

COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

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All UK spontaneous reports received between 9/12/2020 and 9/21/21 for mRNA Pfizer/BioNTech vaccine analysis print

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Case Series Drug Analysis Print

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

Report Run Date: 17-Sep-2021

Data Lock Date: 15-Sep-2021 18:31:25

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	92	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	4	0
Antiphospholipid syndrome	5	0
Coagulopathy	19	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	8	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	1392	0
Lymph node ulcer	1	0
Lymphadenitis	113	0
Lymphadenopathy	8935	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	6	0
<i>Neutropenias</i>		
Autoimmune neutropenia	2	0
Neutropenia	37	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	176	1
Thrombocytopenic purpura	5	0
Thrombotic thrombocytopenic purpura	5	0
<i>Thrombocytoses</i>		
Thrombocytosis	6	0
Blood disorders SOC TOTAL	11051	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	10	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	42	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	13	0
Cardiovascular symptom	1	0
Palpitations	2648	1
<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	57	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	155	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	176	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	2	0
Myocardial disorders NEC		
Cardiac amyloidosis	1	0
Cardiomegaly	22	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	296	2
Noninfectious pericarditis		
Pericarditis	220	1
Pericardial disorders NEC		
Pericardial effusion	25	0
Pericardial haemorrhage	3	3
Pericardial rub	1	0
Rate and rhythm disorders NEC		
Arrhythmia	102	0
Bradycardia	51	0
Bradycardia foetal	2	1
Cardiac flutter	336	0
Extrasystoles	124	0
Paroxysmal arrhythmia	1	0
Postural orthostatic tachycardia syndrome	17	0
Tachyarrhythmia	1	0
Tachycardia	632	0
Tachycardia paroxysmal	1	0
Right ventricular failures		
Cor pulmonale	1	0
Supraventricular arrhythmias		
Arrhythmia supraventricular	10	0
Atrial fibrillation	158	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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Reaction Name	Total	Fatal
Cardiac disorders Cardiac disorders cont'd		
Sinus tachycardia	45	0
Supraventricular extrasystoles	2	0
Supraventricular tachycardia	32	0
<i>Tricuspid valvular disorders</i>		
Tricuspid valve incompetence	3	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	86	31
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	5481	95

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Autosomal chromosomal abnormalities</i>		
Trisomy 8	1	0
<i>Cardiac disorders congenital NEC</i>		
Heart disease congenital	12	0
<i>Cardiac septal defects congenital</i>		
Atrial septal defect	1	0
Hypertrophic cardiomyopathy	1	0
<i>Cardiac valve disorders congenital</i>		
Bicuspid aortic valve	1	0
<i>Central nervous system disorders congenital NEC</i>		
Spina bifida	1	0
<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
<i>Connective tissue disorders congenital</i>		
Ehlers-Danlos syndrome	2	0
<i>External ear disorders congenital</i>		
Anotia	1	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>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
Moebius II syndrome	1	0
Tourette's disorder	2	0

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Reaction Name	Total	Fatal
Congenital disorders Congenital disorders cont'd		
<i>Ocular disorders congenital NEC</i>		
Colour blindness	3	0
<i>Palate disorders congenital</i>		
Cleft lip and palate	1	0
<i>Peripheral nervous system disorders congenital NEC</i>		
Hereditary neuropathy with liability to pressure palsies	1	0
Paroxysmal extreme pain disorder	1	0
<i>Pulmonary and bronchial disorders congenital</i>		
Congenital cystic lung	1	0
<i>Retinal disorders congenital</i>		
Retinitis pigmentosa	1	0
<i>Skin and subcutaneous tissue disorders congenital NEC</i>		
Acral peeling skin syndrome	1	0
<i>Tongue disorders congenital</i>		
Ankyloglossia congenital	1	0
Congenital disorders SOC TOTAL	61	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear canal erythema	1	0
Ear congestion	27	0
Ear discomfort	83	0
Ear disorder	14	0
Ear haemorrhage	9	0
Ear pain	824	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	202	0
Deafness bilateral	6	0
Deafness neurosensory	15	0
Deafness transitory	6	0
Deafness unilateral	25	0
Hypoacusis	156	0
Sudden hearing loss	37	0
<i>Hyperacusia</i>		
Hyperacusis	47	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	9	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	1632	0
Vertigo	1158	0
Vertigo labyrinthine	9	0
Vertigo positional	63	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	4495	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Autoimmune thyroiditis	2	0
Thyroiditis	14	0
Thyroiditis acute	2	0
Thyroiditis subacute	3	0
<i>Adrenal cortical hypofunctions</i>		
Addison's disease	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	14	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	36	0
Ovulation delayed	26	0
<i>Thyroid disorders NEC</i>		
Autoimmune thyroid disorder	1	0
Goitre	12	0
Thyroid disorder	7	0
Thyroid mass	1	0
Thyroid pain	5	0
<i>Thyroid hyperfunction disorders</i>		
Basedow's disease	7	0
Hyperthyroidism	27	0
Thyrotoxic crisis	3	0
<i>Thyroid hypofunction disorders</i>		
Autoimmune hypothyroidism	1	0
Hypothyroidism	22	0
Myxoedema	1	0
Endocrine disorders SOC TOTAL	204	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	68	0
<i>Colour blindness (incl acquired)</i>		
Dyschromatopsia	7	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	4	0
<i>Eyelid movement disorders</i>		
Blepharospasm	122	0
Excessive eye blinking	5	0
Eyelid function disorder	3	0
Eyelid myokymia	4	0
Eyelid ptosis	38	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	38	0
<i>Lacrimation disorders</i>		
Dry eye	121	0
Lacrimation increased	110	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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Reaction Name	Total	Fatal
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	109	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	888	0
Eye swelling	418	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	104	0
Retinal disorder	2	0
Vitreous disorder	1	0
Ocular infections, inflammations and associated manifestations		
Eye allergy	11	0
Eye discharge	22	0
Eye inflammation	20	0
Eye irritation	81	0
Eye pruritus	201	0
Limbal swelling	2	0
Ocular hyperaemia	183	0
Ocular nerve and muscle disorders		
Binocular eye movement disorder	1	0
Extraocular muscle disorder	1	0
Extraocular muscle paresis	1	0
Eye movement disorder	29	0
Gaze palsy	1	0
Ocular myasthenia	1	0
Ophthalmoplegia	3	0

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Strabismus	5	0
Ocular sensation disorders		
Abnormal sensation in eye	16	0
Asthenopia	130	0
Eye paraesthesia	2	0
Foreign body sensation in eyes	16	0
Hypoaesthesia eye	14	0
Photophobia	369	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	11	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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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Retinopathy	2	0
<i>Scleral infections, irritations and inflammations</i>		
Episcleritis	7	0
Scleritis	3	0
<i>Scleral structural change, deposit and degeneration</i>		
Scleral discolouration	2	0
<i>Visual colour distortions</i>		
Chloropsia	2	0
Cyanopsia	1	0
Erythropsia	2	0
Xanthopsia	1	0
<i>Visual disorders NEC</i>		
Charles Bonnet syndrome	1	0
Diplopia	132	0
Glare	1	0
Halo vision	7	0
Heteronymous diplopia	1	0
Metamorphopsia	15	0
Oscillopsia	2	0
Photopsia	110	0
Scintillating scotoma	4	0
Vision blurred	999	0
Visual brightness	3	0
Visual snow syndrome	7	0
<i>Visual field disorders</i>		
Visual field defect	19	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Amaurosis fugax	2	0
Blindness	104	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	19	0
Visual acuity reduced transiently	1	0
Visual impairment	286	0
<i>Visual pathway disorders</i>		
Optic nerve disorder	1	0
Eye disorders SOC TOTAL	5397	0

Case Series Drug Analysis Print

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Report Run Date: 17-Sep-2021

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MedDRA Version: MedDRA 24.0

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	11	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	58	0
Crohn's disease	39	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
Teeth brittle	3	0
Teething	5	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
<i>Diaphragmatic hernias</i>		

