensation	188	0
Skin degenerative disorder	1	0
Skin discolouration	110	0
Skin discomfort	4	0
Skin disorder	21	0
Skin fissures	7	0
Skin indentation	2	0
Skin induration	4	0
Skin lesion	37	0
Skin lesion inflammation	1	0
Skin necrosis	2	0
Skin odour abnormal	15	0
Skin plaque	3	0
Skin reaction	122	0
Skin sensitisation	33	0
Skin swelling	73	0
Skin texture abnormal	2	0
Skin tightness	25	0
Skin warm	254	0
Skin weeping	10	0
Sticky skin	2	0
Target skin lesion	2	0
Transient acantholytic dermatosis	1	0
Yellow skin	24	0
<i>Dermatitis and eczema</i>		
Dermatitis	107	0
Dermatitis allergic	200	0
Dermatitis atopic	28	0
Dermatitis contact	16	0
Dermatitis diaper	3	0
Dyshidrotic eczema	24	0
Eczema	265	0
Eczema asteatotic	9	0
Eczema infantile	1	0
Eczema nummular	5	0
Eczema weeping	1	0
Hand dermatitis	1	0
Intertrigo	1	0
Perioral dermatitis	1	0
Seborrhoeic dermatitis	3	0
Skin irritation	102	0
Stasis dermatitis	1	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	30	0
Drug reaction with eosinophilia and systemic symptoms	1	0
Fixed eruption	2	0
Palmar-plantar erythrodysesthesia syndrome	1	0
Toxic skin eruption	2	0
<i>Erythemas</i>		
Erythema	1836	0
Palmar erythema	4	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Red man syndrome	2	0
Exfoliative conditions		
Dermatitis exfoliative	2	0
Dermatitis exfoliative generalised	5	0
Exfoliative rash	18	0
Keratolysis exfoliativa acquired	2	0
Skin exfoliation	100	0
Granulomatous and deep cutaneous inflammatory conditions		
Cutaneous sarcoidosis	1	0
Granuloma annulare	5	0
Hyperkeratoses		
Hyperkeratosis	1	0
Keratosis pilaris	3	0
Lichenoid keratosis	3	0
Hyperpigmentation disorders		
Argyria	1	0
Chloasma	1	0
Ephelides	1	0
Skin hyperpigmentation	3	0
Solar lentigo	2	0
Hypertrichoses		
Hirsutism	2	0
Hypopigmentation disorders		
Skin depigmentation	4	0
Skin hypopigmentation	1	0
Vitiligo	15	0
Lipodystrophies		
Lipoatrophy	4	0
Lipodystrophy acquired	1	0
Nail and nail bed conditions (excl infections and infestations)		
Nail discolouration	9	0
Nail disorder	2	0
Nail pigmentation	2	0
Nail ridging	3	0
Onychalgia	7	0
Onychoclasia	4	0
Onychomadesis	2	0
Splinter haemorrhages	3	0
Panniculitides		
Erythema nodosum	22	0
Panniculitis	1	0
Papulosquamous conditions		
Erythema annulare	2	0
Lichen planus	16	0
Lichen sclerosus	8	0
Parapsoriasis	2	0
Pityriasis rosea	102	0
Photosensitivity and photodermatosis conditions		
Photosensitivity reaction	56	0
Polymorphic light eruption	2	0
Solar dermatitis	1	0
Pigmentation changes NEC		
Haemosiderin stain	1	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Pigmentation disorder	13	0
<i>Pilar disorders NEC</i>		
Hair colour changes	8	0
Hair disorder	1	0
Hair growth abnormal	5	0
Hair texture abnormal	5	0
Piloerection	24	0
Pseudofolliculitis	3	0
Trichorrhexis	2	0
<i>Pruritus NEC</i>		
Itching scar	5	0
Pruritus	4532	0
<i>Psoriatic conditions</i>		
Dermatitis psoriasiform	3	0
Guttate psoriasis	14	0
Nail psoriasis	1	0
Palmoplantar pustulosis	2	0
Psoriasis	155	0
Pustular psoriasis	2	0
<i>Purpura and related conditions</i>		
Ecchymosis	1	0
Henoch-Schonlein purpura	8	0
Petechiae	122	0
Purpura	44	0
<i>Pustular conditions</i>		
Acute generalised exanthematous pustulosis	1	0
<i>Rashes, eruptions and exanthems NEC</i>		
Butterfly rash	4	0
Rash	4816	1
Rash erythematous	1010	0
Rash macular	447	0
Rash maculo-papular	55	0
Rash morbilliform	41	0
Rash papular	298	0
Rash pruritic	1013	0
Rash vesicular	65	0
Systemic lupus erythematosus rash	6	0
<i>Rosaceas</i>		
Rosacea	27	0
<i>Scaly conditions</i>		
Dandruff	4	0
Pityriasis	21	0
<i>Sebaceous gland disorders</i>		
Seborrhoea	9	0
<i>Skin and subcutaneous conditions NEC</i>		
Cutaneous symptom	4	0
Reactive perforating collagenosis	1	0
Skin mass	18	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

