

COVID-19 mRNA Pfizer- BioNTech Vaccine Analysis Print

All UK spontaneous reports received between 9/12/20 and 22/09/21 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

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 24-Sep-2021

Data Lock Date: 22-Sep-2021 18:30:09

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	6	0
<i>Anaemias NEC</i>		
Anaemia	97	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	35	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	21	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	1407	0
Lymph node ulcer	1	0
Lymphadenitis	116	0
Lymphadenopathy	9042	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	68	0
Thrombocytopenia	173	1
Thrombocytopenic purpura	5	0
Thrombotic thrombocytopenic purpura	5	0
<i>Thrombocytoses</i>		
Thrombocytosis	6	0
Blood disorders SOC TOTAL	11182	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	43	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	2	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	2730	0
<i>Cardiac valve disorders NEC</i>		
Cardiac valve disease	2	0
Heart valve incompetence	1	0
<i>Cardiomyopathies</i>		
Cardiomyopathy	3	0
Congestive cardiomyopathy	5	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	58	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	162	0
Angina unstable	2	0
Arteriospasm coronary	1	0

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Reaction Name	Total	Fatal
Cardiac disorders Cardiac disorders cont'd		
Microvascular coronary artery disease	2	0
Myocardial infarction	177	29
Myocardial ischaemia	6	2
Left ventricular failures		
Acute left ventricular failure	1	1
Left ventricular failure	6	2
Mitral valvular disorders		
Mitral valve incompetence	4	0
Mitral valve prolapse	1	0
Myocardial disorders NEC		
Cardiac amyloidosis	1	0
Cardiomegaly	24	1
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	308	2
Noninfectious pericarditis		
Pericarditis	230	1
Pericardial disorders NEC		
Pericardial effusion	25	0
Pericardial haemorrhage	3	3
Pericardial rub	1	0
Rate and rhythm disorders NEC		
Arrhythmia	104	0
Bradycardia	53	0
Bradycardia foetal	2	1
Cardiac flutter	343	0
Extrasystoles	126	0
Paroxysmal arrhythmia	1	0
Postural orthostatic tachycardia syndrome	16	0
Tachyarrhythmia	1	0
Tachycardia	634	0
Tachycardia paroxysmal	1	0
Right ventricular failures		
Cor pulmonale	1	0
Supraventricular arrhythmias		
Arrhythmia supraventricular	10	0
Atrial fibrillation	161	0
Atrial flutter	17	0
Atrial tachycardia	6	0
Nodal arrhythmia	1	0
Sinus arrest	1	0
Sinus arrhythmia	2	0
Sinus bradycardia	8	0
Sinus node dysfunction	1	0

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Cardiac disorders Cardiac disorders cont'd		
Sinus tachycardia	46	0
Supraventricular extrasystoles	2	0
Supraventricular tachycardia	33	0
<i>Tricuspid valvular disorders</i>		
Tricuspid valve incompetence	3	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	87	32
Cardio-respiratory arrest	1	1
Pulseless electrical activity	3	0
Ventricular arrhythmia	4	0
Ventricular extrasystoles	17	0
Ventricular fibrillation	6	1
Ventricular tachycardia	10	0
Cardiac disorders SOC TOTAL	5620	95

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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	2	0
<i>Chemically-induced congenital syndromes</i>		
Foetal warfarin syndrome	1	0
<i>Coagulation disorders congenital</i>		
Haemophilia	1	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	1	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>Musculoskeletal disorders congenital NEC</i>		
Congenital multiplex arthrogryposis	1	0
<i>Neurological disorders congenital NEC</i>		
Familial hemiplegic migraine	2	0
Familial periodic paralysis	1	0

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Reaction Name	Total	Fatal
Congenital disorders Congenital disorders cont'd		
Moebius II syndrome	1	0
Tourette's disorder	2	0
Ocular disorders congenital NEC		
Colour blindness	3	0
Palate disorders congenital		
Cleft lip and palate	1	0
Peripheral nervous system disorders congenital NEC		
Hereditary neuropathy with liability to pressure palsies	1	0
Paroxysmal extreme pain disorder	1	0
Pulmonary and bronchial disorders congenital		
Congenital cystic lung	1	0
Retinal disorders congenital		
Retinitis pigmentosa	1	0
Skin and subcutaneous tissue disorders congenital NEC		
Acral peeling skin syndrome	1	0
Tongue disorders congenital		
Ankyloglossia congenital	1	0
Congenital disorders SOC TOTAL	63	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	831	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	203	0
Deafness bilateral	6	0
Deafness neurosensory	15	0
Deafness transitory	6	0
Deafness unilateral	28	0
Hypoacusis	157	0
Sudden hearing loss	37	0
<i>Hyperacusia</i>		
Hyperacusis	48	0
Misophonia	3	0
<i>Inner ear disorders NEC</i>		
Acute vestibular syndrome	1	0
Inner ear disorder	9	0
Meniere's disease	10	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	47	0
Tinnitus	1652	0
Vertigo	1171	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	4546	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	10	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	3	0
Premature menarche	15	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	7	0
Hyperthyroidism	28	0
Thyrotoxic crisis	3	0
<i>Thyroid hypofunction disorders</i>		
Autoimmune hypothyroidism	1	0
Hypothyroidism	24	0
Myxoedema	1	0
Endocrine disorders SOC TOTAL	219	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	70	0
<i>Colour blindness (incl acquired)</i>		
Dyschromatopsia	8	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	33	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	125	0
Excessive eye blinking	5	0
Eyelid function disorder	3	0
Eyelid myokymia	4	0
Eyelid ptosis	39	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	12	0
Iritis	5	0
Uveitis	40	0
<i>Lacrimation disorders</i>		
Dry eye	124	0
Lacrimation increased	111	0
<i>Lid bleeding and vascular disorders</i>		
Eyelid bleeding	1	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Blepharitis	11	0
Chalazion	7	0
Eczema eyelids	5	0
Erythema of eyelid	7	0
Eyelid cyst	4	0

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Eye disorders Eye disorders cont'd		
Eyelid irritation	2	0
Eyelid margin crusting	3	0
Eyelid oedema	4	0
Eyelid rash	15	0
Swelling of eyelid	108	0
Swollen tear duct	1	0
Lid, lash and lacrimal structural disorders		
Dermatochalasis	1	0
Eyelash changes	1	0
Eyelid exfoliation	2	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	23	0
Ocular vascular disorder	1	0
Ophthalmic vein thrombosis	1	0
Ocular disorders NEC		
Dark circles under eyes	6	0
Eye disorder	30	0
Eye oedema	12	0
Eye pain	902	0
Eye swelling	423	0
Eye symptom	9	0
Eye ulcer	3	0
Eyelid disorder	11	0
Eyelid pain	10	0
Eyelids pruritus	5	0
Ocular discomfort	25	0
Periorbital oedema	16	0
Periorbital pain	1	0
Periorbital swelling	105	0
Retinal disorder	2	0
Vitreous disorder	1	0
Ocular infections, inflammations and associated manifestations		
Eye allergy	11	0
Eye discharge	23	0
Eye inflammation	22	0
Eye irritation	81	0
Eye pruritus	203	0
Limbal swelling	2	0
Ocular hyperaemia	186	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	30	0
Gaze palsy	1	0
Ocular myasthenia	1	0
Ophthalmoplegia	3	0

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Eye disorders Eye disorders cont'd		
Strabismus	5	0
Ocular sensation disorders		
Abnormal sensation in eye	16	0
Asthenopia	130	0
Eye paraesthesia	2	0
Foreign body sensation in eyes	16	0
Hypoaesthesia eye	14	0
Photophobia	382	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	5	0
Retinal vascular thrombosis	1	0
Retinal vein occlusion	30	0
Retinal vein thrombosis	2	0
Retinal structural change, deposit and degeneration		
Macular degeneration	3	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	1	0
Cystoid macular oedema	1	0
Macular oedema	3	0
Retinal vasculitis	3	0
Retinopathies NEC		
Acute macular outer retinopathy	1	0
Retinal exudates	2	0

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Eye disorders Eye disorders cont'd		
Retinopathy	2	0
Scleral infections, irritations and inflammations		
Episcleritis	7	0
Scleritis	3	0
Scleral structural change, deposit and degeneration		
Scleral discolouration	2	0
Visual colour distortions		
Chloropsia	2	0
Chromatopsia	1	0
Cyanopsia	2	0
Erythropsia	2	0
Xanthopsia	1	0
Visual disorders NEC		
Charles Bonnet syndrome	1	0
Diplopia	135	0
Glare	1	0
Halo vision	7	0
Heteronymous diplopia	1	0
Metamorphopsia	16	0
Oscillopsia	2	0
Photopsia	112	0
Scintillating scotoma	4	0
Vision blurred	1018	0
Visual brightness	3	0
Visual snow syndrome	7	0
Visual field disorders		
Visual field defect	20	0
Visual impairment and blindness (excl colour blindness)		
Amaurosis fugax	2	0
Blindness	106	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	290	0
Visual pathway disorders		
Optic nerve disorder	1	0
Eye disorders SOC TOTAL	5488	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	12	0
Pancreatitis acute	12	1
Pancreatitis necrotising	1	0
<i>Anal and rectal disorders NEC</i>		
Anal fissure	2	0
Anal sphincter atony	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	34	1
Colitis ischaemic	1	0
Colitis microscopic	1	0
Colitis ulcerative	60	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	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	132	0
<i>Dental surface disorders</i>		
Tooth discolouration	9	0

Case Series Drug Analysis Print

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Report Run Date: 24-Sep-2021