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Hiatus hernia	5	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	4354	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	345	0
Epigastric discomfort	13	0
Eructation	41	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	17	0
Faecaloma	4	0
Faeces discoloured	50	0
Faeces hard	2	0
Faeces pale	3	0
Faeces soft	10	0
Mucous stools	7	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	423	0
Aerophagia	3	0
Flatulence	153	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	1160	0
Abdominal pain lower	104	0
Abdominal pain upper	1923	0
Abdominal rigidity	22	0
Abdominal tenderness	9	0
Gastrointestinal pain	106	0
Oesophageal pain	6	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	207	0
Duodenogastric reflux	3	0
Gastric dilatation	7	0
Gastrooesophageal reflux disease	119	0
Impaired gastric emptying	7	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Infrequent bowel movements	3	0
Intestinal dilatation	1	0
Intestinal pseudo-obstruction	2	0
<i>Gastrointestinal disorders NEC</i>		
Food poisoning	5	0
Functional gastrointestinal disorder	8	0
Gastric disorder	6	0
Gastrointestinal disorder	19	0
Stomach mass	4	0
<i>Gastrointestinal dyskinetic disorders</i>		
Bowel movement irregularity	4	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	507	0
Abdominal symptom	1	0
Acute abdomen	4	0
Anal incontinence	19	0
Breath odour	16	0
Dysphagia	170	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	70	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
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival blister	11	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Gingival discomfort	4	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	16	1
Intestinal haemorrhage	1	0
Rectal haemorrhage	55	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	11432	0
Regurgitation	1	0
Retching	85	0
Vomiting	3451	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	46	0
Melaena	8	0
Upper gastrointestinal haemorrhage	8	0
<i>Oesophageal stenosis and obstruction</i>		
Oesophageal stenosis	3	0
<i>Oesophagitis (excl infective)</i>		
Eosinophilic oesophagitis	1	0
Oesophagitis	3	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Oral dryness and saliva altered</i>		
Aptyalism	3	0
Dry mouth	418	0
Lip dry	35	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	14	0
Oral lichen planus	9	0
Oral mucosal hypertrophy	1	0
Oral papule	1	0
Uvulitis	2	0
<i>Oral soft tissue haemorrhages</i>		
Mouth haemorrhage	11	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	406	0
Lip discolouration	7	0
Lip erythema	2	0
Lip exfoliation	5	0
Lip pain	47	0
Lip pruritus	13	0
Lip scab	1	0
Oral discomfort	67	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	141	0
Oral pruritus	20	0
Paraesthesia oral	801	0
Pigmentation lip	1	0
<i>Oral soft tissue swelling and oedema</i>		
Lip oedema	4	0
Lip swelling	600	0
Mouth swelling	75	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Oedema mouth	4	0
Palatal oedema	2	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	39	0
Lip ulceration	16	0
Mouth ulceration	372	0
Oral mucosa erosion	1	0
Palatal ulcer	1	0
Stomatitis	55	0
<i>Tongue disorders</i>		
Glossitis	15	0
Hypertrophy of tongue papillae	1	0
Plicated tongue	3	0
Tongue disorder	32	0
Tongue geographic	1	0
Tongue haemorrhage	2	0
Tongue ulceration	27	0
Trichoglossia	4	0
<i>Tongue signs and symptoms</i>		
Glossodynia	173	0
Scalloped tongue	5	0
Stiff tongue	3	0
Swollen tongue	405	0
Tongue blistering	16	0
Tongue coated	16	0
Tongue discolouration	33	0
Tongue discomfort	36	0
Tongue dry	13	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
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	3	0
Tongue spasm	8	0
<i>Tooth missing</i>		
Tooth loss	6	0
Gastrointestinal disorders SOC TOTAL	30335	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	3	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	12	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	1496	0
Chronic fatigue syndrome	60	0
Decreased activity	8	0
Fatigue	18248	0
Malaise	4074	0
Sluggishness	12	0
<i>Body temperature altered</i>		

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Hyperthermia	5	0
Hypothermia	21	0
Temperature regulation disorder	10	0
Breast complications associated with device		
Breast implant palpable	1	0
Capsular contracture associated with breast implant	1	0
Cardiac complications associated with device		
Prosthetic cardiac valve thrombosis	2	0
Complications associated with device NEC		
Capsular contracture associated with implant	1	0
Complication of device removal	3	0
Injury associated with device	3	0
Medical device pain	1	0
Medical device site swelling	1	0
Phantom shocks	1	0
Death and sudden death		
Brain death	3	H
Cardiac death	1	1
Clinical death	1	1
Death	144	141
Drowning	2	0
Sudden death	27	27
Febrile disorders		
Hyperpyrexia	7	0
Pyrexia	11847	0
Feelings and sensations NEC		
Chills	7545	0
Feeling abnormal	1285	0
Feeling cold	916	0
Feeling drunk	68	0
Feeling hot	934	0
Feeling jittery	20	0
Feeling of body temperature change	262	0
Feeling of relaxation	3	0
Hangover	73	0
Hunger	37	0
Sensation of blood flow	3	0
Sensation of foreign body	43	0
Temperature intolerance	36	0
Thirst	277	0
Fibrosis NEC		
Fibrosis	1	0
Gait disturbances		
Gait disturbance	177	0
Gait inability	59	0
Loss of control of legs	14	0
General signs and symptoms NEC		
Adhesion	1	0
Chronic disease	1	0
Condition aggravated	165	0
Crepitations	1	0
Crying	127	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	18	0
Exercise tolerance decreased	17	0
Foaming at mouth	1	0
General physical health deterioration	14	1
General symptom	2	0
Glassy eyes	3	0
High-pitched crying	2	0
Illness	1444	0
Induration	13	0
Influenza like illness	1852	0
Irritability postvaccinal	2	0
Local reaction	69	0
Moaning	3	0
Multiple organ dysfunction syndrome	8	4
Nonspecific reaction	1	0
Organ failure	1	1
Perforation	2	0
Peripheral swelling	2788	0
Physical deconditioning	1	0
Pre-existing condition improved	8	0
Prolapse	1	0
Screaming	19	0
Secretion discharge	18	0
Swelling	2286	0
Swelling face	656	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	347	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 swelling	1	0
Infusion site urticaria	1	0
Infusion site warmth	1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
<i>Injection site reactions</i>		
Injected limb mobility decreased	25	0
Injection site bruising	55	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	304	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	29	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	414	0
Injection site movement impairment	1	0
Injection site necrosis	3	0
Injection site nerve damage	1	0
Injection site oedema	12	0
Injection site pain	2423	0
Injection site paraesthesia	11	0
Injection site pruritus	147	0
Injection site rash	133	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	157	0
<i>Interactions</i>		
Alcohol interaction	3	0
Drug interaction	23	0
Inhibitory drug interaction	3	0
<i>Mass conditions NEC</i>		
Cyst	34	0
Mass	58	0
Nodule	30	0
<i>Mucosal findings abnormal</i>		
Mucosa vesicle	1	0
Mucosal dryness	1	0
Mucosal haemorrhage	9	0
Mucosal inflammation	2	0
Oedema mucosal	1	0
Polyp	2	0
<i>Necrosis NEC</i>		

