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COVID-19 mRNA Pfizer- BioNTech Vaccine Analysis Print

Report Run Date: 06-Jan-2022

Data Lock Date: 05-Jan-2022 18:30:04

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All UK spontaneous reports received between 09/12/20 and 05/01/22 for mRNA Pfizer/BioNTech vaccine

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Reaction Name	Total	Fatal
Blood disorders		
Anaemia deficiencies		
Anaemia folate deficiency	1	0
Anaemia vitamin B12 deficiency	4	0
Deficiency anaemia	1	0
Iron deficiency anaemia	8	0
Pernicious anaemia	1	0
Anaemias NEC		
Anaemia	131	0
Anaemia macrocytic	2	0
Anaemia megaloblastic	1	0
Autoimmune anaemia	3	0
Blood loss anaemia	1	0
Microcytic anaemia	1	0
Anaemias haemolytic NEC		
Coombs negative haemolytic anaemia	1	0
Haemolytic anaemia	7	0
Anaemias haemolytic immune		
Autoimmune haemolytic anaemia	16	0
Cold type haemolytic anaemia	1	0
Evans syndrome	1	0
Warm type haemolytic anaemia	1	0
Anaemias haemolytic mechanical factor		
Microangiopathic haemolytic anaemia	1	0
Bleeding tendencies		
Haemorrhagic diathesis	1	0
Increased tendency to bruise	52	0
Spontaneous haematoma	2	0
Coagulation factor deficiencies		
Acquired haemophilia	2	0
Coagulopathies		
Abnormal clotting factor	4	0
Antiphospholipid syndrome	6	0
Coagulopathy	25	1
Disseminated intravascular coagulation	2	0
Hypercoagulation	3	0
Thrombotic microangiopathy	3	0
Eosinophilic disorders		
Eosinophilia	13	0
Haematological disorders		
Blood disorder	4	0
Bone marrow disorder	1	0
Hypergammaglobulinaemia	1	0
Hyperviscosity syndrome	1	0
Mast cell activation syndrome	10	0
Methaemoglobinemia	1	0
Haemolyses NEC		
Haemolysis	6	0
Intravascular haemolysis	1	0
Jaundice acholuric	1	0
Leukocytoses NEC		
Leukocytosis	2	0
Lymphocytic infiltration	1	0
Lymphocytosis	6	0

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Reaction Name		Total	Fatal
Blood disorders	Blood disorders cont'd		
Neutrophilia		11	0
Leukopenias NEC			
Leukopenia		4	1
Lymphopenia		4	0
Lymphatic system disorders NEC			
Abdominal lymphadenopathy		3	0
Hilar lymphadenopathy		2	0
Lymph node pain		2121	0
Lymph node ulcer		1	0
Lymphadenitis		170	0
Lymphadenopathy		12976	0
Lymphatic disorder		3	0
Lymphatic insufficiency		1	0
Necrotic lymphadenopathy		3	0
Pseudolymphoma		12	0
Retroperitoneal lymphadenopathy		1	0
Marrow depression and hypoplastic anaemias			
Aplasia pure red cell		2	0
Aplastic anaemia		1	1
Hypoplastic anaemia		2	0
Myelosuppression		1	0
Pancytopenia		8	0
Neutropenias			
Autoimmune neutropenia		2	0
Neutropenia		41	0
Platelet disorders NEC			
Platelet anisocytosis		1	0
Platelet disorder		3	0
Polycythaemia (excl rubra vera)			
Polycythaemia		3	0
Purpuras (excl thrombocytopenic)			
Purpura non-thrombocytopenic		1	0
Red blood cell abnormal findings NEC			
Macrocytosis		1	0
Polychromasia		2	0
Red blood cell abnormality		2	0
Spleen disorders			
Spleen atrophy		1	0
Splenic infarction		3	0
Splenic thrombosis		1	0
Splenic vein thrombosis		2	0
Splenomegaly		12	0
Thrombocytopenias			
Acquired amegakaryocytic thrombocytopenia		1	0
Immune thrombocytopenia		79	0
Thrombocytopenia		225	1
Thrombocytopenic purpura		8	0
Thrombotic thrombocytopenic purpura		6	0
Thrombocytoses			
Thrombocytosis		6	0
Blood disorders SOC TOTAL		16056	4

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Reaction Name	Total	Fatal
Cardiac disorders		
Aortic valvular disorders		
Aortic valve incompetence	1	0
Cardiac conduction disorders		
Atrioventricular block	26	1
Atrioventricular block complete	3	1
Atrioventricular block first degree	2	0
Atrioventricular block second degree	3	0
Bundle branch block	2	0
Bundle branch block left	4	0
Bundle branch block right	4	0
Trifascicular block	1	0
Cardiac disorders NEC		
Acute cardiac event	5	0
Cardiac disorder	74	2
Cardiac dysfunction	1	0
Cardiac ventricular thrombosis	1	0
Cardiovascular deconditioning	1	0
Cardiovascular disorder	8	0
Intracardiac thrombus	5	0
Cardiac hypertensive complications		
Hypertensive heart disease	2	1
Cardiac infections and inflammations NEC		
Carditis	7	0
Cardiac neoplasms NEC		
Pericardial cyst	1	0
Cardiac signs and symptoms NEC		
Cardiac discomfort	33	0
Cardiovascular symptom	1	0
Palpitations	5093	1
Cardiac valve disorders NEC		
Cardiac valve disease	2	0
Heart valve incompetence	3	0
Cardiomyopathies		
Cardiomyopathy	11	0
Congestive cardiomyopathy	7	0
Stress cardiomyopathy	3	0
Coronary artery disorders NEC		
Arteriosclerosis coronary artery	1	0
Coronary artery disease	7	3
Coronary artery dissection	1	0
Coronary artery occlusion	3	0
Coronary artery thrombosis	4	2
Endocarditis NEC		
Endocarditis noninfective	1	1
Heart failures NEC		
Cardiac failure	77	9
Cardiac failure acute	5	1
Cardiac failure chronic	2	0
Cardiac failure congestive	4	1
Cardiogenic shock	4	1
Cardiopulmonary failure	1	1
Ischaemic coronary artery disorders		
Acute coronary syndrome	7	1

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Reaction Name	Total	Fatal
Cardiac disorders Cardiac disorders cont'd		
Acute myocardial infarction	25	1
Angina pectoris	276	1
Angina unstable	4	0
Arteriospasm coronary	3	0
Microvascular coronary artery disease	2	0
Myocardial infarction	253	37
Myocardial ischaemia	10	6
Left ventricular failures		
Acute left ventricular failure	1	1
Left ventricular failure	7	2
Mitral valvular disorders		
Mitral valve incompetence	8	0
Mitral valve prolapse	1	0
Myocardial disorders NEC		
Cardiac amyloidosis	1	0
Cardiac aneurysm	1	1
Cardiac ventricular scarring	1	0
Cardiomegaly	41	2
Left atrial dilatation	1	0
Left ventricular dysfunction	13	0
Left ventricular enlargement	2	0
Left ventricular hypertrophy	2	0
Myocardial fibrosis	6	0
Myocardial haemorrhage	1	0
Myocardial injury	13	0
Myocardial necrosis	1	0
Myocardial oedema	6	0
Myocardial rupture	1	0
Right atrial enlargement	1	0
Right ventricular dysfunction	2	0
Right ventricular enlargement	1	0
Ventricular dysfunction	2	0
Ventricular hypertrophy	1	0
Ventricular hypokinesia	2	0
Noninfectious myocarditis		
Eosinophilic myocarditis	1	0
Hypersensitivity myocarditis	1	0
Myocarditis	617	1
Myocarditis post infection	1	0
Noninfectious pericarditis		
Pericarditis	425	2
Pericarditis constrictive	1	0
Pleuropericarditis	1	0
Pericardial disorders NEC		
Cardiac tamponade	1	1
Pericardial effusion	40	2
Pericardial fibrosis	1	0
Pericardial haemorrhage	4	3
Pericardial rub	2	0
Rate and rhythm disorders NEC		
Arrhythmia	167	1
Arrhythmia neonatal	1	0
Bradycardia	66	0

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Reaction Name		Total	Fatal
Cardiac disorders	Cardiac disorders cont'd		
Bradycardia foetal		2	1
Cardiac flutter		537	0
Extrasystoles		192	0
Heart alternation		3	0
Paroxysmal arrhythmia		1	0
Postural orthostatic tachycardia syndrome		22	0
Tachyarrhythmia		8	0
Tachycardia		1850	0
Tachycardia foetal		1	0
Tachycardia paroxysmal		1	0
Right ventricular failures			
Cor pulmonale		1	0
Right ventricular failure		1	0
Supraventricular arrhythmias			
Arrhythmia supraventricular		15	0
Atrial fibrillation		256	1
Atrial flutter		37	0
Atrial tachycardia		10	0
Nodal arrhythmia		1	0
Sinus arrest		1	0
Sinus arrhythmia		7	0
Sinus bradycardia		13	0
Sinus node dysfunction		1	0
Sinus tachycardia		69	0
Supraventricular extrasystoles		4	0
Supraventricular tachycardia		42	0
Tricuspid valvular disorders			
Tricuspid valve incompetence		6	0
Ventricular arrhythmias and cardiac arrest			
Cardiac arrest		118	43
Cardio-respiratory arrest		1	1
Pulseless electrical activity		5	0
Ventricular arrhythmia		5	0
Ventricular extrasystoles		30	0
Ventricular fibrillation		9	1
Ventricular tachycardia		15	0
Cardiac disorders SOC TOTAL		10703	134

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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	15	0
<i>Cardiac hypoplasias congenital</i>		
Ventricular hypoplasia	1	0
<i>Cardiac septal defects congenital</i>		
Atrial septal defect	2	0
Hypertrophic cardiomyopathy	1	0
Ventricular septal defect	1	0
<i>Cardiac valve disorders congenital</i>		
Bicuspid aortic valve	1	0
<i>Central nervous system disorders congenital NEC</i>		
Spina bifida	2	1
Syringomyelia	2	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	4	0
Congenital hydrocephalus	1	0
<i>Coagulation disorders congenital</i>		
Factor IX deficiency	1	0
Haemophilia	2	0
<i>Congenital disorders NEC</i>		
Foetal malformation	1	0
Heterotaxia	1	0
<i>Connective tissue disorders congenital</i>		
Ehlers-Danlos syndrome	3	0
<i>Gastrointestinal tract disorders congenital NEC</i>		
Gastroschisis	3	0
<i>Great vessel disorders congenital</i>		
Congenital great vessel anomaly	1	0
Transposition of the great vessels	1	0
<i>Haematological disorders congenital NEC</i>		
Amegakaryocytic thrombocytopenia	1	0
Neonatal alloimmune thrombocytopenia	1	0
<i>Haemoglobinopathies congenital</i>		
Congenital methaemoglobinemia	1	0
<i>Inborn errors of bilirubin metabolism</i>		
Gilbert's syndrome	1	0
<i>Inborn errors of lipid metabolism</i>		
Short-chain acyl-coenzyme A dehydrogenase deficiency	1	0
<i>Inborn errors of metabolism NEC</i>		
Alpha-1 antitrypsin deficiency	1	0
<i>Inborn errors of porphyrin metabolism</i>		
Porphyria	1	0
<i>Laryngeal and tracheal disorders congenital</i>		
Laryngomalacia	1	0
<i>Lymphatic system disorders congenital</i>		
Cystic lymphangioma	3	0
<i>Male reproductive tract disorders congenital</i>		

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Reaction Name	Total	Fatal
Congenital disorders Congenital disorders cont'd		
Cryptorchism	1	0
Micropenis	4	0
Penoscrotal fusion	1	0
Phimosis	1	0
Musculoskeletal and connective tissue disorders of limbs congenital		
Developmental hip dysplasia	1	0
Limb malformation	1	0
Musculoskeletal and connective tissue disorders of skull congenital		
Platybasia	1	0
Musculoskeletal and connective tissue disorders of spine congenital		
Block vertebra	1	0
Brachyolmia	1	0
Neurological disorders congenital NEC		
Familial hemiplegic migraine	2	0
Familial periodic paralysis	1	0
Moebius II syndrome	1	0
Neurofibromatosis	1	0
Tourette's disorder	3	0
Ocular disorders congenital NEC		
Colour blindness	4	0
Congenital eye disorder	1	0
Palate disorders congenital		
Cleft lip and palate	2	0
Peripheral nervous system disorders congenital NEC		
Hereditary neuropathy with liability to pressure palsies	1	0
Paroxysmal extreme pain disorder	1	0
Pulmonary and bronchial disorders congenital		
Congenital cystic lung	1	0
Retinal disorders congenital		
Retinitis pigmentosa	1	0
Sex chromosomal abnormalities		
Turner's syndrome	1	0
Skin and subcutaneous tissue disorders congenital NEC		
Acral peeling skin syndrome	1	0
Tongue disorders congenital		
Ankyloglossia congenital	1	0
Vascular anomalies congenital NEC		
Congenital LUMBAR syndrome	1	0
Venous disorders congenital		
Anomalous pulmonary venous connection	1	0
Congenital disorders SOC TOTAL	95	1

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Reaction Name	Total	Fatal
Ear disorders		
 <i>Ear disorders NEC</i>		
Ear canal erythema	1	0
Ear congestion	34	0
Ear discomfort	99	0
Ear disorder	22	0
Ear haemorrhage	13	0
Ear inflammation	1	0
Ear pain	1083	0
Ear pruritus	12	0
Ear swelling	37	0
Otorrhoea	6	0
Paraesthesia ear	1	0
 <i>Eustachian tube disorders</i>		
Eustachian tube disorder	4	0
Eustachian tube dysfunction	9	0
Eustachian tube obstruction	5	0
 <i>External ear disorders NEC</i>		
Auricular swelling	2	0
Excessive cerumen production	11	0
External ear pain	6	0
Red ear syndrome	2	0
 <i>External ear infections and inflammations</i>		
External ear inflammation	2	0
 <i>Hearing disorders NEC</i>		
Auditory disorder	6	0
Diplacusis	2	0
 <i>Hearing losses</i>		
Conductive deafness	1	0
Deafness	268	0
Deafness bilateral	10	0
Deafness neurosensory	18	0
Deafness transitory	9	0
Deafness unilateral	35	0
Hypoacusis	212	0
Sudden hearing loss	50	0
 <i>Hyperacusia</i>		
Hyperacusis	66	0
Misophonia	3	0
 <i>Inner ear disorders NEC</i>		
Acute vestibular syndrome	2	0
Inner ear disorder	13	0
Meniere's disease	12	0
Vestibular disorder	12	0
 <i>Inner ear infections and inflammations</i>		
Inner ear inflammation	11	0
 <i>Inner ear signs and symptoms</i>		
Motion sickness	65	0
Tinnitus	2230	0
Vertigo	1543	0
Vertigo labyrinthine	12	0
Vertigo positional	80	0
 <i>Mastoid disorders</i>		
Mastoid effusion	1	0

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Reaction Name	Total	Fatal
Ear disorders Ear disorders cont'd		
Middle ear disorders NEC		
Middle ear disorder	3	0
Middle ear effusion	1	0
Middle ear infections and inflammations		
Middle ear inflammation	1	0
Tympanic membrane disorders (excl infections)		
Tympanic membrane perforation	3	0
Ear disorders SOC TOTAL	6019	0

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Reaction Name	Total	Fatal
Endocrine disorders		
Acute and chronic thyroiditis		
Autoimmune thyroiditis	2	0
Thyroiditis	23	0
Thyroiditis acute	3	0
Thyroiditis subacute	3	0
Adrenal cortical hypofunctions		
Addison's disease	2	0
Adrenal insufficiency	3	0
Adrenocortical insufficiency acute	16	0
Adrenal gland disorders NEC		
Adrenal disorder	2	0
Adrenal haemorrhage	3	0
Anterior pituitary hyperfunction		
Pituitary-dependent Cushing's syndrome	1	0
Anterior pituitary hypofunction		
Hypopituitarism	1	0
Endocrine abnormalities of gonadal function NEC		
Oestrogen deficiency	1	0
Endocrine abnormalities of puberty		
Delayed menarche	4	0
Premature menarche	19	0
Female gonadal function disorders		
Anovulatory cycle	54	0
Ovulation delayed	32	0
Male gonadal function disorders		
Androgen deficiency	1	0
Thyroid disorders NEC		
Autoimmune thyroid disorder	1	0
Goitre	16	0
Thyroid disorder	10	0
Thyroid mass	2	0
Thyroid pain	10	0
Thyroid hyperfunction disorders		
Basedow's disease	11	0
Hyperthyroidism	45	0
Thyrotoxic crisis	4	0
Thyroid hypofunction disorders		
Autoimmune hypothyroidism	1	0
Hypothyroidism	37	0
Immune-mediated hypothyroidism	1	0
Myxoedema	1	0
Endocrine disorders SOC TOTAL	309	0

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Reaction Name	Total	Fatal
Eye disorders		
Amblyopic vision impairment		
Amblyopia	7	0
Anterior chamber bleeding and vascular disorders		
Spontaneous hyphaema	1	0
Cataract conditions		
Cataract	13	0
Choroid and vitreous haemorrhages and vascular disorders		
Choroidal haemorrhage	1	0
Choroidal neovascularisation	1	0
Vitreous haemorrhage	4	0
Choroid and vitreous structural change, deposit and degeneration		
Chorioretinopathy	7	0
Vitreous detachment	18	0
Vitreous floaters	103	0
Colour blindness (incl acquired)		
Dyschromatopsia	10	0
Conjunctival and corneal bleeding and vascular disorders		
Conjunctival haemorrhage	50	0
Scleral haemorrhage	1	0
Conjunctival infections, irritations and inflammations		
Conjunctival hyperaemia	2	0
Conjunctival irritation	1	0
Conjunctival oedema	3	0
Conjunctivitis allergic	2	0
Corneal infections, oedemas and inflammations		
Corneal oedema	2	0
Keratitis	7	0
Ulcerative keratitis	5	0
Corneal structural change, deposit and degeneration		
Corneal scar	1	0
Eyelid movement disorders		
Blepharospasm	154	0
Excessive eye blinking	6	0
Eyelid function disorder	3	0
Eyelid myokymia	4	0
Eyelid ptosis	46	0
Paralytic lagophthalmos	2	0
Glaucomas (excl congenital)		
Angle closure glaucoma	2	0
Glaucoma	6	0
Ocular hypertension	1	0
Iris and ciliary body structural change, deposit and degeneration		
Eye colour change	3	0
Iris and uveal tract infections, irritations and inflammations		
Autoimmune uveitis	3	0
Iridocyclitis	17	0
Iritis	11	0
Uveitis	54	0
Lacrimation disorders		
Dry eye	161	0
Lacrimation increased	151	0
Lid bleeding and vascular disorders		
Eyelid bleeding	1	0

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Eye disorders Eye disorders cont'd		
Lid, lash and lacrimal infections, irritations and inflammations		
Blepharitis	17	0
Blepharitis allergic	1	0
Chalazion	7	0
Eczema eyelids	9	0
Erythema of eyelid	10	0
Eyelid cyst	6	0
Eyelid irritation	3	0
Eyelid margin crusting	5	0
Eyelid oedema	13	0
Eyelid rash	17	0
Meibomian gland dysfunction	1	0
Swelling of eyelid	137	0
Swollen tear duct	2	0
Lid, lash and lacrimal structural disorders		
Dacryostenosis acquired	1	0
Dermatochalasis	1	0
Ectropion	1	0
Eyelash changes	1	0
Eyelid exfoliation	3	0
Eyelid skin dryness	2	0
Eyelid thickening	1	0
Floppy eyelid syndrome	1	0
Growth of eyelashes	3	0
Lagophthalmos	3	0
Ocular bleeding and vascular disorders NEC		
Eye haematoma	4	0
Eye haemorrhage	34	0
Ocular vascular disorder	2	0
Ophthalmic vein thrombosis	1	0
Ocular disorders NEC		
Chorioretinal disorder	1	0
Dark circles under eyes	8	0
Eye disorder	38	0
Eye oedema	18	0
Eye pain	1209	0
Eye swelling	590	0
Eye symptom	9	0
Eye ulcer	5	0
Eyelid disorder	16	0
Eyelid pain	13	0
Eyelids pruritus	7	0
Ocular discomfort	29	0
Periorbital oedema	19	0
Periorbital pain	2	0
Periorbital swelling	122	0
Retinal disorder	2	0
Vitreous disorder	1	0
Ocular infections, inflammations and associated manifestations		
Eye allergy	20	0
Eye discharge	32	0
Eye inflammation	34	0
Eye irritation	98	0

