

COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

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All UK spontaneous reports received between 9/12/20Á and €FFG/21 for mRNA Pfizer/BioNTech vaccineÁ analysis print

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Case Series Drug Analysis Print

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

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemia deficiencies</i>		
Anaemia folate deficiency	1	0
Anaemia vitamin B12 deficiency	3	0
Deficiency anaemia	1	0
Iron deficiency anaemia	8	0
<i>Anaemias NEC</i>		
Anaemia	118	0
Anaemia macrocytic	2	0
Anaemia megaloblastic	1	0
Autoimmune anaemia	3	0
Blood loss anaemia	1	0
Microcytic anaemia	1	0
<i>Anaemias haemolytic NEC</i>		
Coombs negative haemolytic anaemia	1	0
Haemolytic anaemia	6	0
<i>Anaemias haemolytic immune</i>		
Autoimmune haemolytic anaemia	16	0
Cold type haemolytic anaemia	1	0
Evans syndrome	1	0
Warm type 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	45	0
Spontaneous haematoma	2	0
<i>Coagulation factor deficiencies</i>		
Acquired haemophilia	2	0
<i>Coagulopathies</i>		
Abnormal clotting factor	4	0
Antiphospholipid syndrome	6	0
Coagulopathy	23	1
Disseminated intravascular coagulation	2	0
Hypercoagulation	3	0
Thrombotic microangiopathy	2	0
<i>Eosinophilic disorders</i>		
Eosinophilia	12	0
<i>Haematological disorders</i>		
Blood disorder	4	0
Hypergammaglobulinaemia	1	0
Hyperviscosity syndrome	1	0
Mast cell activation syndrome	7	0
Methaemoglobinaemia	1	0
<i>Haemolyses NEC</i>		
Haemolysis	6	0
Intravascular haemolysis	1	0
<i>Leukocytoses NEC</i>		
Leukocytosis	2	0
Lymphocytosis	6	0
Neutrophilia	10	0
<i>Leukopenias NEC</i>		
Leukopenia	4	1
Lymphopenia	4	0

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Reaction Name	Total	Fatal
Blood disorders Blood disorders cont'd		
<i>Lymphatic system disorders NEC</i>		
Abdominal lymphadenopathy	3	0
Hilar lymphadenopathy	2	0
Lymph node pain	1765	0
Lymph node ulcer	1	0
Lymphadenitis	146	0
Lymphadenopathy	10904	0
Lymphatic disorder	2	0
Lymphatic insufficiency	1	0
Necrotic lymphadenopathy	3	0
Pseudolymphoma	11	0
Retroperitoneal lymphadenopathy	1	0
<i>Marrow depression and hypoplastic anaemias</i>		
Aplasia pure red cell	2	0
Aplastic anaemia	1	1
Hypoplastic anaemia	2	0
Myelosuppression	1	0
Pancytopenia	8	0
<i>Neutropenias</i>		
Autoimmune neutropenia	2	0
Neutropenia	39	0
<i>Platelet disorders NEC</i>		
Platelet anisocytosis	1	0
Platelet disorder	3	0
<i>Polycythaemia (excl rubra vera)</i>		
Polycythaemia	3	0
<i>Purpuras (excl thrombocytopenic)</i>		
Purpura non-thrombocytopenic	1	0
<i>Red blood cell abnormal findings NEC</i>		
Macrocytosis	1	0
Polychromasia	2	0
Red blood cell abnormality	2	0
<i>Spleen disorders</i>		
Spleen atrophy	1	0
Splenic infarction	2	0
Splenic thrombosis	1	0
Splenic vein thrombosis	1	0
Splenomegaly	11	0
<i>Thrombocytopenias</i>		
Acquired amegakaryocytic thrombocytopenia	1	0
Immune thrombocytopenia	78	0
Thrombocytopenia	220	1
Thrombocytopenic purpura	7	0
Thrombotic thrombocytopenic purpura	6	0
<i>Thrombocytoses</i>		
Thrombocytosis	6	0
Blood disorders SOC TOTAL	13556	4

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Aortic valvular disorders</i>		
Aortic valve incompetence	1	0
<i>Cardiac conduction disorders</i>		
Atrioventricular block	21	1
Atrioventricular block complete	3	1
Atrioventricular block first degree	1	0
Atrioventricular block second degree	3	0
Bundle branch block	2	0
Bundle branch block left	3	0
Bundle branch block right	2	0
<i>Cardiac disorders NEC</i>		
Acute cardiac event	4	0
Cardiac disorder	58	0
Cardiac dysfunction	1	0
Cardiovascular deconditioning	1	0
Cardiovascular disorder	5	0
Intracardiac thrombus	6	0
<i>Cardiac hypertensive complications</i>		
Hypertensive heart disease	2	1
<i>Cardiac infections and inflammations NEC</i>		
Cauditis	4	0
<i>Cardiac neoplasms NEC</i>		
Pericardial cyst	1	0
<i>Cardiac signs and symptoms NEC</i>		
Cardiac discomfort	25	0
Cardiovascular symptom	1	0
Palpitations	3885	1
<i>Cardiac valve disorders NEC</i>		
Cardiac valve disease	2	0
Heart valve incompetence	2	0
<i>Cardiomyopathies</i>		
Cardiomyopathy	11	0
Congestive cardiomyopathy	5	0
Stress cardiomyopathy	2	0
<i>Coronary artery disorders NEC</i>		
Arteriosclerosis coronary artery	1	0
Coronary artery disease	6	3
Coronary artery occlusion	2	0
Coronary artery thrombosis	2	1
<i>Endocarditis NEC</i>		
Endocarditis noninfective	1	1
<i>Heart failures NEC</i>		
Cardiac failure	72	9
Cardiac failure acute	5	1
Cardiac failure chronic	2	0
Cardiac failure congestive	3	1
Cardiogenic shock	4	1
Cardiopulmonary failure	1	1
<i>Ischaemic coronary artery disorders</i>		
Acute coronary syndrome	5	0
Acute myocardial infarction	23	1
Angina pectoris	227	1
Angina unstable	3	0

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Reaction Name	Total	Fatal
Cardiac disorders Cardiac disorders cont'd		
Arteriospasm coronary	3	0
Microvascular coronary artery disease	2	0
Myocardial infarction	227	36
Myocardial ischaemia	10	5
Left ventricular failures		
Acute left ventricular failure	1	1
Left ventricular failure	7	2
Mitral valvular disorders		
Mitral valve incompetence	6	0
Mitral valve prolapse	1	0
Myocardial disorders NEC		
Cardiac amyloidosis	1	0
Cardiac aneurysm	1	1
Cardiomegaly	32	2
Left atrial dilatation	1	0
Left ventricular dysfunction	10	0
Left ventricular enlargement	2	0
Left ventricular hypertrophy	2	0
Myocardial fibrosis	5	0
Myocardial haemorrhage	1	0
Myocardial injury	12	0
Myocardial necrosis	1	0
Myocardial oedema	5	0
Myocardial rupture	1	0
Right ventricular enlargement	1	0
Ventricular hypertrophy	1	0
Ventricular hypokinesia	1	0
Noninfectious myocarditis		
Hypersensitivity myocarditis	1	0
Myocarditis	473	1
Noninfectious pericarditis		
Pericarditis	352	1
Pericarditis constrictive	1	0
Pericardial disorders NEC		
Cardiac tamponade	1	1
Pericardial effusion	37	1
Pericardial fibrosis	1	0
Pericardial haemorrhage	4	3
Pericardial rub	2	0
Rate and rhythm disorders NEC		
Arrhythmia	138	0
Bradycardia	61	0
Bradycardia foetal	2	1
Cardiac flutter	435	0
Extrasystoles	163	0
Heart alternation	1	0
Paroxysmal arrhythmia	1	0
Postural orthostatic tachycardia syndrome	21	0
Tachyarrhythmia	6	0
Tachycardia	1169	0
Tachycardia foetal	1	0
Tachycardia paroxysmal	1	0
Right ventricular failures		

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Cardiac disorders Cardiac disorders cont'd		
Cor pulmonale	1	0
Right ventricular failure	1	0
<i>Supraventricular arrhythmias</i>		
Arrhythmia supraventricular	12	0
Atrial fibrillation	218	0
Atrial flutter	31	0
Atrial tachycardia	10	0
Nodal arrhythmia	1	0
Sinus arrest	1	0
Sinus arrhythmia	5	0
Sinus bradycardia	13	0
Sinus node dysfunction	1	0
Sinus tachycardia	58	0
Supraventricular extrasystoles	3	0
Supraventricular tachycardia	39	0
<i>Tricuspid valvular disorders</i>		
Tricuspid valve incompetence	5	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	106	40
Cardio-respiratory arrest	1	1
Pulseless electrical activity	4	0
Ventricular arrhythmia	5	0
Ventricular extrasystoles	25	0
Ventricular fibrillation	7	1
Ventricular tachycardia	13	0
Cardiac disorders SOC TOTAL	8173	121

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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	13	0
<i>Cardiac hypoplasias congenital</i>		
Ventricular hypoplasia	1	0
<i>Cardiac septal defects congenital</i>		
Atrial septal defect	2	0
Hypertrophic cardiomyopathy	1	0
Ventricular septal defect	1	0
<i>Cardiac valve disorders congenital</i>		
Bicuspid aortic valve	1	0
<i>Central nervous system disorders congenital NEC</i>		
Spina bifida	2	1
Syringomyelia	1	0
<i>Cerebellar disorders congenital</i>		
Arnold-Chiari malformation	1	0
Hereditary ataxia	1	0
<i>Cerebral disorders congenital</i>		
Anencephaly	2	0
Cerebral palsy	3	0
<i>Coagulation disorders congenital</i>		
Haemophilia	2	0
<i>Congenital disorders NEC</i>		
Foetal malformation	1	0
Heterotaxia	1	0
<i>Connective tissue disorders congenital</i>		
Ehlers-Danlos syndrome	2	0
<i>Gastrointestinal tract disorders congenital NEC</i>		
Gastroschisis	2	0
<i>Great vessel disorders congenital</i>		
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>Inborn errors of lipid metabolism</i>		
Short-chain acyl-coenzyme A dehydrogenase deficiency	1	0
<i>Inborn errors of metabolism NEC</i>		
Alpha-1 antitrypsin deficiency	1	0
<i>Inborn errors of porphyrin metabolism</i>		
Porphyria	1	0
<i>Lymphatic system disorders congenital</i>		
Cystic lymphangioma	3	0
<i>Male reproductive tract disorders congenital</i>		
Cryptorchism	1	0
Micropenis	3	0
Phimosis	1	0
<i>Musculoskeletal and connective tissue disorders of limbs congenital</i>		
Developmental hip dysplasia	1	0
<i>Musculoskeletal and connective tissue disorders of skull congenital</i>		

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Reaction Name	Total	Fatal
Congenital disorders Congenital disorders cont'd		
Platybasia	1	0
Musculoskeletal and connective tissue disorders of spine congenital		
Block vertebra	1	0
Brachyolmia	1	0
Neurological disorders congenital NEC		
Familial hemiplegic migraine	2	0
Familial periodic paralysis	1	0
Moebius II syndrome	1	0
Tourette's disorder	2	0
Ocular disorders congenital NEC		
Colour blindness	4	0
Congenital eye disorder	1	0
Palate disorders congenital		
Cleft lip and palate	2	0
Peripheral nervous system disorders congenital NEC		
Hereditary neuropathy with liability to pressure palsies	1	0
Paroxysmal extreme pain disorder	1	0
Pulmonary and bronchial disorders congenital		
Congenital cystic lung	1	0
Retinal disorders congenital		
Retinitis pigmentosa	1	0
Sex chromosomal abnormalities		
Turner's syndrome	1	0
Skin and subcutaneous tissue disorders congenital NEC		
Acral peeling skin syndrome	1	0
Tongue disorders congenital		
Ankyloglossia congenital	1	0
Vascular anomalies congenital NEC		
Congenital LUMBAR syndrome	1	0
Venous disorders congenital		
Anomalous pulmonary venous connection	1	0
Congenital disorders SOC TOTAL	80	1

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear canal erythema	1	0
Ear congestion	31	0
Ear discomfort	94	0
Ear disorder	17	0
Ear haemorrhage	12	0
Ear pain	953	0
Ear pruritus	9	0
Ear swelling	33	0
Otorrhoea	5	0
Paraesthesia ear	1	0
<i>Eustachian tube disorders</i>		
Eustachian tube disorder	4	0
Eustachian tube dysfunction	9	0
Eustachian tube obstruction	4	0
<i>External ear disorders NEC</i>		
Auricular swelling	2	0
Excessive cerumen production	10	0
External ear pain	4	0
Red ear syndrome	2	0
<i>External ear infections and inflammations</i>		
External ear inflammation	2	0
<i>Hearing disorders NEC</i>		
Auditory disorder	6	0
Diplacusis	2	0
<i>Hearing losses</i>		
Conductive deafness	1	0
Deafness	239	0
Deafness bilateral	9	0
Deafness neurosensory	18	0
Deafness transitory	6	0
Deafness unilateral	32	0
Hypoacusis	183	0
Sudden hearing loss	48	0
<i>Hyperacusia</i>		
Hyperacusis	56	0
Misophonia	3	0
<i>Inner ear disorders NEC</i>		
Acute vestibular syndrome	2	0
Inner ear disorder	13	0
Meniere's disease	11	0
Vestibular disorder	10	0
<i>Inner ear infections and inflammations</i>		
Inner ear inflammation	10	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	61	0
Tinnitus	1968	0
Vertigo	1388	0
Vertigo labyrinthine	10	0
Vertigo positional	74	0
<i>Mastoid disorders</i>		
Mastoid effusion	1	0
<i>Middle ear disorders NEC</i>		

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Reaction Name	Total	Fatal
Ear disorders Ear disorders cont'd		
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	3	0
Ear disorders SOC TOTAL	5352	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Autoimmune thyroiditis	2	0
Thyroiditis	20	0
Thyroiditis acute	3	0
Thyroiditis subacute	3	0
<i>Adrenal cortical hypofunctions</i>		
Addison's disease	2	0
Adrenal insufficiency	2	0
Adrenocortical insufficiency acute	14	0
<i>Adrenal gland disorders NEC</i>		
Adrenal haemorrhage	2	0
<i>Anterior pituitary hyperfunction</i>		
Pituitary-dependent Cushing's syndrome	1	0
<i>Anterior pituitary hypofunction</i>		
Hypopituitarism	1	0
<i>Endocrine abnormalities of gonadal function NEC</i>		
Oestrogen deficiency	1	0
<i>Endocrine abnormalities of puberty</i>		
Delayed menarche	4	0
Premature menarche	19	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	47	0
Ovulation delayed	32	0
<i>Male gonadal function disorders</i>		
Androgen deficiency	1	0
<i>Thyroid disorders NEC</i>		
Autoimmune thyroid disorder	1	0
Goitre	12	0
Thyroid disorder	8	0
Thyroid mass	1	0
Thyroid pain	9	0
<i>Thyroid hyperfunction disorders</i>		
Basedow's disease	10	0
Hyperthyroidism	40	0
Thyrotoxic crisis	3	0
<i>Thyroid hypofunction disorders</i>		
Autoimmune hypothyroidism	1	0
Hypothyroidism	29	0
Immune-mediated hypothyroidism	1	0
Myxoedema	1	0
Endocrine disorders SOC TOTAL	270	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	11	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>		
Chorioretinopathy	5	0
Vitreous detachment	17	0
Vitreous floaters	94	0
<i>Colour blindness (incl acquired)</i>		
Dyschromatopsia	9	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	44	0
Scleral haemorrhage	1	0
<i>Conjunctival infections, irritations and inflammations</i>		
Conjunctival hyperaemia	2	0
Conjunctival irritation	1	0
Conjunctival oedema	3	0
Conjunctivitis allergic	1	0
<i>Corneal infections, oedemas and inflammations</i>		
Corneal oedema	2	0
Keratitis	6	0
Ulcerative keratitis	5	0
<i>Corneal structural change, deposit and degeneration</i>		
Corneal scar	1	0
<i>Eyelid movement disorders</i>		
Blepharospasm	140	0
Excessive eye blinking	6	0
Eyelid function disorder	3	0
Eyelid myokymia	4	0
Eyelid ptosis	44	0
Paralytic lagophthalmos	2	0
<i>Glaucomas (excl congenital)</i>		
Angle closure glaucoma	2	0
Glaucoma	6	0
<i>Iris and ciliary body structural change, deposit and degeneration</i>		
Eye colour change	3	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Autoimmune uveitis	2	0
Iridocyclitis	14	0
Iritis	10	0
Uveitis	47	0
<i>Lacrimation disorders</i>		
Dry eye	149	0
Lacrimation increased	133	0
<i>Lid bleeding and vascular disorders</i>		
Eyelid bleeding	1	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Blepharitis	15	0
Chalazion	7	0
Eczema eyelids	8	0
Erythema of eyelid	9	0
Eyelid cyst	5	0
Eyelid irritation	3	0
Eyelid margin crusting	4	0
Eyelid oedema	6	0
Eyelid rash	16	0
Meibomian gland dysfunction	1	0
Swelling of eyelid	120	0
Swollen tear duct	2	0
<i>Lid, lash and lacrimal structural disorders</i>		
Dacryostenosis acquired	1	0
Dermatochalasis	1	0
Eyelash changes	1	0
Eyelid exfoliation	3	0
Eyelid skin dryness	2	0
Eyelid thickening	1	0
Floppy eyelid syndrome	1	0
Growth of eyelashes	3	0
Lagophthalmos	3	0
<i>Ocular bleeding and vascular disorders NEC</i>		
Eye haematoma	4	0
Eye haemorrhage	29	0
Ocular vascular disorder	2	0
Ophthalmic vein thrombosis	1	0
<i>Ocular disorders NEC</i>		
Dark circles under eyes	7	0
Eye disorder	34	0
Eye oedema	17	0
Eye pain	1085	0
Eye swelling	510	0
Eye symptom	9	0
Eye ulcer	4	0
Eyelid disorder	14	0
Eyelid pain	12	0
Eyelids pruritus	6	0
Ocular discomfort	25	0
Periorbital oedema	18	0
Periorbital pain	1	0
Periorbital swelling	118	0
Retinal disorder	2	0
Vitreous disorder	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye allergy	15	0
Eye discharge	29	0
Eye inflammation	29	0
Eye irritation	91	0
Eye pruritus	236	0
Limbal swelling	4	0
Ocular hyperaemia	220	0
<i>Ocular nerve and muscle disorders</i>		

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Binocular eye movement disorder	1	0
Extraocular muscle disorder	1	0
Extraocular muscle paresis	2	0
Eye movement disorder	36	0
Gaze palsy	1	0
Ocular myasthenia	1	0
Ophthalmoplegia	5	0
Strabismus	8	0
Ocular sensation disorders		
Abnormal sensation in eye	19	0
Asthenopia	149	0
Eye paraesthesia	2	0
Eyelid sensory disorder	2	0
Foreign body sensation in eyes	16	0
Hypoaesthesia eye	15	0
Photophobia	467	0
Optic disc abnormalities NEC		
Papilloedema	7	0
Optic nerve bleeding and vascular disorders		
Optic disc haemorrhage	1	0
Optic ischaemic neuropathy	2	0
Orbital infections, inflammations and irritations		
Parophthalmia	1	0
Orbital structural change, deposit and degeneration		
Orbital oedema	2	0
Pupil disorders		
Miosis	2	0
Mydriasis	22	0
Pupil fixed	2	0
Pupillary disorder	1	0
Pupils unequal	12	0
Refractive and accommodative disorders		
Accommodation disorder	1	0
Altered visual depth perception	3	0
Astigmatism	2	0
Hypermetropia	2	0
Myopia	1	0
Retinal bleeding and vascular disorders (excl retinopathy)		
Retinal artery occlusion	14	0
Retinal artery thrombosis	2	0
Retinal haemorrhage	7	0
Retinal vascular thrombosis	1	0
Retinal vein occlusion	35	0
Retinal vein thrombosis	2	0
Retinal structural change, deposit and degeneration		
Macular degeneration	4	0
Macular hole	2	0
Macular rupture	1	0
Maculopathy	1	0
Neovascular age-related macular degeneration	4	0
Retinal degeneration	1	0
Retinal detachment	6	0
Retinal tear	2	0