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Diaphragmatic hernias</i>		
Hiatus hernia	5	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	4402	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	353	0
Epigastric discomfort	14	0
Eructation	42	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	17	0
Faecaloma	4	0
Faeces discoloured	51	0
Faeces hard	2	0
Faeces pale	3	0
Faeces soft	10	0
Mucous stools	8	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	439	0
Aerophagia	3	0
Flatulence	157	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	1186	0
Abdominal pain lower	106	0
Abdominal pain upper	1968	0
Abdominal rigidity	22	0
Abdominal tenderness	9	0
Gastrointestinal pain	107	0
Oesophageal pain	6	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	214	0
Duodenogastric reflux	3	0
Gastric dilatation	7	0
Gastrooesophageal reflux disease	122	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Impaired gastric emptying	7	0
Infrequent bowel movements	3	0
Intestinal dilatation	1	0
Intestinal pseudo-obstruction	2	0
<i>Gastrointestinal disorders NEC</i>		
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
<i>Gastrointestinal dyskinetic disorders</i>		
Bowel movement irregularity	5	0
Change of bowel habit	5	0
Dyschezia	2	0
Gastrointestinal motility disorder	2	0
Oesophageal achalasia	1	0
<i>Gastrointestinal fistulae</i>		
Diverticular fistula	1	0
<i>Gastrointestinal inflammatory disorders NEC</i>		
Duodenitis	1	0
Enteritis	5	0
Epiploic appendagitis	2	0
Gastrointestinal inflammation	3	0
Intestinal angioedema	2	0
<i>Gastrointestinal mucosal dystrophies and secretion disorders</i>		
Hyperchlorhydria	4	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	512	0
Abdominal symptom	1	0
Acute abdomen	4	0
Anal incontinence	19	0
Breath odour	16	0
Dysphagia	172	1
Odynophagia	28	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Cardiospasm	1	0
Defaecation urgency	8	0
Frequent bowel movements	22	0
Irritable bowel syndrome	73	0
Oesophageal spasm	3	0
Pylorospasm	1	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Intestinal obstruction	2	0
Neonatal intestinal obstruction	1	0
<i>Gastrointestinal vascular malformations</i>		
Gastric antral vascular ectasia	8	0
<i>Gastrointestinal vascular occlusion and infarction</i>		
Intestinal ischaemia	5	2
Mesenteric vein thrombosis	6	0
Omental infarction	1	0
Thrombosis mesenteric vessel	2	0
Visceral venous thrombosis	1	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<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	91	0
Gingival pruritus	1	0
Gingival swelling	31	0
Gingival ulceration	1	0
Gingivitis ulcerative	1	0
Noninfective gingivitis	6	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	54	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>Intestinal haemorrhages</i>		
Anal haemorrhage	17	1
Intestinal haemorrhage	1	0
Rectal haemorrhage	60	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	8	0
Malabsorption	1	0
Steatorrhoea	4	0
<i>Nausea and vomiting symptoms</i>		
Discoloured vomit	11	0
Infantile vomiting	5	0
Nausea	11552	0
Regurgitation	1	0
Retching	85	0
Vomiting	3511	1
Vomiting projectile	52	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	47	0
Melaena	8	0
Upper gastrointestinal haemorrhage	8	0
<i>Oesophageal stenosis and obstruction</i>		
Oesophageal stenosis	3	0
<i>Oesophagitis (excl infective)</i>		

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Eosinophilic oesophagitis	1	0
Oesophagitis	3	0
<i>Oral dryness and saliva altered</i>		
Aptyalism	3	0
Dry mouth	423	0
Lip dry	36	0
Saliva altered	5	0
Salivary hypersecretion	42	0
<i>Oral soft tissue disorders NEC</i>		
Angina bullosa haemorrhagica	1	0
Chapped lips	19	0
Cheilitis	23	0
Enlarged uvula	13	0
Leukoplakia oral	2	0
Lip blister	25	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	1	0
Burning mouth syndrome	6	0
Coating in mouth	1	0
Hypoaesthesia oral	412	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	68	0
Oral dysaesthesia	1	0
Oral mucosal blistering	13	0
Oral mucosal discolouration	1	0
Oral mucosal eruption	11	0
Oral mucosal erythema	5	0
Oral mucosal exfoliation	8	0
Oral mucosal roughening	3	0
Oral mucosal scab	1	0
Oral pain	142	0
Oral pruritus	20	0
Paraesthesia oral	805	0
Pigmentation lip	1	0
<i>Oral soft tissue swelling and oedema</i>		
Lip oedema	4	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Lip swelling	609	0
Mouth swelling	76	0
Oedema mouth	4	0
Palatal oedema	3	0
Palatal swelling	2	0
<i>Pancreatic disorders NEC</i>		
Pancreatic mass	1	0
<i>Peptic ulcers and perforation</i>		
Peptic ulcer	1	0
Peptic ulcer haemorrhage	11	0
<i>Peritoneal and retroperitoneal disorders</i>		
Ascites	1	0
<i>Peritoneal and retroperitoneal fibrosis and adhesions</i>		
Abdominal adhesions	1	0
<i>Peritoneal and retroperitoneal haemorrhages</i>		
Haemoperitoneum	1	0
Retroperitoneal haemorrhage	1	1
<i>Rectal inflammations NEC</i>		
Proctitis	2	0
Proctitis ulcerative	1	0
<i>Salivary gland disorders NEC</i>		
Salivary gland disorder	1	0
Salivary gland pain	12	0
<i>Salivary gland enlargements</i>		
Parotid gland enlargement	9	0
Salivary gland enlargement	5	0
Submaxillary gland enlargement	7	0
<i>Salivary gland infections and inflammations</i>		
Noninfective sialoadenitis	1	0
<i>Stomatitis and ulceration</i>		
Aphthous ulcer	40	0
Lip ulceration	16	0
Mouth ulceration	376	0
Oral mucosa erosion	1	0
Palatal ulcer	1	0
Stomatitis	56	0
<i>Tongue disorders</i>		
Glossitis	15	0
Hypertrophy of tongue papillae	1	0
Plicated tongue	3	0
Tongue disorder	33	0
Tongue geographic	1	0
Tongue haemorrhage	3	0
Tongue ulceration	28	0
Trichoglossia	4	0
<i>Tongue signs and symptoms</i>		
Glossodynia	174	0
Scalloped tongue	5	0
Stiff tongue	3	0
Swollen tongue	413	0
Tongue blistering	16	0
Tongue coated	16	0
Tongue discolouration	33	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Tongue discomfort	38	0
Tongue dry	13	0
Tongue eruption	9	0
Tongue erythema	7	0
Tongue exfoliation	1	0
Tongue movement disturbance	6	0
Tongue oedema	19	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	30757	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	3	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	28	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	1517	0
Chronic fatigue syndrome	61	0
Decreased activity	8	0
Fatigue	18442	0
Malaise	4115	0
Sluggishness	12	0
<i>Body temperature altered</i>		

Case Series Drug Analysis Print

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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 swelling	1	0
Phantom shocks	1	0
Death and sudden death		
Brain death	3	3
Cardiac death	1	1
Clinical death	1	1
Death	148	148
Drowning	2	0
Sudden death	26	26
Febrile disorders		
Hyperpyrexia	7	0
Pyrexia	11954	0
Feelings and sensations NEC		
Chills	7581	0
Feeling abnormal	1304	0
Feeling cold	924	0
Feeling drunk	70	0
Feeling hot	946	0
Feeling jittery	20	0
Feeling of body temperature change	265	0
Feeling of relaxation	3	0
Hangover	74	0
Hunger	38	0
Sensation of blood flow	3	0
Sensation of foreign body	44	0
Temperature intolerance	36	0
Thirst	281	0
Fibrosis NEC		
Fibrosis	1	0
Gait disturbances		
Gait disturbance	181	0
Gait inability	59	0
Loss of control of legs	16	0
General signs and symptoms NEC		
Adhesion	1	0
Chronic disease	1	0
Condition aggravated	175	0
Crepitations	1	0
Crying	130	0
Deformity	2	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Discharge	10	0
Disease progression	2	0
Disease recurrence	25	0
Effusion	2	0
Energy increased	19	0
Exercise tolerance decreased	17	0
Foaming at mouth	1	0
General physical health deterioration	14	2
General symptom	2	0
Glassy eyes	3	0
High-pitched crying	2	0
Illness	1468	0
Induration	13	0
Influenza like illness	1865	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	2820	0
Physical deconditioning	2	0
Pre-existing condition improved	8	0
Prolapse	1	0
Screaming	20	0
Secretion discharge	18	0
Swelling	2312	0
Swelling face	663	0
Symptom recurrence	1	0
Terminal state	1	0
Implant and catheter site reactions		
Implant site discolouration	2	0
Implant site pain	1	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	355	0
Papillitis	1	0
Serositis	1	0
Systemic inflammatory response syndrome	2	0
Infusion site reactions		
Infusion site coldness	1	0
Infusion site joint pain	2	0
Infusion site mass	1	0
Infusion site nerve damage	1	0
Infusion site pain	1	0
Infusion site pruritus	1	0
Infusion site swelling	1	0
Infusion site urticaria	1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Infusion site warmth	1	0
<i>Injection site reactions</i>		
Injected limb mobility decreased	26	0
Injection site bruising	56	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	309	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 joint discomfort	2	0
Injection site joint erythema	1	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	421	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	2440	0
Injection site paraesthesia	11	0
Injection site pruritus	148	0
Injection site rash	135	0
Injection site reaction	21	0
Injection site scab	3	0
Injection site scar	5	0
Injection site swelling	247	0
Injection site urticaria	24	0
Injection site vesicles	9	0
Injection site warmth	158	0
<i>Interactions</i>		
Alcohol interaction	3	0
Drug interaction	25	0
Inhibitory drug interaction	3	0
<i>Mass conditions NEC</i>		
Cyst	35	0
Mass	58	0
Nodule	30	0
<i>Mucosal findings abnormal</i>		
Mucosa vesicle	1	0
Mucosal dryness	1	0
Mucosal haemorrhage	8	0
Mucosal inflammation	2	0
Oedema mucosal	1	0
Polyp	2	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
<i>Necrosis NEC</i>		
Fat necrosis	2	0
Necrosis	4	0
<i>Oedema NEC</i>		
Face oedema	26	0
Generalised oedema	3	0
Localised oedema	15	0
Oedema	57	0
Oedema peripheral	72	0
<i>Pain and discomfort NEC</i>		
Axillary pain	2400	0
Chest discomfort	1337	0
Chest pain	3156	0
Discomfort	377	0
Facial discomfort	17	0
Facial pain	176	0
Inflammatory pain	11	0
Non-cardiac chest pain	23	0
Pain	7106	0
Suprapubic pain	1	0
Tenderness	538	0
Visceral pain	1	0
<i>Therapeutic and nontherapeutic responses</i>		
Adverse drug reaction	13	0
Adverse event	1	0
Adverse food reaction	2	0
Adverse reaction	1	0
Drug ineffective	240	1
Drug intolerance	2	0
Drug tolerance decreased	1	0
Immediate post-injection reaction	2	0
Inadequate analgesia	8	0
No reaction on previous exposure to drug	27	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	21	0
<i>Trophic disorders</i>		
Atrophy	2	0
Calcinosis	1	0
Hyperplasia	1	0
<i>Ulcers NEC</i>		
Ulcer	27	0
Ulcer haemorrhage	1	0
<i>Vaccination site reactions</i>		
Extensive swelling of vaccinated limb	10	0
Shoulder injury related to vaccine administration	20	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site anaesthesia	1	0
Vaccination site bruising	105	0
Vaccination site coldness	2	0
Vaccination site cyst	5	0
Vaccination site dermatitis	1	0
Vaccination site discolouration	13	0
Vaccination site discomfort	41	0
Vaccination site dryness	1	0
Vaccination site eczema	1	0
Vaccination site erythema	509	0
Vaccination site granuloma	3	0
Vaccination site haematoma	2	0
Vaccination site haemorrhage	18	0
Vaccination site hypersensitivity	2	0
Vaccination site hypoaesthesia	15	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	28	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	225	0
Vaccination site movement impairment	72	0
Vaccination site nerve damage	1	0
Vaccination site nodule	2	0
Vaccination site oedema	3	0
Vaccination site pain	1888	0
Vaccination site paraesthesia	6	0
Vaccination site phlebitis	1	0
Vaccination site pruritus	136	0
Vaccination site rash	110	0
Vaccination site reaction	30	0
Vaccination site scab	2	0
Vaccination site scar	1	0
Vaccination site swelling	477	0
Vaccination site thrombosis	1	0
Vaccination site ulcer	1	0
Vaccination site urticaria	10	0
Vaccination site vesicles	9	0
Vaccination site warmth	237	0
Vascular complications associated with device		
Vascular stent thrombosis	1	0
Withdrawal and rebound effects		
Drug withdrawal syndrome	4	0
Withdrawal syndrome	33	0
General disorders SOC TOTAL	82664	187

