

## COVID-19 mRNA Pfizer- BioNTech Vaccine Analysis Print

Report Run Date: 18-Nov-2021  
Data Lock Date: 17-Nov-2021 18:30:04

All UK spontaneous reports received between 09/12/20 and 17/11/21 for mRNA Pfizer/BioNTech vaccine

A report of a suspected ADR to the Yellow Card scheme does not necessarily mean that it was caused by the vaccine, only that the reporter has a suspicion it may have. Underlying or previously undiagnosed illness unrelated to vaccination can also be factors in such reports. The relative number and nature of reports should therefore not be used to compare the safety of the different vaccines. All reports are kept under continual review in order to identify possible new risks.

## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<b><i>Anaemia deficiencies</i></b>		
Anaemia folate deficiency	1	0
Anaemia vitamin B12 deficiency	3	0
Deficiency anaemia	1	0
Iron deficiency anaemia	8	0
<b><i>Anaemias NEC</i></b>		
Anaemia	113	0
Anaemia macrocytic	2	0
Anaemia megaloblastic	1	0
Autoimmune anaemia	3	0
Blood loss anaemia	1	0
Microcytic anaemia	1	0
<b><i>Anaemias haemolytic NEC</i></b>		
Coombs negative haemolytic anaemia	1	0
Haemolytic anaemia	6	0
<b><i>Anaemias haemolytic immune</i></b>		
Autoimmune haemolytic anaemia	15	0
Evans syndrome	1	0
Warm type haemolytic anaemia	1	0
<b><i>Anaemias haemolytic mechanical factor</i></b>		
Microangiopathic haemolytic anaemia	1	0
<b><i>Bleeding tendencies</i></b>		
Haemorrhagic diathesis	1	0
Increased tendency to bruise	46	0
Spontaneous haematoma	2	0
<b><i>Coagulation factor deficiencies</i></b>		
Acquired haemophilia	2	0
<b><i>Coagulopathies</i></b>		
Abnormal clotting factor	4	0
Antiphospholipid syndrome	5	0
Coagulopathy	24	1
Disseminated intravascular coagulation	2	0
Hypercoagulation	3	0
Thrombotic microangiopathy	2	0
<b><i>Eosinophilic disorders</i></b>		
Eosinophilia	12	0
<b><i>Haematological disorders</i></b>		
Blood disorder	3	0
Hypergammaglobulinaemia	1	0
Hyperviscosity syndrome	1	0
Mast cell activation syndrome	7	0
Methaemoglobinaemia	1	0
<b><i>Haemolyses NEC</i></b>		
Haemolysis	6	0
Intravascular haemolysis	1	0
<b><i>Leukocytoses NEC</i></b>		
Leukocytosis	1	0
Lymphocytosis	6	0
Neutrophilia	10	0
<b><i>Leukopenias NEC</i></b>		
Leukopenia	4	1
Lymphopenia	4	0
<b><i>Lymphatic system disorders NEC</i></b>		

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Reaction Name	Total	Fatal
<b>Blood disorders</b> Blood disorders cont'd		
Abdominal lymphadenopathy	3	0
Hilar lymphadenopathy	2	0
Lymph node pain	1661	0
Lymph node ulcer	1	0
Lymphadenitis	139	0
Lymphadenopathy	10409	0
Lymphatic disorder	2	0
Lymphatic insufficiency	1	0
Necrotic lymphadenopathy	3	0
Pseudolymphoma	11	0
Retroperitoneal lymphadenopathy	1	0
<b><i>Marrow depression and hypoplastic anaemias</i></b>		
Aplasia pure red cell	2	0
Hypoplastic anaemia	2	0
Myelosuppression	1	0
Pancytopenia	7	0
<b><i>Neutropenias</i></b>		
Autoimmune neutropenia	2	0
Neutropenia	37	0
<b><i>Platelet disorders NEC</i></b>		
Platelet anisocytosis	1	0
Platelet disorder	4	0
<b><i>Polycythaemia (excl rubra vera)</i></b>		
Polycythaemia	3	0
<b><i>Purpuras (excl thrombocytopenic)</i></b>		
Purpura non-thrombocytopenic	1	0
<b><i>Red blood cell abnormal findings NEC</i></b>		
Macrocytosis	1	0
Polychromasia	2	0
Red blood cell abnormality	2	0
<b><i>Spleen disorders</i></b>		
Spleen atrophy	1	0
Splenic infarction	2	0
Splenic thrombosis	1	0
Splenic vein thrombosis	1	0
Splenomegaly	11	0
<b><i>Thrombocytopenias</i></b>		
Acquired amegakaryocytic thrombocytopenia	1	0
Immune thrombocytopenia	74	0
Thrombocytopenia	211	1
Thrombocytopenic purpura	7	0
Thrombotic thrombocytopenic purpura	6	0
<b><i>Thrombocytoses</i></b>		
Thrombocytosis	6	0
<b>Blood disorders SOC TOTAL</b>	<b>12926</b>	<b>3</b>