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Fat necrosis	2	0
Necrosis	3	0
Oedema NEC		
Face oedema	26	0
Generalised oedema	3	0
Localised oedema	15	0
Oedema	55	0
Oedema peripheral	72	0
Pain and discomfort NEC		
Axillary pain	2364	0
Chest discomfort	1311	0
Chest pain	3066	0
Discomfort	373	0
Facial discomfort	17	0
Facial pain	176	0
Inflammatory pain	9	0
Non-cardiac chest pain	23	0
Pain	6993	0
Suprapubic pain	1	0
Tenderness	536	0
Visceral pain	1	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	7	0
Adverse event	1	0
Adverse food reaction	2	0
Drug ineffective	231	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	25	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	70	0
Therapy non-responder	1	0
Treatment failure	6	0
Vaccination failure	20	0
Trophic disorders		
Atrophy	1	0
Calcinosis	1	0
Hyperplasia	1	0
Ulcers NEC		
Ulcer	25	0
Ulcer haemorrhage	1	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	10	0
Shoulder injury related to vaccine administration	20	0
Vaccination site anaesthesia	1	0
Vaccination site bruising	102	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
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	506	0
Vaccination site granuloma	3	0
Vaccination site haematoma	2	0
Vaccination site haemorrhage	18	0
Vaccination site hypersensitivity	2	0
Vaccination site hypoaesthesia	14	0
Vaccination site induration	69	0
Vaccination site inflammation	50	0
Vaccination site irritation	12	0
Vaccination site joint discomfort	2	0
Vaccination site joint erythema	7	0
Vaccination site joint inflammation	1	0
Vaccination site joint movement impairment	17	0
Vaccination site joint pain	27	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	222	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	1874	0
Vaccination site paraesthesia	6	0
Vaccination site phlebitis	1	0
Vaccination site pruritus	134	0
Vaccination site rash	110	0
Vaccination site reaction	30	0
Vaccination site scab	2	0
Vaccination site scar	1	0
Vaccination site swelling	474	0
Vaccination site thrombosis	1	0
Vaccination site ulcer	1	0
Vaccination site urticaria	10	0
Vaccination site vesicles	9	0
Vaccination site warmth	236	0
Vascular complications associated with device		
Vascular stent thrombosis	1	0
Withdrawal and rebound effects		
Drug withdrawal syndrome	5	0
Withdrawal syndrome	32	0
General disorders SOC TOTAL	81704	18H

Case Series Drug Analysis Print

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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	2	0
Cholecystitis acute	2	0
Cholelithiasis	8	0
<i>Cholestasis and jaundice</i>		
Cholestasis	2	0
Jaundice	19	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	22	0
Hepatomegaly	1	0
Liver tenderness	3	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Autoimmune hepatitis	5	0
Drug-induced liver injury	2	0
Hepatic steatosis	1	0
Hepatitis	10	0
Immune-mediated hepatic disorder	1	0
Liver injury	11	0
Hepatic disorders SOC TOTAL	148	1

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	12	0
<i>Allergic conditions NEC</i>		
Allergic oedema	12	0
Allergy to animal	1	0
Allergy to arthropod bite	5	0
Allergy to arthropod sting	2	0
Allergy to metals	1	0
Allergy to sting	1	0
Hypersensitivity	781	0
Infusion related hypersensitivity reaction	2	0
Mite allergy	2	0
Multiple allergies	6	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
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	96	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	35	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	44	0
Graft versus host disease	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
<i>Immunodeficiency disorders NEC</i>		
Hypogammaglobulinaemia	1	0
Immunodeficiency	1	0

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Reaction Name	Total	Fatal
Immune system disorders		
Immune system disorders cont'd		
Immunosuppression	3	0
Transplant rejections		
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	1653	2

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Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Abdominal abscess	1	0
Abdominal infection	1	0
Anal abscess	3	0
Appendicitis	34	0
Appendicitis perforated	4	0
Diverticulitis	10	0
Dysentery	1	0
Gastric infection	2	0
Gastroenteritis	22	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	142	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	67	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	53	0
Oral candidiasis	36	0
Respiratory moniliasis	1	0
Skin candida	1	0
Systemic candida	1	0
Vulvovaginal candidiasis	38	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
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	1066	39
COVID-19 pneumonia	43	13
Coronavirus infection	7	0
Post-acute COVID-19 syndrome	1	0
Severe acute respiratory syndrome	2	0
Suspected COVID-19	52	1
<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	1	0
Pulpitis dental	1	0
Sialoadenitis	3	0
Tooth abscess	8	0
Tooth infection	8	0
<i>Ear infections</i>		
Ear infection	68	0
Labyrinthitis	84	0
Mastoiditis	1	0
Otitis externa	2	0

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
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	22	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	59	0
Eye abscess	1	0
Eye infection	16	0
Eyelid boil	1	0
Eyelid infection	2	0
Hordeolum	22	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	12	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	76	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	1204	0
Herpes zoster meningoencephalitis	1	0
Herpes zoster oticus	12	0
Herpes zoster reactivation	1	0
Nasal herpes	3	0

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Ophthalmic herpes zoster	3	0
Oral herpes	258	0
Varicella	22	0
Varicella zoster virus infection	1	0
<i>Infections NEC</i>		
Abscess	34	0
Abscess limb	6	0
Abscess soft tissue	1	0
Genital abscess	2	0
Infected bite	3	0
Infected cyst	2	0
Infection	198	0
Infection susceptibility increased	1	0
Injection site abscess	1	0
Injection site infection	5	0
Localised infection	21	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	1250	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	173	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>Mumps viral infections</i>		
Mumps	6	0
<i>Muscle and soft tissue infections</i>		
Abscess neck	1	0
Infective tenosynovitis	1	0
Necrotising fasciitis	2	0
Soft tissue infection	1	0
<i>Neisseria infections</i>		
Gonorrhoea	1	0

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
<i>Plasmodia infections</i>		
Malaria	2	0
<i>Pneumocystis infections</i>		
Pneumocystis jirovecii pneumonia	2	0
<i>Prion-associated disorders</i>		
Creutzfeldt-Jakob disease	1	0
<i>Retroviral infections</i>		
Acquired immunodeficiency syndrome	1	0
HIV infection	1	0
<i>Rotaviral infections</i>		
Gastroenteritis rotavirus	1	0
<i>Rubeola viral infections</i>		
Measles	4	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Bacteraemia	1	0
Neutropenic sepsis	3	1
Sepsis	41	6
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	26	0
Subcutaneous abscess	6	0
Sweat gland infection	1	0
Vaccination site pustule	4	0
<i>Staphylococcal infections</i>		
Furuncle	33	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
<i>Tinea infections</i>		
Body tinea	1	0
Tinea infection	1	0
Tinea pedis	2	0

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Reaction Name	Total	Fatal
Infections Infections cont'd		
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	841	0
Peritonsillar abscess	3	0
Pharyngitis	28	0
Rhinitis	36	0
Sinusitis	130	0
Tonsillitis	98	0
Tracheitis	4	0
Tracheostomy infection	1	0
Upper respiratory tract infection	6	0
<i>Urinary tract infections</i>		
Cystitis	63	0
Kidney infection	38	0
Pyelonephritis	2	0
Urethritis	1	0
Urinary tract infection	161	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	22	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
Post viral fatigue syndrome	38	0
Sweating fever	85	0
Vestibular neuronitis	24	0
Viral diarrhoea	2	0

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Viral infection	41	0
Viral labyrinthitis	3	0
Viral myocarditis	1	0
Viral pericarditis	4	0
Viral pharyngitis	13	0
Viral rash	45	0
Viral sinusitis	1	0
Viral tonsillitis	1	0
Infections SOC TOTAL	7657	85

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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	1	0
Joint injury	7	0
<i>Cardiovascular injuries</i>		
Heart injury	7	0
Vascular injury	5	0
<i>Cerebral injuries NEC</i>		
Brain contusion	2	0
Brain herniation	1	0
Concussion	3	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	1	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	8	0
Exposure via breast milk	58	0
Foetal exposure during pregnancy	31	0
Maternal exposure before pregnancy	5	0
Maternal exposure during breast feeding	1376	0
Maternal exposure during pregnancy	725	0
Maternal exposure timing unspecified	7	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
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		
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
Prescription drug used without a prescription	2	0
Product use complaint	1	0
Product use issue	20	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
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	8	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	72	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		
Arthropod bite	4	0
Arthropod sting	5	0
Bite	1	0
Electric shock	17	0
Fall	150	0
Foreign body	2	0
Injury	10	0
Multiple injuries	1	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
Occupational exposures		
Occupational exposure to SARS-CoV-2	1	0
Occupational exposure to product	1	0
Off label uses		

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Reaction Name	Total	Fatal
Injuries		
Injuries cont'd		
Off label use	55	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	10	0
Inappropriate schedule of product administration	435	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	5	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
Reproductive system and breast injuries		
Penis injury	1	0
Site specific injuries NEC		
Face crushing	1	0