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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	8	0
<i>Cholestasis and jaundice</i>		
Cholestasis	2	0
Jaundice	20	0
Jaundice cholestatic	11	0
Ocular icterus	2	0
<i>Gallbladder disorders NEC</i>		
Gallbladder disorder	1	0
<i>Hepatic and hepatobiliary disorders NEC</i>		
Liver disorder	10	0
<i>Hepatic enzymes and function abnormalities</i>		
Hepatic function abnormal	3	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	10	0
Immune-mediated hepatic disorder	1	0
Liver injury	12	0
Hepatic disorders SOC TOTAL	155	1

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Immune system disorders		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	12	0
<i>Allergic conditions NEC</i>		
Allergic oedema	12	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	792	0
Infusion related hypersensitivity reaction	2	0
Mite allergy	2	0
Multiple allergies	7	0
Serum sickness	2	0
Serum sickness-like reaction	3	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	21	0
Food allergy	22	0
Milk allergy	1	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	418	2
Anaphylactic shock	43	0
Anaphylactoid reaction	19	0
Anaphylactoid shock	4	0
<i>Atopic disorders</i>		
Atopy	1	0
Seasonal allergy	97	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	44	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
Sensitisation	4	0
Systemic immune activation	2	0

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Immune system disorders		
Immune system disorders cont'd		
<i>Immunodeficiency disorders NEC</i>		
Hypogammaglobulinaemia	1	0
Immunodeficiency	1	0
Immunosuppression	3	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	1672	2

Case Series Drug Analysis Print

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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	5	0
Diverticulitis	10	0
Dysentery	1	0
Gastric infection	2	0
Gastroenteritis	23	0
Mesenteric abscess	1	0
Peritonitis	1	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
Cellulitis	144	0
Conjunctivitis bacterial	1	0
Ear infection bacterial	1	0
Folliculitis	14	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	1	0
<i>Breast infections</i>		
Breast abscess	3	0
Mastitis	68	0
<i>Caliciviral infections</i>		
Gastroenteritis norovirus	3	0

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Reaction Name	Total	Fatal
Infections Infections cont'd		
<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	54	0
Oral candidiasis	36	0
Respiratory moniliasis	1	0
Skin candida	1	0
Systemic candida	1	0
Vulvovaginal candidiasis	39	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	1	0
Myelitis	5	0
Subdural abscess	1	0
<i>Clostridia infections</i>		
Clostridium difficile infection	2	0
<i>Coronavirus infections</i>		
Asymptomatic COVID-19	12	0
COVID-19	1123	39
COVID-19 pneumonia	44	13
Coronavirus infection	7	0
Post-acute COVID-19 syndrome	1	0
Severe acute respiratory syndrome	2	0
Suspected COVID-19	56	2
<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	4	0
Gingivitis	10	0
Oral infection	1	0
Parotitis	9	0
Pericoronitis	2	0
Pulpitis dental	1	0
Sialoadenitis	3	0
Tooth abscess	8	0
Tooth infection	8	0
<i>Ear infections</i>		
Ear infection	73	0
Labyrinthitis	85	0
Mastoiditis	1	0

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Otitis externa	2	0
Otitis media	6	0
Otitis media acute	1	0
<i>Ectoparasitic infestations</i>		
Acarodermatitis	4	0
Bed bug infestation	1	0
<i>Epstein-Barr viral infections</i>		
Epstein-Barr virus infection	3	0
Infectious mononucleosis	23	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	60	0
Eye abscess	1	0
Eye infection	16	0
Eyelid boil	2	0
Eyelid infection	2	0
Hordeolum	23	0
Periorbital infection	2	0
<i>Female reproductive tract infections</i>		
Bartholin's abscess	1	0
Bartholinitis	1	0
Endometritis	3	0
Funisitis	1	0
Pelvic inflammatory disease	1	0
Vaginal infection	1	0
Vulval abscess	1	0
Vulvitis	1	0
<i>Fungal infections NEC</i>		
Fungal infection	14	0
Fungal skin infection	5	0
Onychomycosis	1	0
Oral fungal infection	2	0
Pneumonia fungal	2	0
Vulvovaginal mycotic infection	6	0
<i>Hepatitis virus infections</i>		
Hepatitis A	1	0
Hepatitis E	1	0
<i>Hepatobiliary and spleen infections</i>		
Biliary sepsis	2	0
Cholecystitis infective	1	0
<i>Herpes viral infections</i>		
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	23	0
Herpes simplex encephalitis	1	1
Herpes simplex reactivation	2	0
Herpes virus infection	9	0
Herpes zoster	1221	0
Herpes zoster meningoencephalitis	1	0
Herpes zoster oticus	13	0
Herpes zoster reactivation	1	0

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Nasal herpes	3	0
Ophthalmic herpes zoster	3	0
Oral herpes	262	0
Varicella	23	0
Varicella zoster virus infection	1	0
<i>Infections NEC</i>		
Abscess	34	0
Abscess limb	6	0
Abscess soft tissue	1	0
Catheter site infection	1	0
Genital abscess	2	0
Infected bite	3	0
Infected cyst	2	0
Infection	200	0
Infection susceptibility increased	1	0
Injection site abscess	1	0
Injection site infection	5	0
Localised infection	22	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	9	0
Vaccination site abscess	6	0
Vaccination site infection	13	0
Vaccine breakthrough infection	23	0
Vestibulitis	3	0
Wound infection	1	0
<i>Infectious transmissions</i>		
Secondary transmission	8	0
Vaccine virus shedding	1	0
<i>Influenza viral infections</i>		
Influenza	1260	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	175	7
Pneumonia	106	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
<i>Muscle and soft tissue infections</i>		
Abscess neck	1	0
Infective tenosynovitis	1	0

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Necrotising fasciitis	2	0
Soft tissue infection	1	0
<i>Neisseria infections</i>		
Gonorrhoea	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	2	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	3	0
Impetigo	10	0
Infected skin ulcer	1	0
Injection site pustule	1	0
Nail infection	1	0
Pustule	12	0
Rash pustular	9	0
Skin infection	27	0
Subcutaneous abscess	6	0
Sweat gland infection	1	0
Vaccination site pustule	4	0
<i>Staphylococcal infections</i>		
Furuncle	34	0
Pneumonia staphylococcal	1	0
Staphylococcal abscess	1	0
Staphylococcal infection	3	0
Staphylococcal sepsis	1	0
<i>Streptococcal infections</i>		
Meningitis pneumococcal	1	0
Pharyngitis streptococcal	5	0
Streptococcal abscess	1	0
Streptococcal endocarditis	1	0
Streptococcal infection	1	0
Streptococcal sepsis	1	0

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
<i>Tinea infections</i>		
Body tinea	1	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>		
Latent tuberculosis	1	0
Lymph node tuberculosis	1	0
Pulmonary tuberculosis	1	0
Tuberculosis	1	0
Tuberculosis of central nervous system	1	0
<i>Upper respiratory tract infections</i>		
Acute sinusitis	4	0
Chronic sinusitis	1	0
Croup infectious	1	0
Epiglottitis	1	0
Laryngitis	25	0
Nasopharyngitis	850	0
Peritonsillar abscess	3	0
Pharyngitis	29	0
Rhinitis	37	0
Sinusitis	131	0
Tonsillitis	98	0
Tracheitis	4	0
Tracheostomy infection	1	0
Upper respiratory tract infection	6	0
<i>Urinary tract infections</i>		
Cystitis	64	0
Kidney infection	39	0
Pyelonephritis	2	0
Urethritis	1	0
Urinary tract infection	163	0
<i>Vascular infections</i>		
Haematoma infection	1	0
Infected lymphocele	1	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	23	0
Hepatitis viral	2	0
Meningitis viral	8	0
Meningoencephalitis viral	1	0
Oral viral infection	1	0
Pleurisy viral	1	0
Pneumonia viral	2	1