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Retinal toxicity	3	0
Retinal, choroid and vitreous infections and inflammations		
Birdshot chorioretinopathy	2	0
Cystoid macular oedema	1	0
Macular oedema	5	0
Retinal vasculitis	3	0
Retinopathies NEC		
Acute macular neuroretinopathy	2	0
Retinal exudates	2	0
Retinopathy	4	0
Scleral infections, irritations and inflammations		
Episcleritis	7	0
Scleritis	6	0
Scleral structural change, deposit and degeneration		
Scleral discolouration	2	0
Structural change, deposit and degeneration of eye NEC		
Endocrine ophthalmopathy	1	0
Exophthalmos	1	0
Visual colour distortions		
Chloropsia	2	0
Chromatopsia	1	0
Cyanopsia	3	0
Erythropsia	2	0
Xanthopsia	1	0
Visual disorders NEC		
Charles Bonnet syndrome	2	0
Diplopia	158	0
Dysmetropsia	1	0
Glare	1	0
Halo vision	7	0
Heteronymous diplopia	1	0
Metamorphopsia	19	0
Oscillopsia	3	0
Photopsia	133	0
Scintillating scotoma	4	0
Vision blurred	1197	0
Visual brightness	3	0
Visual snow syndrome	8	0
Visual field disorders		
Visual field defect	30	0
Visual impairment and blindness (excl colour blindness)		
Amaurosis fugax	3	0
Blindness	126	0
Blindness cortical	1	0
Blindness transient	14	0
Blindness unilateral	15	0
Central vision loss	4	0
Sudden visual loss	3	0
Visual acuity reduced	23	0
Visual acuity reduced transiently	1	0
Visual impairment	372	0
Visual pathway disorders		
Optic nerve disorder	1	0

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Eye disorders SOC TOTAL	6563	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Abdominal findings abnormal</i>		
Abdominal mass	2	0
Gastrointestinal sounds abnormal	16	0
<i>Abdominal hernias NEC</i>		
Abdominal hernia	2	0
<i>Abdominal wall conditions NEC</i>		
Abdominal wall haematoma	1	0
<i>Acute and chronic pancreatitis</i>		
Alcoholic pancreatitis	1	0
Obstructive pancreatitis	1	0
Pancreatitis	14	0
Pancreatitis acute	15	1
Pancreatitis necrotising	1	0
<i>Anal and rectal disorders NEC</i>		
Anal fissure	2	0
Anal sphincter atony	1	0
Rectal prolapse	1	0
<i>Anal and rectal pains</i>		
Proctalgia	14	0
<i>Anal and rectal signs and symptoms</i>		
Anal hypoaesthesia	1	0
Anal pruritus	1	0
Anal spasm	1	0
Anorectal discomfort	4	0
Anorectal swelling	1	0
Rectal discharge	2	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
<i>Colitis (excl infective)</i>		
Autoimmune colitis	2	0
Colitis	46	1
Colitis ischaemic	1	0
Colitis microscopic	2	0
Colitis ulcerative	70	0
Crohn's disease	40	0
Eosinophilic colitis	1	0
Inflammatory bowel disease	8	0
<i>Dental and periodontal infections and inflammations</i>		
Dental caries	1	0
<i>Dental disorders NEC</i>		
Loose tooth	1	0
Malpositioned teeth	2	0
Periodontal disease	1	0
Teeth brittle	3	0
Teething	8	0
Tooth disorder	2	0
Tooth socket haemorrhage	1	0
<i>Dental pain and sensation disorders</i>		
Dental discomfort	6	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Dental paraesthesia	12	0
Hyperaesthesia teeth	35	0
Toothache	158	0
<i>Dental surface disorders</i>		
Tooth discolouration	9	0
<i>Diaphragmatic hernias</i>		
Hiatus hernia	7	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	5302	0
Diarrhoea haemorrhagic	22	0
<i>Diverticula</i>		
Diverticulum	5	0
Diverticulum intestinal	1	0
<i>Duodenal and small intestinal stenosis and obstruction</i>		
Small intestinal obstruction	1	0
<i>Duodenal ulcers and perforation</i>		
Duodenal ulcer haemorrhage	1	0
Duodenal ulcer perforation	3	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	436	0
Epigastric discomfort	14	0
Eructation	51	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	19	0
Faecaloma	4	0
Faeces discoloured	59	0
Faeces hard	2	0
Faeces pale	3	0
Faeces soft	12	0
Mucous stools	10	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	510	0
Aerophagia	3	0
Flatulence	179	0
<i>Gastric and oesophageal haemorrhages</i>		
Gastric haemorrhage	5	1
Mallory-Weiss syndrome	1	0
Oesophageal varices haemorrhage	1	0
<i>Gastric ulcers and perforation</i>		
Gastric ulcer	6	0
<i>Gastritis (excl infective)</i>		
Chronic gastritis	3	0
Gastritis	55	0
Reflux gastritis	6	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal migraine	2	0
Abdominal pain	1423	0
Abdominal pain lower	129	0
Abdominal pain upper	2342	0
Abdominal rigidity	22	0
Abdominal tenderness	13	0
Gastrointestinal pain	132	0
Oesophageal pain	12	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	249	0
Duodenogastric reflux	4	0
Gastric dilatation	7	0
Gastrooesophageal reflux disease	147	0
Impaired gastric emptying	9	0
Infrequent bowel movements	3	0
Intestinal dilatation	1	0
Intestinal pseudo-obstruction	2	0
<i>Gastrointestinal disorders NEC</i>		
Appendix disorder	1	0
Food poisoning	7	0
Functional gastrointestinal disorder	10	0
Gastric disorder	10	0
Gastrointestinal disorder	23	0
Stomach mass	4	0
<i>Gastrointestinal dyskinetic disorders</i>		
Bowel movement irregularity	6	0
Change of bowel habit	6	0
Dyschezia	3	0
Gastrointestinal motility disorder	3	0
Oesophageal achalasia	1	0
<i>Gastrointestinal fistulae</i>		
Diverticular fistula	2	0
<i>Gastrointestinal inflammatory disorders NEC</i>		
Duodenitis	1	0
Enteritis	6	0
Epiplonic appendagitis	2	0
Gastrointestinal inflammation	3	0
Gastrointestinal tract irritation	1	0
Intestinal angioedema	2	0
<i>Gastrointestinal mucosal dystrophies and secretion disorders</i>		
Barrett's oesophagus	1	0
Hyperchlorhydria	4	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	597	0
Abdominal symptom	1	0
Acute abdomen	6	0
Anal incontinence	19	0
Breath odour	18	0
Dysphagia	201	1
Gastrointestinal wall thickening	1	0
Odynophagia	36	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Cardiospasm	1	0
Defaecation urgency	11	0
Frequent bowel movements	28	0
Gastrointestinal hypermotility	1	0
Irritable bowel syndrome	84	0
Oesophageal spasm	4	0
Pylorospasm	1	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Intestinal obstruction	3	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Neonatal intestinal obstruction	1	0
<i>Gastrointestinal vascular malformations</i>		
Gastric antral vascular ectasia	11	0
<i>Gastrointestinal vascular occlusion and infarction</i>		
Intestinal ischaemia	5	2
Mesenteric vein thrombosis	6	0
Omental infarction	1	0
Thrombosis mesenteric vessel	2	0
Visceral venous thrombosis	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival blister	13	0
Gingival discomfort	8	0
Gingival disorder	4	0
Gingival erythema	2	0
Gingival hypertrophy	1	0
Gingival oedema	1	0
Gingival pain	105	0
Gingival pruritus	1	0
Gingival recession	1	0
Gingival swelling	35	0
Gingival ulceration	2	0
Gingivitis ulcerative	1	0
Noninfective gingivitis	8	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	62	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Gastric varices	1	0
Haemorrhoidal haemorrhage	1	0
Haemorrhoids	31	1
Haemorrhoids thrombosed	1	0
<i>Inguinal hernias</i>		
Inguinal hernia	1	0
<i>Intestinal haemorrhages</i>		
Anal haemorrhage	20	1
Intestinal haemorrhage	1	0
Rectal haemorrhage	69	0
Small intestinal haemorrhage	5	0
<i>Intestinal ulcers and perforation NEC</i>		
Intestinal perforation	5	2
Large intestinal ulcer	1	0
Large intestine perforation	1	0
<i>Large intestinal stenosis and obstruction</i>		
Large intestinal obstruction	1	1
<i>Malabsorption syndromes</i>		
Bile acid malabsorption	2	0
Coeliac disease	12	0
Malabsorption	1	0
Steatorrhoea	4	0
<i>Nausea and vomiting symptoms</i>		
Discoloured vomit	12	0
Infantile vomiting	7	0
Nausea	13381	0
Regurgitation	1	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Retching	104	0
Vomiting	4348	1
Vomiting projectile	61	0
Non-mechanical ileus		
Ileus paralytic	2	0
Non-site specific gastrointestinal haemorrhages		
Gastrointestinal haemorrhage	16	1
Haematemesis	30	2
Haematochezia	51	0
Melaena	9	0
Upper gastrointestinal haemorrhage	12	0
Oesophageal stenosis and obstruction		
Oesophageal stenosis	3	0
Oesophagitis (excl infective)		
Eosinophilic oesophagitis	1	0
Oesophagitis	4	0
Oral dryness and saliva altered		
Aptyalism	3	0
Dry mouth	482	0
Lip dry	38	0
Saliva altered	6	0
Salivary hypersecretion	49	0
Oral soft tissue disorders NEC		
Angina bullosa haemorrhagica	1	0
Chapped lips	20	0
Cheilitis	25	0
Enlarged uvula	14	0
Leukoplakia oral	2	0
Lip blister	29	0
Lip disorder	5	0
Oral disorder	18	0
Oral lichen planus	12	0
Oral mucosal hypertrophy	1	0
Oral papule	1	0
Uvulitis	5	0
Oral soft tissue haemorrhages		
Mouth haemorrhage	15	0
Oral blood blister	13	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	6	0
Coating in mouth	1	0
Hypoaesthesia oral	462	0
Lip discolouration	7	0
Lip erythema	4	0
Lip exfoliation	5	0
Lip pain	50	0
Lip pruritus	14	0
Lip scab	1	0
Oral discomfort	78	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Oral dysaesthesia	1	0
Oral mucosal blistering	14	0
Oral mucosal discolouration	1	0
Oral mucosal eruption	16	0
Oral mucosal erythema	7	0
Oral mucosal exfoliation	9	0
Oral mucosal roughening	3	0
Oral mucosal scab	1	0
Oral pain	164	0
Oral pruritus	22	0
Paraesthesia oral	873	0
Pigmentation lip	1	0
Oral soft tissue swelling and oedema		
Lip oedema	4	0
Lip swelling	732	0
Mouth swelling	91	0
Oedema mouth	4	0
Palatal oedema	3	0
Palatal swelling	2	0
Pancreatic disorders NEC		
Pancreatic disorder	1	0
Pancreatic failure	2	0
Pancreatic mass	1	0
Peptic ulcers and perforation		
Peptic ulcer	1	0
Peptic ulcer haemorrhage	13	0
Peritoneal and retroperitoneal disorders		
Ascites	1	0
Peritoneal and retroperitoneal fibrosis and adhesions		
Abdominal adhesions	2	0
Peritoneal and retroperitoneal haemorrhages		
Haemoperitoneum	1	0
Retroperitoneal haemorrhage	1	1
Rectal inflammations NEC		
Proctitis	3	0
Proctitis ulcerative	1	0
Salivary gland disorders NEC		
Salivary gland disorder	1	0
Salivary gland pain	12	0
Salivary gland enlargements		
Parotid gland enlargement	10	0
Salivary gland enlargement	5	0
Submaxillary gland enlargement	7	0
Salivary gland infections and inflammations		
Noninfective sialoadenitis	1	0
Stomatitis and ulceration		
Aphthous ulcer	50	0
Lip ulceration	18	0
Mouth ulceration	432	0
Oral mucosa erosion	1	0
Palatal ulcer	1	0
Stomatitis	64	0
Tongue disorders		

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Glossitis	20	0
Hypertrophy of tongue papillae	1	0
Plicated tongue	3	0
Tongue disorder	39	0
Tongue geographic	6	0
Tongue haemorrhage	3	0
Tongue ulceration	29	0
Trichoglossia	4	0
<i>Tongue signs and symptoms</i>		
Glossodynia	205	0
Scalloped tongue	5	0
Stiff tongue	4	0
Swollen tongue	467	0
Tongue blistering	18	0
Tongue coated	17	0
Tongue discolouration	36	0
Tongue discomfort	40	0
Tongue dry	14	0
Tongue eruption	9	0
Tongue erythema	12	0
Tongue exfoliation	1	0
Tongue movement disturbance	6	0
Tongue oedema	23	0
Tongue pruritus	2	0
Tongue rough	4	0
Tongue spasm	9	0
<i>Tooth missing</i>		
Tooth loss	6	0
Gastrointestinal disorders SOC TOTAL	36234	16

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site bruise	7	0
Administration site erythema	4	0
Administration site extravasation	3	0
Administration site haematoma	3	0
Administration site inflammation	1	0
Administration site irritation	1	0
Administration site joint discomfort	1	0
Administration site joint movement impairment	1	0
Administration site nerve damage	1	0
Administration site pain	17	0
Administration site rash	5	0
Administration site reaction	1	0
Administration site swelling	4	0
Administration site urticaria	2	0
Administration site warmth	2	0
Puncture site bruise	36	0
Puncture site pain	7	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	5	0
<i>Application and instillation site reactions</i>		
Application site acne	2	0
Application site bruise	9	0
Application site burn	1	0
Application site erythema	17	0
Application site haemorrhage	1	0
Application site hypoaesthesia	1	0
Application site irritation	1	0
Application site joint erythema	1	0
Application site joint pain	1	0
Application site mass	1	0
Application site odour	2	0
Application site pain	12	0
Application site pruritus	4	0
Application site rash	2	0
Application site reaction	1	0
Application site swelling	2	0
Application site vesicles	7	0
Application site warmth	1	0
Instillation site warmth	8	0
<i>Asthenic conditions</i>		
Asthenia	1885	0
Chronic fatigue syndrome	74	0
Decreased activity	9	0
Fatigue	21703	0
Malaise	5025	1
Sluggishness	17	0
<i>Body temperature altered</i>		

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Hyperthermia	7	0
Hypothermia	24	0
Temperature regulation disorder	13	0
Breast complications associated with device		
Breast implant palpable	1	0
Capsular contracture associated with breast implant	1	0
Cardiac complications associated with device		
Prosthetic cardiac valve thrombosis	2	0
Complications associated with device NEC		
Capsular contracture associated with implant	1	0
Complication of device removal	3	0
Injury associated with device	4	0
Medical device pain	1	0
Medical device site swelling	1	0
Phantom shocks	2	0
Death and sudden death		
Brain death	3	2
Cardiac death	2	2
Clinical death	1	1
Death	176	174
Decapitation	1	1
Drowning	1	0
Sudden death	27	27
Febrile disorders		
Hyperpyrexia	9	0
Pyrexia	14218	0
Feelings and sensations NEC		
Chills	9082	0
Feeling abnormal	1555	0
Feeling cold	1159	0
Feeling drunk	77	0
Feeling hot	1117	0
Feeling jittery	27	0
Feeling of body temperature change	315	0
Feeling of relaxation	3	0
Hangover	76	0
Hunger	47	0
Sensation of blood flow	4	0
Sensation of foreign body	53	0
Temperature intolerance	43	0
Thirst	328	0
Fibrosis NEC		
Fibrosis	1	0
Gait disturbances		
Gait disturbance	220	0
Gait inability	88	0
Loss of control of legs	23	0
General signs and symptoms NEC		
Adhesion	1	0
Chronic disease	1	0
Condition aggravated	222	0
Crepitations	3	0
Crying	149	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Deformity	2	0
Discharge	12	0
Disease progression	2	0
Disease recurrence	28	0
Effusion	3	0
Energy increased	22	0
Exercise tolerance decreased	24	0
Fat tissue increased	1	0
Foaming at mouth	3	0
General physical health deterioration	15	2
General symptom	3	0
Glassy eyes	5	0
High-pitched crying	3	0
Illness	1846	0
Induration	15	0
Influenza like illness	2296	0
Irritability postvaccinal	2	0
Local reaction	79	0
Moaning	3	0
Multiple organ dysfunction syndrome	10	4
Nonspecific reaction	1	0
Organ failure	2	1
Perforation	2	0
Peripheral swelling	3530	0
Physical deconditioning	2	0
Pre-existing condition improved	8	0
Prolapse	1	0
Screaming	20	0
Secretion discharge	24	0
Swelling	2831	0
Swelling face	785	0
Symptom recurrence	1	0
Terminal state	1	0
Tissue irritation	1	0
Healing abnormal NEC		
Impaired healing	2	0
Implant and catheter site reactions		
Implant site discolouration	2	0
Implant site pain	3	0
Implant site rash	1	0
Implant site swelling	2	0
Implant site urticaria	1	0
Implant site warmth	3	0
Inflamations		
Granuloma	1	0
Inflammation	465	0
Papillitis	1	0
Scar inflammation	3	0
Serositis	1	0
Systemic inflammatory response syndrome	2	0
Infusion site reactions		
Infusion site coldness	1	0
Infusion site discolouration	1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Infusion site joint effusion	1	0
Infusion site joint pain	2	0
Infusion site mass	1	0
Infusion site nerve damage	1	0
Infusion site pain	4	0
Infusion site pruritus	2	0
Infusion site swelling	2	0
Infusion site urticaria	1	0
Infusion site warmth	2	0
Injection site reactions		
Injected limb mobility decreased	30	0
Injection site bruising	65	0
Injection site coldness	1	0
Injection site cyst	2	0
Injection site discolouration	5	0
Injection site discomfort	10	0
Injection site eczema	1	0
Injection site erythema	368	0
Injection site extravasation	1	0
Injection site haemorrhage	7	0
Injection site hypersensitivity	2	0
Injection site hypoaesthesia	11	0
Injection site indentation	9	0
Injection site induration	4	0
Injection site inflammation	40	0
Injection site irritation	1	0
Injection site joint discomfort	2	0
Injection site joint erythema	3	0
Injection site joint movement impairment	1	0
Injection site joint pain	14	0
Injection site lymphadenopathy	1	0
Injection site macule	1	0
Injection site mass	520	0
Injection site movement impairment	1	0
Injection site necrosis	4	0
Injection site nerve damage	1	0
Injection site oedema	16	0
Injection site pain	2817	0
Injection site paraesthesia	12	0
Injection site pruritus	194	0
Injection site rash	166	0
Injection site reaction	41	0
Injection site scab	4	0
Injection site scar	5	0
Injection site swelling	281	0
Injection site urticaria	29	0
Injection site vesicles	10	0
Injection site warmth	183	0
Interactions		
Alcohol interaction	4	0
Drug interaction	26	0
Inhibitory drug interaction	3	0
Mass conditions NEC		