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Reaction Name		Total	Fatal
Eye disorders	Eye disorders cont'd		
Eye pruritus		264	0
Limbal swelling		4	0
Ocular hyperaemia		242	0
Ocular nerve and muscle disorders			
Binocular eye movement disorder		1	0
Extraocular muscle disorder		1	0
Extraocular muscle paresis		2	0
Eye movement disorder		39	0
Gaze palsy		1	0
Ocular myasthenia		1	0
Ophthalmoplegia		5	0
Strabismus		10	0
Ocular sensation disorders			
Abnormal sensation in eye		20	0
Asthenopia		166	0
Eye paraesthesia		2	0
Eyelid sensory disorder		2	0
Foreign body sensation in eyes		17	0
Hypoaesthesia eye		17	0
Photophobia		507	0
Optic disc abnormalities NEC			
Papilloedema		7	0
Optic nerve bleeding and vascular disorders			
Optic disc haemorrhage		1	0
Optic ischaemic neuropathy		2	0
Orbital infections, inflammations and irritations			
Parophthalmia		1	0
Orbital structural change, deposit and degeneration			
Orbital oedema		2	0
Pupil disorders			
Miosis		2	0
Mydriasis		23	0
Pupil fixed		2	0
Pupillary disorder		1	0
Pupils unequal		13	0
Refractive and accommodative disorders			
Accommodation disorder		1	0
Altered visual depth perception		5	0
Astigmatism		2	0
Hypermetropia		3	0
Myopia		1	0
Retinal bleeding and vascular disorders (excl retinopathy)			
Retinal artery occlusion		16	0
Retinal artery thrombosis		2	0
Retinal haemorrhage		10	0
Retinal vascular thrombosis		1	0
Retinal vein occlusion		38	0
Retinal vein thrombosis		2	0
Retinal structural change, deposit and degeneration			
Macular degeneration		4	0
Macular hole		3	0
Macular rupture		1	0
Maculopathy		1	0

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Reaction Name		Total	Fatal
Eye disorders	Eye disorders cont'd		
Neovascular age-related macular degeneration		4	0
Retinal degeneration		1	0
Retinal detachment		7	0
Retinal tear		3	0
Retinal toxicity		3	0
Retinal, choroid and vitreous infections and inflammations			
Birdshot chorioretinopathy		2	0
Cystoid macular oedema		1	0
Macular oedema		5	0
Retinal oedema		1	0
Retinal vasculitis		3	0
Retinopathies NEC			
Acute macular neuroretinopathy		3	0
Retinal exudates		2	0
Retinopathy		4	0
Scleral infections, irritations and inflammations			
Episcleritis		8	0
Scleritis		6	0
Scleral structural change, deposit and degeneration			
Scleral discolouration		2	0
Structural change, deposit and degeneration of eye NEC			
Endocrine ophthalmopathy		1	0
Exophthalmos		4	0
Visual colour distortions			
Chloropsia		2	0
Chromatopsia		1	0
Cyanopsia		4	0
Erythropsia		2	0
Xanthopsia		1	0
Visual disorders NEC			
Charles Bonnet syndrome		2	0
Diplopia		169	0
Dysmetropsia		1	0
Glare		1	0
Halo vision		7	0
Heteronymous diplopia		1	0
Metamorphopsia		23	0
Oscillopsia		3	0
Photopsia		150	0
Scintillating scotoma		4	0
Vision blurred		1329	0
Visual brightness		3	0
Visual snow syndrome		8	0
Visual field disorders			
Visual field defect		34	0
Visual impairment and blindness (excl colour blindness)			
Amaurosis fugax		4	0
Blindness		142	0
Blindness cortical		1	0
Blindness transient		17	0
Blindness unilateral		17	0
Central vision loss		6	0
Sudden visual loss		3	0

Case Series Drug Analysis Print

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

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Visual acuity reduced	27	0
Visual acuity reduced transiently	1	0
Visual impairment	418	0
Visual pathway disorders		
Optic nerve disorder	1	0
Eye disorders SOC TOTAL	7310	0

Case Series Drug Analysis Print

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

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Gastrointestinal disorders		
Abdominal findings abnormal		
Abdominal mass	2	0
Gastrointestinal sounds abnormal	17	0
Abdominal hernias NEC		
Abdominal hernia	2	0
Abdominal wall conditions NEC		
Abdominal wall haematoma	2	0
Acute and chronic pancreatitis		
Alcoholic pancreatitis	1	0
Autoimmune pancreatitis	1	0
Obstructive pancreatitis	1	0
Pancreatitis	16	0
Pancreatitis acute	16	1
Pancreatitis chronic	1	0
Pancreatitis necrotising	1	0
Anal and rectal disorders NEC		
Anal fissure	3	0
Anal sphincter atony	1	0
Rectal prolapse	1	0
Anal and rectal pains		
Proctalgia	15	0
Anal and rectal signs and symptoms		
Anal blister	1	0
Anal erythema	1	0
Anal hypoesthesia	1	0
Anal pruritus	2	0
Anal spasm	1	0
Anorectal discomfort	5	0
Anorectal swelling	1	0
Rectal discharge	2	0
Rectal tenesmus	1	0
Anal and rectal ulcers and perforation		
Anal ulcer	1	0
Benign oral cavity neoplasms		
Mouth cyst	6	0
Tongue cyst	4	0
Tongue polyp	2	0
Colitis (excl infective)		
Autoimmune colitis	2	0
Colitis	50	1
Colitis ischaemic	1	0
Colitis microscopic	2	0
Colitis ulcerative	75	0
Crohn's disease	44	0
Eosinophilic colitis	1	0
Inflammatory bowel disease	10	0
Dental and periodontal infections and inflammations		
Dental caries	2	0
Periodontal inflammation	1	0
Dental developmental disorders and anomalies		
Tooth impacted	1	0
Dental disorders NEC		
Loose tooth	5	0

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Malpositioned teeth	2	0
Periodontal disease	1	0
Teeth brittle	3	0
Teething	9	0
Tooth disorder	2	0
Tooth erosion	1	0
Tooth socket haemorrhage	1	0
Dental pain and sensation disorders		
Dental discomfort	7	0
Dental paraesthesia	14	0
Hyperaesthesia teeth	38	0
Toothache	185	0
Dental surface disorders		
Tooth discolouration	9	0
Diaphragmatic hernias		
Hiatus hernia	8	0
Diarrhoea (excl infective)		
Diarrhoea	5836	0
Diarrhoea haemorrhagic	26	0
Diverticula		
Diverticulum	6	0
Diverticulum intestinal	1	0
Duodenal and small intestinal stenosis and obstruction		
Small intestinal obstruction	2	0
Duodenal ulcers and perforation		
Duodenal ulcer haemorrhage	1	0
Duodenal ulcer perforation	3	0
Dyspeptic signs and symptoms		
Dyspepsia	500	0
Epigastric discomfort	14	0
Eruption	58	0
Faecal abnormalities NEC		
Abnormal faeces	20	0
Faecaloma	5	0
Faeces discoloured	62	0
Faeces hard	2	0
Faeces pale	4	0
Faeces soft	12	0
Mucous stools	10	0
Flatulence, bloating and distension		
Abdominal distension	554	0
Aerophagia	3	0
Flatulence	193	0
Gastric and oesophageal haemorrhages		
Gastric haemorrhage	5	1
Mallory-Weiss syndrome	1	0
Oesophageal varices haemorrhage	1	0
Gastric ulcers and perforation		
Gastric ulcer	7	0
Gastritis (excl infective)		
Chronic gastritis	4	0
Gastritis	63	0
Reflux gastritis	8	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Gastrointestinal and abdominal pains (excl oral and throat)		
Abdominal migraine	2	0
Abdominal pain	1570	0
Abdominal pain lower	141	0
Abdominal pain upper	2629	0
Abdominal rigidity	25	0
Abdominal tenderness	13	0
Gastrointestinal pain	152	0
Oesophageal pain	13	0
Gastrointestinal atonic and hypomotility disorders NEC		
Constipation	267	0
Duodenogastric reflux	4	0
Gastric dilatation	7	0
Gastrooesophageal reflux disease	173	0
Impaired gastric emptying	9	0
Infrequent bowel movements	3	0
Intestinal dilatation	1	0
Intestinal pseudo-obstruction	2	0
Gastrointestinal disorders NEC		
Appendix disorder	2	0
Food poisoning	7	0
Functional gastrointestinal disorder	10	0
Gastric disorder	10	0
Gastrointestinal disorder	25	0
Stomach mass	4	0
Gastrointestinal dyskinetic disorders		
Bowel movement irregularity	7	0
Change of bowel habit	11	0
Dyschezia	4	0
Gastrointestinal motility disorder	3	0
Oesophageal achalasia	1	0
Gastrointestinal fistulae		
Diverticular fistula	2	0
Gastrointestinal inflammatory disorders NEC		
Duodenitis	1	0
Enteritis	6	0
Epiploic appendagitis	2	0
Gastrointestinal inflammation	3	0
Gastrointestinal tract irritation	1	0
Intestinal angioedema	2	0
Gastrointestinal mucosal dystrophies and secretion disorders		
Barrett's oesophagus	1	0
Hyperchlorhydria	4	0
Gastrointestinal signs and symptoms NEC		
Abdominal discomfort	658	0
Abdominal symptom	1	0
Acute abdomen	7	0
Anal incontinence	19	0
Breath odour	22	0
Dysphagia	217	2
Gastrointestinal wall thickening	1	0
Odynophagia	41	0
Gastrointestinal spastic and hypermotility disorders		

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Cardiospasm	1	0
Defaecation urgency	11	0
Frequent bowel movements	30	0
Gastrointestinal hypermotility	1	0
Irritable bowel syndrome	91	0
Oesophageal spasm	5	0
Pylorospasm	1	0
Gastrointestinal stenosis and obstruction NEC		
Intestinal obstruction	6	0
Neonatal intestinal obstruction	1	0
Gastrointestinal vascular malformations		
Gastric antral vascular ectasia	11	0
Gastrointestinal vascular occlusion and infarction		
Intestinal ischaemia	7	2
Mesenteric vein thrombosis	8	0
Omental infarction	1	0
Thrombosis mesenteric vessel	2	0
Visceral venous thrombosis	1	0
Gingival disorders, signs and symptoms NEC		
Gingival blister	13	0
Gingival discomfort	8	0
Gingival disorder	4	0
Gingival erythema	2	0
Gingival hypertrophy	1	0
Gingival oedema	1	0
Gingival pain	124	0
Gingival pruritus	1	0
Gingival recession	1	0
Gingival swelling	40	0
Gingival ulceration	2	0
Gingivitis ulcerative	1	0
Noninfective gingivitis	9	0
Gingival haemorrhages		
Gingival bleeding	75	0
Haemorrhoids and gastrointestinal varices (excl oesophageal)		
Gastric varices	1	0
Haemorrhoidal haemorrhage	1	0
Haemorrhoids	34	1
Haemorrhoids thrombosed	1	0
Inguinal hernias		
Inguinal hernia	1	0
Intestinal haemorrhages		
Anal haemorrhage	22	1
Intestinal haemorrhage	1	0
Rectal haemorrhage	78	0
Small intestinal haemorrhage	5	0
Intestinal ulcers and perforation NEC		
Intestinal perforation	5	2
Large intestinal ulcer	1	0
Large intestinal ulcer haemorrhage	1	0
Large intestine perforation	1	0
Large intestinal stenosis and obstruction		
Large intestinal obstruction	1	1

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Malabsorption syndromes		
Bile acid malabsorption	4	0
Coeliac disease	14	0
Malabsorption	1	0
Steatorrhoea	4	0
Nausea and vomiting symptoms		
Discoloured vomit	12	0
Infantile vomiting	7	0
Nausea	14634	0
Regurgitation	1	0
Retching	109	0
Vomiting	4849	1
Vomiting projectile	65	0
Non-mechanical ileus		
Ileus paralytic	2	0
Non-site specific gastrointestinal haemorrhages		
Gastrointestinal haemorrhage	17	1
Haematemesis	36	2
Haematochezia	58	0
Melaena	9	0
Upper gastrointestinal haemorrhage	13	0
Oesophageal stenosis and obstruction		
Oesophageal stenosis	3	0
Oesophagitis (excl infective)		
Eosinophilic oesophagitis	1	0
Oesophagitis	5	0
Oral dryness and saliva altered		
Aptyalism	4	0
Dry mouth	516	0
Lip dry	46	0
Saliva altered	8	0
Salivary hypersecretion	50	0
Oral soft tissue disorders NEC		
Angina bullosa haemorrhagica	1	0
Chapped lips	24	0
Cheilitis	25	0
Enlarged uvula	15	0
Leukoplakia oral	2	0
Lip blister	32	0
Lip disorder	5	0
Oral disorder	21	0
Oral lichen planus	14	0
Oral mucosal hypertrophy	1	0
Oral papule	1	0
Uvulitis	6	0
Oral soft tissue haemorrhages		
Lip haemorrhage	1	0
Mouth haemorrhage	16	0
Oral blood blister	17	0
Oral purpura	2	0
Oral soft tissue infections		
Angular cheilitis	4	0
Oral soft tissue signs and symptoms		

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Anaesthesia oral	3	0
Burning mouth syndrome	6	0
Coating in mouth	1	0
Hypoaesthesia oral	493	0
Lip discolouration	7	0
Lip erythema	4	0
Lip exfoliation	5	0
Lip pain	58	0
Lip pruritus	17	0
Lip scab	1	0
Oral discomfort	86	0
Oral dysaesthesia	1	0
Oral mucosal blistering	16	0
Oral mucosal discolouration	1	0
Oral mucosal eruption	18	0
Oral mucosal erythema	7	0
Oral mucosal exfoliation	10	0
Oral mucosal roughening	3	0
Oral mucosal scab	1	0
Oral pain	177	0
Oral pruritus	23	0
Paraesthesia oral	918	0
Pigmentation lip	1	0
Oral soft tissue swelling and oedema		
Lip oedema	4	0
Lip swelling	818	0
Mouth swelling	109	0
Oedema mouth	4	0
Palatal oedema	4	0
Palatal swelling	3	0
Pancreatic disorders NEC		
Pancreatic disorder	1	0
Pancreatic failure	1	0
Pancreatic mass	1	0
Peptic ulcers and perforation		
Peptic ulcer	1	0
Peptic ulcer haemorrhage	14	0
Peritoneal and retroperitoneal disorders		
Ascites	2	0
Peritoneal and retroperitoneal fibrosis and adhesions		
Abdominal adhesions	2	0
Peritoneal and retroperitoneal haemorrhages		
Haemoperitoneum	1	0
Retroperitoneal haemorrhage	1	1
Rectal inflammations NEC		
Proctitis	3	0
Proctitis ulcerative	1	0
Salivary gland disorders NEC		
Salivary gland disorder	1	0
Salivary gland pain	12	0
Salivary gland enlargements		
Parotid gland enlargement	10	0
Salivary gland enlargement	5	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Submaxillary gland enlargement	7	0
Salivary gland infections and inflammations		
Noninfective sialoadenitis	1	0
Stomatitis and ulceration		
Aphthous ulcer	55	0
Lip ulceration	21	0
Mouth ulceration	465	0
Oral mucosa erosion	1	0
Palatal ulcer	1	0
Stomatitis	67	0
Tongue disorders		
Glossitis	21	0
Hypertrophy of tongue papillae	1	0
Plicated tongue	4	0
Tongue disorder	43	0
Tongue geographic	7	0
Tongue haemorrhage	3	0
Tongue ulceration	32	0
Trichoglossia	4	0
Tongue signs and symptoms		
Glossodynia	220	0
Scalloped tongue	5	0
Stiff tongue	4	0
Swollen tongue	512	0
Tongue blistering	19	0
Tongue coated	19	0
Tongue discolouration	38	0
Tongue discomfort	42	0
Tongue dry	16	0
Tongue eruption	9	0
Tongue erythema	13	0
Tongue exfoliation	2	0
Tongue movement disturbance	7	0
Tongue oedema	23	0
Tongue pruritus	2	0
Tongue rough	5	0
Tongue spasm	12	0
Tooth missing		
Tooth loss	6	0
Gastrointestinal disorders SOC TOTAL	39875	17

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Reaction Name	Total	Fatal
General disorders		
Administration site reactions NEC		
Administration site bruise	8	0
Administration site erythema	4	0
Administration site extravasation	3	0
Administration site haematoma	3	0
Administration site inflammation	1	0
Administration site irritation	1	0
Administration site joint discomfort	1	0
Administration site joint movement impairment	2	0
Administration site nerve damage	1	0
Administration site pain	20	0
Administration site rash	5	0
Administration site reaction	1	0
Administration site swelling	4	0
Administration site urticaria	2	0
Administration site warmth	2	0
Puncture site bruise	42	0
Puncture site pain	8	0
Puncture site reaction	1	0
Puncture site swelling	2	0
Vessel puncture site bruise	2	0
Vessel puncture site erythema	1	0
Vessel puncture site pain	1	0
Adverse effect absent		
No adverse event	9	0
Application and instillation site reactions		
Application site acne	2	0
Application site bruise	12	0
Application site burn	1	0
Application site dryness	1	0
Application site erythema	18	0
Application site haemorrhage	1	0
Application site hypoesthesia	1	0
Application site irritation	1	0
Application site joint erythema	1	0
Application site joint pain	1	0
Application site mass	1	0
Application site odour	2	0
Application site pain	12	0
Application site pruritus	4	0
Application site rash	2	0
Application site reaction	1	0
Application site swelling	2	0
Application site vesicles	7	0
Application site warmth	1	0
Instillation site warmth	9	0
Asthenic conditions		
Asthenia	2162	0
Chronic fatigue syndrome	79	0
Decreased activity	10	0
Fatigue	24274	1
Malaise	5534	1
Sluggishness	19	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Body temperature altered		
Hyperthermia	7	0
Hyperthermia malignant	1	0
Hypothermia	25	0
Temperature regulation disorder	13	0
Breast complications associated with device		
Breast implant palpable	1	0
Capsular contracture associated with breast implant	2	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	5	0
Medical device pain	1	0
Medical device site swelling	1	0
Phantom shocks	2	0
Death and sudden death		
Brain death	3	2
Cardiac death	3	2
Clinical death	1	1
Death	190	1J€
Sudden cardiac death	1	1
Sudden death	26	26
Febrile disorders		
Hyperpyrexia	9	0
Pyrexia	15874	0
Feelings and sensations NEC		
Chills	10056	0
Feeling abnormal	1719	0
Feeling cold	1299	0
Feeling drunk	81	0
Feeling hot	1219	0
Feeling jittery	33	0
Feeling of body temperature change	346	0
Feeling of relaxation	3	0
Hangover	82	0
Hunger	49	0
Sensation of blood flow	4	0
Sensation of foreign body	57	0
Temperature intolerance	49	0
Thirst	370	0
Thirst decreased	1	0
Fibrosis NEC		
Fibrosis	1	0
Gait disturbances		
Gait disturbance	251	0
Gait inability	98	0
Loss of control of legs	25	0
General signs and symptoms NEC		
Adhesion	1	0
Chronic disease	1	0
Concomitant disease progression	1	1