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Post viral fatigue syndrome	39	0
Sweating fever	85	0
Vestibular neuronitis	24	0
Viral diarrhoea	2	0
Viral infection	43	0
Viral labyrinthitis	3	0
Viral myocarditis	2	0
Viral pericarditis	4	0
Viral pharyngitis	15	0
Viral rash	45	0
Viral sinusitis	1	0
Viral tonsillitis	1	0
Infections SOC TOTAL	7810	87

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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	7	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	2	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	49	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	58	0
Foetal exposure during pregnancy	35	0
Maternal exposure before pregnancy	5	0
Maternal exposure during breast feeding	1449	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Maternal exposure during pregnancy	754	0
Maternal exposure timing unspecified	8	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	2	0
Multiple fractures	1	0
Gastrointestinal and hepatobiliary procedural complications		
Post procedural constipation	1	0
Postoperative ileus	1	0
Procedural nausea	7	0
Procedural vomiting	1	0
Heat injuries (excl thermal burns)		
Heat cramps	2	0
Heat exhaustion	3	0
Heat illness	1	0
Heat oedema	7	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	1	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
Medication error	16	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
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	15	0
Muscle rupture	7	0
Muscle strain	27	0
Post-traumatic neck syndrome	1	0
Tendon injury	5	0
Tendon rupture	16	0
Musculoskeletal procedural complications		
Periprosthetic osteolysis	2	0
Post laminectomy syndrome	1	0
Nerve injuries NEC		
Nerve injury	73	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	151	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	4	0
Non-site specific procedural complications		
Incision site pain	3	0
Infusion related reaction	6	0
Injection related reaction	37	0
Post procedural complication	3	0
Procedural pain	2	0
Seroma	1	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Occupational exposures		
Occupational exposure to SARS-CoV-2	1	0
Occupational exposure to product	1	0
Off label uses		
Off label use	56	0
Overdoses NEC		
Overdose	50	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	11	0
Inappropriate schedule of product administration	451	0
Incomplete course of vaccination	1	0
Incorrect dose administered	51	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	12	0
Product administered to patient of inappropriate age	1	0
Product administration error	6	0
Product dose omission issue	8	0
Wrong product administered	18	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		
Sunburn	19	0
Renal and urinary tract injuries NEC		
Foreign body in urogenital tract	1	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
<i>Reproductive system and breast injuries</i>		
Penis injury	1	0
<i>Site specific injuries NEC</i>		
Face crushing	2	0
Face injury	1	0
Head injury	33	0
Limb crushing injury	2	0
Limb injury	90	0
Nasal injury	1	0
Neck crushing	1	0
Neck injury	1	0
<i>Skin injuries NEC</i>		
Contusion	997	0
Nail avulsion	1	0
Scar	18	0
Scratch	7	0
Skin abrasion	6	0
Skin injury	4	0
Skin laceration	2	0
Skin wound	3	0
Subcutaneous haematoma	2	0
<i>Skin procedural complications</i>		
Dermal filler overcorrection	1	0
Recall phenomenon	1	0
<i>Skull fractures, facial bone fractures and dislocations</i>		
Facial bones fracture	1	0
Fractured skull depressed	1	0
<i>Spinal cord injuries NEC</i>		
Spinal cord injury cervical	1	0
<i>Spinal fractures and dislocations</i>		
Spinal fracture	3	0
<i>Stoma complications</i>		
Gastrointestinal stoma complication	1	0
Stoma site discharge	1	0
Stoma site extravasation	1	0
Stoma site haemorrhage	1	0
<i>Thermal burns</i>		
Airway burns	1	0
Burn oesophageal	2	0
Burn of internal organs	2	0
Burn oral cavity	4	0
Burns second degree	5	0
Thermal burn	19	0
Thermal burns of eye	10	0
<i>Underdoses NEC</i>		
Underdose	6	0
<i>Vaccination related complications</i>		
Vaccination complication	44	0
Injuries SOC TOTAL	5124	1

Case Series Drug Analysis Print

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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	2	0
Blood lactic acid	4	0
Blood lactic acid decreased	1	0
Blood lactic acid increased	4	0
Blood pH	7	0
Blood pH increased	6	0
Oxygen consumption decreased	2	0
Oxygen saturation	8	0
Oxygen saturation decreased	54	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	14	0
Blood glucose increased	87	0
Blood glucose normal	1	0
Glycosylated haemoglobin increased	1	0
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	29	0
Heart sounds	4	0
Heart sounds abnormal	4	0
<i>Cardiac function diagnostic procedures</i>		
Cardiac monitoring	2	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 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	6	0
Blood thromboplastin	1	0
Clot retraction	1	1
Coagulation factor VIII level decreased	1	0
Coagulation time prolonged	9	0
Coagulation time shortened	4	0
Fibrin D dimer increased	8	0
International normalised ratio abnormal	6	0
International normalised ratio decreased	20	0
International normalised ratio fluctuation	2	0
International normalised ratio increased	48	0
Prothrombin time shortened	1	0
Digestive enzymes		
Amylase increased	1	0
ECG investigations		
Electrocardiogram	2	0
Electrocardiogram QRS complex prolonged	1	0
Electrocardiogram QT prolonged	5	0
Electrocardiogram ST segment depression	1	0
Electrocardiogram ST segment elevation	6	0
Electrocardiogram ST-T segment abnormal	1	0
Electrocardiogram T wave inversion	4	0
Electrocardiogram abnormal	16	0
Electrocardiogram change	1	0
Electrocardiogram normal	2	0

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Electrocardiogram repolarisation abnormality	1	0
QRS axis abnormal	1	0
Endocrine analyses and imaging NEC		
Hormone level abnormal	44	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	1	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	374	0
Heart rate abnormal	50	0
Heart rate decreased	62	0
Heart rate increased	706	0
Heart rate irregular	150	0
Heart rate normal	1	0
Maximum heart rate	2	0
Pulse abnormal	16	0
Pulse pressure increased	1	0
Radial pulse abnormal	1	0
Sinus rhythm	5	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
Blood immunoglobulin M	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
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	23	0
Blood test abnormal	47	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	25	0
Liver function test increased	19	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	1	0
Blood copper increased	1	0
Blood iron	1	0
Blood iron decreased	8	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	6	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	218	0
Body temperature abnormal	39	0
Body temperature decreased	35	0
Body temperature fluctuation	40	0
Body temperature increased	344	0
Body temperature normal	1	0
Breath sounds abnormal	2	0
General physical condition abnormal	1	0
Grip strength	2	0
Grip strength decreased	18	0
Head lag	6	0
Lymph node palpable	35	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	1	0
Respiratory rate	8	0
Respiratory rate decreased	16	0
Respiratory rate increased	32	0
Skin temperature	35	0
Temperature difference of extremities	9	0
Weight	1	0
Weight decreased	87	0
Weight increased	30	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	64	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
Renal function test	1	0
Renal function test abnormal	1	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
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>		
Hysteroscopy	2	0
<i>Respiratory and pulmonary function diagnostic procedures</i>		
Forced expiratory volume increased	2	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
<i>Skeletal and cardiac muscle analyses</i>		

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
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	12	0
Therapeutic drug monitoring analyses		
Analgesic drug level	6	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
Thyroid analyses		
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
Tissue enzyme analyses NEC		
Blood alkaline phosphatase increased	3	0
Enzyme level increased	1	0
Toxicology laboratory analyses		
Blood caffeine decreased	1	0
Blood lead	1	0
Drug screen positive	2	0
Opiates	1	0
Urinalysis NEC		
Blood urine	13	0
Blood urine present	43	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
Urinary tract function analyses NEC		
Urine output	12	0
Urine output decreased	9	0
Urine output increased	6	0
Urinary tract imaging procedures		
Cystoscopy	2	0
Vascular imaging procedures NEC		
Venogram	2	0
Vascular tests NEC (incl blood pressure)		
Blood pressure abnormal	6	0
Blood pressure decreased	60	0
Blood pressure diastolic	1	0
Blood pressure diastolic decreased	1	0
Blood pressure diastolic increased	2	0
Blood pressure increased	189	0
Blood pressure measurement	32	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
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	10	0
SARS-CoV-2 antibody test negative	12	0
SARS-CoV-2 antibody test positive	3	0
SARS-CoV-2 test	26	0
SARS-CoV-2 test false negative	1	0
SARS-CoV-2 test false positive	3	0
SARS-CoV-2 test negative	7	0
SARS-CoV-2 test positive	91	0
Viral test	5	0
<i>Vitamin analyses</i>		
Blood folate decreased	6	0
Vitamin B12	1	0
Vitamin B12 abnormal	1	0
Vitamin B12 decreased	1	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	1	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	4134	3

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	13	0
Decreased appetite	987	0
Diet refusal	1	0
Eating disorder symptom	2	0
Food craving	10	0
Food refusal	11	0
Hyperphagia	13	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	41	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	14	0
Type 2 diabetes mellitus	3	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	80	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	1	0
Food intolerance	12	0
Gluten sensitivity	6	0
Histamine intolerance	3	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	14	0
Abnormal weight gain	18	0
Cachexia	1	0
Feeding disorder	62	0
Food aversion	8	0
Malnutrition	1	0
Neonatal insufficient breast milk syndrome	3	0
Overweight	1	0
Poor feeding infant	15	0
Weight loss poor	3	0
<i>Hyperglycaemic conditions NEC</i>		