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Cyst	40	0
Mass	67	0
Nodule	36	0
<i>Mucosal findings abnormal</i>		
Mucosa vesicle	1	0
Mucosal dryness	1	0
Mucosal haemorrhage	9	0
Mucosal inflammation	2	0
Oedema mucosal	1	0
Polyp	5	0
<i>Necrosis NEC</i>		
Fat necrosis	3	0
Necrosis	4	0
<i>Oedema NEC</i>		
Face oedema	30	0
Generalised oedema	3	0
Localised oedema	18	0
Oedema	73	0
Oedema peripheral	87	0
<i>Pain and discomfort NEC</i>		
Axillary pain	2971	0
Breakthrough pain	1	0
Chest discomfort	1636	0
Chest pain	4442	0
Discomfort	455	0
Facial discomfort	19	0
Facial pain	199	0
Inflammatory pain	16	0
Non-cardiac chest pain	29	0
Pain	8408	0
Suprapubic pain	1	0
Tenderness	644	0
Visceral pain	2	0
<i>Therapeutic and nontherapeutic responses</i>		
Adverse drug reaction	46	0
Adverse event	2	0
Adverse food reaction	3	0
Adverse reaction	9	0
Drug ineffective	301	0
Drug intolerance	4	0
Drug resistance	1	0
Immediate post-injection reaction	2	0
Inadequate analgesia	8	0
No reaction on previous exposure to drug	42	0
Product intolerance	1	0
Therapeutic product effect decreased	1	0
Therapeutic product effect delayed	2	0
Therapeutic product effect increased	1	0
Therapeutic product ineffective	2	0
Therapeutic response decreased	2	0
Therapeutic response unexpected	74	0
Therapy non-responder	1	0
Treatment failure	8	0

Case Series Drug Analysis Print

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

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination failure	39	0
Trophic disorders		
Atrophy	2	0
Calcinosis	2	0
Hyperplasia	1	0
Ulcers NEC		
Ulcer	32	0
Ulcer haemorrhage	1	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	14	0
Shoulder injury related to vaccine administration	33	0
Vaccination site anaesthesia	1	0
Vaccination site bruising	126	0
Vaccination site coldness	3	0
Vaccination site cyst	5	0
Vaccination site dermatitis	1	0
Vaccination site discolouration	14	0
Vaccination site discomfort	49	0
Vaccination site dryness	1	0
Vaccination site eczema	1	0
Vaccination site erythema	624	0
Vaccination site granuloma	5	0
Vaccination site haematoma	2	0
Vaccination site haemorrhage	22	0
Vaccination site hypersensitivity	4	0
Vaccination site hypoaesthesia	17	0
Vaccination site induration	73	0
Vaccination site inflammation	56	0
Vaccination site irritation	13	0
Vaccination site joint discomfort	2	0
Vaccination site joint erythema	11	0
Vaccination site joint inflammation	1	0
Vaccination site joint movement impairment	18	0
Vaccination site joint pain	31	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	279	0
Vaccination site movement impairment	87	0
Vaccination site nerve damage	1	0
Vaccination site nodule	4	0
Vaccination site oedema	3	0
Vaccination site pain	2112	0
Vaccination site paraesthesia	9	0
Vaccination site phlebitis	1	0
Vaccination site photosensitivity reaction	1	0
Vaccination site pruritus	164	0
Vaccination site rash	131	0
Vaccination site reaction	34	0
Vaccination site scab	2	0
Vaccination site scar	1	0
Vaccination site swelling	573	0

Case Series Drug Analysis Print

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

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site thrombosis	1	0
Vaccination site ulcer	1	0
Vaccination site urticaria	10	0
Vaccination site vesicles	9	0
Vaccination site warmth	266	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	44	0
General disorders SOC TOTAL	99640	215

Case Series Drug Analysis Print

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

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	12	0
Cholangitis	1	0
<i>Cholecystitis and cholelithiasis</i>		
Cholecystitis	3	0
Cholecystitis acute	2	0
Cholelithiasis	10	0
<i>Cholestasis and jaundice</i>		
Cholestasis	2	0
Jaundice	22	0
Jaundice cholestatic	10	0
Ocular icterus	2	0
<i>Gallbladder disorders NEC</i>		
Gallbladder disorder	2	0
<i>Hepatic and hepatobiliary disorders NEC</i>		
Liver disorder	13	0
<i>Hepatic enzymes and function abnormalities</i>		
Hepatic function abnormal	7	0
<i>Hepatic failure and associated disorders</i>		
Acute hepatic failure	1	0
Hepatic failure	2	1
<i>Hepatic fibrosis and cirrhosis</i>		
Hepatic cirrhosis	1	0
<i>Hepatic vascular disorders</i>		
Congestive hepatopathy	2	0
Hepatic artery embolism	1	0
Hepatic haemorrhage	2	0
Hepatic vein thrombosis	5	0
Portal vein thrombosis	6	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	27	0
Hepatomegaly	3	0
Liver tenderness	3	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Autoimmune hepatitis	10	0
Drug-induced liver injury	3	0
Hepatic steatosis	3	0
Hepatitis	12	0
Hepatitis acute	2	0
Immune-mediated hepatic disorder	1	0
Liver injury	23	0
Hepatic disorders SOC TOTAL	193	1

Case Series Drug Analysis Print

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

Report Run Date: 02-Dec-2021

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Immune system disorders		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	16	0
<i>Allergic conditions NEC</i>		
Allergic oedema	15	0
Allergy to animal	2	0
Allergy to arthropod bite	6	0
Allergy to arthropod sting	2	0
Allergy to metals	1	0
Allergy to sting	1	0
Hypersensitivity	947	0
Infusion related hypersensitivity reaction	3	0
Mite allergy	2	0
Multiple allergies	11	0
Serum sickness	2	0
Serum sickness-like reaction	5	0
Type I hypersensitivity	1	0
Type III immune complex mediated reaction	4	0
Type IV hypersensitivity reaction	6	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergic reaction to excipient	5	0
Allergy to chemicals	3	0
Allergy to vaccine	40	0
Contrast media reaction	2	0
Drug hypersensitivity	27	0
Food allergy	27	0
Milk allergy	2	0
Oral allergy syndrome	2	0
Reaction to colouring	1	0
Reaction to excipient	10	0
Reaction to preservatives	5	0
Rubber sensitivity	1	0
Smoke sensitivity	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	490	2
Anaphylactic shock	54	0
Anaphylactoid reaction	20	0
Anaphylactoid shock	4	0
<i>Atopic disorders</i>		
Atopy	1	0
Seasonal allergy	104	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	45	0
<i>Immune and associated conditions NEC</i>		
Anamnestic reaction	1	0
Bacille Calmette-Guerin scar reactivation	52	0
Cytokine storm	1	0
Decreased immune responsiveness	3	0
Graft versus host disease	2	0
Haemophagocytic lymphohistiocytosis	2	0
Immune reconstitution inflammatory syndrome	1	0
Immune system disorder	26	0
Immune-mediated adverse reaction	7	0
Immunisation reaction	1	0

Case Series Drug Analysis Print

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

Report Run Date: 02-Dec-2021

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Immune system disorders		
Immune system disorders cont'd		
Multisystem inflammatory syndrome in children	3	0
Sensitisation	5	0
Systemic immune activation	2	0
<i>Immunodeficiency disorders NEC</i>		
Hypogammaglobulinaemia	1	0
Immunodeficiency	2	0
Immunosuppression	3	0
<i>Transplant rejections</i>		
Corneal graft rejection	9	0
Kidney transplant rejection	1	0
Solid organ transplant rejection	1	0
Transplant rejection	1	0
Immune system disorders SOC TOTAL	1992	2

Case Series Drug Analysis Print

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

Report Run Date: 02-Dec-2021

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Abdominal abscess	2	0
Abdominal infection	1	0
Anal abscess	3	0
Appendicitis	39	0
Appendicitis perforated	7	0
Diverticulitis	11	0
Dysentery	1	0
Gastric infection	2	0
Gastroenteritis	26	0
Mesenteric abscess	1	0
Peritonitis	2	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
Arthritis bacterial	4	0
Bacterial colitis	1	0
Bacterial diarrhoea	1	0
Bacterial infection	14	0
Bacterial sepsis	1	0
Bacterial vaginosis	1	0
Cellulitis	177	0
Conjunctivitis bacterial	1	0
Ear infection bacterial	1	0
External ear cellulitis	1	0
Folliculitis	16	0
Gangrene	1	0
Gastrointestinal bacterial overgrowth	1	0
Injection site cellulitis	2	0
Meningitis bacterial	3	0
Paronychia	3	0
Perichondritis	2	0
Periorbital cellulitis	2	0
Pneumonia bacterial	1	0
Sinusitis bacterial	2	0
Skin bacterial infection	3	0
Tonsillitis bacterial	3	0
Urinary tract infection bacterial	1	0
Vaccination site cellulitis	20	0
Zoonotic bacterial infection	1	1
<i>Bartonella infections</i>		
Cat scratch disease	1	0
<i>Bone and joint infections</i>		
Abscess jaw	1	0
Arthritis infective	1	0
Osteomyelitis	2	0
<i>Borreliac infections</i>		
Lyme disease	2	0

Case Series Drug Analysis Print

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

Report Run Date: 02-Dec-2021

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Relapsing fever	1	0
Breast infections		
Breast abscess	3	0
Mastitis	77	0
Caliciviral infections		
Gastroenteritis norovirus	3	0
Campylobacter infections		
Campylobacter gastroenteritis	1	0
Campylobacter infection	1	0
Candida infections		
Anal candidiasis	3	0
Balanitis candida	1	0
Candida infection	61	0
Oral candidiasis	36	0
Respiratory moniliasis	1	0
Skin candida	2	0
Systemic candida	1	0
Urinary tract candidiasis	1	0
Vulvovaginal candidiasis	48	0
Cardiac infections		
Cardiac infection	1	0
Cardiac valve vegetation	1	0
Pericarditis infective	2	0
Central nervous system and spinal infections		
Brain abscess	1	0
CNS ventriculitis	1	0
Cavernous sinus thrombosis	1	0
Encephalitis	18	0
Encephalomyelitis	1	0
Meningitis	8	0
Meningitis aseptic	3	0
Myelitis	6	0
Subdural abscess	1	0
Clostridia infections		
Clostridium difficile infection	2	0
Coronavirus infections		
Asymptomatic COVID-19	15	0
COVID-19	1426	43
COVID-19 pneumonia	50	14
Coronavirus infection	7	0
Post-acute COVID-19 syndrome	2	0
Severe acute respiratory syndrome	4	0
Suspected COVID-19	67	4
Corynebacteria infections		
Diphtheria	1	0
Coxiella infections		
Q fever	12	0
Cytomegaloviral infections		
Cytomegalovirus infection	2	0
Cytomegalovirus syndrome	1	0
Dental and oral soft tissue infections		
Abscess oral	6	0
Gingivitis	11	0

Case Series Drug Analysis Print

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

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Oral infection	1	0
Parotitis	11	0
Pericoronitis	2	0
Pulpitis dental	1	0
Sialoadenitis	3	0
Tongue abscess	1	0
Tooth abscess	8	0
Tooth infection	9	0
Ear infections		
Ear infection	87	0
Labyrinthitis	101	0
Mastoiditis	1	0
Otitis externa	2	0
Otitis media	2	0
Otitis media acute	1	0
Otitis media chronic	4	0
Ectoparasitic infestations		
Acarodermatitis	4	0
Bed bug infestation	1	0
Epstein-Barr viral infections		
Epstein-Barr virus infection	3	0
Epstein-Barr virus infection reactivation	1	0
Infectious mononucleosis	26	0
Escherichia infections		
Escherichia bacteraemia	1	0
Eye and eyelid infections		
Conjunctivitis	70	0
Eye abscess	1	0
Eye infection	21	0
Eye infection intraocular	1	0
Eyelid boil	2	0
Eyelid infection	2	0
Hordeolum	27	0
Keratouveitis	1	0
Periorbital infection	2	0
Female reproductive tract infections		
Bartholin's abscess	1	0
Bartholinitis	1	0
Endometritis	3	0
Funisitis	1	0
Pelvic inflammatory disease	1	0
Vaginal infection	1	0
Vulval abscess	1	0
Vulvitis	1	0
Fungal infections NEC		
Fungal infection	17	0
Fungal skin infection	5	0
Onychomycosis	2	0
Oral fungal infection	2	0
Pneumonia fungal	2	0
Vulvovaginal mycotic infection	7	0
Hepatitis virus infections		
Hepatitis A	1	0

Case Series Drug Analysis Print

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

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Hepatitis E	1	0
Hepatobiliary and spleen infections		
Biliary sepsis	3	0
Cholecystitis infective	2	0
Hepatic infection	1	0
Herpes viral infections		
Eczema herpeticum	2	0
Genital herpes	83	0
Genital herpes simplex	6	0
Herpes ophthalmic	3	0
Herpes simplex	26	0
Herpes simplex encephalitis	1	1
Herpes simplex reactivation	2	0
Herpes virus infection	13	0
Herpes zoster	1391	0
Herpes zoster disseminated	1	0
Herpes zoster meningoencephalitis	1	0
Herpes zoster oticus	13	0
Herpes zoster reactivation	1	0
Nasal herpes	4	0
Ophthalmic herpes simplex	2	0
Ophthalmic herpes zoster	4	0
Oral herpes	302	0
Varicella	30	0
Varicella zoster virus infection	2	0
Infections NEC		
Abscess	35	0
Abscess limb	9	0
Abscess soft tissue	1	0
Catheter site infection	1	0
Genital abscess	2	0
Infected bite	3	0
Infected cyst	2	0
Infection	229	0
Infection susceptibility increased	2	0
Injection site abscess	1	0
Injection site infection	5	0
Localised infection	31	0
Lymph gland infection	11	0
Lymph node abscess	5	0
Opportunistic infection	1	0
Pathogen resistance	1	0
Purulent discharge	1	0
Respiratory tract infection	10	0
Vaccination site abscess	10	0
Vaccination site infection	13	0
Vaccine breakthrough infection	23	0
Vestibulitis	2	0
Wound infection	2	0
Infectious transmissions		
Secondary transmission	8	0
Vaccine virus shedding	1	0
Influenza viral infections		

Case Series Drug Analysis Print

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

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Infections Infections cont'd		
Influenza	1538	0
<i>Klebsiella infections</i>		
Klebsiella infection	1	0
<i>Lower respiratory tract and lung infections</i>		
Bronchitis	22	0
Infectious pleural effusion	1	0
Lower respiratory tract infection	228	8
Pneumonia	136	12
Pneumonia aspiration	9	6
Sputum purulent	1	0
<i>Male reproductive tract infections</i>		
Epididymitis	8	0
Orchitis	5	0
Prostate infection	2	0
<i>Molluscum contagiosum viral infections</i>		
Molluscum contagiosum	1	0
<i>Mumps viral infections</i>		
Mumps	7	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
<i>Orthopox viral infections</i>		
Vaccinia virus infection	1	0
<i>Plasmodia infections</i>		
Malaria	2	0
<i>Pneumocystis infections</i>		
Pneumocystis jirovecii pneumonia	2	0
<i>Retroviral infections</i>		
Acquired immunodeficiency syndrome	1	0
HIV infection	2	0
Persistent generalised lymphadenopathy	1	0
<i>Rotaviral infections</i>		
Gastroenteritis rotavirus	1	0
<i>Rubeola viral infections</i>		
Measles	4	0
<i>Salmonella infections</i>		
Typhoid fever	1	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Neutropenic sepsis	3	1
Sepsis	52	7
Sepsis syndrome	2	0
Septic rash	1	0
Septic shock	5	1
Urosepsis	5	0
<i>Skin structures and soft tissue infections</i>		
Abscess sweat gland	1	0
Acne pustular	1	0

Case Series Drug Analysis Print

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Report Run Date: 02-Dec-2021

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Blister infected	1	0
Dermatitis infected	3	0
Impetigo	11	0
Infected skin ulcer	1	0
Injection site pustule	2	0
Nail infection	2	0
Pustule	19	0
Pyoderma	1	0
Rash pustular	11	0
Skin infection	32	0
Subcutaneous abscess	11	0
Sweat gland infection	1	0
Vaccination site pustule	4	0
<i>Staphylococcal infections</i>		
Furuncle	39	1
Pneumonia staphylococcal	1	0
Staphylococcal abscess	1	0
Staphylococcal infection	4	0
Staphylococcal sepsis	1	0
<i>Streptococcal infections</i>		
Meningitis pneumococcal	1	0
Pharyngitis streptococcal	6	0
Streptococcal abscess	1	0
Streptococcal endocarditis	1	0
Streptococcal infection	1	0
Streptococcal sepsis	1	0
<i>Tinea infections</i>		
Body tinea	3	0
Tinea infection	1	0
Tinea pedis	3	0
Tinea versicolour	4	0
<i>Treponema infections</i>		
Syphilis	2	0
<i>Trypanosomal infections</i>		
African trypanosomiasis	4	0
<i>Tuberculous infections</i>		
Lymph node tuberculosis	1	0
Pulmonary tuberculosis	1	0
Tuberculosis	1	0
Tuberculosis of central nervous system	1	0
<i>Upper respiratory tract infections</i>		
Acute sinusitis	4	0
Chronic sinusitis	2	0
Croup infectious	1	0
Epiglottitis	1	0
Laryngitis	29	0
Nasopharyngitis	1013	1
Peritonsillar abscess	4	0
Pharyngitis	30	0
Rhinitis	43	0
Sinusitis	156	0
Tonsillitis	117	0
Tracheitis	4	0

Case Series Drug Analysis Print

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

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Tracheostomy infection	1	0
Upper respiratory tract infection	10	0
Urinary tract infections		
Cystitis	75	0
Kidney infection	43	0
Pyelonephritis	2	0
Urethritis	1	0
Urinary tract infection	191	0
Vascular infections		
Haematoma infection	1	0
Infected lymphocele	2	0
Infusion site infection	1	0
Lymphangitis	9	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	29	0
Hepatitis viral	3	0
Meningitis viral	8	0
Meningoencephalitis viral	1	0
Oral viral infection	1	0
Pleurisy viral	1	0
Pneumonia viral	3	1
Post viral fatigue syndrome	45	0
Sweating fever	102	0
Vestibular neuronitis	30	0
Viral diarrhoea	2	0
Viral infection	53	0
Viral labyrinthitis	4	0
Viral myocarditis	3	0
Viral pericarditis	3	0
Viral pharyngitis	19	0
Viral rash	54	0
Viral sinusitis	1	0
Viral tonsillitis	2	0
Infections SOC TOTAL	9353	103

Case Series Drug Analysis Print

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Report Run Date: 02-Dec-2021

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Injuries		
<i>Abdominal and gastrointestinal injuries NEC</i>		
Gallbladder injury	1	0
Liver contusion	1	0
Mouth injury	3	0
Oral contusion	5	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	20	0
<i>Anaesthetic and allied procedural complications</i>		
Airway complication of anaesthesia	1	0
Delayed recovery from anaesthesia	2	0
Sedation complication	1	0
<i>Atmospheric pressure injuries</i>		
Barotitis media	1	0
Hypobarism	1	0
<i>Bone and joint injuries NEC</i>		
Bursa injury	2	0
Joint injury	8	0
Meniscus injury	1	0
<i>Cardiac and vascular procedural complications</i>		
Shunt blood flow excessive	1	0
Vascular pseudoaneurysm	1	0
<i>Cardiovascular injuries</i>		
Vascular injury	8	0
<i>Cerebral injuries NEC</i>		
Brain contusion	4	0
Brain herniation	2	0
Concussion	4	0
Craniocerebral injury	1	0
Subarachnoid haematoma	1	0
Subdural haematoma	5	0
Subdural haemorrhage	5	0
Traumatic intracranial haemorrhage	1	1
<i>Chemical injuries</i>		
Chemical burn of skin	5	0
Chemical cystitis	2	0
<i>Chest and respiratory tract injuries NEC</i>		
Bronchial injury	1	0
Chest crushing	10	0
Foreign body in throat	1	0
Traumatic lung injury	1	0
<i>Conditions caused by cold</i>		
Chillblains	56	0
Cold shock response	1	0
Frostbite	1	0
<i>Cranial nerve injuries</i>		
Vth nerve injury	1	0
<i>Ear injuries NEC</i>		

