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COVID-19 mRNA Pfizer- BioNTech Vaccine Analysis Print

All UK spontaneous reports received between 09/12/20 and 25/05/22 for mRNA Pfizer/BioNTech vaccine

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Case Series Drug Analysis Print

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

Report Run Date: 26-May-2022

Data Lock Date: 25-May-2022 18:30:05

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemia deficiencies</i>		
Anaemia folate deficiency	1	0
Anaemia vitamin B12 deficiency	7	0
Deficiency anaemia	1	0
Iron deficiency anaemia	8	0
Pernicious anaemia	2	0
<i>Anaemias NEC</i>		
Anaemia	149	0
Anaemia macrocytic	2	0
Anaemia megaloblastic	1	0
Autoimmune anaemia	3	0
Blood loss anaemia	1	0
Microcytic anaemia	1	0
Normocytic anaemia	1	0
<i>Anaemias haemolytic NEC</i>		
Coombs negative haemolytic anaemia	1	0
Haemolytic anaemia	7	0
<i>Anaemias haemolytic immune</i>		
Autoimmune haemolytic anaemia	19	0
Cold type haemolytic anaemia	1	0
Evans syndrome	1	0
Warm autoimmune haemolytic anaemia	1	0
<i>Anaemias haemolytic mechanical factor</i>		
Microangiopathic haemolytic anaemia	1	0
<i>Bleeding tendencies</i>		
Haemorrhagic diathesis	1	0
Increased tendency to bruise	55	0
Spontaneous haematoma	2	0
<i>Coagulation factor deficiencies</i>		
Acquired factor VIII deficiency	1	0
Acquired haemophilia	4	0
<i>Coagulopathies</i>		
Abnormal clotting factor	4	0
Antiphospholipid syndrome	6	0
Coagulopathy	31	1
Disseminated intravascular coagulation	3	0
Hypercoagulation	4	0
Thrombotic microangiopathy	4	0
<i>Eosinophilic disorders</i>		
Eosinophilia	12	0
<i>Haematological disorders</i>		
Blood disorder	7	0
Bone marrow disorder	1	0
Bone marrow oedema	1	0
Hypergammaglobulinaemia	1	0
Hyperviscosity syndrome	1	0
Mast cell activation syndrome	14	0
Methaemoglobinaemia	1	0
<i>Haemolyses NEC</i>		
Haemolysis	6	0
Intravascular haemolysis	1	0
Jaundice acholuric	1	0
<i>Leukocytoses NEC</i>		

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Reaction Name	Total	Fatal
Blood disorders Blood disorders cont'd		
Leukocytosis	3	0
Lymphocytic infiltration	1	0
Lymphocytosis	6	0
Neutrophilia	12	0
Leukopenias NEC		
Leukopenia	4	1
Lymphopenia	4	0
Lymphatic system disorders NEC		
Abdominal lymphadenopathy	4	0
Hilar lymphadenopathy	3	0
Lymph node pain	2282	0
Lymph node ulcer	1	0
Lymphadenitis	192	0
Lymphadenopathy	13786	0
Lymphadenopathy mediastinal	1	0
Lymphatic disorder	3	0
Lymphatic insufficiency	1	0
Lymphoid tissue hyperplasia	1	0
Necrotic lymphadenopathy	4	0
Pseudolymphoma	9	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	9	0
Neutropenias		
Autoimmune neutropenia	2	0
Neutropenia	44	0
Platelet disorders NEC		
Platelet anisocytosis	1	0
Platelet disorder	4	0
Polycythaemia (excl rubra vera)		
Polycythaemia	3	0
Purpuras (excl thrombocytopenic)		
Purpura non-thrombocytopenic	1	0
Red blood cell abnormal findings NEC		
Macrocytosis	2	0
Polychromasia	2	0
Red blood cell abnormality	2	0
Spleen disorders		
Spleen atrophy	1	0
Splenic infarction	4	0
Splenic lesion	1	0
Splenic thrombosis	2	0
Splenic vein thrombosis	2	0
Splenomegaly	12	0
Thrombocytopenias		
Acquired amegakaryocytic thrombocytopenia	1	0
Immune thrombocytopenia	87	0
Thrombocytopenia	243	1
Thrombocytopenic purpura	9	0

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Reaction Name	Total	Fatal
Blood disorders Blood disorders cont'd		
Thrombotic thrombocytopenic purpura	7	0
Thrombocytoses		
Thrombocytosis	7	0
Blood disorders SOC TOTAL	17139	4

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Aortic valvular disorders</i>		
Aortic valve incompetence	2	0
<i>Cardiac conduction disorders</i>		
Atrioventricular block	34	1
Atrioventricular block complete	3	1
Atrioventricular block first degree	3	0
Atrioventricular block second degree	5	0
Bundle branch block	2	0
Bundle branch block left	6	0
Bundle branch block right	5	0
Trifascicular block	1	0
<i>Cardiac disorders NEC</i>		
Acute cardiac event	7	0
Atrial thrombosis	1	0
Cardiac disorder	105	3
Cardiac dysfunction	2	0
Cardiac ventricular thrombosis	2	0
Cardiovascular deconditioning	1	0
Cardiovascular disorder	9	0
Intracardiac thrombus	7	0
<i>Cardiac hypertensive complications</i>		
Hypertensive heart disease	3	2
<i>Cardiac infections and inflammations NEC</i>		
Carditis	10	0
<i>Cardiac neoplasms NEC</i>		
Pericardial cyst	1	0
<i>Cardiac signs and symptoms NEC</i>		
Cardiac discomfort	39	0
Cardiovascular symptom	4	0
Palpitations	6262	1
<i>Cardiac valve disorders NEC</i>		
Cardiac valve disease	4	0
Heart valve incompetence	3	0
<i>Cardiomyopathies</i>		
Cardiomyopathy	17	1
Congestive cardiomyopathy	9	0
Stress cardiomyopathy	3	0
<i>Coronary artery disorders NEC</i>		
Arteriosclerosis coronary artery	2	0
Coronary artery disease	10	3
Coronary artery dissection	1	0
Coronary artery occlusion	4	0
Coronary artery thrombosis	8	2
<i>Endocarditis NEC</i>		
Endocarditis noninfective	1	1
<i>Heart failures NEC</i>		
Cardiac failure	87	10
Cardiac failure acute	9	2
Cardiac failure chronic	2	0
Cardiac failure congestive	7	4
Cardiogenic shock	6	2
Cardiopulmonary failure	2	1
<i>Ischaemic coronary artery disorders</i>		

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Reaction Name	Total	Fatal
Cardiac disorders Cardiac disorders cont'd		
Acute coronary syndrome	10	1
Acute myocardial infarction	32	5
Angina pectoris	343	1
Angina unstable	5	0
Arteriospasm coronary	4	0
Microvascular coronary artery disease	3	0
Myocardial infarction	301	43
Myocardial ischaemia	12	7
Left ventricular failures		
Acute left ventricular failure	2	2
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	56	3
Dilatation ventricular	1	0
Left atrial dilatation	1	0
Left ventricular dysfunction	19	0
Left ventricular enlargement	3	0
Left ventricular hypertrophy	2	0
Myocardial fibrosis	9	0
Myocardial haemorrhage	1	0
Myocardial injury	26	0
Myocardial necrosis	1	0
Myocardial oedema	7	0
Myocardial rupture	1	0
Right atrial enlargement	1	0
Right ventricular dilatation	1	0
Right ventricular dysfunction	2	0
Right ventricular enlargement	1	0
Systolic dysfunction	1	0
Ventricular dysfunction	2	0
Ventricular hypertrophy	1	0
Ventricular hypokinesia	4	0
Noninfectious myocarditis		
Eosinophilic myocarditis	1	0
Hypersensitivity myocarditis	1	0
Myocarditis	701	3
Myocarditis post infection	1	0
Myopericarditis	93	0
Noninfectious pericarditis		
Pericarditis	538	2
Pericarditis constrictive	1	0
Pericarditis lupus	1	0
Pleuropericarditis	1	0
Pericardial disorders NEC		
Cardiac tamponade	2	1
Pericardial effusion	51	2
Pericardial fibrosis	1	0

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Reaction Name	Total	Fatal
Cardiac disorders Cardiac disorders cont'd		
Pericardial haemorrhage	4	3
Pericardial rub	2	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	192	1
Arrhythmia neonatal	1	0
Bradycardia	80	0
Bradycardia foetal	2	0
Cardiac flutter	627	0
Extrasystoles	223	0
Heart alternation	3	0
Paroxysmal arrhythmia	1	0
Postural orthostatic tachycardia syndrome	49	0
Tachyarrhythmia	11	0
Tachycardia	2505	0
Tachycardia foetal	1	0
Tachycardia paroxysmal	1	0
<i>Right ventricular failures</i>		
Cor pulmonale	1	0
Right ventricular failure	1	0
<i>Supraventricular arrhythmias</i>		
Arrhythmia supraventricular	16	0
Atrial fibrillation	294	1
Atrial flutter	46	0
Atrial tachycardia	12	0
Nodal arrhythmia	1	0
Sinus arrest	1	0
Sinus arrhythmia	9	0
Sinus bradycardia	15	0
Sinus node dysfunction	1	0
Sinus tachycardia	87	0
Supraventricular extrasystoles	6	0
Supraventricular tachycardia	51	0
<i>Tricuspid valvular disorders</i>		
Tricuspid valve incompetence	6	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	132	45
Cardio-respiratory arrest	1	1
Pulseless electrical activity	7	0
Ventricular arrhythmia	6	0
Ventricular extrasystoles	32	0
Ventricular fibrillation	10	1
Ventricular tachycardia	18	0
Cardiac disorders SOC TOTAL	13407	159

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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	20	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	2	0
<i>Central nervous system disorders congenital NEC</i>		
Spina bifida	2	1
Syringomyelia	1	0
<i>Cerebellar disorders congenital</i>		
Arnold-Chiari malformation	1	0
Hereditary ataxia	2	0
<i>Cerebral disorders congenital</i>		
Anencephaly	2	0
Cerebral palsy	4	0
Congenital hydrocephalus	1	0
<i>Chromosomal abnormalities NEC</i>		
Cytogenetic abnormality	1	0
<i>Coagulation disorders congenital</i>		
Factor IX deficiency	1	0
Haemophilia	2	0
<i>Congenital disorders NEC</i>		
Congenital anomaly	1	0
Foetal malformation	1	0
Heterotaxia	1	0
<i>Connective tissue disorders congenital</i>		
Ehlers-Danlos syndrome	5	0
<i>Diaphragmatic disorders congenital</i>		
Congenital diaphragmatic hernia	1	0
<i>Gastrointestinal tract disorders congenital NEC</i>		
Gastroschisis	3	0
<i>Genetic polymorphisms</i>		
Genetic polymorphism	1	0
<i>Great vessel disorders congenital</i>		
Congenital great vessel anomaly	1	0
Transposition of the great vessels	1	0
<i>Haematological disorders congenital NEC</i>		
Amegakaryocytic thrombocytopenia	1	0
Neonatal alloimmune thrombocytopenia	1	0
<i>Haemoglobinopathies congenital</i>		
Congenital methaemoglobinaemia	1	0
<i>Immune system abnormalities congenital</i>		
Combined immunodeficiency	1	0
<i>Inborn errors of lipid metabolism</i>		
Short-chain acyl-coenzyme A dehydrogenase deficiency	1	0
<i>Inborn errors of metabolism NEC</i>		
Alpha-1 antitrypsin deficiency	1	0

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Reaction Name	Total	Fatal
Congenital disorders Congenital disorders cont'd		
<i>Inborn errors of porphyrin metabolism</i>		
Porphyria	1	0
<i>Lymphatic system disorders congenital</i>		
Cystic lymphangioma	3	0
<i>Male reproductive tract disorders congenital</i>		
Cryptorchism	1	0
Micropenis	4	0
Penoscrotal fusion	1	0
Phimosis	1	0
<i>Musculoskeletal and connective tissue disorders of limbs congenital</i>		
Congenital musculoskeletal disorder of limbs	1	0
Developmental hip dysplasia	1	0
<i>Musculoskeletal and connective tissue disorders of skull congenital</i>		
Platybasia	1	0
<i>Musculoskeletal and connective tissue disorders of spine congenital</i>		
Block vertebra	1	0
Brachyolmia	1	0
<i>Neurological disorders congenital NEC</i>		
Familial hemiplegic migraine	2	0
Familial periodic paralysis	1	0
Moebius II syndrome	1	0
Neurofibromatosis	1	0
Tourette's disorder	4	0
<i>Ocular disorders congenital NEC</i>		
Colour blindness	4	0
Congenital eye disorder	1	0
<i>Palate disorders congenital</i>		
Cleft lip and palate	2	0
<i>Peripheral nervous system disorders congenital NEC</i>		
Hereditary neuropathy with liability to pressure palsies	1	0
Paroxysmal extreme pain disorder	1	0
<i>Pulmonary and bronchial disorders congenital</i>		
Congenital cystic lung	1	0
<i>Retinal disorders congenital</i>		
Retinitis pigmentosa	1	0
<i>Sex chromosomal abnormalities</i>		
Turner's syndrome	1	0
<i>Skin and subcutaneous tissue disorders congenital NEC</i>		
Acral peeling skin syndrome	1	0
<i>Tongue disorders congenital</i>		
Ankyloglossia congenital	1	0
<i>Vascular anomalies congenital NEC</i>		
Congenital LUMBAR syndrome	1	0
<i>Venous disorders congenital</i>		
Anomalous pulmonary venous connection	1	0
Congenital disorders SOC TOTAL	107	1

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear canal erythema	1	0
Ear congestion	39	0
Ear discomfort	108	0
Ear disorder	23	0
Ear haemorrhage	15	0
Ear inflammation	2	0
Ear pain	1187	0
Ear pruritus	12	0
Ear swelling	39	0
Otorrhoea	8	0
Ototoxicity	1	0
Paraesthesia ear	1	0
<i>Eustachian tube disorders</i>		
Eustachian tube disorder	5	0
Eustachian tube dysfunction	11	0
Eustachian tube obstruction	7	0
<i>External ear disorders NEC</i>		
Auricular swelling	2	0
Excessive cerumen production	12	0
External ear pain	6	0
Red ear syndrome	2	0
<i>External ear infections and inflammations</i>		
Chondrodermatitis nodularis chronica heliis	1	0
External ear inflammation	2	0
<i>Hearing disorders NEC</i>		
Auditory disorder	6	0
Diplacusis	2	0
Dysacusis	1	0
<i>Hearing losses</i>		
Conductive deafness	1	0
Deafness	306	0
Deafness bilateral	12	0
Deafness neurosensory	27	0
Deafness transitory	10	0
Deafness unilateral	40	0
Hypoacusis	234	0
Mixed deafness	1	0
Sudden hearing loss	52	0
<i>Hyperacusia</i>		
Hyperacusis	80	0
Misophonia	3	0
<i>Inner ear disorders NEC</i>		
Acute vestibular syndrome	2	0
Inner ear disorder	13	0
Meniere's disease	16	0
Vestibular disorder	15	0
<i>Inner ear infections and inflammations</i>		
Autoimmune inner ear disease	1	0
Inner ear inflammation	11	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	70	0
Phobic postural vertigo	1	0

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Reaction Name	Total	Fatal
Ear disorders Ear disorders cont'd		
Tinnitus	2544	0
Vertigo	1678	0
Vertigo labyrinthine	13	0
Vertigo positional	88	0
<i>Mastoid disorders</i>		
Mastoid effusion	1	0
<i>Middle ear disorders NEC</i>		
Middle ear disorder	3	0
Middle ear effusion	1	0
<i>Middle ear infections and inflammations</i>		
Middle ear inflammation	1	0
<i>Tympanic membrane disorders (excl infections)</i>		
Tympanic membrane perforation	4	0
Ear disorders SOC TOTAL	6721	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Autoimmune thyroiditis	4	0
Thyroiditis	24	0
Thyroiditis acute	4	0
Thyroiditis subacute	9	0
<i>Adrenal cortical hyperfunctions</i>		
Cushingoid	1	0
<i>Adrenal cortical hypofunctions</i>		
Addison's disease	3	0
Adrenal insufficiency	3	0
Adrenocortical insufficiency acute	16	0
<i>Adrenal gland disorders NEC</i>		
Adrenal disorder	3	0
Adrenal haemorrhage	3	0
Adrenal mass	1	0
<i>Anterior pituitary hyperfunction</i>		
Pituitary-dependent Cushing's syndrome	1	0
<i>Anterior pituitary hypofunction</i>		
Hypopituitarism	2	0
Luteal phase deficiency	1	0
<i>Endocrine abnormalities of gonadal function NEC</i>		
Oestrogen deficiency	1	0
<i>Endocrine abnormalities of puberty</i>		
Delayed menarche	5	0
Premature menarche	21	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	68	0
Ovulation delayed	35	0
<i>Male gonadal function disorders</i>		
Androgen deficiency	1	0
<i>Thyroid disorders NEC</i>		
Autoimmune thyroid disorder	1	0
Goitre	18	0
Thyroid disorder	15	0
Thyroid mass	2	0
Thyroid pain	12	0
<i>Thyroid hyperfunction disorders</i>		
Basedow's disease	14	0
Hyperthyroidism	59	0
Primary hyperthyroidism	1	0
Thyrotoxic crisis	6	0
<i>Thyroid hypofunction disorders</i>		
Autoimmune hypothyroidism	1	0
Hypothyroidic goitre	1	0
Hypothyroidism	47	0
Immune-mediated hypothyroidism	1	0
Myxoedema	1	0
<i>Thyroid neoplasms</i>		
Thyroid cyst	1	0
Endocrine disorders SOC TOTAL	386	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Amblyopic vision impairment</i>		
Amblyopia	7	0
<i>Anterior chamber bleeding and vascular disorders</i>		
Spontaneous hyphaema	1	0
<i>Cataract conditions</i>		
Cataract	18	0
<i>Choroid and vitreous haemorrhages and vascular disorders</i>		
Choroidal haemorrhage	1	0
Choroidal neovascularisation	1	0
Vitreous haemorrhage	4	0
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Vitreous detachment	22	0
Vitreous floaters	122	0
<i>Colour blindness (incl acquired)</i>		
Colour blindness acquired	2	0
Dyschromatopsia	15	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	52	0
Scleral haemorrhage	1	0
<i>Conjunctival infections, irritations and inflammations</i>		
Conjunctival hyperaemia	2	0
Conjunctival irritation	1	0
Conjunctival oedema	3	0
Conjunctival ulcer	1	0
Conjunctivitis allergic	2	0
<i>Corneal infections, oedemas and inflammations</i>		
Corneal oedema	3	0
Keratitis	7	0
Ulcerative keratitis	6	0
<i>Corneal structural change, deposit and degeneration</i>		
Corneal scar	1	0
<i>Eyelid movement disorders</i>		
Blepharospasm	172	0
Excessive eye blinking	6	0
Eyelid function disorder	3	0
Eyelid myokymia	4	0
Eyelid ptosis	52	0
Paralytic lagophthalmos	2	0
<i>Glaucomas (excl congenital)</i>		
Angle closure glaucoma	2	0
Glaucoma	8	0
Ocular hypertension	1	0
<i>Iris and ciliary body structural change, deposit and degeneration</i>		
Eye colour change	3	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Autoimmune uveitis	3	0
Iridocyclitis	21	0
Iritis	13	0
Uveitis	57	0
Vogt-Koyanagi-Harada disease	1	0
<i>Lacrimation disorders</i>		
Dry eye	180	0
Lacrimation decreased	1	0

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Lacrimation increased	169	0
<i>Lid bleeding and vascular disorders</i>		
Eyelid bleeding	1	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Blepharitis	20	0
Blepharitis allergic	1	0
Chalazion	7	0
Eczema eyelids	11	0
Erythema of eyelid	11	0
Eyelid cyst	7	0
Eyelid irritation	4	0
Eyelid margin crusting	5	0
Eyelid oedema	15	0
Eyelid rash	20	0
Meibomian gland dysfunction	1	0
Swelling of eyelid	149	0
Swollen tear duct	2	0
<i>Lid, lash and lacrimal structural disorders</i>		
Dacryostenosis acquired	2	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
Lacrimal gland enlargement	1	0
Lagophthalmos	4	0
<i>Ocular bleeding and vascular disorders NEC</i>		
Eye haematoma	4	0
Eye haemorrhage	39	0
Ocular vascular disorder	2	0
Ophthalmic vein thrombosis	1	0
<i>Ocular disorders NEC</i>		
Dark circles under eyes	10	0
Eye disorder	44	0
Eye oedema	19	0
Eye pain	1311	0
Eye swelling	663	0
Eye symptom	10	0
Eye ulcer	6	0
Eyelid disorder	17	0
Eyelid pain	16	0
Eyelids pruritus	8	0
Ocular discomfort	35	0
Periorbital oedema	22	0
Periorbital pain	5	0
Periorbital swelling	135	0
Retinal disorder	2	0
Vitreous disorder	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye allergy	22	0