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Condition aggravated	272	0
Crepitations	4	0
Crying	159	0
Deformity	2	0
Discharge	13	0
Disease progression	2	0
Disease recurrence	32	0
Effusion	3	0
Energy increased	25	0
Exercise tolerance decreased	26	0
Exercise tolerance increased	1	0
Fat tissue increased	1	0
Foaming at mouth	3	0
General physical health deterioration	17	2
General symptom	3	0
Glassy eyes	6	0
High-pitched crying	3	0
Illness	2104	0
Induration	16	0
Influenza like illness	2523	0
Irritability postvaccinal	2	0
Local reaction	90	0
Moaning	3	0
Multiple organ dysfunction syndrome	12	4
Nonspecific reaction	2	0
Organ failure	3	1
Perforation	2	0
Peripheral swelling	4128	0
Physical deconditioning	2	0
Pre-existing condition improved	9	0
Prolapse	1	0
Screaming	24	0
Secretion discharge	24	0
Swelling	3327	0
Swelling face	905	0
Symptom recurrence	1	0
Terminal state	1	0
Tissue irritation	1	0
Healing abnormal NEC		
Impaired healing	4	0
Implant and catheter site reactions		
Implant site discolouration	2	0
Implant site pain	3	0
Implant site rash	1	0
Implant site swelling	2	0
Implant site urticaria	1	0
Implant site warmth	3	0
Inflammations		
Granuloma	1	0
Inflammation	569	0
Papillitis	1	0
Scar inflammation	3	0
Serositis	1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Systemic inflammatory response syndrome	5	0
Infusion site reactions		
Infusion site coldness	1	0
Infusion site discolouration	1	0
Infusion site joint effusion	1	0
Infusion site joint pain	2	0
Infusion site mass	1	0
Infusion site nerve damage	1	0
Infusion site pain	4	0
Infusion site pruritus	3	0
Infusion site swelling	2	0
Infusion site urticaria	1	0
Infusion site warmth	2	0
Injection site reactions		
Injected limb mobility decreased	35	0
Injection site bruising	70	0
Injection site coldness	1	0
Injection site cyst	3	0
Injection site discolouration	5	0
Injection site discomfort	11	0
Injection site eczema	1	0
Injection site erythema	416	0
Injection site extravasation	1	0
Injection site haematoma	1	0
Injection site haemorrhage	7	0
Injection site hypersensitivity	2	0
Injection site hypoesthesia	14	0
Injection site indentation	9	0
Injection site induration	4	0
Injection site inflammation	46	0
Injection site injury	2	0
Injection site irritation	2	0
Injection site joint discomfort	2	0
Injection site joint erythema	4	0
Injection site joint movement impairment	1	0
Injection site joint pain	15	0
Injection site lymphadenopathy	1	0
Injection site macule	1	0
Injection site mass	611	0
Injection site movement impairment	1	0
Injection site muscle weakness	1	0
Injection site necrosis	4	0
Injection site nerve damage	1	0
Injection site nodule	1	0
Injection site oedema	18	0
Injection site pain	3090	0
Injection site pallor	1	0
Injection site paraesthesia	13	0
Injection site pruritus	233	0
Injection site rash	193	0
Injection site reaction	56	0
Injection site scab	4	0
Injection site scar	5	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Injection site swelling	325	0
Injection site urticaria	35	0
Injection site vesicles	10	0
Injection site warmth	204	0
Interactions		
Alcohol interaction	5	0
Drug interaction	30	0
Inhibitory drug interaction	3	0
Mass conditions NEC		
Cyst	49	0
Mass	80	0
Nodule	39	0
Mucosal findings abnormal		
Mucosa vesicle	1	0
Mucosal dryness	1	0
Mucosal haemorrhage	10	0
Mucosal inflammation	3	0
Oedema mucosal	2	0
Polyp	5	0
Necrosis NEC		
Fat necrosis	4	0
Necrosis	5	0
Oedema NEC		
Face oedema	33	0
Generalised oedema	4	0
Localised oedema	21	0
Oedema	83	0
Oedema peripheral	92	0
Pain and discomfort NEC		
Axillary pain	3761	0
Breakthrough pain	1	0
Chest discomfort	1862	0
Chest pain	5649	0
Discomfort	514	0
Facial discomfort	20	0
Facial pain	223	0
Inflammatory pain	18	0
Non-cardiac chest pain	32	0
Pain	9370	0
Suprapubic pain	1	0
Tenderness	700	0
Visceral pain	2	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	79	0
Adverse event	2	0
Adverse food reaction	3	0
Adverse reaction	13	0
Drug ineffective	346	0
Drug intolerance	4	0
Drug resistance	1	0
Immediate post-injection reaction	3	0
Inadequate analgesia	8	0
No reaction on previous exposure to drug	19	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
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	76	0
Therapy non-responder	1	0
Treatment failure	10	0
Vaccination failure	48	0
Trophic disorders		
Atrophy	2	0
Calcinosis	2	0
Hyperplasia	1	0
Hypertrophy	1	0
Ulcers NEC		
Ulcer	36	0
Ulcer haemorrhage	1	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	18	0
Shoulder injury related to vaccine administration	46	0
Vaccination site anaesthesia	1	0
Vaccination site bruising	138	0
Vaccination site coldness	3	0
Vaccination site cyst	6	0
Vaccination site dermatitis	1	0
Vaccination site discolouration	17	0
Vaccination site discomfort	51	0
Vaccination site dryness	1	0
Vaccination site eczema	1	0
Vaccination site erythema	666	0
Vaccination site granuloma	5	0
Vaccination site haematoma	2	0
Vaccination site haemorrhage	26	0
Vaccination site hypersensitivity	4	0
Vaccination site hypoesthesia	18	0
Vaccination site induration	77	0
Vaccination site inflammation	60	0
Vaccination site irritation	14	0
Vaccination site joint discomfort	3	0
Vaccination site joint erythema	12	0
Vaccination site joint inflammation	1	0
Vaccination site joint movement impairment	19	0
Vaccination site joint pain	33	0
Vaccination site joint swelling	4	0
Vaccination site joint warmth	1	0
Vaccination site lymphadenopathy	8	0
Vaccination site macule	1	0
Vaccination site mass	313	0
Vaccination site movement impairment	92	0
Vaccination site nerve damage	1	0
Vaccination site nodule	4	0
Vaccination site oedema	3	0

Case Series Drug Analysis Print

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

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site pain	2257	0
Vaccination site paraesthesia	9	0
Vaccination site phlebitis	1	0
Vaccination site photosensitivity reaction	1	0
Vaccination site pruritus	178	0
Vaccination site rash	145	0
Vaccination site reaction	36	0
Vaccination site scab	2	0
Vaccination site scar	1	0
Vaccination site swelling	621	0
Vaccination site thrombosis	1	0
Vaccination site ulcer	1	0
Vaccination site urticaria	10	0
Vaccination site vesicles	12	0
Vaccination site warmth	287	0
Vascular complications associated with device		
Vascular stent thrombosis	1	0
Withdrawal and rebound effects		
Drug withdrawal syndrome	4	0
Withdrawal syndrome	48	0
General disorders SOC TOTAL	112579	2HG

Case Series Drug Analysis Print

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

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	15	0
Cholangitis	1	0
<i>Cholecystitis and cholelithiasis</i>		
Cholecystitis	4	0
Cholecystitis acute	2	0
Cholelithiasis	11	0
<i>Cholestasis and jaundice</i>		
Cholestasis	2	0
Jaundice	25	0
Jaundice cholestatic	10	0
Ocular icterus	2	0
<i>Gallbladder disorders NEC</i>		
Gallbladder disorder	2	0
Gallbladder enlargement	1	0
<i>Hepatic and hepatobiliary disorders NEC</i>		
Hepatic cyst	1	0
Liver disorder	14	0
<i>Hepatic enzymes and function abnormalities</i>		
Hepatic function abnormal	7	0
<i>Hepatic failure and associated disorders</i>		
Acute hepatic failure	2	0
Hepatic failure	2	1
<i>Hepatic fibrosis and cirrhosis</i>		
Hepatic cirrhosis	1	0
<i>Hepatic vascular disorders</i>		
Congestive hepatopathy	2	0
Hepatic artery embolism	1	0
Hepatic haemorrhage	2	0
Hepatic vein thrombosis	5	0
Portal vein thrombosis	7	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	31	0
Hepatomegaly	6	0
Liver tenderness	3	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Autoimmune hepatitis	12	0
Drug-induced liver injury	3	0
Hepatic steatosis	5	0
Hepatitis	14	0
Hepatitis acute	2	0
Immune-mediated hepatic disorder	1	0
Liver injury	24	0
Hepatic disorders SOC TOTAL	220	1

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Immune system disorders		
Acute and chronic sarcoidosis		
Loefgren syndrome	1	0
Sarcoidosis	18	0
Allergic conditions NEC		
Allergic oedema	18	0
Allergy to animal	2	0
Allergy to arthropod bite	6	0
Allergy to arthropod sting	2	0
Allergy to metals	3	0
Allergy to sting	1	0
Hypersensitivity	1070	0
Infusion related hypersensitivity reaction	3	0
Mite allergy	2	0
Multiple allergies	16	0
Serum sickness	3	0
Serum sickness-like reaction	5	0
Type I hypersensitivity	1	0
Type III immune complex mediated reaction	4	0
Type IV hypersensitivity reaction	6	0
Allergies to foods, food additives, drugs and other chemicals		
Allergic reaction to excipient	6	0
Allergy to chemicals	5	0
Allergy to vaccine	43	0
Contrast media reaction	2	0
Drug hypersensitivity	33	0
Food allergy	33	0
Milk allergy	2	0
Oral allergy syndrome	3	0
Polymers allergy	1	0
Reaction to colouring	1	0
Reaction to excipient	10	0
Reaction to preservatives	5	0
Rubber sensitivity	1	0
Smoke sensitivity	1	0
Anaphylactic and anaphylactoid responses		
Anaphylactic reaction	529	1
Anaphylactic shock	60	0
Anaphylactoid reaction	22	0
Anaphylactoid shock	4	0
Atopic disorders		
Atopy	3	0
Seasonal allergy	106	0
Autoimmune disorders NEC		
Autoimmune disorder	49	0
Immune and associated conditions NEC		
Anamnestic reaction	1	0
Bacille Calmette-Guerin scar reactivation	61	0
Cytokine storm	1	0
Decreased immune responsiveness	3	0
Graft versus host disease	2	0
Haemophagocytic lymphohistiocytosis	3	0
Immune reconstitution inflammatory syndrome	1	0
Immune system disorder	31	0

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Reaction Name	Total	Fatal
Immune system disorders		
Immune system disorders cont'd		
Immune-mediated adverse reaction	7	0
Immunisation reaction	2	0
Multisystem inflammatory syndrome in children	4	0
Sensitisation	9	0
Systemic immune activation	2	0
Immunodeficiency disorders NEC		
Hypogammaglobulinaemia	1	0
Immunodeficiency	3	0
Immunosuppression	4	0
Transplant rejections		
Corneal graft rejection	10	0
Kidney transplant rejection	1	0
Solid organ transplant rejection	1	0
Transplant rejection	2	0
Immune system disorders SOC TOTAL	2229	1

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Infections		
Abdominal and gastrointestinal infections		
Abdominal abscess	2	0
Abdominal infection	1	0
Anal abscess	3	0
Appendicitis	42	0
Appendicitis perforated	7	0
Diverticulitis	14	0
Dysentery	1	0
Gastric infection	2	0
Gastroenteritis	30	0
Mesenteric abscess	1	0
Peritonitis	3	1
Rectal abscess	1	0
Adenoviral infections		
Adenoviral conjunctivitis	1	0
Adenovirus infection	1	0
Aspergillus infections		
Bronchopulmonary aspergillosis	1	0
Bacterial infections NEC		
Abscess bacterial	2	0
Administration site cellulitis	1	0
Arthritis bacterial	4	0
Bacterial colitis	1	0
Bacterial diarrhoea	1	0
Bacterial infection	15	0
Bacterial sepsis	1	0
Bacterial vaginosis	2	0
Cellulitis	194	0
Cellulitis orbital	1	0
Conjunctivitis bacterial	1	0
Ear infection bacterial	1	0
External ear cellulitis	1	0
Folliculitis	18	0
Gangrene	1	0
Gastrointestinal bacterial overgrowth	1	0
Injection site cellulitis	2	0
Meningitis bacterial	3	0
Myocarditis bacterial	1	0
Paronychia	3	0
Perichondritis	3	0
Periorbital cellulitis	3	0
Pneumonia bacterial	1	0
Sinusitis bacterial	2	0
Skin bacterial infection	4	0
Tonsillitis bacterial	3	0
Urinary tract infection bacterial	1	0
Vaccination site cellulitis	20	0
Zoonotic bacterial infection	1	1
Bartonella infections		
Cat scratch disease	1	0
Bone and joint infections		
Abscess jaw	1	0
Arthritis infective	2	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

Reaction Name		Total	Fatal
Infections	Infections cont'd		
Osteomyelitis		2	0
Borrelial infections			
Lyme disease		3	0
Relapsing fever		1	0
Breast infections			
Breast abscess		3	0
Mastitis		80	0
Caliciviral infections			
Gastroenteritis norovirus		3	0
Campylobacter infections			
Campylobacter gastroenteritis		1	0
Campylobacter infection		1	0
Candida infections			
Anal candidiasis		3	0
Balanitis candida		1	0
Candida infection		70	0
Oral candidiasis		39	0
Respiratory moniliasis		1	0
Skin candida		2	0
Systemic candida		1	0
Urinary tract candidiasis		1	0
Vulvovaginal candidiasis		53	0
Cardiac infections			
Cardiac infection		1	0
Cardiac valve vegetation		1	0
Endocarditis		1	0
Pericarditis infective		2	0
Central nervous system and spinal infections			
Brain abscess		2	0
CNS ventriculitis		1	0
Cavernous sinus thrombosis		1	0
Encephalitis		21	0
Encephalomyelitis		1	0
Meningitis		12	0
Meningitis aseptic		3	0
Myelitis		9	0
Subdural abscess		1	0
Clostridia infections			
Clostridium difficile infection		2	0
Coronavirus infections			
Asymptomatic COVID-19		18	0
COVID-19		1771	4H
COVID-19 pneumonia		51	14
Coronavirus infection		7	0
Post-acute COVID-19 syndrome		3	0
Severe acute respiratory syndrome		4	0
Suspected COVID-19		74	4
Corynebacteria infections			
Diphtheria		2	0
Coxiella infections			
Q fever		13	0
Cytomegaloviral infections			
Cytomegalovirus infection		2	0

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Reaction Name		Total	Fatal
Infections	Infections cont'd		
Cytomegalovirus syndrome		1	0
Dental and oral soft tissue infections			
Abscess oral		6	0
Gingival abscess		1	0
Gingivitis		13	0
Oral infection		1	0
Parotitis		12	0
Pericoronitis		2	0
Periodontitis		1	0
Pulpitis dental		2	0
Sialoadenitis		3	0
Tongue abscess		1	0
Tooth abscess		8	0
Tooth infection		9	0
Ear infections			
Ear infection		96	0
Labyrinthitis		109	0
Mastoiditis		3	0
Otitis externa		3	0
Otitis media		3	0
Otitis media acute		1	0
Otitis media chronic		5	0
Ectoparasitic infestations			
Acarodermatitis		5	0
Bed bug infestation		1	0
Demodicidosis		1	0
Epstein-Barr viral infections			
Epstein-Barr virus infection		5	0
Epstein-Barr virus infection reactivation		1	0
Infectious mononucleosis		29	0
Escherichia infections			
Escherichia bacteraemia		1	0
Eye and eyelid infections			
Conjunctivitis		81	0
Eye abscess		1	0
Eye infection		26	0
Eye infection intraocular		1	0
Eyelid boil		2	0
Eyelid infection		2	0
Hordeolum		29	0
Keratouveitis		1	0
Periorbital infection		2	0
Female reproductive tract infections			
Bartholin's abscess		1	0
Bartholinitis		1	0
Endometritis		3	0
Funisitis		1	0
Pelvic inflammatory disease		2	0
Vaginal infection		1	0
Vulval abscess		1	0
Vulvitis		1	0
Fungal infections NEC			
Fungal infection		19	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Fungal skin infection	5	0
Myocarditis mycotic	1	0
Onychomycosis	2	0
Oral fungal infection	2	0
Pneumonia fungal	2	0
Severe asthma with fungal sensitisation	1	0
Vulvovaginal mycotic infection	8	0
Hepatitis virus infections		
Hepatitis A	1	0
Hepatitis E	1	0
Hepatobiliary and spleen infections		
Biliary sepsis	3	0
Cholecystitis infective	2	0
Hepatic infection	1	0
Herpes viral infections		
Eczema herpeticum	3	0
Genital herpes	91	0
Genital herpes simplex	6	0
Genital herpes zoster	1	0
Herpes ophthalmic	3	0
Herpes simplex	31	0
Herpes simplex encephalitis	1	1
Herpes simplex reactivation	2	0
Herpes virus infection	13	0
Herpes zoster	1508	0
Herpes zoster disseminated	1	0
Herpes zoster meningoencephalitis	1	0
Herpes zoster oticus	15	0
Herpes zoster reactivation	2	0
Meningitis herpes	1	0
Nasal herpes	4	0
Ophthalmic herpes simplex	3	0
Ophthalmic herpes zoster	4	0
Oral herpes	325	0
Varicella	30	0
Varicella zoster virus infection	3	0
Infections NEC		
Abscess	39	0
Abscess limb	9	0
Abscess soft tissue	1	0
Catheter site infection	1	0
Genital abscess	2	0
Groin abscess	1	0
Infected bite	3	0
Infected cyst	2	0
Infection	255	0
Infection susceptibility increased	2	0
Injection site abscess	1	0
Injection site infection	5	0
Localised infection	35	0
Lymph gland infection	18	0
Lymph node abscess	6	0
Opportunistic infection	1	0

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Reaction Name		Total	Fatal
Infections	Infections cont'd		
Pathogen resistance		1	0
Purulent discharge		1	0
Respiratory tract infection		12	0
Vaccination site abscess		11	0
Vaccination site infection		13	0
Vaccine breakthrough infection		23	0
Vestibulitis		2	0
Wound infection		2	0
Infectious transmissions			
Nosocomial infection		1	0
Secondary transmission		8	0
Vaccine virus shedding		1	0
Influenza viral infections			
H1N1 influenza		1	0
Influenza		1734	0
Klebsiella infections			
Klebsiella infection		1	0
Lower respiratory tract and lung infections			
Bronchitis		23	0
Infectious pleural effusion		1	0
Lower respiratory tract infection		262	8
Pneumonia		156	13
Pneumonia aspiration		10	6
Sputum purulent		1	0
Male reproductive tract infections			
Epididymitis		9	0
Orchitis		6	0
Prostate infection		2	0
Molluscum contagiosum viral infections			
Molluscum contagiosum		1	0
Mumps viral infections			
Mumps		8	0
Muscle and soft tissue infections			
Abscess neck		1	0
Infective tenosynovitis		1	0
Necrotising fasciitis		2	0
Psoas abscess		1	0
Soft tissue infection		2	0
Neisseria infections			
Gonorrhoea		1	0
Meningococcal bacteraemia		1	0
Meningococcal infection		1	0
Orthopox viral infections			
Smallpox		1	0
Vaccinia virus infection		2	0
Plasmodia infections			
Malaria		2	0
Pneumocystis infections			
Pneumocystis jirovecii pneumonia		2	0
Pseudomonal infections			
Pseudomonas infection		1	0
Retroviral infections			
Acquired immunodeficiency syndrome		1	0

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Reaction Name		Total	Fatal
Infections	Infections cont'd		
HIV infection		2	0
Persistent generalised lymphadenopathy		1	0
Rhinoviral infections			
Rhinovirus infection		1	0
Rotaviral infections			
Gastroenteritis rotavirus		1	0
Rubeola viral infections			
Measles		5	0
Salmonella infections			
Typhoid fever		1	0
Sepsis, bacteraemia, viraemia and fungaemia NEC			
Neutropenic sepsis		3	1
Sepsis		56	8
Sepsis syndrome		2	0
Septic rash		2	0
Septic shock		6	1
Urosepsis		5	0
Skin structures and soft tissue infections			
Abscess sweat gland		1	0
Acne pustular		1	0
Blister infected		1	0
Dermatitis infected		3	0
Impetigo		11	0
Infected skin ulcer		2	0
Injection site pustule		2	0
Nail infection		2	0
Pustule		19	0
Pyoderma		1	0
Rash pustular		12	0
Skin infection		32	0
Subcutaneous abscess		11	0
Sweat gland infection		1	0
Vaccination site pustule		4	0
Staphylococcal infections			
Furuncle		42	1
Pneumonia staphylococcal		1	0
Staphylococcal abscess		1	0
Staphylococcal infection		5	0
Staphylococcal sepsis		1	0
Streptococcal infections			
Meningitis pneumococcal		1	0
Pharyngitis streptococcal		7	0
Pneumonia pneumococcal		1	0
Streptococcal abscess		1	0
Streptococcal endocarditis		1	0
Streptococcal infection		1	0
Streptococcal sepsis		1	0
Tinea infections			
Body tinea		4	0
Tinea capitis		1	0
Tinea infection		1	0
Tinea pedis		3	0
Tinea versicolour		4	0

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Reaction Name		Total	Fatal
Infections	Infections cont'd		
<i>Treponema infections</i>			
Syphilis		2	0
<i>Trypanosomal infections</i>			
African trypanosomiasis		3	0
<i>Tuberculous infections</i>			
Disseminated Bacillus Calmette-Guerin infection		1	0
Lymph node tuberculosis		1	0
Pulmonary tuberculosis		1	0
Tuberculosis		1	0
Tuberculosis of central nervous system		1	0
<i>Upper respiratory tract infections</i>			
Acute sinusitis		4	0
Chronic sinusitis		3	0
Croup infectious		1	0
Epiglottitis		1	0
Laryngitis		32	0
Nasopharyngitis		1111	1
Peritonsillar abscess		4	0
Pharyngitis		33	0
Rhinitis		52	0
Sinusitis		180	0
Tonsillitis		130	0
Tracheitis		5	0
Tracheostomy infection		1	0
Upper respiratory tract infection		12	0
<i>Urinary tract infections</i>			
Cystitis		84	0
Kidney infection		50	0
Pyelonephritis		3	0
Urethritis		1	0
Urinary tract infection		208	0
<i>Vascular infections</i>			
Haematoma infection		1	0
Infected lymphocele		2	0
Infusion site infection		1	0
Lymphangitis		10	0
<i>Viral infections NEC</i>			
Arthritis viral		1	0
Conjunctivitis viral		2	0
Ear infection viral		1	0
Encephalitis viral		6	1
Eye infection viral		2	0
Gastroenteritis viral		32	0
Hepatitis viral		3	0
Meningitis viral		8	0
Meningoencephalitis viral		1	0
Oral viral infection		1	0
Pleurisy viral		1	0
Pneumonia viral		4	2
Post viral fatigue syndrome		48	0
Sweating fever		121	0
Vestibular neuritis		34	0
Viral diarrhoea		2	0

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Reaction Name	Total	Fatal
Infections	Infections cont'd	
Viral infection	61	0
Viral labyrinthitis	4	0
Viral myocarditis	3	0
Viral pericarditis	3	0
Viral pharyngitis	21	0
Viral rash	64	0
Viral sinusitis	1	0
Viral tonsillitis	2	0
Infections SOC TOTAL	10568	10†