Case Series Drug Analysis Print

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

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Deafness traumatic	1	0
Ear injury	1	0
Exposures associated with pregnancy, delivery and lactation		
Exposure during pregnancy	11	0
Exposure via breast milk	140	0
Foetal exposure during pregnancy	50	0
Maternal exposure before pregnancy	17	0
Maternal exposure during breast feeding	1640	0
Maternal exposure during delivery	1	0
Maternal exposure during pregnancy	893	0
Maternal exposure timing unspecified	10	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	13	0
Eye injury	23	0
Foreign body in eye	3	0
Injury corneal	1	0
Periorbital haematoma	1	0
Retinal injury	2	0
Superficial injury of eye	1	0
Foetal and neonatal conditions associated with product exposure		
Intoxication by breast feeding	1	0
Fractures and dislocations NEC		
Bone fragmentation	1	0
Fracture	3	0
Joint dislocation	3	0
Multiple fractures	1	0
Gastrointestinal and hepatobiliary procedural complications		
Post procedural constipation	1	0
Postoperative ileus	1	0
Procedural nausea	10	0
Procedural vomiting	2	0
Heat injuries (excl thermal burns)		
Heat cramps	2	0
Heat exhaustion	3	0
Heat illness	1	0
Heat oedema	13	0
Heat stroke	3	0
Intentional product use issues		
Intentional dose omission	1	0
Intentional product use issue	1	0
Limb fractures and dislocations		
Atypical femur fracture	1	0
Clavicle fracture	27	0
Femoral neck fracture	1	0
Femur fracture	1	0
Fibula fracture	1	0

Case Series Drug Analysis Print

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

Report Run Date: 02-Dec-2021

Data Lock Date: 01-Dec-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Hip fracture	2	0
Tibia fracture	1	0
Upper limb fracture	1	0
Wrist fracture	1	0
Medication errors, product use errors and issues NEC		
Circumstance or information capable of leading to medication error	2	0
Dose calculation error	1	0
Inadequate aseptic technique in use of product	1	0
Medication error	21	0
Prescription drug used without a prescription	2	0
Product use complaint	1	0
Product use issue	24	0
Vaccination error	5	0
Wrong dose	4	0
Wrong drug	11	0
Wrong schedule	1	0
Wrong technique in product usage process	5	0
Muscle, tendon and ligament injuries		
Epicondylitis	20	0
Ligament injury	2	0
Ligament sprain	9	0
Mallet finger	1	0
Muscle injury	29	0
Muscle rupture	8	0
Muscle strain	30	0
Post-traumatic neck syndrome	2	0
Tendon injury	7	0
Tendon rupture	21	0
Musculoskeletal procedural complications		
Periprosthetic osteolysis	1	0
Post laminectomy syndrome	1	0
Nerve injuries NEC		
Nerve injury	93	0
Neurological and psychiatric procedural complications		
Post lumbar puncture syndrome	1	0
Post procedural stroke	1	0
Procedural dizziness	11	0
Non-occupational environmental exposures		
Exposure to extreme temperature	2	0
Non-site specific injuries NEC		
Animal scratch	1	0
Arthropod bite	5	0
Arthropod sting	5	0
Bite	1	0
Electric shock	18	0
Fall	181	0
Foreign body	2	0
Injury	11	0
Multiple injuries	2	0
Nervous system injury	2	0
Post concussion syndrome	1	0
Traumatic haematoma	1	0
Wound	7	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Wound complication	10	0
Wound haematoma	1	0
Wound haemorrhage	2	0
Wound secretion	5	0
<i>Non-site specific procedural complications</i>		
Incision site pain	3	0
Infusion related reaction	7	0
Injection related reaction	60	0
Post procedural complication	5	0
Post procedural erythema	1	0
Post procedural inflammation	1	0
Post procedural pruritus	1	0
Procedural pain	2	0
Seroma	1	0
<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	259	0
<i>Overdoses NEC</i>		
Overdose	52	0
<i>Pathways and sources of exposure</i>		
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
Sciatic nerve injury	1	0
Ulnar nerve injury	4	0
<i>Poisoning and toxicity</i>		
Alcohol poisoning	1	0
Poisoning	12	0
Toxicity to various agents	3	0
<i>Product administration errors and issues</i>		
Accidental overdose	8	0
Contraindicated product administered	1	0
Duplicate therapy error	2	0
Expired product administered	12	0
Extra dose administered	1	0
Inappropriate schedule of product administration	576	0
Incomplete course of vaccination	1	0
Incorrect dose administered	52	0
Incorrect drug administration rate	1	0
Incorrect product formulation administered	2	0
Incorrect route of product administration	5	0
Lack of vaccination site rotation	1	0
Poor quality product administered	3	0
Product administered at inappropriate site	18	0
Product administered to patient of inappropriate age	1	0
Product administration error	8	0
Product dose omission issue	6	0
Wrong product administered	20	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
<i>Product confusion errors and issues</i>		
Product dosage form confusion	1	0
Product label confusion	3	0
<i>Product dispensing errors and issues</i>		
Product dispensing error	4	0
<i>Product monitoring errors and issues</i>		
Drug monitoring procedure incorrectly performed	1	0
<i>Product preparation errors and issues</i>		
Product preparation error	3	0
Product preparation issue	6	0
<i>Product prescribing errors and issues</i>		
Contraindicated product prescribed	2	0
Product prescribing error	2	0
<i>Product selection errors and issues</i>		
Product selection error	2	0
<i>Radiation injuries</i>		
Radiation sickness syndrome	1	0
Sunburn	22	0
<i>Renal and urinary tract injuries NEC</i>		
Bladder injury	1	0
Foreign body in urogenital tract	1	0
<i>Reproductive system and breast injuries</i>		
Penile contusion	1	0
Penis injury	1	0
<i>Site specific injuries NEC</i>		
Back injury	2	0
Face crushing	3	0
Face injury	1	0
Head injury	33	0
Limb crushing injury	4	0
Limb injury	116	0
Nasal injury	1	0
Neck crushing	1	0
Neck injury	1	0
Pharyngeal contusion	1	0
<i>Site specific procedural complications NEC</i>		
Axillary web syndrome	2	0
<i>Skin injuries NEC</i>		
Contusion	1175	0
Hair injury	1	0
Nail avulsion	1	0
Scar	22	0
Scratch	7	0
Skin abrasion	6	0
Skin injury	4	0
Skin laceration	2	0
Skin wound	3	0
Splinter	1	0
Subcutaneous haematoma	2	0
<i>Skin procedural complications</i>		
Dermal filler overcorrection	1	0
Recall phenomenon	1	0
<i>Skull fractures, facial bone fractures and dislocations</i>		

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Facial bones fracture	1	0
Fractured skull depressed	1	0
Spinal cord injuries NEC		
Spinal cord injury cervical	1	0
Spinal fractures and dislocations		
Spinal fracture	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	5	0
Burns second degree	6	0
Burns third degree	4	0
Thermal burn	20	0
Thermal burns of eye	15	0
Underdoses NEC		
Underdose	6	0
Vaccination related complications		
Post vaccination syndrome	1	0
Vaccination complication	50	0
Injuries SOC TOTAL	6354	1

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Reaction Name	Total	Fatal
Investigations		
<i>Adrenal cortex tests</i>		
Cortisol decreased	4	0
<i>Adrenal medulla tests</i>		
Epinephrine abnormal	1	0
Epinephrine increased	1	0
<i>Auditory and vestibular diagnostic procedures</i>		
Acoustic stimulation tests	5	0
Audiogram abnormal	1	0
<i>Autoimmunity analyses</i>		
Antinuclear antibody	1	0
Antinuclear antibody increased	1	0
Antinuclear antibody positive	1	0
Rheumatoid factor	3	0
<i>Bacteria identification and serology (excl mycobacteria)</i>		
Bacterial test positive	1	0
<i>Blood counts NEC</i>		
Full blood count	5	0
Full blood count abnormal	2	0
<i>Blood gas and acid base analyses</i>		
Acid base balance abnormal	1	0
Blood lactic acid	4	0
Blood lactic acid decreased	1	0
Blood lactic acid increased	5	0
Blood pH	7	0
Blood pH abnormal	1	0
Blood pH increased	11	0
Oxygen consumption	1	0
Oxygen consumption decreased	2	0
Oxygen saturation	8	0
Oxygen saturation abnormal	1	0
Oxygen saturation decreased	75	0
PO2 decreased	1	0
Venous oxygen saturation decreased	1	0
<i>Bone marrow and immune tissue histopathology procedures</i>		
Aspiration bone marrow	1	0
Biopsy lymph gland	1	0
<i>Bone marrow and immune tissue imaging procedures</i>		
Lymph nodes scan abnormal	1	0
Scan lymph nodes	4	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose	9	0
Blood glucose abnormal	12	0
Blood glucose decreased	33	0
Blood glucose fluctuation	15	0
Blood glucose increased	101	0
Blood glucose normal	1	0
Glycosylated haemoglobin increased	1	0
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	36	0
Heart sounds	6	0
Heart sounds abnormal	4	0
<i>Cardiac function diagnostic procedures</i>		
Cardiac monitoring	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Cardiac output	1	0
Central venous pressure	1	0
Echocardiogram	1	0
Ejection fraction decreased	1	0
Myocardial strain imaging	1	0
Stroke volume decreased	1	0
Cardiac imaging procedures		
Magnetic resonance imaging heart	1	0
Scan myocardial perfusion abnormal	1	0
Cell marker analyses		
Carcinoembryonic antigen increased	1	0
HLA-B*27 positive	1	0
Prostatic specific antigen increased	2	0
Central nervous system imaging procedures		
Computerised tomogram head	7	0
Magnetic resonance imaging head	12	0
Magnetic resonance imaging head abnormal	1	0
Cerebrospinal fluid tests (excl microbiology)		
CSF pressure	1	0
Chemistry analyses NEC		
Histamine abnormal	1	0
Histamine level	1	0
Histamine level increased	1	0
Inflammatory marker decreased	1	0
Inflammatory marker increased	3	0
Renin	1	0
Cholesterol analyses		
Blood cholesterol increased	10	0
Remnant-like lipoprotein particles	3	0
Coagulation and bleeding analyses		
Activated partial thromboplastin time prolonged	15	0
Activated partial thromboplastin time shortened	1	0
Bleeding time	1	0
Bleeding time abnormal	1	0
Bleeding time prolonged	8	0
Blood thromboplastin	1	0
Clot retraction	1	1
Coagulation factor VIII level decreased	2	0
Coagulation time prolonged	9	0
Coagulation time shortened	4	0
Fibrin D dimer increased	15	0
International normalised ratio abnormal	8	0
International normalised ratio decreased	21	0
International normalised ratio fluctuation	2	0
International normalised ratio increased	50	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

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Electrocardiogram QT prolonged	10	0
Electrocardiogram ST segment depression	2	0
Electrocardiogram ST segment elevation	10	0
Electrocardiogram ST-T segment abnormal	2	0
Electrocardiogram T wave inversion	5	0
Electrocardiogram abnormal	19	0
Electrocardiogram change	1	0
Electrocardiogram normal	2	0
Electrocardiogram repolarisation abnormality	1	0
QRS axis abnormal	1	0
Endocrine analyses and imaging NEC		
Hormone level abnormal	51	0
Faecal analyses NEC		
Faecal calprotectin	2	0
Faecal calprotectin increased	4	0
Fertility analyses		
Infertility tests	1	0
Semen analysis abnormal	1	0
Sperm concentration	2	0
Sperm concentration decreased	1	0
Foetal and neonatal diagnostic procedures		
Foetal heart rate abnormal	4	2
Foetal heart rate increased	1	0
Foetal monitoring	1	0
Foetal non-stress test	1	0
Gastrointestinal and abdominal imaging procedures		
Computerised tomogram abdomen	1	0
Sigmoidoscopy abnormal	1	0
X-ray with contrast upper gastrointestinal tract	1	0
Gastrointestinal function diagnostic procedures		
Gastric pH decreased	1	0
Gastrointestinal, pancreatic and APUD hormone analyses		
Blood insulin	2	0
Blood insulin decreased	1	0
Haematological analyses NEC		
Blood viscosity abnormal	1	0
Blood viscosity decreased	1	0
Plasma viscosity	1	0
Plasma viscosity abnormal	1	0
Red blood cell sedimentation rate increased	6	0
Heart rate and pulse investigations		
Carotid pulse	1	0
Heart rate	419	0
Heart rate abnormal	60	0
Heart rate decreased	81	0
Heart rate increased	911	0
Heart rate irregular	221	0
Heart rate normal	1	0
Maximum heart rate	2	0
Pulse abnormal	18	0
Pulse pressure increased	1	0
Radial pulse abnormal	1	0
Sinus rhythm	6	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
<i>Hepatobiliary imaging procedures</i>		
Liver scan	1	0
<i>Imaging procedures NEC</i>		
Computerised tomogram	3	0
Magnetic resonance imaging	4	0
Magnetic resonance imaging abnormal	1	0
Scan	2	0
X-ray	1	0
<i>Immune response protein analyses NEC</i>		
Cytokine test	1	0
<i>Immunoglobulin analyses</i>		
Blood immunoglobulin G increased	1	0
Blood immunoglobulin M	1	0
Blood immunoglobulin M increased	1	0
<i>Immunology analyses NEC</i>		
Antibody test	4	0
Immunology test	11	0
<i>Immunology skin tests NEC</i>		
Skin test positive	1	0
<i>Investigations NEC</i>		
Blood test	23	0
Blood test abnormal	45	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	2	0
Systemic lupus erythematosus disease activity index increased	1	0
<i>Liver function analyses</i>		
Alanine aminotransferase increased	25	0
Aspartate aminotransferase	1	0
Aspartate aminotransferase abnormal	1	0
Aspartate aminotransferase increased	2	0
Blood bilirubin increased	4	0
Gamma-glutamyltransferase increased	4	0
Hepatic enzyme increased	7	0
Liver function test	1	0
Liver function test abnormal	30	0
Liver function test increased	24	0
Transaminases increased	5	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	2	0
Brain natriuretic peptide increased	1	0
Ubiquinone	1	0
Urine ketone body present	1	0
<i>Microbiology and serology tests NEC</i>		
Culture negative	1	0
Culture throat	1	0
Culture urine	1	0
Vaccine induced antibody absent	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
<i>Mineral and electrolyte analyses</i>		
Blood calcium increased	1	0
Blood copper increased	1	0
Blood iron	1	0
Blood iron decreased	9	0
Blood iron increased	1	0
Blood magnesium decreased	1	0
Blood phosphorus decreased	1	0
Blood phosphorus increased	1	0
Blood potassium abnormal	1	0
Blood potassium decreased	4	0
Blood potassium increased	3	0
Blood sodium decreased	10	0
Serum ferritin	1	0
Serum ferritin decreased	4	0
Serum ferritin increased	1	0
Sweat test	1	0
Urine copper	2	0
<i>Musculoskeletal and soft tissue imaging procedures</i>		
Skull X-ray	6	0
<i>Musculoskeletal and soft tissue tests NEC</i>		
Swollen joint count increased	1	0
<i>Mycobacteria identification and serology</i>		
Tuberculin test positive	1	0
<i>Neurologic diagnostic procedures</i>		
Coma scale abnormal	5	0
Hoover's sign of leg paresis	1	0
Joint position sense decreased	1	0
Lumbar puncture	6	0
Temperature perception test abnormal	1	0
Temperature perception test increased	1	0
<i>Ophthalmic function diagnostic procedures</i>		
Corneal reflex decreased	1	0
Intraocular pressure increased	7	0
Intraocular pressure test	2	0
Visual acuity tests	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature	240	0
Body temperature abnormal	44	0
Body temperature decreased	40	0
Body temperature fluctuation	51	0
Body temperature increased	422	0
Body temperature normal	1	0
Breath sounds abnormal	2	0
General physical condition abnormal	1	0
Grip strength	2	0
Grip strength decreased	22	0
Head lag	8	0
Lymph node palpable	40	0
Menstruation normal	2	0
Muscle strength abnormal	1	0
Ophthalmological examination	2	0
Orthopaedic examination	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Palpatory finding abnormal	2	0
Product residue present	2	0
Psoriasis area severity index decreased	2	0
Respiratory rate	9	0
Respiratory rate decreased	22	0
Respiratory rate increased	40	0
Skin temperature	41	0
Temperature difference of extremities	10	0
Weight	1	0
Weight abnormal	1	0
Weight decreased	108	0
Weight increased	37	0
<i>Pituitary analyses anterior</i>		
Blood corticotrophin	1	0
Blood follicle stimulating hormone increased	3	0
Blood growth hormone	3	0
Blood prolactin	2	0
Blood prolactin increased	2	0
Blood thyroid stimulating hormone decreased	1	0
Blood thyroid stimulating hormone increased	8	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	72	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	21	0
<i>Red blood cell analyses</i>		
Haematocrit	1	0
Haematocrit decreased	1	0
Haematocrit increased	1	0
Haemoglobin decreased	12	0
Haemoglobin increased	2	0
Red blood cell count decreased	1	0
Red blood cell rouleaux formation present	1	0
<i>Renal function analyses</i>		
Blood creatinine	1	0
Blood creatinine increased	3	0
Glomerular filtration rate decreased	3	0
<i>Reproductive hormone analyses</i>		
Blood oestrogen decreased	2	0
Blood testosterone decreased	1	0
Blood testosterone increased	1	0
False negative pregnancy test	7	0
Female sex hormone level	3	0
Human chorionic gonadotropin increased	1	0
Pregnancy test	18	0
Pregnancy test false positive	1	0
Pregnancy test positive	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
<i>Reproductive organ and breast histopathology procedures</i>		
Biopsy breast	1	0
Biopsy endometrium	1	0
Smear cervix	2	0
<i>Reproductive organ and breast imaging procedures</i>		
Breast scan	1	0
Hysteroscopy	2	0
<i>Respiratory and pulmonary function diagnostic procedures</i>		
Forced expiratory volume increased	2	0
Fractional exhaled nitric oxide normal	1	0
Maximal voluntary ventilation	2	0
Peak expiratory flow rate	1	0
Peak expiratory flow rate decreased	5	0
Pulmonary function test	3	0
Total lung capacity decreased	3	0
Vital capacity	1	0
<i>Respiratory tract and thoracic histopathology procedures</i>		
Sputum abnormal	3	0
<i>Respiratory tract and thoracic imaging procedures</i>		
Chest X-ray	19	0
Chest X-ray abnormal	1	0
Chest X-ray normal	2	0
Chest scan	2	0
Computerised tomogram thorax	1	0
<i>Skeletal and cardiac muscle analyses</i>		
Blood creatine phosphokinase increased	7	0
Muscle enzyme	1	0
Myocardial necrosis marker	1	0
Myocardial necrosis marker increased	3	0
Troponin I increased	2	0
Troponin T increased	1	0
Troponin increased	15	0
<i>Therapeutic drug monitoring analyses</i>		
Analgesic drug level	6	0
Anti-polyethylene glycol antibody present	1	0
Anticoagulation drug level above therapeutic	1	0
Anticoagulation drug level below therapeutic	5	0
Anticoagulation drug level increased	1	0
Drug clearance increased	1	0
Drug level decreased	1	0
<i>Thyroid analyses</i>		
Anti-thyroid antibody	1	0
Thyroid function test abnormal	5	0
Thyroxine free increased	2	0
Tri-iodothyronine	1	0
Tri-iodothyronine decreased	5	0
<i>Tissue enzyme analyses NEC</i>		
Blood alkaline phosphatase increased	5	0
Enzyme level increased	1	0
<i>Toxicology laboratory analyses</i>		
Blood caffeine decreased	1	0
Blood lead	1	0
Drug screen positive	2	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Opiates	1	0
Urinalysis NEC		
Blood urine	15	0
Blood urine present	54	0
Cells in urine	1	0
Glucose urine present	1	0
Protein urine absent	1	0
Protein urine present	1	0
Urine analysis abnormal	6	0
Urine uric acid increased	1	0
pH urine	6	0
pH urine increased	2	0
Urinary tract function analyses NEC		
Urine output	12	0
Urine output decreased	13	0
Urine output increased	7	0
Urinary tract histopathology procedures		
Urine cytology	1	0
Urinary tract imaging procedures		
Cystoscopy	2	0
Ultrasound kidney normal	1	0
Vascular imaging procedures NEC		
Venogram	2	0
Vascular tests NEC (incl blood pressure)		
Blood pressure abnormal	7	0
Blood pressure ambulatory increased	1	0
Blood pressure decreased	81	0
Blood pressure diastolic	1	0
Blood pressure diastolic decreased	1	0
Blood pressure diastolic increased	3	0
Blood pressure increased	240	0
Blood pressure measurement	38	0
Blood pressure normal	2	0
Blood pressure systolic	1	0
Blood pressure systolic decreased	4	0
Blood pressure systolic increased	1	0
Virus identification and serology		
Coronavirus test	11	0
Coronavirus test positive	4	0
Cytomegalovirus test positive	1	0
HIV 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	32	0
SARS-CoV-2 test false negative	2	0
SARS-CoV-2 test false positive	4	0
SARS-CoV-2 test negative	8	0
SARS-CoV-2 test positive	99	0
Viral load	1	0
Viral test	4	0