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Skin erosion	20	0
Skin ulcer	17	0
Skin cysts and polyps		
Dermal cyst	13	0
Skin dystrophies		
Keloid scar	3	0
Skin wrinkling	2	0
Skin haemorrhages		
Haemorrhage subcutaneous	8	0
Skin haemorrhage	15	0
Skin hyperplasias and hypertrophies		
Skin hypertrophy	2	0
Skin hypoplasias and atrophies		
Skin atrophy	2	0
Skin striae	7	0
Skin injuries and mechanical dermatoses		
Decubitus ulcer	2	0
Needle track marks	3	0
Skin preneoplastic conditions NEC		
Actinic keratosis	1	0
Skin vascular conditions NEC		
Skin oedema	4	0
Skin vasculitides		
Capillaritis	2	0
Cutaneous vasculitis	13	0
Hypersensitivity vasculitis	1	0
Vasculitic rash	18	0
Skin vasomotor conditions		
Livedo reticularis	20	0
Telangiectasia and related conditions		
Spider naevus	1	0
Telangiectasia	1	0
Urticarias		
Chronic spontaneous urticaria	6	0
Cold urticaria	5	0
Idiopathic urticaria	1	0
Mechanical urticaria	7	0
Solar urticaria	2	0
Urticaria	1568	0
Urticaria cholinergic	1	0
Urticaria chronic	16	0
Urticaria contact	1	0
Urticaria papular	4	0
Urticaria thermal	4	0
Urticularial vasculitis	3	0
Skin disorders SOC TOTAL	23592	2

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Reaction Name	Total	Fatal
Social circumstances		
<i>Age related issues</i>		
Infant	3	0
Menarche	1	0
Menopause	31	0
Postmenopause	3	0
<i>Criminal activity</i>		
Verbal abuse	1	0
<i>Dependents</i>		
Sick relative	2	0
<i>Dietary and nutritional issues</i>		
Feeding tube user	1	0
<i>Disability issues</i>		
Bedridden	21	0
Breast prosthesis user	3	0
Disability	2	0
Hearing disability	1	0
Housebound	1	0
Immobile	12	0
Impaired driving ability	4	0
Impaired work ability	11	0
Loss of personal independence in daily activities	39	0
Physical disability	4	0
Sight disability	10	0
Sitting disability	3	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	1	0
<i>Employment issues</i>		
Retirement	4	0
Stress at work	1	0
<i>Family and partner issues</i>		
Bed sharing	1	0
<i>Non-occupational and unspecified environmental problems</i>		
Flooding	1	0
Water pollution	2	0
<i>Pregnancy related circumstances</i>		
Breast feeding	14	0
Multigravida	1	0
Parity	1	0
<i>Social issues NEC</i>		
Exercise adequate	1	0
Hair dye user	2	0
Impaired quality of life	2	0
<i>Tobacco use</i>		
Ex-tobacco user	1	0
Non-tobacco user	3	0
Tobacco user	1	0
Social circumstances SOC TOTAL	194	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Anaesthesia and allied procedures</i>		
Local anaesthesia	2	0
Nerve block	4	0
<i>Analgesia supportive care</i>		
Analgesic therapy	1	0
<i>Antiinfective therapies</i>		
COVID-19 prophylaxis	1	0
COVID-19 treatment	3	0
<i>Arterial therapeutic procedures (excl aortic)</i>		
Splenic artery embolisation	1	0
<i>Autonomic nerve therapeutic procedures</i>		
Vagotomy	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	7	0
Wheat-free diet	1	0
<i>External ear therapeutic procedures</i>		
Ear irrigation	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	13	0
<i>Gynaecological therapeutic procedures NEC</i>		
Menstrual cycle management	11	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>		
COVID-19 immunisation	87	0

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Reaction Name	Total	Fatal
Surgical & medical procedures Surgical & medical procedures cont'd		
Immunisation	64	1
Induced abortions		
Abortion induced	1	0
Joint therapeutic procedures		
Joint injection	2	0
Joint surgery	1	0
Knee arthroplasty	1	0
Large intestine therapeutic procedures		
Appendectomy	4	0
Limb therapeutic procedures		
Limb immobilisation	8	0
Limb operation	5	0
Lymphoid tissue therapeutic procedures		
Lymphadenectomy	2	0
Splenectomy	1	0
Mastectomies		
Breast conserving surgery	3	0
Nail therapeutic procedures		
Nail operation	3	0
Nervous system therapeutic procedures NEC		
Multiple sclerosis relapse prophylaxis	2	0
Obstetric therapeutic procedures		
Labour stimulation	1	0
Orbit and globe therapeutic procedures		
Strabismus correction	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
Therapeutic skin care topical	1	0
Skull and brain therapeutic procedures		
Cerebrovascular operation	1	0
Posterior fossa decompression	1	0
Therapeutic bladder catheterisation		
Bladder catheterisation	2	0
Therapeutic procedures NEC		
Abscess drainage	1	0