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<b>Cardiac disorders</b>		
<i><b>Aortic valvular disorders</b></i>		
Aortic valve incompetence	1	0
<i><b>Cardiac conduction disorders</b></i>		
Atrioventricular block	16	1
Atrioventricular block complete	2	1
Atrioventricular block first degree	1	0
Atrioventricular block second degree	3	0
Bundle branch block	2	0
Bundle branch block left	2	0
Bundle branch block right	1	0
<i><b>Cardiac disorders NEC</b></i>		
Acute cardiac event	4	0
Cardiac disorder	56	0
Cardiac dysfunction	1	0
Cardiovascular deconditioning	1	0
Cardiovascular disorder	5	0
Intracardiac thrombus	6	0
<i><b>Cardiac hypertensive complications</b></i>		
Hypertensive heart disease	1	0
<i><b>Cardiac infections and inflammations NEC</b></i>		
Carditis	3	0
<i><b>Cardiac neoplasms NEC</b></i>		
Pericardial cyst	1	0
<i><b>Cardiac signs and symptoms NEC</b></i>		
Cardiac discomfort	21	0
Cardiovascular symptom	1	0
Palpitations	3532	1
<i><b>Cardiac valve disorders NEC</b></i>		
Cardiac valve disease	2	0
Heart valve incompetence	2	0
<i><b>Cardiomyopathies</b></i>		
Cardiomyopathy	9	0
Congestive cardiomyopathy	6	0
Stress cardiomyopathy	2	0
<i><b>Coronary artery disorders NEC</b></i>		
Coronary artery disease	6	3
Coronary artery occlusion	2	0
Coronary artery thrombosis	2	1
<i><b>Endocarditis NEC</b></i>		
Endocarditis noninfective	1	1
<i><b>Heart failures NEC</b></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><b>Ischaemic coronary artery disorders</b></i>		
Acute coronary syndrome	3	0
Acute myocardial infarction	23	1
Angina pectoris	202	1
Angina unstable	2	0
Arteriospasm coronary	3	0

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<b>Cardiac disorders</b> Cardiac disorders cont'd		
Microvascular coronary artery disease	2	0
Myocardial infarction	215	35
Myocardial ischaemia	9	4
<b>Left ventricular failures</b>		
Acute left ventricular failure	1	1
Left ventricular failure	7	2
<b>Mitral valvular disorders</b>		
Mitral valve incompetence	6	0
Mitral valve prolapse	1	0
<b>Myocardial disorders NEC</b>		
Cardiac amyloidosis	1	0
Cardiac aneurysm	1	1
Cardiomegaly	30	2
Left atrial dilatation	1	0
Left ventricular dysfunction	11	0
Left ventricular enlargement	2	0
Left ventricular hypertrophy	2	0
Myocardial fibrosis	4	0
Myocardial haemorrhage	1	0
Myocardial injury	11	0
Myocardial necrosis	1	0
Myocardial oedema	5	0
Myocardial rupture	1	0
Right ventricular enlargement	1	0
Ventricular hypertrophy	1	0
<b>Noninfectious myocarditis</b>		
Myocarditis	432	1
<b>Noninfectious pericarditis</b>		
Pericarditis	332	1
<b>Pericardial disorders NEC</b>		
Cardiac tamponade	1	1
Pericardial effusion	34	1
Pericardial fibrosis	1	0
Pericardial haemorrhage	4	3
Pericardial rub	2	0
<b>Rate and rhythm disorders NEC</b>		
Arrhythmia	130	0
Bradycardia	61	0
Bradycardia foetal	2	1
Cardiac flutter	410	0
Extrasystoles	151	0
Heart alternation	1	0
Paroxysmal arrhythmia	1	0
Postural orthostatic tachycardia syndrome	19	0
Tachyarrhythmia	5	0
Tachycardia	985	0
Tachycardia foetal	1	0
Tachycardia paroxysmal	1	0
<b>Right ventricular failures</b>		
Cor pulmonale	1	0
Right ventricular failure	1	0
<b>Supraventricular arrhythmias</b>		
Arrhythmia supraventricular	12	0