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

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Face injury	1	0
Head injury	32	0
Limb crushing injury	2	0
Limb injury	85	0
Nasal injury	1	0
Neck crushing	1	0
Neck injury	1	0
Skin injuries NEC		
Contusion	981	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
Skin procedural complications		
Recall phenomenon	1	0
Skull fractures, facial bone fractures and dislocations		
Facial bones fracture	1	0
Fractured skull depressed	1	0
Spinal cord injuries NEC		
Spinal cord injury cervical	1	0
Spinal fractures and dislocations		
Spinal fracture	3	0
Stoma complications		
Gastrointestinal stoma complication	1	0
Stoma site discharge	1	0
Stoma site extravasation	1	0
Stoma site haemorrhage	1	0
Thermal burns		
Airway burns	1	0
Burn oesophageal	2	0
Burn of internal organs	2	0
Burn oral cavity	4	0
Burns second degree	5	0
Thermal burn	19	0
Thermal burns of eye	10	0
Underdoses NEC		
Underdose	6	0
Vaccination related complications		
Vaccination complication	44	0
Injuries SOC TOTAL	4961	1

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Reaction Name	Total	Fatal
Investigations		
<i>Adrenal cortex tests</i>		
Cortisol decreased	4	0
<i>Adrenal medulla tests</i>		
Epinephrine abnormal	1	0
Epinephrine increased	1	0
<i>Auditory and vestibular diagnostic procedures</i>		
Acoustic stimulation tests	5	0
Audiogram abnormal	1	0
<i>Autoimmunity analyses</i>		
Antinuclear antibody	1	0
Antinuclear antibody increased	1	0
Antinuclear antibody positive	2	0
Rheumatoid factor	3	0
<i>Bacteria identification and serology (excl mycobacteria)</i>		
Klebsiella test positive	1	0
<i>Blood counts NEC</i>		
Blood count	4	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	27	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
Ejection fraction decreased	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
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	5	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
Electrocardiogram repolarisation abnormality	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
QRS axis abnormal	1	0
Endocrine analyses and imaging NEC		
Hormone level abnormal	41	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	365	0
Heart rate abnormal	50	0
Heart rate decreased	60	0
Heart rate increased	697	0
Heart rate irregular	141	0
Heart rate normal	1	0
Maximum heart rate	2	0
Pulse abnormal	15	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
Immunoglobulin analyses		
Blood immunoglobulin G increased	1	0
Blood immunoglobulin M	1	0
Blood immunoglobulin M increased	1	0
Immunology analyses NEC		
Antibody test	4	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Immunology test	9	0
Immunology skin tests NEC		
Skin test positive	1	0
Investigations NEC		
Blood test	22	0
Blood test abnormal	48	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	24	0
Liver function test increased	19	0
Transaminases increased	4	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	2	0
Blood sodium decreased	9	0
Serum ferritin	1	0
Serum ferritin decreased	4	0
Serum ferritin increased	1	0
Sweat test	1	0
Urine copper	1	0
Musculoskeletal and soft tissue imaging procedures		
Skull X-ray	6	0
Musculoskeletal and soft tissue tests NEC		

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
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	5	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	217	0
Body temperature abnormal	38	0
Body temperature decreased	34	0
Body temperature fluctuation	38	0
Body temperature increased	343	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	5	0
Lymph node palpable	34	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	33	0
Temperature difference of extremities	9	0
Weight	1	0
Weight decreased	85	0
Weight increased	29	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
<i>Platelet analyses</i>		
Mean platelet volume decreased	1	0
Mean platelet volume increased	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Platelet count	3	0
Platelet count decreased	62	0
Platelet count increased	2	0
Protein analyses NEC		
Alpha 1 globulin decreased	1	0
Alpha 2 globulin decreased	1	0
C-reactive protein increased	17	0
Red blood cell analyses		
Haematocrit	1	0
Haematocrit increased	1	0
Haemoglobin	1	0
Haemoglobin decreased	10	0
Haemoglobin increased	1	0
Renal function analyses		
Blood creatinine increased	1	0
Glomerular filtration rate decreased	3	0
Renal function test	1	0
Renal function test abnormal	1	0
Reproductive hormone analyses		
Blood testosterone increased	1	0
False negative pregnancy test	7	0
Female sex hormone level	2	0
Pregnancy test	18	0
Pregnancy test false positive	1	0
Pregnancy test positive	1	0
Reproductive organ and breast histopathology procedures		
Biopsy endometrium	1	0
Smear cervix	1	0
Reproductive organ and breast imaging procedures		
Hysteroscopy	2	0
Respiratory and pulmonary function diagnostic procedures		
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
Respiratory tract and thoracic histopathology procedures		
Sputum abnormal	3	0
Respiratory tract and thoracic imaging procedures		
Chest X-ray	18	0
Chest X-ray abnormal	1	0
Chest X-ray normal	1	0
Chest scan	2	0
Computerised tomogram thorax	1	0
Skeletal and cardiac muscle analyses		
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

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
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	2	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	42	0
Cells in urine	1	0
Glucose urine present	1	0
Protein urine absent	1	0
Urine analysis abnormal	5	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	59	0
Blood pressure diastolic	1	0
Blood pressure diastolic decreased	1	0
Blood pressure diastolic increased	2	0
Blood pressure increased	187	0
Blood pressure measurement	32	0
Blood pressure normal	2	0
Blood pressure systolic	1	0
Blood pressure systolic decreased	3	0
Blood pressure systolic increased	1	0
Virus identification and serology		
Coronavirus test	11	0

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
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	9	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	2	0
SARS-CoV-2 test negative	7	0
SARS-CoV-2 test positive	91	0
Viral test	5	0
Vitamin analyses		
Blood folate decreased	5	0
Vitamin B12	1	0
Vitamin B12 abnormal	1	0
Vitamin B12 decreased	1	0
Vitamin D	2	0
Vitamin D decreased	3	0
Water and electrolyte analyses NEC		
Urine osmolarity	1	0
Volume blood	1	0
White blood cell analyses		
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	4060	3

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	13	0
Decreased appetite	979	0
Diet refusal	1	0
Eating disorder symptom	2	0
Food craving	9	0
Food refusal	11	0
Hyperphagia	12	0
Hypophagia	16	0
Increased appetite	28	0
Salt craving	2	0
<i>Calcium metabolism disorders</i>		
Hypocalcaemia	3	0
Tetany	3	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	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	79	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	3	0
<i>Fluid intake increased</i>		
Polydipsia	6	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Alcohol intolerance	3	0
Dairy intolerance	2	0
Food intolerance	11	0
Gluten sensitivity	6	0
Histamine intolerance	3	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	14	0
Abnormal weight gain	15	0
Cachexia	1	0
Feeding disorder	61	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 <small>Metabolic disorders cont'd</small>		
Glucose tolerance impaired	1	0
Hyperglycaemia	60	0
Insulin resistance	4	0
<i>Hypoglycaemic conditions NEC</i>		
Glycopenia	1	0
Hypoglycaemia	71	0
Hypoglycaemia unawareness	1	0
Postprandial hypoglycaemia	1	0
<i>Iron deficiencies</i>		
Iron deficiency	11	0
<i>Iron excess</i>		
Haemochromatosis	1	0
Iron overload	1	0
<i>Lipid metabolism and deposit disorders NEC</i>		
Body fat disorder	1	0
<i>Metabolic acidoses (excl diabetic acidoses)</i>		
Ketoacidosis	4	0
Lactic acidosis	2	0
Metabolic acidosis	2	0
<i>Metabolic disorders NEC</i>		
Metabolic disorder	1	0
<i>Mixed acid-base disorders</i>		
Acidosis	3	0
<i>Potassium imbalance</i>		
Hyperkalaemia	3	0
Hypokalaemia	3	0
Hypokalaemic syndrome	1	0
<i>Sodium imbalance</i>		
Hyponatraemia	7	0
Hyponatraemic syndrome	3	0
Salt intoxication	1	0
<i>Sugar intolerance (excl glucose intolerance)</i>		
Lactose intolerance	1	0
<i>Total fluid volume decreased</i>		
Dehydration	167	0
<i>Total fluid volume increased</i>		
Fluid overload	1	0
Fluid retention	45	0
Hypervolaemia	1	0
<i>Vitamin deficiencies NEC</i>		
Hypovitaminosis	4	0
<i>Water soluble vitamin deficiencies</i>		
Folate deficiency	3	0
Vitamin B12 deficiency	4	0
Metabolic disorders SOC TOTAL	1813	1