Case Series Drug Analysis Print

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

Report Run Date: 26-May-2022

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MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Eye discharge	35	0
Eye inflammation	40	0
Eye irritation	107	0
Eye pruritus	287	0
Limbal swelling	4	0
Ocular hyperaemia	270	0
Ocular vasculitis	1	0
Ocular nerve and muscle disorders		
Binocular eye movement disorder	1	0
Extraocular muscle disorder	1	0
Eye movement disorder	44	0
Gaze palsy	3	0
Ocular myasthenia	1	0
Ophthalmoplegia	8	0
Strabismus	10	0
Ocular sensation disorders		
Abnormal sensation in eye	24	0
Asthenopia	175	0
Eye paraesthesia	2	0
Eyelid sensory disorder	3	0
Foreign body sensation in eyes	19	0
Hypoaesthesia eye	18	0
Photophobia	530	0
Optic disc abnormalities NEC		
Papilloedema	8	0
Optic nerve bleeding and vascular disorders		
Optic disc haemorrhage	1	0
Optic ischaemic neuropathy	4	0
Orbital infections, inflammations and irritations		
Parophthalmia	1	0
Orbital structural change, deposit and degeneration		
Orbital oedema	2	0
Pupil disorders		
Anisocoria	15	0
Miosis	2	0
Mydriasis	24	0
Pupil fixed	4	0
Pupillary disorder	1	0
Refractive and accommodative disorders		
Accommodation disorder	1	0
Altered visual depth perception	5	0
Astigmatism	3	0
Hypermetropia	4	0
Myopia	4	0
Retinal bleeding and vascular disorders (excl retinopathy)		
Papillophlebitis	1	0
Retinal artery occlusion	18	0
Retinal artery thrombosis	2	0
Retinal haemorrhage	12	0
Retinal ischaemia	1	0
Retinal vascular thrombosis	1	0
Retinal vein occlusion	48	0
Retinal vein thrombosis	2	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
<i>Retinal structural change, deposit and degeneration</i>		
Age-related macular degeneration	1	0
Chorioretinal disorder	1	0
Dry age-related macular degeneration	1	0
Epiretinal membrane	1	0
Macular degeneration	4	0
Macular hole	3	0
Macular rupture	1	0
Maculopathy	1	0
Neovascular age-related macular degeneration	4	0
Retinal degeneration	1	0
Retinal detachment	9	0
Retinal tear	3	0
Retinal toxicity	3	0
<i>Retinal, choroid and vitreous infections and inflammations</i>		
Birdshot chorioretinopathy	2	0
Choroiditis	1	0
Cystoid macular oedema	1	0
Macular oedema	7	0
Retinal oedema	2	0
Retinal vasculitis	3	0
<i>Retinopathies NEC</i>		
Acute macular neuroretinopathy	3	0
Central serous chorioretinopathy	8	0
Retinal exudates	3	0
Retinopathy	4	0
<i>Scleral infections, irritations and inflammations</i>		
Episcleritis	9	0
Scleritis	6	0
<i>Scleral structural change, deposit and degeneration</i>		
Scleral discolouration	2	0
<i>Structural change, deposit and degeneration of eye NEC</i>		
Endocrine ophthalmopathy	2	0
Exophthalmos	4	0
<i>Visual colour distortions</i>		
Chloropsia	2	0
Chromatopsia	1	0
Cyanopsia	5	0
Erythropsia	2	0
Xanthopsia	1	0
<i>Visual disorders NEC</i>		
Charles Bonnet syndrome	2	0
Diplopia	191	0
Dysmetropsia	1	0
Glare	1	0
Halo vision	10	0
Heteronymous diplopia	1	0
Metamorphopsia	25	0
Oscillopsia	3	0
Photopsia	169	0
Scintillating scotoma	4	0
Vision blurred	1468	0
Visual brightness	3	0

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Visual snow syndrome	8	0
Visual field disorders		
Visual field defect	42	0
Visual impairment and blindness (excl colour blindness)		
Amaurosis fugax	4	0
Blindness	168	0
Blindness cortical	1	0
Blindness transient	22	0
Blindness unilateral	20	0
Central vision loss	6	0
Sudden visual loss	5	0
Visual acuity reduced	30	0
Visual acuity reduced transiently	1	0
Visual impairment	480	0
Visual pathway disorders		
Optic nerve disorder	1	0
Eye disorders SOC TOTAL	8130	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Abdominal findings abnormal</i>		
Abdominal mass	2	0
Gastrointestinal sounds abnormal	18	0
<i>Abdominal hernias NEC</i>		
Abdominal hernia	2	0
<i>Abdominal wall conditions NEC</i>		
Abdominal wall haematoma	2	0
<i>Acute and chronic pancreatitis</i>		
Alcoholic pancreatitis	1	0
Autoimmune pancreatitis	1	0
Obstructive pancreatitis	1	0
Pancreatitis	19	0
Pancreatitis acute	17	1
Pancreatitis chronic	1	0
Pancreatitis necrotising	2	0
<i>Anal and rectal disorders NEC</i>		
Anal fissure	2	0
Anal sphincter atony	1	0
Rectal prolapse	1	0
<i>Anal and rectal pains</i>		
Proctalgia	15	0
<i>Anal and rectal signs and symptoms</i>		
Anal blister	1	0
Anal eczema	1	0
Anal erythema	1	0
Anal hypoaesthesia	2	0
Anal pruritus	2	0
Anal rash	1	0
Anal spasm	1	0
Anorectal discomfort	5	0
Anorectal swelling	1	0
Rectal discharge	2	0
Rectal spasm	1	0
Rectal tenesmus	1	0
<i>Anal and rectal ulcers and perforation</i>		
Anal ulcer	1	0
<i>Benign oral cavity neoplasms</i>		
Mouth cyst	6	0
Tongue cyst	4	0
Tongue polyp	2	0
<i>Colitis (excl infective)</i>		
Autoimmune colitis	2	0
Colitis	60	1
Colitis ischaemic	1	0
Colitis microscopic	3	0
Colitis ulcerative	84	0
Crohn's disease	52	0
Eosinophilic colitis	1	0
Inflammatory bowel disease	12	0
<i>Dental and periodontal infections and inflammations</i>		
Dental caries	2	0
Periodontal inflammation	1	0
<i>Dental developmental disorders and anomalies</i>		

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Tooth impacted	1	0
Dental disorders NEC		
Loose tooth	5	0
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	39	0
Toothache	198	0
Dental surface disorders		
Tooth discolouration	10	0
Diaphragmatic hernias		
Hiatus hernia	8	0
Diarrhoea (excl infective)		
Diarrhoea	6151	0
Diarrhoea haemorrhagic	27	0
Diverticula		
Diverticulum	7	0
Diverticulum intestinal	1	0
Duodenal and small intestinal stenosis and obstruction		
Small intestinal obstruction	4	0
Duodenal ulcers and perforation		
Duodenal ulcer haemorrhage	1	0
Duodenal ulcer perforation	3	0
Dyspeptic signs and symptoms		
Dyspepsia	550	0
Epigastric discomfort	15	0
Eructation	64	0
Faecal abnormalities NEC		
Abnormal faeces	23	0
Faecaloma	7	0
Faeces discoloured	63	0
Faeces hard	2	0
Faeces pale	5	0
Faeces soft	13	0
Mucous stools	12	0
Flatulence, bloating and distension		
Abdominal distension	608	0
Aerophagia	3	0
Flatulence	204	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)		

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Chronic gastritis	4	0
Gastritis	72	0
Reflux gastritis	8	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal migraine	2	0
Abdominal pain	1716	0
Abdominal pain lower	154	0
Abdominal pain upper	2838	0
Abdominal rigidity	27	0
Abdominal tenderness	15	0
Gastrointestinal pain	170	0
Oesophageal pain	14	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	281	0
Duodenogastric reflux	4	0
Gastric dilatation	8	0
Gastrooesophageal reflux disease	197	0
Impaired gastric emptying	10	0
Infrequent bowel movements	3	0
Intestinal dilatation	1	0
Intestinal pseudo-obstruction	2	0
<i>Gastrointestinal disorders NEC</i>		
Appendicolith	1	0
Appendix disorder	2	0
Food poisoning	7	0
Functional gastrointestinal disorder	11	0
Gastric disorder	10	0
Gastrointestinal disorder	31	0
Stomach mass	4	0
<i>Gastrointestinal dyskinetic disorders</i>		
Bowel movement irregularity	9	0
Change of bowel habit	14	0
Dyschezia	4	0
Gastrointestinal motility disorder	5	0
Oesophageal achalasia	1	0
<i>Gastrointestinal fistulae</i>		
Diverticular fistula	2	0
<i>Gastrointestinal inflammatory disorders NEC</i>		
Appendicitis noninfective	1	0
Duodenitis	1	0
Enteritis	6	0
Epiplonic appendagitis	2	0
Gastrointestinal inflammation	5	0
Gastrointestinal tract irritation	1	0
Intestinal angioedema	2	0
<i>Gastrointestinal mucosal dystrophies and secretion disorders</i>		
Barrett's oesophagus	2	0
Hyperchlorhydria	4	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	713	0
Abdominal symptom	2	0
Acute abdomen	8	0
Anal incontinence	23	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Breath odour	22	0
Dysphagia	248	1
Gastrointestinal wall thickening	1	0
Malignant dysphagia	1	0
Odynophagia	48	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Cardiospasm	1	0
Defaecation urgency	12	0
Frequent bowel movements	35	0
Gastrointestinal hypermotility	1	0
Irritable bowel syndrome	106	0
Oesophageal spasm	5	0
Pylorospasm	1	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Ileus	2	0
Intestinal obstruction	8	0
Neonatal intestinal obstruction	1	0
Volvulus	1	0
<i>Gastrointestinal vascular malformations</i>		
Gastric antral vascular ectasia	11	0
<i>Gastrointestinal vascular occlusion and infarction</i>		
Intestinal infarction	1	1
Intestinal ischaemia	10	2
Mesenteric vein thrombosis	10	0
Omental infarction	1	0
Thrombosis mesenteric vessel	2	0
Visceral venous thrombosis	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival blister	13	0
Gingival discomfort	8	0
Gingival disorder	5	0
Gingival erythema	2	0
Gingival hypertrophy	1	0
Gingival oedema	2	0
Gingival pain	138	0
Gingival pruritus	2	0
Gingival recession	1	0
Gingival swelling	43	0
Gingival ulceration	3	0
Gingivitis ulcerative	1	0
Noninfective gingivitis	14	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	86	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Gastric varices	1	0
Haemorrhoidal haemorrhage	1	0
Haemorrhoids	35	1
Haemorrhoids thrombosed	1	0
<i>Inguinal hernias</i>		
Inguinal hernia	1	0
<i>Intestinal haemorrhages</i>		
Anal haemorrhage	23	1
Intestinal haemorrhage	1	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Rectal haemorrhage	84	0
Small intestinal haemorrhage	5	0
<i>Intestinal ulcers and perforation NEC</i>		
Intestinal perforation	6	2
Large intestinal ulcer	1	0
Large intestinal ulcer haemorrhage	1	0
Large intestine perforation	1	0
<i>Large intestinal stenosis and obstruction</i>		
Large intestinal obstruction	2	2
<i>Malabsorption syndromes</i>		
Bile acid malabsorption	5	0
Celiac disease	14	0
Malabsorption	1	0
Steatorrhoea	4	0
<i>Nausea and vomiting symptoms</i>		
Cyclic vomiting syndrome	1	0
Discoloured vomit	13	0
Infantile vomiting	7	0
Nausea	15436	0
Regurgitation	1	0
Retching	117	0
Vomiting	5290	1
Vomiting projectile	76	0
<i>Non-mechanical ileus</i>		
Ileus paralytic	2	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Gastrointestinal haemorrhage	19	1
Haematemesis	42	2
Haematochezia	61	0
Melaena	11	0
Upper gastrointestinal haemorrhage	14	1
<i>Oesophageal disorders NEC</i>		
Oesophageal disorder	1	0
<i>Oesophageal stenosis and obstruction</i>		
Oesophageal stenosis	3	0
<i>Oesophagitis (excl infective)</i>		
Eosinophilic oesophagitis	2	0
Oesophagitis	6	0
<i>Oral dryness and saliva altered</i>		
Aptyalism	5	0
Dry mouth	550	0
Lip dry	50	0
Saliva altered	8	0
Salivary hypersecretion	55	0
<i>Oral soft tissue disorders NEC</i>		
Angina bullosa haemorrhagica	1	0
Chapped lips	29	0
Cheilitis	32	0
Enlarged uvula	15	0
Leukoplakia oral	2	0
Lip blister	36	0
Lip disorder	7	0
Oral disorder	23	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Oral lichen planus	17	0
Oral mucosal hypertrophy	1	0
Oral papule	1	0
Uvulitis	7	0
Oral soft tissue haemorrhages		
Lip haemorrhage	2	0
Mouth haemorrhage	23	0
Oral blood blister	19	0
Oral purpura	2	0
Oral soft tissue infections		
Angular cheilitis	4	0
Oral soft tissue signs and symptoms		
Anaesthesia oral	3	0
Burning mouth syndrome	7	0
Coating in mouth	1	0
Hypoaesthesia oral	521	0
Lip discolouration	11	0
Lip erythema	4	0
Lip exfoliation	6	0
Lip pain	67	0
Lip pruritus	18	0
Lip scab	1	0
Oral discomfort	91	0
Oral dysaesthesia	1	0
Oral mucosal blistering	18	0
Oral mucosal discolouration	2	0
Oral mucosal eruption	22	0
Oral mucosal erythema	9	0
Oral mucosal exfoliation	10	0
Oral mucosal roughening	3	0
Oral mucosal scab	2	0
Oral pain	191	0
Oral pruritus	24	0
Paraesthesia oral	977	0
Pigmentation lip	1	0
Oral soft tissue swelling and oedema		
Lip oedema	4	0
Lip swelling	904	0
Mouth swelling	120	0
Oedema mouth	4	0
Palatal oedema	4	0
Palatal swelling	5	0
Pancreatic disorders NEC		
Pancreatic disorder	3	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	3	0
Peritoneal disorder	1	0
Peritoneal and retroperitoneal fibrosis and adhesions		

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Abdominal adhesions	2	0
<i>Peritoneal and retroperitoneal haemorrhages</i>		
Haemoperitoneum	1	0
Retroperitoneal haematoma	1	0
Retroperitoneal haemorrhage	2	1
<i>Rectal inflammations NEC</i>		
Proctitis	4	0
Proctitis ulcerative	1	0
<i>Salivary gland disorders NEC</i>		
Salivary gland disorder	1	0
Salivary gland mucocoele	1	0
Salivary gland pain	13	0
<i>Salivary gland enlargements</i>		
Parotid gland enlargement	12	0
Salivary gland enlargement	5	0
Submaxillary gland enlargement	7	0
<i>Salivary gland infections and inflammations</i>		
Noninfective sialoadenitis	2	0
<i>Stomatitis and ulceration</i>		
Aphthous ulcer	61	0
Lip ulceration	23	0
Mouth ulceration	496	0
Oral mucosa erosion	1	0
Palatal ulcer	1	0
Stomatitis	69	0
<i>Tongue disorders</i>		
Glossitis	23	0
Hypertrophy of tongue papillae	2	0
Plicated tongue	4	0
Tongue disorder	45	0
Tongue geographic	8	0
Tongue haemorrhage	3	0
Tongue ulceration	34	0
Trichoglossia	4	0
<i>Tongue signs and symptoms</i>		
Glossodynia	234	0
Scalloped tongue	5	0
Stiff tongue	4	0
Swollen tongue	560	0
Tongue blistering	19	0
Tongue coated	20	0
Tongue discolouration	40	0
Tongue discomfort	48	0
Tongue dry	17	0
Tongue eruption	11	0
Tongue erythema	13	0
Tongue exfoliation	2	0
Tongue movement disturbance	8	0
Tongue oedema	24	0
Tongue pruritus	2	0
Tongue rough	5	0
Tongue spasm	12	0
<i>Tooth missing</i>		

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Tooth loss	6	0
Gastrointestinal disorders SOC TOTAL	42747	19

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site bruise	9	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	2	0
Administration site joint movement impairment	2	0
Administration site joint pain	1	0
Administration site nerve damage	1	0
Administration site pain	21	0
Administration site rash	5	0
Administration site reaction	1	0
Administration site swelling	5	0
Administration site urticaria	2	0
Administration site warmth	2	0
Puncture site bruise	43	0
Puncture site pain	9	0
Puncture site reaction	1	0
Puncture site swelling	2	0
Vessel puncture site bruise	2	0
Vessel puncture site erythema	1	0
Vessel puncture site pain	1	0
<i>Adverse effect absent</i>		
No adverse event	9	0
<i>Application and instillation site reactions</i>		
Application site acne	2	0
Application site bruise	12	0
Application site burn	1	0
Application site dryness	2	0
Application site erythema	18	0
Application site haemorrhage	1	0
Application site hypoaesthesia	2	0
Application site irritation	1	0
Application site joint erythema	1	0
Application site joint pain	1	0
Application site mass	1	0
Application site odour	2	0
Application site pain	12	0
Application site pruritus	4	0
Application site rash	2	0
Application site reaction	1	0
Application site swelling	2	0
Application site vesicles	7	0
Application site warmth	1	0
Instillation site warmth	9	0
<i>Asthenic conditions</i>		
Asthenia	2451	0
Chronic fatigue syndrome	88	0
Decreased activity	10	0
Fatigue	26352	1
Malaise	5971	2

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Sluggishness	19	0
Body temperature altered		
Hyperthermia	7	0
Hyperthermia malignant	1	0
Hypothermia	27	0
Temperature regulation disorder	16	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	4	3
Cardiac death	3	2
Clinical death	1	1
Death	197	197
Sudden cardiac death	1	1
Sudden death	28	28
Febrile disorders		
Hyperpyrexia	10	0
Pyrexia	17033	0
Feelings and sensations NEC		
Chills	10577	0
Feeling abnormal	1862	0
Feeling cold	1384	0
Feeling drunk	83	0
Feeling hot	1316	0
Feeling jittery	34	0
Feeling of body temperature change	371	0
Feeling of relaxation	3	0
Hangover	85	0
Hunger	51	0
Sensation of blood flow	5	0
Sensation of foreign body	64	0
Sense of oppression	1	0
Temperature intolerance	56	0
Thirst	386	0
Thirst decreased	2	0
Fibrosis NEC		
Fibrosis	1	0
Gait disturbances		
Gait deviation	1	0
Gait disturbance	295	0
Gait inability	119	0
Loss of control of legs	29	0
General signs and symptoms NEC		

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Adhesion	2	0
Chronic disease	1	0
Concomitant disease progression	1	1
Condition aggravated	364	0
Crepitations	5	0
Crying	169	0
Deformity	2	0
Developmental delay	1	0
Discharge	12	0
Disease progression	2	0
Disease recurrence	32	0
Effusion	3	0
Energy increased	27	0
Exercise tolerance decreased	46	0
Exercise tolerance increased	2	0
Fat tissue increased	1	0
Foaming at mouth	3	0
General physical health deterioration	18	3
General symptom	3	0
Glassy eyes	8	0
High-pitched crying	3	0
Illness	2300	0
Induration	18	0
Influenza like illness	2710	0
Irritability postvaccinal	2	0
Local reaction	93	0
Moaning	4	0
Multiple organ dysfunction syndrome	13	5
Nonspecific reaction	2	0
Organ failure	4	2
Perforation	2	0
Peripheral swelling	4473	0
Physical deconditioning	2	0
Pre-existing condition improved	9	0
Prolapse	1	0
Screaming	24	0
Secretion discharge	27	0
Stenosis	1	0
Swelling	3605	0
Swelling face	992	0
Symptom recurrence	1	0
Terminal state	1	0
Tissue irritation	1	0
Tissue rupture	1	0
Unevaluable event	1	0
Healing abnormal NEC		
Impaired healing	7	0
Implant and catheter site reactions		
Catheter site pain	1	0
Implant site discolouration	2	0
Implant site pain	3	0
Implant site rash	1	0
Implant site reaction	1	0

Case Series Drug Analysis Print

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

Report Run Date: 26-May-2022

Data Lock Date: 25-May-2022 18:30:05

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Implant site swelling	2	0
Implant site urticaria	1	0
Implant site warmth	3	0
Inflammations		
Chronic inflammatory response syndrome	1	0
Foreign body reaction	1	0
Granuloma	1	0
Inflammation	668	0
Papillitis	1	0
Scar inflammation	3	0
Serositis	1	0
Soft tissue inflammation	1	0
Systemic inflammatory response syndrome	6	0
Infusion site reactions		
Infusion site coldness	1	0
Infusion site discolouration	1	0
Infusion site joint effusion	1	0
Infusion site joint pain	2	0
Infusion site mass	1	0
Infusion site nerve damage	1	0
Infusion site pain	5	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	38	0
Injection site bruising	73	0
Injection site coldness	1	0
Injection site cyst	3	0
Injection site discolouration	5	0
Injection site discomfort	10	0
Injection site eczema	1	0
Injection site erythema	445	0
Injection site extravasation	1	0
Injection site haematoma	2	0
Injection site haemorrhage	10	0
Injection site hypersensitivity	3	0
Injection site hypoaesthesia	17	0
Injection site indentation	10	0
Injection site induration	4	0
Injection site inflammation	50	0
Injection site injury	2	0
Injection site irritation	3	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	646	0
Injection site movement impairment	1	0
Injection site muscle weakness	1	0