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Investigations Investigations cont'd		
Viral test positive	1	0
Vitamin analyses		
Blood folate decreased	6	0
Vitamin B12	1	0
Vitamin B12 abnormal	2	0
Vitamin B12 decreased	2	0
Vitamin D	2	0
Vitamin D decreased	3	0
Water and electrolyte analyses NEC		
Urine osmolarity	1	0
Volume blood	1	0
White blood cell analyses		
Eosinophil count	1	0
Eosinophil count 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	1	0
Neutrophil count	3	0
Neutrophil count decreased	9	0
Neutrophil count increased	3	0
White blood cell count	2	0
White blood cell count decreased	12	0
White blood cell count increased	10	0
Investigations SOC TOTAL	5010	3

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	17	0
Decreased appetite	1188	0
Diet refusal	1	0
Eating disorder symptom	2	0
Food craving	12	0
Food refusal	14	0
Hyperphagia	16	0
Hypophagia	18	0
Increased appetite	32	0
Salt craving	2	0
<i>Calcium metabolism disorders</i>		
Hypocalcaemia	3	0
Tetany	3	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	49	0
Diabetes mellitus inadequate control	15	1
Increased insulin requirement	2	0
Insulin resistant diabetes	1	0
Latent autoimmune diabetes in adults	2	0
Type 1 diabetes mellitus	16	0
Type 2 diabetes mellitus	4	0
<i>Diabetic complications NEC</i>		
Diabetic complication	2	0
Diabetic ketoacidosis	11	0
Diabetic ketosis	1	0
<i>Disorders of purine metabolism</i>		
Gout	94	0
<i>Electrolyte imbalance NEC</i>		
Electrolyte imbalance	1	0
Fluid imbalance	2	0
<i>Fat soluble vitamin deficiencies and disorders</i>		
Vitamin D deficiency	5	0
<i>Fluid intake decreased</i>		
Fluid intake reduced	2	0
<i>Fluid intake increased</i>		
Polydipsia	6	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Alcohol intolerance	4	0
Breast milk substitute intolerance	1	0
Dairy intolerance	3	0
Food intolerance	16	0
Gluten sensitivity	7	0
Histamine intolerance	4	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	23	0
Abnormal weight gain	20	0
Cachexia	1	0
Feeding disorder	83	0
Food aversion	8	0
Malnutrition	1	0
Neonatal insufficient breast milk syndrome	3	0
Obesity	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Metabolic disorders <small>Metabolic disorders cont'd</small>		
Overweight	1	0
Poor feeding infant	15	0
Weight loss poor	3	0
<i>Hyperglycaemic conditions NEC</i>		
Glucose tolerance impaired	1	0
Hyperglycaemia	66	0
Insulin resistance	4	0
<i>Hypoglycaemic conditions NEC</i>		
Glycopenia	1	0
Hypoglycaemia	77	0
Hypoglycaemia unawareness	1	0
Postprandial hypoglycaemia	1	0
<i>Iron deficiencies</i>		
Iron deficiency	12	0
<i>Iron excess</i>		
Haemochromatosis	1	0
Iron overload	1	0
<i>Lipid metabolism and deposit disorders NEC</i>		
Body fat disorder	1	0
<i>Magnesium metabolism disorders</i>		
Magnesium deficiency	1	0
<i>Metabolic acidoses (excl diabetic acidoses)</i>		
Ketoacidosis	5	1
Lactic acidosis	2	0
Metabolic acidosis	2	0
<i>Metabolic disorders NEC</i>		
Hypercatabolism	1	0
Metabolic disorder	1	0
<i>Mixed acid-base disorders</i>		
Acidosis	4	0
<i>Potassium imbalance</i>		
Hyperkalaemia	6	0
Hypokalaemia	3	0
Hypokalaemic syndrome	1	0
<i>Sodium imbalance</i>		
Hyponatraemia	9	0
Hyponatraemic syndrome	3	0
Salt intoxication	1	0
<i>Sugar intolerance (excl glucose intolerance)</i>		
Lactose intolerance	2	0
<i>Total fluid volume decreased</i>		
Dehydration	199	0
<i>Total fluid volume increased</i>		
Fluid retention	53	0
Hypervolaemia	5	0
<i>Vitamin deficiencies NEC</i>		
Hypovitaminosis	6	0
<i>Water soluble vitamin deficiencies</i>		
Folate deficiency	5	0
Vitamin B12 deficiency	5	0
Metabolic disorders SOC TOTAL	2195	2

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	299	0
Arthropathy	27	0
Autoimmune arthritis	7	0
Haemarthrosis	5	0
Joint microhaemorrhage	1	0
Palindromic rheumatism	1	0
Polyarthritis	15	0
Rheumatic fever	3	0
Sacroiliitis	5	0
Seronegative arthritis	2	0
<i>Bone disorders NEC</i>		
Bone cyst	1	0
Exostosis	1	0
Jaw disorder	4	0
Medial tibial stress syndrome	4	0
Osteitis	6	0
Osteonecrosis	1	0
Osteonecrosis of jaw	3	0
Spinal disorder	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	365	0
Bone swelling	9	0
Coccydynia	3	0
Metatarsalgia	1	0
Pain in jaw	362	0
Pubic pain	2	0
Spinal pain	80	0
<i>Bursal disorders</i>		
Bursitis	73	0
<i>Cartilage disorders</i>		
Chondritis	1	0
Costochondritis	95	0
Osteochondritis	1	0
Polychondritis	3	0
<i>Connective tissue disorders NEC</i>		
Connective tissue disorder	1	0
Polymyalgia rheumatica	57	0
Reynold's syndrome	1	0
Sjogren's syndrome	5	0
Systemic scleroderma	1	0
<i>Crystal arthropathic disorders</i>		
Chondrocalcinosis pyrophosphate	3	0
Crystal arthropathy	1	0
<i>Epiphyseal disorders</i>		
Epiphyses premature fusion	1	0
<i>Extremity deformities</i>		
Bone deformity	1	0
Finger deformity	2	0
Foot deformity	2	0
Hand deformity	2	0
Knee deformity	1	0
Limb deformity	5	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Musculoskeletal deformity	1	0
Fractures NEC		
Osteoporotic fracture	1	0
Intervertebral disc disorders NEC		
Intervertebral disc protrusion	3	0
Joint related disorders NEC		
Carpal collapse	1	0
Chondromalacia	1	0
Hypermobility syndrome	1	0
Joint deposit	1	0
Joint destruction	1	0
Joint instability	1	0
Joint laxity	3	0
Joint lock	28	0
Patellofemoral pain syndrome	1	0
Periarthritis	180	0
Rotator cuff syndrome	30	0
Temporomandibular joint syndrome	8	0
Joint related signs and symptoms		
Arthralgia	8778	0
Jaw clicking	6	0
Joint effusion	16	0
Joint noise	34	0
Joint range of motion decreased	30	0
Joint stiffness	236	0
Joint swelling	528	0
Joint vibration	3	0
Joint warmth	14	0
Loose body in joint	1	0
Ligament disorders		
Ligament pain	2	0
Symphysiolysis	1	0
Lupus erythematosus (incl subtypes)		
Lupus-like syndrome	1	0
Systemic lupus erythematosus	22	0
Metabolic bone disorders		
Osteopenia	3	0
Osteoporosis	5	0
Muscle infections and inflammations		
Antisynthetase syndrome	3	0
Immune-mediated myositis	1	0
Myositis	38	0
Polymyositis	8	0
Muscle pains		
Fibromyalgia	110	0
Myalgia	10347	0
Myalgia intercostal	2	0
Myofascial pain syndrome	11	0
Muscle related signs and symptoms NEC		
Haematoma muscle	1	0
Muscle atrophy	23	0
Muscle discomfort	7	0
Muscle disorder	8	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Muscle & tissue disorders cont'd		
Muscle fatigue	340	0
Muscle haemorrhage	1	0
Muscle mass	5	0
Muscle oedema	3	0
Muscle spasms	2005	0
Muscle swelling	38	0
Muscle tightness	85	0
Muscle twitching	465	0
Muscle tone abnormalities		
Muscle rigidity	16	0
Nuchal rigidity	11	0
Torticollis	6	0
Trismus	34	0
Muscle weakness conditions		
Muscular weakness	907	0
Musculoskeletal and connective tissue conditions NEC		
Back disorder	2	0
Chest wall mass	1	0
Growth disorder	2	0
Limb mass	20	0
Mandibular mass	2	0
Mastication disorder	5	0
Mobility decreased	112	0
Muscle contracture	1	0
Musculoskeletal disorder	11	0
Musculoskeletal stiffness	1236	0
Posture abnormal	2	0
Sacroiliac joint dysfunction	1	0
Weight bearing difficulty	4	0
Musculoskeletal and connective tissue deformities of skull, face and buccal cavity		
Facial asymmetry	1	0
Head deformity	2	0
Musculoskeletal and connective tissue infections and inflammations NEC		
Connective tissue inflammation	1	0
Dactylitis	2	0
Dupuytren's contracture	1	0
Fasciitis	1	0
Plantar fasciitis	13	0
Musculoskeletal and connective tissue pain and discomfort		
Back pain	2338	0
Flank pain	72	0
Limb discomfort	1453	0
Musculoskeletal chest pain	235	0
Musculoskeletal discomfort	97	0
Musculoskeletal pain	117	0
Neck pain	1843	0
Pain in extremity	12363	2
Rheumatic disorder	14	0
Sacral pain	3	0
Myopathies		
Mitochondrial myopathy acquired	1	0
Myopathy	6	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Muscle & tissue disorders cont'd		
Rhabdomyolysis	12	0
Osteoarthropathies		
Nodal osteoarthritis	1	0
Osteoarthritis	47	0
Spinal osteoarthritis	2	0
Psoriatic arthropathies		
Psoriatic arthropathy	17	0
Rheumatoid arthropathies		
Juvenile idiopathic arthritis	1	0
Rheumatoid arthritis	115	0
Still's disease	2	0
Soft tissue disorders NEC		
Axillary mass	247	0
Fluctuance	1	0
Groin pain	107	0
Neck mass	34	0
Purple glove syndrome	1	0
Soft tissue disorder	3	0
Soft tissue swelling	6	0
Spine and neck deformities		
Kyphosis	2	0
Lordosis	1	0
Neck deformity	1	0
Scoliosis	1	0
Spinal stenosis	2	0
Spondyloarthropathies		
Ankylosing spondylitis	8	0
Arthritis reactive	46	0
Spondylitis	3	0
Spondyloarthropathy	1	0
Synovial disorders		
Synovial cyst	18	0
Synovitis	10	0
Tendon disorders		
Enthesopathy	2	0
Posterior tibial tendon dysfunction	1	0
Tendon disorder	5	0
Tendon pain	20	0
Tendonitis	44	0
Tenosynovitis	4	0
Tenosynovitis stenosaurs	2	0
Trigger finger	28	0
Trunk deformities		
Drooping shoulder syndrome	2	0
Shoulder deformity	2	0
Muscle & tissue disorders SOC TOTAL	46641	2

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Reaction Name	Total	Fatal
Neoplasms		
<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>Bone neoplasms malignant (excl sarcomas)</i>		
Bone cancer	1	1
<i>Bone neoplasms unspecified malignancy</i>		
Bone neoplasm	1	0
<i>Breast and nipple neoplasms benign</i>		
Benign breast neoplasm	1	0
Fibroadenoma of breast	1	0
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	37	0
Breast cancer female	1	0
Breast cancer male	2	0
Breast cancer stage I	1	0
Breast cancer stage III	3	0
Invasive ductal breast carcinoma	1	0
Triple negative breast cancer	2	0
<i>Cardiovascular neoplasms benign</i>		
Haemangioma	1	0
Pericardial lipoma	1	0
<i>Cartilage sarcomas</i>		
Chondrosarcoma	1	0
<i>Cervix neoplasms malignant</i>		
Cervix carcinoma	1	0
<i>Colorectal neoplasms malignant</i>		
Colon cancer	2	0
Colorectal cancer	1	0
Rectal cancer	2	0
<i>Endocrine neoplasms malignant and unspecified NEC</i>		
Neuroendocrine tumour	1	0
Thyroid neoplasm	1	0
<i>Endometrial neoplasms malignant</i>		
Endometrial cancer	1	0
<i>Follicular lymphomas</i>		
Primary gastrointestinal follicular lymphoma	1	0
<i>Gastric neoplasms malignant</i>		
Gastric cancer	1	1
<i>Gastrointestinal neoplasms malignant NEC</i>		
Gastrointestinal carcinoma	3	0
<i>Hepatic neoplasms malignant</i>		
Hepatocellular carcinoma	1	0
<i>Hepatobiliary neoplasms malignancy unspecified</i>		
Hepatic neoplasm	1	0
<i>Hodgkin's disease NEC</i>		
Hodgkin's disease	4	0
<i>Islet cell neoplasms and APUDoma NEC</i>		
Pancreatic neuroendocrine tumour	1	0
<i>Leukaemias NEC</i>		
Leukaemia	4	1
<i>Leukaemias acute NEC</i>		

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
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	34	1
Metastases to specified sites		
Metastases to bone	1	0
Metastases to liver	1	0
Metastases to lymph nodes	5	0
Metastases to unknown and unspecified sites		
Metastasis	1	0
Myelodysplastic syndromes		
Myelodysplastic syndrome	3	0
Myeloproliferative disorders (excl leukaemias)		
Essential thrombocythaemia	1	0
Neoplasms malignant site unspecified NEC		
Adenocarcinoma metastatic	1	0
Metastatic neoplasm	2	0
Neoplasm malignant	8	0
Second primary malignancy	1	0
Squamous cell carcinoma	5	0
Neoplasms unspecified malignancy and site unspecified NEC		
Neoplasm	1	0
Neoplasm recurrence	1	0
Nervous system neoplasms benign NEC		
Cranial nerve neoplasm benign	1	0
Neurilemmoma benign	1	0
Nervous system neoplasms unspecified malignancy NEC		
Brain neoplasm	2	0
Spinal cord neoplasm	1	0
Neuromas		
Acoustic neuroma	2	0
Non-Hodgkin's lymphomas NEC		
Non-Hodgkin's lymphoma	2	0
Ocular neoplasms benign		
Eye naevus	1	0
Oesophageal neoplasms malignant		
Oesophageal cancer metastatic	4	0
Oncologic complications and emergencies		
Cancer pain	1	0
Tumour haemorrhage	1	0
Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified		
Tonsil cancer	3	0
Ovarian neoplasms malignant (excl germ cell)		
Ovarian cancer	1	0
Pancreatic neoplasms malignant (excl islet cell and carcinoid)		

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
Pancreatic carcinoma	4	0
<i>Plasma cell myelomas</i>		
POEMS syndrome	1	0
Plasma cell myeloma	2	0
<i>Plasma cell neoplasms NEC</i>		
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	2	0
<i>Respiratory tract and pleural neoplasms malignant cell type unspecified NEC</i>		
Bronchial carcinoma	1	0
Lung neoplasm malignant	12	1
<i>Salivary gland neoplasms unspecified malignancy</i>		
Salivary gland neoplasm	1	0
<i>Skin melanomas (excl ocular)</i>		
Malignant melanoma	1	0
<i>Skin neoplasms benign</i>		
Acrochordon	4	0
Anogenital warts	7	0
Haemangioma of skin	4	0
Melanocytic naevus	6	0
Pyogenic granuloma	1	0
Seborrhoeic keratosis	1	0
Skin papilloma	18	0
<i>Skin neoplasms malignant and unspecified (excl melanoma)</i>		
Basal cell carcinoma	3	0
Bowen's disease	1	0
Neoplasm skin	2	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>		
Papillary thyroid cancer	2	0
Thyroid cancer	1	0
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	11	0
Neoplasms SOC TOTAL	285	6

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Areflexia	7	0
Extensor plantar response	2	0
Hoffmann's sign	1	0
Hyperreflexia	4	0
Hyporeflexia	8	0
Reflexes abnormal	2	0
<i>Abnormal sleep-related events</i>		
Sleep paralysis	25	0
<i>Absence seizures</i>		
Petit mal epilepsy	27	0
<i>Acute polyneuropathies</i>		
Acute motor axonal neuropathy	1	0
Acute motor-sensory axonal neuropathy	1	0
Guillain-Barre syndrome	69	2
Miller Fisher syndrome	1	0
Subacute inflammatory demyelinating polyneuropathy	1	0
<i>Autonomic nervous system disorders</i>		
Anticholinergic syndrome	1	0
Autonomic nervous system imbalance	10	0
Autonomic neuropathy	2	0
Horner's syndrome	2	0
Orthostatic intolerance	2	0
<i>Central nervous system aneurysms and dissections</i>		
Carotid artery dissection	1	0
Intracranial aneurysm	2	1
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Brain stem haemorrhage	1	1
Brain stem infarction	1	1
Brain stem stroke	1	0
Carotid artery occlusion	1	0
Carotid artery thrombosis	4	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	3	0
Cerebral haemorrhage	49	9
Cerebral infarction	28	2
Cerebral thrombosis	13	0
Cerebrovascular accident	412	17
Embolic stroke	7	0
Haemorrhage intracranial	10	2
Haemorrhagic cerebral infarction	1	0
Haemorrhagic stroke	11	4
Internal capsule infarction	1	0
Intracranial haematoma	1	0
Ischaemic cerebral infarction	1	0
Ischaemic stroke	54	2
Lacunar infarction	3	0
Lacunar stroke	5	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Lateral medullary syndrome	1	0
Pseudostroke	1	0
Subarachnoid haemorrhage	14	6
Thalamic infarction	1	0
Thrombotic stroke	3	1
Central nervous system inflammatory disorders NEC		
Arachnoiditis	1	0
Gliosis	1	0
Central nervous system vascular disorders NEC		
Brain hypoxia	4	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	1	0
Cerebrovascular disorder	2	0
Post cardiac arrest syndrome	1	0
Reversible cerebral vasoconstriction syndrome	1	0
Cerebrovascular venous and sinus thrombosis		
Cerebral venous sinus thrombosis	50	5
Cerebral venous thrombosis	6	0
Superior sagittal sinus thrombosis	6	0
Transverse sinus thrombosis	1	0
Cervical spinal cord and nerve root disorders		
Cervical radiculopathy	1	0
Cervicobrachial syndrome	4	0
Choreiform movements		
Chorea	3	0
Chronic polyneuropathies		
Chronic inflammatory demyelinating polyradiculoneuropathy	2	0
Demyelinating polyneuropathy	1	0
Diabetic neuropathy	1	0
Coma states		
Coma	14	0
Diabetic coma	1	0
Hypoglycaemic coma	1	0
Coordination and balance disturbances		
Ataxia	18	0
Balance disorder	409	0
Cerebellar ataxia	1	0
Coordination abnormal	58	0
Dysdiadochokinesis	1	0
Dysstasia	61	0
Nystagmus	12	0
Cortical dysfunction NEC		
Alexia	2	0
Aphasia	81	0
Apraxia	1	0
Dysgraphia	1	0
Dyslexia	1	0
Dyspraxia	1	0
Neurologic neglect syndrome	1	0
Sensory processing disorder	2	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Visuospatial deficit	1	0
Cranial nerve disorders NEC		
Cranial nerve disorder	2	0
Cranial nerve paralysis	1	0
Dementia (excl Alzheimer's type)		
Dementia	17	0
Dementia with Lewy bodies	1	0
Senile dementia	1	0
Demyelinating disorders NEC		
Acute disseminated encephalomyelitis	6	0
Clinically isolated syndrome	1	0
Demyelination	8	0
Neuromyelitis optica spectrum disorder	2	0
Disturbances in consciousness NEC		
Altered state of consciousness	12	0
Consciousness fluctuating	2	0
Depressed level of consciousness	45	0
Infant sedation	1	0
Lethargy	2206	0
Loss of consciousness	663	1
Postictal state	5	0
Sedation	8	0
Somnolence	1031	0
Stupor	4	0
Syncope	2217	0
Disturbances in sleep phase rhythm		
Circadian rhythm sleep disorder	1	0
Irregular sleep phase	2	0
Irregular sleep wake rhythm disorder	1	0
Dyskinesias and movement disorders NEC		
Akathisia	5	0
Bradykinesia	19	0
Clumsiness	22	0
Dyskinesia	67	0
Extrapyramidal disorder	3	0
Fine motor skill dysfunction	12	0
Foetal movement disorder	4	0
Hyperkinesia	3	0
Hypokinesia	78	0
Motor dysfunction	4	0
Movement disorder	55	0
Psychomotor hyperactivity	26	0
Synkinesis	2	0
Tardive dyskinesia	2	0
Dystonias		
Dystonia	15	0
Writer's cramp	1	0
Encephalitis NEC		
Encephalitis autoimmune	1	0
Limbic encephalitis	1	0
Noninfective encephalitis	5	0
Encephalopathies NEC		
Autoimmune encephalopathy	1	1