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	222	0
Arthropathy	22	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	302	0
Bone swelling	7	0
Coccydynia	3	0
Metatarsalgia	1	0
Pain in jaw	294	0
Pubic pain	2	0
Spinal pain	62	0
<i>Bursal disorders</i>		
Bursitis	55	0
<i>Cartilage disorders</i>		
Chondritis	1	0
Costochondritis	69	0
Osteochondritis	1	0
Polychondritis	3	0
<i>Connective tissue disorders NEC</i>		
Connective tissue disorder	1	0
Polymyalgia rheumatica	48	0
Reynold's syndrome	1	0
Sjogren's syndrome	5	0
<i>Crystal arthropathic disorders</i>		
Chondrocalcinosis pyrophosphate	2	0
Crystal arthropathy	1	0
<i>Epiphyseal disorders</i>		
Epiphyses premature fusion	1	0
<i>Extremity deformities</i>		
Bone deformity	1	0
Finger deformity	1	0
Foot deformity	1	0
Hand deformity	2	0
Knee deformity	1	0
Limb deformity	4	0
Musculoskeletal deformity	1	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<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	22	0
Patellofemoral pain syndrome	1	0
Periarthritis	130	0
Rotator cuff syndrome	21	0
Temporomandibular joint syndrome	8	0
Joint related signs and symptoms		
Arthralgia	7269	0
Jaw clicking	4	0
Joint effusion	14	0
Joint noise	32	0
Joint range of motion decreased	27	0
Joint stiffness	194	0
Joint swelling	416	0
Joint vibration	2	0
Joint warmth	13	0
Loose body in joint	1	0
Ligament disorders		
Ligament pain	1	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	5	0
Muscle pains		
Fibromyalgia	80	0
Myalgia	8952	0
Myalgia intercostal	1	0
Myofascial pain syndrome	11	0
Muscle related signs and symptoms NEC		
Haematoma muscle	1	0
Muscle atrophy	15	0
Muscle discomfort	2	0
Muscle disorder	4	0
Muscle fatigue	295	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	1673	0
Muscle swelling	26	0
Muscle tightness	75	0
Muscle twitching	389	0
Muscle tone abnormalities		
Muscle rigidity	13	0
Nuchal rigidity	10	0
Torticollis	4	0
Trismus	28	0
Muscle weakness conditions		
Muscular weakness	737	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	85	0
Musculoskeletal disorder	10	0
Musculoskeletal stiffness	1039	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	7	0
Musculoskeletal and connective tissue pain and discomfort		
Back pain	1909	0
Flank pain	50	0
Limb discomfort	1255	0
Musculoskeletal chest pain	171	0
Musculoskeletal discomfort	78	0
Musculoskeletal pain	37	0
Neck pain	1518	0
Pain in extremity	10453	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		
Muscle & tissue disorders cont'd		
Rheumatoid arthritis	98	0
Soft tissue disorders NEC		
Axillary mass	192	0
Fluctuance	1	0
Groin pain	92	0
Neck mass	27	0
Purple glove syndrome	1	0
Soft tissue disorder	2	0
Soft tissue swelling	5	0
Spine and neck deformities		
Kyphosis	2	0
Lordosis	1	0
Neck deformity	1	0
Scoliosis	1	0
Spinal stenosis	1	0
Spondyloarthropathies		
Ankylosing spondylitis	6	0
Arthritis reactive	34	0
Spondylitis	2	0
Spondyloarthropathy	1	0
Synovial disorders		
Synovial cyst	18	0
Synovitis	6	0
Tendon disorders		
Enthesopathy	2	0
Tendon disorder	4	0
Tendon pain	18	0
Tendonitis	34	0
Tenosynovitis	2	0
Tenosynovitis stenosaurs	2	0
Trigger finger	23	0
Trunk deformities		
Drooping shoulder syndrome	1	0
Shoulder deformity	2	0
Muscle & tissue disorders SOC TOTAL	39027	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 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>Colorectal neoplasms malignant</i>		
Colon cancer	1	0
Colorectal cancer	1	0
Rectal cancer	1	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>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>		
Lymphoma	27	1
<i>Metastases to specified sites</i>		
Metastases to liver	1	0
Metastases to lymph nodes	5	0
<i>Metastases to unknown and unspecified sites</i>		
Metastasis	1	0

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
<i>Myelodysplastic syndromes</i>		
Myelodysplastic syndrome	2	0
<i>Myeloproliferative disorders (excl leukaemias)</i>		
Essential thrombocythaemia	1	0
<i>Neoplasms benign site unspecified NEC</i>		
Adenoma benign	1	0
<i>Neoplasms malignant site unspecified NEC</i>		
Adenocarcinoma metastatic	1	0
Metastatic neoplasm	1	0
Neoplasm malignant	7	0
Second primary malignancy	1	0
Squamous cell carcinoma	4	0
<i>Neoplasms unspecified malignancy and site unspecified NEC</i>		
Neoplasm	2	0
Neoplasm recurrence	1	0
<i>Nervous system neoplasms benign NEC</i>		
Cranial nerve neoplasm benign	1	0
Neurilemmoma benign	1	0
<i>Nervous system neoplasms unspecified malignancy NEC</i>		
Brain neoplasm	2	0
Spinal cord neoplasm	1	0
<i>Neuromas</i>		
Acoustic neuroma	2	0
<i>Non-Hodgkin's lymphomas NEC</i>		
Non-Hodgkin's lymphoma	3	0
<i>Ocular neoplasms benign</i>		
Eye naevus	1	0
<i>Oesophageal neoplasms malignant</i>		
Oesophageal cancer metastatic	4	0
<i>Oncologic complications and emergencies</i>		
Cancer pain	1	0
<i>Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified</i>		
Tonsil cancer	3	0
<i>Pancreatic neoplasms malignant (excl islet cell and carcinoid)</i>		
Pancreatic carcinoma	4	0
<i>Plasma cell myelomas</i>		
POEMS syndrome	1	0
Plasma cell myeloma	1	0
<i>Plasma cell neoplasms NEC</i>		
TEMPI syndrome	1	0
<i>Prostatic neoplasms malignant</i>		
Prostate cancer	3	0
<i>Renal neoplasms malignant</i>		
Clear cell renal cell carcinoma	1	0
Renal cancer	2	0
<i>Respiratory tract and pleural neoplasms malignant cell type unspecified NEC</i>		
Bronchial carcinoma	1	0
Lung neoplasm malignant	9	0
<i>Skin melanomas (excl ocular)</i>		
Malignant melanoma	1	0
<i>Skin neoplasms benign</i>		

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
Acrochordon	2	0
Anogenital warts	6	0
Haemangioma of skin	3	0
Melanocytic naevus	4	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	224	4

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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
<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	49	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	43	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
<i>Central nervous system inflammatory disorders NEC</i>		