Case Series Drug Analysis Print

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

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Reaction Name	Total	Fatal
Surgical & medical procedures		
Surgical & medical procedures cont'd		
Anaphylaxis treatment	5	0
Bed rest	2	0
Fatigue management	1	0
Hospitalisation	10	0
Injection	39	0
Interchange of vaccine products	8	0
Localised alternating hot and cold therapy	1	0
Magnetic therapy	1	0
Mass excision	2	0
Medical procedure	1	0
Medication dilution	2	0
Physical fitness training	1	0
Product used for unknown indication	2	0
Specialist consultation	1	0
Therapeutic procedure	1	0
Therapy change	1	0
Tracheal therapeutic procedures		
Tracheostomy	1	0
Uterine therapeutic procedures		
Endometrial ablation	2	0
Surgical & medical procedures SOC TOTAL	374	1

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Accelerated and malignant hypertension</i>		
Hypertensive crisis	10	0
Hypertensive urgency	1	0
Malignant hypertension	3	0
<i>Aneurysms and dissections non-site specific</i>		
Aneurysm	2	0
Artery dissection	1	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	2	0
<i>Aortic necrosis and vascular insufficiency</i>		
Aortic occlusion	1	0
<i>Arterial infections and inflammations</i>		
Arteritis	1	0
Giant cell arteritis	11	0
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	10	0
Labile blood pressure	3	0
<i>Bruising, ecchymosis and purpura</i>		
Achenbach syndrome	3	0
<i>Circulatory collapse and shock</i>		
CT hypotension complex	2	0
Circulatory collapse	59	0
Hypoperfusion	2	0
Hypovolaemic shock	1	1
Neurogenic shock	21	0
Peripheral circulatory failure	5	0
Shock	17	0
<i>Haemorrhages NEC</i>		
Bloody discharge	20	0
Haematoma	38	0
Haemorrhage	1064	2
Internal haemorrhage	7	0
Venous haemorrhage	2	0
<i>Lymphangiopathies</i>		
Lymphangiopathy	1	0
Lymphocele	4	0
<i>Lymphoedemas</i>		
Lymphoedema	166	0
<i>Non-site specific embolism and thrombosis</i>		
Arterial thrombosis	4	0
Embolism	60	0
Embolism venous	5	0
Microembolism	1	0
Thrombosis	362	7
Venous thrombosis	6	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Arterial occlusive disease	2	0
Arterial spasm	1	0

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Reaction Name	Total	Fatal
Vascular disorders <small>Vascular disorders cont'd</small>		
Arteriosclerosis	2	0
Haemorrhagic infarction	1	0
Infarction	3	0
Ischaemia	9	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	1	0
Superficial vein prominence	1	0
Vascular pain	29	0
Vascular wall hypertrophy	1	0
Vasodilatation	33	0
Vein discolouration	5	0
Vein disorder	6	0
Vein rupture	5	0
<i>Peripheral embolism and thrombosis</i>		
Axillary vein thrombosis	1	0
Blue toe syndrome	24	0
Deep vein thrombosis	247	1
Femoral artery embolism	1	0
Jugular vein thrombosis	3	0
Pelvic venous thrombosis	4	0
Peripheral artery thrombosis	1	0
Peripheral embolism	1	0
Subclavian vein thrombosis	3	0
Thrombophlebitis	19	0
Thrombophlebitis superficial	13	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	37	0
Erythromelalgia	1	0
Flushing	371	0
Hot flush	1012	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	1	0
Jugular vein occlusion	1	0
Peripheral arterial occlusive disease	2	0
Peripheral artery occlusion	1	0
Peripheral coldness	275	0
Peripheral ischaemia	12	0
Poor peripheral circulation	13	0
Raynaud's phenomenon	50	0
Subclavian vein occlusion	1	0
Vasoconstriction	2	0
<i>Phlebitis NEC</i>		
Phlebitis	28	0

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Reaction Name	Total	Fatal
Vascular disorders <small>Vascular disorders cont'd</small>		
Phlebitis superficial	6	0
Site specific vascular disorders NEC		
Inferior vena cava dilatation	1	0
Pallor	313	0
Varicose veins NEC		
Spider vein	5	0
Varicophlebitis	4	0
Varicose vein	26	0
Vascular hypertensive disorders NEC		
Diastolic hypertension	2	0
Essential hypertension	3	0
Hypertension	485	1
Labile hypertension	1	0
Orthostatic hypertension	1	0
Secondary hypertension	1	0
Systolic hypertension	5	0
White coat hypertension	1	0
Vascular hypotensive disorders		
Hypotension	344	1
Orthostatic hypotension	30	0
Vasculitides NEC		
Behcet's syndrome	3	0
Diffuse vasculitis	1	0
Granulomatosis with polyangiitis	2	0
MAGIC syndrome	1	0
Thromboangiitis obliterans	1	0
Vasculitis	43	0
Vena caval embolism and thrombosis		
Vena cava embolism	1	0
Vena cava thrombosis	1	0
Vascular disorders SOC TOTAL	5421	14
TOTAL REACTIONS FOR DRUG	339672	562
TOTAL REPORTS	120578	
TOTAL FATAL OUTCOME REPORTS		562