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Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
Glucose tolerance impaired	1	0
Hyperglycaemia	60	0
Insulin resistance	4	0
Hypoglycaemic conditions NEC		
Glycopenia	1	0
Hypoglycaemia	71	0
Hypoglycaemia unawareness	1	0
Postprandial hypoglycaemia	1	0
Iron deficiencies		
Iron deficiency	11	0
Iron excess		
Haemochromatosis	1	0
Iron overload	1	0
Lipid metabolism and deposit disorders NEC		
Body fat disorder	1	0
Metabolic acidoses (excl diabetic acidoses)		
Ketoacidosis	5	1
Lactic acidosis	2	0
Metabolic acidosis	2	0
Metabolic disorders NEC		
Metabolic disorder	1	0
Mixed acid-base disorders		
Acidosis	3	0
Potassium imbalance		
Hyperkalaemia	3	0
Hypokalaemia	3	0
Hypokalaemic syndrome	1	0
Sodium imbalance		
Hyponatraemia	7	0
Hyponatraemic syndrome	3	0
Salt intoxication	1	0
Sugar intolerance (excl glucose intolerance)		
Lactose intolerance	1	0
Total fluid volume decreased		
Dehydration	171	0
Total fluid volume increased		
Fluid overload	1	0
Fluid retention	45	0
Hypervolaemia	1	0
Vitamin deficiencies NEC		
Hypovitaminosis	4	0
Water soluble vitamin deficiencies		
Folate deficiency	3	0
Vitamin B12 deficiency	4	0
Metabolic disorders SOC TOTAL	1834	2

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	225	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	305	0
Bone swelling	7	0
Coccydynia	3	0
Metatarsalgia	1	0
Pain in jaw	298	0
Pubic pain	2	0
Spinal pain	63	0
<i>Bursal disorders</i>		
Bursitis	57	0
<i>Cartilage disorders</i>		
Chondritis	1	0
Costochondritis	70	0
Osteochondritis	1	0
Polychondritis	3	0
<i>Connective tissue disorders NEC</i>		
Connective tissue disorder	1	0
Polymyalgia rheumatica	50	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	5	0
Musculoskeletal deformity	1	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
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	133	0
Rotator cuff syndrome	21	0
Temporomandibular joint syndrome	8	0
Joint related signs and symptoms		
Arthralgia	7356	0
Jaw clicking	5	0
Joint effusion	14	0
Joint noise	32	0
Joint range of motion decreased	27	0
Joint stiffness	200	0
Joint swelling	429	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	25	0
Polymyositis	6	0
Muscle pains		
Fibromyalgia	82	0
Myalgia	9037	0
Myalgia intercostal	1	0
Myofascial pain syndrome	11	0
Muscle related signs and symptoms NEC		
Haematoma muscle	1	0
Muscle atrophy	16	0
Muscle discomfort	4	0
Muscle disorder	4	0
Muscle fatigue	296	0
Muscle haemorrhage	1	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Muscle mass	4	0
Muscle oedema	1	0
Muscle spasms	1746	0
Muscle swelling	27	0
Muscle tightness	77	0
Muscle twitching	395	0
Muscle tone abnormalities		
Muscle rigidity	13	0
Nuchal rigidity	10	0
Torticollis	4	0
Trismus	29	0
Muscle weakness conditions		
Muscular weakness	744	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	90	0
Musculoskeletal disorder	10	0
Musculoskeletal stiffness	1056	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	1946	0
Flank pain	53	0
Limb discomfort	1274	0
Musculoskeletal chest pain	180	0
Musculoskeletal discomfort	78	0
Musculoskeletal pain	37	0
Neck pain	1538	0
Pain in extremity	10577	0
Rheumatic disorder	13	0
Myopathies		
Myopathy	4	0
Rhabdomyolysis	10	0
Osteoarthropathies		
Nodal osteoarthritis	1	0
Osteoarthritis	35	0
Spinal osteoarthritis	1	0
Psoriatic arthropathies		
Psoriatic arthropathy	16	0
Rheumatoid arthropathies		

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Juvenile idiopathic arthritis	1	0
Rheumatoid arthritis	99	0
<i>Soft tissue disorders NEC</i>		
Axillary mass	196	0
Fluctuance	1	0
Groin pain	93	0
Neck mass	27	0
Purple glove syndrome	1	0
Soft tissue disorder	3	0
Soft tissue swelling	5	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	36	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	34	0
Tenosynovitis	2	0
Tenosynovitis stenosaurs	2	0
Trigger finger	23	0
<i>Trunk deformities</i>		
Drooping shoulder syndrome	1	0
Shoulder deformity	2	0
Muscle & tissue disorders SOC TOTAL	39588	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	30	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	2	0
<i>Follicular lymphomas</i>		
Primary gastrointestinal follicular lymphoma	1	0
<i>Gastric neoplasms malignant</i>		
Gastric cancer	1	1
<i>Gastrointestinal neoplasms malignant NEC</i>		
Gastrointestinal carcinoma	3	0
<i>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	2	1
<i>Leukaemias acute NEC</i>		
Acute leukaemia	1	0
<i>Leukaemias chronic NEC</i>		
Chronic leukaemia	1	0
<i>Leukaemias chronic lymphocytic</i>		
Chronic lymphocytic leukaemia	2	0
<i>Lip and oral cavity neoplasms malignant</i>		
Lip and/or oral cavity cancer recurrent	1	0
<i>Lymphomas unspecified NEC</i>		

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
Lymphoma	28	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	3	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
Renal neoplasms malignant		
Clear cell renal cell carcinoma	1	0

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
Renal cancer	2	0
<i>Respiratory tract and pleural neoplasms malignant cell type unspecified</i>		
NEC		
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	2	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	236	5

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Areflexia	5	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	23	0
<i>Acute polyneuropathies</i>		
Acute motor axonal neuropathy	1	0
Guillain-Barre syndrome	52	1
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	44	8
Cerebral infarction	25	1
Cerebral thrombosis	12	0
Cerebrovascular accident	333	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	38	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
Thrombotic stroke	3	1

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Central nervous system inflammatory disorders NEC		
Arachnoiditis	1	0
Gliosis	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	5	0
Superior sagittal sinus thrombosis	3	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	10	0
Balance disorder	314	0
Coordination abnormal	46	0
Dysdiadochokinesis	1	0
Dysstasia	48	0
Nystagmus	10	0
Cortical dysfunction NEC		
Alexia	2	0
Aphasia	68	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
Dementia (excl Alzheimer's type)		
Dementia	14	0
Dementia with Lewy bodies	1	0
Senile dementia	1	0
Demyelinating disorders NEC		
Acute disseminated encephalomyelitis	5	0
Clinically isolated syndrome	1	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Demyelination	8	0
Neuromyelitis optica spectrum disorder	3	0
<i>Disturbances in consciousness NEC</i>		
Altered state of consciousness	10	0
Consciousness fluctuating	2	0
Depressed level of consciousness	40	0
Infant sedation	1	0
Lethargy	1877	0
Loss of consciousness	523	0
Postictal state	4	0
Sedation	8	0
Somnolence	860	0
Stupor	4	0
Syncope	1756	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	16	0
Clumsiness	17	0
Dyskinesia	56	0
Extrapyramidal disorder	2	0
Fine motor skill dysfunction	11	0
Foetal movement disorder	1	0
Hyperkinesia	3	0
Hypokinesia	59	0
Motor dysfunction	2	0
Movement disorder	46	0
Psychomotor hyperactivity	19	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>		
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
VIth nerve disorder	1	0
VIth nerve paralysis	10	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	427	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Facial nerve disorder	8	0
Facial paralysis	325	0
Facial paresis	82	0
Facial spasm	42	0
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	43	0
Headaches NEC		
Cervicogenic headache	3	0
Cluster headache	192	0
Cold-stimulus headache	18	0
Drug withdrawal headache	2	0
Exertional headache	8	0
External compression headache	2	0
Headache	22074	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	304	0
Tension headache	478	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	70	0
Memory loss (excl dementia)		
Amnesia	150	0
Memory impairment	159	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	276	0
Mental impairment	43	0
Migraine headaches		
Hemiplegic migraine	28	0
Migraine	2487	0
Migraine with aura	166	0
Migraine without aura	17	0
Ophthalmic migraine	5	0
Retinal migraine	30	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
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	2	0
Nerve compression	20	0
Peripheral nerve lesion	1	0
Peroneal nerve palsy	12	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	26	0
Multiple sclerosis relapse	20	0
Tumefactive multiple sclerosis	1	1
Muscle tone abnormal		
Drop attacks	1	0
Hypertonia	2	0
Hypotonia	22	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	99	0
Narcolepsy	6	0
Nervous system disorders NEC		
Central nervous system lesion	2	0
Cerebral disorder	1	0
Nervous system disorder	11	0
Neurotoxicity	3	0
Neurologic visual problems NEC		
Hemianopia	1	0
Hemianopia homonymous	2	0
Quadrantanopia	1	0
Tunnel vision	17	0
Neurological signs and symptoms NEC		
Agitation neonatal	2	0
Clonus	3	0
Decerebrate posture	1	0
Decorticate posture	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Dizziness	8371	0
Dizziness exertional	38	0
Dizziness postural	627	0
Drooling	21	0
Fontanelle bulging	2	0
Head discomfort	288	0
Hyporesponsive to stimuli	2	0
Inability to crawl	2	0
Infant irritability	7	0
Myoclonus	24	0
Neurological symptom	39	0
Patient elopement	1	0
Persistent postural-perceptual dizziness	13	0
Presyncope	550	0
Sensory overload	4	0
Slow response to stimuli	4	0
Tongue biting	4	0
Unresponsive to stimuli	39	0
Neuromuscular disorders NEC		
Muscle contractions involuntary	17	0
Muscle spasticity	10	0
Neuromuscular pain	3	0
Neuromuscular junction dysfunction		
Myasthenia gravis	7	0
Myasthenia gravis crisis	2	0
Olfactory nerve disorders		
Anosmia	220	0
Hyposmia	16	0
Parosmia	210	0
Optic nerve disorders NEC		
Optic neuritis	27	0
Paraesthesias and dysaesthesias		
Burning feet syndrome	7	0
Burning sensation	445	0
Burning sensation mucosal	2	0
Dysaesthesia	6	0
Formication	35	0
Hand-arm vibration syndrome	3	0
Hemianaesthesia	1	0
Hemiparaesthesia	2	0
Hyperaesthesia	79	0
Hypoaesthesia	2504	0
Paraesthesia	3451	0
Reversed hot-cold sensation	4	0
Synaesthesia	1	0
Paralysis and paresis (excl cranial nerve)		
Diplegia	11	0
Hemiparesis	41	0
Hemiplegia	36	0
Locked-in syndrome	1	0
Monoparesis	48	0
Monoplegia	63	0
Paralysis	112	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Paraparesis	3	0
Paresis	6	0
Quadriparesis	1	0
Quadriplegia	1	0
<i>Parkinson's disease and parkinsonism</i>		
Freezing phenomenon	8	0
Parkinson's disease	3	0
Parkinsonian gait	1	0
Parkinsonian rest tremor	1	0
Parkinsonism	4	0
Reduced facial expression	9	0
<i>Partial complex seizures</i>		
Dreamy state	6	0
Focal dyscognitive seizures	3	0
Temporal lobe epilepsy	2	0
<i>Partial simple seizures NEC</i>		
Autonomic seizure	1	0
<i>Peripheral neuropathies NEC</i>		
Axonal neuropathy	2	0
Neuralgic amyotrophy	3	0
Neuritis	7	0
Neuropathy peripheral	87	0
Peripheral sensorimotor neuropathy	1	0
Peripheral sensory neuropathy	11	0
Polyneuropathy	2	0
Thoracic outlet syndrome	1	0
<i>Seizures and seizure disorders NEC</i>		
Atonic seizures	4	0
Change in seizure presentation	3	0
Clonic convulsion	3	0
Convulsions local	1	0
Epilepsy	144	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	523	0
Seizure anoxic	1	0
Seizure cluster	6	0
Seizure like phenomena	2	0
Status epilepticus	40	0
Tonic clonic movements	2	0
Tonic convulsion	22	0
Tonic posturing	1	0
<i>Sensory abnormalities NEC</i>		
Ageusia	442	0
Allodynia	22	0
Aura	17	0
Complex regional pain syndrome	5	0
Dysgeusia	1022	0
Electric shock sensation	34	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Hypergeusia	1	0
Hypogeusia	7	0
Intercostal neuralgia	1	0
Loss of proprioception	3	0
Morton's neuralgia	1	0
Neuralgia	443	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	110	0
Sensory disturbance	89	0
Sensory loss	64	0
Taste disorder	229	0
Visual perseveration	3	0
Sleep disturbances NEC		
Sleep deficit	7	0
Sudden onset of sleep	1	0
Speech and language abnormalities		
Dysarthria	165	0
Incoherent	9	0
Language disorder	1	0
Repetitive speech	3	0
Slow speech	15	0
Speech disorder	57	0
Spinal cord and nerve root disorders NEC		
Myelopathy	1	0
Radiculitis brachial	8	0
Radiculopathy	5	0
Structural brain disorders NEC		
Brain injury	7	2
Hyperintensity in brain deep nuclei	1	0
Transient cerebrovascular events		
Transient ischaemic attack	132	3
Tremor (excl congenital)		
Essential tremor	3	0
Head titubation	12	0
Resting tremor	4	0
Tremor	1407	0
Trigeminal disorders		
Facial neuralgia	15	0
Numb chin syndrome	2	0
Trigeminal nerve disorder	3	0
Trigeminal neuralgia	39	0
Vagus nerve disorders		
Vocal cord paralysis	1	0
Vertigos NEC		
Cervicogenic vertigo	1	0
Vertigo CNS origin	3	0
Nervous system disorders SOC TOTAL	57379	54