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Encephalopathy	5	0
Hashimoto's encephalopathy	1	0
Posterior reversible encephalopathy syndrome	1	0
Eye movement disorders		
IIIrd nerve disorder	1	0
IIIrd nerve paralysis	7	0
IVth nerve paralysis	1	0
Microvascular cranial nerve palsy	1	0
VIth nerve disorder	1	0
VIth nerve paralysis	10	0
Facial cranial nerve disorders		
Bell's palsy	502	0
Facial nerve disorder	9	0
Facial paralysis	387	0
Facial paresis	91	0
Facial spasm	48	0
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	60	0
Headaches NEC		
Cervicogenic headache	3	0
Cluster headache	237	0
Cold-stimulus headache	26	0
Drug withdrawal headache	3	0
Exertional headache	8	0
External compression headache	2	0
Headache	25959	0
Medication overuse headache	2	0
New daily persistent headache	8	0
Occipital neuralgia	13	0
Ophthalmoplegic migraine	1	0
Primary cough headache	4	0
Primary headache associated with sexual activity	8	0
Sinus headache	354	0
Tension headache	557	0
Thunderclap headache	14	0
Vascular headache	17	0
Hydrocephalic conditions		
Hydrocephalus	3	0
Hypoglossal nerve disorders		
Tongue paralysis	1	0
Increased intracranial pressure disorders		
Brain compression	1	0
Brain oedema	8	2
Idiopathic intracranial hypertension	7	0
Intracranial pressure increased	3	0
Intellectual disabilities		
Intellectual disability	3	0
Lumbar spinal cord and nerve root disorders		
Sciatica	99	0
Memory loss (excl dementia)		
Amnesia	187	0
Memory impairment	198	0
Transient global amnesia	9	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	87	0
Cognitive linguistic deficit	1	0
Disturbance in attention	323	0
Mental impairment	47	0
<i>Migraine headaches</i>		
Basilar migraine	1	0
Hemiplegic migraine	29	0
Migraine	2964	0
Migraine with aura	191	0
Migraine without aura	18	0
Ophthalmic migraine	5	0
Retinal migraine	33	0
Typical aura without headache	8	0
Vestibular migraine	18	0
<i>Mixed cranial nerve disorders</i>		
Bulbar palsy	2	0
<i>Mononeuropathies</i>		
Carpal tunnel syndrome	23	0
Cubital tunnel syndrome	3	0
Meralgia paraesthetica	2	0
Mononeuritis	2	0
Mononeuropathy	4	0
Nerve compression	24	0
Peripheral nerve lesion	2	0
Peroneal nerve palsy	16	0
Piriformis syndrome	1	0
Sciatic nerve neuropathy	2	0
Ulnar nerve palsy	2	0
Ulnar neuritis	3	0
Ulnar tunnel syndrome	2	0
<i>Motor neurone diseases</i>		
Lower motor neurone lesion	1	0
Motor neurone disease	2	1
<i>Multiple sclerosis acute and progressive</i>		
Band sensation	1	0
Multiple sclerosis	34	0
Multiple sclerosis relapse	24	0
Tumefactive multiple sclerosis	1	1
<i>Muscle tone abnormal</i>		
Drop attacks	2	0
Hypertonia	2	0
Hypotonia	31	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	27	0
<i>Narcolepsy and hypersomnia</i>		
Cataplexy	3	0
Hypersomnia	111	0
Narcolepsy	5	0

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
<i>Nervous system disorders NEC</i>		
Central nervous system lesion	2	0
Cerebral disorder	1	0
Nervous system disorder	15	0
Neurotoxicity	4	0
Psychomotor skills impaired	1	0
<i>Neurologic visual problems NEC</i>		
Hemianopia	1	0
Hemianopia homonymous	2	0
Quadrantanopia	1	0
Tunnel vision	19	0
<i>Neurological signs and symptoms NEC</i>		
Agitation neonatal	1	0
Clonus	5	0
Decerebrate posture	1	0
Decorticate posture	1	0
Dizziness	9745	0
Dizziness exertional	43	0
Dizziness postural	736	0
Drooling	22	0
Fontanelle bulging	2	0
Head discomfort	338	0
Hyporesponsive to stimuli	2	0
Inability to crawl	3	0
Infant irritability	10	0
Meningism	2	0
Myoclonus	29	0
Neurological symptom	48	0
Patient elopement	1	0
Persistent postural-perceptual dizziness	16	0
Presyncope	631	0
Sensory overload	4	0
Slow response to stimuli	4	0
Tongue biting	7	0
Unresponsive to stimuli	54	0
<i>Neuromuscular disorders NEC</i>		
Muscle contractions involuntary	26	0
Muscle spasticity	13	0
Neuromuscular pain	3	0
<i>Neuromuscular junction dysfunction</i>		
Myasthenia gravis	8	0
Myasthenia gravis crisis	2	0
<i>Olfactory nerve disorders</i>		
Anosmia	272	0
Hyposmia	16	0
Parosmia	258	0
<i>Optic nerve disorders NEC</i>		
Optic neuritis	28	0
<i>Paraesthesias and dysaesthesias</i>		
Burning feet syndrome	7	0
Burning sensation	541	0
Burning sensation mucosal	2	0
Dysaesthesia	7	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Formication	40	0
Hand-arm vibration syndrome	3	0
Hemianaesthesia	2	0
Hemiparaesthesia	5	0
Hyperaesthesia	98	0
Hypoaesthesia	2909	0
Lhermitte's sign	1	0
Paraesthesia	4022	0
Reversed hot-cold sensation	4	0
Synaesthesia	1	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Diplegia	16	0
Hemiparesis	51	0
Hemiplegia	41	0
Locked-in syndrome	1	0
Monoparesis	67	0
Monoplegia	85	0
Paralysis	127	0
Paraparesis	3	0
Paraplegia	3	0
Paresis	6	0
Quadriparesis	1	0
Quadriplegia	1	0
<i>Parkinson's disease and parkinsonism</i>		
Freezing phenomenon	12	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	10	0
<i>Partial complex seizures</i>		
Dreamy state	6	0
Focal dyscognitive seizures	4	0
Temporal lobe epilepsy	2	0
<i>Partial simple seizures NEC</i>		
Autonomic seizure	1	0
<i>Peripheral neuropathies NEC</i>		
Axonal neuropathy	2	0
Neuralgic amyotrophy	4	0
Neuritis	7	0
Neuropathy peripheral	124	0
Peripheral sensorimotor neuropathy	1	0
Peripheral sensory neuropathy	12	0
Polyneuropathy	3	0
Thoracic outlet syndrome	2	0
<i>Seizures and seizure disorders NEC</i>		
Atonic seizures	6	0
Change in seizure presentation	2	0
Clonic convulsion	3	0
Convulsions local	1	0
Epilepsy	159	0
Epileptic aura	2	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Epileptic encephalopathy	1	0
Febrile convulsion	17	0
Idiopathic generalised epilepsy	1	0
Partial seizures	21	0
Post stroke seizure	1	0
Psychogenic seizure	10	0
Seizure	616	0
Seizure anoxic	2	0
Seizure cluster	6	0
Seizure like phenomena	3	0
Status epilepticus	42	0
Tonic clonic movements	4	0
Tonic convulsion	29	0
Tonic posturing	1	0
Sensory abnormalities NEC		
Ageusia	526	0
Allodynia	26	0
Aura	24	0
Complex regional pain syndrome	5	0
Dysgeusia	1159	0
Electric shock sensation	39	0
Hypergeusia	1	0
Hypogeusia	7	0
Intercostal neuralgia	1	0
Loss of proprioception	3	0
Morton's neuralgia	1	0
Neuralgia	541	0
Persistent genital arousal disorder	1	0
Phantom limb syndrome	5	0
Post herpetic neuralgia	15	0
Restless arm syndrome	2	0
Restless legs syndrome	140	0
Sensory disturbance	109	0
Sensory loss	83	0
Taste disorder	263	0
Visual perseveration	3	0
Sleep disturbances NEC		
Microsleep	1	0
Sleep deficit	10	0
Sudden onset of sleep	1	0
Speech and language abnormalities		
Dysarthria	200	0
Incoherent	14	0
Language disorder	2	0
Repetitive speech	3	0
Slow speech	19	0
Speech disorder	73	0
Speech disorder developmental	1	0
Spinal cord and nerve root disorders NEC		
Myelopathy	1	0
Radiculitis brachial	14	0
Radiculopathy	7	0
Structural brain disorders NEC		

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Brain injury	8	2
Cerebral ventricle dilatation	1	0
Hyperintensity in brain deep nuclei	1	0
<i>Transient cerebrovascular events</i>		
Transient ischaemic attack	152	3
<i>Tremor (excl congenital)</i>		
Essential tremor	5	0
Head titubation	13	0
Resting tremor	4	0
Tremor	1784	0
<i>Trigeminal disorders</i>		
Numb chin syndrome	2	0
Trigeminal nerve disorder	3	0
Trigeminal neuralgia	62	0
Trigeminal neuritis	2	0
<i>Vagus nerve disorders</i>		
Vocal cord paralysis	2	0
<i>Vertigos NEC</i>		
Cervicogenic vertigo	1	0
Vertigo CNS origin	3	0
Nervous system disorders SOC TOTAL	67953	67

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortion related conditions and complications</i>		
Anembryonic gestation	2	0
<i>Abortions not specified as induced or spontaneous</i>		
Abortion	1	0
Abortion missed	5	0
<i>Abortions spontaneous</i>		
Abortion spontaneous	390	0
Abortion threatened	2	0
<i>Amniotic fluid and cavity disorders of pregnancy NEC</i>		
Amniorrhoea	2	0
<i>Foetal complications NEC</i>		
Foetal cardiac disorder	1	0
Foetal distress syndrome	1	0
Foetal hypokinesia	14	0
<i>Foetal growth complications</i>		
Foetal growth restriction	5	0
<i>Gestational age and weight conditions</i>		
Low birth weight baby	1	0
Premature baby	5	1
<i>Haemorrhagic complications of pregnancy</i>		
Haemorrhage in pregnancy	3	0
Premature separation of placenta	3	0
Subchorionic haematoma	2	0
Subchorionic haemorrhage	1	0
<i>Hypertension associated disorders of pregnancy</i>		
Pre-eclampsia	1	0
<i>Labour onset and length abnormalities</i>		
Induced labour	1	0
Premature delivery	1	0
Premature labour	7	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	1	0
Complication of pregnancy	1	0
Decidual cast	4	0
Ectopic pregnancy	10	0
Hyperemesis gravidarum	1	0
Morning sickness	15	0
Preterm premature rupture of membranes	3	0
Ruptured ectopic pregnancy	1	0
Somatic symptom disorder of pregnancy	3	0
<i>Normal newborn status</i>		
Normal newborn	1	0
<i>Normal pregnancy, labour and delivery</i>		
Labour pain	1	0
Live birth	7	0
Pregnancy	32	0

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Reaction Name	Total	Fatal
Pregnancy conditions <small>Pregnancy conditions cont'd</small>		
Uterine contractions during pregnancy	6	0
Placental abnormalities (excl neoplasms)		
Foetal vascular malperfusion	2	0
Placental disorder	1	0
Placental insufficiency	1	0
Small size placenta	1	0
Postpartum complications NEC		
Postpartum haemorrhage	3	0
Pregnancy complicated by maternal disorders		
Gestational diabetes	2	0
Peripartum cardiomyopathy	1	0
Stillbirth and foetal death		
Foetal death	4	2
Stillbirth	8	6
Unintended pregnancies		
Pregnancy after post coital contraception	2	0
Pregnancy on contraceptive	2	0
Pregnancy on oral contraceptive	2	0
Pregnancy with contraceptive device	1	0
Pregnancy with implant contraceptive	1	0
Unintended pregnancy	2	0
Unwanted pregnancy	1	0
Pregnancy conditions SOC TOTAL	583	9

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Reaction Name	Total	Fatal
<i>Device issues NEC</i>		
Device connection issue	1	0
Device failure	1	0
Device issue	2	0
<i>Device malfunction events NEC</i>		
Device infusion issue	1	0
Device malfunction	1	0
Device pacing issue	1	0
Device stimulation issue	1	0
Oversensing	17	0
Thrombosis in device	11	0
<i>Device physical property and chemical issues</i>		
Device breakage	1	0
Device defective	9	0
Device kink	1	0
Needle issue	2	0
<i>Product contamination and sterility issues</i>		
Product contamination	12	0
Product contamination physical	6	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	9	0
Product after taste	2	0
Product deposit	1	0
Product odour abnormal	3	0
Product physical issue	2	0
Product taste abnormal	9	0
<i>Product quality issues NEC</i>		
Product complaint	1	0
Product origin unknown	5	0
<i>Product supply and availability issues</i>		
Product availability issue	1	0
null SOC TOTAL	102	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	29	0
Behaviour disorder	2	0
Breath holding	6	0
Staring	7	0
<i>Adjustment disorders</i>		
Adjustment disorder	1	0
Adjustment disorder with depressed mood	4	0
<i>Affect alterations NEC</i>		
Affect lability	14	0
Constricted affect	3	0
Flat affect	10	0
Inappropriate affect	22	0
<i>Amnesic symptoms</i>		
Paramnesia	7	0
<i>Anxiety disorders NEC</i>		
Anxiety disorder	1	0
Generalised anxiety disorder	1	0
Neurosis	1	0
<i>Anxiety symptoms</i>		
Agitation	82	0
Anxiety	873	0
Immunisation anxiety related reaction	3	0
Nervousness	180	0
Stress	105	0
Tension	39	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	7	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	14	0
Attention-seeking behaviour	1	0
Aversion	1	0
Disinhibition	2	0
Indifference	6	0
Paranoia	25	0
Personality change	4	0
Social avoidant behaviour	5	0
Soliloquy	2	0
Suspiciousness	1	0
<i>Bipolar disorders</i>		
Bipolar I disorder	2	0
Bipolar disorder	4	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Daydreaming	8	0
Distractibility	1	0
Mental fatigue	209	0
<i>Communications disorders</i>		
Communication disorder	5	0
Mutism	3	0
<i>Confusion and disorientation</i>		
Confusional state	906	0
Disorientation	289	0
<i>Decreased physical activity levels</i>		

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Reaction Name	Total	Fatal
Psychiatric disorders ^{Psychiatric disorders cont'd}		
Catatonia	1	0
Deliria		
Delirium	125	0
Delusional symptoms		
Delusion	14	0
Depressive disorders		
Agitated depression	5	0
Depression	342	0
Depression suicidal	15	0
Major depression	11	0
Mixed anxiety and depressive disorder	3	0
Dissociative states		
Depersonalisation/derealisation disorder	11	0
Dissociation	31	0
Dissociative amnesia	3	0
Dissociative disorder	2	0
Disturbances in initiating and maintaining sleep		
Initial insomnia	23	0
Insomnia	1513	0
Middle insomnia	32	0
Terminal insomnia	31	0
Dyssomnias		
Breathing-related sleep disorder	1	0
Dyssomnia	1	0
Poor quality sleep	221	0
Eating disorders NEC		
Bulimia nervosa	1	0
Eating disorder	11	0
Selective eating disorder	1	0
Emotional and mood disturbances NEC		
Anger	38	0
Dysphoria	2	0
Emotional disorder	58	0
Emotional distress	44	0
Emotional poverty	1	0
Euphoric mood	45	0
Frustration tolerance decreased	2	0
Irritability	203	0
Mood altered	57	0
Factitious disorders		
Factitious disorder	4	0
Fear symptoms and phobic disorders (incl social phobia)		
Agoraphobia	2	0
Fear	21	0
Fear of death	1	0
Fear of eating	1	0
Fear of falling	3	0
Fear of injection	6	0
Osmophobia	1	0
Phobia	3	0
Phonophobia	3	0
Social anxiety disorder	2	0
Social fear	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders ^{Psychiatric disorders cont'd}		
<i>Fluctuating mood symptoms</i>		
Mood swings	143	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	214	0
Hallucination, auditory	19	0
Hallucination, olfactory	14	0
Hallucination, tactile	1	0
Hallucination, visual	28	0
Hallucinations, mixed	3	0
<i>Increased physical activity levels</i>		
Restlessness	153	0
<i>Infancy, childhood and adolescence psychiatric disorders NEC</i>		
Social (pragmatic) communication disorder	1	0
<i>Learning disorders</i>		
Learning disability	1	0
Learning disorder	1	0
<i>Mental disorders NEC</i>		
Mental disorder	16	0
Mental status changes	1	0
Psychological factor affecting medical condition	1	0
<i>Mood alterations with depressive symptoms</i>		
Anhedonia	3	0
Decreased interest	9	0
Depressed mood	399	0
Depressive symptom	2	0
Feeling guilty	1	0
Feeling of despair	5	0
Feelings of worthlessness	1	0
Negative thoughts	1	0
Psychomotor retardation	2	0
Sense of a foreshortened future	3	0
Tearfulness	42	0
<i>Mood alterations with manic symptoms</i>		
Hypomania	2	0
Mania	11	0
<i>Mood disorders NEC</i>		
Affective disorder	3	0
Apathy	32	0
Boredom	1	0
Laziness	3	0
Listless	22	0
Mood disorder due to a general medical condition	1	0
<i>Narcolepsy and associated conditions</i>		
Hypnagogic hallucination	4	0
Hypnopompic hallucination	2	0
Sleep attacks	3	0
<i>Obsessive-compulsive disorders and symptoms</i>		
Obsessive-compulsive symptom	1	0
<i>Orgasmic disorders and disturbances</i>		
Anorgasmia	4	0
Female orgasmic disorder	2	0
Orgasm abnormal	4	0
Orgasmic sensation decreased	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Premature ejaculation	1	0
Panic attacks and disorders		
Panic attack	199	0
Panic disorder	5	0
Panic reaction	28	0
Paraphilias and paraphilic disorders		
Transvestism	1	0
Parasomnias		
Abnormal dreams	190	0
Abnormal sleep-related event	1	0
Confusional arousal	1	0
Exploding head syndrome	2	0
Nightmare	202	0
Parasomnia	4	0
Sleep inertia	1	0
Sleep talking	6	0
Sleep terror	24	0
Somnambulism	7	0
Perception disturbances NEC		
Autoscopy	17	0
Deja vu	2	0
Derealisation	9	0
Flashback	4	0
Illusion	4	0
Near death experience	1	0
Time perception altered	2	0
Personality disorders NEC		
Personality disorder	1	0
Self esteem decreased	1	0
Pervasive developmental disorders NEC		
Autism spectrum disorder	3	0
Psychiatric elimination disorders		
Enuresis	26	0
Psychiatric symptoms NEC		
Helplessness	1	0
Hypervigilance	9	0
Psychiatric symptom	5	0
Psychological trauma	4	0
Trance	1	0
Psychotic disorder NEC		
Acute psychosis	1	0
Psychotic behaviour	1	0
Psychotic disorder	25	0
Schizophrenia NEC		
Schizophrenia	1	0
Sexual and gender identity disorders NEC		
Gender dysphoria	1	0
Sexual arousal disorders		
Disturbance in sexual arousal	3	0
Sexual inhibition	1	0
Sexual desire disorders		
Hypersexuality	1	0
Libido decreased	17	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Libido increased	6	0
Loss of libido	17	0
<i>Sexual dysfunction NEC</i>		
Genito-pelvic pain/penetration disorder	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	222	0
Sleep disorder due to general medical condition, insomnia type	5	0
<i>Somatic symptom disorders</i>		
Conversion disorder	22	0
Habit cough	20	0
Somatic symptom disorder	2	0
Vomiting psychogenic	1	0
<i>Speech and language usage disturbances</i>		
Disorganised speech	7	0
Logorrhoea	2	0
<i>Speech articulation and rhythm disturbances</i>		
Dysphemia	24	0
Lack of spontaneous speech	1	0
Pressure of speech	1	0
<i>Stereotypies and automatisms</i>		
Automatism	1	0
Bruxism	13	0
Head banging	11	0
Stereotypy	1	0
<i>Stress disorders</i>		
Burnout syndrome	2	0
Post-traumatic stress disorder	4	0
<i>Substance related and addictive disorders</i>		
Alcohol problem	1	0
Alcoholic hangover	1	0
Alcoholism	5	0
Nicotine dependence	2	0
<i>Suicidal and self-injurious behaviour</i>		
Completed suicide	1	1
Intentional self-injury	6	0
Self-injurious ideation	2	0
Suicidal ideation	39	0
Suicide attempt	8	0
Suicide threat	1	0
<i>Thinking disturbances</i>		
Bradyphrenia	40	0
Flight of ideas	1	0
Intrusive thoughts	7	0
Morbid thoughts	1	0
Tachyphrenia	7	0
Thinking abnormal	19	0
Thought blocking	1	0
<i>Tic disorders</i>		
Tic	13	0
Psychiatric disorders SOC TOTAL	8272	1