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Reaction Name	Total	Fatal
Injuries		
Abdominal and gastrointestinal injuries NEC		
Gallbladder injury	1	0
Liver contusion	1	0
Mouth injury	3	0
Oral contusion	5	0
Oral mucosal scar	1	0
Palate injury	1	0
Rectal injury	1	0
Splenic rupture	7	0
Tongue injury	2	0
Tooth fracture	1	0
Tooth injury	1	0
Accidental exposures to product		
Accidental exposure to product	20	0
Anaesthetic and allied procedural complications		
Airway complication of anaesthesia	2	0
Delayed recovery from anaesthesia	3	0
Sedation complication	1	0
Atmospheric pressure injuries		
Barotitis media	1	0
Barotrauma	1	0
Hypobarism	1	0
Bone and joint injuries NEC		
Bursa injury	2	0
Joint injury	9	0
Meniscus injury	2	0
Cardiac and vascular procedural complications		
Ischaemic contracture of the left ventricle	1	0
Shunt blood flow excessive	1	0
Vascular pseudoaneurysm	1	0
Cardiovascular injuries		
Vascular injury	8	0
Cerebral injuries NEC		
Brain contusion	4	0
Brain herniation	2	0
Concussion	4	0
Craniocerebral injury	1	0
Subarachnoid haematoma	1	0
Subdural haematoma	6	0
Subdural haemorrhage	7	0
Traumatic intracranial haemorrhage	1	1
Chemical injuries		
Chemical burn of skin	9	0
Chemical cystitis	2	0
Chest and respiratory tract injuries NEC		
Bronchial injury	1	0
Chest crushing	12	0
Foreign body in throat	1	0
Traumatic lung injury	1	0
Conditions caused by cold		
Chillblains	67	0
Cold shock response	1	0
Frostbite	1	0

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Reaction Name		Total	Fatal
Injuries	Injuries cont'd		
Cranial nerve injuries			
Vth nerve injury		1	0
Ear injuries NEC			
Deafness traumatic		1	0
Ear injury		1	0
Exposures associated with pregnancy, delivery and lactation			
Exposure during pregnancy		11	0
Exposure via breast milk		152	0
Foetal exposure during pregnancy		55	0
Foetal exposure timing unspecified		1	0
Maternal exposure before pregnancy		17	0
Maternal exposure during breast feeding		1857	0
Maternal exposure during delivery		1	0
Maternal exposure during pregnancy		994	0
Maternal exposure timing unspecified		11	0
Paternal exposure before pregnancy		3	0
Exposures to agents or circumstances NEC			
Exposure to SARS-CoV-2		3	0
Exposure to vaccinated person		4	0
Eye and ear procedural complications			
Toxic anterior segment syndrome		1	0
Eye injuries NEC			
Corneal abrasion		1	0
Eye contusion		15	0
Eye injury		27	0
Foreign body in eye		3	0
Injury corneal		1	0
Periorbital haematoma		1	0
Retinal injury		2	0
Superficial injury of eye		1	0
Foetal and neonatal conditions associated with product exposure			
Intoxication by breast feeding		1	0
Fractures and dislocations NEC			
Bone fragmentation		1	0
Fracture		3	0
Joint dislocation		3	0
Multiple fractures		1	0
Gastrointestinal and hepatobiliary procedural complications			
Post procedural constipation		1	0
Postoperative ileus		1	0
Procedural nausea		11	0
Procedural vomiting		2	0
Heat injuries (excl thermal burns)			
Heat cramps		2	0
Heat exhaustion		3	0
Heat illness		2	0
Heat oedema		14	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

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Reaction Name		Total	Fatal
Injuries	Injuries cont'd		
Clavicle fracture		28	0
Femoral neck fracture		1	0
Femur fracture		1	0
Fibula fracture		1	0
Hip fracture		2	0
Tibia fracture		1	0
Upper limb fracture		1	0
Wrist fracture		1	0
Medication errors, product use errors and issues NEC			
Circumstance or information capable of leading to medication error		2	0
Dose calculation error		1	0
Inadequate aseptic technique in use of product		1	0
Medication error		25	0
Prescription drug used without a prescription		3	0
Product use complaint		2	0
Product use issue		28	0
Vaccination error		5	0
Wrong dose		4	0
Wrong drug		11	0
Wrong schedule		1	0
Wrong technique in product usage process		6	0
Muscle, tendon and ligament injuries			
Epicondylitis		21	0
Ligament injury		2	0
Ligament sprain		9	0
Mallet finger		1	0
Muscle hernia		1	0
Muscle injury		31	0
Muscle rupture		9	0
Muscle strain		33	0
Post-traumatic neck syndrome		2	0
Tendon injury		7	0
Tendon rupture		23	0
Musculoskeletal procedural complications			
Periprosthetic osteolysis		1	0
Post laminectomy syndrome		1	0
Nerve injuries NEC			
Nerve injury		101	0
Neurological and psychiatric procedural complications			
Post lumbar puncture syndrome		1	0
Post procedural stroke		1	0
Procedural dizziness		12	0
Non-occupational environmental exposures			
Exposure to extreme temperature		2	0
Non-site specific injuries NEC			
Animal scratch		1	0
Arthropod bite		9	0
Arthropod sting		6	0
Bite		1	0
Bone contusion		1	0
Crush injury		1	0
Electric shock		19	0
Fall		202	0

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Reaction Name		Total	Fatal
Injuries	Injuries cont'd		
Foreign body		2	0
Injury		14	0
Multiple injuries		2	0
Nervous system injury		2	0
Post concussion syndrome		2	0
Traumatic haematoma		1	0
Wound		7	0
Wound complication		12	0
Wound haematoma		1	0
Wound haemorrhage		2	0
Wound secretion		6	0
Non-site specific procedural complications			
Administration related reaction		2	0
Incision site pain		3	0
Infusion related reaction		8	0
Injection related reaction		65	0
Post procedural complication		5	0
Post procedural erythema		1	0
Post procedural inflammation		1	0
Post procedural pruritus		1	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			
Off label use		374	0
Overdoses NEC			
Intentional overdose		1	0
Overdose		52	0
Pathways and sources of exposure			
Exposure via contaminated device		1	0
Exposure via unknown route		1	0
Pelvic fractures and dislocations			
Pelvic fracture		1	0
Peripheral nerve injuries			
Axillary nerve injury		1	0
Brachial plexus injury		1	0
Sciatic nerve injury		2	0
Ulnar nerve injury		4	0
Poisoning and toxicity			
Alcohol poisoning		1	0
Poisoning		14	0
Toxicity to various agents		4	0
Product administration errors and issues			
Accidental overdose		8	0
Contraindicated product administered		1	0
Duplicate therapy error		1	0
Expired product administered		12	0
Inappropriate schedule of product administration		646	0
Incomplete course of vaccination		2	0
Incorrect dose administered		54	0
Incorrect drug administration rate		1	0

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Reaction Name		Total	Fatal
Injuries	Injuries cont'd		
Incorrect product formulation administered		2	0
Incorrect route of product administration		7	0
Lack of vaccination site rotation		1	0
Poor quality product administered		3	0
Product administered at inappropriate site		21	0
Product administered to patient of inappropriate age		1	0
Product administration error		9	0
Product dose omission issue		6	0
Wrong product administered		20	0
Product confusion errors and issues			
Product dosage form confusion		1	0
Product label confusion		6	0
Product packaging confusion		1	0
Product dispensing errors and issues			
Product dispensing error		4	0
Product monitoring errors and issues			
Drug monitoring procedure incorrectly performed		1	0
Product preparation errors and issues			
Product preparation error		3	0
Product preparation issue		6	0
Product prescribing errors and issues			
Contraindicated product prescribed		2	0
Product prescribing error		2	0
Product selection errors and issues			
Product selection error		2	0
Radiation injuries			
Sunburn		23	0
Renal and urinary tract injuries NEC			
Bladder injury		1	0
Foreign body in urogenital tract		1	0
Reproductive system and breast injuries			
Breast injury		1	0
Cervix injury		1	0
Penile contusion		1	0
Penis injury		2	0
Reproductive tract and breast procedural complications			
Failed in vitro fertilisation		1	0
Site specific injuries NEC			
Back injury		2	0
Face crushing		3	0
Face injury		1	0
Head injury		36	0
Limb crushing injury		4	0
Limb injury		165	0
Nasal injury		1	0
Neck crushing		1	0
Neck injury		1	0
Pharyngeal contusion		1	0
Site specific procedural complications NEC			
Axillary web syndrome		3	0
Skin injuries NEC			
Contusion		1294	0
Hair injury		1	0

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Reaction Name		Total	Fatal
Injuries	Injuries cont'd		
Nail avulsion		1	0
Scar		27	0
Scratch		7	0
Skin abrasion		6	0
Skin injury		4	0
Skin laceration		4	0
Skin wound		3	0
Splinter		1	0
Subcutaneous haematoma		2	0
Skin procedural complications			
Dermal filler overcorrection		1	0
Recall phenomenon		1	0
Skull fractures, facial bone fractures and dislocations			
Facial bones fracture		1	0
Fractured skull depressed		1	0
Spinal cord injuries NEC			
Spinal cord injury cervical		1	0
Spinal fractures and dislocations			
Spinal compression fracture		1	0
Spinal fracture		5	0
Stoma complications			
Gastrointestinal stoma complication		2	0
Stoma site discharge		1	0
Stoma site extravasation		1	0
Stoma site haemorrhage		1	0
Thermal burns			
Airway burns		1	0
Burn oesophageal		4	0
Burn of internal organs		4	0
Burn oral cavity		5	0
Burns second degree		3	0
Burns third degree		1	0
Cold burn		1	0
Thermal burn		23	0
Thermal burns of eye		17	0
Underdoses NEC			
Underdose		6	0
Vaccination related complications			
Adverse event following immunisation		1	0
Post vaccination syndrome		1	0
Vaccination complication		51	0
Injuries SOC TOTAL		7191	1

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Reaction Name	Total	Fatal
Investigations		
Adrenal cortex tests		
Cortisol decreased	4	0
Adrenal medulla tests		
Epinephrine	1	0
Epinephrine abnormal	1	0
Epinephrine increased	1	0
Auditory and vestibular diagnostic procedures		
Acoustic stimulation tests	5	0
Audiogram abnormal	1	0
Autoimmunity analyses		
Antinuclear antibody	2	0
Antinuclear antibody increased	1	0
Antinuclear antibody positive	1	0
Beta-2 glycoprotein antibody positive	1	0
Cardiolipin antibody positive	1	0
Rheumatoid factor	3	0
Bacteria identification and serology (excl mycobacteria)		
Bacterial test positive	1	0
Blood counts NEC		
Full blood count	5	0
Full blood count abnormal	2	0
Blood gas and acid base analyses		
Acid base balance abnormal	1	0
Blood lactic acid	4	0
Blood lactic acid decreased	1	0
Blood lactic acid increased	5	0
Blood pH	7	0
Blood pH abnormal	1	0
Blood pH increased	12	0
Oxygen consumption	1	0
Oxygen consumption decreased	2	0
Oxygen saturation	10	0
Oxygen saturation abnormal	2	0
Oxygen saturation decreased	86	0
PO2 decreased	1	0
Venous oxygen saturation decreased	1	0
Bone marrow and immune tissue histopathology procedures		
Aspiration bone marrow	1	0
Biopsy lymph gland	1	0
Bone marrow and immune tissue imaging procedures		
Lymph nodes scan abnormal	1	0
Scan lymph nodes	4	0
Carbohydrate tolerance analyses (incl diabetes)		
Blood glucose	11	0
Blood glucose abnormal	14	0
Blood glucose decreased	37	0
Blood glucose fluctuation	17	0
Blood glucose increased	105	0
Blood glucose normal	1	0
Glycosylated haemoglobin increased	1	0
Cardiac auscultatory investigations		
Cardiac murmur	44	0
Heart sounds	8	0

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

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Reaction Name		Total	Fatal
Investigations	Investigations cont'd		
Digestive enzymes			
Amylase increased		1	0
ECG investigations			
Electrocardiogram		5	0
Electrocardiogram QRS complex prolonged		1	0
Electrocardiogram QT prolonged		11	0
Electrocardiogram ST segment depression		2	0
Electrocardiogram ST segment elevation		10	0
Electrocardiogram ST-T segment abnormal		2	0
Electrocardiogram T wave inversion		5	0
Electrocardiogram abnormal		20	0
Electrocardiogram change		1	0
Electrocardiogram normal		2	0
Electrocardiogram repolarisation abnormality		1	0
QRS axis abnormal		1	0
Endocrine analyses and imaging NEC			
Hormone level abnormal		70	0
Faecal analyses NEC			
Faecal calprotectin		2	0
Faecal calprotectin increased		4	0
Fertility analyses			
Infertility tests		1	0
Semen analysis abnormal		1	0
Sperm concentration		2	0
Sperm concentration decreased		1	0
Spermatozoa abnormal		1	0
Foetal and neonatal diagnostic procedures			
Foetal heart rate abnormal		5	2
Foetal heart rate increased		1	0
Foetal monitoring		1	0
Foetal non-stress test		1	0
Gastrointestinal and abdominal imaging procedures			
Computerised tomogram abdomen		1	0
Sigmoidoscopy abnormal		1	0
X-ray with contrast upper gastrointestinal tract		1	0
Gastrointestinal function diagnostic procedures			
Gastric pH decreased		4	0
Gastrointestinal, pancreatic and APUD hormone analyses			
Blood insulin		2	0
Blood insulin decreased		1	0
Haematological analyses NEC			
Blood viscosity abnormal		1	0
Blood viscosity decreased		1	0
Blood viscosity increased		1	0
Plasma viscosity		1	0
Plasma viscosity abnormal		1	0
Red blood cell sedimentation rate increased		7	0
Heart rate and pulse investigations			
Carotid pulse		1	0
Heart rate		512	0
Heart rate abnormal		68	0
Heart rate decreased		97	0
Heart rate increased		1057	0

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Reaction Name		Total	Fatal
Investigations	Investigations cont'd		
Heart rate irregular		259	0
Heart rate normal		1	0
Heart rate variability decreased		1	0
Maximum heart rate		2	0
Maximum heart rate increased		1	0
Pulse abnormal		21	0
Pulse absent		1	0
Pulse pressure increased		1	0
Radial pulse abnormal		1	0
Sinus rhythm		7	0
Hepatobiliary imaging procedures			
Liver scan		1	0
Imaging procedures NEC			
Computerised tomogram		4	0
Magnetic resonance imaging		4	0
Magnetic resonance imaging abnormal		1	0
Scan		2	0
X-ray		1	0
Immune response protein analyses NEC			
Cytokine test		1	0
Immunoglobulin analyses			
Blood immunoglobulin E increased		2	0
Blood immunoglobulin G increased		1	0
Blood immunoglobulin M		1	0
Blood immunoglobulin M increased		2	0
Immunology analyses NEC			
Antibody test		4	0
Antibody test positive		1	0
Immunology test		12	0
Immunology skin tests NEC			
Allergy alert test		1	0
Skin test positive		2	0
Investigations NEC			
Blood test		26	0
Blood test abnormal		47	0
False positive investigation result		1	0
Laboratory test		1	0
Polymerase chain reaction		1	0
Polymerase chain reaction positive		33	0
Quality of life decreased		1	0
Systemic lupus erythematosus disease activity index increased		1	0
Liver function analyses			
Alanine aminotransferase increased		26	0
Aspartate aminotransferase		1	0
Aspartate aminotransferase abnormal		1	0
Aspartate aminotransferase increased		2	0
Blood bilirubin increased		5	0
Gamma-glutamyltransferase increased		5	0
Hepatic enzyme increased		9	0
Liver function test		1	0
Liver function test abnormal		31	0
Liver function test increased		27	0
Transaminases increased		5	0

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Reaction Name		Total	Fatal
Investigations	Investigations cont'd		
Metabolism tests NEC			
Blood ketone body		3	0
Blood ketone body increased		1	0
Blood ketone body present		1	0
Blood uric acid increased		2	0
Brain natriuretic peptide increased		1	0
Ubiquinone		1	0
Urine ketone body present		1	0
Microbiology and serology tests NEC			
Culture negative		1	0
Culture throat		1	0
Culture urine		1	0
Vaccine induced antibody absent		1	0
Mineral and electrolyte analyses			
Blood calcium increased		1	0
Blood copper increased		1	0
Blood iron		1	0
Blood iron decreased		9	0
Blood iron increased		1	0
Blood magnesium decreased		1	0
Blood phosphorus decreased		1	0
Blood phosphorus increased		1	0
Blood potassium abnormal		1	0
Blood potassium decreased		4	0
Blood potassium increased		3	0
Blood sodium decreased		10	0
Serum ferritin		1	0
Serum ferritin decreased		4	0
Serum ferritin increased		1	0
Sweat test		1	0
Urine copper		2	0
Musculoskeletal and soft tissue imaging procedures			
Skull X-ray		6	0
Musculoskeletal and soft tissue tests NEC			
Swollen joint count increased		1	0
Mycobacteria identification and serology			
Tuberculin test positive		1	0
Neurologic diagnostic procedures			
Coma scale abnormal		5	0
Hoover's sign of leg paresis		1	0
Joint position sense decreased		1	0
Lumbar puncture		6	0
Magnetic resonance neurography		1	0
Pain threshold decreased		1	0
Temperature perception test abnormal		1	0
Temperature perception test increased		1	0
Ophthalmic function diagnostic procedures			
Corneal reflex decreased		1	0
Intraocular pressure increased		7	0
Intraocular pressure test		3	0
Visual acuity tests		1	0
Physical examination procedures and organ system status			
Body temperature		280	0

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Reaction Name		Total	Fatal
Investigations	Investigations cont'd		
Body temperature abnormal		52	0
Body temperature decreased		44	0
Body temperature fluctuation		58	0
Body temperature increased		478	0
Body temperature normal		1	0
Breath sounds abnormal		2	0
General physical condition abnormal		1	0
Grip strength		2	0
Grip strength decreased		22	0
Gynaecological examination		1	0
Head lag		8	0
Lymph node palpable		44	0
Male genital examination abnormal		1	0
Menstruation normal		3	0
Muscle strength abnormal		3	0
Ophthalmological examination		2	0
Orthopaedic examination		1	0
Palpatory finding abnormal		2	0
Product residue present		2	0
Psoriasis area severity index decreased		2	0
Psoriasis area severity index increased		1	0
Respiratory rate		9	0
Respiratory rate decreased		25	0
Respiratory rate increased		44	0
Skin temperature		43	0
Temperature difference of extremities		13	0
Weight		1	0
Weight abnormal		1	0
Weight decreased		119	0
Weight increased		44	0
Pituitary analyses anterior			
Blood corticotrophin		1	0
Blood follicle stimulating hormone increased		3	0
Blood growth hormone		3	0
Blood prolactin		3	0
Blood prolactin increased		3	0
Blood thyroid stimulating hormone decreased		1	0
Blood thyroid stimulating hormone increased		8	0
Platelet analyses			
Mean platelet volume decreased		1	0
Mean platelet volume increased		1	0
Platelet count		3	0
Platelet count abnormal		1	0
Platelet count decreased		77	0
Platelet count increased		6	0
Protein analyses NEC			
Alpha 1 globulin decreased		1	0
Alpha 2 globulin decreased		1	0
C-reactive protein increased		25	0
Red blood cell analyses			
Haematocrit		1	0
Haematocrit decreased		1	0
Haematocrit increased		1	0

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Reaction Name		Total	Fatal
Investigations	Investigations cont'd		
Haemoglobin decreased		13	0
Haemoglobin increased		2	0
Red blood cell count decreased		1	0
Red blood cell rouleaux formation present		1	0
Renal function analyses			
Blood creatinine		1	0
Blood creatinine decreased		1	0
Blood creatinine increased		4	0
Glomerular filtration rate decreased		4	0
Glomerular filtration rate increased		1	0
Reproductive hormone analyses			
Blood oestrogen		1	0
Blood oestrogen decreased		2	0
Blood testosterone decreased		1	0
Blood testosterone increased		2	0
False negative pregnancy test		7	0
Female sex hormone level		3	0
Human chorionic gonadotropin increased		1	0
Pregnancy test		18	0
Pregnancy test false positive		1	0
Pregnancy test positive		1	0
Reproductive organ and breast histopathology procedures			
Biopsy breast		2	0
Biopsy endometrium		1	0
Smear cervix		3	0
Reproductive organ and breast imaging procedures			
Breast scan		1	0
Hysteroscopy		2	0
Respiratory and pulmonary function diagnostic procedures			
Forced expiratory volume increased		2	0
Fractional exhaled nitric oxide normal		1	0
Maximal voluntary ventilation		2	0
Peak expiratory flow rate		2	0
Peak expiratory flow rate decreased		5	0
Pulmonary function test		3	0
Total lung capacity decreased		3	0
Vital capacity		1	0
Respiratory tract and thoracic histopathology procedures			
Sputum abnormal		3	0
Respiratory tract and thoracic imaging procedures			
Chest X-ray		19	0
Chest X-ray abnormal		1	0
Chest X-ray normal		2	0
Chest scan		2	0
Computerised tomogram thorax		1	0
Ventilation/perfusion scan		1	0
Skeletal and cardiac muscle analyses			
Blood creatine phosphokinase increased		8	0
Muscle enzyme		1	0
Myocardial necrosis marker		1	0
Myocardial necrosis marker increased		3	0
Troponin I increased		2	0
Troponin T increased		1	0