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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	336	6
Abortion threatened	2	0
<i>Amniotic fluid and cavity disorders of pregnancy NEC</i>		
Amniorrhoea	1	0
<i>Foetal complications NEC</i>		
Foetal disorder	1	0
Foetal distress syndrome	1	0
Foetal hypokinesia	10	0
<i>Foetal growth complications</i>		
Foetal growth restriction	5	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	4	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	7	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	41	0
Uterine contractions during pregnancy	3	0

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Reaction Name	Total	Fatal
Pregnancy conditions <small>Pregnancy conditions cont'd</small>		
<i>Placental abnormalities (excl neoplasms)</i>		
Placental disorder	1	0
Placental insufficiency	1	0
<i>Postpartum complications NEC</i>		
Postpartum haemorrhage	5	0
<i>Pregnancy complicated by maternal disorders</i>		
Gestational diabetes	2	0
Peripartum cardiomyopathy	1	0
<i>Stillbirth and foetal death</i>		
Foetal death	3	2
Stillbirth	5	3
<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
Pregnancy conditions SOC TOTAL	504	13

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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	10	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	5	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
null 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	3	0
<i>Affect alterations NEC</i>		
Affect lability	12	0
Constricted affect	3	0
Flat affect	6	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	67	0
Anxiety	713	0
Immunisation anxiety related reaction	2	0
Nervousness	148	0
Stress	83	0
Tension	35	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	5	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	12	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	188	0
<i>Communications disorders</i>		
Communication disorder	5	0
Mutism	3	0
<i>Confusion and disorientation</i>		
Confusional state	758	0
Disorientation	245	0
<i>Decreased physical activity levels</i>		
Catatonia	1	0
<i>Deliria</i>		

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Delirium	91	0
<i>Delusional symptoms</i>		
Delusion	9	0
<i>Depressive disorders</i>		
Agitated depression	4	0
Depression	295	0
Depression suicidal	12	0
Major depression	7	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	18	0
Insomnia	1197	0
Middle insomnia	24	0
Terminal insomnia	31	0
<i>Dyssomnias</i>		
Breathing-related sleep disorder	1	0
Dyssomnia	1	0
Poor quality sleep	187	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	33	0
Dysphoria	2	0
Emotional disorder	52	0
Emotional distress	36	0
Emotional poverty	1	0
Euphoric mood	41	0
Frustration tolerance decreased	2	0
Irritability	187	0
Mood altered	51	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>		
Mood swings	124	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	163	0
Hallucination, auditory	13	0
Hallucination, olfactory	10	0
Hallucination, tactile	1	0
Hallucination, visual	23	0
Hallucinations, mixed	2	0
<i>Increased physical activity levels</i>		
Restlessness	133	0
<i>Infancy, childhood and adolescence psychiatric disorders NEC</i>		
Social (pragmatic) communication disorder	1	0
<i>Learning disorders</i>		
Learning disability	1	0
Learning disorder	1	0
<i>Mental disorders NEC</i>		
Mental disorder	15	0
Mental status changes	1	0
Psychological factor affecting medical condition	1	0
<i>Mood alterations with depressive symptoms</i>		
Anhedonia	3	0
Decreased interest	9	0
Depressed mood	332	0
Depressive symptom	2	0
Feeling guilty	1	0
Feeling of despair	4	0
Feelings of worthlessness	1	0
Negative thoughts	1	0
Psychomotor retardation	2	0
Sense of a foreshortened future	2	0
Tearfulness	33	0
<i>Mood alterations with manic symptoms</i>		
Hypomania	2	0
Mania	10	0
<i>Mood disorders NEC</i>		
Affective disorder	3	0
Apathy	28	0
Boredom	1	0
Laziness	3	0
Listless	16	0
Mood disorder due to a general medical condition	1	0
<i>Narcolepsy and associated conditions</i>		
Hypnagogic hallucination	3	0
Hypnopompic hallucination	2	0
Sleep attacks	3	0
<i>Obsessive-compulsive disorders and symptoms</i>		
Obsessive-compulsive symptom	1	0
<i>Orgasmic disorders and disturbances</i>		
Anorgasmia	4	0
Female orgasmic disorder	2	0
Orgasm abnormal	4	0
Orgasmic sensation decreased	1	0
Premature ejaculation	1	0
<i>Panic attacks and disorders</i>		