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<b>Cardiac disorders</b> Cardiac disorders cont'd		
Atrial fibrillation	196	0
Atrial flutter	27	0
Atrial tachycardia	10	0
Nodal arrhythmia	1	0
Sinus arrest	1	0
Sinus arrhythmia	5	0
Sinus bradycardia	11	0
Sinus node dysfunction	1	0
Sinus tachycardia	55	0
Supraventricular extrasystoles	2	0
Supraventricular tachycardia	39	0
<b><i>Tricuspid valvular disorders</i></b>		
Tricuspid valve incompetence	4	0
<b><i>Ventricular arrhythmias and cardiac arrest</i></b>		
Cardiac arrest	98	38
Cardio-respiratory arrest	1	1
Pulseless electrical activity	4	0
Ventricular arrhythmia	5	0
Ventricular extrasystoles	23	0
Ventricular fibrillation	6	1
Ventricular tachycardia	12	0
<b>Cardiac disorders SOC TOTAL</b>	<b>7414</b>	<b>116</b>

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Reaction Name	Total	Fatal
<b>Congenital disorders</b>		
<i><b>Autosomal chromosomal abnormalities</b></i>		
Trisomy 8	1	0
<i><b>Cardiac disorders congenital NEC</b></i>		
Heart disease congenital	12	0
<i><b>Cardiac hypoplasias congenital</b></i>		
Ventricular hypoplasia	1	0
<i><b>Cardiac septal defects congenital</b></i>		
Atrial septal defect	2	0
Hypertrophic cardiomyopathy	1	0
Ventricular septal defect	1	0
<i><b>Cardiac valve disorders congenital</b></i>		
Bicuspid aortic valve	2	0
<i><b>Central nervous system disorders congenital NEC</b></i>		
Spina bifida	1	0
Syringomyelia	1	0
<i><b>Cerebellar disorders congenital</b></i>		
Arnold-Chiari malformation	1	0
Hereditary ataxia	1	0
<i><b>Cerebral disorders congenital</b></i>		
Anencephaly	2	0
Cerebral palsy	3	0
<i><b>Coagulation disorders congenital</b></i>		
Haemophilia	2	0
<i><b>Congenital disorders NEC</b></i>		
Foetal malformation	1	0
Heterotaxia	1	0
Young's syndrome	1	0
<i><b>Connective tissue disorders congenital</b></i>		
Ehlers-Danlos syndrome	2	0
<i><b>Gastrointestinal tract disorders congenital NEC</b></i>		
Gastroschisis	2	0
<i><b>Great vessel disorders congenital</b></i>		
Congenital great vessel anomaly	1	0
Transposition of the great vessels	1	0
<i><b>Haematological disorders congenital NEC</b></i>		
Amegakaryocytic thrombocytopenia	1	0
Neonatal alloimmune thrombocytopenia	1	0
<i><b>Haemoglobinopathies congenital</b></i>		
Congenital methaemoglobinaemia	1	0
<i><b>Inborn errors of lipid metabolism</b></i>		
Short-chain acyl-coenzyme A dehydrogenase deficiency	1	0
<i><b>Inborn errors of metabolism NEC</b></i>		
Alpha-1 antitrypsin deficiency	1	0
<i><b>Inborn errors of porphyrin metabolism</b></i>		
Porphyria	1	0
<i><b>Lymphatic system disorders congenital</b></i>		
Cystic lymphangioma	3	0
<i><b>Male reproductive tract disorders congenital</b></i>		
Cryptorchism	1	0
Micropenis	3	0
Phimosis	1	0
<i><b>Musculoskeletal and connective tissue disorders of limbs congenital</b></i>		
Developmental hip dysplasia	1	0