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Reaction Name		Total	Fatal
Investigations	Investigations cont'd		
Troponin increased		17	0
<i>Therapeutic drug monitoring analyses</i>			
Analgesic drug level		8	0
Anticoagulation drug level above therapeutic		1	0
Anticoagulation drug level below therapeutic		5	0
Anticoagulation drug level increased		1	0
Drug level decreased		1	0
<i>Thyroid analyses</i>			
Anti-thyroid antibody		1	0
Thyroid function test abnormal		5	0
Thyroxine		1	0
Thyroxine free increased		2	0
Tri-iodothyronine		1	0
Tri-iodothyronine decreased		5	0
<i>Tissue enzyme analyses NEC</i>			
Blood alkaline phosphatase abnormal		1	0
Blood alkaline phosphatase increased		5	0
Enzyme level increased		1	0
<i>Toxicology laboratory analyses</i>			
Blood caffeine decreased		1	0
Blood lead		1	0
Drug screen positive		2	0
Opiates		1	0
<i>Urinalysis NEC</i>			
Blood urine		15	0
Blood urine present		68	0
Cells in urine		1	0
Glucose urine present		1	0
Protein urine absent		1	0
Protein urine present		1	0
Red blood cells urine		1	0
Urine analysis abnormal		6	0
Urine leukocyte esterase positive		1	0
Urine uric acid increased		1	0
pH urine		6	0
pH urine increased		2	0
<i>Urinary tract function analyses NEC</i>			
Urine output		13	0
Urine output decreased		14	0
Urine output increased		7	0
<i>Urinary tract histopathology procedures</i>			
Urine cytology		1	0
<i>Urinary tract imaging procedures</i>			
Bladder scan		1	0
Cystoscopy		2	0
Ultrasound kidney normal		1	0
<i>Vascular imaging procedures NEC</i>			
Venogram		2	0
<i>Vascular tests NEC (incl blood pressure)</i>			
Blood pressure abnormal		7	0
Blood pressure ambulatory increased		1	0
Blood pressure decreased		86	0
Blood pressure diastolic		1	0

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Reaction Name		Total	Fatal
Investigations	Investigations cont'd		
Blood pressure diastolic decreased		1	0
Blood pressure diastolic increased		4	0
Blood pressure difference of extremities		1	0
Blood pressure increased		275	0
Blood pressure measurement		45	0
Blood pressure normal		2	0
Blood pressure systolic		1	0
Blood pressure systolic decreased		4	0
Blood pressure systolic increased		1	0
Virus identification and serology			
Coronavirus test		11	0
Coronavirus test positive		4	0
Cytomegalovirus test positive		1	0
HIV antibody positive		1	0
HIV test		1	0
SARS-CoV-1 test		1	0
SARS-CoV-1 test positive		1	0
SARS-CoV-2 antibody test		10	0
SARS-CoV-2 antibody test negative		15	0
SARS-CoV-2 antibody test positive		6	0
SARS-CoV-2 test		34	0
SARS-CoV-2 test false negative		2	0
SARS-CoV-2 test false positive		4	0
SARS-CoV-2 test negative		10	0
SARS-CoV-2 test positive		102	0
Viral load		2	0
Viral test		4	0
Viral test positive		1	0
Vitamin analyses			
Blood folate decreased		6	0
Vitamin B12		1	0
Vitamin B12 abnormal		2	0
Vitamin B12 decreased		2	0
Vitamin D		3	0
Vitamin D decreased		3	0
Water and electrolyte analyses NEC			
Urine osmolarity		1	0
Volume blood		1	0
White blood cell analyses			
Eosinophil count		1	0
Eosinophil count decreased		1	0
Eosinophil count increased		3	0
Lymphocyte count		1	0
Lymphocyte count decreased		3	0
Lymphocyte count increased		1	0
Monocyte count increased		2	0
Neutrophil count		3	0
Neutrophil count decreased		10	0
Neutrophil count increased		4	0
White blood cell count		4	0
White blood cell count decreased		13	0
White blood cell count increased		11	0
Investigations SOC TOTAL		5701	3

Case Series Drug Analysis Print

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

Report Run Date: 06-Jan-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Metabolic disorders		
Appetite disorders		
Appetite disorder	19	0
Decreased appetite	1384	0
Diet refusal	1	0
Eating disorder symptom	3	0
Food craving	12	0
Food refusal	15	0
Hyperphagia	15	0
Hypophagia	19	0
Increased appetite	35	0
Salt craving	2	0
Calcium metabolism disorders		
Hypocalcaemia	3	0
Tetany	3	0
Copper metabolism disorders		
Copper deficiency	1	0
Diabetes mellitus (incl subtypes)		
Diabetes mellitus	52	0
Diabetes mellitus inadequate control	16	1
Increased insulin requirement	2	0
Insulin resistant diabetes	1	0
Latent autoimmune diabetes in adults	2	0
Type 1 diabetes mellitus	16	0
Type 2 diabetes mellitus	4	0
Diabetic complications NEC		
Diabetic complication	2	0
Diabetic ketoacidosis	12	0
Diabetic ketosis	1	0
Disorders of purine metabolism		
Gout	103	0
Electrolyte imbalance NEC		
Electrolyte imbalance	1	0
Fluid imbalance	2	0
Fat soluble vitamin deficiencies and disorders		
Vitamin D deficiency	8	0
Fluid intake decreased		
Fluid intake reduced	2	0
Fluid intake increased		
Polydipsia	7	0
Food malabsorption and intolerance syndromes (excl sugar intolerance)		
Alcohol intolerance	6	0
Breast milk substitute intolerance	1	0
Dairy intolerance	3	0
Food intolerance	17	0
Gluten sensitivity	7	0
Histamine intolerance	4	0
General nutritional disorders NEC		
Abnormal loss of weight	33	0
Abnormal weight gain	20	0
Cachexia	1	0
Feeding disorder	95	0
Food aversion	10	0
Malnutrition	2	0

Case Series Drug Analysis Print

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

Report Run Date: 06-Jan-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
Neonatal insufficient breast milk syndrome	5	0
Obesity	1	0
Overweight	1	0
Poor feeding infant	16	0
Weight loss poor	3	0
Hyperglycaemic conditions NEC		
Glucose tolerance impaired	1	0
Hyperglycaemia	68	0
Insulin resistance	5	0
Hyperlipidaemias NEC		
Hyperlipidaemia	1	0
Hypoglycaemic conditions NEC		
Glycopenia	1	0
Hypoglycaemia	79	0
Hypoglycaemia unawareness	1	0
Postprandial hypoglycaemia	1	0
Iron deficiencies		
Iron deficiency	12	0
Iron excess		
Haemochromatosis	1	0
Iron overload	1	0
Lipid metabolism and deposit disorders NEC		
Body fat disorder	1	0
Magnesium metabolism disorders		
Hypomagnesaemia	1	0
Magnesium deficiency	1	0
Metabolic acidoses (excl diabetic acidoses)		
Ketoacidosis	5	1
Lactic acidosis	2	0
Metabolic acidosis	2	0
Metabolic disorders NEC		
Hypercatabolism	1	0
Metabolic disorder	1	0
Mixed acid-base disorders		
Acidosis	4	0
Phosphorus metabolism disorders		
Hypophosphataemia	1	0
Potassium imbalance		
Hyperkalaemia	6	0
Hypokalaemia	3	0
Hypokalaemic syndrome	1	0
Sodium imbalance		
Hyponatraemia	10	0
Hyponatraemic syndrome	3	0
Salt intoxication	1	0
Sugar intolerance (excl glucose intolerance)		
Lactose intolerance	2	0
Total fluid volume decreased		
Dehydration	224	0
Total fluid volume increased		
Fluid retention	59	0
Hypervolaemia	5	0
Vitamin deficiencies NEC		

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
Hypovitaminosis	6	0
Water soluble vitamin deficiencies		
Folate deficiency	6	0
Vitamin B complex deficiency	1	0
Vitamin B12 deficiency	6	0
Metabolic disorders SOC TOTAL	2491	2

Case Series Drug Analysis Print

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

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Muscle & tissue disorders		
Arthropathies NEC		
Arthritis	350	0
Arthropathy	30	0
Autoimmune arthritis	9	0
Haemarthrosis	5	0
Joint microhaemorrhage	1	0
Palindromic rheumatism	2	0
Polyarthritis	15	0
Rheumatic fever	2	0
Sacroiliitis	5	0
Seronegative arthritis	2	0
Bone disorders NEC		
Bone cyst	1	0
Exostosis	1	0
Jaw disorder	4	0
Medial tibial stress syndrome	6	0
Osteitis	9	0
Osteonecrosis	1	0
Osteonecrosis of jaw	3	0
Spinal disorder	1	0
Bone related signs and symptoms		
Bone pain	415	0
Bone swelling	10	0
Coccydynia	3	0
Metatarsalgia	1	0
Pain in jaw	408	0
Pubic pain	2	0
Spinal pain	88	0
Bursal disorders		
Bursitis	89	0
Cartilage disorders		
Chondritis	1	0
Costochondritis	118	0
Osteochondritis	1	0
Polychondritis	3	0
Connective tissue disorders NEC		
Connective tissue disorder	1	0
Polymyalgia rheumatica	67	0
Reynold's syndrome	1	0
Sjogren's syndrome	6	0
Systemic scleroderma	1	0
Crystal arthropathic disorders		
Chondrocalcinosis pyrophosphate	3	0
Crystal arthropathy	2	0
Gouty arthritis	1	0
Epiphyseal disorders		
Epiphyses premature fusion	1	0
Extremity deformities		
Bone deformity	1	0
Finger deformity	2	0
Foot deformity	2	0
Hand deformity	2	0
Knee deformity	1	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

Reaction Name		Total	Fatal
Muscle & tissue disorders	Muscle & tissue disorders cont'd		
Limb deformity		5	0
Musculoskeletal deformity		1	0
Fractures NEC			
Osteoporotic fracture		1	0
Intervertebral disc disorders NEC			
Intervertebral disc protrusion		3	0
Joint related disorders NEC			
Carpal collapse		1	0
Chondromalacia		1	0
Hypermobility syndrome		1	0
Joint deposit		1	0
Joint destruction		1	0
Joint instability		2	0
Joint laxity		3	0
Joint lock		30	0
Ligament laxity		1	0
Patellofemoral pain syndrome		2	0
Periarthritis		217	0
Rotator cuff syndrome		35	0
Temporomandibular joint syndrome		12	0
Joint related signs and symptoms			
Arthralgia		9797	0
Jaw clicking		6	0
Joint effusion		16	0
Joint noise		37	0
Joint range of motion decreased		32	0
Joint stiffness		265	0
Joint swelling		607	0
Joint vibration		3	0
Joint warmth		16	0
Loose body in joint		1	0
Ligament disorders			
Ligament pain		4	0
Ligamentitis		1	0
Sympsiyolysis		1	0
Lupus erythematosus (incl subtypes)			
Lupus-like syndrome		1	0
Systemic lupus erythematosus		25	0
Metabolic bone disorders			
Osteopenia		3	0
Osteoporosis		6	0
Muscle infections and inflammations			
Antisynthetase syndrome		3	0
Immune-mediated myositis		1	0
Myositis		42	0
Polymyositis		8	0
Muscle pains			
Fibromyalgia		130	0
Myalgia		11280	0
Myalgia intercostal		2	0
Myofascial pain syndrome		12	0
Muscle related signs and symptoms NEC			
Haematoma muscle		1	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Muscle atrophy	24	0
Muscle discomfort	8	0
Muscle disorder	10	0
Muscle fatigue	375	0
Muscle haemorrhage	1	0
Muscle mass	5	0
Muscle oedema	4	0
Muscle spasms	2186	0
Muscle swelling	40	0
Muscle tightness	93	0
Muscle twitching	517	0
Muscle tone abnormalities		
Muscle rigidity	17	0
Nuchal rigidity	12	0
Torticollis	7	0
Trismus	39	0
Muscle weakness conditions		
Muscular weakness	1019	0
Musculoskeletal and connective tissue conditions NEC		
Back disorder	2	0
Chest wall mass	1	0
Growth disorder	2	0
Limb mass	20	0
Mandibular mass	2	0
Mastication disorder	7	0
Mobility decreased	125	0
Muscle contracture	1	0
Musculoskeletal disorder	11	0
Musculoskeletal stiffness	1397	0
Posture abnormal	2	0
Sacroiliac joint dysfunction	1	0
Weight bearing difficulty	4	0
Musculoskeletal and connective tissue deformities of skull, face and buccal cavity		
Facial asymmetry	1	0
Head deformity	2	0
Nose deformity	1	0
Musculoskeletal and connective tissue infections and inflammations NEC		
Connective tissue inflammation	1	0
Dactylitis	2	0
Dupuytren's contracture	1	0
Fasciitis	1	0
Plantar fasciitis	13	0
Musculoskeletal and connective tissue pain and discomfort		
Back pain	2644	0
Flank pain	83	0
Growing pains	1	0
Limb discomfort	1576	0
Musculoskeletal chest pain	281	0
Musculoskeletal discomfort	114	0
Musculoskeletal pain	128	0
Neck pain	2062	0
Pain in extremity	13677	1

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MedDRA Version: MedDRA 24.1

Reaction Name		Total	Fatal
Muscle & tissue disorders	Muscle & tissue disorders cont'd		
Rheumatic disorder		15	0
Sacral pain		4	0
Myopathies			
Mitochondrial myopathy acquired		1	0
Myopathy		6	0
Rhabdomyolysis		14	0
Osteoarthropathies			
Nodal osteoarthritis		1	0
Osteoarthritis		52	0
Spinal osteoarthritis		2	0
Psoriatic arthropathies			
Psoriatic arthropathy		19	0
Rheumatoid arthropathies			
Juvenile idiopathic arthritis		1	0
Rheumatoid arthritis		127	0
Rheumatoid nodule		1	0
Still's disease		2	0
Soft tissue disorders NEC			
Axillary mass		281	0
Fluctuance		1	0
Groin pain		121	0
Neck mass		43	0
Purple glove syndrome		1	0
Soft tissue disorder		3	0
Soft tissue swelling		7	0
Spine and neck deformities			
Kyphosis		2	0
Lordosis		1	0
Neck deformity		1	0
Scoliosis		1	0
Spinal stenosis		2	0
Spondyloarthropathies			
Ankylosing spondylitis		9	0
Arthritis reactive		62	0
Spondylitis		4	0
Spondyloarthropathy		1	0
Synovial disorders			
Synovial cyst		22	0
Synovitis		11	0
Tendon disorders			
Enthesopathy		2	0
Posterior tibial tendon dysfunction		1	0
Tendon disorder		5	0
Tendon pain		26	0
Tendonitis		55	0
Tenosynovitis		4	0
Tenosynovitis stenosans		2	0
Trigger finger		30	0
Trunk deformities			
Deformity thorax		1	0
Drooping shoulder syndrome		2	0
Shoulder deformity		2	0
Muscle & tissue disorders SOC TOTAL		51762	1

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

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

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

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Reaction Name		Total	Fatal
Neoplasms	Neoplasms cont'd		
Tonsil cancer		4	0
Ovarian neoplasms malignant (excl germ cell)			
Ovarian cancer		1	0
Pancreatic neoplasms malignant (excl islet cell and carcinoid)			
Pancreatic carcinoma		4	0
Plasma cell myelomas			
POEMS syndrome		1	0
Plasma cell myeloma		2	0
Plasma cell neoplasms NEC			
Hypergammaglobulinaemia benign monoclonal		1	0
TEMPI syndrome		2	0
Prostatic neoplasms malignant			
Prostate cancer		4	0
Renal neoplasms malignant			
Clear cell renal cell carcinoma		1	0
Renal cancer		3	0
Reproductive neoplasms female benign NEC			
Benign hydatidiform mole		2	0
Respiratory tract and pleural neoplasms malignant cell type unspecified NEC			
Bronchial carcinoma		1	0
Lung neoplasm malignant		12	1
Salivary gland neoplasms unspecified malignancy			
Salivary gland neoplasm		2	0
Skin melanomas (excl ocular)			
Malignant melanoma		2	0
Skin neoplasms benign			
Acrochordon		5	0
Anogenital warts		7	0
Fibrous histiocytoma		1	0
Haemangioma of skin		5	0
Melanocytic naevus		7	0
Pyogenic granuloma		1	0
Seborrhoeic keratosis		1	0
Skin papilloma		21	0
Skin neoplasms malignant and unspecified (excl melanoma)			
Basal cell carcinoma		3	0
Bowen's disease		1	0
Neoplasm skin		3	0
Skin cancer		1	0
Squamous cell carcinoma of skin		1	0
Soft tissue neoplasms benign NEC			
Lipoma		7	0
Lymphangioma		1	0
Soft tissue sarcomas histology unspecified			
Sarcoma		1	0
Thyroid neoplasms malignant			
Papillary thyroid cancer		2	0
Thyroid cancer		1	0
Uterine neoplasms benign			
Uterine leiomyoma		12	0
Neoplasms SOC TOTAL		321	6

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Nervous system disorders		
Abnormal reflexes		
Areflexia	7	0
Extensor plantar response	2	0
Hoffmann's sign	1	0
Hyperreflexia	4	0
Hyporeflexia	9	0
Reflexes abnormal	2	0
Abnormal sleep-related events		
Sleep paralysis	29	0
Absence seizures		
Petit mal epilepsy	27	0
Acute polyneuropathies		
Acute motor axonal neuropathy	1	0
Acute motor-sensory axonal neuropathy	1	0
Guillain-Barre syndrome	83	2
Miller Fisher syndrome	3	0
Subacute inflammatory demyelinating polyneuropathy	1	0
Autonomic nervous system disorders		
Anticholinergic syndrome	1	0
Autonomic nervous system imbalance	10	0
Autonomic neuropathy	2	0
Horner's syndrome	2	0
Orthostatic intolerance	2	0
Central nervous system aneurysms and dissections		
Carotid artery dissection	1	0
Intracranial aneurysm	2	1
Central nervous system haemorrhages and cerebrovascular accidents		
Basal ganglia haemorrhage	1	0
Brain stem haemorrhage	1	1
Brain stem infarction	1	1
Brain stem stroke	1	0
Carotid artery occlusion	1	0
Carotid artery thrombosis	4	0
Cerebellar artery thrombosis	1	0
Cerebellar haemorrhage	3	0
Cerebellar infarction	3	0
Cerebellar ischaemia	1	0
Cerebellar stroke	8	1
Cerebral artery embolism	3	1
Cerebral artery occlusion	2	0
Cerebral artery thrombosis	4	0
Cerebral haemorrhage	54	12
Cerebral infarction	30	2
Cerebral ischaemia	1	0
Cerebral thrombosis	13	0
Cerebrovascular accident	449	20
Embolic stroke	7	0
Haemorrhage intracranial	12	3
Haemorrhagic cerebral infarction	1	0
Haemorrhagic stroke	11	4
Internal capsule infarction	1	0
Intracranial haematoma	1	0
Ischaemic cerebral infarction	1	0