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder discomfort	3	0
Bladder irritation	8	0
Bladder pain	30	0
Dysuria	49	0
Incontinence	34	0
Lower urinary tract symptoms	3	0
Micturition disorder	2	0
Micturition urgency	44	0
Pollakiuria	139	0
Stress urinary incontinence	1	0
Urethral pain	7	0
Urge incontinence	3	0
Urinary hesitation	2	0
Urinary incontinence	62	0
Urinary retention	42	0
Urine flow decreased	17	0
<i>Bladder disorders NEC</i>		
Bladder disorder	9	0
Bladder fibrosis	1	0
Bladder prolapse	1	0
Urinary bladder haemorrhage	3	0
<i>Bladder infections and inflammations</i>		
Cystitis interstitial	5	0
Cystitis noninfective	1	0
<i>Genital and urinary tract disorders NEC</i>		
Genitourinary symptom	2	0
Urinary tract disorder	4	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
Glomerulonephritis minimal lesion	5	0
Glomerulonephritis rapidly progressive	2	0
IgA nephropathy	4	0
Nephrotic syndrome	18	0
<i>Myoneurogenic bladder disorders</i>		
Bladder dysfunction	5	0
Hypertonic bladder	3	0
Hypotonic urinary bladder	1	0
Loss of bladder sensation	3	0
Neurogenic bladder	2	0
<i>Nephritis NEC</i>		
Lupus nephritis	1	0
Nephritis	3	0
Tubulointerstitial nephritis	2	0
<i>Nephropathies and tubular disorders NEC</i>		
Nephropathy	1	0
<i>Renal disorders NEC</i>		
Renal disorder	6	1
Renal haemorrhage	1	0
Renal mass	1	0
<i>Renal failure and impairment</i>		
Acute kidney injury	47	4
Anuria	3	0
Chronic kidney disease	4	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
Renal & urinary disorders cont'd		
Oliguria	1	0
Renal failure	22	1
Renal impairment	25	0
Renal injury	2	0
Renal lithiasis		
Nephrolithiasis	9	0
Renal neoplasms		
Renal cyst	1	0
Renal obstructive disorders		
Hydronephrosis	2	0
Renal structural abnormalities and trauma		
Kidney small	1	0
Renal vascular and ischaemic conditions		
Renal aneurysm	1	0
Renal infarct	1	0
Renal tubular necrosis	1	0
Renal vasculitis	1	1
Structural and obstructive urethral disorders (excl congenital)		
Urethral stenosis	1	0
Ureteric disorders NEC		
Ureteric stenosis	1	0
Urinary abnormalities		
Albuminuria	1	0
Chromaturia	56	0
Haematuria	38	0
Ketonuria	1	0
Myoglobinuria	1	0
Proteinuria	12	0
Urine abnormality	11	0
Urine odour abnormal	9	0
Urinary tract lithiasis (excl renal)		
Calculus urinary	1	0
Urinary tract signs and symptoms NEC		
Costovertebral angle tenderness	1	0
Cystitis-like symptom	1	0
Haemorrhage urinary tract	24	1
Nocturia	3	0
Polyuria	9	0
Renal colic	4	0
Renal pain	292	0
Urinary tract discomfort	1	0
Urinary tract pain	6	0
Renal & urinary disorders SOC TOTAL	1124	8

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Benign and malignant breast neoplasms</i>		
Breast cyst	14	0
<i>Breast disorders NEC</i>		
Breast disorder	1	0
Breast enlargement	26	0
Breast mass	119	0
Gynaecomastia	4	0
Mastoptosis	1	0
Nipple disorder	1	0
<i>Breast infections and inflammations</i>		
Breast inflammation	3	0
Nipple inflammation	2	0
<i>Breast signs and symptoms</i>		
Breast discharge	4	0
Breast discomfort	11	0
Breast engorgement	11	0
Breast haematoma	1	0
Breast oedema	5	0
Breast pain	664	0
Breast swelling	145	0
Breast tenderness	81	0
Nipple pain	38	1
Nipple swelling	4	0
<i>Cervix disorders NEC</i>		
Cervical dysplasia	2	0
Cervix disorder	1	0
Cervix haemorrhage uterine	5	0
Ectropion of cervix	4	0
<i>Cervix infections and inflammations</i>		
Cervix inflammation	1	0
<i>Cervix neoplasms</i>		
Cervical polyp	1	0
<i>Erection and ejaculation conditions and disorders</i>		
Ejaculation disorder	2	0
Ejaculation failure	3	0
Erectile dysfunction	66	0
Erection increased	3	0
Organic erectile dysfunction	16	0
Painful ejaculation	1	0
Spontaneous ejaculation	1	0
Spontaneous penile erection	2	0
<i>Fallopian tube and ovary infections and inflammations</i>		
Noninfective oophoritis	4	0
<i>Lactation disorders</i>		
Breast milk discolouration	3	0
Breast milk odour abnormal	2	0
Galactorrhoea	5	0
Galactostasis	1	0
Lactation disorder	9	0
Lactation puerperal increased	5	0
Suppressed lactation	45	0
<i>Menopausal effects NEC</i>		
Artificial menopause	1	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Menopausal disorder	1	0
Menopausal symptoms	29	0
Menopause delayed	1	0
Premature menopause	18	0
<i>Menopausal effects on the genitourinary tract</i>		
Atrophic vulvovaginitis	2	0
Postmenopausal haemorrhage	95	0
<i>Menstruation and uterine bleeding NEC</i>		
Abnormal uterine bleeding	6	0
Abnormal withdrawal bleeding	1	0
Bleeding anovulatory	1	0
Dysmenorrhoea	2731	0
Intermenstrual bleeding	1052	0
Menstrual discomfort	27	0
Menstrual disorder	1786	0
Menstruation irregular	3146	0
Premenstrual dysphoric disorder	11	0
Premenstrual headache	10	0
Premenstrual pain	115	0
Premenstrual syndrome	104	0
Retrograde menstruation	1	0
Withdrawal bleed	15	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	571	0
Hypomenorrhoea	635	0
Menstruation delayed	4716	0
Oligomenorrhoea	154	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	5208	0
Menometrorrhagia	17	0
Polymenorrhoea	820	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>		
Haemorrhagic ovarian cyst	1	0
Ovarian cyst	23	0
Ovarian cyst ruptured	1	0
Polycystic ovaries	44	0
<i>Ovarian and fallopian tube disorders NEC</i>		
Adnexal torsion	1	0
Hydrosalpinx	2	0
Ovarian enlargement	1	0
Ovarian haemorrhage	6	0
Ovulation disorder	2	0
Ovulation pain	63	0
Premature ovulation	4	0
<i>Pelvic prolapse conditions</i>		
Vaginal prolapse	1	0
<i>Pelvis and broad ligament disorders NEC</i>		
Adnexa uteri mass	1	0
Adnexa uteri pain	48	0
Pelvic congestion	1	0
Pelvic floor muscle weakness	1	0
Pelvic haemorrhage	20	0
<i>Penile and scrotal infections and inflammations</i>		

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Balanoposthitis	2	0
<i>Penile disorders NEC (excl erection and ejaculation)</i>		
Penile blister	1	0
Penile discharge	1	0
Penile discomfort	1	0
Penile erythema	1	0
Penile haemorrhage	3	0
Penile oedema	1	0
Penile pain	1	0
Penile size reduced	1	0
Penile swelling	5	0
Penis disorder	9	0
<i>Prostate and seminal vesicles infections and inflammations</i>		
Prostatitis	3	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	24	0
Genital hypoaesthesia	1	0
Genital lesion	2	0
Genital paraesthesia	1	0
Genital ulceration	6	0
Perineal ulceration	1	0
<i>Reproductive tract infections and inflammations NEC</i>		
Genital tract inflammation	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Genital burning sensation	2	0
Genital erythema	1	0
Genital pain	5	0
Genital rash	4	0
Genital swelling	3	0
Pelvic discomfort	5	0
Pelvic pain	102	0
Perineal pain	2	0
Perineal rash	1	0
Pruritus genital	4	0
<i>Scrotal disorders NEC</i>		
Acquired hydrocele	1	0
Scrotal angiokeratoma	1	0
Scrotal discomfort	1	0
Scrotal erythema	2	0
Scrotal exfoliation	2	0
Scrotal pain	21	0
Scrotal swelling	4	0
Scrotum erosion	1	0
Varicocele	2	0
<i>Sexual function and fertility disorders NEC</i>		
Dyspareunia	6	0
Infertility	11	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Infertility female	3	0
Sexual dysfunction	7	0
<i>Spermatogenesis and semen disorders</i>		
Aspermia	1	0
Haemospermia	6	0
Semen discolouration	1	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular disorder	3	0
Testicular oedema	1	0
Testicular pain	58	0
Testicular swelling	10	0
Testicular torsion	1	0
Testis discomfort	3	0
<i>Uterine disorders NEC</i>		
Adenomyosis	7	0
Endometrial thickening	4	0
Endometriosis	83	0
Uterine haemorrhage	37	0
Uterine pain	14	0
<i>Uterine infections and inflammations (excl cervix)</i>		
Uterine inflammation	1	0
<i>Uterine neoplasms</i>		
Uterine polyp	4	0
<i>Uterine tone disorders</i>		
Uterine spasm	29	0
<i>Vulvovaginal cysts and neoplasms</i>		
Bartholin's cyst	1	0
Vaginal cyst	7	0
Vaginal polyp	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	1484	0
Vaginal mucosal blistering	1	0
Vaginal ulceration	2	0
Vulval disorder	1	0
Vulval haemorrhage	25	0
Vulval ulceration	7	0
Vulvovaginal ulceration	4	0
<i>Vulvovaginal signs and symptoms</i>		
Clitoral engorgement	1	0
Coital bleeding	6	0
Labia enlarged	1	0
Vaginal discharge	75	0
Vaginal lesion	1	0
Vaginal odour	2	0
Vulval oedema	1	0
Vulvovaginal burning sensation	5	0
Vulvovaginal dryness	5	0
Vulvovaginal erythema	1	0
Vulvovaginal pain	26	0
Vulvovaginal pruritus	10	0
Vulvovaginal rash	2	0
Vulvovaginal swelling	4	0
Reproductive & breast disorders SOC TOTAL	25010	1

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	6	0
Apnoeic attack	1	0
Dyspnoea	4857	5
Dyspnoea at rest	11	0
Dyspnoea exertional	36	1
Grunting	1	0
Hyperventilation	50	0
Hypopnoea	112	0
Hypoventilation	1	0
Irregular breathing	21	0
Mouth breathing	5	0
Nocturnal dyspnoea	2	0
Orthopnoea	3	0
Respiration abnormal	57	0
Respiratory arrest	15	0
Respiratory depression	1	0
Respiratory distress	18	0
Sleep apnoea syndrome	13	0
Tachypnoea	27	0
<i>Bronchial conditions NEC</i>		
Bronchial secretion retention	4	0
Bronchiectasis	13	0
<i>Bronchospasm and obstruction</i>		
Asthma	351	0
Asthma late onset	3	0
Bronchospasm	17	0
Chronic obstructive pulmonary disease	19	1
Cough variant asthma	6	0
Obstructive airways disorder	9	0
Reversible airways obstruction	1	0
Wheezing	401	0
<i>Conditions associated with abnormal gas exchange</i>		
Asphyxia	2	0
Cyanosis central	1	0
Hyperoxia	1	0
Hypoxia	29	2
Respiratory acidosis	2	0
<i>Coughing and associated symptoms</i>		
Allergic cough	7	0
Cough	2472	2
Cough decreased	2	0
Haemoptysis	60	0
Productive cough	170	0
Sputum discoloured	9	0
Sputum increased	3	0
<i>Diaphragmatic disorders</i>		
Acquired diaphragmatic eventration	1	0
Diaphragm muscle weakness	1	0
<i>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</i>		
Laryngeal disorder	1	0
Reflux laryngitis	2	0

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Vocal cord disorder	1	0
Vocal cord dysfunction	2	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Epiglottic oedema	1	0
Laryngeal obstruction	1	0
Laryngeal oedema	4	0
Laryngospasm	1	0
Stridor	24	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	28	1
Pulmonary sarcoidosis	2	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	32	0
Increased bronchial secretion	2	0
Increased viscosity of bronchial secretion	1	0
Lung hyperinflation	2	0
Lung opacity	2	0
Pleuritic pain	21	0
Pulmonary haemorrhage	1	0
Pulmonary pain	96	0
Rales	5	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	285	0
Nasal inflammation	3	0
Rhinitis allergic	20	0
<i>Nasal disorders NEC</i>		
Epistaxis	910	0
Intranasal hypoaesthesia	2	0
Intranasal paraesthesia	1	0
Nasal crusting	2	0
Nasal disorder	3	0
Nasal dryness	36	0
Nasal mucosal discolouration	1	0
Nasal odour	6	0
Nasal oedema	8	0
Nasal polyps	1	0
Nasal pruritus	12	0
Nasal ulcer	1	0
<i>Neonatal hypoxic conditions</i>		
Dry lung syndrome	1	0
Gasping syndrome	1	0
Infantile apnoea	2	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Allergic sinusitis	1	0
Paranasal sinus inflammation	4	0

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Sinonasal obstruction	11	0
Sinus congestion	63	0
Sinus disorder	6	0
<i>Parenchymal lung disorders NEC</i>		
Atelectasis	3	0
Combined pulmonary fibrosis and emphysema	1	0
Emphysema	3	0
Interstitial lung disease	11	0
Lung consolidation	3	0
Lung infiltration	2	1
Organising pneumonia	1	0
Pulmonary alveolar haemorrhage	1	0
Pulmonary cavitation	1	0
Pulmonary fibrosis	8	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Hyperactive pharyngeal reflex	1	0
Pharyngeal enanthema	1	0
Pharyngeal erythema	7	0
Pharyngeal haemorrhage	2	0
Pharyngeal hypoaesthesia	37	0
Pharyngeal inflammation	4	0
Pharyngeal lesion	1	0
Pharyngeal mass	1	0
Pharyngeal oedema	14	0
Pharyngeal paraesthesia	54	0
Pharyngeal swelling	253	0
Pharyngeal ulceration	14	0
Tonsillar erythema	10	0
Tonsillar haemorrhage	1	0
Tonsillar hypertrophy	84	0
Tonsillar inflammation	3	0
Tonsillar ulcer	1	0
Tonsillolith	1	0
<i>Pleural infections and inflammations</i>		
Pleurisy	35	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	30	0
Pneumothorax	8	0
Pneumothorax spontaneous	3	0
<i>Pulmonary hypertension</i>		
Pulmonary hypertension	3	0
<i>Pulmonary oedemas</i>		
Acute respiratory distress syndrome	2	1
Pulmonary congestion	15	0
Pulmonary oedema	20	1
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary artery thrombosis	1	0
Pulmonary embolism	428	32
Pulmonary infarction	6	0
Pulmonary thrombosis	8	1
<i>Respiratory failures (excl neonatal)</i>		
Acute respiratory failure	3	1
Respiratory failure	12	2

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
<i>Respiratory signs and symptoms NEC</i>		
Allergic respiratory symptom	6	0
Diaphragmalgia	7	0
Nasal flaring	1	0
Painful respiration	12	1
Pleural rub	1	0
Respiratory symptom	18	0
Suffocation feeling	2	0
<i>Respiratory tract disorders NEC</i>		
Aspiration	3	0
Lung disorder	7	1
Pulmonary mass	4	0
Respiratory disorder	15	1
Respiratory tract congestion	4	0
Respiratory tract haemorrhage	1	0
Respiratory tract inflammation	2	0
Respiratory tract irritation	9	0
Respiratory tract oedema	3	0
<i>Thoracic musculoskeletal disorders</i>		
Respiratory muscle weakness	2	0
<i>Tracheal disorders (excl infections and neoplasms)</i>		
Tracheal disorder	1	0
Tracheal pain	2	0
<i>Upper respiratory tract neoplasms</i>		
Tonsillar cyst	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	116	0
Catarrh	29	0
Choking	16	0
Choking sensation	3	0
Dry throat	170	0
Dysphonia	159	0
Increased upper airway secretion	6	0
Increased viscosity of upper respiratory secretion	32	0
Laryngeal pain	1	0
Nasal discharge discolouration	3	0
Nasal discomfort	48	0
Nasal obstruction	2	0
Oropharyngeal blistering	11	0
Oropharyngeal discomfort	68	0
Oropharyngeal pain	2828	0
Oropharyngeal plaque	2	0
Paranasal sinus discomfort	45	0
Rhinalgia	11	0
Rhinorrhoea	904	0
Sinus pain	212	0
Sneezing	380	0
Snoring	7	0
Throat clearing	8	0
Throat irritation	230	0
Throat tightness	258	0
Upper airway obstruction	2	0
Upper respiratory tract congestion	2	0