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



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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i><b>Ear disorders NEC</b></i>		
Ear canal erythema	1	0
Ear congestion	29	0
Ear discomfort	93	0
Ear disorder	16	0
Ear haemorrhage	10	0
Ear pain	923	0
Ear pruritus	9	0
Ear swelling	33	0
Otorrhoea	4	0
<i><b>Eustachian tube disorders</b></i>		
Eustachian tube disorder	4	0
Eustachian tube dysfunction	8	0
Eustachian tube obstruction	4	0
<i><b>External ear disorders NEC</b></i>		
Auricular swelling	2	0
Excessive cerumen production	8	0
External ear pain	3	0
Red ear syndrome	2	0
<i><b>External ear infections and inflammations</b></i>		
External ear inflammation	2	0
<i><b>Hearing disorders NEC</b></i>		
Auditory disorder	6	0
Diplacusis	2	0
<i><b>Hearing losses</b></i>		
Conductive deafness	1	0
Deafness	234	0
Deafness bilateral	8	0
Deafness neurosensory	17	0
Deafness transitory	6	0
Deafness unilateral	32	0
Hypoacusis	173	0
Sudden hearing loss	46	0
<i><b>Hyperacusia</b></i>		
Hyperacusis	52	0
Misophonia	3	0
<i><b>Inner ear disorders NEC</b></i>		
Acute vestibular syndrome	2	0
Inner ear disorder	12	0
Meniere's disease	11	0
Vestibular disorder	10	0
<i><b>Inner ear infections and inflammations</b></i>		
Inner ear inflammation	8	0
<i><b>Inner ear signs and symptoms</b></i>		
Motion sickness	58	0
Tinnitus	1889	0
Vertigo	1342	0
Vertigo labyrinthine	10	0
Vertigo positional	72	0
<i><b>Mastoid disorders</b></i>		
Mastoid effusion	1	0
<i><b>Middle ear disorders NEC</b></i>		
Middle ear disorder	3	0

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Reaction Name	Total	Fatal
<b>Ear disorders</b> Ear disorders cont'd		
Middle ear effusion	1	0
<b><i>Middle ear infections and inflammations</i></b>		
Middle ear inflammation	1	0
<b><i>Tympanic membrane disorders (excl infections)</i></b>		
Tympanic membrane perforation	3	0
<b>Ear disorders SOC TOTAL</b>	<b>5154</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Endocrine disorders</b>		
<i><b>Acute and chronic thyroiditis</b></i>		
Autoimmune thyroiditis	2	0
Thyroiditis	18	0
Thyroiditis acute	3	0
Thyroiditis subacute	3	0
<i><b>Adrenal cortical hypofunctions</b></i>		
Addison's disease	2	0
Adrenal insufficiency	2	0
Adrenocortical insufficiency acute	13	0
<i><b>Adrenal gland disorders NEC</b></i>		
Adrenal haemorrhage	2	0
<i><b>Anterior pituitary hyperfunction</b></i>		
Pituitary-dependent Cushing's syndrome	1	0
<i><b>Anterior pituitary hypofunction</b></i>		
Hypopituitarism	1	0
<i><b>Endocrine abnormalities of gonadal function NEC</b></i>		
Oestrogen deficiency	1	0
<i><b>Endocrine abnormalities of puberty</b></i>		
Delayed menarche	4	0
Premature menarche	17	0
<i><b>Female gonadal function disorders</b></i>		
Anovulatory cycle	47	0
Ovulation delayed	32	0
<i><b>Male gonadal function disorders</b></i>		
Androgen deficiency	1	0
<i><b>Thyroid disorders NEC</b></i>		
Autoimmune thyroid disorder	1	0
Goitre	12	0
Thyroid disorder	8	0
Thyroid mass	1	0
Thyroid pain	8	0
<i><b>Thyroid hyperfunction disorders</b></i>		
Basedow's disease	10	0
Hyperthyroidism	37	0
Thyrotoxic crisis	3	0
<i><b>Thyroid hypofunction disorders</b></i>		
Autoimmune hypothyroidism	1	0
Hypothyroidism	30	0
Immune-mediated hypothyroidism	1	0
Myxoedema	1	0
<b>Endocrine disorders SOC TOTAL</b>	<b>262</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<b><i>Amblyopic vision impairment</i></b>		
Amblyopia	6	0
<b><i>Anterior chamber bleeding and vascular disorders</i></b>		
Spontaneous hyphaema	1	0
<b><i>Cataract conditions</i></b>		
Cataract	11	0
<b><i>Choroid and vitreous haemorrhages and vascular disorders</i></b>		
Choroidal haemorrhage	1	0
Choroidal neovascularisation	1	0
Vitreous haemorrhage	3	0
<b><i>Choroid and vitreous structural change, deposit and degeneration</i></b>		
Chorioretinopathy	5	0
Vitreous detachment	17	0
Vitreous floaters	91	0
<b><i>Colour blindness (incl acquired)</i></b>		
Dyschromatopsia	9	0
<b><i>Conjunctival and corneal bleeding and vascular disorders</i></b>		
Conjunctival haemorrhage	43	0
<b><i>Conjunctival infections, irritations and inflammations</i></b>		
Conjunctival hyperaemia	2	0
Conjunctival irritation	1	0
Conjunctival oedema	3	0
Conjunctivitis allergic	1	0
<b><i>Corneal infections, oedemas and inflammations</i></b>		
Corneal oedema	2	0
Keratitis	6	0
Ulcerative keratitis	5	0
<b><i>Eyelid movement disorders</i></b>		
Blepharospasm	139	0
Excessive eye blinking	6	0
Eyelid function disorder	3	0
Eyelid myokymia	4	0
Eyelid ptosis	42	0
Paralytic lagophthalmos	2	0
<b><i>Glaucomas (excl congenital)</i></b>		
Angle closure glaucoma	2	0
Glaucoma	6	0
<b><i>Iris and ciliary body structural change, deposit and degeneration</i></b>		
Eye colour change	3	0
<b><i>Iris and uveal tract infections, irritations and inflammations</i></b>		
Autoimmune uveitis	1	0
Iridocyclitis	15	0
Iritis	10	0
Uveitis	45	0
<b><i>Lacrimation disorders</i></b>		
Dry eye	142	0
Lacrimation increased	129	0
<b><i>Lid bleeding and vascular disorders</i></b>		
Eyelid bleeding	1	0
<b><i>Lid, lash and lacrimal infections, irritations and inflammations</i></b>		
Blepharitis	15	0
Chalazion	7	0
Eczema eyelids	8	0