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
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	41	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	11	0
Balance disorder	311	0
Coordination abnormal	45	0
Dysdiadochokinesis	1	0
Dysstasia	49	0
Nystagmus	10	0
Cortical dysfunction NEC		
Alexia	2	0
Aphasia	67	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	13	0
Dementia with Lewy bodies	1	0
Senile dementia	1	0
Demyelinating disorders NEC		
Acute disseminated encephalomyelitis	4	0
Clinically isolated syndrome	1	0
Demyelination	8	0
Neuromyelitis optica spectrum disorder	3	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
<i>Disturbances in consciousness NEC</i>		
Altered state of consciousness	10	0
Consciousness fluctuating	2	0
Depressed level of consciousness	39	0
Infant sedation	1	0
Lethargy	1861	0
Loss of consciousness	517	0
Postictal state	4	0
Sedation	8	0
Somnolence	853	0
Stupor	4	0
Syncope	1727	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	10	0
Foetal movement disorder	1	0
Hyperkinesia	3	0
Hypokinesia	58	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	4	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 paralysis	10	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	422	0
Facial nerve disorder	8	0
Facial paralysis	325	0
Facial paresis	82	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Facial spasm	38	0
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	43	0
Headaches NEC		
Cervicogenic headache	3	0
Cluster headache	187	0
Cold-stimulus headache	18	0
Drug withdrawal headache	2	0
Exertional headache	8	0
External compression headache	2	0
Headache	21847	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	299	0
Tension headache	471	0
Thunderclap headache	8	0
Vascular headache	13	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	68	0
Memory loss (excl dementia)		
Amnesia	142	0
Memory impairment	153	0
Transient global amnesia	7	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	72	0
Cognitive linguistic deficit	1	0
Disturbance in attention	273	0
Mental impairment	42	0
Migraine headaches		
Hemiplegic migraine	27	0
Migraine	2450	0
Migraine with aura	161	0
Migraine without aura	17	0
Ophthalmic migraine	5	0
Retinal migraine	29	0
Typical aura without headache	7	0
Vestibular migraine	17	0
Mixed cranial nerve disorders		

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
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	19	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	25	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	96	0
Narcolepsy	6	0
Nervous system disorders NEC		
Central nervous system lesion	2	0
Cerebral disorder	1	0
Nervous system disorder	10	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	1	0
Clonus	3	0
Decerebrate posture	1	0
Dizziness	8256	0
Dizziness exertional	38	0
Dizziness postural	623	0
Droling	21	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Fontanelle bulging	2	0
Head discomfort	285	0
Hyporesponsive to stimuli	2	0
Inability to crawl	2	0
Infant irritability	7	0
Myoclonus	20	0
Neurological symptom	39	0
Patient elopement	1	0
Persistent postural-perceptual dizziness	13	0
Presyncope	545	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	219	0
Hyposmia	16	0
Parosmia	206	0
Optic nerve disorders NEC		
Optic neuritis	28	0
Paraesthesias and dysaesthesias		
Burning feet syndrome	7	0
Burning sensation	440	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	78	0
Hypoaesthesia	2470	0
Paraesthesia	3399	0
Reversed hot-cold sensation	4	0
Synaesthesia	1	0
Paralysis and paresis (excl cranial nerve)		
Diplegia	11	0
Hemiparesis	40	0
Hemiplegia	35	0
Locked-in syndrome	1	0
Monoparesis	48	0
Monoplegia	63	0
Paralysis	110	0
Paraparesis	3	0
Paresis	6	0
Quadriparesis	1	0
Quadriplegia	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
<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	2	0
Neuritis	7	0
Neuropathy peripheral	83	0
Peripheral sensorimotor neuropathy	1	0
Peripheral sensory neuropathy	10	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	142	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	514	0
Seizure anoxic	1	0
Seizure cluster	6	0
Seizure like phenomena	2	0
Status epilepticus	39	0
Tonic clonic movements	2	0
Tonic convulsion	19	0
Tonic posturing	1	0
<i>Sensory abnormalities NEC</i>		
Ageusia	440	0
Allodynia	22	0
Aura	17	0
Complex regional pain syndrome	5	0
Dysgeusia	1018	0
Electric shock sensation	34	0
Hypergeusia	1	0
Hypogeusia	7	0
Intercostal neuralgia	1	0
Loss of proprioception	3	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Morton's neuralgia	1	0
Neuralgia	439	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	87	0
Sensory loss	63	0
Taste disorder	226	0
Visual perseveration	3	0
Sleep disturbances NEC		
Sleep deficit	7	0
Sudden onset of sleep	1	0
Speech and language abnormalities		
Dysarthria	161	0
Incoherent	9	0
Language disorder	1	0
Repetitive speech	3	0
Slow speech	14	0
Speech disorder	56	0
Spinal cord and nerve root disorders NEC		
Myelopathy	1	0
Radiculitis brachial	8	0
Radiculopathy	5	0
Structural brain disorders NEC		
Brain injury	6	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	3	0
Tremor	1381	0
Trigeminal disorders		
Facial neuralgia	15	0
Numb chin syndrome	2	0
Trigeminal nerve disorder	3	0
Trigeminal neuralgia	38	0
Vagus nerve disorders		
Vocal cord paralysis	1	0
Vertigos NEC		
Cervicogenic vertigo	1	0
Vertigo CNS origin	2	0
Nervous system disorders SOC TOTAL	56670	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	3	1
<i>Abortions spontaneous</i>		
Abortion spontaneous	317	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	7	0
<i>Foetal growth complications</i>		
Foetal growth restriction	2	0
<i>Foetal position and presentation abnormalities</i>		
Oblique presentation	1	0
<i>Gestational age and weight conditions</i>		
Premature baby	2	1
Term baby	1	0
<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>		
Premature delivery	1	0
Premature labour	6	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	2	0
Decidual cast	4	0
Ectopic pregnancy	4	0
Hyperemesis gravidarum	1	0
Morning sickness	14	0
Preterm premature rupture of membranes	3	0
Somatic symptom disorder of pregnancy	3	0
<i>Neonatal hepatobiliary disorders</i>		
Jaundice neonatal	1	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

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Pregnancy conditions <small>Pregnancy conditions cont'd</small>		
Live birth	3	0
Pregnancy	46	0
Uterine contractions during pregnancy	2	0
Placental abnormalities (excl neoplasms)		
Placental disorder	1	0
Postpartum complications NEC		
Postpartum haemorrhage	5	0
Pregnancy complicated by maternal disorders		
Gestational diabetes	2	0
Peripartum cardiomyopathy	1	0
Stillbirth and foetal death		
Foetal death	3	2
Stillbirth	4	3
Unintended pregnancies		
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	480	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	4	0
<i>Product packaging issues</i>		
Product closure issue	1	0
<i>Product physical issues</i>		
Liquid product physical issue	9	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	6	0
<i>Product supply and availability issues</i>		
Product availability issue	1	0
null SOC TOTAL	90	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	5	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	689	0
Immunisation anxiety related reaction	2	0
Nervousness	146	0
Stress	81	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	22	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	187	0
<i>Communications disorders</i>		
Communication disorder	5	0
Mutism	3	0
<i>Confusion and disorientation</i>		
Confusional state	747	0
Disorientation	242	0
<i>Decreased physical activity levels</i>		
Catatonia	1	0
<i>Deliria</i>		

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Reaction Name	Total	Fatal
Psychiatric disorders ^{Psychiatric disorders cont'd}		
Delirium	91	0
<i>Delusional symptoms</i>		
Delusion	9	0
<i>Depressive disorders</i>		
Agitated depression	3	0
Depression	287	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	1172	0
Middle insomnia	24	0
Terminal insomnia	29	0
<i>Dyssomnias</i>		
Breathing-related sleep disorder	1	0
Dyssomnia	1	0
Poor quality sleep	185	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	32	0
Dysphoria	2	0
Emotional disorder	50	0
Emotional distress	34	0
Emotional poverty	1	0
Euphoric mood	41	0
Frustration tolerance decreased	2	0
Irritability	178	0
Mood altered	50	0
<i>Factitious disorders</i>		
Factitious disorder	4	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Agoraphobia	2	0
Fear	17	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	117	0