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Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Upper respiratory tract irritation	1	0
Upper-airway cough syndrome	11	0
Yawning	27	0
Vascular pulmonary disorders NEC		
Acute chest syndrome	1	0
Respiratory disorders SOC TOTAL	17228	54

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	187	0
Acne cystic	21	0
Dermatitis acneiform	12	0
<i>Alopecias</i>		
Alopecia	297	0
Alopecia areata	46	0
Alopecia totalis	3	0
Androgenetic alopecia	2	0
Diffuse alopecia	3	0
Hypotrichosis	1	0
Lichen planopilaris	1	0
Madarosis	6	0
<i>Angioedemas</i>		
Angioedema	219	0
Circumoral swelling	1	0
Idiopathic angioedema	1	0
<i>Apocrine and eccrine gland disorders</i>		
Anhidrosis	1	0
Bromhidrosis	1	0
Cold sweat	759	0
Hidradenitis	4	0
Hyperhidrosis	2248	0
Hypohidrosis	2	0
Milia	2	0
Miliaria	91	0
Night sweats	654	0
Sweat discolouration	1	0
<i>Bullous conditions</i>		
Blister	457	0
Blister rupture	1	0
Blood blister	28	0
Dermatitis bullous	12	0
Erythema multiforme	38	0
Fracture blisters	1	0
Herpes gestationis	1	0
Pemphigoid	27	0
Pemphigus	9	0
Stevens-Johnson syndrome	6	0
Toxic epidermal necrolysis	2	1
<i>Connective tissue disorders</i>		
Cutaneous lupus erythematosus	2	0
Dermatomyositis	7	0
Subacute cutaneous lupus erythematosus	1	0
<i>Dermal and epidermal conditions NEC</i>		
Acute febrile neutrophilic dermatosis	1	0
Dermatosis	1	0
Dry skin	228	0
Koebner phenomenon	1	0
Macule	5	0
Neutrophilic dermatosis	1	0
Pain of skin	269	0
Papule	105	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Pathergy reaction	1	0
Scab	22	0
Scar pain	15	0
Sensitive skin	174	0
Shagreen skin	1	0
Skin burning sensation	221	0
Skin degenerative disorder	1	0
Skin discolouration	135	0
Skin discomfort	5	0
Skin disorder	29	0
Skin fissures	8	0
Skin indentation	2	0
Skin induration	5	0
Skin lesion	44	0
Skin lesion inflammation	1	0
Skin necrosis	2	0
Skin odour abnormal	20	0
Skin plaque	3	0
Skin reaction	144	0
Skin sensitisation	38	0
Skin swelling	93	0
Skin texture abnormal	2	0
Skin tightness	26	0
Skin warm	301	0
Skin weeping	11	0
Sticky skin	3	0
Target skin lesion	3	0
Transient acantholytic dermatosis	1	0
Yellow skin	25	0
<i>Dermatitis and eczema</i>		
Dermatitis	132	0
Dermatitis allergic	233	0
Dermatitis atopic	41	0
Dermatitis contact	20	0
Dermatitis diaper	4	0
Dyshidrotic eczema	28	0
Eczema	318	0
Eczema asteatotic	11	0
Eczema infantile	1	0
Eczema nummular	5	0
Eczema weeping	3	0
Hand dermatitis	1	0
Intertrigo	1	0
Neurodermatitis	2	0
Perioral dermatitis	2	0
Seborrhoeic dermatitis	5	0
Skin irritation	118	0
Stasis dermatitis	1	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	33	0
Drug reaction with eosinophilia and systemic symptoms	2	0
Fixed eruption	2	0
Palmar-plantar erythrodysesthesia syndrome	1	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Toxic skin eruption	2	0
Erythemas		
Erythema	2144	0
Palmar erythema	4	0
Red man syndrome	2	0
Exfoliative conditions		
Dermatitis exfoliative	2	0
Dermatitis exfoliative generalised	5	0
Exfoliative rash	20	0
Keratolysis exfoliativa acquired	2	0
Skin exfoliation	120	0
Granulomatous and deep cutaneous inflammatory conditions		
Cutaneous sarcoidosis	1	0
Granuloma annulare	5	0
Necrobiosis lipoidica diabetorum	1	0
Hyperkeratoses		
Hyperkeratosis	1	0
Keratosis pilaris	3	0
Lichenoid keratosis	3	0
Hyperpigmentation disorders		
Argyria	1	0
Chloasma	1	0
Ephelides	1	0
Skin hyperpigmentation	6	0
Solar lentigo	3	0
Hypertrichoses		
Hirsutism	2	0
Hypertrichosis	1	0
Hypopigmentation disorders		
Skin depigmentation	4	0
Skin hypopigmentation	1	0
Vitiligo	18	0
Lipodystrophies		
Lipoatrophy	4	0
Lipodystrophy acquired	1	0
Nail and nail bed conditions (excl infections and infestations)		
Nail discolouration	11	0
Nail disorder	3	0
Nail pigmentation	2	0
Nail ridging	3	0
Onychalgia	8	0
Onychoclasis	5	0
Onychomadesis	2	0
Splinter haemorrhages	3	0
Panniculitides		
Erythema nodosum	26	0
Panniculitis	1	0
Papulosquamous conditions		
Erythema annulare	2	0
Lichen planus	20	0
Lichen sclerosus	9	0
Parapsoriasis	4	0
Pityriasis rosea	117	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	63	0
Polymorphic light eruption	3	0
Solar dermatitis	2	0
<i>Pigmentation changes NEC</i>		
Haemosiderin stain	1	0
Pigmentation disorder	15	0
<i>Pilar disorders NEC</i>		
Hair colour changes	10	0
Hair disorder	1	0
Hair growth abnormal	5	0
Hair texture abnormal	6	0
Piloerection	26	0
Pseudofolliculitis	3	0
Trichorrhexis	3	0
<i>Pruritus NEC</i>		
Itching scar	7	0
Pruritus	5323	0
<i>Psoriatic conditions</i>		
Dermatitis psoriasiform	5	0
Guttate psoriasis	16	0
Nail psoriasis	2	0
Palmoplantar pustulosis	2	0
Psoriasis	190	0
Pustular psoriasis	3	0
Rebound psoriasis	1	0
<i>Purpura and related conditions</i>		
Ecchymosis	1	0
Henoch-Schonlein purpura	10	0
Petechiae	141	0
Purpura	56	0
<i>Pustular conditions</i>		
Acute generalised exanthematous pustulosis	2	0
<i>Rashes, eruptions and exanthems NEC</i>		
Butterfly rash	5	0
Rash	5597	1
Rash erythematous	1169	0
Rash macular	493	0
Rash maculo-papular	62	0
Rash morbilliform	43	0
Rash papular	337	0
Rash pruritic	1176	0
Rash vesicular	75	0
Systemic lupus erythematosus rash	7	0
<i>Rosaceas</i>		
Rosacea	32	0
<i>Scaly conditions</i>		
Dandruff	5	0
Pityriasis	25	0
<i>Sebaceous gland disorders</i>		
Seborrhoea	10	0
<i>Skin and subcutaneous conditions NEC</i>		
Cellulite	2	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Cutaneous symptom	5	0
Reactive perforating collagenosis	1	0
Skin mass	20	0
<i>Skin and subcutaneous tissue ulcerations</i>		
Ischaemic skin ulcer	1	0
Mucocutaneous ulceration	1	0
Pyoderma gangrenosum	1	0
Scleroderma associated digital ulcer	1	0
Skin erosion	23	0
Skin ulcer	21	0
<i>Skin cysts and polyps</i>		
Dermal cyst	13	0
<i>Skin dystrophies</i>		
Keloid scar	3	0
Skin wrinkling	2	0
<i>Skin haemorrhages</i>		
Haemorrhage subcutaneous	14	0
Skin haemorrhage	19	0
<i>Skin hyperplasias and hypertrophies</i>		
Skin hypertrophy	2	0
<i>Skin hypoplasias and atrophies</i>		
Skin atrophy	3	0
Skin striae	7	0
<i>Skin injuries and mechanical dermatoses</i>		
Decubitus ulcer	2	0
Needle track marks	4	0
<i>Skin preneoplastic conditions NEC</i>		
Actinic keratosis	1	0
<i>Skin vascular conditions NEC</i>		
Skin oedema	4	0
<i>Skin vasculitides</i>		
Capillaritis	2	0
Cutaneous vasculitis	14	0
Hypersensitivity vasculitis	1	0
Vasculitic rash	20	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	23	0
<i>Telangiectasia and related conditions</i>		
Spider naevus	1	0
Telangiectasia	1	0
<i>Urticarias</i>		
Chronic spontaneous urticaria	12	0
Cold urticaria	6	0
Idiopathic urticaria	1	0
Mechanical urticaria	9	0
Solar urticaria	2	0
Urticaria	1845	0
Urticaria cholinergic	1	0
Urticaria chronic	21	0
Urticaria contact	1	0
Urticaria papular	4	0
Urticaria thermal	6	0
Urticular vasculitis	5	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Skin disorders SOC TOTAL	27698	2

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Reaction Name	Total	Fatal
Social circumstances		
<i>Age related issues</i>		
Infant	2	0
Menarche	2	0
Menopause	39	0
Postmenopause	3	0
<i>Criminal activity</i>		
Verbal abuse	1	0
<i>Dependents</i>		
Sick relative	5	0
<i>Dietary and nutritional issues</i>		
Feeding tube user	1	0
<i>Disability issues</i>		
Bedridden	25	0
Breast prosthesis user	3	0
Disability	2	0
Hearing disability	1	0
Housebound	1	0
Immobile	13	0
Impaired driving ability	4	0
Impaired work ability	15	0
Loss of personal independence in daily activities	40	0
Physical disability	5	0
Sight disability	10	0
Sitting disability	4	0
Walking disability	1	0
Wheelchair user	1	0
<i>Economic circumstances</i>		
High income	1	0
Low income	1	0
<i>Educational issues</i>		
Educational problem	1	0
Illiteracy	1	0
<i>Employment issues</i>		
Job dissatisfaction	1	0
Retirement	4	0
Stress at work	3	0
<i>Family and partner issues</i>		
Bed sharing	1	0
<i>Non-occupational and unspecified environmental problems</i>		
Flooding	1	0
Water pollution	2	0
<i>Pregnancy related circumstances</i>		
Breast feeding	16	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	3	0
<i>Tobacco use</i>		
Ex-tobacco user	1	0
Non-tobacco user	4	0
Tobacco user	1	0

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Reaction Name	Total	Fatal
Social circumstances Social circumstances cont'd		
Social circumstances SOC TOTAL	225	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Anaesthesia and allied procedures</i>		
Local anaesthesia	2	0
Nerve block	5	0
<i>Analgesia supportive care</i>		
Analgesic therapy	1	0
<i>Antiinfective therapies</i>		
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 device therapeutic procedures</i>		
Cardiac pacemaker insertion	1	0
<i>Cardiac therapeutic procedures NEC</i>		
Cardiac operation	1	0
<i>Contraceptive methods female</i>		
Contraception	1	0
Contraceptive implant	3	0
Oral contraception	1	0
<i>Contraceptive methods male</i>		
Condom	1	0
<i>Dietary and nutritional therapies</i>		
Medical diet	8	0
Nothing by mouth order	12	0
Wheat-free diet	1	0
<i>External ear therapeutic procedures</i>		
Ear irrigation	1	0
<i>Fertility and fertilisation interventions female</i>		
Endometrial scratching	1	0
<i>Gastrointestinal therapeutic procedures NEC</i>		
Intestinal anastomosis	1	0
Prophylaxis of nausea and vomiting	15	0
<i>Gynaecological therapeutic procedures NEC</i>		
Menstrual cycle management	13	0
<i>Haematological therapeutic procedures NEC</i>		
Anticoagulant therapy	1	0
<i>Head, neck and oral cavity therapeutic procedures NEC</i>		
Neck lift	1	0
<i>Hernia repairs</i>		
Hernia repair	1	0
<i>Hormonal therapeutic procedures NEC</i>		
Hormone replacement therapy	1	0
Hormone therapy	8	0
<i>Immunisations</i>		
COVID-19 immunisation	102	0
Immunisation	278	1
<i>Induced abortions</i>		

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Surgical & medical procedures cont'd</i>		
Abortion induced	2	0
Joint therapeutic procedures		
Joint injection	4	0
Joint surgery	1	0
Knee arthroplasty	1	0
Large intestine therapeutic procedures		
Appendectomy	3	0
Limb therapeutic procedures		
Arm amputation	1	0
Limb immobilisation	10	0
Limb operation	7	0
Lymphoid tissue therapeutic procedures		
Lymphadenectomy	3	0
Splenectomy	1	0
Mastectomies		
Breast conserving surgery	4	0
Nail therapeutic procedures		
Nail operation	3	0
Nervous system therapeutic procedures NEC		
Multiple sclerosis relapse prophylaxis	2	0
Obstetric therapeutic procedures		
Caesarean section	1	0
Labour stimulation	1	0
Orbit and globe therapeutic procedures		
Strabismus correction	1	0
Ovarian therapeutic procedures		
Ovarian operation	1	0
Peripheral nerve therapeutic procedures		
Neurolysis	1	0
Peripheral nerve neurostimulation	1	0
Phototherapies		
UV light therapy	1	0
Prophylactic procedures NEC		
Anaphylaxis prophylaxis	2	0
Immune tolerance induction	1	0
Prophylaxis against transplant rejection	1	0
Reproductive system disorder prophylaxis	1	0
Psychiatric therapies		
Electroconvulsive therapy	1	0
Renal therapeutic procedures		
Dialysis	1	0
Respiratory tract therapeutic procedures NEC		
Asthma prophylaxis	3	0
Retinal therapeutic procedures		
Retinopexy	1	0
Skin and subcutaneous tissue therapeutic procedures NEC		
Dermal filler injection	4	0
Therapeutic skin care topical	1	0
Skull and brain therapeutic procedures		
Cerebrovascular operation	1	0
Posterior fossa decompression	1	0
Small intestine therapeutic procedures		
Ileostomy	1	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Surgical & medical procedures cont'd</i>		
<i>Therapeutic bladder catheterisation</i>		
Bladder catheterisation	2	0
<i>Therapeutic procedures NEC</i>		
Abscess drainage	1	0
Anaphylaxis treatment	7	0
Bed rest	5	0
Fatigue management	1	0
Hospitalisation	14	0
Injection	59	0
Interchange of vaccine products	74	0
Localised alternating hot and cold therapy	2	0
Magnetic therapy	1	0
Mass excision	3	0
Medical procedure	1	0
Medication dilution	2	0
Physical fitness training	1	0
Product used for unknown indication	3	0
Promotion of wound healing	1	0
Specialist consultation	1	0
Stoma care	1	0
Therapeutic procedure	1	0
Therapy change	1	0
<i>Tracheal therapeutic procedures</i>		
Tracheostomy	1	0
<i>Uterine therapeutic procedures</i>		
Endometrial ablation	2	0
<i>Vascular therapeutic procedures NEC</i>		
Vasodilation procedure	1	0
Surgical & medical procedures SOC TOTAL	726	1

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Accelerated and malignant hypertension</i>		
Hypertensive crisis	12	0
Hypertensive urgency	2	0
Malignant hypertension	4	0
<i>Aneurysms and dissections non-site specific</i>		
Aneurysm	2	0
Artery dissection	2	0
<i>Aortic aneurysms and dissections</i>		
Acute aortic syndrome	1	0
Aortic aneurysm rupture	1	1
Aortic dissection	1	0
<i>Aortic embolism and thrombosis</i>		
Aortic embolus	5	0
Aortic thrombosis	3	0
<i>Aortic infections and inflammations</i>		
Aortitis	1	0
<i>Aortic necrosis and vascular insufficiency</i>		
Aortic occlusion	1	0
<i>Arterial infections and inflammations</i>		
Arteritis	1	0
Giant cell arteritis	14	0
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	12	0
Labile blood pressure	3	0
<i>Bruising, ecchymosis and purpura</i>		
Achenbach syndrome	3	0
<i>Circulatory collapse and shock</i>		
CT hypotension complex	2	0
Circulatory collapse	73	0
Hypoperfusion	2	0
Hypovolaemic shock	1	1
Neurogenic shock	21	0
Peripheral circulatory failure	6	0
Shock	20	0
<i>Haemorrhages NEC</i>		
Arterial haemorrhage	1	0
Bloody discharge	24	0
Haematoma	50	0
Haemorrhage	1169	2
Internal haemorrhage	10	0
Venous haemorrhage	2	0
<i>Lymphangiopathies</i>		
Lymphangiopathy	1	0
Lymphocele	5	0
Lymphorrhoea	1	0
<i>Lymphoedemas</i>		
Lymphoedema	206	0
<i>Non-site specific embolism and thrombosis</i>		
Arterial thrombosis	4	0
Embolism	61	0
Embolism venous	7	0
Microembolism	1	0
Thrombosis	422	8

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Reaction Name	Total	Fatal
Vascular disorders <small>Vascular disorders cont'd</small>		
Venous thrombosis	7	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Arterial occlusive disease	2	0
Arterial spasm	1	0
Arteriosclerosis	3	0
Haemorrhagic infarction	1	0
Infarction	3	0
Ischaemia	10	0
Peripheral venous disease	1	0
Vascular occlusion	1	0
Vasospasm	1	0
<i>Non-site specific vascular disorders NEC</i>		
Capillary disorder	1	0
Capillary fragility	4	0
Superficial vein prominence	2	0
Vascular pain	32	0
Vascular wall hypertrophy	1	0
Vasodilatation	36	0
Vein discolouration	5	0
Vein disorder	6	0
Vein rupture	5	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	28	0
Deep vein thrombosis	291	1
Femoral artery embolism	1	0
Jugular vein thrombosis	3	0
Pelvic venous thrombosis	4	0
Peripheral artery thrombosis	1	0
Peripheral embolism	2	0
Subclavian vein thrombosis	3	0
Superficial vein thrombosis	20	0
Thrombophlebitis	26	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	45	0
Erythromelalgia	2	0
Flushing	422	0
Hot flush	1116	0
Peripheral vascular disorder	1	0
Vein wall hypertrophy	1	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Claudication of jaw muscles	1	0
Extremity necrosis	3	0
Iliac artery occlusion	1	0
Intermittent claudication	3	0
Ischaemic limb pain	1	0
Jugular vein occlusion	2	0
Peripheral arterial occlusive disease	2	0
Peripheral artery occlusion	1	0
Peripheral coldness	333	0
Peripheral ischaemia	12	0

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Reaction Name	Total	Fatal
Vascular disorders <small>Vascular disorders cont'd</small>		
Poor peripheral circulation	17	0
Raynaud's phenomenon	55	0
Subclavian vein occlusion	1	0
Vasoconstriction	2	0
Phlebitis NEC		
Phlebitis	33	0
Phlebitis superficial	8	0
Site specific vascular disorders NEC		
Inferior vena cava dilatation	1	0
Pallor	381	0
Varicose veins NEC		
Spider vein	6	0
Varicophlebitis	4	0
Varicose vein	31	0
Vascular hypertensive disorders NEC		
Diastolic hypertension	4	0
Essential hypertension	3	0
Hypertension	600	0
Labile hypertension	1	0
Orthostatic hypertension	1	0
Secondary hypertension	1	0
Systolic hypertension	7	0
White coat hypertension	1	0
Vascular hypotensive disorders		
Diastolic hypotension	1	0
Hypotension	387	1
Orthostatic hypotension	31	0
Vasculitides NEC		
Behcet's syndrome	5	0
Diffuse vasculitis	1	0
Granulomatosis with polyangiitis	2	0
MAGIC syndrome	1	0
Thromboangiitis obliterans	1	0
Vasculitis	48	0
Vena caval embolism and thrombosis		
Vena cava embolism	1	0
Vena cava thrombosis	1	0
Vascular disorders SOC TOTAL	6242	14
TOTAL REACTIONS FOR DRUG	397054	634
TOTAL REPORTS	139263	
TOTAL FATAL OUTCOME REPORTS		634