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Panic attack	171	0
Panic disorder	3	0
Panic reaction	24	0
Paraphilias and paraphilic disorders		
Transvestism	1	0
Parasomnias		
Abnormal dreams	157	0
Abnormal sleep-related event	1	0
Confusional arousal	1	0
Exploding head syndrome	2	0
Nightmare	173	0
Parasomnia	1	0
Sleep inertia	1	0
Sleep talking	6	0
Sleep terror	20	0
Somnambulism	5	0
Perception disturbances NEC		
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
Personality disorders NEC		
Personality disorder	1	0
Pervasive developmental disorders NEC		
Autism spectrum disorder	3	0
Psychiatric elimination disorders		
Enuresis	19	0
Psychiatric symptoms NEC		
Hypervigilance	9	0
Psychiatric symptom	4	0
Psychological trauma	2	0
Trance	1	0
Psychotic disorder NEC		
Acute psychosis	1	0
Psychotic behaviour	1	0
Psychotic disorder	22	0
Schizophrenia NEC		
Schizophrenia	1	0
Sexual arousal disorders		
Disturbance in sexual arousal	2	0
Sexual inhibition	1	0
Sexual desire disorders		
Hypersexuality	1	0
Libido decreased	12	0
Libido increased	6	0
Loss of libido	15	0
Sexual dysfunction NEC		
Genito-pelvic pain/penetration disorder	1	0
Sleep disorders NEC		
Sleep disorder	179	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Sleep disorder due to general medical condition, insomnia type	2	0
<i>Somatic symptom disorders</i>		
Conversion disorder	19	0
Habit cough	17	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	7	0
Self-injurious ideation	2	0
Suicidal ideation	34	0
Suicide attempt	8	0
Suicide threat	1	0
<i>Thinking disturbances</i>		
Bradyphrenia	37	0
Intrusive thoughts	6	0
Morbid thoughts	1	0
Tachyphrenia	5	0
Thinking abnormal	17	0
Thought blocking	1	0
<i>Tic disorders</i>		
Tic	9	0
Psychiatric disorders SOC TOTAL	6869	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	25	0
Bladder spasm	1	0
Dysuria	42	0
Incontinence	21	0
Lower urinary tract symptoms	2	0
Micturition disorder	2	0
Micturition urgency	36	0
Pollakiuria	106	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	10	0
<i>Bladder disorders NEC</i>		
Bladder disorder	7	0
Bladder fibrosis	1	0
Urinary bladder haemorrhage	2	0
<i>Bladder infections and inflammations</i>		
Cystitis interstitial	5	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	6	0
Glomerulonephritis rapidly progressive	2	0
IgA nephropathy	2	0
Nephrotic syndrome	18	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
Oliguria	1	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Renal & urinary disorders cont'd</i>		
Renal failure	17	1
Renal impairment	20	0
Renal injury	1	0
Renal lithiasis		
Nephrolithiasis	8	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	30	0
Ketonuria	1	0
Myoglobinuria	1	0
Proteinuria	10	0
Urine abnormality	9	0
Urine odour abnormal	6	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	237	0
Urinary tract discomfort	1	0
Urinary tract pain	4	0
Renal & urinary disorders SOC TOTAL	898	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	23	0
Breast mass	100	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	8	0
Breast engorgement	7	0
Breast haematoma	1	0
Breast oedema	4	0
Breast pain	534	0
Breast swelling	117	0
Breast tenderness	60	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	45	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	6	0
Lactation puerperal increased	4	0
Suppressed lactation	26	0
<i>Menopausal effects NEC</i>		
Artificial menopause	1	0
Menopausal symptoms	15	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Menopause delayed	1	0
Premature menopause	12	0
<i>Menopausal effects on the genitourinary tract</i>		
Atrophic vulvovaginitis	1	0
Postmenopausal haemorrhage	77	0
<i>Menstruation and uterine bleeding NEC</i>		
Abnormal uterine bleeding	6	0
Dysmenorrhoea	2387	0
Intermenstrual bleeding	900	0
Menstrual discomfort	20	0
Menstrual disorder	1443	0
Menstruation irregular	2590	0
Premenstrual dysphoric disorder	8	0
Premenstrual headache	7	0
Premenstrual pain	90	0
Premenstrual syndrome	97	0
Retrograde menstruation	1	0
Withdrawal bleed	15	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	477	0
Hypomenorrhoea	543	0
Menstruation delayed	4046	0
Oligomenorrhoea	122	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	4523	0
Menometrorrhagia	17	0
Polymenorrhoea	680	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>		
Ovarian cyst	14	0
Ovarian cyst ruptured	1	0
Polycystic ovaries	40	0
<i>Ovarian and fallopian tube disorders NEC</i>		
Adnexal torsion	1	0
Hydrosalpinx	2	0
Ovarian enlargement	1	0
Ovarian haemorrhage	5	0
Ovulation disorder	2	0
Ovulation pain	54	0
Premature ovulation	4	0
<i>Pelvis and broad ligament disorders NEC</i>		
Adnexa uteri mass	1	0
Adnexa uteri pain	40	0
Pelvic congestion	1	0
Pelvic floor muscle weakness	1	0
Pelvic haemorrhage	17	0
<i>Penile and scrotal infections and inflammations</i>		
Balanoposthitis	2	0
<i>Penile disorders NEC (excl erection and ejaculation)</i>		
Penile blister	1	0
Penile discharge	1	0
Penile discomfort	1	0
Penile erythema	1	0
Penile haemorrhage	2	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Penile pain	1	0
Penile swelling	4	0
Penis disorder	8	0
<i>Prostate and seminal vesicles infections and inflammations</i>		
Prostatitis	3	0
<i>Prostatic signs, symptoms and disorders NEC</i>		
Prostatic pain	1	0
Prostatomegaly	3	0
<i>Reproductive tract disorders NEC (excl neoplasms)</i>		
Genital haemorrhage	18	0
Genital hypoaesthesia	1	0
Genital lesion	1	0
Genital paraesthesia	1	0
Genital ulceration	5	0
Perineal ulceration	1	0
<i>Reproductive tract infections and inflammations NEC</i>		
Genital tract inflammation	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Genital burning sensation	2	0
Genital pain	4	0
Genital rash	4	0
Genital swelling	2	0
Pelvic discomfort	5	0
Pelvic pain	86	0
Perineal pain	2	0
Perineal rash	1	0
Pruritus genital	3	0
<i>Scrotal disorders NEC</i>		
Acquired hydrocele	1	0
Scrotal angiokeratoma	1	0
Scrotal discomfort	1	0
Scrotal erythema	1	0
Scrotal exfoliation	1	0
Scrotal pain	17	0
Scrotal swelling	4	0
Varicocele	1	0
<i>Sexual function and fertility disorders NEC</i>		
Dyspareunia	5	0
Infertility	5	0
Infertility female	1	0
Sexual dysfunction	6	0
<i>Spermatogenesis and semen disorders</i>		
Aspermia	1	0
Haemospermia	6	0
Semen discolouration	1	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular disorder	3	0
Testicular pain	48	0
Testicular swelling	8	0
Testis discomfort	1	0
<i>Uterine disorders NEC</i>		
Adenomyosis	7	0
Endometrial thickening	2	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Endometriosis	72	0
Uterine haemorrhage	27	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	27	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	1212	0
Vaginal mucosal blistering	1	0
Vaginal ulceration	1	0
Vulval disorder	1	0
Vulval haemorrhage	22	0
Vulval ulceration	6	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	64	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	6	0
Vulvovaginal rash	2	0
Vulvovaginal swelling	3	0
Reproductive & breast disorders SOC TOTAL	21103	1

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	5	0
Apnoeic attack	1	0
Dyspnoea	3710	5
Dyspnoea at rest	9	0
Dyspnoea exertional	33	1
Hyperventilation	42	0
Hypopnoea	90	0
Hypoventilation	1	0
Irregular breathing	18	0
Mouth breathing	3	0
Nocturnal dyspnoea	2	0
Orthopnoea	3	0
Respiration abnormal	46	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	2	0
Bronchiectasis	12	0
<i>Bronchospasm and obstruction</i>		
Asthma	288	0
Asthma late onset	2	0
Bronchospasm	14	0
Chronic obstructive pulmonary disease	15	1
Cough variant asthma	4	0
Obstructive airways disorder	9	0
Reversible airways obstruction	1	0
Wheezing	336	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	2043	3
Cough decreased	2	0
Haemoptysis	47	0
Productive cough	137	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

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Vocal cord dysfunction	1	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Epiglottic oedema	1	0
Laryngeal obstruction	1	0
Laryngeal oedema	2	0
Laryngospasm	1	0
Stridor	20	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Alveolitis	1	0
Hypersensitivity pneumonitis	1	0
Lower respiratory tract inflammation	1	0
Pneumonia aspiration	8	5
Pneumonitis	27	1
Pulmonary sarcoidosis	2	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	25	0
Increased bronchial secretion	1	0
Lung hyperinflation	1	0
Lung opacity	2	0
Pleuritic pain	17	0
Pulmonary haemorrhage	1	0
Pulmonary pain	75	0
Rales	4	0
Respiratory fremitus	1	0
<i>Mediastinal disorders</i>		
Mediastinal mass	1	0
Pulmonary hilum mass	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	244	0
Nasal inflammation	2	0
Rhinitis allergic	18	0
<i>Nasal disorders NEC</i>		
Epistaxis	779	0
Intranasal hyposaesthesia	1	0
Intranasal paraesthesia	1	0
Nasal crusting	1	0
Nasal disorder	3	0
Nasal dryness	31	0
Nasal mucosal discolouration	1	0
Nasal odour	6	0
Nasal oedema	5	0
Nasal polyps	1	0
Nasal pruritus	9	0
<i>Neonatal hypoxic conditions</i>		
Dry lung syndrome	1	0
Gasping syndrome	1	0
Infantile apnoea	1	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Allergic sinusitis	1	0
Paranasal sinus inflammation	3	0
Sinonasal obstruction	9	0
Sinus congestion	52	0
Sinus disorder	5	0

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
<i>Parenchymal lung disorders NEC</i>		
Atelectasis	2	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	6	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	50	0
Pharyngeal swelling	216	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	28	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	19	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	373	26
Pulmonary infarction	6	0
Pulmonary thrombosis	6	1
<i>Respiratory failures (excl neonatal)</i>		
Acute respiratory failure	2	1
Respiratory failure	10	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
Respiratory symptom	15	0

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
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	7	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	148	0
Dysphonia	141	0
Increased upper airway secretion	5	0
Increased viscosity of upper respiratory secretion	27	0
Nasal discharge discolouration	3	0
Nasal discomfort	44	0
Nasal obstruction	2	0
Oropharyngeal blistering	10	0
Oropharyngeal discomfort	54	0
Oropharyngeal pain	2455	0
Oropharyngeal plaque	2	0
Paranasal sinus discomfort	41	0
Rhinalgia	11	0
Rhinorrhoea	766	0
Sinus pain	178	0
Sneezing	314	0
Snoring	7	0
Throat clearing	8	0
Throat irritation	206	0
Throat tightness	220	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	14181	50