Case Series Drug Analysis Print

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Report Run Date: 26-May-2022

Data Lock Date: 25-May-2022 18:30:05

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Injection site necrosis	4	0
Injection site nerve damage	1	0
Injection site nodule	1	0
Injection site oedema	19	0
Injection site pain	3223	0
Injection site pallor	1	0
Injection site paraesthesia	15	0
Injection site pruritus	249	0
Injection site rash	206	0
Injection site reaction	58	0
Injection site scab	4	0
Injection site scar	4	0
Injection site swelling	352	0
Injection site urticaria	36	0
Injection site vesicles	10	0
Injection site warmth	211	0
Interactions		
Alcohol interaction	5	0
Drug interaction	32	0
Drug-device interaction	3	0
Inhibitory drug interaction	3	0
Mass conditions NEC		
Cyst	59	0
Mass	91	0
Nodule	45	0
Mucosal findings abnormal		
Mucosa vesicle	1	0
Mucosal dryness	1	0
Mucosal haemorrhage	10	0
Mucosal inflammation	3	0
Mucosal ulceration	1	0
Oedema mucosal	2	0
Polyp	5	0
Necrosis NEC		
Fat necrosis	4	0
Necrosis	5	0
Oedema NEC		
Face oedema	37	0
Generalised oedema	7	0
Localised oedema	21	0
Oedema	95	0
Oedema peripheral	105	0
Pain and discomfort NEC		
Axillary pain	4079	0
Breakthrough pain	1	0
Chest discomfort	2100	0
Chest pain	6924	0
Discomfort	590	0
Facial discomfort	21	0
Facial pain	242	0
First bite syndrome	1	0
Inflammatory pain	21	0
Non-cardiac chest pain	36	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Pain	10190	0
Suprapubic pain	1	0
Tenderness	745	0
Visceral pain	2	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	59	1
Adverse food reaction	3	0
Adverse reaction	2	0
Drug ineffective	562	0
Drug intolerance	4	0
Drug resistance	1	0
Immediate post-injection reaction	5	0
Inadequate analgesia	9	0
No reaction on previous exposure to drug	27	0
Product intolerance	1	0
Therapeutic product effect decreased	2	0
Therapeutic product effect delayed	2	0
Therapeutic product effect increased	1	0
Therapeutic product ineffective	3	0
Therapeutic response decreased	2	0
Therapeutic response unexpected	99	0
Therapy non-responder	1	0
Treatment failure	12	0
Vaccination failure	120	0
Trophic disorders		
Abnormal organ growth	1	0
Atrophy	3	0
Calcinosis	2	0
Hyperplasia	1	0
Hypertrophy	1	0
Ulcers NEC		
Ulcer	39	0
Ulcer haemorrhage	1	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	25	0
Shoulder injury related to vaccine administration	71	0
Vaccination site anaesthesia	1	0
Vaccination site bruising	144	0
Vaccination site coldness	4	0
Vaccination site cyst	7	0
Vaccination site dermatitis	2	0
Vaccination site discharge	1	0
Vaccination site discolouration	17	0
Vaccination site discomfort	54	0
Vaccination site dryness	2	0
Vaccination site eczema	1	0
Vaccination site erythema	685	0
Vaccination site granuloma	5	0
Vaccination site haematoma	2	0
Vaccination site haemorrhage	34	0
Vaccination site hypersensitivity	5	0
Vaccination site hypoaesthesia	20	0
Vaccination site induration	82	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site inflammation	66	0
Vaccination site injury	1	0
Vaccination site irritation	16	0
Vaccination site joint discomfort	3	0
Vaccination site joint erythema	12	0
Vaccination site joint inflammation	1	0
Vaccination site joint movement impairment	22	0
Vaccination site joint pain	36	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	340	0
Vaccination site movement impairment	97	0
Vaccination site necrosis	1	0
Vaccination site nerve damage	1	0
Vaccination site nodule	6	0
Vaccination site oedema	3	0
Vaccination site pain	2425	0
Vaccination site papule	2	0
Vaccination site paraesthesia	10	0
Vaccination site phlebitis	1	0
Vaccination site photosensitivity reaction	1	0
Vaccination site pruritus	190	0
Vaccination site rash	155	0
Vaccination site reaction	37	0
Vaccination site scab	3	0
Vaccination site scar	3	0
Vaccination site swelling	659	0
Vaccination site thrombosis	1	0
Vaccination site ulcer	3	0
Vaccination site urticaria	11	0
Vaccination site vesicles	13	0
Vaccination site warmth	305	0
<i>Vascular complications associated with device</i>		
Vascular stent thrombosis	1	0
<i>Withdrawal and rebound effects</i>		
Drug withdrawal syndrome	4	0
Withdrawal syndrome	48	0
General disorders SOC TOTAL	122739	247

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	19	0
Cholangitis	1	0
<i>Cholecystitis and cholelithiasis</i>		
Cholecystitis	4	0
Cholecystitis acute	2	0
Cholelithiasis	13	0
<i>Cholestasis and jaundice</i>		
Cholestasis	2	0
Cholestasis of pregnancy	1	0
Jaundice	29	0
Jaundice cholestatic	10	0
Ocular icterus	2	0
<i>Gallbladder disorders NEC</i>		
Gallbladder disorder	4	0
Gallbladder enlargement	2	0
<i>Hepatic and hepatobiliary disorders NEC</i>		
Hepatic cyst	1	0
Hepatic lesion	1	0
Liver disorder	17	0
<i>Hepatic enzymes and function abnormalities</i>		
Hepatic function abnormal	9	0
Hypertransaminasaemia	5	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	4	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	9	0
Portosplenomesenteric venous thrombosis	1	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	37	0
Hepatomegaly	7	0
Liver tenderness	3	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Autoimmune hepatitis	16	0
Drug-induced liver injury	3	0
Hepatic steatosis	5	0
Hepatitis	19	0
Hepatitis acute	4	0
Hepatitis toxic	1	0
Hepatotoxicity	1	0
Immune-mediated hepatic disorder	1	0
Liver injury	29	0
<i>Obstructive bile duct disorders (excl neoplasms)</i>		
Bile duct stenosis	1	0
Hepatic disorders SOC TOTAL	277	1

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MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Immune system disorders		
<i>Acute and chronic sarcoidosis</i>		
Loefgren syndrome	1	0
Sarcoidosis	20	0
<i>Allergic conditions NEC</i>		
Allergic oedema	19	0
Allergy to animal	2	0
Allergy to arthropod bite	7	0
Allergy to arthropod sting	2	0
Allergy to metals	3	0
Allergy to sting	1	0
Hypersensitivity	1179	0
Infusion related hypersensitivity reaction	3	0
Mite allergy	2	0
Multiple allergies	17	0
Serum sickness	3	0
Serum sickness-like reaction	6	0
Type I hypersensitivity	1	0
Type III immune complex mediated reaction	4	0
Type IV hypersensitivity reaction	7	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergic reaction to excipient	7	0
Allergy to chemicals	7	0
Allergy to vaccine	50	0
Contrast media reaction	2	0
Drug hypersensitivity	43	0
Food allergy	46	0
Milk allergy	3	0
Oral allergy syndrome	3	0
Polymers allergy	1	0
Reaction to colouring	1	0
Reaction to excipient	11	0
Reaction to preservatives	5	0
Rubber sensitivity	1	0
Smoke sensitivity	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	568	2
Anaphylactic shock	67	0
Anaphylactoid reaction	25	0
Anaphylactoid shock	4	0
<i>Atopic disorders</i>		
Atopy	3	0
Seasonal allergy	117	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	61	0
<i>Autoinflammatory diseases</i>		
Autoinflammatory disease	1	0
<i>Immune and associated conditions NEC</i>		
Anamnestic reaction	1	0
Bacille Calmette-Guerin scar reactivation	67	0
Cytokine release syndrome	1	0
Cytokine storm	1	0
Decreased immune responsiveness	4	0
Graft versus host disease	2	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Immune system disorders		
Immune system disorders cont'd		
Haemophagocytic lymphohistiocytosis	4	0
Immune reconstitution inflammatory syndrome	1	0
Immune system disorder	40	0
Immune-mediated adverse reaction	7	0
Immunisation reaction	58	0
Multisystem inflammatory syndrome in children	6	0
Sensitisation	9	0
Systemic immune activation	2	0
Immunodeficiency disorders NEC		
Hypogammaglobulinaemia	1	0
Immunodeficiency	7	0
Immunosuppression	4	0
Transplant rejections		
Corneal graft rejection	10	0
Kidney transplant rejection	2	0
Solid organ transplant rejection	1	0
Transplant rejection	2	0
Immune system disorders SOC TOTAL	2534	2

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MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Abdominal abscess	3	0
Abdominal infection	2	0
Anal abscess	3	0
Anorectal infection	1	0
Appendicitis	51	0
Appendicitis perforated	7	0
Complicated appendicitis	1	0
Diarrhoea infectious	1	0
Diverticulitis	19	0
Dysentery	1	0
Gastric infection	2	0
Gastroenteritis	34	0
Gastrointestinal infection	1	0
Mesenteric abscess	1	0
Peritonitis	3	1
Rectal abscess	1	0
<i>Adenoviral infections</i>		
Adenoviral conjunctivitis	1	0
Adenovirus infection	1	0
<i>Aspergillus infections</i>		
Bronchopulmonary aspergillosis	1	0
<i>Bacterial infections NEC</i>		
Abscess bacterial	2	0
Administration site cellulitis	2	0
Arthritis bacterial	4	0
Bacterial colitis	1	0
Bacterial diarrhoea	1	0
Bacterial infection	17	0
Bacterial sepsis	1	0
Bacterial vaginosis	2	0
Cellulitis	205	0
Cellulitis orbital	2	0
Conjunctivitis bacterial	1	0
Ear infection bacterial	1	0
External ear cellulitis	1	0
Folliculitis	20	0
Gangrene	2	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	5	0
Sinusitis bacterial	2	0
Skin bacterial infection	4	0
Small intestine gangrene	1	0
Tonsillitis bacterial	3	0
Urinary tract infection bacterial	1	0
Vaccination site cellulitis	21	0
Zoonotic bacterial infection	1	1

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Reaction Name	Total	Fatal
Infections Infections cont'd		
<i>Bartonella infections</i>		
Cat scratch disease	1	0
<i>Bone and joint infections</i>		
Abscess jaw	1	0
Arthritis infective	3	0
Intervertebral discitis	1	0
Osteomyelitis	3	0
Osteomyelitis acute	2	0
Osteomyelitis chronic	1	0
<i>Bordetella infections</i>		
Pertussis	1	0
<i>Borrelial infections</i>		
Lyme disease	4	0
Relapsing fever	1	0
<i>Breast infections</i>		
Breast abscess	3	0
Mastitis	87	0
<i>Caliciviral infections</i>		
Gastroenteritis norovirus	3	0
<i>Campylobacter infections</i>		
Campylobacter gastroenteritis	1	0
Campylobacter infection	1	0
<i>Candida infections</i>		
Anal candidiasis	3	0
Balanitis candida	1	0
Candida infection	75	0
Oral candidiasis	43	0
Respiratory moniliasis	1	0
Skin candida	2	0
Systemic candida	1	0
Urinary tract candidiasis	1	0
Vulvovaginal candidiasis	56	0
<i>Cardiac infections</i>		
Cardiac infection	1	0
Cardiac valve vegetation	1	0
Endocarditis	2	0
Myocarditis infectious	1	0
Myocarditis septic	1	0
Pericarditis infective	4	0
<i>Central nervous system and spinal infections</i>		
Brain abscess	2	0
CNS ventriculitis	1	0
Cavernous sinus thrombosis	1	0
Encephalitis	23	0
Encephalomyelitis	1	0
Meningitis	11	0
Meningitis aseptic	3	0
Myelitis	15	0
Subdural abscess	1	0
<i>Clostridia infections</i>		
Clostridium difficile infection	2	0
<i>Coronavirus infections</i>		
Asymptomatic COVID-19	21	0

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Reaction Name	Total	Fatal
Infections Infections cont'd		
COVID-19	2916	42
COVID-19 pneumonia	54	15
Coronavirus infection	7	0
Coronavirus pneumonia	1	0
Post-acute COVID-19 syndrome	13	0
Severe acute respiratory syndrome	4	0
Suspected COVID-19	104	4
<i>Corynebacteria infections</i>		
Diphtheria	2	0
<i>Coxiella infections</i>		
Q fever	13	0
<i>Cytomegaloviral infections</i>		
Cytomegalovirus colitis	1	0
Cytomegalovirus infection	2	0
Cytomegalovirus syndrome	1	0
<i>Dental and oral soft tissue infections</i>		
Abscess oral	6	0
Gingival abscess	1	0
Gingivitis	15	0
Oral infection	1	0
Parotitis	15	0
Pericoronitis	3	0
Periodontitis	1	0
Pulpitis dental	2	0
Sialoadenitis	3	0
Tongue abscess	1	0
Tooth abscess	8	0
Tooth infection	10	0
<i>Ear infections</i>		
Ear infection	105	0
Labyrinthitis	116	0
Mastoiditis	3	0
Otitis externa	7	0
Otitis media	4	0
Otitis media acute	1	0
Otitis media chronic	5	0
<i>Ectoparasitic infestations</i>		
Acarodermatitis	6	0
Bed bug infestation	1	0
Demodicidosis	1	0
Lice infestation	1	0
<i>Epstein-Barr viral infections</i>		
Epstein-Barr virus infection	5	0
Epstein-Barr virus infection reactivation	2	0
Infectious mononucleosis	31	0
<i>Escherichia infections</i>		
Escherichia bacteraemia	1	0
Escherichia infection	1	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	88	0
Eye abscess	1	0
Eye infection	30	0
Eye infection intraocular	1	0

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Eyelid boil	2	0
Eyelid infection	2	0
Hordeolum	30	0
Keratouveitis	1	0
Orbital infection	1	0
Periorbital infection	2	0
Female reproductive tract infections		
Bartholin's abscess	1	0
Bartholinitis	1	0
Endometritis	3	0
Fallopian tube abscess	1	0
Funisitis	1	0
Ovarian abscess	1	0
Pelvic inflammatory disease	2	0
Vaginal infection	3	0
Vulval abscess	1	0
Vulvitis	1	0
Fungal infections NEC		
Fungal infection	20	0
Fungal skin infection	5	0
Mycotoxicosis	1	0
Myocarditis mycotic	2	0
Onychomycosis	3	0
Oral fungal infection	2	0
Pneumonia fungal	2	0
Severe asthma with fungal sensitisation	2	0
Vulvovaginal mycotic infection	8	0
Helminthic infections NEC		
Helminthic infection	1	0
Hepatitis virus infections		
Hepatitis A	2	0
Hepatitis E	1	0
Hepatobiliary and spleen infections		
Biliary sepsis	3	0
Cholecystitis infective	2	0
Hepatic infection	1	0
Liver abscess	1	0
Herpes viral infections		
Eczema herpeticum	4	0
Genital herpes	97	0
Genital herpes simplex	6	0
Genital herpes zoster	1	0
Herpes ophthalmic	3	0
Herpes simplex	35	0
Herpes simplex encephalitis	1	1
Herpes simplex reactivation	3	0
Herpes virus infection	13	0
Herpes zoster	1657	0
Herpes zoster disseminated	1	0
Herpes zoster meningoencephalitis	1	0
Herpes zoster oticus	17	0
Herpes zoster reactivation	5	0
Meningitis herpes	1	0

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Nasal herpes	5	0
Ophthalmic herpes simplex	3	0
Ophthalmic herpes zoster	5	0
Oral herpes	345	0
Varicella	37	0
Varicella zoster virus infection	6	0
<i>Infections NEC</i>		
Abscess	40	0
Abscess limb	9	0
Abscess soft tissue	1	0
Catheter site infection	1	0
Device related infection	1	0
Genital abscess	2	0
Groin abscess	2	0
Groin infection	1	0
Infected bite	3	0
Infected cyst	2	0
Infection	291	0
Infection susceptibility increased	2	0
Injection site abscess	1	0
Injection site infection	5	0
Localised infection	41	0
Lymph gland infection	19	0
Lymph node abscess	7	0
Opportunistic infection	1	0
Pathogen resistance	1	0
Purulent discharge	1	0
Respiratory tract infection	15	0
Superinfection	1	0
Vaccination site abscess	12	0
Vaccination site infection	13	0
Vaccine breakthrough infection	23	0
Vestibulitis	2	0
Wound infection	2	0
<i>Infectious transmissions</i>		
Nosocomial infection	1	0
Secondary transmission	8	0
Vaccine virus shedding	1	0
<i>Influenza viral infections</i>		
H1N1 influenza	1	0
Influenza	1815	0
<i>Klebsiella infections</i>		
Klebsiella infection	1	0
<i>Lower respiratory tract and lung infections</i>		
Bronchitis	30	0
Infectious pleural effusion	1	0
Lower respiratory tract infection	313	10
Pneumonia	187	17
Pneumonia aspiration	11	7
Sputum purulent	1	0
<i>Male reproductive tract infections</i>		
Epididymitis	10	0
Orchitis	6	0

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Prostate infection	2	0
<i>Molluscum contagiosum viral infections</i>		
Molluscum contagiosum	1	0
<i>Mumps viral infections</i>		
Mumps	9	0
<i>Muscle and soft tissue infections</i>		
Abscess neck	1	0
Infective tenosynovitis	1	0
Necrotising fasciitis	2	0
Psoas abscess	1	0
Soft tissue infection	2	0
<i>Neisseria infections</i>		
Gonorrhoea	1	0
Meningococcal bacteraemia	1	0
Meningococcal infection	1	0
<i>Orthopox viral infections</i>		
Smallpox	1	0
Vaccinia virus infection	2	0
<i>Plasmodia infections</i>		
Malaria	2	0
<i>Pneumocystis infections</i>		
Pneumocystis jirovecii pneumonia	2	0
<i>Pseudomonal infections</i>		
Pseudomonas infection	1	0
<i>Retroviral infections</i>		
Acquired immunodeficiency syndrome	1	0
HIV infection	2	0
Persistent generalised lymphadenopathy	1	0
<i>Rhinoviral infections</i>		
Rhinovirus infection	1	0
<i>Rotaviral infections</i>		
Gastroenteritis rotavirus	1	0
<i>Rubeola viral infections</i>		
Measles	5	0
<i>Salmonella infections</i>		
Typhoid fever	1	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Neutropenic sepsis	4	1
Sepsis	74	11
Sepsis syndrome	2	0
Septic rash	3	0
Septic shock	6	1
Urosepsis	6	0
<i>Skin structures and soft tissue infections</i>		
Abscess sweat gland	1	0
Acne pustular	1	0
Blister infected	1	0
Dermatitis infected	3	0
Eczema infected	1	0
Impetigo	11	0
Infected skin ulcer	4	0
Injection site pustule	3	0
Nail infection	2	0

Case Series Drug Analysis Print

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

Report Run Date: 26-May-2022

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MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Pustule	21	0
Pyoderma	1	0
Rash pustular	12	0
Skin infection	34	0
Subcutaneous abscess	12	0
Sweat gland infection	1	0
Vaccination site pustule	4	0
<i>Staphylococcal infections</i>		
Furuncle	46	1
Pneumonia staphylococcal	1	0
Septic arthritis staphylococcal	1	0
Staphylococcal abscess	1	0
Staphylococcal infection	5	0
Staphylococcal sepsis	1	0
<i>Streptococcal infections</i>		
Meningitis pneumococcal	1	0
Pharyngitis streptococcal	8	0
Pneumonia pneumococcal	1	0
Scarlet fever	1	0
Streptococcal abscess	1	0
Streptococcal endocarditis	1	0
Streptococcal infection	2	0
Streptococcal sepsis	1	0
<i>Tinea infections</i>		
Body tinea	6	0
Tinea capitis	1	0
Tinea infection	1	0
Tinea pedis	3	0
Tinea versicolour	4	0
<i>Toxoplasma infections</i>		
Toxoplasmosis	1	0
<i>Treponema infections</i>		
Syphilis	2	0
<i>Trypanosomal infections</i>		
African trypanosomiasis	4	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	5	0
Chronic sinusitis	6	0
Croup infectious	1	0
Epiglottitis	1	0
Laryngitis	35	0
Nasopharyngitis	1194	1
Peritonsillar abscess	6	0
Pharyngitis	40	0
Rhinitis	58	0
Sinusitis	210	0
Tonsillitis	146	0