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<b>Eye disorders</b> Eye disorders cont'd		
Erythema of eyelid	9	0
Eyelid cyst	4	0
Eyelid irritation	2	0
Eyelid margin crusting	4	0
Eyelid oedema	5	0
Eyelid rash	16	0
Meibomian gland dysfunction	1	0
Swelling of eyelid	118	0
Swollen tear duct	2	0
<b>Lid, lash and lacrimal structural disorders</b>		
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
<b>Ocular bleeding and vascular disorders NEC</b>		
Eye haematoma	4	0
Eye haemorrhage	28	0
Ocular vascular disorder	2	0
Ophthalmic vein thrombosis	1	0
<b>Ocular disorders NEC</b>		
Dark circles under eyes	7	0
Eye disorder	32	0
Eye oedema	17	0
Eye pain	1024	0
Eye swelling	493	0
Eye symptom	9	0
Eye ulcer	4	0
Eyelid disorder	12	0
Eyelid pain	12	0
Eyelids pruritus	6	0
Ocular discomfort	25	0
Periorbital oedema	18	0
Periorbital pain	1	0
Periorbital swelling	115	0
Retinal disorder	2	0
Vitreous disorder	1	0
<b>Ocular infections, inflammations and associated manifestations</b>		
Eye allergy	13	0
Eye discharge	28	0
Eye inflammation	28	0
Eye irritation	84	0
Eye pruritus	225	0
Limbal swelling	3	0
Ocular hyperaemia	209	0
<b>Ocular nerve and muscle disorders</b>		
Binocular eye movement disorder	1	0
Extraocular muscle disorder	1	0
Extraocular muscle paresis	2	0

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<b>Eye disorders</b> Eye disorders cont'd		
Eye movement disorder	33	0
Gaze palsy	1	0
Ocular myasthenia	1	0
Ophthalmoplegia	5	0
Strabismus	5	0
<b>Ocular sensation disorders</b>		
Abnormal sensation in eye	19	0
Asthenopia	143	0
Eye paraesthesia	2	0
Eyelid sensory disorder	1	0
Foreign body sensation in eyes	16	0
Hypoaesthesia eye	15	0
Photophobia	447	0
<b>Optic disc abnormalities NEC</b>		
Papilloedema	6	0
<b>Optic nerve bleeding and vascular disorders</b>		
Optic disc haemorrhage	1	0
Optic ischaemic neuropathy	2	0
<b>Orbital infections, inflammations and irritations</b>		
Parophthalmia	1	0
<b>Orbital structural change, deposit and degeneration</b>		
Orbital oedema	2	0
<b>Pupil disorders</b>		
Miosis	2	0
Mydriasis	22	0
Pupil fixed	2	0
Pupillary disorder	1	0
Pupils unequal	12	0
<b>Refractive and accommodative disorders</b>		
Accommodation disorder	1	0
Altered visual depth perception	3	0
Astigmatism	2	0
Hypermetropia	2	0
Myopia	1	0
<b>Retinal bleeding and vascular disorders (excl retinopathy)</b>		
Retinal artery occlusion	11	0
Retinal artery thrombosis	1	0
Retinal haemorrhage	7	0
Retinal vascular thrombosis	1	0
Retinal vein occlusion	32	0
Retinal vein thrombosis	2	0
<b>Retinal structural change, deposit and degeneration</b>		
Macular degeneration	4	0
Macular hole	2	0
Macular rupture	1	0
Maculopathy	1	0
Neovascular age-related macular degeneration	2	0
Retinal degeneration	1	0
Retinal detachment	5	0
Retinal tear	2	0
Retinal toxicity	3	0
<b>Retinal, choroid and vitreous infections and inflammations</b>		
Birdshot chorioretinopathy	2	0

## Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<b>Eye disorders</b> Eye disorders cont'd		
Cystoid macular oedema	1	0
Macular oedema	4	0
Retinal vasculitis	3	0
<b>Retinopathies NEC</b>		
Acute macular neuroretinopathy	1	0
Retinal exudates	2	0
Retinopathy	3	0
<b>Scleral infections, irritations and inflammations</b>		
Episcleritis	7	0
Scleritis	3	0
<b>Scleral structural change, deposit and degeneration</b>		
Scleral discolouration	2	0
<b>Structural change, deposit and degeneration of eye NEC</b>		
Exophthalmos	1	0
<b>Visual colour distortions</b>		
Chloropsia	2	0
Chromatopsia	1	0
Cyanopsia	2	0
Erythropsia	2	0
Xanthopsia	1	0
<b>Visual disorders NEC</b>		
Charles Bonnet syndrome	2	0
Diplopia	150	0
Glare	1	0
Halo vision	7	0
Heteronymous diplopia	1	0
Metamorphopsia	18	0
Oscillopsia	3	0
Photopsia	127	0
Scintillating scotoma	4	0
Vision blurred	1152	0
Visual brightness	3	0
Visual snow syndrome	7	0
<b>Visual field disorders</b>		
Visual field defect	28	0
<b>Visual impairment and blindness (excl colour blindness)</b>		
Amaurosis fugax	3	0
Blindness	121	0
Blindness cortical	1	0
Blindness transient	12	0
Blindness unilateral	12	0
Central vision loss	3	0
Sudden visual loss	3	0
Visual acuity reduced	23	0
Visual acuity reduced transiently	1	0
Visual impairment	349	0
<b>Visual pathway disorders</b>		
Optic nerve disorder	1	0
<b>Eye disorders SOC TOTAL</b>	<b>6264</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<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	12	0
<i>Anal and rectal signs and symptoms</i>		
Anal hypoaesthesia	1	0
Anal spasm	1	0
Anorectal discomfort	4	0
Anorectal swelling	1	0
Rectal discharge	2	0
Rectal tenesmus	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	45	1
Colitis ischaemic	1	0
Colitis microscopic	2	0
Colitis ulcerative	67	0
Crohn's disease	41	0
Eosinophilic colitis	1	0
Inflammatory bowel disease	6	0
<i>Dental and periodontal infections and inflammations</i>		
Dental caries	1	0
<i>Dental disorders NEC</i>		
Loose tooth	1	0
Malpositioned teeth	3	0
Periodontal disease	1	0
Teeth brittle	2	0
Teething	7	0
Tooth disorder	2	0
Tooth socket haemorrhage	1	0
<i>Dental pain and sensation disorders</i>		
Dental discomfort	6	0
Dental paraesthesia	10	0
Hyperaesthesia teeth	34	0
Toothache	149	0



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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
<b><i>Dental surface disorders</i></b>		
Tooth discolouration	9	0
<b><i>Diaphragmatic hernias</i></b>		
Hiatus hernia	6	0
<b><i>Diarrhoea (excl infective)</i></b>		
Diarrhoea	5069	2
Diarrhoea haemorrhagic	22	0
<b><i>Diverticula</i></b>		
Diverticulum	4	0
Diverticulum intestinal	1	0
<b><i>Duodenal and small intestinal stenosis and obstruction</i></b>		
Small intestinal obstruction	1	0
<b><i>Duodenal ulcers and perforation</i></b>		
Duodenal ulcer haemorrhage	1	0
Duodenal ulcer perforation	3	0
<b><i>Dyspeptic signs and symptoms</i></b>		
Dyspepsia	412	0
Epigastric discomfort	14	0
Eructation	48	0
<b><i>Faecal abnormalities NEC</i></b>		
Abnormal faeces	19	0
Faecaloma	4	0
Faeces discoloured	57	0
Faeces hard	2	0
Faeces pale	3	0
Faeces soft	11	0
Mucous stools	10	0
<b><i>Flatulence, bloating and distension</i></b>		
Abdominal distension	495	0
Aerophagia	3	0
Flatulence	172	0
<b><i>Gastric and oesophageal haemorrhages</i></b>		
Gastric haemorrhage	5	1
Mallory-Weiss syndrome	1	0
Oesophageal varices haemorrhage	1	0
<b><i>Gastric ulcers and perforation</i></b>		
Gastric ulcer	6	0
<b><i>Gastritis (excl infective)</i></b>		
Chronic gastritis	3	0
Gastritis	54	0
Reflux gastritis	6	0
<b><i>Gastrointestinal and abdominal pains (excl oral and throat)</i></b>		
Abdominal migraine	2	0
Abdominal pain	1367	0
Abdominal pain lower	125	0
Abdominal pain upper	2257	0
Abdominal rigidity	22	0
Abdominal tenderness	12	0
Gastrointestinal pain	127	0
Oesophageal pain	12	0
<b><i>Gastrointestinal atonic and hypomotility disorders NEC</i></b>		
Constipation	244	0
Duodenogastric reflux	4	0