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Ischaemic stroke	54	2
Lacunar infarction	4	0
Lacunar stroke	5	0
Lateral medullary syndrome	2	0
Pseudostroke	2	0
Ruptured cerebral aneurysm	1	0
Subarachnoid haemorrhage	18	7
Thalamic infarction	1	0
Thrombotic stroke	5	1
Central nervous system inflammatory disorders NEC		
Arachnoiditis	1	0
Gliosis	1	0
Central nervous system vascular disorders NEC		
Brain hypoxia	5	1
Carotid arteriosclerosis	1	0
Central nervous system vasculitis	1	0
Cerebral amyloid angiopathy	1	0
Cerebral congestion	5	0
Cerebral small vessel ischaemic disease	2	0
Cerebrovascular disorder	2	0
Post cardiac arrest syndrome	1	0
Reversible cerebral vasoconstriction syndrome	1	0
Cerebrovascular venous and sinus thrombosis		
Cerebral venous sinus thrombosis	52	5
Cerebral venous thrombosis	6	0
Superior sagittal sinus thrombosis	6	0
Transverse sinus thrombosis	2	0
Cervical spinal cord and nerve root disorders		
Cervical radiculopathy	2	0
Cervicobrachial syndrome	6	0
Choreiform movements		
Chorea	3	0
Chronic polyneuropathies		
Chronic inflammatory demyelinating polyradiculoneuropathy	2	0
Demyelinating polyneuropathy	1	0
Diabetic neuropathy	1	0
Coma states		
Coma	14	0
Diabetic coma	1	0
Hypoglycaemic coma	1	0
Coordination and balance disturbances		
Ataxia	20	0
Balance disorder	463	0
Cerebellar ataxia	1	0
Coordination abnormal	65	0
Dysdiadochokinesis	1	0
Dysstasia	63	0
Nystagmus	16	0
Cortical dysfunction NEC		
Alexia	2	0
Aphasia	93	0
Apraxia	1	0
Dysgraphia	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Dyslexia	1	0
Dyspraxia	1	0
Neurologic neglect syndrome	1	0
Sensory processing disorder	2	0
Visuospatial deficit	1	0
Cranial nerve disorders NEC		
Cranial nerve disorder	2	0
Cranial nerve paralysis	1	0
Dementia (excl Alzheimer's type)		
Dementia	18	0
Dementia with Lewy bodies	1	0
Senile dementia	1	0
Demyelinating disorders NEC		
Acute disseminated encephalomyelitis	6	0
Clinically isolated syndrome	1	0
Demyelination	9	0
Neuromyelitis optica spectrum disorder	2	0
Disturbances in consciousness NEC		
Altered state of consciousness	12	0
Consciousness fluctuating	3	0
Depressed level of consciousness	50	0
Infant sedation	1	0
Lethargy	2411	0
Loss of consciousness	749	1
Postictal state	5	0
Sedation	8	0
Somnolence	1136	0
Stupor	5	0
Syncope	2552	0
Disturbances in sleep phase rhythm		
Circadian rhythm sleep disorder	1	0
Irregular sleep phase	2	0
Irregular sleep wake rhythm disorder	2	0
Non-24-hour sleep-wake disorder	1	0
Dyskinetic and movement disorders NEC		
Akathisia	6	0
Bradykinesia	20	0
Clumsiness	22	0
Dyskinesia	74	0
Extrapyramidal disorder	3	0
Fine motor skill dysfunction	13	0
Foetal movement disorder	4	0
Hyperkinesia	3	0
Hypokinesia	90	0
Motor dysfunction	4	0
Movement disorder	59	0
Psychomotor hyperactivity	28	0
Synkinesis	2	0
Tardive dyskinesia	2	0
Dystonias		
Dystonia	16	0
Writer's cramp	1	0
Encephalitis NEC		

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Encephalitis autoimmune	1	0
Limbic encephalitis	1	0
Noninfective encephalitis	6	0
Encephalopathies NEC		
Autoimmune encephalopathy	1	1
Encephalopathy	5	0
Hashimoto's encephalopathy	1	0
Posterior reversible encephalopathy syndrome	1	0
Eye movement disorders		
IIIrd nerve disorder	1	0
IIIrd nerve paralysis	7	0
IVth nerve paralysis	1	0
Microvascular cranial nerve palsy	1	0
VIth nerve disorder	1	0
VIth nerve paralysis	11	0
Facial cranial nerve disorders		
Bell's palsy	567	0
Facial nerve disorder	9	0
Facial paralysis	434	0
Facial paresis	101	0
Facial spasm	52	0
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	65	0
Headaches NEC		
Cervicogenic headache	3	0
Cluster headache	266	0
Cold-stimulus headache	29	0
Drug withdrawal headache	3	0
Exertional headache	9	0
External compression headache	2	0
Headache	28636	0
Medication overuse headache	2	0
New daily persistent headache	8	0
Occipital neuralgia	15	0
Ophthalmoplegic migraine	1	0
Primary cough headache	4	0
Primary headache associated with sexual activity	9	0
Sinus headache	384	0
Tension headache	599	0
Thunderclap headache	19	0
Vascular headache	20	0
Hydrocephalic conditions		
Hydrocephalus	4	0
Hypoglossal nerve disorders		
Tongue paralysis	1	0
Increased intracranial pressure disorders		
Brain compression	2	0
Brain oedema	11	2
Idiopathic intracranial hypertension	11	0
Intracranial pressure increased	3	0
Intellectual disabilities		
Intellectual disability	3	0
Lumbar spinal cord and nerve root disorders		

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Sciatica	119	0
<i>Memory loss (excl dementia)</i>		
Amnesia	204	0
Memory impairment	225	0
Transient global amnesia	9	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	94	0
Cognitive linguistic deficit	1	0
Disturbance in attention	359	0
Mental impairment	53	0
<i>Migraine headaches</i>		
Basilar migraine	1	0
Hemiplegic migraine	33	0
Migraine	3276	0
Migraine with aura	218	0
Migraine without aura	21	0
Ophthalmic migraine	7	0
Retinal migraine	36	0
Typical aura without headache	8	0
Vestibular migraine	26	0
<i>Mixed cranial nerve disorders</i>		
Bulbar palsy	2	0
<i>Mononeuropathies</i>		
Carpal tunnel syndrome	27	0
Cubital tunnel syndrome	4	0
Meralgia paraesthesia	2	0
Mononeuritis	2	0
Mononeuropathy	4	0
Nerve compression	27	0
Peripheral nerve lesion	2	0
Peroneal nerve palsy	20	0
Piriformis syndrome	1	0
Pudendal canal syndrome	2	0
Sciatic nerve neuropathy	2	0
Ulnar nerve palsy	2	0
Ulnar neuritis	3	0
Ulnar tunnel syndrome	2	0
<i>Motor neurone diseases</i>		
Lower motor neurone lesion	1	0
Motor neurone disease	6	2
Upper motor neurone lesion	1	0
<i>Multiple sclerosis acute and progressive</i>		
Band sensation	1	0
Multiple sclerosis	36	0
Multiple sclerosis relapse	25	0
Tumefactive multiple sclerosis	1	1
<i>Muscle tone abnormal</i>		
Drop attacks	2	0
Hypertonia	2	0
Hypotonia	35	0
Morvan syndrome	1	0
Muscle tone disorder	1	0
Serotonin syndrome	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Stiff leg syndrome	1	0
<i>Myelitis (incl infective)</i>		
Myelitis transverse	30	0
<i>Narcolepsy and hypersomnia</i>		
Cataplexy	3	0
Hypersomnia	118	0
Narcolepsy	6	0
<i>Nervous system disorders NEC</i>		
Central nervous system lesion	2	0
Cerebral disorder	1	0
Nervous system disorder	21	0
Neurotoxicity	4	0
Psychomotor skills impaired	1	0
<i>Neurologic visual problems NEC</i>		
Hemianopia	1	0
Hemianopia homonymous	2	0
Quadrantanopia	2	0
Tunnel vision	21	0
<i>Neurological signs and symptoms NEC</i>		
Agitation neonatal	1	0
Cerebrospinal fluid leakage	1	0
Clonus	5	0
Decerebrate posture	1	0
Decorticate posture	1	0
Dizziness	10667	0
Dizziness exertional	48	0
Dizziness postural	805	0
Drooling	23	0
Fontanelle bulging	2	0
Head discomfort	370	0
Hyporesponsive to stimuli	2	0
Inability to crawl	3	0
Infant irritability	10	0
Meningism	2	0
Myoclonus	30	0
Neurological symptom	56	0
Patient elopement	1	0
Persistent postural-perceptual dizziness	17	0
Presyncope	681	0
Sensory overload	4	0
Slow response to stimuli	4	0
Tongue biting	8	0
Unresponsive to stimuli	60	0
<i>Neuromuscular disorders NEC</i>		
Muscle contractions involuntary	29	0
Muscle spasticity	17	0
Neuromuscular pain	3	0
<i>Neuromuscular junction dysfunction</i>		
Myasthenia gravis	8	0
Myasthenia gravis crisis	2	0
<i>Olfactory nerve disorders</i>		
Anosmia	307	0
Hyposmia	18	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Parosmia	291	0
<i>Optic nerve disorders NEC</i>		
Optic neuritis	33	0
<i>Paraesthesia and dysaesthesia</i>		
Burning feet syndrome	12	0
Burning sensation	608	0
Burning sensation mucosal	2	0
Dysaesthesia	8	0
Formication	44	0
Hand-arm vibration syndrome	3	0
Hemianaesthesia	3	0
Hemiparaesthesia	5	0
Hyperaesthesia	116	0
Hypoesthesia	3250	0
Lhermitte's sign	1	0
Paraesthesia	4469	0
Reversed hot-cold sensation	4	0
Synaesthesia	1	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Diplegia	18	0
Hemiparesis	61	0
Hemiplegia	45	0
Locked-in syndrome	1	0
Monoparesis	82	0
Monoplegia	93	0
Paralysis	147	0
Paraparesis	3	0
Paraplegia	3	0
Paresis	8	0
Quadriparesis	1	0
Quadriplegia	1	0
<i>Parkinson's disease and parkinsonism</i>		
Freezing phenomenon	15	0
Hypokinetic dysarthria	1	0
Parkinson's disease	4	0
Parkinsonian gait	1	0
Parkinsonian rest tremor	1	0
Parkinsonism	4	0
Reduced facial expression	11	0
<i>Partial complex seizures</i>		
Dreamy state	6	0
Focal dyscognitive seizures	4	0
Temporal lobe epilepsy	2	0
<i>Partial simple seizures NEC</i>		
Autonomic seizure	1	0
<i>Peripheral neuropathies NEC</i>		
Axonal neuropathy	2	0
Neuralgic amyotrophy	4	0
Neuritis	7	0
Neuropathy peripheral	136	0
Peripheral sensorimotor neuropathy	1	0
Peripheral sensory neuropathy	12	0
Polyneuropathy	3	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Small fibre neuropathy	1	0
Thoracic outlet syndrome	2	0
Seizures and seizure disorders NEC		
Atonic seizures	8	0
Change in seizure presentation	2	0
Clonic convulsion	4	0
Convulsions local	1	0
Convulsive threshold lowered	1	0
Epilepsy	165	0
Epileptic aura	2	0
Epileptic encephalopathy	1	0
Febrile convulsion	17	0
Idiopathic generalised epilepsy	1	0
Neonatal epileptic seizure	1	0
Neonatal seizure	1	0
Partial seizures	28	0
Post stroke seizure	1	0
Psychogenic seizure	11	0
Seizure	689	1
Seizure anoxic	3	0
Seizure cluster	6	0
Seizure like phenomena	3	0
Status epilepticus	38	0
Tonic clonic movements	4	0
Tonic convulsion	35	0
Tonic posturing	1	0
Sensory abnormalities NEC		
Ageusia	575	0
Allodynia	30	0
Aura	27	0
Central pain syndrome	1	0
Complex regional pain syndrome	6	0
Dysgeusia	1258	0
Electric shock sensation	46	0
Hypergeusia	1	0
Hypogeusia	8	0
Intercostal neuralgia	1	0
Loss of proprioception	3	0
Morton's neuralgia	3	0
Neuralgia	641	0
Persistent genital arousal disorder	2	0
Phantom limb syndrome	7	0
Post herpetic neuralgia	15	0
Restless arm syndrome	3	0
Restless legs syndrome	148	0
Sensory disturbance	118	0
Sensory loss	91	0
Taste disorder	288	0
Visual perseveration	3	0
Sleep disturbances NEC		
Microsleep	1	0
Sleep deficit	12	0
Sudden onset of sleep	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
<i>Speech and language abnormalities</i>		
Dysarthria	221	0
Incoherent	14	0
Language disorder	2	0
Repetitive speech	5	0
Slow speech	22	0
Speech disorder	79	0
Speech disorder developmental	1	0
<i>Spinal cord and nerve root disorders NEC</i>		
Cauda equina syndrome	1	0
Myelopathy	1	0
Radiculitis brachial	15	0
Radiculopathy	8	0
<i>Structural brain disorders NEC</i>		
Brain injury	9	2
Cerebral ventricle dilatation	1	0
Hyperintensity in brain deep nuclei	1	0
<i>Transient cerebrovascular events</i>		
Transient ischaemic attack	171	3
<i>Tremor (excl congenital)</i>		
Essential tremor	5	0
Head titubation	13	0
Resting tremor	4	0
Tremor	1998	0
<i>Trigeminal disorders</i>		
Numb chin syndrome	2	0
Trigeminal nerve disorder	3	0
Trigeminal neuralgia	77	0
Trigeminal neuritis	3	0
<i>Vagus nerve disorders</i>		
Vocal cord paralysis	2	0
<i>Vertigos NEC</i>		
Cervicogenic vertigo	1	0
Vertigo CNS origin	3	0
Nervous system disorders SOC TOTAL	75192	77

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortion related conditions and complications</i>		
Anembryonic gestation	3	0
<i>Abortions not specified as induced or spontaneous</i>		
Abortion	1	0
Abortion missed	7	0
<i>Abortions spontaneous</i>		
Abortion spontaneous	425	1
Abortion threatened	2	0
<i>Amniotic fluid and cavity disorders of pregnancy NEC</i>		
Amniorrhoea	2	0
<i>Foetal complications NEC</i>		
Foetal cardiac disorder	1	0
Foetal distress syndrome	1	0
Foetal hypokinesia	14	0
<i>Foetal conditions due to maternal conditions</i>		
Maternal condition affecting foetus	1	0
<i>Foetal growth complications</i>		
Foetal growth restriction	5	0
<i>Gestational age and weight conditions</i>		
Low birth weight baby	1	0
Premature baby	6	1
<i>Haemorrhagic complications of pregnancy</i>		
Haemorrhage in pregnancy	3	0
Premature separation of placenta	3	0
Subchorionic haematoma	3	0
Subchorionic haemorrhage	1	0
<i>High risk pregnancies</i>		
High risk pregnancy	1	0
<i>Hypertension associated disorders of pregnancy</i>		
Pre-eclampsia	1	0
<i>Labour onset and length abnormalities</i>		
Induced labour	1	0
Premature delivery	1	0
Premature labour	8	0
Premature rupture of membranes	3	0
Threatened labour	1	0
<i>Maternal complications of delivery NEC</i>		
Retained placenta or membranes	2	0
<i>Maternal complications of labour NEC</i>		
Uterine contractions abnormal	1	0
Uterine hypertonus	9	0
<i>Maternal complications of pregnancy NEC</i>		
Biochemical pregnancy	1	0
Complication of pregnancy	1	0
Decidual cast	4	0
Ectopic pregnancy	12	0
Hyperemesis gravidarum	2	0
Morning sickness	15	0
Preterm premature rupture of membranes	3	0
Ruptured ectopic pregnancy	1	0
Somatic symptom disorder of pregnancy	3	0
<i>Normal newborn status</i>		
Normal newborn	1	0

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Reaction Name	Total	Fatal
Pregnancy conditions Pregnancy conditions cont'd		
Normal pregnancy, labour and delivery		
Labour pain	1	0
Live birth	7	0
Pregnancy	35	0
Uterine contractions during pregnancy	6	0
Placental abnormalities (excl neoplasms)		
Foetal vascular malperfusion	2	0
Placental disorder	1	0
Placental insufficiency	1	0
Small size placenta	1	0
Postpartum complications NEC		
Postpartum haemorrhage	4	0
Pregnancy complicated by maternal disorders		
Gestational diabetes	2	0
Peripartum cardiomyopathy	1	0
Stillbirth and foetal death		
Foetal death	4	2
Stillbirth	9	7
Umbilical cord complications		
Umbilical cord thrombosis	1	0
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	3	0
Unwanted pregnancy	1	0
Pregnancy conditions SOC TOTAL	637	11

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Reaction Name	Total	Fatal
<i>Device electrical issues</i>		
Electromagnetic interference	1	0
<i>Device issues NEC</i>		
Device connection issue	1	0
Device failure	1	0
Device issue	2	0
<i>Device malfunction events NEC</i>		
Device infusion issue	1	0
Device malfunction	1	0
Device pacing issue	1	0
Device stimulation issue	1	0
Oversensing	19	0
Thrombosis in device	13	0
Undersensing	1	0
<i>Device physical property and chemical issues</i>		
Device breakage	1	0
Device defective	9	0
Device kink	1	0
Needle issue	3	0
<i>Manufacturing materials issues</i>		
Manufacturing materials contamination	1	0
<i>Product contamination and sterility issues</i>		
Product contamination	13	0
Product contamination physical	8	0
<i>Product packaging issues</i>		
Packaging design issue	1	0
Product closure issue	1	0
<i>Product physical issues</i>		
Liquid product physical issue	11	0
Product after taste	2	0
Product deposit	1	0
Product odour abnormal	3	0
Product physical issue	2	0
Product taste abnormal	9	0
<i>Product quality issues NEC</i>		
Product complaint	1	0
Product origin unknown	5	0
<i>Product supply and availability issues</i>		
Product availability issue	1	0
null SOC TOTAL	115	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
Abnormal behaviour NEC		
Abnormal behaviour	28	0
Behaviour disorder	2	0
Breath holding	6	0
Staring	7	0
Adjustment disorders		
Adjustment disorder	1	0
Adjustment disorder with depressed mood	4	0
Affect alterations NEC		
Affect lability	15	0
Constricted affect	3	0
Flat affect	13	0
Inappropriate affect	23	0
Amnestic symptoms		
Paramnesia	7	0
Anxiety disorders NEC		
Anxiety disorder	2	0
Generalised anxiety disorder	2	0
Neurosis	1	0
Anxiety symptoms		
Agitation	89	0
Anxiety	985	0
Immunisation anxiety related reaction	3	0
Nervousness	199	0
Stress	119	0
Tension	39	0
Attention deficit and disruptive behaviour disorders		
Attention deficit hyperactivity disorder	7	0
Behaviour and socialisation disturbances		
Aggression	16	0
Attention-seeking behaviour	1	0
Aversion	1	0
Disinhibition	3	0
Indifference	6	0
Paranoia	27	0
Personality change	5	0
Social avoidant behaviour	5	0
Soliloquy	2	0
Suspiciousness	1	0
Bipolar disorders		
Bipolar I disorder	2	0
Bipolar disorder	5	0
Cognitive and attention disorders and disturbances NEC		
Daydreaming	8	0
Distractibility	3	0
Mental fatigue	231	0
Communications disorders		
Communication disorder	5	0
Mutism	4	0
Confusion and disorientation		
Confusional state	992	0
Disorientation	315	0
Decreased physical activity levels		

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Reaction Name	Total	Fatal
Psychiatric disorders Psychiatric disorders cont'd		
Catatonia	1	0
Deliria		
Delirium	142	0
Delusional symptoms		
Delusion	16	0
Depressive disorders		
Agitated depression	6	0
Depression	378	0
Depression suicidal	19	0
Major depression	13	0
Mixed anxiety and depressive disorder	4	0
Dissociative states		
Depersonalisation/derealisation disorder	13	0
Dissociation	36	0
Dissociative amnesia	3	0
Dissociative disorder	2	0
Disturbances in initiating and maintaining sleep		
Initial insomnia	29	0
Insomnia	1795	0
Middle insomnia	32	0
Terminal insomnia	32	0
Dyssomnias		
Breathing-related sleep disorder	1	0
Dyssomnia	1	0
Poor quality sleep	253	0
Eating disorders NEC		
Bulimia nervosa	1	0
Eating disorder	12	0
Selective eating disorder	1	0
Emotional and mood disturbances NEC		
Anger	42	0
Dysphoria	2	0
Emotional disorder	64	0
Emotional distress	54	0
Emotional poverty	2	0
Euphoric mood	47	0
Frustration tolerance decreased	2	0
Irritability	219	0
Mood altered	62	0
Factitious disorders		
Factitious disorder	4	0
Fear symptoms and phobic disorders (incl social phobia)		
Agoraphobia	2	0
Claustrophobia	1	0
Fear	27	0
Fear of death	1	0
Fear of eating	1	0
Fear of falling	3	0
Fear of injection	6	0
Osmophobia	1	0
Performance fear	1	0
Phobia	3	0
Phonophobia	3	0

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Reaction Name	Total	Fatal
Psychiatric disorders Psychiatric disorders cont'd		
Social anxiety disorder	2	0
Social fear	1	0
Fluctuating mood symptoms		
Mood swings	155	0
Hallucinations (excl sleep-related)		
Hallucination	243	0
Hallucination, auditory	21	0
Hallucination, olfactory	15	0
Hallucination, tactile	1	0
Hallucination, visual	31	0
Hallucinations, mixed	3	0
Increased physical activity levels		
Restlessness	169	0
Infancy, childhood and adolescence psychiatric disorders NEC		
Social (pragmatic) communication disorder	1	0
Learning disorders		
Learning disability	1	0
Learning disorder	1	0
Mental disorders NEC		
Mental disorder	19	0
Mental status changes	1	0
Psychological factor affecting medical condition	1	0
Mood alterations with depressive symptoms		
Anhedonia	3	0
Decreased interest	9	0
Depressed mood	433	0
Depressive symptom	2	0
Feeling guilty	1	0
Feeling of despair	5	0
Feelings of worthlessness	2	0
Negative thoughts	3	0
Psychomotor retardation	2	0
Sense of a foreshortened future	3	0
Tearfulness	46	0
Mood alterations with manic symptoms		
Hypomania	2	0
Mania	11	0
Mood disorders NEC		
Affective disorder	4	0
Apathy	36	0
Boredom	1	0
Laziness	3	0
Listless	23	0
Mood disorder due to a general medical condition	1	0
Narcolepsy and associated conditions		
Hypnagogic hallucination	4	0
Hypnopompic hallucination	2	0
Sleep attacks	3	0
Obsessive-compulsive disorders and symptoms		
Obsessive-compulsive symptom	1	0
Orgasmic disorders and disturbances		
Anorgasmia	5	0
Female orgasmic disorder	2	0