Case Series Drug Analysis Print

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

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MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Tracheitis	5	0
Tracheostomy infection	1	0
Upper respiratory tract infection	12	0
Urinary tract infections		
Cystitis	86	0
Kidney infection	56	0
Pyelonephritis	3	0
Urethritis	2	0
Urinary tract infection	224	0
Vascular infections		
Haematoma infection	1	0
Infected lymphocele	2	0
Infusion site infection	1	0
Lymphangitis	14	0
Viral infections NEC		
Arthritis viral	1	0
Conjunctivitis viral	2	0
Ear infection viral	1	0
Encephalitis viral	6	1
Eye infection viral	2	0
Gastroenteritis viral	34	0
Gianotti-Crosti syndrome	1	0
Hepatitis viral	4	0
Meningitis viral	9	0
Meningoencephalitis viral	1	0
Oral viral infection	1	0
Pleurisy viral	2	0
Pneumonia viral	5	2
Post viral fatigue syndrome	63	0
Sweating fever	128	0
Vestibular neuronitis	35	0
Viral diarrhoea	2	0
Viral infection	69	0
Viral labyrinthitis	4	0
Viral myocarditis	5	0
Viral pericarditis	3	0
Viral pharyngitis	24	0
Viral rash	69	0
Viral sinusitis	1	0
Viral tonsillitis	2	0
Infections SOC TOTAL	12601	116

Case Series Drug Analysis Print

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

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MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Injuries		
<i>Abdominal and gastrointestinal injuries NEC</i>		
Gallbladder injury	1	0
Gingival injury	1	0
Liver contusion	1	0
Mouth injury	3	0
Oral contusion	5	0
Oral mucosal scar	1	0
Palate injury	1	0
Rectal injury	1	0
Splenic rupture	7	0
Tongue injury	2	0
Tooth fracture	1	0
Tooth injury	1	0
<i>Accidental exposures to product</i>		
Accidental exposure to product	21	0
<i>Anaesthetic and allied procedural complications</i>		
Airway complication of anaesthesia	2	0
Delayed recovery from anaesthesia	3	0
<i>Atmospheric pressure injuries</i>		
Barotitis media	1	0
Barotrauma	2	0
Hypobarism	2	0
<i>Bone and joint injuries NEC</i>		
Bursa injury	3	0
Joint injury	12	0
Meniscus injury	2	0
<i>Cardiac and vascular procedural complications</i>		
Ischaemic contracture of the left ventricle	1	0
Shunt blood flow excessive	1	0
Vascular pseudoaneurysm	1	0
<i>Cardiovascular injuries</i>		
Vascular injury	9	0
<i>Cerebral injuries NEC</i>		
Brain contusion	4	0
Brain herniation	2	0
Concussion	5	0
Craniocerebral injury	1	0
Subarachnoid haematoma	1	0
Subdural haematoma	6	0
Subdural haemorrhage	7	0
Traumatic intracranial haemorrhage	1	1
<i>Chemical injuries</i>		
Chemical burn	1	0
Chemical burn of skin	9	0
Chemical cystitis	2	0
<i>Chest and respiratory tract injuries NEC</i>		
Bronchial injury	1	0
Chest crushing	15	0
Foreign body in throat	2	0
Traumatic lung injury	1	0
<i>Conditions caused by cold</i>		
Chillblains	75	0
Cold shock response	1	0

Case Series Drug Analysis Print

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

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Frostbite	1	0
Cranial nerve injuries		
IIIrd nerve injury	1	0
Vth nerve injury	1	0
Ear injuries NEC		
Deafness traumatic	1	0
Ear injury	2	0
Exposures associated with pregnancy, delivery and lactation		
Exposure during pregnancy	10	0
Exposure via breast milk	155	0
Foetal exposure during pregnancy	72	0
Foetal exposure timing unspecified	1	0
Maternal exposure before pregnancy	31	0
Maternal exposure during breast feeding	2022	0
Maternal exposure during pregnancy	1096	0
Maternal exposure timing unspecified	15	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	18	0
Eye injury	33	0
Foreign body in eye	4	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		
Fracture	3	0
Joint dislocation	4	0
Multiple fractures	1	0
Gastrointestinal and hepatobiliary procedural complications		
Diversion colitis	1	0
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		

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Ankle fracture	1	0
Atypical femur fracture	1	0
Clavicle fracture	27	0
Femoral neck fracture	1	0
Femur fracture	1	0
Fibula fracture	1	0
Hip fracture	2	0
Lower limb fracture	1	0
Tibia fracture	1	0
Upper limb fracture	1	0
Wrist fracture	1	0
Medication errors, product use errors and issues NEC		
Circumstance or information capable of leading to medication error	2	0
Dose calculation error	1	0
Inadequate aseptic technique in use of product	1	0
Medication error	88	0
Prescription drug used without a prescription	3	0
Product use complaint	2	0
Product use issue	34	0
Vaccination error	6	0
Wrong dose	4	0
Wrong drug	11	0
Wrong schedule	1	0
Wrong technique in product usage process	10	0
Muscle, tendon and ligament injuries		
Epicondylitis	25	0
Ligament injury	2	0
Ligament sprain	11	0
Mallet finger	1	0
Muscle hernia	1	0
Muscle injury	43	0
Muscle rupture	10	0
Muscle strain	38	0
Post-traumatic neck syndrome	3	0
Tendon injury	7	0
Tendon rupture	26	0
Musculoskeletal procedural complications		
Periprosthetic osteolysis	1	0
Post laminectomy syndrome	1	0
Nerve injuries NEC		
Nerve injury	122	0
Neurological and psychiatric procedural complications		
Post lumbar puncture syndrome	1	0
Post procedural stroke	1	0
Procedural dizziness	14	0
Non-occupational environmental exposures		
Exposure to extreme temperature	2	0
Non-site specific injuries NEC		
Accident	2	0
Animal scratch	1	0
Arthropod bite	11	0
Arthropod sting	6	0
Bite	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Bone contusion	2	0
Crush injury	1	0
Electric shock	20	0
Fall	222	0
Foreign body	6	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	3	0
Wound secretion	7	0
<i>Non-site specific procedural complications</i>		
Administration related reaction	1	0
Anastomotic leak	1	0
Incision site pain	3	0
Infusion related reaction	8	0
Injection related reaction	68	0
Post procedural complication	5	0
Post procedural erythema	1	0
Post procedural inflammation	1	0
Post procedural pruritus	1	0
Procedural pain	4	0
Seroma	1	0
<i>Occupational exposures</i>		
Occupational exposure to SARS-CoV-2	1	0
Occupational exposure to product	1	0
<i>Off label uses</i>		
Off label use	506	0
<i>Overdoses NEC</i>		
Intentional overdose	1	0
Overdose	56	0
<i>Pathways and sources of exposure</i>		
Exposure via contaminated device	1	0
Exposure via unknown route	1	0
<i>Pelvic fractures and dislocations</i>		
Pelvic fracture	1	0
<i>Peripheral nerve injuries</i>		
Axillary nerve injury	1	0
Brachial plexus injury	1	0
Radial nerve injury	2	0
Sciatic nerve injury	2	0
Ulnar nerve injury	6	0
<i>Poisoning and toxicity</i>		
Alcohol poisoning	1	0
Poisoning	14	0
Toxicity to various agents	5	0
<i>Product administration errors and issues</i>		
Accidental overdose	8	0
Contraindicated product administered	3	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Injuries		
Injuries cont'd		
Duplicate therapy error	1	0
Expired product administered	14	0
Inappropriate schedule of product administration	743	0
Incomplete course of vaccination	2	0
Incorrect dose administered	65	0
Incorrect drug administration rate	1	0
Incorrect product formulation administered	2	0
Incorrect route of product administration	12	0
Lack of vaccination site rotation	1	0
Poor quality product administered	5	0
Product administered at inappropriate site	26	0
Product administered to patient of inappropriate age	3	0
Product administration error	22	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	2	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	4	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
Product storage errors and issues in the product use system		
Product storage error	1	0
Radiation injuries		
Sunburn	24	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
Uterine rupture	1	0
Reproductive tract and breast procedural complications		
Failed in vitro fertilisation	1	0
Site specific injuries NEC		
Back injury	4	0
Face crushing	3	0
Face injury	1	0
Head injury	36	0
Limb crushing injury	4	0
Limb injury	209	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Nasal injury	2	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	1400	0
Hair injury	2	0
Nail avulsion	1	0
Scar	37	0
Scratch	9	0
Skin abrasion	7	0
Skin injury	5	0
Skin laceration	4	0
Skin pressure mark	1	0
Skin wound	3	0
Splinter	1	0
Subcutaneous haematoma	2	0
Skin procedural complications		
Dermal filler overcorrection	1	0
Recall phenomenon	1	0
Skin procedural complication	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	4	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	6	0
Burns second degree	3	0
Burns third degree	1	0
Cold burn	1	0
Thermal burn	28	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
Injuries SOC TOTAL	8101	1

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Reaction Name	Total	Fatal
Investigations		
<i>Adrenal cortex tests</i>		
Cortisol decreased	5	0
<i>Adrenal medulla tests</i>		
Epinephrine	1	0
Epinephrine abnormal	1	0
Epinephrine increased	1	0
<i>Auditory and vestibular diagnostic procedures</i>		
Acoustic stimulation tests	5	0
Audiogram abnormal	1	0
Weber tuning fork test abnormal	1	0
<i>Autoimmunity analyses</i>		
Antineutrophil cytoplasmic antibody positive	1	0
Antinuclear antibody	3	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
Rheumatoid factor increased	3	0
Rheumatoid factor positive	1	0
<i>Bacteria identification and serology (excl mycobacteria)</i>		
Bacterial test positive	1	0
<i>Blood counts NEC</i>		
Full blood count	8	0
Full blood count abnormal	3	0
<i>Blood gas and acid base analyses</i>		
Acid base balance abnormal	1	0
Blood lactic acid	4	0
Blood lactic acid decreased	1	0
Blood lactic acid increased	5	0
Blood pH	7	0
Blood pH abnormal	1	0
Blood pH increased	12	0
Oxygen consumption	1	0
Oxygen consumption decreased	2	0
Oxygen saturation	12	0
Oxygen saturation abnormal	2	0
Oxygen saturation decreased	104	0
PCO2 increased	1	0
PO2 decreased	1	0
Venous oxygen saturation decreased	1	0
<i>Blood grouping and cross-matching analyses</i>		
Rhesus antigen positive	1	0
<i>Bone marrow and immune tissue histopathology procedures</i>		
Aspiration bone marrow	1	0
Biopsy lymph gland	2	0
<i>Bone marrow and immune tissue imaging procedures</i>		
Lymph nodes scan abnormal	1	0
Scan lymph nodes	4	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose	12	0
Blood glucose abnormal	15	0
Blood glucose decreased	38	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Blood glucose fluctuation	17	0
Blood glucose increased	115	0
Blood glucose normal	1	0
Glycosylated haemoglobin increased	1	0
Cardiac auscultatory investigations		
Cardiac murmur	50	0
Heart sounds	10	0
Heart sounds abnormal	6	0
Cardiac function diagnostic procedures		
Cardiac monitoring	1	0
Cardiac output	1	0
Central venous pressure	1	0
Echocardiogram	1	0
Ejection fraction decreased	3	0
Myocardial strain imaging	2	0
Right atrial volume abnormal	1	0
Stroke volume decreased	1	0
Cardiac imaging procedures		
Catheterisation cardiac	1	0
Magnetic resonance imaging heart	1	0
Scan myocardial perfusion abnormal	1	0
Cell marker analyses		
Carbohydrate antigen 15-3 increased	1	0
Carcinoembryonic antigen increased	1	0
HLA-B*27 positive	1	0
Prostatic specific antigen increased	4	0
Central nervous system imaging procedures		
Computerised tomogram head	11	0
Magnetic resonance imaging head	13	0
Magnetic resonance imaging head abnormal	2	0
Cerebrospinal fluid tests (excl microbiology)		
CSF pressure	1	0
CSF protein increased	1	0
Chemistry analyses NEC		
Histamine abnormal	1	0
Histamine level	1	0
Histamine level increased	2	0
Inflammatory marker decreased	1	0
Inflammatory marker increased	5	0
Inflammatory marker test	1	0
Renin	1	0
Cholesterol analyses		
Blood cholesterol increased	14	0
Remnant-like lipoprotein particles	4	0
Coagulation and bleeding analyses		
ADAMTS13 activity decreased	1	0
Activated partial thromboplastin time prolonged	15	0
Activated partial thromboplastin time shortened	1	0
Bleeding time	1	0
Bleeding time abnormal	2	0
Bleeding time prolonged	11	0
Blood thromboplastin	1	0
Clot retraction	1	1

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Coagulation factor VIII level decreased	1	0
Coagulation time prolonged	9	0
Coagulation time shortened	4	0
Fibrin D dimer increased	26	0
International normalised ratio abnormal	9	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
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	12	0
Electrocardiogram ST-T segment abnormal	2	0
Electrocardiogram T wave inversion	6	0
Electrocardiogram abnormal	25	0
Electrocardiogram change	1	0
Electrocardiogram normal	3	0
Electrocardiogram repolarisation abnormality	1	0
QRS axis abnormal	1	0
Endocrine analyses and imaging NEC		
Hormone level abnormal	87	0
Faecal analyses NEC		
Faecal calprotectin	2	0
Faecal calprotectin increased	4	0
Fertility analyses		
Infertility tests	1	0
Semen analysis abnormal	1	0
Semen volume increased	1	0
Sperm concentration	2	0
Sperm concentration decreased	2	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
Gene analyses		

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
EGFR status assay	1	0
<i>Haematological analyses NEC</i>		
Blood viscosity abnormal	1	0
Blood viscosity decreased	1	0
Blood viscosity increased	2	0
Plasma viscosity	1	0
Plasma viscosity abnormal	1	0
Red blood cell sedimentation rate increased	8	0
<i>Heart rate and pulse investigations</i>		
Carotid pulse	2	0
Carotid pulse abnormal	1	0
Heart rate	602	0
Heart rate abnormal	82	0
Heart rate decreased	109	0
Heart rate increased	1216	0
Heart rate irregular	304	0
Heart rate normal	1	0
Heart rate variability decreased	1	0
Heart rate variability increased	1	0
Maximum heart rate	5	0
Maximum heart rate increased	2	0
Pulse abnormal	24	0
Pulse absent	1	0
Pulse pressure increased	3	0
Radial pulse abnormal	1	0
Sinus rhythm	9	0
<i>Hepatobiliary function diagnostic procedures</i>		
Alanine aminotransferase increased	29	0
Aspartate aminotransferase	1	0
Aspartate aminotransferase abnormal	1	0
Aspartate aminotransferase increased	2	0
Blood bilirubin increased	7	0
Gamma-glutamyltransferase	2	0
Gamma-glutamyltransferase increased	5	0
Hepatic enzyme	1	0
Hepatic enzyme increased	10	0
Liver function test	1	0
Liver function test abnormal	36	0
Liver function test increased	30	0
<i>Hepatobiliary imaging procedures</i>		
Computerised tomogram liver	1	0
Liver scan	1	0
<i>Imaging procedures NEC</i>		
Computerised tomogram	4	0
Magnetic resonance imaging	6	0
Magnetic resonance imaging abnormal	1	0
Scan	2	0
X-ray	2	0
<i>Immune response protein analyses NEC</i>		
Cytokine test	1	0
<i>Immunoglobulin analyses</i>		
Blood immunoglobulin E increased	2	0
Blood immunoglobulin G increased	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Blood immunoglobulin M	1	0
Blood immunoglobulin M increased	2	0
<i>Immunology analyses NEC</i>		
Antibody test	4	0
Antibody test positive	1	0
Immunology test	14	0
<i>Immunology skin tests NEC</i>		
Allergy alert test	2	0
Allergy alert test positive	1	0
Skin test positive	2	0
<i>Investigations NEC</i>		
Blood test	27	0
Blood test abnormal	49	0
Blood test normal	1	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
<i>Metabolism tests NEC</i>		
Blood ketone body	3	0
Blood ketone body increased	1	0
Blood ketone body present	1	0
Blood uric acid increased	3	0
Brain natriuretic peptide increased	1	0
N-terminal prohormone brain natriuretic peptide increased	1	0
Ubiquinone	1	0
Urine ketone body	1	0
Urine ketone body present	1	0
<i>Microbiology and serology tests NEC</i>		
Culture negative	1	0
Culture urine	1	0
Nasopharyngeal swab	1	0
Vaccine induced antibody absent	1	0
<i>Mineral and electrolyte analyses</i>		
Blood calcium increased	1	0
Blood copper increased	1	0
Blood iron	4	0
Blood iron decreased	14	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	5	0
Blood potassium increased	3	0
Blood sodium decreased	11	0
Serum ferritin	2	0
Serum ferritin abnormal	1	0
Serum ferritin decreased	5	0
Serum ferritin increased	3	0
Sweat test	2	0

Case Series Drug Analysis Print

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

Report Run Date: 26-May-2022

Data Lock Date: 25-May-2022 18:30:05

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Urine copper	2	0
<i>Musculoskeletal and soft tissue histopathology procedures</i>		
Biopsy bone	1	0
<i>Musculoskeletal and soft tissue imaging procedures</i>		
Skull X-ray	6	0
<i>Musculoskeletal and soft tissue tests NEC</i>		
Swollen joint count	1	0
Swollen joint count increased	1	0
<i>Mycobacteria identification and serology</i>		
Tuberculin test positive	1	0
<i>Neurologic diagnostic procedures</i>		
Balance test	1	0
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
Nerve conduction studies	1	0
Pain threshold decreased	1	0
Sensory level	2	0
Temperature perception test abnormal	1	0
Temperature perception test increased	1	0
<i>Ophthalmic function diagnostic procedures</i>		
Corneal reflex decreased	1	0
Intraocular pressure increased	9	0
Intraocular pressure test	3	0
Pupil dilation procedure	1	0
Visual acuity tests	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature	299	0
Body temperature abnormal	55	0
Body temperature decreased	48	0
Body temperature fluctuation	69	0
Body temperature increased	539	0
Body temperature normal	1	0
Breath sounds abnormal	2	0
General physical condition abnormal	1	0
Grip strength	3	0
Grip strength decreased	27	0
Gynaecological examination	1	0
Head lag	9	0
Intelligence test	1	0
Lymph node palpable	45	0
Male genital examination abnormal	1	0
Menstruation normal	4	0
Muscle strength abnormal	5	0
Ophthalmological examination	3	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

Case Series Drug Analysis Print

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

Report Run Date: 26-May-2022

Data Lock Date: 25-May-2022 18:30:05

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Respiratory rate decreased	28	0
Respiratory rate increased	49	0
Skin temperature	48	0
Temperature difference of extremities	13	0
Weight	1	0
Weight abnormal	1	0
Weight decreased	141	0
Weight increased	56	0
<i>Pituitary analyses anterior</i>		
Blood corticotrophin	1	0
Blood follicle stimulating hormone increased	3	0
Blood growth hormone	3	0
Blood prolactin	3	0
Blood prolactin increased	4	0
Blood thyroid stimulating hormone decreased	1	0
Blood thyroid stimulating hormone increased	11	0
<i>Platelet analyses</i>		
Mean platelet volume decreased	1	0
Mean platelet volume increased	1	0
Platelet count	3	0
Platelet count abnormal	1	0
Platelet count decreased	90	0
Platelet count increased	6	0
<i>Protein analyses NEC</i>		
Alpha 1 globulin decreased	1	0
Alpha 2 globulin decreased	1	0
C-reactive protein increased	32	0
<i>Red blood cell analyses</i>		
Haematocrit	1	0
Haematocrit decreased	1	0
Haematocrit increased	1	0
Haemoglobin decreased	16	0
Haemoglobin increased	2	0
Red blood cell count decreased	1	0
Red blood cell count increased	1	0
Red blood cell rouleaux formation present	1	0
<i>Renal function analyses</i>		
Blood creatine decreased	1	0
Blood creatinine	2	0
Blood creatinine decreased	1	0
Blood creatinine increased	5	0
Glomerular filtration rate decreased	4	0
Glomerular filtration rate increased	1	0
<i>Reproductive hormone analyses</i>		
Blood oestrogen	2	0
Blood oestrogen decreased	2	0
Blood testosterone decreased	2	0
Blood testosterone increased	2	0
False negative pregnancy test	9	0
Female sex hormone level	3	0
Human chorionic gonadotropin increased	1	0
Pregnancy test	18	0
Pregnancy test false positive	1	0

Case Series Drug Analysis Print

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

Report Run Date: 26-May-2022

Data Lock Date: 25-May-2022 18:30:05

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Pregnancy test positive	1	0
Progesterone decreased	2	0
<i>Reproductive organ and breast histopathology procedures</i>		
Biopsy breast	2	0
Biopsy endometrium	1	0
Smear cervix	3	0
<i>Reproductive organ and breast imaging procedures</i>		
Breast scan	1	0
Hysteroscopy	2	0
<i>Respiratory and pulmonary function diagnostic procedures</i>		
Airway peak pressure increased	1	0
Forced expiratory volume	1	0
Forced expiratory volume increased	3	0
Fractional exhaled nitric oxide normal	1	0
Maximal voluntary ventilation	2	0
Peak expiratory flow rate	2	0
Peak expiratory flow rate decreased	7	0
Pulmonary function test	3	0
Spirometry abnormal	1	0
Total lung capacity decreased	4	0
Vital capacity	1	0
<i>Respiratory tract and thoracic histopathology procedures</i>		
Sputum abnormal	3	0
<i>Respiratory tract and thoracic imaging procedures</i>		
Chest X-ray	19	0
Chest X-ray abnormal	1	0
Chest X-ray normal	2	0
Chest scan	2	0
Computerised tomogram thorax	2	0
Ventilation/perfusion scan	2	0
<i>Skeletal and cardiac muscle analyses</i>		
Blood creatine phosphokinase increased	12	0
Muscle enzyme	1	0
Myocardial necrosis marker	1	0
Myocardial necrosis marker increased	3	0
Troponin I increased	2	0
Troponin T increased	2	0
Troponin increased	29	0
<i>Therapeutic drug monitoring analyses</i>		
Analgesic drug level	9	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	1	0
Thyroxine	1	0
Thyroxine decreased	1	0
Thyroxine free increased	2	0
Tri-iodothyronine	1	0
Tri-iodothyronine decreased	5	0
<i>Tissue enzyme analyses NEC</i>		