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
Gastric dilatation	7	0
Gastrooesophageal reflux disease	138	0
Impaired gastric emptying	9	0
Infrequent bowel movements	3	0
Intestinal dilatation	1	0
Intestinal pseudo-obstruction	2	0
<b><i>Gastrointestinal disorders NEC</i></b>		
Appendix disorder	1	0
Food poisoning	7	0
Functional gastrointestinal disorder	10	0
Gastric disorder	9	0
Gastrointestinal disorder	22	0
Stomach mass	4	0
<b><i>Gastrointestinal dyskinetic disorders</i></b>		
Bowel movement irregularity	6	0
Change of bowel habit	6	0
Dyschezia	3	0
Gastrointestinal motility disorder	3	0
Oesophageal achalasia	1	0
<b><i>Gastrointestinal fistulae</i></b>		
Diverticular fistula	2	0
<b><i>Gastrointestinal inflammatory disorders NEC</i></b>		
Duodenitis	1	0
Enteritis	6	0
Epiploic appendagitis	2	0
Gastrointestinal inflammation	3	0
Gastrointestinal tract irritation	1	0
Intestinal angioedema	2	0
<b><i>Gastrointestinal mucosal dystrophies and secretion disorders</i></b>		
Barrett's oesophagus	1	0
Hyperchlorhydria	4	0
<b><i>Gastrointestinal signs and symptoms NEC</i></b>		
Abdominal discomfort	579	0
Abdominal symptom	1	0
Acute abdomen	5	0
Anal incontinence	19	0
Breath odour	18	0
Dysphagia	196	1
Gastrointestinal wall thickening	1	0
Odynophagia	33	0
<b><i>Gastrointestinal spastic and hypermotility disorders</i></b>		
Cardiospasm	1	0
Defaecation urgency	11	0
Frequent bowel movements	27	0
Gastrointestinal hypermotility	1	0
Irritable bowel syndrome	82	0
Oesophageal spasm	3	0
Pylorospasm	1	0
<b><i>Gastrointestinal stenosis and obstruction NEC</i></b>		
Intestinal obstruction	3	0
Neonatal intestinal obstruction	1	0
<b><i>Gastrointestinal vascular malformations</i></b>		
Gastric antral vascular ectasia	11	0

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
<b><i>Gastrointestinal vascular occlusion and infarction</i></b>		
Intestinal ischaemia	5	2
Mesenteric vein thrombosis	6	0
Omental infarction	1	0
Thrombosis mesenteric vessel	2	0
Visceral venous thrombosis	1	0
<b><i>Gingival disorders, signs and symptoms NEC</i></b>		
Gingival blister	12	0
Gingival discomfort	7	0
Gingival disorder	4	0
Gingival erythema	2	0
Gingival hypertrophy	1	0
Gingival oedema	1	0
Gingival pain	98	0
Gingival pruritus	1	0
Gingival swelling	32	0
Gingival ulceration	2	0
Gingivitis ulcerative	1	0
Noninfective gingivitis	8	0
<b><i>Gingival haemorrhages</i></b>		
Gingival bleeding	59	0
<b><i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i></b>		
Gastric varices	1	0
Haemorrhoidal haemorrhage	1	0
Haemorrhoids	31	1
Haemorrhoids thrombosed	1	0
<b><i>Inguinal hernias</i></b>		
Inguinal hernia	1	0
<b><i>Intestinal haemorrhages</i></b>		
Anal haemorrhage	20	1
Intestinal haemorrhage	1	0
Rectal haemorrhage	67	0
Small intestinal haemorrhage	5	0
<b><i>Intestinal ulcers and perforation NEC</i></b>		
Intestinal perforation	5	2
Large intestinal ulcer	1	0
Large intestine perforation	1	0
<b><i>Large intestinal stenosis and obstruction</i></b>		
Large intestinal obstruction	1	1
<b><i>Malabsorption syndromes</i></b>		
Bile acid malabsorption	2	0
Coeliac disease	10	0
Malabsorption	1	0
Steatorrhoea	4	0
<b><i>Nausea and vomiting symptoms</i></b>		
Discoloured vomit	12	0
Infantile vomiting	7	0
Nausea	12907	0
Regurgitation	1	0
Retching	100	0
Vomiting	4136	1
Vomiting projectile	58	0
<b><i>Non-mechanical ileus</i></b>		