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Reaction Name	Total	Fatal
Psychiatric disorders Psychiatric disorders cont'd		
Orgasm abnormal	4	0
Orgasmic sensation decreased	1	0
Premature ejaculation	1	0
Panic attacks and disorders		
Limited symptom panic attack	1	0
Panic attack	239	0
Panic disorder	7	0
Panic reaction	30	0
Paraphilic and paraphilic disorders		
Transvestism	1	0
Parasomnias		
Abnormal dreams	207	0
Abnormal sleep-related event	1	0
Confusional arousal	1	0
Exploding head syndrome	2	0
Nightmare	221	0
Parasomnia	4	0
Sleep inertia	1	0
Sleep talking	6	0
Sleep terror	29	0
Somnambulism	8	0
Perception disturbances NEC		
Autoscopy	20	0
Deja vu	2	0
Derealisation	12	0
Flashback	4	0
Illusion	5	0
Near death experience	1	0
Time perception altered	2	0
Personality disorders NEC		
Personality disorder	1	0
Self esteem decreased	1	0
Pervasive developmental disorders NEC		
Autism spectrum disorder	3	0
Psychiatric elimination disorders		
Enuresis	30	0
Psychiatric symptoms NEC		
Helplessness	1	0
Hypervigilance	9	0
Psychiatric symptom	11	0
Psychological trauma	4	0
Trance	1	0
Psychotic disorder NEC		
Acute psychosis	1	0
Psychotic behaviour	1	0
Psychotic disorder	29	0
Schizophrenia NEC		
Schizophrenia	2	0
Sexual and gender identity disorders NEC		
Gender dysphoria	1	0
Sexual arousal disorders		
Disturbance in sexual arousal	4	0
Sexual inhibition	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders Psychiatric disorders cont'd		
Sexual desire disorders		
Hypersexuality	1	0
Libido decreased	19	0
Libido disorder	1	0
Libido increased	8	0
Loss of libido	20	0
Sexual dysfunction NEC		
Genito-pelvic pain/penetration disorder	1	0
Sleep disorders NEC		
Sleep disorder	255	0
Sleep disorder due to general medical condition, insomnia type	5	0
Somatic symptom disorders		
Conversion disorder	25	0
Habit cough	22	0
Somatic symptom disorder	2	0
Vomiting psychogenic	1	0
Speech and language usage disturbances		
Disorganised speech	7	0
Logorrhoea	2	0
Speech articulation and rhythm disturbances		
Dysphemia	27	0
Lack of spontaneous speech	1	0
Pressure of speech	1	0
Stereotypies and automatisms		
Automatism	1	0
Bruxism	14	0
Head banging	12	0
Stereotypy	1	0
Stress disorders		
Burnout syndrome	2	0
Post-traumatic stress disorder	4	0
Substance related and addictive disorders		
Alcohol problem	1	0
Alcoholic hangover	1	0
Alcoholism	5	0
Nicotine dependence	2	0
Suicidal and self-injurious behaviour		
Completed suicide	2	2
Intentional self-injury	6	0
Self-injurious ideation	2	0
Suicidal ideation	46	0
Suicide attempt	8	0
Suicide threat	1	0
Thinking disturbances		
Bradyphrenia	41	0
Flight of ideas	1	0
Intrusive thoughts	7	0
Morbid thoughts	1	0
Tachyphrenia	8	0
Thinking abnormal	21	0
Thought blocking	1	0
Tic disorders		
Tic	15	0

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Reaction Name	Total	Fatal
Psychiatric disorders ^{Psychiatric disorders cont'd}		
Psychiatric disorders SOC TOTAL	9307	2

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Reaction Name	Total	Fatal
Renal & urinary disorders		
Bladder and urethral symptoms		
Bladder discomfort	3	0
Bladder irritation	10	0
Bladder pain	34	0
Bladder spasm	2	0
Dysuria	54	0
Incontinence	36	0
Lower urinary tract symptoms	3	0
Micturition disorder	2	0
Micturition urgency	50	0
Pollakiuria	149	0
Stress urinary incontinence	2	0
Urethral pain	7	0
Urge incontinence	3	0
Urinary hesitation	2	0
Urinary incontinence	68	0
Urinary retention	50	0
Urine flow decreased	18	0
Bladder disorders NEC		
Bladder disorder	11	0
Bladder fibrosis	1	0
Bladder prolapse	1	0
Urinary bladder haemorrhage	4	0
Bladder infections and inflammations		
Cystitis interstitial	6	0
Cystitis noninfective	1	0
Genital and urinary tract disorders NEC		
Genitourinary symptom	2	0
Urinary tract disorder	4	0
Glomerulonephritis and nephrotic syndrome		
Glomerulonephritis minimal lesion	5	0
Glomerulonephritis rapidly progressive	2	0
IgA nephropathy	4	0
Nephrotic syndrome	18	0
Myoneurogenic bladder disorders		
Bladder dysfunction	6	0
Hypertonic bladder	3	0
Hypotonic urinary bladder	1	0
Loss of bladder sensation	3	0
Neurogenic bladder	2	0
Nephritis NEC		
Lupus nephritis	1	0
Nephritis	3	0
Tubulointerstitial nephritis	2	0
Nephropathies and tubular disorders NEC		
Nephropathy	1	0
Renal disorders NEC		
Renal disorder	7	1
Renal haemorrhage	1	0
Renal mass	1	0
Renal failure and impairment		
Acute kidney injury	50	4
Anuria	3	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
Renal & urinary disorders cont'd		
Chronic kidney disease	4	0
Oliguria	1	0
Renal failure	23	1
Renal impairment	27	0
Renal injury	2	0
Renal lithiasis		
Nephrolithiasis	11	0
Renal neoplasms		
Renal cyst	1	0
Renal obstructive disorders		
Hydronephrosis	2	0
Renal structural abnormalities and trauma		
Kidney enlargement	1	0
Kidney small	2	0
Renal vascular and ischaemic conditions		
Renal aneurysm	1	0
Renal infarct	4	0
Renal tubular necrosis	2	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	63	0
Haematuria	46	0
Ketonuria	1	0
Myoglobinuria	1	0
Proteinuria	12	0
Urine abnormality	12	0
Urine odour abnormal	9	0
Urinary tract lithiasis (excl renal)		
Calculus bladder	1	0
Calculus urinary	1	0
Urinary tract signs and symptoms NEC		
Costovertebral angle tenderness	1	0
Cystitis-like symptom	1	0
Haemorrhage urinary tract	27	1
Nocturia	3	0
Polyuria	9	0
Renal colic	4	0
Renal pain	346	0
Urinary tract discomfort	2	0
Urinary tract pain	6	0
Renal & urinary disorders SOC TOTAL	1266	8

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
Benign and malignant breast neoplasms		
Breast cyst	14	0
Breast disorders NEC		
Breast disorder	3	0
Breast enlargement	30	0
Breast mass	131	0
Fibrocystic breast disease	1	0
Gynaecomastia	5	0
Mastoptosis	1	0
Nipple disorder	1	0
Breast infections and inflammations		
Breast inflammation	6	0
Nipple inflammation	2	0
Breast signs and symptoms		
Breast discharge	4	0
Breast discomfort	13	0
Breast engorgement	11	0
Breast haematoma	1	0
Breast oedema	7	0
Breast pain	787	0
Breast swelling	175	0
Breast tenderness	90	0
Nipple pain	44	1
Nipple swelling	4	0
Cervix disorders NEC		
Cervical dysplasia	2	0
Cervix disorder	1	0
Cervix haemorrhage uterine	5	0
Ectropion of cervix	4	0
Cervix infections and inflammations		
Cervix inflammation	1	0
Cervix neoplasms		
Cervical polyp	1	0
Erection and ejaculation conditions and disorders		
Ejaculation disorder	3	0
Ejaculation failure	3	0
Erectile dysfunction	70	0
Erection increased	4	0
Organic erectile dysfunction	14	0
Painful ejaculation	1	0
Spontaneous ejaculation	1	0
Spontaneous penile erection	2	0
Fallopian tube and ovary infections and inflammations		
Noninfective oophoritis	5	0
Lactation disorders		
Breast milk discolouration	3	0
Breast milk odour abnormal	2	0
Galactorrhoea	5	0
Galactostasis	1	0
Lactation disorder	10	0
Lactation puerperal increased	5	0
Suppressed lactation	46	0
Menopausal effects NEC		

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
Reproductive & breast disorders cont'd		
Artificial menopause	1	0
Menopausal disorder	1	0
Menopausal symptoms	37	0
Menopause delayed	1	0
Premature menopause	22	0
Menopausal effects on the genitourinary tract		
Atrophic vulvovaginitis	2	0
Postmenopausal haemorrhage	103	0
Menstruation and uterine bleeding NEC		
Abnormal uterine bleeding	6	0
Abnormal withdrawal bleeding	2	0
Bleeding anovulatory	1	0
Dysmenorrhoea	3005	0
Intermenstrual bleeding	1196	0
Menstrual discomfort	30	0
Menstrual disorder	2016	0
Menstruation irregular	3551	0
Premenstrual dysphoric disorder	11	0
Premenstrual headache	11	0
Premenstrual pain	133	0
Premenstrual syndrome	119	0
Retrograde menstruation	1	0
Withdrawal bleed	16	0
Menstruation with decreased bleeding		
Amenorrhoea	635	0
Hypomenorrhoea	681	0
Menstruation delayed	5108	0
Oligomenorrhoea	186	0
Menstruation with increased bleeding		
Heavy menstrual bleeding	5706	0
Menometrorrhagia	18	0
Polymenorrhoea	913	0
Ovarian and fallopian tube cysts and neoplasms		
Haemorrhagic ovarian cyst	2	0
Ovarian cyst	27	0
Ovarian cyst ruptured	1	0
Polycystic ovaries	49	0
Ovarian and fallopian tube disorders NEC		
Adnexal torsion	1	0
Hydrosalpinx	2	0
Ovarian enlargement	1	0
Ovarian haemorrhage	7	0
Ovulation disorder	2	0
Ovulation pain	74	0
Premature ovulation	4	0
Pelvic prolapse conditions		
Vaginal prolapse	1	0
Pelvis and broad ligament disorders NEC		
Adnexa uteri mass	1	0
Adnexa uteri pain	63	0
Pelvic congestion	1	0
Pelvic floor muscle weakness	1	0
Pelvic haemorrhage	22	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
Reproductive & breast disorders cont'd		
<i>Penile and scrotal infections and inflammations</i>		
Balanoposthitis	4	0
<i>Penile disorders NEC (excl erection and ejaculation)</i>		
Penile blister	1	0
Penile discharge	1	0
Penile discomfort	1	0
Penile erythema	1	0
Penile haemorrhage	3	0
Penile oedema	1	0
Penile pain	1	0
Penile size reduced	1	0
Penile swelling	5	0
Penis disorder	12	0
<i>Prostate and seminal vesicles infections and inflammations</i>		
Prostatitis	4	0
<i>Prostatic neoplasms and hypertrophy</i>		
Benign prostatic hyperplasia	2	0
<i>Prostatic signs, symptoms and disorders NEC</i>		
Prostatic pain	1	0
Prostatomegaly	3	0
<i>Reproductive tract disorders NEC (excl neoplasms)</i>		
Genital erosion	1	0
Genital haemorrhage	25	0
Genital hypoesthesia	1	0
Genital lesion	2	0
Genital paraesthesia	1	0
Genital ulceration	8	0
Perineal ulceration	1	0
<i>Reproductive tract infections and inflammations NEC</i>		
Genital tract inflammation	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Genital burning sensation	2	0
Genital erythema	1	0
Genital pain	6	0
Genital rash	5	0
Genital swelling	3	0
Pelvic discomfort	6	0
Pelvic pain	115	0
Perineal pain	2	0
Perineal rash	1	0
Pruritus genital	5	0
<i>Scrotal disorders NEC</i>		
Acquired hydrocele	1	0
Scrotal angiokeratoma	1	0
Scrotal discomfort	1	0
Scrotal erythema	2	0
Scrotal exfoliation	2	0
Scrotal pain	22	0
Scrotal swelling	4	0
Scrotum erosion	1	0
Varicocele	2	0
<i>Sexual function and fertility disorders NEC</i>		
Dyspareunia	6	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
Reproductive & breast disorders cont'd		
Infertility	12	0
Infertility female	4	0
Sexual dysfunction	9	0
Spermatogenesis and semen disorders		
Aspermia	1	0
Haematospermia	7	0
Semen discolouration	1	0
Testicular and epididymal disorders NEC		
Testicular atrophy	1	0
Testicular disorder	4	0
Testicular oedema	1	0
Testicular pain	65	0
Testicular swelling	11	0
Testicular torsion	1	0
Testis discomfort	3	0
Testicular and epididymal neoplasms		
Testicular cyst	1	0
Uterine disorders NEC		
Adenomyosis	10	0
Endometrial thickening	4	0
Endometriosis	90	0
Uterine haemorrhage	42	0
Uterine pain	16	0
Uterine infections and inflammations (excl cervix)		
Uterine inflammation	1	0
Uterine neoplasms		
Uterine polyp	5	0
Uterine tone disorders		
Uterine spasm	33	0
Vulvovaginal cysts and neoplasms		
Bartholin's cyst	2	0
Vaginal cyst	7	0
Vaginal polyp	1	0
Vulva cyst	1	0
Vulvovaginal disorders NEC		
Vaginal haemorrhage	1636	0
Vaginal mucosal blistering	1	0
Vaginal ulceration	3	0
Vulval disorder	2	0
Vulval haemorrhage	32	0
Vulval ulceration	7	0
Vulvovaginal ulceration	5	0
Vulvovaginal signs and symptoms		
Clitoral engorgement	1	0
Coital bleeding	6	0
Labia enlarged	2	0
Vaginal discharge	83	0
Vaginal lesion	1	0
Vaginal odour	3	0
Vulval oedema	2	0
Vulvovaginal burning sensation	7	0
Vulvovaginal discomfort	2	0
Vulvovaginal dryness	5	0

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Reproductive & breast disorders		
Reproductive & breast disorders cont'd		
Vulvovaginal erythema	2	0
Vulvovaginal pain	29	0
Vulvovaginal pruritus	10	0
Vulvovaginal rash	2	0
Vulvovaginal swelling	5	0
Reproductive & breast disorders SOC TOTAL	27738	1

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	6	0
Apnoeic attack	1	0
Dyspnoea	5918	5
Dyspnoea at rest	11	0
Dyspnoea exertional	39	1
Grunting	1	0
Hyperventilation	57	0
Hypopnoea	123	0
Hypoventilation	1	0
Irregular breathing	22	0
Mouth breathing	7	0
Nocturnal dyspnoea	2	0
Orthopnoea	3	0
Respiration abnormal	61	0
Respiratory arrest	18	0
Respiratory depression	1	0
Respiratory distress	20	0
Sleep apnoea syndrome	13	0
Tachypnoea	30	0
<i>Bronchial conditions NEC</i>		
Bronchial secretion retention	4	0
Bronchiectasis	15	0
<i>Bronchospasm and obstruction</i>		
Asthma	388	0
Asthma late onset	3	0
Bronchospasm	17	0
Chronic obstructive pulmonary disease	24	1
Cough variant asthma	6	0
Obstructive airways disorder	9	0
Reversible airways obstruction	1	0
Wheezing	446	0
<i>Conditions associated with abnormal gas exchange</i>		
Asphyxia	2	0
Cyanosis central	1	0
Hyperoxia	1	0
Hypoxia	32	2
Respiratory acidosis	2	0
<i>Coughing and associated symptoms</i>		
Allergic cough	8	0
Cough	2789	1
Cough decreased	2	0
Haemoptysis	65	0
Productive cough	186	0
Sputum discoloured	11	0
Sputum increased	4	0
<i>Diaphragmatic disorders</i>		
Acquired diaphragmatic eventration	1	0
Diaphragm muscle weakness	1	0
Diaphragmatic disorder	1	0
<i>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</i>		
Laryngeal disorder	1	0

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Reaction Name	Total	Fatal
Respiratory disorders		
Respiratory disorders cont'd		
Reflux laryngitis	2	0
Vocal cord disorder	1	0
Vocal cord dysfunction	3	0
Laryngeal spasm, oedema and obstruction		
Epiglottic oedema	1	0
Laryngeal obstruction	1	0
Laryngeal oedema	4	0
Laryngospasm	3	0
Stridor	28	0
Lower respiratory tract inflammatory and immunologic conditions		
Alveolitis	1	0
Autoimmune lung disease	1	0
Hypersensitivity pneumonitis	1	0
Lower respiratory tract inflammation	1	0
Pneumonitis	33	2
Pulmonary sarcoidosis	2	0
Lower respiratory tract signs and symptoms		
Hiccups	34	0
Increased bronchial secretion	3	0
Increased viscosity of bronchial secretion	1	0
Lung hyperinflation	2	0
Lung opacity	3	0
Pleuritic pain	22	0
Pulmonary haemorrhage	1	0
Pulmonary pain	110	0
Rales	5	0
Respiratory fremitus	1	0
Mediastinal disorders		
Mediastinal mass	1	0
Pulmonary hilum mass	1	0
Nasal congestion and inflammations		
Nasal congestion	319	0
Nasal inflammation	4	0
Rhinitis allergic	24	0
Nasal disorders NEC		
Epistaxis	1018	0
Intranasal hypoesthesia	2	0
Intranasal paraesthesia	1	0
Nasal crusting	2	0
Nasal disorder	3	0
Nasal dryness	36	0
Nasal mucosal discolouration	1	0
Nasal odour	6	0
Nasal oedema	8	0
Nasal polyps	1	0
Nasal pruritus	12	0
Nasal ulcer	1	0
Neonatal hypoxic conditions		
Dry lung syndrome	1	0
Gasping syndrome	1	0
Infantile apnoea	2	0
Paranasal sinus disorders (excl infections and neoplasms)		
Allergic sinusitis	1	0

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Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Paranasal sinus inflammation	4	0
Sinonasal obstruction	14	0
Sinus congestion	69	0
Sinus disorder	6	0
Parenchymal lung disorders NEC		
Atelectasis	3	0
Combined pulmonary fibrosis and emphysema	1	0
Emphysema	3	0
Interstitial lung disease	11	0
Lung consolidation	5	0
Lung infiltration	2	1
Organising pneumonia	2	0
Pulmonary alveolar haemorrhage	1	0
Pulmonary cavitation	1	0
Pulmonary fibrosis	8	0
Pharyngeal disorders (excl infections and neoplasms)		
Hyperactive pharyngeal reflex	1	0
Pharyngeal enanthema	1	0
Pharyngeal erythema	8	0
Pharyngeal haemorrhage	2	0
Pharyngeal hypoesthesia	39	0
Pharyngeal inflammation	4	0
Pharyngeal lesion	1	0
Pharyngeal mass	1	0
Pharyngeal oedema	14	0
Pharyngeal paraesthesia	55	0
Pharyngeal swelling	274	0
Pharyngeal ulceration	15	0
Tonsillar erythema	13	0
Tonsillar haemorrhage	1	0
Tonsillar hypertrophy	94	0
Tonsillar inflammation	3	0
Tonsillar ulcer	1	0
Tonsillolith	1	0
Pleural infections and inflammations		
Pleurisy	36	0
Pneumothorax and pleural effusions NEC		
Pleural effusion	36	0
Pneumothorax	10	0
Pneumothorax spontaneous	4	0
Pulmonary hypertension		
Pulmonary hypertension	3	0
Pulmonary oedemas		
Acute respiratory distress syndrome	2	1
Pulmonary congestion	19	0
Pulmonary oedema	22	2
Pulmonary thrombotic and embolic conditions		
Pulmonary artery thrombosis	2	0
Pulmonary embolism	483	35
Pulmonary infarction	6	0
Pulmonary thrombosis	8	1
Respiratory failures (excl neonatal)		
Acute respiratory failure	3	1

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Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Respiratory failure	13	2
Respiratory signs and symptoms NEC		
Allergic respiratory symptom	6	0
Diaphragmalagia	8	0
Nasal flaring	1	0
Painful respiration	16	1
Pleural rub	1	0
Respiratory symptom	21	0
Suffocation feeling	2	0
Use of accessory respiratory muscles	2	0
Respiratory tract disorders NEC		
Allergic respiratory disease	1	0
Aspiration	3	0
Lung disorder	7	1
Pulmonary mass	5	0
Respiratory disorder	15	1
Respiratory tract congestion	4	0
Respiratory tract haemorrhage	2	0
Respiratory tract inflammation	2	0
Respiratory tract irritation	9	0
Respiratory tract oedema	4	0
Thoracic musculoskeletal disorders		
Respiratory muscle weakness	2	0
Tracheal disorders (excl infections and neoplasms)		
Tracheal disorder	1	0
Tracheal pain	2	0
Upper respiratory tract neoplasms		
Tonsillar cyst	1	0
Upper respiratory tract signs and symptoms		
Aphonia	135	0
Catarrh	31	0
Choking	18	0
Choking sensation	5	0
Dry throat	179	0
Dysphonia	175	0
Increased upper airway secretion	6	0
Increased viscosity of upper respiratory secretion	35	0
Laryngeal pain	1	0
Nasal discharge discolouration	3	0
Nasal discomfort	54	0
Nasal obstruction	2	0
Oropharyngeal blistering	11	0
Oropharyngeal discomfort	69	0
Oropharyngeal pain	3095	0
Oropharyngeal plaque	2	0
Paranasal sinus discomfort	50	0
Rhinalgia	14	0
Rhinorrhoea	1007	0
Sinus pain	237	0
Sneezing	433	0
Snoring	8	0
Throat clearing	8	0
Throat irritation	248	0