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Blood alkaline phosphatase abnormal	1	0
Blood alkaline phosphatase increased	6	0
Blood lactate dehydrogenase	1	0
Blood lactate dehydrogenase increased	1	0
Enzyme level increased	1	0
Toxicology laboratory analyses		
Blood caffeine decreased	1	0
Blood lead	1	0
Drug screen positive	2	0
Opiates	1	0
Toxicologic test abnormal	1	0
Urinalysis NEC		
Blood urine	19	0
Blood urine present	80	0
Cells in urine	1	0
Glucose urine present	1	0
Protein urine	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
Urinary tract function analyses NEC		
Urine output	14	0
Urine output decreased	15	0
Urine output increased	7	0
Urinary tract histopathology procedures		
Urine cytology	1	0
Urinary tract imaging procedures		
Bladder scan	1	0
Cystoscopy	2	0
Ultrasound kidney normal	1	0
Vascular imaging procedures NEC		
Venogram	2	0
Vascular tests NEC (incl blood pressure)		
Blood pressure abnormal	14	0
Blood pressure ambulatory increased	1	0
Blood pressure decreased	92	0
Blood pressure diastolic	2	0
Blood pressure diastolic decreased	1	0
Blood pressure diastolic increased	4	0
Blood pressure difference of extremities	1	0
Blood pressure increased	308	0
Blood pressure measurement	49	0
Blood pressure normal	2	0
Blood pressure orthostatic	1	0
Blood pressure systolic	1	0
Blood pressure systolic decreased	4	0
Blood pressure systolic increased	1	0
Virus identification and serology		

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
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	36	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	112	0
Viral load	2	0
Viral test	4	0
Viral test positive	1	0
Vitamin analyses		
Blood folate decreased	8	0
Vitamin B12	1	0
Vitamin B12 abnormal	2	0
Vitamin B12 decreased	3	0
Vitamin D	4	0
Vitamin D decreased	4	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	4	0
Neutrophil count decreased	13	0
Neutrophil count increased	4	0
White blood cell count	5	0
White blood cell count decreased	17	0
White blood cell count increased	13	0
Investigations SOC TOTAL	6522	3

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	23	0
Decreased appetite	1551	0
Diet refusal	1	0
Eating disorder symptom	3	0
Food craving	13	0
Food refusal	16	0
Hyperphagia	15	0
Hypophagia	21	0
Increased appetite	38	0
Salt craving	2	0
<i>Calcium metabolism disorders</i>		
Hypocalcaemia	3	0
Tetany	5	0
<i>Copper metabolism disorders</i>		
Copper deficiency	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	63	0
Diabetes mellitus inadequate control	18	1
Increased insulin requirement	2	0
Insulin resistant diabetes	1	0
Latent autoimmune diabetes in adults	2	0
Type 1 diabetes mellitus	17	0
Type 2 diabetes mellitus	5	0
<i>Diabetic complications NEC</i>		
Diabetic complication	2	0
Diabetic ketoacidosis	12	0
Diabetic ketosis	1	0
<i>Disorders of purine metabolism</i>		
Gout	111	0
<i>Electrolyte imbalance NEC</i>		
Electrolyte imbalance	1	0
Fluid imbalance	2	0
Tumour lysis syndrome	1	0
<i>Elevated cholesterol</i>		
Hypercholesterolaemia	1	0
<i>Fat soluble vitamin deficiencies and disorders</i>		
Vitamin D deficiency	11	0
<i>Fluid intake decreased</i>		
Fluid intake reduced	2	0
<i>Fluid intake increased</i>		
Polydipsia	7	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Alcohol intolerance	8	0
Breast milk substitute intolerance	1	0
Dairy intolerance	3	0
Food intolerance	24	0
Gluten sensitivity	7	0
Histamine intolerance	7	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	43	0
Abnormal weight gain	21	0
Cachexia	1	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Metabolic disorders <small>Metabolic disorders cont'd</small>		
Feeding disorder	114	0
Food aversion	14	0
Malnutrition	3	0
Neonatal insufficient breast milk syndrome	7	0
Obesity	1	0
Overweight	1	0
Poor feeding infant	17	0
Weight loss poor	3	0
Hyperglycaemic conditions NEC		
Glucose tolerance impaired	2	0
Hyperglycaemia	69	0
Insulin resistance	5	0
Hyperlipidaemias NEC		
Hyperlipidaemia	1	0
Hypoglycaemic conditions NEC		
Glycopenia	1	0
Hypoglycaemia	84	0
Hypoglycaemia unawareness	1	0
Postprandial hypoglycaemia	3	0
Iron deficiencies		
Iron deficiency	13	0
Iron excess		
Haemochromatosis	2	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	7	1
Lactic acidosis	3	0
Metabolic acidosis	4	0
Metabolic disorders NEC		
Hypercarotinaemia	1	0
Hypercatabolism	1	0
Hypometabolism	1	0
Metabolic disorder	1	0
Mixed acid-base disorders		
Acidosis	4	0
Phosphorus metabolism disorders		
Hypophosphataemia	1	0
Potassium imbalance		
Hyperkalaemia	6	0
Hypokalaemia	5	0
Hypokalaemic syndrome	1	0
Sodium imbalance		
Hypernatraemia	1	0
Hyponatraemia	12	0
Hyponatraemic syndrome	3	0
Salt intoxication	1	0
Sugar intolerance (excl glucose intolerance)		
Lactose intolerance	5	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
<i>Total fluid volume decreased</i>		
Dehydration	245	0
<i>Total fluid volume increased</i>		
Fluid retention	68	0
Hypervolaemia	5	0
<i>Vitamin deficiencies NEC</i>		
Hypovitaminosis	6	0
<i>Water soluble vitamin deficiencies</i>		
Folate deficiency	11	0
Vitamin B complex deficiency	1	0
Vitamin B12 deficiency	8	0
Metabolic disorders SOC TOTAL	2812	2

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	412	0
Arthropathy	35	0
Autoimmune arthritis	10	0
Haemarthrosis	5	0
Joint microhaemorrhage	1	0
Palindromic rheumatism	3	0
Polyarthritis	17	0
Rheumatic fever	2	0
Sacroiliitis	6	0
Seronegative arthritis	4	0
<i>Bone disorders NEC</i>		
Bone cyst	2	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	3	0
<i>Bone related signs and symptoms</i>		
Bone pain	460	0
Bone swelling	10	0
Coccydynia	4	0
Metatarsalgia	1	0
Pain in jaw	437	0
Pubic pain	2	0
Spinal pain	102	0
<i>Bursal disorders</i>		
Bursitis	107	0
<i>Cartilage disorders</i>		
Chondritis	1	0
Costochondritis	145	0
Osteochondritis	1	0
Polychondritis	3	0
<i>Connective tissue disorders NEC</i>		
Connective tissue disorder	3	0
Polymyalgia rheumatica	95	0
Reynold's syndrome	3	0
Scleroderma	1	0
Sjogren's syndrome	9	0
Systemic scleroderma	1	0
<i>Crystal arthropathic disorders</i>		
Chondrocalcinosis pyrophosphate	3	0
Crystal arthropathy	2	0
Gouty arthritis	2	0
<i>Epiphyseal disorders</i>		
Epiphyses premature fusion	1	0
<i>Extremity deformities</i>		
Bone deformity	1	0
Finger deformity	3	0
Foot deformity	4	0
Hand deformity	4	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Knee deformity	1	0
Limb deformity	6	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
Greater trochanteric pain syndrome	2	0
Hypermobility syndrome	1	0
Joint ankylosis	1	0
Joint deposit	1	0
Joint destruction	1	0
Joint instability	2	0
Joint laxity	3	0
Joint lock	36	0
Ligament laxity	1	0
Patellofemoral pain syndrome	2	0
Periarthritis	279	0
Rotator cuff syndrome	43	0
Temporomandibular joint syndrome	17	0
Joint related signs and symptoms		
Arthralgia	10644	0
Jaw clicking	7	0
Joint effusion	16	0
Joint noise	44	0
Joint range of motion decreased	39	0
Joint stiffness	310	0
Joint swelling	694	0
Joint vibration	4	0
Joint warmth	17	0
Loose body in joint	1	0
Ligament disorders		
Ligament pain	4	0
Ligamentitis	3	0
Symphysiolysis	1	0
Lupus erythematosus (incl subtypes)		
Lupus-like syndrome	1	0
Systemic lupus erythematosus	30	0
Metabolic bone disorders		
Osteopenia	4	0
Osteoporosis	8	0
Muscle infections and inflammations		
Antisynthetase syndrome	3	0
Immune-mediated myositis	2	0
Myositis	53	0
Polymyositis	9	0
Muscle pains		
Fibromyalgia	146	0
Myalgia	11926	1
Myalgia intercostal	2	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Myofascial pain syndrome	13	0
Muscle related signs and symptoms NEC		
Haematoma muscle	1	0
Muscle atrophy	33	0
Muscle discomfort	8	0
Muscle disorder	12	0
Muscle fatigue	407	0
Muscle haemorrhage	1	0
Muscle mass	5	0
Muscle oedema	5	0
Muscle spasms	2371	0
Muscle swelling	45	0
Muscle tightness	113	0
Muscle twitching	570	0
Myofascial spasm	1	0
Muscle tone abnormalities		
Muscle rigidity	25	0
Nuchal rigidity	13	0
Torticollis	7	0
Trismus	42	0
Muscle weakness conditions		
Muscular weakness	1201	0
Musculoskeletal and connective tissue conditions NEC		
Back disorder	5	0
Chest wall mass	1	0
Growth disorder	2	0
Limb mass	24	0
Mandibular mass	3	0
Mastication disorder	8	0
Mobility decreased	163	0
Muscle contracture	1	0
Musculoskeletal disorder	13	0
Musculoskeletal stiffness	1527	0
Pelvic misalignment	1	0
Posture abnormal	2	0
Sacroiliac joint dysfunction	1	0
Weight bearing difficulty	5	0
Musculoskeletal and connective tissue deformities of skull, face and buccal cavity		
Facial asymmetry	1	0
Head deformity	2	0
Nose deformity	1	0
Musculoskeletal and connective tissue infections and inflammations NEC		
Connective tissue inflammation	1	0
Dactylitis	3	0
Dupuytren's contracture	1	0
Fasciitis	1	0
Plantar fasciitis	18	0
Musculoskeletal and connective tissue pain and discomfort		
Back pain	2915	0
Flank pain	87	0
Growing pains	1	0
Limb discomfort	1690	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Musculoskeletal chest pain	316	0
Musculoskeletal discomfort	130	0
Musculoskeletal pain	145	0
Neck pain	2266	0
Pain in extremity	14764	1
Rheumatic disorder	17	0
Sacral pain	4	0
Myopathies		
Mitochondrial myopathy acquired	1	0
Myopathy	9	0
Rhabdomyolysis	14	0
Osteoarthropathies		
Nodal osteoarthritis	1	0
Osteoarthritis	67	0
Spinal osteoarthritis	2	0
Psoriatic arthropathies		
Psoriatic arthropathy	29	0
Rheumatoid arthropathies		
Juvenile idiopathic arthritis	1	0
Rheumatoid arthritis	152	0
Rheumatoid nodule	1	0
Still's disease	2	0
Soft tissue disorders NEC		
Axillary mass	324	0
Fistula	1	0
Fistula discharge	1	0
Fluctuance	1	0
Groin pain	128	0
Neck mass	47	0
Purple glove syndrome	1	0
Soft tissue disorder	3	0
Soft tissue necrosis	1	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	3	0
Spondyloarthropathies		
Ankylosing spondylitis	10	0
Arthritis reactive	80	0
Spondylitis	4	0
Spondyloarthropathy	1	0
Synovial disorders		
Synovial cyst	23	0
Synovitis	13	0
Tendon disorders		
Enthesopathy	3	0
Posterior tibial tendon dysfunction	1	0
Tendon disorder	7	0
Tendon pain	28	0
Tendonitis	65	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Tenosynovitis	4	0
Tenosynovitis stenosaurs	2	0
Trigger finger	34	0
Trunk deformities		
Deformity thorax	1	0
Drooping shoulder syndrome	3	0
Shoulder deformity	4	0
Muscle & tissue disorders SOC TOTAL	56376	2

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Reaction Name	Total	Fatal
Neoplasms		
<i>Adrenal neoplasms malignant</i>		
Adrenal gland cancer	1	0
<i>Angioimmunoblastic T-cell lymphomas</i>		
Angioimmunoblastic T-cell lymphoma	1	0
<i>B-cell lymphomas NEC</i>		
B-cell lymphoma	2	1
Follicular lymphoma	4	0
<i>Bile duct neoplasms malignant</i>		
Bile duct cancer	1	0
<i>Bladder neoplasms malignant</i>		
Bladder cancer	1	0
<i>Bone neoplasms malignant (excl sarcomas)</i>		
Bone cancer	1	1
<i>Bone neoplasms unspecified malignancy</i>		
Bone neoplasm	1	0
<i>Breast and nipple neoplasms benign</i>		
Benign breast neoplasm	3	0
Fibroadenoma of breast	2	0
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	45	0
Breast cancer female	1	0
Breast cancer male	2	0
Breast cancer stage I	1	0
Breast cancer stage III	3	0
HER2 positive breast cancer	1	0
Inflammatory carcinoma of the breast	1	0
Invasive ductal breast carcinoma	1	0
Triple negative breast cancer	4	0
<i>Cardiovascular neoplasms benign</i>		
Haemangioma	2	0
Pericardial lipoma	1	0
<i>Cardiovascular neoplasms malignant and unspecified</i>		
Cardiac neoplasm unspecified	1	0
<i>Cartilage sarcomas</i>		
Chondrosarcoma	1	0
<i>Central nervous system neoplasms malignant NEC</i>		
Brain cancer metastatic	1	0
<i>Cervix neoplasms malignant</i>		
Cervix carcinoma	3	0
<i>Colorectal neoplasms malignant</i>		
Colon cancer	2	0
Colorectal cancer	2	0
Rectal cancer	2	0
<i>Endocrine neoplasms benign NEC</i>		
Pituitary tumour benign	1	0
<i>Endocrine neoplasms malignant and unspecified NEC</i>		
Neuroendocrine tumour	1	0
Thyroid neoplasm	1	0
<i>Endometrial neoplasms malignant</i>		
Endometrial cancer	2	0
<i>Follicular lymphomas</i>		
Primary gastrointestinal follicular lymphoma	1	0
<i>Gastric neoplasms malignant</i>		

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
Gastric cancer	1	1
Gastrointestinal neoplasms malignant NEC		
Gastrointestinal carcinoma	4	0
Hepatic neoplasms malignant		
Hepatic cancer	1	1
Hepatocellular carcinoma	1	0
Hepatobiliary neoplasms benign		
Haemangioma of liver	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		
Leukaemia	7	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	48	1
Lymphoproliferative disorders NEC (excl leukaemias and lymphomas)		
Histiocytic necrotising lymphadenitis	1	0
Mantle cell lymphomas		
Mantle cell lymphoma	2	0
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	4	0
Myeloproliferative disorders (excl leukaemias)		
Essential thrombocythaemia	2	0
Neoplasms malignant site unspecified NEC		
Adenocarcinoma metastatic	1	0
Metastatic neoplasm	2	0
Neoplasm malignant	14	3
Second primary malignancy	1	0
Squamous cell carcinoma	5	0
Neoplasms unspecified malignancy and site unspecified NEC		
Neoplasm	2	0
Neoplasm recurrence	1	0

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
<i>Nervous system neoplasms benign NEC</i>		
Cranial nerve neoplasm benign	1	0
Neurilemmoma benign	1	0
<i>Nervous system neoplasms unspecified malignancy NEC</i>		
Brain neoplasm	5	0
Meningioma	1	0
Spinal cord neoplasm	1	1
<i>Neuromas</i>		
Acoustic neuroma	3	0
Neuroma	1	0
<i>Non-Hodgkin's lymphomas NEC</i>		
Non-Hodgkin's lymphoma	3	0
<i>Ocular neoplasms benign</i>		
Eye naevus	3	0
<i>Ocular neoplasms malignancy unspecified</i>		
Eyelid tumour	1	0
<i>Oesophageal neoplasms malignant</i>		
Oesophageal cancer metastatic	4	0
<i>Oncologic complications and emergencies</i>		
Cancer pain	1	0
Tumour haemorrhage	1	0
<i>Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified</i>		
Tonsil cancer	4	0
<i>Ovarian neoplasms malignant (excl germ cell)</i>		
Ovarian cancer	1	0
<i>Pancreatic neoplasms malignant (excl islet cell and carcinoid)</i>		
Pancreatic carcinoma	4	0
<i>Paraneoplastic syndromes NEC</i>		
Paraneoplastic syndrome	2	0
<i>Plasma cell myelomas</i>		
POEMS syndrome	1	0
Plasma cell myeloma	2	0
<i>Plasma cell neoplasms NEC</i>		
Hypergammaglobulinaemia benign monoclonal	1	0
TEMPI syndrome	2	0
<i>Prostatic neoplasms malignant</i>		
Prostate cancer	4	0
<i>Renal neoplasms malignant</i>		
Clear cell renal cell carcinoma	1	0
Renal cancer	3	0
<i>Reproductive neoplasms female benign NEC</i>		
Benign hydatidiform mole	5	0
<i>Respiratory tract and pleural neoplasms malignant cell type unspecified NEC</i>		
Bronchial carcinoma	1	0
Lung cancer metastatic	1	1
Lung neoplasm malignant	15	1
<i>Salivary gland neoplasms unspecified malignancy</i>		
Salivary gland neoplasm	2	0
<i>Skin melanomas (excl ocular)</i>		
Malignant melanoma	3	0
Metastatic malignant melanoma	1	0

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
<i>Skin neoplasms benign</i>		
Acrochordon	7	0
Anogenital warts	7	0
Fibrous histiocytoma	1	0
Haemangioma of skin	7	0
Melanocytic naevus	10	0
Pyogenic granuloma	1	0
Seborrheic keratosis	2	0
Skin papilloma	22	0
<i>Skin neoplasms malignant and unspecified (excl melanoma)</i>		
Basal cell carcinoma	3	0
Bowen's disease	1	0
Neoplasm skin	3	0
Skin cancer	1	0
Squamous cell carcinoma of skin	1	0
<i>Soft tissue neoplasms benign NEC</i>		
Lipoma	7	0
Lymphangioma	1	0
<i>Soft tissue sarcomas histology unspecified</i>		
Sarcoma	1	0
<i>Thyroid neoplasms malignant</i>		
Anaplastic thyroid cancer	1	0
Huerthle cell carcinoma	1	0
Papillary thyroid cancer	2	0
Thyroid cancer	1	0
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	18	0
Neoplasms SOC TOTAL	395	12

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Areflexia	9	0
Extensor plantar response	2	0
Hoffmann's sign	1	0
Hyperreflexia	5	0
Hyporeflexia	11	0
Reflexes abnormal	2	0
<i>Abnormal sleep-related events</i>		
Sleep paralysis	32	0
<i>Absence seizures</i>		
Petit mal epilepsy	32	0
<i>Acute polyneuropathies</i>		
Acute motor axonal neuropathy	1	0
Acute motor-sensory axonal neuropathy	1	0
Guillain-Barre syndrome	105	2
Miller Fisher syndrome	5	0
Subacute inflammatory demyelinating polyneuropathy	1	0
<i>Alzheimer's disease (incl subtypes)</i>		
Dementia Alzheimer's type	3	2
<i>Autonomic nervous system disorders</i>		
Anticholinergic syndrome	1	0
Autonomic nervous system imbalance	16	0
Autonomic neuropathy	3	0
Horner's syndrome	2	0
Orthostatic intolerance	2	0
<i>Central nervous system aneurysms and dissections</i>		
Carotid artery dissection	2	0
Intracranial aneurysm	2	1
Vertebral artery dissection	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Basal ganglia haemorrhage	1	0
Basal ganglia infarction	1	0
Brain stem haemorrhage	4	3
Brain stem infarction	1	1
Brain stem stroke	3	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	5	0
Cerebral haemorrhage	66	16
Cerebral infarction	33	3
Cerebral ischaemia	1	0
Cerebral thrombosis	15	0
Cerebrovascular accident	508	20
Embolic stroke	8	0
Haemorrhage intracranial	16	4
Haemorrhagic cerebral infarction	1	0