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	164	0
Acne cystic	15	0
Dermatitis acneiform	8	0
<i>Alopecias</i>		
Alopecia	201	0
Alopecia areata	33	0
Alopecia totalis	2	0
Androgenetic alopecia	1	0
Diffuse alopecia	2	0
Hypotrichosis	1	0
Madarosis	3	0
<i>Angioedemas</i>		
Angioedema	176	0
Circumoral swelling	1	0
<i>Apocrine and eccrine gland disorders</i>		
Anhidrosis	1	0
Bromhidrosis	1	0
Cold sweat	641	0
Hidradenitis	3	0
Hyperhidrosis	1843	0
Hypohidrosis	2	0
Milia	2	0
Miliaria	76	0
Night sweats	514	0
<i>Bullous conditions</i>		
Blister	392	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	4	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	186	0
Macule	4	0
Neutrophilic dermatosis	1	0
Pain of skin	229	0
Papule	98	0
Pathergy reaction	1	0
Peau d'orange	2	0
Scab	18	0
Scar pain	12	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Sensitive skin	144	0
Shagreen skin	1	0
Skin burning sensation	186	0
Skin degenerative disorder	1	0
Skin discolouration	110	0
Skin discomfort	4	0
Skin disorder	19	0
Skin fissures	7	0
Skin indentation	2	0
Skin induration	3	0
Skin lesion	37	0
Skin lesion inflammation	1	0
Skin necrosis	1	0
Skin odour abnormal	15	0
Skin plaque	3	0
Skin reaction	120	0
Skin sensitisation	32	0
Skin swelling	72	0
Skin texture abnormal	2	0
Skin tightness	24	0
Skin warm	251	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	103	0
Dermatitis allergic	195	0
Dermatitis atopic	28	0
Dermatitis contact	14	0
Dermatitis diaper	3	0
Dyshidrotic eczema	24	0
Eczema	254	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	99	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	29	0
Drug reaction with eosinophilia and systemic symptoms	1	0
Fixed eruption	2	0
Toxic skin eruption	2	0
<i>Erythemas</i>		
Erythema	1794	0
Palmar erythema	4	0
Red man syndrome	2	0
<i>Exfoliative conditions</i>		

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Dermatitis exfoliative	2	0
Dermatitis exfoliative generalised	4	0
Exfoliative rash	18	0
Keratolysis exfoliativa acquired	2	0
Skin exfoliation	97	0
<i>Granulomatous and deep cutaneous inflammatory conditions</i>		
Cutaneous sarcoidosis	1	0
Granuloma annulare	5	0
<i>Hyperkeratoses</i>		
Hyperkeratosis	1	0
Keratosis pilaris	3	0
Lichenoid keratosis	3	0
<i>Hyperpigmentation disorders</i>		
Argyria	1	0
Chloasma	1	0
Ephelides	1	0
Skin hyperpigmentation	3	0
Solar lentigo	2	0
<i>Hypertrichoses</i>		
Hirsutism	1	0
<i>Hypopigmentation disorders</i>		
Skin depigmentation	4	0
Skin hypopigmentation	1	0
Vitiligo	12	0
<i>Lipodystrophies</i>		
Lipoatrophy	4	0
Lipodystrophy acquired	1	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
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
<i>Panniculitides</i>		
Erythema nodosum	22	0
Panniculitis	1	0
<i>Papulosquamous conditions</i>		
Erythema annulare	2	0
Lichen planus	16	0
Lichen sclerosus	8	0
Parapsoriasis	2	0
Pityriasis rosea	99	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	55	0
Polymorphic light eruption	2	0
Solar dermatitis	1	0
<i>Pigmentation changes NEC</i>		
Haemosiderin stain	1	0
Pigmentation disorder	11	0
<i>Pilar disorders NEC</i>		

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Hair colour changes	8	0
Hair disorder	1	0
Hair growth abnormal	5	0
Hair texture abnormal	5	0
Piloerection	23	0
Pseudofolliculitis	2	0
Trichorrhexis	2	0
Pruritus NEC		
Itching scar	5	0
Pruritus	4422	0
Psoriatic conditions		
Dermatitis psoriasiform	3	0
Guttate psoriasis	13	0
Nail psoriasis	1	0
Palmoplantar pustulosis	2	0
Psoriasis	145	0
Pustular psoriasis	2	0
Purpura and related conditions		
Ecchymosis	1	0
Henoch-Schonlein purpura	6	0
Petechiae	119	0
Purpura	43	0
Pustular conditions		
Acute generalised exanthematous pustulosis	1	0
Rashes, eruptions and exanthems NEC		
Butterfly rash	4	0
Rash	4704	0
Rash erythematous	991	0
Rash macular	441	0
Rash maculo-papular	53	0
Rash morbilliform	37	0
Rash papular	291	0
Rash pruritic	994	0
Rash vesicular	58	0
Systemic lupus erythematosus rash	6	0
Rosaceas		
Rosacea	27	0
Scaly conditions		
Dandruff	4	0
Pityriasis	21	0
Sebaceous gland disorders		
Seborrhoea	9	0
Skin and subcutaneous conditions NEC		
Cutaneous symptom	4	0
Reactive perforating collagenosis	1	0
Skin mass	18	0
Skin and subcutaneous tissue ulcerations		
Mucocutaneous ulceration	1	0
Pyoderma gangrenosum	1	0
Scleroderma associated digital ulcer	1	0
Skin erosion	20	0
Skin ulcer	13	0
Skin cysts and polyps		

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Dermal cyst	12	0
Skin dystrophies		
Keloid scar	3	0
Skin wrinkling	2	0
Skin haemorrhages		
Haemorrhage subcutaneous	7	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	12	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	5	0
Cold urticaria	5	0
Idiopathic urticaria	1	0
Mechanical urticaria	6	0
Solar urticaria	2	0
Urticaria	1519	0
Urticaria cholinergic	1	0
Urticaria chronic	15	0
Urticaria contact	1	0
Urticaria papular	3	0
Urticaria thermal	4	0
Urticularial vasculitis	3	0
Skin disorders SOC TOTAL	23007	1

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Reaction Name	Total	Fatal
Social circumstances		
<i>Age related issues</i>		
Infant	3	0
Menopause	27	0
Postmenopause	3	0
<i>Criminal activity</i>		
Verbal abuse	1	0
<i>Dependents</i>		
Sick relative	3	0
<i>Dietary and nutritional issues</i>		
Feeding tube user	1	0
<i>Disability issues</i>		
Bedridden	20	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	10	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	15	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	1	0
<i>Tobacco use</i>		
Ex-tobacco user	1	0
Non-tobacco user	3	0
Tobacco user	1	0
Social circumstances SOC TOTAL	188	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	2	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
Pericardial drainage	1	0
<i>Contraceptive methods female</i>		
Contraception	1	0
Contraceptive implant	3	0
Oral contraception	1	0
<i>Contraceptive methods male</i>		
Condom	2	0
<i>Dietary and nutritional therapies</i>		
Medical diet	8	0
Nothing by mouth order	5	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	8	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	7	0
<i>Immunisations</i>		

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Reaction Name	Total	Fatal
Surgical & medical procedures		
COVID-19 immunisation	81	0
Immunisation	62	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		
Leg amputation	1	0
Limb immobilisation	8	0
Limb operation	5	0
Lymphoid tissue therapeutic procedures		
Lymphadenectomy	1	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
Skull and brain therapeutic procedures		
Cerebrovascular operation	1	0
Posterior fossa decompression	1	0
Therapeutic bladder catheterisation		
Bladder catheterisation	2	0
Therapeutic procedures NEC		

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Surgical & medical procedures cont'd</i>		
Abscess drainage	1	0
Anaphylaxis treatment	5	0
Bed rest	2	0
Fatigue management	1	0
Hospitalisation	10	0
Injection	42	0
Interchange of vaccine products	6	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
<i>Tracheal therapeutic procedures</i>		
Tracheostomy	1	0
<i>Uterine therapeutic procedures</i>		
Endometrial ablation	2	0
Surgical & medical procedures SOC TOTAL	363	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	1	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>Arterial infections and inflammations</i>		
Arteritis	1	0
Giant cell arteritis	10	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	60	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	18	0
Haematoma	37	0
Haemorrhage	1023	2
Internal haemorrhage	7	0
Venous haemorrhage	2	0
<i>Lymphangiopathies</i>		
Lymphangiopathy	1	0
Lymphocele	4	0
<i>Lymphoedemas</i>		
Lymphoedema	160	0
<i>Non-site specific embolism and thrombosis</i>		
Arterial thrombosis	4	0
Embolism	59	0
Embolism venous	5	0
Microembolism	1	0
Thrombosis	370	7
Venous thrombosis	6	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Arterial occlusive disease	2	0
Arterial spasm	1	0
Arteriosclerosis	2	0
Haemorrhagic infarction	1	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 24-Sep-2021

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Reaction Name	Total	Fatal
Vascular disorders <small>Vascular disorders cont'd</small>		
Infarction	3	0
Ischaemia	9	0
Peripheral venous disease	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	26	0
Vascular wall hypertrophy	1	0
Vasodilatation	32	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	251	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	10	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	36	0
Erythromelalgia	1	0
Flushing	365	0
Hot flush	989	0
Peripheral vascular disorder	1	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Claudication of jaw muscles	1	0
Extremity necrosis	3	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	269	0
Peripheral ischaemia	12	0
Poor peripheral circulation	13	0
Raynaud's phenomenon	49	0
Subclavian vein occlusion	1	0
Vasoconstriction	2	0
<i>Phlebitis NEC</i>		
Phlebitis	27	0
Phlebitis superficial	6	0
<i>Site specific vascular disorders NEC</i>		
Inferior vena cava dilatation	1	0
Pallor	307	0
<i>Varicose veins NEC</i>		

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Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
Spider vein	5	0
Varicophlebitis	4	0
Varicose vein	24	0
<i>Vascular hypertensive disorders NEC</i>		
Diastolic hypertension	2	0
Essential hypertension	3	0
Hypertension	478	1
Labile hypertension	1	0
Orthostatic hypertension	1	0
Secondary hypertension	1	0
Systolic hypertension	5	0
White coat hypertension	1	0
<i>Vascular hypotensive disorders</i>		
Hypotension	338	1
Orthostatic hypotension	28	0
<i>Vasculitides NEC</i>		
Behcet's syndrome	3	0
Diffuse vasculitis	1	0
Granulomatosis with polyangiitis	2	0
MAGIC syndrome	1	0
Thromboangiitis obliterans	1	0
Vasculitis	42	0
<i>Vena caval embolism and thrombosis</i>		
Vena cava embolism	1	0
Vena cava thrombosis	1	0
Vascular disorders SOC TOTAL	5308	14
TOTAL REACTIONS FOR DRUG	330983	544
TOTAL REPORTS	117297	
TOTAL FATAL OUTCOME REPORTS		544