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Reaction Name	Total	Fatal
Psychiatric disorders ^{Psychiatric disorders cont'd}		
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	163	0
Hallucination, auditory	12	0
Hallucination, olfactory	10	0
Hallucination, tactile	1	0
Hallucination, visual	23	0
Hallucinations, mixed	2	0
<i>Increased physical activity levels</i>		
Restlessness	134	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	318	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	9	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 ^{Psychiatric disorders cont'd}		
Panic attack	164	0
Panic disorder	3	0
Panic reaction	23	0
Paraphilias and paraphilic disorders		
Transvestism	1	0
Parasomnias		
Abnormal dreams	154	0
Abnormal sleep-related event	1	0
Confusional arousal	1	0
Exploding head syndrome	2	0
Nightmare	172	0
Parasomnia	1	0
Sleep inertia	1	0
Sleep talking	6	0
Sleep terror	19	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	20	0
Psychiatric symptoms NEC		
Hypervigilance	9	0
Psychiatric symptom	3	0
Psychological trauma	2	0
Trance	1	0
Psychotic disorder NEC		
Psychotic behaviour	1	0
Psychotic disorder	19	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	10	0
Libido increased	5	0
Loss of libido	15	0
Sexual dysfunction NEC		
Genito-pelvic pain/penetration disorder	1	0
Sleep disorders NEC		
Sleep disorder	174	0
Sleep disorder due to general medical condition, insomnia type	2	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Somatic symptom disorders</i>		
Conversion disorder	18	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	23	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	3	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	31	0
Suicide attempt	8	0
Suicide threat	1	0
<i>Thinking disturbances</i>		
Bradyphrenia	37	0
Intrusive thoughts	5	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	6716	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	35	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	16	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	15	1
Renal impairment	19	0
Renal injury	1	0
Renal lithiasis		
Nephrolithiasis	7	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	9	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	232	0
Urinary tract discomfort	1	0
Urinary tract pain	4	0
Renal & urinary disorders SOC TOTAL	885	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	21	0
Breast mass	97	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	516	0
Breast swelling	115	0
Breast tenderness	58	0
Nipple pain	32	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 neoplasms</i>		
Cervical polyp	1	0
<i>Erection and ejaculation conditions and disorders</i>		
Ejaculation disorder	2	0
Ejaculation failure	3	0
Erectile dysfunction	44	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	5	0
Lactation puerperal increased	4	0
Suppressed lactation	25	0
<i>Menopausal effects NEC</i>		
Artificial menopause	1	0
Menopausal symptoms	13	0
Menopause delayed	1	0
Premature menopause	12	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
<i>Menopausal effects on the genitourinary tract</i>		
Atrophic vulvovaginitis	1	0
Postmenopausal haemorrhage	74	0
<i>Menstruation and uterine bleeding NEC</i>		
Abnormal uterine bleeding	6	0
Dysmenorrhoea	2148	0
Intermenstrual bleeding	842	0
Menstrual discomfort	18	0
Menstrual disorder	1300	0
Menstruation irregular	2265	0
Premenstrual dysphoric disorder	7	0
Premenstrual headache	6	0
Premenstrual pain	82	0
Premenstrual syndrome	94	0
Retrograde menstruation	1	0
Withdrawal bleed	14	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	438	0
Hypomenorrhoea	507	0
Menstruation delayed	3613	0
Oligomenorrhoea	106	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	4109	0
Menometrorrhagia	15	0
Polymenorrhoea	602	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>		
Ovarian cyst	11	0
Polycystic ovaries	36	0
<i>Ovarian and fallopian tube disorders NEC</i>		
Adnexal torsion	1	0
Hydrosalpinx	2	0
Ovarian haemorrhage	4	0
Ovulation disorder	2	0
Ovulation pain	44	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	16	0
<i>Penile and scrotal infections and inflammations</i>		
Balanoposthitis	2	0
<i>Penile disorders NEC (excl erection and ejaculation)</i>		
Penile discharge	1	0
Penile discomfort	1	0
Penile erythema	1	0
Penile haemorrhage	2	0
Penile pain	1	0
Penile size reduced	1	0
Penile swelling	4	0
Penis disorder	8	0
<i>Prostate and seminal vesicles infections and inflammations</i>		

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</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	3	0
Genital rash	4	0
Genital swelling	2	0
Pelvic discomfort	5	0
Pelvic pain	81	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	4	0
Sexual dysfunction	5	0
<i>Spermatogenesis and semen disorders</i>		
Aspermia	1	0
Haematospermia	6	0
Semen discolouration	1	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular disorder	2	0
Testicular pain	45	0
Testicular swelling	7	0
Testis discomfort	1	0
<i>Uterine disorders NEC</i>		
Adenomyosis	7	0
Endometrial thickening	2	0
Endometriosis	71	0
Uterine haemorrhage	25	0
Uterine pain	13	0
<i>Uterine infections and inflammations (excl cervix)</i>		
Uterine inflammation	1	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
<i>Uterine neoplasms</i>		
Uterine polyp	3	0
<i>Uterine tone disorders</i>		
Uterine spasm	26	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	1128	0
Vaginal mucosal blistering	1	0
Vaginal ulceration	1	0
Vulval disorder	1	0
Vulval haemorrhage	18	0
Vulval ulceration	6	0
Vulvovaginal ulceration	3	0
<i>Vulvovaginal signs and symptoms</i>		
Clitoral engorgement	1	0
Coital bleeding	3	0
Labia enlarged	1	0
Vaginal discharge	59	0
Vaginal lesion	1	0
Vaginal odour	1	0
Vulval oedema	1	0
Vulvovaginal burning sensation	4	0
Vulvovaginal dryness	3	0
Vulvovaginal erythema	1	0
Vulvovaginal pain	22	0
Vulvovaginal pruritus	6	0
Vulvovaginal rash	2	0
Vulvovaginal swelling	3	0
Reproductive & breast disorders SOC TOTAL	19128	1

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	5	0
Apnoeic attack	1	0
Dyspnoea	3647	6
Dyspnoea at rest	9	0
Dyspnoea exertional	32	1
Hyperventilation	42	0
Hypopnoea	89	0
Hypoventilation	1	0
Irregular breathing	18	0
Mouth breathing	3	0
Nocturnal dyspnoea	2	0
Orthopnoea	3	0
Respiration abnormal	45	0
Respiratory arrest	14	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	284	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	335	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	2011	2
Cough decreased	2	0
Haemoptysis	46	0
Productive cough	134	0
Sputum discoloured	6	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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MedDRA Version: MedDRA 24.0

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 opacity	2	0
Pleuritic pain	17	0
Pulmonary haemorrhage	1	0
Pulmonary pain	74	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	239	0
Nasal inflammation	2	0
Rhinitis allergic	17	0
<i>Nasal disorders NEC</i>		
Epistaxis	768	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	51	0
Sinus disorder	5	0
<i>Parenchymal lung disorders NEC</i>		

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
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	211	0
Pharyngeal ulceration	14	0
Tonsillar erythema	9	0
Tonsillar haemorrhage	1	0
Tonsillar hypertrophy	67	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	9	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	372	25
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
Suffocation feeling	2	0

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
<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	6	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	95	0
Catarrh	18	0
Choking	13	0
Choking sensation	3	0
Dry throat	146	0
Dysphonia	140	0
Increased upper airway secretion	5	0
Increased viscosity of upper respiratory secretion	26	0
Nasal discharge discolouration	3	0
Nasal discomfort	43	0
Nasal obstruction	2	0
Oropharyngeal blistering	10	0
Oropharyngeal discomfort	52	0
Oropharyngeal pain	2421	0
Oropharyngeal plaque	2	0
Paranasal sinus discomfort	40	0
Rhinalgia	11	0
Rhinorrhoea	752	0
Sinus pain	178	0
Sneezing	310	0
Snoring	7	0
Throat clearing	8	0
Throat irritation	205	0
Throat tightness	218	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	13981	49