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Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Haemorrhagic stroke	12	5
Internal capsule infarction	1	0
Intracranial haematoma	2	0
Ischaemic cerebral infarction	1	0
Ischaemic stroke	66	3
Lacunar infarction	4	0
Lacunar stroke	6	0
Lateral medullary syndrome	2	0
Pseudostroke	3	0
Ruptured cerebral aneurysm	1	0
Spinal cord infarction	1	0
Spinal stroke	1	0
Stroke in evolution	1	0
Subarachnoid haemorrhage	19	8
Thalamic infarction	1	0
Thrombotic stroke	6	1
Vertebrobasilar stroke	1	0
Central nervous system inflammatory disorders NEC		
Arachnoiditis	1	0
Gliosis	3	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	4	0
Cerebrovascular disorder	3	0
Post cardiac arrest syndrome	1	0
Reversible cerebral vasoconstriction syndrome	1	0
Cerebrovascular venous and sinus thrombosis		
Cerebral venous sinus thrombosis	58	5
Cerebral venous thrombosis	9	0
Superior sagittal sinus thrombosis	6	0
Transverse sinus thrombosis	3	0
Cervical spinal cord and nerve root disorders		
Cervical radiculopathy	2	0
Cervicobrachial syndrome	7	0
Choreiform movements		
Chorea	3	0
Chronic polyneuropathies		
Chronic inflammatory demyelinating polyradiculoneuropathy	2	0
Demyelinating polyneuropathy	2	0
Diabetic neuropathy	1	0
Coma states		
Coma	19	0
Diabetic coma	1	0
Hypoglycaemic coma	1	0
Coordination and balance disturbances		
Ataxia	23	0
Balance disorder	522	0
Cerebellar ataxia	1	0
Cerebellar syndrome	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Coordination abnormal	77	0
Dysdiadochokinesis	1	0
Dysstasia	76	0
Nystagmus	17	0
Cortical dysfunction NEC		
Alexia	2	0
Aphasia	107	0
Apraxia	1	0
Dysgraphia	4	0
Dyslexia	1	0
Dyspraxia	2	0
Neurologic neglect syndrome	1	0
Sensory processing disorder	3	0
Visuospatial deficit	1	0
Cranial nerve disorders NEC		
Cranial nerve disorder	3	0
Cranial nerve paralysis	1	0
Dementia (excl Alzheimer's type)		
Dementia	19	0
Dementia with Lewy bodies	2	0
Senile dementia	1	0
Demyelinating disorders NEC		
Acute disseminated encephalomyelitis	9	0
Clinically isolated syndrome	1	0
Demyelination	13	0
Neuromyelitis optica spectrum disorder	2	0
Disturbances in consciousness NEC		
Altered state of consciousness	14	0
Consciousness fluctuating	4	0
Depressed level of consciousness	57	0
Infant sedation	1	0
Lethargy	2579	0
Loss of consciousness	828	1
Postictal state	6	0
Sedation	9	0
Sedation complication	1	0
Somnolence	1227	0
Stupor	5	0
Syncope	2861	0
Disturbances in sleep phase rhythm		
Circadian rhythm sleep disorder	2	0
Irregular sleep phase	2	0
Irregular sleep wake rhythm disorder	2	0
Non-24-hour sleep-wake disorder	1	0
Dyskinesias and movement disorders NEC		
Akathisia	7	0
Ballismus	1	0
Bradykinesia	26	0
Clumsiness	25	0
Dyskinesia	86	0
Extrapyramidal disorder	3	0
Fine motor skill dysfunction	13	0
Foetal movement disorder	7	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Hyperkinesia	4	0
Hypokinesia	115	0
Micrographia	1	0
Motor dysfunction	5	0
Movement disorder	73	0
Psychomotor hyperactivity	30	0
Synkinesis	2	0
Tardive dyskinesia	2	0
Dystonias		
Dystonia	17	0
Writer's cramp	1	0
Encephalitis NEC		
Encephalitis autoimmune	1	0
Limbic encephalitis	1	0
Noninfective encephalitis	7	0
Encephalopathies NEC		
Autoimmune encephalopathy	2	1
Encephalopathy	6	0
Hashimoto's encephalopathy	2	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	2	0
VIth nerve disorder	1	0
VIth nerve paralysis	13	0
Facial cranial nerve disorders		
Bell's palsy	651	0
Facial nerve disorder	9	0
Facial paralysis	488	0
Facial paresis	108	0
Facial spasm	57	0
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	85	0
Glossopharyngeal nerve disorders		
Glossopharyngeal neuralgia	1	0
Headaches NEC		
Cervicogenic headache	3	0
Cluster headache	297	0
Cold-stimulus headache	37	0
Drug withdrawal headache	3	0
Exertional headache	10	0
External compression headache	2	0
Headache	30498	1
Medication overuse headache	2	0
New daily persistent headache	8	0
Occipital neuralgia	17	0
Ophthalmoplegic migraine	1	0
Primary cough headache	4	0
Primary headache associated with sexual activity	10	0
Sinus headache	403	0
Tension headache	639	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Thunderclap headache	25	0
Vascular headache	22	0
Hydrocephalic conditions		
Hydrocephalus	5	0
Hypoglossal nerve disorders		
Tongue paralysis	1	0
Increased intracranial pressure disorders		
Brain compression	2	0
Brain oedema	13	2
Idiopathic intracranial hypertension	12	0
Intracranial pressure increased	5	0
Intellectual disabilities		
Intellectual disability	4	0
Lumbar spinal cord and nerve root disorders		
Cauda equina syndrome	1	0
Sciatica	140	0
Memory loss (excl dementia)		
Amnesia	239	0
Memory impairment	261	0
Retrograde amnesia	1	0
Transient global amnesia	10	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	112	0
Cognitive linguistic deficit	1	0
Disturbance in attention	409	0
Mental impairment	65	0
Migraine headaches		
Basilar migraine	1	0
Hemiplegic migraine	44	0
Migraine	3574	0
Migraine with aura	235	0
Migraine without aura	22	0
Ophthalmic migraine	7	0
Retinal migraine	39	0
Typical aura without headache	9	0
Vestibular migraine	30	0
Mixed cranial nerve disorders		
Bulbar palsy	2	0
Mononeuropathies		
Carpal tunnel syndrome	36	0
Cubital tunnel syndrome	4	0
Meralgia paraesthetica	2	0
Mononeuritis	2	0
Mononeuropathy	4	0
Nerve compression	32	0
Peripheral nerve lesion	2	0
Peroneal nerve palsy	21	0
Piriformis syndrome	2	0
Pudendal canal syndrome	3	0
Sciatic nerve neuropathy	2	0
Ulnar nerve palsy	2	0
Ulnar neuritis	3	0
Ulnar tunnel syndrome	2	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
<i>Motor neurone diseases</i>		
Amyotrophic lateral sclerosis	1	0
Lower motor neurone lesion	2	0
Motor neurone disease	7	3
Progressive bulbar palsy	1	0
Upper motor neurone lesion	1	0
<i>Multiple sclerosis acute and progressive</i>		
Band sensation	1	0
Multiple sclerosis	39	0
Multiple sclerosis relapse	26	0
Relapsing-remitting multiple sclerosis	1	0
Tumefactive multiple sclerosis	1	1
<i>Muscle tone abnormal</i>		
Drop attacks	3	0
Hypertonia	2	0
Hypotonia	40	0
Morvan syndrome	1	0
Muscle tone disorder	1	0
Serotonin syndrome	1	0
Stiff leg syndrome	1	0
<i>Myelitis (incl infective)</i>		
Myelitis transverse	39	0
<i>Narcolepsy and hypersomnia</i>		
Cataplexy	3	0
Hypersomnia	126	0
Narcolepsy	7	0
<i>Nervous system disorders NEC</i>		
Central nervous system lesion	3	0
Cerebral disorder	3	0
Nervous system disorder	28	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	24	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	11494	0
Dizziness exertional	53	0
Dizziness postural	862	0
Drooling	27	0
Fontanelle bulging	2	0
Head discomfort	414	0
Hyporesponsive to stimuli	2	0
Inability to crawl	3	0
Infant irritability	10	0
Meningism	2	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Myoclonus	35	0
Neurological symptom	78	0
Patient elopement	1	0
Persistent postural-perceptual dizziness	18	0
Presyncope	726	0
Sensory overload	5	0
Slow response to stimuli	4	0
Tongue biting	9	0
Unresponsive to stimuli	67	0
Neuromuscular disorders NEC		
Muscle contractions involuntary	32	0
Muscle spasticity	20	0
Neuromuscular pain	3	0
Neuromuscular junction dysfunction		
Myasthenia gravis	17	0
Myasthenia gravis crisis	2	0
Myasthenic syndrome	1	0
Olfactory nerve disorders		
Anosmia	336	0
Hyposmia	19	0
Parosmia	341	0
Optic nerve disorders NEC		
Optic neuritis	45	0
Paraesthesias and dysaesthesias		
Burning feet syndrome	15	0
Burning sensation	686	0
Burning sensation mucosal	2	0
Dysaesthesia	8	0
Formication	47	0
Hemianaesthesia	1	0
Hemihypoaesthesia	3	0
Hemiparaesthesia	5	0
Hyperaesthesia	126	0
Hypoaesthesia	3581	0
Lhermitte's sign	1	0
Paraesthesia	4887	0
Reversed hot-cold sensation	4	0
Synaesthesia	2	0
Vibration syndrome	3	0
Paralysis and paresis (excl cranial nerve)		
Diplegia	22	0
Hemiparesis	72	0
Hemiplegia	50	0
Locked-in syndrome	1	0
Monoparesis	94	0
Monoplegia	103	0
Paralysis	159	1
Paraparesis	4	0
Paraplegia	3	0
Paresis	10	0
Quadriparesis	1	0
Quadriplegia	1	0
Parkinson's disease and parkinsonism		

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Freezing phenomenon	18	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
Partial complex seizures		
Dreamy state	6	0
Focal dyscognitive seizures	6	0
Temporal lobe epilepsy	2	0
Partial simple seizures NEC		
Autonomic seizure	1	0
Peripheral neuropathies NEC		
Axonal neuropathy	2	0
Brachial plexopathy	2	0
Neuralgic amyotrophy	11	0
Neuritis	12	0
Neuropathy peripheral	166	0
Peripheral sensorimotor neuropathy	1	0
Peripheral sensory neuropathy	13	0
Polyneuropathy	5	0
Small fibre neuropathy	4	0
Thoracic outlet syndrome	2	0
Seizures and seizure disorders NEC		
Atonic seizures	10	0
Change in seizure presentation	2	0
Clonic convulsion	6	0
Convulsions local	1	0
Convulsive threshold lowered	1	0
Epilepsy	178	0
Epileptic aura	2	0
Epileptic encephalopathy	2	0
Febrile convulsion	21	0
Idiopathic generalised epilepsy	1	0
Neonatal epileptic seizure	1	0
Partial seizures	30	0
Partial seizures with secondary generalisation	1	0
Post stroke seizure	1	0
Psychogenic seizure	11	0
Seizure	775	2
Seizure anoxic	3	0
Seizure cluster	7	0
Seizure like phenomena	4	0
Status epilepticus	41	0
Tonic clonic movements	7	0
Tonic convulsion	39	0
Tonic posturing	1	0
Sensory abnormalities NEC		
Ageusia	612	0
Allodynia	33	0
Aura	30	0
Central pain syndrome	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Complex regional pain syndrome	6	0
Dysgeusia	1339	0
Electric shock sensation	60	0
Hypergeusia	1	0
Hypogeusia	9	0
Intercostal neuralgia	3	0
Loss of proprioception	3	0
Morton's neuralgia	4	0
Neuralgia	746	0
Persistent genital arousal disorder	2	0
Phantom limb syndrome	8	0
Post herpetic neuralgia	18	0
Restless arm syndrome	4	0
Restless legs syndrome	165	0
Sensory disturbance	132	0
Sensory loss	118	0
Taste disorder	320	0
Visual perseveration	3	0
Sleep disturbances NEC		
Microsleep	1	0
Sleep deficit	13	0
Sudden onset of sleep	1	0
Speech and language abnormalities		
Dysarthria	252	0
Incoherent	15	0
Language disorder	2	0
Repetitive speech	5	0
Slow speech	24	0
Speech disorder	86	0
Speech disorder developmental	3	0
Spinal cord and nerve root disorders NEC		
Acquired syringomyelia	1	0
Myelopathy	1	0
Radiculitis brachial	18	0
Radiculopathy	8	0
Structural brain disorders NEC		
Brain injury	12	2
Cerebral ventricle dilatation	2	0
Hyperintensity in brain deep nuclei	1	0
Intracranial mass	1	0
White matter lesion	2	0
Transient cerebrovascular events		
Transient ischaemic attack	203	3
Tremor (excl congenital)		
Essential tremor	6	0
Head titubation	15	0
Resting tremor	4	0
Tremor	2193	0
Trigeminal disorders		
Numb chin syndrome	2	0
Trigeminal nerve disorder	3	0
Trigeminal neuralgia	89	0
Trigeminal neuritis	3	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
<i>Vagus nerve disorders</i>		
Vagus nerve disorder	1	0
Vocal cord paralysis	4	0
<i>Vertigos NEC</i>		
Cervicogenic vertigo	1	0
Vertigo CNS origin	3	0
Nervous system disorders SOC TOTAL	81800	94

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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	491	0
Abortion threatened	2	0
<i>Amniotic fluid and cavity disorders of pregnancy NEC</i>		
Amniorrhoea	2	0
Oligohydramnios	1	0
<i>Foetal complications NEC</i>		
Foetal cardiac disorder	1	0
Foetal distress syndrome	1	0
Foetal hypokinesia	13	0
<i>Foetal conditions due to maternal conditions</i>		
Maternal condition affecting foetus	1	0
<i>Foetal growth complications</i>		
Foetal growth restriction	8	1
<i>Gestational age and weight conditions</i>		
Low birth weight baby	1	0
Premature baby	8	1
Small for dates baby	1	0
<i>Haemorrhagic complications of pregnancy</i>		
Haemorrhage in pregnancy	3	0
Premature separation of placenta	3	0
Retroplacental haematoma	1	0
Subchorionic haematoma	3	0
Subchorionic haemorrhage	1	0
<i>Hypertension associated disorders of pregnancy</i>		
Pre-eclampsia	4	0
<i>Labour onset and length abnormalities</i>		
Induced labour	1	0
Premature delivery	1	0
Premature labour	9	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	8	0
<i>Maternal complications of pregnancy NEC</i>		
Biochemical pregnancy	4	0
Complication of pregnancy	1	0
Decidual cast	8	0
Ectopic pregnancy	15	0
Hyperemesis gravidarum	1	0
Morning sickness	17	0
Preterm premature rupture of membranes	3	0
Ruptured ectopic pregnancy	1	0
Somatic symptom disorder of pregnancy	3	0
<i>Neonatal hepatobiliary disorders</i>		

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Reaction Name	Total	Fatal
Pregnancy conditions <small>Pregnancy conditions cont'd</small>		
Jaundice neonatal	1	0
Normal newborn status		
Normal newborn	2	0
Normal pregnancy, labour and delivery		
Labour pain	1	0
Live birth	8	0
Pregnancy	35	0
Term birth	2	0
Uterine contractions during pregnancy	6	0
Placental abnormalities (excl neoplasms)		
Foetal vascular malperfusion	2	0
Placental calcification	1	0
Placental disorder	2	0
Placental insufficiency	1	0
Small size placenta	2	0
Postpartum complications NEC		
Postpartum haemorrhage	5	0
Pregnancy complicated by maternal disorders		
Gestational diabetes	2	0
Peripartum cardiomyopathy	1	0
Stillbirth and foetal death		
Foetal death	2	2
Stillbirth	10	10
Umbilical cord complications		
Umbilical cord abnormality	1	0
Umbilical cord thrombosis	1	0
Unintended pregnancies		
Pregnancy after post coital contraception	2	0
Pregnancy on contraceptive	3	0
Pregnancy on oral contraceptive	2	0
Pregnancy with contraceptive device	2	0
Pregnancy with implant contraceptive	1	0
Unintended pregnancy	4	0
Unwanted pregnancy	1	0
Pregnancy conditions SOC TOTAL	735	14

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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	3	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	21	0
Thrombosis in device	16	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	17	0
Product contamination physical	11	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	12	0
Product after taste	3	0
Product deposit	1	0
Product odour abnormal	3	0
Product physical issue	2	0
Product taste abnormal	10	0
<i>Product quality issues NEC</i>		
Product complaint	2	0
Product origin unknown	5	0
<i>Product supply and availability issues</i>		
Product availability issue	1	0
null SOC TOTAL	132	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	28	0
Behaviour disorder	2	0
Breath holding	7	0
Staring	8	0
<i>Adjustment disorders</i>		
Adjustment disorder	1	0
Adjustment disorder with depressed mood	5	0
<i>Affect alterations NEC</i>		
Affect lability	16	0
Constricted affect	8	0
Flat affect	12	0
Inappropriate affect	23	0
<i>Amnesic symptoms</i>		
Paramnesia	7	0
<i>Anxiety disorders NEC</i>		
Anxiety disorder	2	0
Generalised anxiety disorder	3	0
Neurosis	1	0
<i>Anxiety symptoms</i>		
Agitation	100	0
Anxiety	1125	0
Immunisation stress-related response	4	0
Nervousness	220	0
Stress	144	0
Tension	47	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	7	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	18	0
Attention-seeking behaviour	1	0
Aversion	1	0
Disinhibition	3	0
Indifference	7	0
Paranoia	31	0
Personality change	6	0
Social avoidant behaviour	6	0
Soliloquy	2	0
Suspiciousness	1	0
<i>Bipolar disorders</i>		
Bipolar I disorder	2	0
Bipolar disorder	5	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Daydreaming	9	0
Distractibility	4	0
Mental fatigue	252	0
<i>Communications disorders</i>		
Communication disorder	8	0
Mutism	4	0
Speech sound disorder	1	0
<i>Confusion and disorientation</i>		
Confusional state	1080	0
Disorientation	332	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Decreased physical activity levels</i>		
Catatonia	1	0
<i>Deliria</i>		
Delirium	153	0
<i>Delusional symptoms</i>		
Delusion	20	0
<i>Depressive disorders</i>		
Agitated depression	6	0
Depression	437	0
Depression suicidal	20	0
Major depression	15	0
Mixed anxiety and depressive disorder	4	0
<i>Dissociative states</i>		
Depersonalisation/derealisation disorder	13	0
Dissociation	40	0
Dissociative amnesia	4	0
Dissociative disorder	2	0
<i>Disturbances in initiating and maintaining sleep</i>		
Initial insomnia	30	0
Insomnia	2008	0
Middle insomnia	34	0
Terminal insomnia	35	0
<i>Dyssomnias</i>		
Breathing-related sleep disorder	1	0
Dyssomnia	1	0
Poor quality sleep	272	0
<i>Eating disorders NEC</i>		
Bulimia nervosa	1	0
Eating disorder	16	0
Selective eating disorder	1	0
<i>Emotional and mood disturbances NEC</i>		
Anger	49	0
Dysphoria	3	0
Emotional disorder	77	0
Emotional distress	65	0
Emotional poverty	2	0
Euphoric mood	51	0
Frustration tolerance decreased	2	0
Irritability	241	0
Mood altered	67	0
Morose	1	0
<i>Factitious disorders</i>		
Factitious disorder	4	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Agoraphobia	2	0
Claustrophobia	1	0
Fear	34	0
Fear of death	2	0
Fear of eating	1	0
Fear of falling	3	0
Fear of injection	6	0
Osmophobia	1	0
Performance fear	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Phobia	3	0
Phonophobia	3	0
Social anxiety disorder	2	0
Social fear	1	0
Fluctuating mood symptoms		
Mood swings	174	0
Hallucinations (excl sleep-related)		
Hallucination	263	0
Hallucination, auditory	23	0
Hallucination, olfactory	15	0
Hallucination, tactile	1	0
Hallucination, visual	33	0
Hallucinations, mixed	4	0
Increased physical activity levels		
Restlessness	178	0
Infancy, childhood and adolescence psychiatric disorders NEC		
Social (pragmatic) communication disorder	1	0
Learning disorders		
Learning disability	1	0
Learning disorder	1	0
Reading disorder	2	0
Mental disorders NEC		
Mental disorder	24	0
Mental status changes	1	0
Psychological factor affecting medical condition	1	0
Mood alterations with depressive symptoms		
Anhedonia	3	0
Decreased interest	13	0
Depressed mood	461	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	50	0
Mood alterations with manic symptoms		
Hypomania	2	0
Mania	11	0
Mood disorders NEC		
Affective disorder	4	0
Apathy	39	0
Boredom	1	0
Laziness	3	0
Listless	26	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