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Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Throat lesion	1	0
Throat tightness	275	0
Upper airway obstruction	3	0
Upper respiratory tract congestion	2	0
Upper respiratory tract irritation	1	0
Upper-airway cough syndrome	13	0
Yawning	28	0
Vascular pulmonary disorders NEC		
Acute chest syndrome	1	0
Respiratory disorders SOC TOTAL	19633	58

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Reaction Name	Total	Fatal
Skin disorders		
Acnes		
Acne	204	0
Acne cystic	25	0
Dermatitis acneiform	13	0
Alopecias		
Alopecia	357	0
Alopecia areata	52	0
Alopecia totalis	3	0
Alopecia universalis	1	0
Androgenetic alopecia	2	0
Diffuse alopecia	3	0
Hypotrichosis	3	0
Lichen planopilaris	1	0
Madarosis	8	0
Angioedemas		
Angioedema	251	0
Circumoral oedema	1	0
Circumoral swelling	1	0
Idiopathic angioedema	1	0
Apocrine and eccrine gland disorders		
Anhidrosis	1	0
Bromhidrosis	1	0
Cold sweat	840	0
Hidradenitis	5	0
Hyperhidrosis	2539	0
Hypohidrosis	2	0
Milia	2	0
Miliaria	110	0
Night sweats	852	0
Sweat discolouration	1	0
Bullous conditions		
Blister	502	0
Blister rupture	1	0
Blood blister	35	0
Dermatitis bullous	14	0
Erythema multiforme	42	0
Fracture blisters	1	0
Herpes gestationis	1	0
Pemphigoid	28	0
Pemphigus	9	0
Stevens-Johnson syndrome	6	0
Toxic epidermal necrolysis	2	1
Connective tissue disorders		
Cutaneous lupus erythematosus	2	0
Dermatomyositis	9	0
Subacute cutaneous lupus erythematosus	2	0
Dermal and epidermal conditions NEC		
Acute febrile neutrophilic dermatosis	1	0
Dermatosis	1	0
Dry skin	263	0
Koebner phenomenon	1	0
Macule	5	0
Neutrophilic dermatosis	1	0

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Reaction Name	Total	Fatal
Skin disorders	Skin disorders cont'd	
Pain of skin	312	0
Papule	114	0
Pathergy reaction	1	0
Scab	24	0
Scar pain	16	0
Sensitive skin	211	0
Shagreen skin	1	0
Skin burning sensation	247	0
Skin degenerative disorder	1	0
Skin discolouration	145	0
Skin discomfort	4	0
Skin disorder	33	0
Skin fissures	8	0
Skin indentation	2	0
Skin induration	5	0
Skin lesion	49	0
Skin lesion inflammation	1	0
Skin necrosis	2	0
Skin odour abnormal	21	0
Skin plaque	3	0
Skin reaction	163	0
Skin sensitisation	44	0
Skin swelling	110	0
Skin texture abnormal	2	0
Skin tightness	27	0
Skin warm	349	0
Skin weeping	12	0
Sticky skin	3	0
Target skin lesion	3	0
Transient acantholytic dermatosis	1	0
Yellow skin	27	0
Dermatitis and eczema		
Dermatitis	151	0
Dermatitis allergic	284	0
Dermatitis atopic	44	0
Dermatitis contact	23	0
Dermatitis diaper	4	0
Dyshidrotic eczema	29	0
Eczema	366	0
Eczema asteatotic	12	0
Eczema infantile	1	0
Eczema nummular	5	0
Eczema weeping	5	0
Hand dermatitis	2	0
Intertrigo	1	0
Neurodermatitis	3	0
Perioral dermatitis	3	0
Seborrhoeic dermatitis	7	0
Skin irritation	142	0
Stasis dermatitis	1	0
Dermatitis ascribed to specific agent		
Drug eruption	34	0
Drug reaction with eosinophilia and systemic symptoms	1	0

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Reaction Name		Total	Fatal
Skin disorders	Skin disorders cont'd		
Fixed eruption		2	0
Palmar-plantar erythrodysesthesia syndrome		2	0
Toxic skin eruption		2	0
Erythemas			
Erythema		2375	0
Palmar erythema		4	0
Red man syndrome		2	0
Exfoliative conditions			
Dermatitis exfoliative		2	0
Dermatitis exfoliative generalised		5	0
Exfoliative rash		24	0
Keratolysis exfoliativa acquired		2	0
Skin exfoliation		127	0
Granulomatous and deep cutaneous inflammatory conditions			
Cutaneous sarcoidosis		1	0
Granuloma annulare		6	0
Necrobiosis lipoidica diabetorum		1	0
Hyperkeratoses			
Hyperkeratosis		2	0
Keratosis pilaris		3	0
Lichenoid keratosis		4	0
Hyperpigmentation disorders			
Argyria		1	0
Chloasma		1	0
Ephelides		1	0
Skin hyperpigmentation		6	0
Solar lentigo		4	0
Hypertrichoses			
Hirsutism		2	0
Hypertrichosis		1	0
Hypopigmentation disorders			
Skin depigmentation		4	0
Skin hypopigmentation		1	0
Vitiligo		21	0
Lipodystrophies			
Lipoatrophy		4	0
Lipodystrophy acquired		1	0
Nail and nail bed conditions (excl infections and infestations)			
Ingrowing nail		1	0
Nail discolouration		11	0
Nail disorder		6	0
Nail pigmentation		2	0
Nail ridging		3	0
Onychalgia		9	0
Onychoclasia		5	0
Onychomadesis		2	0
Splinter haemorrhages		3	0
Panniculitides			
Erythema nodosum		29	0
Panniculitis		1	0
Papulosquamous conditions			
Erythema annulare		2	0
Lichen planus		23	0

Case Series Drug Analysis Print

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Reaction Name		Total	Fatal
Skin disorders	Skin disorders cont'd		
Lichen sclerosus		9	0
Parapsoriasis		4	0
Pityriasis rosea		129	0
Pityriasis rubra pilaris		1	0
Photosensitivity and photodermatoses conditions			
Photosensitivity reaction		69	0
Polymorphic light eruption		3	0
Solar dermatitis		2	0
Pigmentation changes NEC			
Haemosiderin stain		1	0
Pigmentation disorder		15	0
Pilar disorders NEC			
Hair colour changes		11	0
Hair disorder		1	0
Hair growth abnormal		6	0
Hair texture abnormal		6	0
Piloerection		28	0
Pseudofolliculitis		3	0
Trichorrhexis		3	0
Pruritus NEC			
Itching scar		10	0
Pruritus		6007	0
Psoriatic conditions			
Dermatitis psoriasiform		5	0
Guttate psoriasis		19	0
Nail psoriasis		2	0
Palmoplantar pustulosis		2	0
Psoriasis		213	0
Pustular psoriasis		3	0
Rebound psoriasis		1	0
Purpura and related conditions			
Ecchymosis		1	0
Henoch-Schonlein purpura		11	0
Petechiae		150	0
Purpura		60	0
Pustular conditions			
Acute generalised exanthematous pustulosis		2	0
Rashes, eruptions and exanths NEC			
Butterfly rash		6	0
Rash		6253	1
Rash erythematous		1349	0
Rash macular		543	0
Rash maculo-papular		65	0
Rash morbilliform		47	0
Rash papular		384	0
Rash pruritic		1323	0
Rash scarlatiniform		1	0
Rash vesicular		80	0
Systemic lupus erythematosus rash		7	0
Rosaceas			
Rosacea		35	0
Scaly conditions			
Dandruff		5	0

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Reaction Name		Total	Fatal
Skin disorders	Skin disorders cont'd		
Pityriasis		26	0
Sebaceous gland disorders			
Sebaceous glands overactivity		1	0
Seborrhoea		11	0
Skin and subcutaneous conditions NEC			
Cellulite		2	0
Cutaneous symptom		6	0
Reactive perforating collagenosis		1	0
Skin mass		25	0
Skin and subcutaneous tissue ulcerations			
Ischaemic skin ulcer		1	0
Mucocutaneous ulceration		1	0
Pyoderma gangrenosum		1	0
Scleroderma associated digital ulcer		1	0
Skin erosion		25	0
Skin ulcer		23	0
Skin cysts and polyps			
Dermal cyst		16	0
Skin dystrophies			
Keloid scar		3	0
Skin wrinkling		2	0
Skin haemorrhages			
Haemorrhage subcutaneous		15	0
Skin haemorrhage		20	0
Skin hyperplasias and hypertrophies			
Skin hypertrophy		2	0
Skin hypoplasias and atrophies			
Skin atrophy		3	0
Skin striae		8	0
Skin injuries and mechanical dermatoses			
Decubitus ulcer		3	0
Needle track marks		5	0
Skin preneoplastic conditions NEC			
Actinic keratosis		1	0
Skin vascular conditions NEC			
Angiodermatitis		1	0
Skin oedema		4	0
Skin vasculitides			
Capillaritis		3	0
Cutaneous vasculitis		15	0
Hypersensitivity vasculitis		1	0
Vasculitic rash		22	0
Skin vasomotor conditions			
Livedo reticularis		25	0
Telangiectasia and related conditions			
Spider naevus		1	0
Telangiectasia		1	0
Urticarias			
Chronic spontaneous urticaria		13	0
Cold urticaria		7	0
Idiopathic urticaria		2	0
Mechanical urticaria		11	0
Solar urticaria		2	0

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Reaction Name	Total	Fatal
Skin disorders		
Skin disorders cont'd		
Urticaria	2116	0
Urticaria cholinergic	2	0
Urticaria chronic	33	0
Urticaria contact	1	0
Urticaria papular	6	0
Urticaria thermal	8	0
Urticular vasculitis	6	0
Skin disorders SOC TOTAL	31329	2

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

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Reaction Name	Total	Fatal
Social circumstances Social circumstances cont'd		
Tobacco user	1	0
Social circumstances SOC TOTAL	254	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Anaesthesia and allied procedures</i>		
Local anaesthesia	2	0
Nerve block	5	0
<i>Analgesia supportive care</i>		
Analgesic therapy	1	0
<i>Antiinfective therapies</i>		
Antiviral prophylaxis	1	0
COVID-19 prophylaxis	2	0
COVID-19 treatment	4	0
<i>Arterial therapeutic procedures (excl aortic)</i>		
Splenic artery embolisation	1	0
<i>Blood and blood product treatment</i>		
Transfusion	2	0
<i>Breast therapeutic procedures NEC</i>		
Axillary lymphadenectomy	3	0
Mammoplasty	1	0
<i>Bronchial and pulmonary therapeutic procedures</i>		
Airway secretion clearance therapy	1	0
<i>Cardiac device therapeutic procedures</i>		
Cardiac pacemaker insertion	1	0
<i>Cardiac therapeutic procedures NEC</i>		
Cardiac ablation	1	0
Cardiac operation	1	0
<i>Contraceptive methods female</i>		
Contraception	1	0
Contraceptive implant	3	0
Oral contraception	1	0
<i>Contraceptive methods male</i>		
Condom	1	0
<i>Dietary and nutritional therapies</i>		
Medical diet	8	0
Nothing by mouth order	13	0
Wheat-free diet	1	0
<i>External ear therapeutic procedures</i>		
Ear irrigation	1	0
<i>Facial therapeutic procedures</i>		
Face lift	1	0
<i>Fertility and fertilisation interventions female</i>		
Endometrial scratching	1	0
<i>Gastrointestinal therapeutic procedures NEC</i>		
Intestinal anastomosis	1	0
Prophylaxis of nausea and vomiting	16	0
<i>Gynaecological therapeutic procedures NEC</i>		
Menstrual cycle management	14	0
<i>Haematological therapeutic procedures NEC</i>		
Anticoagulant therapy	1	0
<i>Head, neck and oral cavity therapeutic procedures NEC</i>		
Neck lift	1	0
<i>Hernia repairs</i>		
Hernia repair	1	0
<i>Hormonal therapeutic procedures NEC</i>		
Hormone replacement therapy	1	0
Hormone therapy	8	0

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Reaction Name		Total	Fatal
Surgical & medical procedures	Surgical & medical procedures cont'd		
Immunisations			
COVID-19 immunisation		111	0
Immunisation		541	1
Induced abortions			
Abortion induced		2	0
Joint therapeutic procedures			
Joint injection		5	0
Joint surgery		1	0
Knee arthroplasty		1	0
Large intestine therapeutic procedures			
Appendicectomy		3	0
Limb therapeutic procedures			
Arm amputation		1	0
Leg amputation		1	0
Limb immobilisation		15	0
Limb operation		9	0
Lip therapeutic procedures			
Lip lesion excision		1	0
Lymphoid tissue therapeutic procedures			
Lymphadenectomy		3	0
Splenectomy		1	0
Mastectomies			
Breast conserving surgery		4	0
Nail therapeutic procedures			
Nail operation		3	0
Nervous system therapeutic procedures NEC			
Multiple sclerosis relapse prophylaxis		2	0
Obstetric therapeutic procedures			
Caesarean section		1	0
Labour stimulation		1	0
Orbit and globe therapeutic procedures			
Strabismus correction		1	0
Ovarian therapeutic procedures			
Ovarian operation		1	0
Peripheral nerve therapeutic procedures			
Neurolysis		1	0
Peripheral nerve neurostimulation		1	0
Phototherapies			
UV light therapy		1	0
Prophylactic procedures NEC			
Anaphylaxis prophylaxis		2	0
Immune tolerance induction		1	0
Prophylaxis against transplant rejection		1	0
Reproductive system disorder prophylaxis		1	0
Psychiatric therapies			
Electroconvulsive therapy		1	0
Renal therapeutic procedures			
Dialysis		1	0
Respiratory tract therapeutic procedures NEC			
Asthma prophylaxis		3	0
Retinal therapeutic procedures			
Retinopexy		1	0
Skin and subcutaneous tissue therapeutic procedures NEC			

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Reaction Name	Total	Fatal
Surgical & medical procedures		
Surgical & medical procedures cont'd		
Dermal filler injection	4	0
Therapeutic skin care topical	1	0
Skull and brain therapeutic procedures		
Cerebrovascular operation	1	0
Posterior fossa decompression	1	0
Small intestine therapeutic procedures		
Ileostomy	1	0
Therapeutic bladder catheterisation		
Bladder catheterisation	2	0
Therapeutic procedures NEC		
Abscess drainage	1	0
Anaphylaxis treatment	7	0
Bed rest	5	0
Emergency care	1	0
Fatigue management	1	0
Hospitalisation	15	0
Injection	63	0
Interchange of vaccine products	186	0
Localised alternating hot and cold therapy	2	0
Magnetic therapy	1	0
Mass excision	4	0
Medical procedure	1	0
Medication dilution	2	0
Physical fitness training	1	0
Product used for unknown indication	3	0
Promotion of wound healing	1	0
Specialist consultation	1	0
Sterilisation	1	0
Stoma care	1	0
Therapeutic procedure	1	0
Therapy change	1	0
Vehicle solution use	1	0
Tracheal therapeutic procedures		
Tracheostomy	1	0
Uterine therapeutic procedures		
Endometrial ablation	2	0
Vascular therapeutic procedures NEC		
Thrombolysis	1	0
Vasodilation procedure	1	0
Surgical & medical procedures SOC TOTAL	1137	1

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Reaction Name	Total	Fatal
Vascular disorders		
Accelerated and malignant hypertension		
Hypertensive crisis	12	0
Hypertensive urgency	2	0
Malignant hypertension	4	0
Aneurysms and dissections non-site specific		
Aneurysm	3	0
Artery dissection	2	0
Aortic aneurysms and dissections		
Acute aortic syndrome	1	0
Aortic aneurysm	1	0
Aortic aneurysm rupture	1	1
Aortic dissection	1	0
Aortic embolism and thrombosis		
Aortic embolus	5	0
Aortic thrombosis	4	0
Aortic infections and inflammations		
Aortitis	1	0
Aortic necrosis and vascular insufficiency		
Aortic occlusion	1	0
Arterial infections and inflammations		
Arteritis	1	0
Giant cell arteritis	16	0
Blood pressure disorders NEC		
Blood pressure fluctuation	13	0
Labile blood pressure	3	0
Bruising, ecchymosis and purpura		
Achenbach syndrome	4	0
Circulatory collapse and shock		
CT hypotension complex	2	0
Circulatory collapse	80	0
Hypoperfusion	2	0
Hypovolaemic shock	1	1
Neurogenic shock	24	0
Peripheral circulatory failure	6	0
Shock	21	0
Shock symptom	2	0
Haemorrhages NEC		
Arterial haemorrhage	1	0
Bloody discharge	24	0
Haematoma	52	0
Haemorrhage	1292	2
Internal haemorrhage	10	0
Venous haemorrhage	2	0
Lymphangiopathies		
Lymphangiopathy	1	0
Lymphocele	6	0
Lymphorrhoea	2	0
Lymphostasis	1	0
Lymphoedemas		
Lymphoedema	234	0
Non-site specific embolism and thrombosis		
Arterial thrombosis	4	0
Embolism	64	0

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Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
Embolism arterial	1	0
Embolism venous	7	0
Microembolism	1	0
Thrombosis	472	1
Venous thrombosis	7	0
Non-site specific necrosis and vascular insufficiency NEC		
Arterial occlusive disease	2	0
Arterial spasm	1	0
Arteriosclerosis	3	0
Haemorrhagic infarction	1	0
Infarction	3	0
Ischaemia	11	0
Peripheral venous disease	1	0
Vascular occlusion	1	0
Vasospasm	1	0
Non-site specific vascular disorders NEC		
Capillary disorder	1	0
Capillary fragility	4	0
Haemodynamic instability	1	0
Superficial vein prominence	2	0
Vascular pain	38	0
Vascular wall hypertrophy	1	0
Vasodilatation	40	0
Vein discolouration	6	0
Vein disorder	7	0
Vein rupture	7	0
Peripheral aneurysms and dissections		
Peripheral artery aneurysm	1	0
Peripheral embolism and thrombosis		
Axillary vein thrombosis	1	0
Blue toe syndrome	32	0
Deep vein thrombosis	318	1
Femoral artery embolism	1	0
Jugular vein thrombosis	3	0
Pelvic venous thrombosis	4	0
Peripheral artery thrombosis	2	0
Peripheral embolism	2	0
Subclavian vein thrombosis	4	0
Superficial vein thrombosis	29	0
Thrombophlebitis	26	0
Peripheral vascular disorders NEC		
Cyanosis	49	0
Erythromelalgia	2	0
Flushing	452	0
Hot flush	1214	0
Peripheral vascular disorder	1	0
Vein wall hypertrophy	1	0
Peripheral vasoconstriction, necrosis and vascular insufficiency		
Claudication of jaw muscles	1	0
Extremity necrosis	3	0
Iliac artery occlusion	1	0
Intermittent claudication	3	0
Ischaemic limb pain	2	0

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Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
Jugular vein occlusion	2	0
Peripheral arterial occlusive disease	2	0
Peripheral artery occlusion	1	0
Peripheral coldness	359	0
Peripheral ischaemia	12	0
Poor peripheral circulation	19	0
Raynaud's phenomenon	62	0
Subclavian vein occlusion	1	0
Vasoconstriction	2	0
Phlebitis NEC		
Phlebitis	35	0
Phlebitis superficial	9	0
Site specific vascular disorders NEC		
Aortic disorder	1	0
Aortic rupture	1	1
Inferior vena cava dilatation	1	0
Pallor	414	0
Varicose veins NEC		
Spider vein	6	0
Varicophlebitis	4	0
Varicose vein	36	0
Vascular hypertensive disorders NEC		
Diastolic hypertension	6	0
Essential hypertension	4	0
Hypertension	674	0
Labile hypertension	2	0
Orthostatic hypertension	1	0
Secondary hypertension	1	0
Systolic hypertension	7	0
White coat hypertension	1	0
Vascular hypotensive disorders		
Capillary leak syndrome	1	0
Diastolic hypotension	1	0
Hypotension	429	1
Orthostatic hypotension	32	0
Vasculitides NEC		
Behcet's syndrome	5	0
Diffuse vasculitis	1	0
Granulomatosis with polyangiitis	2	0
MAGIC syndrome	1	0
Thromboangiitis obliterans	1	0
Vasculitis	51	0
Vena caval embolism and thrombosis		
Vena cava embolism	1	0
Vena cava thrombosis	1	0
Vascular disorders SOC TOTAL	6866	11
TOTAL REACTIONS FOR DRUG	446903	684
TOTAL REPORTS	156250	
TOTAL FATAL OUTCOME REPORTS		684