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	155	0
Acne cystic	15	0
Dermatitis acneiform	8	0
<i>Alopecias</i>		
Alopecia	193	0
Alopecia areata	32	0
Alopecia totalis	2	0
Androgenetic alopecia	1	0
Diffuse alopecia	2	0
Hypotrichosis	1	0
Madarosis	3	0
<i>Angioedemas</i>		
Angioedema	173	0
Circumoral swelling	1	0
<i>Apocrine and eccrine gland disorders</i>		
Anhidrosis	1	0
Bromhidrosis	1	0
Cold sweat	632	0
Hidradenitis	2	0
Hyperhidrosis	1814	0
Hypohidrosis	2	0
Milia	2	0
Miliaria	76	0
Night sweats	502	0
<i>Bullous conditions</i>		
Blister	388	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	6	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	182	0
Macule	4	0
Neutrophilic dermatosis	1	0
Pain of skin	228	0
Papule	97	0
Pathergy reaction	1	0
Peau d'orange	2	0
Scab	17	0
Scar pain	12	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Sensitive skin	143	0
Shagreen skin	1	0
Skin burning sensation	183	0
Skin degenerative disorder	1	0
Skin discolouration	107	0
Skin discomfort	3	0
Skin disorder	18	0
Skin fissures	8	0
Skin indentation	2	0
Skin induration	3	0
Skin lesion	36	0
Skin lesion inflammation	1	0
Skin necrosis	1	0
Skin odour abnormal	15	0
Skin plaque	3	0
Skin reaction	119	0
Skin sensitisation	30	0
Skin swelling	72	0
Skin texture abnormal	1	0
Skin tightness	24	0
Skin warm	246	0
Skin weeping	9	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	98	0
Dermatitis allergic	193	0
Dermatitis atopic	27	0
Dermatitis contact	14	0
Dermatitis diaper	3	0
Dyshidrotic eczema	24	0
Eczema	244	0
Eczema asteatotic	8	0
Eczema infantile	1	0
Eczema nummular	4	0
Eczema weeping	1	0
Hand dermatitis	1	0
Intertrigo	1	0
Perioral dermatitis	1	0
Seborrhoeic dermatitis	3	0
Skin irritation	97	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	1779	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	94	0
<i>Granulomatous and deep cutaneous inflammatory conditions</i>		
Cutaneous sarcoidosis	1	0
Granuloma annulare	4	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	11	0
<i>Ichthyoses</i>		
Ichthyosis acquired	1	0
<i>Lipodystrophies</i>		
Lipoatrophy	4	0
Lipodystrophy acquired	1	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
Nail discolouration	8	0
Nail disorder	2	0
Nail pigmentation	2	0
Nail ridging	3	0
Onychalgia	7	0
Onychoclasis	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	15	0
Lichen sclerosus	8	0
Parapsoriasis	2	0
Pityriasis rosea	93	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

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Pigmentation disorder	10	0
Pilar disorders NEC		
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	4370	0
Psoriatic conditions		
Dermatitis psoriasiform	3	0
Guttate psoriasis	13	0
Nail psoriasis	1	0
Palmoplantar pustulosis	2	0
Psoriasis	137	0
Pustular psoriasis	2	0
Purpura and related conditions		
Ecchymosis	1	0
Henoch-Schonlein purpura	5	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	4654	0
Rash erythematous	985	0
Rash macular	438	0
Rash maculo-papular	51	0
Rash morbilliform	36	0
Rash papular	288	0
Rash pruritic	980	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
Scleroderma associated digital ulcer	1	0
Skin erosion	20	0
Skin ulcer	13	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
<i>Skin cysts and polyps</i>		
Dermal cyst	11	0
<i>Skin dystrophies</i>		
Keloid scar	3	0
Skin wrinkling	2	0
<i>Skin haemorrhages</i>		
Haemorrhage subcutaneous	7	0
Skin haemorrhage	14	0
<i>Skin hyperplasias and hypertrophies</i>		
Skin hypertrophy	2	0
<i>Skin hypoplasias and atrophies</i>		
Skin atrophy	2	0
Skin striae	7	0
<i>Skin injuries and mechanical dermatoses</i>		
Decubitus ulcer	2	0
Needle track marks	3	0
<i>Skin preneoplastic conditions NEC</i>		
Actinic keratosis	1	0
<i>Skin vascular conditions NEC</i>		
Skin oedema	4	0
<i>Skin vasculitides</i>		
Capillaritis	2	0
Cutaneous vasculitis	12	0
Hypersensitivity vasculitis	1	0
Vasculitic rash	18	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	20	0
<i>Telangiectasia and related conditions</i>		
Spider naevus	1	0
Telangiectasia	1	0
<i>Urticarias</i>		
Chronic spontaneous urticaria	4	0
Cold urticaria	5	0
Idiopathic urticaria	1	0
Mechanical urticaria	5	0
Solar urticaria	2	0
Urticaria	1503	0
Urticaria cholinergic	1	0
Urticaria chronic	15	0
Urticaria contact	1	0
Urticaria papular	3	0
Urticaria thermal	4	0
Urticarial vasculitis	3	0
Skin disorders SOC TOTAL	22693	1

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Reaction Name	Total	Fatal
Social circumstances		
<i>Age related issues</i>		
Infant	2	0
Menopause	24	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	3	0
Sight disability	10	0
Sitting disability	4	0
Walking disability	1	0
Wheelchair user	1	0
<i>Economic circumstances</i>		
High income	1	0
Low income	1	0
<i>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>		
Hair dye user	2	0
Impaired quality of life	1	0
<i>Tobacco use</i>		
Ex-tobacco user	1	0
Non-tobacco user	4	0
Tobacco user	1	0
Social circumstances SOC TOTAL	182	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	79	0
Immunisation	61	1
Induced abortions		
Abortion induced	1	0
Joint therapeutic procedures		
Joint injection	1	0
Joint surgery	1	0
Knee arthroplasty	1	0
Large intestine therapeutic procedures		
Appendectomy	3	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
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	1	0
Therapeutic procedures NEC		
Abscess drainage	1	0
Anaphylaxis treatment	4	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
Surgical & medical procedures cont'd		
Bed rest	2	0
Fatigue management	1	0
Hospitalisation	10	0
Injection	43	0
Interchange of vaccine products	5	0
Localised alternating hot and cold therapy	1	0
Magnetic therapy	1	0
Mass excision	2	0
Medical procedure	1	0
Medication dilution	2	0
Physical fitness training	1	0
Product used for unknown indication	2	0
Specialist consultation	1	0
Therapeutic procedure	1	0
Therapy change	1	0
Tracheal therapeutic procedures		
Tracheostomy	1	0
Uterine therapeutic procedures		
Endometrial ablation	2	0
Surgical & medical procedures SOC TOTAL	355	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	11	0
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	10	0
Labile blood pressure	3	0
<i>Bruising, ecchymosis and purpura</i>		
Achenbach syndrome	3	0
<i>Circulatory collapse and shock</i>		
CT hypotension complex	2	0
Circulatory collapse	61	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	35	0
Haemorrhage	956	2
Internal haemorrhage	6	0
Venous haemorrhage	2	0
<i>Lymphangiopathies</i>		
Lymphangiopathy	1	0
Lymphocele	4	0
<i>Lymphoedemas</i>		
Lymphoedema	159	0
<i>Non-site specific embolism and thrombosis</i>		
Arterial thrombosis	4	0
Embolism	60	0
Embolism venous	5	0
Microembolism	1	0
Thrombosis	369	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

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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	31	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	22	0
Deep vein thrombosis	252	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	978	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	266	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	26	0
Phlebitis superficial	6	0
<i>Site specific vascular disorders NEC</i>		
Inferior vena cava dilatation	1	0
Pallor	300	0
<i>Varicose veins NEC</i>		

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Reaction Name	Total	Fatal
Vascular disorders <small>Vascular disorders cont'd</small>		
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	468	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	332	0
Orthostatic hypotension	28	0
<i>Vasculitides NEC</i>		
Behcet's syndrome	4	0
Diffuse vasculitis	1	0
Granulomatosis with polyangiitis	1	0
MAGIC syndrome	1	0
Thromboangiitis obliterans	1	0
Vasculitis	46	0
<i>Vena caval embolism and thrombosis</i>		
Vena cava embolism	1	0
Vena cava thrombosis	1	0
Vascular disorders SOC TOTAL	5203	13
TOTAL REACTIONS FOR DRUG	324654	531
TOTAL REPORTS	114752	
TOTAL FATAL OUTCOME REPORTS		531