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Orgasmic disorders and disturbances</i>		
Anorgasmia	5	0
Female orgasmic disorder	2	0
Orgasm abnormal	4	0
Orgasmic sensation decreased	1	0
Premature ejaculation	1	0
<i>Panic attacks and disorders</i>		
Limited symptom panic attack	1	0
Panic attack	271	0
Panic disorder	10	0
Panic reaction	32	0
<i>Paraphilias and paraphilic disorders</i>		
Transvestism	1	0
<i>Parasomnias</i>		
Abnormal dreams	213	0
Abnormal sleep-related event	1	0
Confusional arousal	1	0
Exploding head syndrome	2	0
Nightmare	239	0
Parasomnia	5	0
Sleep inertia	1	0
Sleep talking	6	0
Sleep terror	29	0
Somnambulism	10	0
<i>Perception disturbances NEC</i>		
Autoscopy	20	0
Deja vu	3	0
Derealisation	14	0
Flashback	4	0
Illusion	6	0
Near death experience	1	0
Time perception altered	2	0
<i>Personality disorders NEC</i>		
Personality disorder	1	0
Self esteem decreased	1	0
<i>Pervasive developmental disorders NEC</i>		
Autism spectrum disorder	5	0
<i>Psychiatric elimination disorders</i>		
Enuresis	31	0
<i>Psychiatric symptoms NEC</i>		
Helplessness	1	0
Hypervigilance	9	0
Psychiatric symptom	13	0
Psychological trauma	4	0
Trance	1	0
<i>Psychotic disorder NEC</i>		
Acute psychosis	1	0
Psychotic behaviour	1	0
Psychotic disorder	36	1
<i>Schizophrenia NEC</i>		
Schizophrenia	2	0
<i>Sexual and gender identity disorders NEC</i>		
Gender dysphoria	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Sexual arousal disorders</i>		
Disturbance in sexual arousal	4	0
Sexual inhibition	1	0
<i>Sexual desire disorders</i>		
Hypersexuality	1	0
Libido decreased	20	0
Libido disorder	2	0
Libido increased	8	0
Loss of libido	22	0
<i>Sexual dysfunction NEC</i>		
Genito-pelvic pain/penetration disorder	2	0
<i>Sleep disorders NEC</i>		
Sleep disorder	290	0
Sleep disorder due to general medical condition, insomnia type	5	0
<i>Somatic symptom disorders</i>		
Conversion disorder	34	0
Habit cough	22	0
Somatic symptom disorder	2	0
Vomiting psychogenic	1	0
<i>Speech and language usage disturbances</i>		
Disorganised speech	10	0
Logorrhoea	2	0
<i>Speech articulation and rhythm disturbances</i>		
Dysphemia	28	0
Lack of spontaneous speech	1	0
Pressure of speech	1	0
<i>Stereotypies and automatisms</i>		
Automatism	1	0
Bruxism	16	0
Head banging	13	0
Stereotypy	1	0
<i>Stress disorders</i>		
Burnout syndrome	2	0
Post-traumatic stress disorder	6	0
<i>Substance related and addictive disorders</i>		
Alcohol problem	1	0
Alcoholic hangover	1	0
Alcoholism	5	0
Dependence	1	0
Nicotine dependence	2	0
<i>Suicidal and self-injurious behaviour</i>		
Completed suicide	6	2
Intentional self-injury	6	0
Self-injurious ideation	2	0
Suicidal ideation	51	0
Suicide attempt	9	0
Suicide threat	2	0
<i>Thinking disturbances</i>		
Bradyphrenia	45	0
Flight of ideas	1	0
Intrusive thoughts	8	0
Morbid thoughts	1	0
Tachyphrenia	8	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Thinking abnormal	22	0
Thought blocking	3	0
<i>Tic disorders</i>		
Tic	21	0
Psychiatric disorders SOC TOTAL	10326	3

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder discomfort	4	0
Bladder irritation	14	0
Bladder pain	36	0
Bladder spasm	2	0
Dysuria	60	0
Incontinence	47	0
Lower urinary tract symptoms	3	0
Micturition disorder	2	0
Micturition urgency	55	0
Mixed incontinence	1	0
Pollakiuria	164	0
Stress urinary incontinence	2	0
Urethral pain	8	0
Urge incontinence	3	0
Urinary hesitation	3	0
Urinary incontinence	81	0
Urinary retention	56	0
Urine flow decreased	19	0
<i>Bladder disorders NEC</i>		
Bladder dilatation	1	0
Bladder disorder	14	0
Bladder fibrosis	1	0
Bladder prolapse	1	0
Urinary bladder haemorrhage	4	0
<i>Bladder infections and inflammations</i>		
Cystitis haemorrhagic	1	0
Cystitis interstitial	6	0
Cystitis noninfective	1	0
<i>Bladder neoplasms</i>		
Bladder cyst	1	0
<i>Genital and urinary tract disorders NEC</i>		
Genitourinary symptom	2	0
Urinary tract disorder	4	0
Urinary tract obstruction	1	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
Anti-glomerular basement membrane disease	1	0
Focal segmental glomerulosclerosis	1	0
Glomerulonephritis membranous	1	0
Glomerulonephritis minimal lesion	8	0
Glomerulonephritis rapidly progressive	2	0
Goodpasture's syndrome	1	0
IgA nephropathy	4	0
Nephrotic syndrome	22	0
<i>Myoneurogenic bladder disorders</i>		
Automatic bladder	1	0
Bladder dysfunction	8	0
Hypertonic bladder	6	0
Hypotonic urinary bladder	1	0
Loss of bladder sensation	3	0
Neurogenic bladder	2	0
<i>Nephritis NEC</i>		
Lupus nephritis	2	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Renal & urinary disorders cont'd</i>		
Nephritis	3	0
Tubulointerstitial nephritis	3	0
<i>Nephropathies and tubular disorders NEC</i>		
Nephropathy	1	0
<i>Renal disorders NEC</i>		
Kidney fibrosis	1	0
Renal disorder	12	1
Renal haemorrhage	1	0
Renal mass	1	0
<i>Renal failure and impairment</i>		
Acute kidney injury	60	4
Anuria	3	0
Chronic kidney disease	6	0
Oliguria	1	0
Renal failure	27	1
Renal impairment	36	0
Renal injury	3	0
<i>Renal failure complications</i>		
Azotaemia	1	0
<i>Renal lithiasis</i>		
Nephrolithiasis	12	0
<i>Renal neoplasms</i>		
Renal cyst	1	0
<i>Renal obstructive disorders</i>		
Hydronephrosis	2	0
<i>Renal structural abnormalities and trauma</i>		
Kidney enlargement	1	0
Kidney small	2	0
<i>Renal vascular and ischaemic conditions</i>		
Renal aneurysm	1	0
Renal infarct	4	0
Renal tubular necrosis	2	0
Renal vasculitis	2	1
<i>Structural and obstructive urethral disorders (excl congenital)</i>		
Urethral stenosis	1	0
<i>Ureteric disorders NEC</i>		
Ureteric stenosis	1	0
<i>Urinary abnormalities</i>		
Albuminuria	1	0
Chromaturia	69	0
Haematuria	55	0
Ketonuria	1	0
Myoglobinuria	1	0
Proteinuria	13	0
Urine abnormality	13	0
Urine odour abnormal	11	0
<i>Urinary tract lithiasis (excl renal)</i>		
Calculus bladder	1	0
Calculus urinary	1	0
<i>Urinary tract signs and symptoms NEC</i>		
Costovertebral angle tenderness	1	0
Cystitis-like symptom	1	0
Haemorrhage urinary tract	31	1

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Reaction Name	Total	Fatal
Renal & urinary disorders		
Renal & urinary disorders cont'd		
Nocturia	3	0
Polyuria	9	0
Renal colic	5	0
Renal pain	369	0
Urinary tract discomfort	2	0
Urinary tract pain	7	0
Renal & urinary disorders SOC TOTAL	1442	8

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Benign and malignant breast neoplasms</i>		
Breast cyst	18	0
<i>Breast disorders NEC</i>		
Breast atrophy	1	0
Breast disorder	4	0
Breast enlargement	32	0
Breast mass	152	0
Fibrocystic breast disease	1	0
Gynaecomastia	7	0
Mastoptosis	1	0
Nipple disorder	1	0
<i>Breast infections and inflammations</i>		
Breast inflammation	6	0
Nipple inflammation	3	0
<i>Breast signs and symptoms</i>		
Breast discharge	5	0
Breast discomfort	15	0
Breast engorgement	11	0
Breast haematoma	1	0
Breast oedema	9	0
Breast pain	880	0
Breast swelling	196	0
Breast tenderness	107	0
Nipple pain	48	1
Nipple swelling	4	0
<i>Cervix disorders NEC</i>		
Cervical dysplasia	3	0
Cervix disorder	1	0
Cervix haemorrhage uterine	5	0
Ectropion of cervix	5	0
<i>Cervix infections and inflammations</i>		
Cervix inflammation	1	0
<i>Cervix neoplasms</i>		
Cervical polyp	2	0
<i>Erection and ejaculation conditions and disorders</i>		
Ejaculation disorder	3	0
Ejaculation failure	3	0
Erectile dysfunction	78	0
Erection increased	4	0
Organic erectile dysfunction	14	0
Painful ejaculation	1	0
Spontaneous ejaculation	2	0
Spontaneous penile erection	2	0
<i>Fallopian tube and ovary infections and inflammations</i>		
Noninfective oophoritis	6	0
<i>Lactation disorders</i>		
Breast milk discolouration	4	0
Breast milk odour abnormal	2	0
Galactorrhoea	5	0
Galactostasis	1	0
Lactation disorder	11	0
Lactation puerperal increased	6	0
Suppressed lactation	50	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
<i>Menopausal effects NEC</i>		
Artificial menopause	1	0
Menopausal disorder	1	0
Menopausal symptoms	47	0
Menopause delayed	1	0
Premature menopause	25	0
<i>Menopausal effects on the genitourinary tract</i>		
Atrophic vulvovaginitis	2	0
Postmenopausal haemorrhage	117	0
<i>Menstruation and uterine bleeding NEC</i>		
Abnormal uterine bleeding	8	0
Abnormal withdrawal bleeding	3	0
Bleeding anovulatory	1	0
Dysmenorrhoea	3354	0
Intermenstrual bleeding	1327	0
Menstrual discomfort	37	0
Menstrual disorder	2322	0
Menstruation irregular	4122	0
Premenstrual dysphoric disorder	14	0
Premenstrual headache	13	0
Premenstrual pain	152	0
Premenstrual syndrome	142	0
Retrograde menstruation	2	0
Withdrawal bleed	16	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	738	0
Hypomenorrhoea	762	0
Menstruation delayed	5785	0
Oligomenorrhoea	234	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	6394	0
Menometrorrhagia	21	0
Polymenorrhoea	1053	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>		
Haemorrhagic ovarian cyst	3	0
Ovarian cyst	32	0
Ovarian cyst ruptured	2	0
Polycystic ovaries	51	0
<i>Ovarian and fallopian tube disorders NEC</i>		
Adnexal torsion	1	0
Hydrosalpinx	2	0
Ovarian enlargement	1	0
Ovarian failure	1	0
Ovarian haemorrhage	8	0
Ovarian hyperstimulation syndrome	1	0
Ovarian mass	2	0
Ovarian necrosis	1	0
Ovulation disorder	4	0
Ovulation pain	85	0
Premature ovulation	4	0
Superovulation	1	0
<i>Pelvic prolapse conditions</i>		
Vaginal prolapse	1	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
<i>Pelvis and broad ligament disorders NEC</i>		
Adnexa uteri mass	1	0
Adnexa uteri pain	72	0
Pelvic congestion	1	0
Pelvic floor muscle weakness	1	0
Pelvic fluid collection	1	0
Pelvic haemorrhage	22	0
<i>Penile and scrotal infections and inflammations</i>		
Balanoposthitis	5	0
<i>Penile disorders NEC (excl erection and ejaculation)</i>		
Foreskin oedema	1	0
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	2	0
Penile rash	1	0
Penile size reduced	1	0
Penile swelling	6	0
Penis disorder	13	0
Peyronie's disease	1	0
<i>Prostate and seminal vesicles infections and inflammations</i>		
Prostatitis	5	0
<i>Prostatic neoplasms and hypertrophy</i>		
Benign prostatic hyperplasia	2	0
<i>Prostatic signs, symptoms and disorders NEC</i>		
Prostatic pain	1	0
Prostatomegaly	3	0
<i>Reproductive tract disorders NEC (excl neoplasms)</i>		
Genital erosion	1	0
Genital haemorrhage	25	0
Genital hypoaesthesia	2	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	3	0
Genital discolouration	1	0
Genital erythema	1	0
Genital pain	7	0
Genital rash	6	0
Genital swelling	5	0
Pelvic discomfort	6	0
Pelvic pain	134	0
Perineal pain	3	0
Perineal rash	1	0
Pruritus genital	8	0
<i>Scrotal disorders NEC</i>		

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</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	6	0
Scrotum erosion	1	0
Varicocele	2	0
Sexual function and fertility disorders NEC		
Dyspareunia	7	0
Infertility	18	0
Infertility female	5	0
Infertility male	1	0
Sexual dysfunction	10	0
Spermatogenesis and semen disorders		
Aspermia	1	0
Haemospermia	8	0
Semen discolouration	1	0
Testicular and epididymal disorders NEC		
Testicular atrophy	1	0
Testicular disorder	4	0
Testicular oedema	1	0
Testicular pain	74	0
Testicular swelling	14	0
Testicular torsion	1	0
Testis discomfort	3	0
Testicular and epididymal neoplasms		
Testicular cyst	1	0
Uterine disorders NEC		
Adenomyosis	11	0
Endometrial thickening	4	0
Endometriosis	98	0
Uterine haemorrhage	49	0
Uterine pain	19	0
Uterine infections and inflammations (excl cervix)		
Uterine inflammation	1	0
Uterine neoplasms		
Uterine polyp	6	0
Uterine tone disorders		
Uterine spasm	42	0
Vaginal and vulval infections and inflammations		
Vulvovaginal inflammation	2	0
Vulvovaginal cysts and neoplasms		
Bartholin's cyst	2	0
Vaginal cyst	8	0
Vaginal polyp	1	0
Vulva cyst	1	0
Vulvovaginal disorders NEC		
Vaginal haemorrhage	1819	0
Vaginal mucosal blistering	1	0
Vaginal ulceration	4	0
Vulval disorder	2	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Vulval haemorrhage	34	0
Vulval ulceration	8	0
Vulvovaginal ulceration	6	0
<i>Vulvovaginal signs and symptoms</i>		
Clitoral engorgement	1	0
Coital bleeding	8	0
Labia enlarged	2	0
Vaginal discharge	89	0
Vaginal lesion	1	0
Vaginal odour	4	0
Vaginal oedema	1	0
Vulval eczema	1	0
Vulval oedema	2	0
Vulvovaginal burning sensation	9	0
Vulvovaginal discomfort	2	0
Vulvovaginal dryness	6	0
Vulvovaginal erythema	3	0
Vulvovaginal pain	33	0
Vulvovaginal pruritus	11	0
Vulvovaginal rash	2	0
Vulvovaginal swelling	5	0
Reproductive & breast disorders SOC TOTAL	31454	1

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	7	0
Apnoeic attack	1	0
Dyspnoea	7061	5
Dyspnoea at rest	11	0
Dyspnoea exertional	49	1
Grunting	1	0
Hyperventilation	67	0
Hypopnoea	134	0
Hypoventilation	1	0
Irregular breathing	29	0
Mouth breathing	7	0
Nocturnal dyspnoea	2	0
Obstructive sleep apnoea syndrome	1	0
Orthopnoea	4	0
Respiration abnormal	74	0
Respiratory arrest	23	0
Respiratory depression	1	0
Respiratory distress	20	0
Sleep apnoea syndrome	17	0
Tachypnoea	33	0
<i>Bronchial conditions NEC</i>		
Bronchial secretion retention	4	0
Bronchiectasis	16	0
<i>Bronchospasm and obstruction</i>		
Asthma	440	0
Asthma late onset	3	0
Bronchospasm	19	0
Chronic obstructive pulmonary disease	29	1
Cough variant asthma	8	0
Obstructive airways disorder	14	0
Reversible airways obstruction	1	0
Wheezing	488	0
<i>Conditions associated with abnormal gas exchange</i>		
Asphyxia	2	0
Cyanosis central	1	0
Hyperoxia	1	0
Hypoxia	36	2
Respiratory acidosis	2	0
<i>Coughing and associated symptoms</i>		
Allergic cough	9	0
Atopic cough	1	0
Cough	3036	1
Cough decreased	2	0
Haemoptysis	76	0
Productive cough	200	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

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
<i>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</i>		
Laryngeal disorder	1	0
Reflux laryngitis	3	0
Vocal cord disorder	2	0
Vocal cord dysfunction	3	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Epiglottic oedema	1	0
Laryngeal obstruction	1	0
Laryngeal oedema	4	0
Laryngospasm	3	0
Stridor	28	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Alveolitis	1	0
Autoimmune lung disease	1	0
Hypersensitivity pneumonitis	1	0
Lower respiratory tract inflammation	1	0
Pneumonitis	36	2
Pulmonary sarcoidosis	3	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	36	0
Increased bronchial secretion	3	0
Increased viscosity of bronchial secretion	1	0
Lung hyperinflation	2	0
Lung opacity	4	0
Pleuritic pain	27	0
Pulmonary haemorrhage	1	0
Pulmonary pain	122	0
Rales	7	0
Respiratory fremitus	1	0
<i>Mediastinal disorders</i>		
Mediastinal mass	1	0
Pulmonary hilum mass	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	343	0
Nasal inflammation	5	0
Rhinitis allergic	28	0
<i>Nasal disorders NEC</i>		
Epistaxis	1112	0
Intranasal hypoaesthesia	2	0
Intranasal paraesthesia	1	0
Nasal crusting	2	0
Nasal disorder	4	0
Nasal dryness	36	0
Nasal mucosal discolouration	1	0
Nasal odour	7	0
Nasal oedema	8	0
Nasal polyps	2	0
Nasal pruritus	13	0
Nasal ulcer	3	0
<i>Neonatal hypoxic conditions</i>		
Dry lung syndrome	1	0
Gasping syndrome	1	0

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Infantile apnoea	2	0
Paranasal sinus disorders (excl infections and neoplasms)		
Allergic sinusitis	3	0
Paranasal sinus inflammation	5	0
Sinonasal obstruction	15	0
Sinus congestion	74	0
Sinus disorder	9	0
Parenchymal lung disorders NEC		
Atelectasis	5	0
Combined pulmonary fibrosis and emphysema	1	0
Emphysema	3	0
Interstitial lung disease	11	0
Lung consolidation	6	0
Lung infiltration	2	1
Organising pneumonia	2	0
Pulmonary alveolar haemorrhage	1	0
Pulmonary cavitation	1	0
Pulmonary fibrosis	11	0
Pulmonary toxicity	1	0
Pharyngeal disorders (excl infections and neoplasms)		
Hyperactive pharyngeal reflex	1	0
Pharyngeal enanthema	1	0
Pharyngeal erythema	10	0
Pharyngeal haemorrhage	2	0
Pharyngeal hypoaesthesia	40	0
Pharyngeal inflammation	4	0
Pharyngeal lesion	1	0
Pharyngeal mass	1	0
Pharyngeal oedema	15	0
Pharyngeal paraesthesia	57	0
Pharyngeal swelling	303	0
Pharyngeal ulceration	19	0
Tonsillar erythema	14	0
Tonsillar haemorrhage	1	0
Tonsillar hypertrophy	99	0
Tonsillar inflammation	4	0
Tonsillar ulcer	1	0
Tonsillolith	1	0
Pleural infections and inflammations		
Pleurisy	41	0
Pneumothorax and pleural effusions NEC		
Pleural effusion	44	0
Pneumothorax	14	0
Pneumothorax spontaneous	5	0
Pulmonary hypertension		
Pulmonary hypertension	3	0
Pulmonary oedemas		
Acute respiratory distress syndrome	3	1
Pulmonary congestion	20	0
Pulmonary oedema	25	2
Pulmonary thrombotic and embolic conditions		
Pulmonary artery thrombosis	2	0
Pulmonary embolism	563	42

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Pulmonary infarction	7	0
Pulmonary thrombosis	13	1
<i>Respiratory failures (excl neonatal)</i>		
Acute respiratory failure	3	1
Respiratory failure	15	2
<i>Respiratory signs and symptoms NEC</i>		
Allergic respiratory symptom	6	0
Diaphragmalgia	10	0
Nasal flaring	1	0
Painful respiration	19	1
Pleural rub	1	0
Respiratory symptom	21	0
Suffocation feeling	2	0
Use of accessory respiratory muscles	2	0
<i>Respiratory tract disorders NEC</i>		
Allergic respiratory disease	1	0
Aspiration	4	0
Lung disorder	12	0
Pulmonary mass	6	0
Respiratory disorder	16	1
Respiratory tract congestion	5	0
Respiratory tract haemorrhage	2	0
Respiratory tract inflammation	2	0
Respiratory tract irritation	9	0
Respiratory tract oedema	4	0
<i>Thoracic musculoskeletal disorders</i>		
Respiratory muscle weakness	2	0
<i>Tracheal disorders (excl infections and neoplasms)</i>		
Tracheal disorder	1	0
Tracheal pain	2	0
<i>Upper respiratory tract neoplasms</i>		
Tonsillar cyst	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	149	0
Catarrh	34	0
Choking	20	0
Choking sensation	7	0
Dry throat	188	0
Dysphonia	190	0
Increased upper airway secretion	6	0
Increased viscosity of upper respiratory secretion	37	0
Laryngeal pain	1	0
Nasal discharge discolouration	4	0
Nasal discomfort	59	0
Nasal obstruction	3	0
Oropharyngeal blistering	11	0
Oropharyngeal discolouration	1	0
Oropharyngeal discomfort	71	0
Oropharyngeal pain	3317	0
Oropharyngeal plaque	2	0
Paranasal sinus discomfort	55	0
Rhinalgia	15	0
Rhinorrhoea	1097	0

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Sinus pain	252	0
Sneezing	469	0
Snoring	8	0
Throat clearing	8	0
Throat irritation	270	0
Throat lesion	1	0
Throat tightness	295	0
Upper airway obstruction	3	0
Upper respiratory tract congestion	2	0
Upper respiratory tract irritation	1	0
Upper-airway cough syndrome	16	0
Yawning	31	0
<i>Vascular pulmonary disorders NEC</i>		
Acute chest syndrome	1	0
Respiratory disorders SOC TOTAL	22050	64

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	222	0
Acne cystic	28	0
Dermatitis acneiform	13	0
Oil acne	1	0
<i>Alopecias</i>		
Alopecia	489	0
Alopecia areata	82	0
Alopecia totalis	4	0
Alopecia universalis	3	0
Androgenetic alopecia	2	0
Diffuse alopecia	4	0
Hypotrichosis	3	0
Lichen planopilaris	2	0
Madarosis	9	0
<i>Angioedemas</i>		
Angioedema	287	0
Circumoral oedema	1	0
Circumoral swelling	1	0
Idiopathic angioedema	1	0
<i>Apocrine and eccrine gland disorders</i>		
Anhidrosis	2	0
Bromhidrosis	1	0
Cold sweat	891	0
Hidradenitis	5	0
Hyperhidrosis	2747	0
Hypohidrosis	3	0
Milia	2	0
Miliaria	120	0
Night sweats	972	0
Sweat discolouration	1	0
<i>Bullous conditions</i>		
Autoimmune blistering disease	1	0
Blister	559	0
Blister rupture	1	0
Blood blister	37	0
Dermatitis bullous	19	0
Erythema multiforme	45	0
Fracture blisters	1	0
Herpes gestationis	1	0
Mucous membrane pemphigoid	1	0
Pemphigoid	33	0
Pemphigus	9	0
Stevens-Johnson syndrome	7	0
Toxic epidermal necrolysis	2	1
<i>Connective tissue disorders</i>		
Chronic cutaneous lupus erythematosus	3	0
Dermatomyositis	12	0
Subacute cutaneous lupus erythematosus	3	0
<i>Dermal and epidermal conditions NEC</i>		
Acute febrile neutrophilic dermatosis	1	0
Dermatosis	2	0
Dry skin	307	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Koebner phenomenon	1	0
Macule	5	0
Neutrophilic dermatosis	1	0
Pain of skin	351	0
Papule	120	0
Pathergy reaction	1	0
Scab	28	0
Scar discomfort	1	0
Scar pain	20	0
Sensitive skin	238	0
Shagreen skin	1	0
Skin burning sensation	275	0
Skin degenerative disorder	1	0
Skin discolouration	170	0
Skin discomfort	6	0
Skin disorder	37	0
Skin fissures	11	0
Skin indentation	3	0
Skin induration	5	0
Skin lesion	53	0
Skin lesion inflammation	1	0
Skin necrosis	3	0
Skin odour abnormal	27	0
Skin plaque	4	0
Skin reaction	175	0
Skin sensitisation	45	0
Skin swelling	117	0
Skin texture abnormal	2	0
Skin tightness	30	0
Skin warm	372	0
Skin weeping	19	0
Sticky skin	3	0
Target skin lesion	3	0
Transient acantholytic dermatosis	1	0
Yellow skin	29	0
<i>Dermatitis and eczema</i>		
Autoimmune dermatitis	2	0
Dermatitis	170	0
Dermatitis allergic	309	0
Dermatitis atopic	65	0
Dermatitis contact	27	0
Dermatitis diaper	4	0
Dyshidrotic eczema	32	0
Eczema	443	0
Eczema asteatotic	17	0
Eczema infantile	1	0
Eczema nummular	8	0
Eczema vesicular	1	0
Eczema weeping	8	0
Hand dermatitis	5	0
Intertrigo	1	0
Neurodermatitis	4	0
Perioral dermatitis	3	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Seborrhoeic dermatitis	10	0
Skin irritation	160	0
Stasis dermatitis	2	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	35	0
Drug reaction with eosinophilia and systemic symptoms	1	0
Fixed eruption	3	0
Palmar-plantar erythrodysesthesia syndrome	3	0
Toxic skin eruption	2	0
<i>Erythemas</i>		
Erythema	2539	0
Palmar erythema	4	0
Pernio-like erythema	1	0
Vancomycin infusion reaction	2	0
<i>Exfoliative conditions</i>		
Dermatitis exfoliative	2	0
Dermatitis exfoliative generalised	6	0
Exfoliative rash	26	0
Keratolysis exfoliativa acquired	2	0
Skin exfoliation	153	0
<i>Granulomatous and deep cutaneous inflammatory conditions</i>		
Cutaneous sarcoidosis	1	0
Granuloma annulare	8	0
Necrobiosis lipoidica diabetorum	1	0
<i>Hyperkeratoses</i>		
Hyperkeratosis	2	0
Keratosis pilaris	3	0
Lichenoid keratosis	5	0
<i>Hyperpigmentation disorders</i>		
Argyria	1	0
Chloasma	2	0
Ephelides	1	0
Skin hyperpigmentation	7	0
Solar lentigo	4	0
<i>Hypertrichoses</i>		
Hirsutism	2	0
Hypertrichosis	2	0
<i>Hypopigmentation disorders</i>		
Skin depigmentation	5	0
Skin hypopigmentation	1	0
Vitiligo	27	0
<i>Lipodystrophies</i>		
Lipoatrophy	4	0
Lipodystrophy acquired	1	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
Ingrowing nail	2	0
Nail discolouration	12	0
Nail disorder	7	0
Nail growth abnormal	1	0
Nail pigmentation	2	0
Nail ridging	3	0
Onychalgia	10	0
Onychoclasia	6	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Onychomadesis	3	0
Splinter haemorrhages	4	0
<i>Panniculitides</i>		
Erythema nodosum	35	0
Panniculitis	3	0
<i>Papulosquamous conditions</i>		
Erythema annulare	2	0
Lichen planus	28	0
Lichen sclerosus	12	0
Parapsoriasis	9	0
Pityriasis alba	1	0
Pityriasis rosea	146	0
Pityriasis rubra pilaris	1	0
<i>Photosensitivity and photodermatosis conditions</i>		
Actinic prurigo	1	0
Photosensitivity reaction	73	0
Polymorphic light eruption	4	0
Solar dermatitis	2	0
<i>Pigmentation changes NEC</i>		
Haemosiderin stain	1	0
Pigmentation disorder	18	0
<i>Pilar disorders NEC</i>		
Hair colour changes	11	0
Hair disorder	1	0
Hair growth abnormal	14	0
Hair texture abnormal	7	0
Piloerection	29	0
Pseudofolliculitis	3	0
Trichorrhexis	3	0
<i>Pruritus NEC</i>		
Itching scar	10	0
Polymorphic eruption of pregnancy	1	0
Pruritus	6485	0
<i>Psoriatic conditions</i>		
Dermatitis psoriasiform	6	0
Guttate psoriasis	25	0
Nail psoriasis	3	0
Palmoplantar pustulosis	3	0
Psoriasis	267	0
Pustular psoriasis	3	0
Rebound psoriasis	2	0
<i>Purpura and related conditions</i>		
Ecchymosis	1	0
Henoch-Schonlein purpura	16	0
Petechiae	164	0
Purpura	64	0
<i>Pustular conditions</i>		
Acute generalised exanthematous pustulosis	2	0
<i>Rashes, eruptions and exanthems NEC</i>		
Butterfly rash	8	0
Rash	6807	1
Rash erythematous	1477	0
Rash macular	590	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Rash maculo-papular	69	0
Rash morbilliform	50	0
Rash papular	409	0
Rash pruritic	1442	0
Rash scarlatiniform	1	0
Rash vesicular	91	0
Systemic lupus erythematosus rash	9	0
Rosaceas		
Erythematotelangiectatic rosacea	1	0
Papulopustular rosacea	1	0
Rosacea	40	0
Scaly conditions		
Dandruff	5	0
Pityriasis	32	0
Sebaceous gland disorders		
Sebaceous glands overactivity	1	0
Seborrhoea	15	0
Skin and subcutaneous conditions NEC		
Cellulite	2	0
Cutaneous symptom	6	0
Reactive perforating collagenosis	1	0
Skin mass	32	0
Skin and subcutaneous tissue ulcerations		
Ischaemic skin ulcer	1	0
Mucocutaneous ulceration	1	0
Pyoderma gangrenosum	2	0
Scleroderma associated digital ulcer	1	0
Skin erosion	31	0
Skin ulcer	23	0
Skin cysts and polyps		
Dermal cyst	21	0
Skin dystrophies		
Keloid scar	3	0
Skin wrinkling	4	0
Skin haemorrhages		
Haemorrhage subcutaneous	15	0
Skin haemorrhage	24	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	2	0
Skin oedema	5	0
Skin vasculitides		
Capillaritis	4	0
Cutaneous vasculitis	16	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Hypersensitivity vasculitis	1	0
Vasculitic rash	22	0
Skin vasomotor conditions		
Livedo reticularis	31	0
Telangiectasia and related conditions		
Spider naevus	1	0
Telangiectasia	1	0
Urticarias		
Chronic spontaneous urticaria	15	0
Cold urticaria	11	0
Idiopathic urticaria	4	0
Mechanical urticaria	18	0
Solar urticaria	3	0
Urticaria	2364	0
Urticaria cholinergic	2	0
Urticaria chronic	44	0
Urticaria contact	1	0
Urticaria papular	6	0
Urticaria thermal	11	0
Urticularial vasculitis	7	0
Skin disorders SOC TOTAL	34539	2

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Reaction Name	Total	Fatal
Social circumstances		
<i>Age related issues</i>		
Infant	2	0
Menarche	3	0
Menopause	52	0
Postmenopause	5	0
<i>Criminal activity</i>		
Verbal abuse	1	0
<i>Dependents</i>		
Sick relative	7	0
<i>Dietary and nutritional issues</i>		
Feeding tube user	1	0
<i>Disability issues</i>		
Bedridden	39	0
Breast prosthesis user	3	0
Disability	4	0
Hearing disability	4	0
Housebound	1	0
Immobile	13	0
Impaired driving ability	5	0
Impaired work ability	21	0
Loss of personal independence in daily activities	62	0
Mental disability	1	0
Physical disability	6	0
Sight disability	13	0
Sitting disability	4	0
Walking aid user	1	0
Walking disability	3	0
Wheelchair user	1	0
<i>Economic circumstances</i>		
High income	1	0
Low income	1	0
<i>Educational issues</i>		
Educational problem	1	0
Illiteracy	2	0
<i>Employment issues</i>		
Job dissatisfaction	1	0
Retirement	4	0
Sick leave	1	0
Stress at work	3	0
<i>Family and partner issues</i>		
Bed sharing	1	0
Family stress	1	0
<i>Non-occupational and unspecified environmental problems</i>		
Flooding	2	0
Water pollution	2	0
<i>Pregnancy related circumstances</i>		
Breast feeding	17	0
Multigravida	1	0
Parity	1	0
<i>Social issues NEC</i>		
Exercise adequate	2	0
Hair dye user	2	0
Impaired quality of life	4	0

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Reaction Name	Total	Fatal
Social circumstances Social circumstances cont'd		
Patient dissatisfaction with treatment	1	0
Tobacco use		
Ex-tobacco user	1	0
Non-tobacco user	6	0
Tobacco user	1	0
Social circumstances SOC TOTAL	308	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Adrenal gland therapeutic procedures</i>		
Adrenalectomy	1	0
<i>Anaesthesia and allied procedures</i>		
Local anaesthesia	2	0
Nerve block	5	0
<i>Analgesia supportive care</i>		
Analgesic therapy	2	0
<i>Antiinfective therapies</i>		
COVID-19 prophylaxis	1	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 therapeutic procedures NEC</i>		
Cardiac operation	1	0
<i>Contraceptive methods female</i>		
Contraception	1	0
Contraceptive implant	3	0
Oral contraception	1	0
<i>Contraceptive methods male</i>		
Condom	1	0
<i>Dietary and nutritional therapies</i>		
Medical diet	8	0
Nothing by mouth order	13	0
Wheat-free diet	1	0
<i>External ear therapeutic procedures</i>		
Ear irrigation	1	0
<i>Facial therapeutic procedures</i>		
Face lift	1	0
<i>Fertility and fertilisation interventions female</i>		
Endometrial scratching	1	0
Ovulation induction	2	0
<i>Gastric therapeutic procedures</i>		
Gastric operation	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	15	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	2	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
Surgical & medical procedures cont'd		
Hormone therapy	8	0
Immunisations		
COVID-19 immunisation	97	0
Immunisation	496	1
Vaccine coadministration	1	0
Induced abortions		
Abortion induced	1	0
Joint therapeutic procedures		
Joint injection	6	0
Joint surgery	1	0
Knee arthroplasty	1	0
Large intestine therapeutic procedures		
Appendectomy	2	0
Limb therapeutic procedures		
Arm amputation	1	0
Limb immobilisation	12	0
Limb operation	10	0
Lymphoid tissue therapeutic procedures		
Lymphadenectomy	2	0
Splenectomy	1	0
Mastectomies		
Breast conserving surgery	5	0
Nail therapeutic procedures		
Nail operation	3	0
Nervous system therapeutic procedures NEC		
Multiple sclerosis relapse prophylaxis	3	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	3	0
Immune tolerance induction	1	0
Prophylaxis against transplant rejection	1	0
Reproductive system disorder prophylaxis	1	0
Psychiatric therapies		
Electroconvulsive therapy	2	0
Renal therapeutic procedures		
Dialysis	1	0
Respiratory tract therapeutic procedures NEC		
Asthma prophylaxis	4	0
Retinal therapeutic procedures		
Retinopexy	1	0
Skin and subcutaneous tissue therapeutic procedures NEC		
Dermal filler injection	4	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
Surgical & medical procedures cont'd		
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
Spine and spinal cord therapeutic procedures		
Spinal decompression	1	0
Tendon therapeutic procedures		
Tenodesis	1	0
Therapeutic bladder catheterisation		
Bladder catheterisation	2	0
Therapeutic procedures NEC		
Abscess drainage	1	0
Anaphylaxis treatment	7	0
Bed rest	6	0
Fatigue management	1	0
Hospitalisation	15	0
Injection	54	0
Interchange of vaccine products	338	0
Localised alternating hot and cold therapy	2	0
Magnetic therapy	1	0
Mass excision	5	0
Medical procedure	1	0
Medication dilution	2	0
Physical fitness training	1	0
Product used for unknown indication	2	0
Promotion of wound healing	1	0
Specialist consultation	1	0
Stent placement	1	0
Stoma care	1	0
Therapeutic procedure	2	0
Therapy change	2	0
Tracheal therapeutic procedures		
Tracheostomy	1	0
Uterine therapeutic procedures		
Endometrial ablation	2	0
Vascular therapeutic procedures NEC		
Vasodilation procedure	1	0
Surgical & medical procedures SOC TOTAL	1226	1

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Accelerated and malignant hypertension</i>		
Accelerated hypertension	2	0
Hypertensive crisis	16	0
Hypertensive urgency	2	0
Malignant hypertension	4	0
<i>Aneurysms and dissections non-site specific</i>		
Aneurysm	4	0
Aneurysm ruptured	1	0
Artery dissection	2	0
<i>Aortic aneurysms and dissections</i>		
Acute aortic syndrome	1	0
Aortic aneurysm	2	0
Aortic aneurysm rupture	1	1
Aortic dissection	1	0
<i>Aortic embolism and thrombosis</i>		
Aortic embolus	5	0
Aortic thrombosis	4	0
<i>Aortic infections and inflammations</i>		
Aortitis	1	0
<i>Aortic necrosis and vascular insufficiency</i>		
Aortic occlusion	1	0
Aortic stenosis	2	0
<i>Arterial infections and inflammations</i>		
Arteritis	2	0
Giant cell arteritis	23	0
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	17	0
Labile blood pressure	5	0
<i>Bruising, ecchymosis and purpura</i>		
Achenbach syndrome	4	0
<i>Circulatory collapse and shock</i>		
CT hypotension complex	2	0
Circulatory collapse	95	0
Hypoperfusion	2	0
Hypovolaemic shock	2	1
Neurogenic shock	24	0
Peripheral circulatory failure	6	0
Shock	25	0
Shock symptom	4	0
<i>Haemorrhages NEC</i>		
Arterial haemorrhage	1	0
Bloody discharge	26	0
Haematoma	52	0
Haemorrhage	1415	2
Internal haemorrhage	14	1
Venous haemorrhage	2	0
<i>Lymphangiopathies</i>		
Lymphangiopathy	1	0
Lymphocele	7	0
Lymphorrhoea	2	0
Lymphostasis	1	0
<i>Lymphoedemas</i>		
Lymphoedema	251	0

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Reaction Name	Total	Fatal
Vascular disorders <small>Vascular disorders cont'd</small>		
<i>Non-site specific embolism and thrombosis</i>		
Arterial thrombosis	5	0
Embolism	68	0
Embolism arterial	2	0
Embolism venous	8	1
Microembolism	2	0
Thrombosis	550	12
Venous thrombosis	8	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Arterial occlusive disease	2	0
Arterial spasm	1	0
Arteriosclerosis	4	0
Haemorrhagic infarction	1	0
Infarction	3	0
Ischaemia	11	0
Peripheral venous disease	2	0
Vascular compression	1	0
Vascular occlusion	1	0
Vasospasm	1	0
<i>Non-site specific vascular disorders NEC</i>		
Capillary disorder	1	0
Capillary fragility	6	0
Endothelial dysfunction	1	0
Haemodynamic instability	1	0
Superficial vein prominence	3	0
Vascular fragility	1	0
Vascular pain	44	0
Vascular wall hypertrophy	1	0
Vasodilatation	46	0
Vein discolouration	7	0
Vein disorder	9	0
Vein rupture	7	0
<i>Peripheral aneurysms and dissections</i>		
Peripheral artery aneurysm	1	0
<i>Peripheral embolism and thrombosis</i>		
Axillary vein thrombosis	1	0
Blue toe syndrome	36	0
Deep vein thrombosis	371	1
Femoral artery embolism	1	0
Jugular vein thrombosis	5	0
Pelvic venous thrombosis	4	0
Peripheral artery thrombosis	4	0
Peripheral embolism	4	0
Subclavian artery thrombosis	1	0
Subclavian vein thrombosis	4	0
Superficial vein thrombosis	31	0
Thrombophlebitis	31	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	59	0
Erythromelalgia	2	0
Flushing	485	0
Hot flush	1280	0
Peripheral vascular disorder	3	0

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Reaction Name	Total	Fatal
Vascular disorders <small>Vascular disorders cont'd</small>		
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
Jugular vein occlusion	2	0
May-Thurner syndrome	1	0
Peripheral arterial occlusive disease	2	0
Peripheral artery occlusion	1	0
Peripheral coldness	400	0
Peripheral ischaemia	13	0
Poor peripheral circulation	24	0
Raynaud's phenomenon	75	0
Subclavian vein occlusion	1	0
Vasoconstriction	2	0
Phlebitis NEC		
Phlebitis	38	0
Phlebitis superficial	10	0
Site specific embolism and thrombosis NEC		
Brachiocephalic vein thrombosis	1	0
Site specific vascular disorders NEC		
Aortic disorder	1	0
Aortic rupture	2	2
Inferior vena cava dilatation	1	0
Pallor	452	0
Varicose veins NEC		
Spider vein	7	0
Varicophlebitis	4	0
Varicose vein	42	0
Varicose vein ruptured	1	0
Vascular hypertensive disorders NEC		
Diastolic hypertension	6	0
Essential hypertension	6	0
Hypertension	799	0
Labile hypertension	2	0
Orthostatic hypertension	2	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	476	1
Orthostatic hypotension	34	0
Vasculitides NEC		
Behcet's syndrome	5	0
Diffuse vasculitis	1	0
Granulomatosis with polyangiitis	3	0
MAGIC syndrome	2	0
Thromboangiitis obliterans	1	0
Vasculitis	58	0

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Reaction Name	Total	Fatal
Vascular disorders <small>Vascular disorders cont'd</small>		
<i>Vena caval embolism and thrombosis</i>		
Vena cava embolism	1	0
Vena cava thrombosis	1	0
Vascular disorders SOC TOTAL	7651	22
TOTAL REACTIONS FOR DRUG	492657	778
TOTAL REPORTS	171109	
TOTAL FATAL OUTCOME REPORTS		778