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
Ileus paralytic	2	0
<b><i>Non-site specific gastrointestinal haemorrhages</i></b>		
Gastrointestinal haemorrhage	16	1
Haematemesis	29	2
Haematochezia	50	0
Melaena	9	0
Upper gastrointestinal haemorrhage	11	0
<b><i>Oesophageal stenosis and obstruction</i></b>		
Oesophageal stenosis	3	0
<b><i>Oesophagitis (excl infective)</i></b>		
Eosinophilic oesophagitis	1	0
Oesophagitis	4	0
<b><i>Oral dryness and saliva altered</i></b>		
Aptyalism	3	0
Dry mouth	457	0
Lip dry	37	0
Saliva altered	6	0
Salivary hypersecretion	47	0
<b><i>Oral soft tissue disorders NEC</i></b>		
Angina bullosa haemorrhagica	1	0
Chapped lips	20	0
Cheilitis	23	0
Enlarged uvula	14	0
Leukoplakia oral	2	0
Lip blister	29	0
Lip disorder	5	0
Oral disorder	16	0
Oral lichen planus	12	0
Oral mucosal hypertrophy	1	0
Oral papule	1	0
Uvulitis	4	0
<b><i>Oral soft tissue haemorrhages</i></b>		
Mouth haemorrhage	15	0
Oral blood blister	13	0
Oral purpura	2	0
<b><i>Oral soft tissue infections</i></b>		
Angular cheilitis	3	0
<b><i>Oral soft tissue signs and symptoms</i></b>		
Anaesthesia oral	3	0
Burning mouth syndrome	6	0
Coating in mouth	1	0
Hypoaesthesia oral	447	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	76	0
Oral dysaesthesia	1	0
Oral mucosal blistering	13	0
Oral mucosal discolouration	1	0
Oral mucosal eruption	15	0

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
Oral mucosal erythema	6	0
Oral mucosal exfoliation	9	0
Oral mucosal roughening	3	0
Oral mucosal scab	1	0
Oral pain	159	0
Oral pruritus	22	0
Paraesthesia oral	858	0
Pigmentation lip	1	0
<b>Oral soft tissue swelling and oedema</b>		
Lip oedema	4	0
Lip swelling	702	0
Mouth swelling	89	0
Oedema mouth	4	0
Palatal oedema	3	0
Palatal swelling	2	0
<b>Pancreatic disorders NEC</b>		
Pancreatic failure	2	0
Pancreatic mass	1	0
<b>Peptic ulcers and perforation</b>		
Peptic ulcer	1	0
Peptic ulcer haemorrhage	13	0
<b>Peritoneal and retroperitoneal disorders</b>		
Ascites	1	0
<b>Peritoneal and retroperitoneal fibrosis and adhesions</b>		
Abdominal adhesions	2	0
<b>Peritoneal and retroperitoneal haemorrhages</b>		
Haemoperitoneum	1	0
Retroperitoneal haemorrhage	1	1
<b>Rectal inflammations NEC</b>		
Proctitis	3	0
Proctitis ulcerative	1	0
<b>Salivary gland disorders NEC</b>		
Salivary gland disorder	1	0
Salivary gland pain	12	0
<b>Salivary gland enlargements</b>		
Parotid gland enlargement	10	0
Salivary gland enlargement	5	0
Submaxillary gland enlargement	7	0
<b>Salivary gland infections and inflammations</b>		
Noninfective sialoadenitis	1	0
<b>Stomatitis and ulceration</b>		
Aphthous ulcer	47	0
Lip ulceration	16	0
Mouth ulceration	416	0
Oral mucosa erosion	1	0
Palatal ulcer	1	0
Stomatitis	60	0
<b>Tongue disorders</b>		
Glossitis	18	0
Hypertrophy of tongue papillae	1	0
Plicated tongue	3	0
Tongue disorder	36	0
Tongue geographic	2	0

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
Gastrointestinal disorders cont'd		
Tongue haemorrhage	3	0
Tongue ulceration	29	0
Trichoglossia	4	0
<b><i>Tongue signs and symptoms</i></b>		
Glossodynia	196	0
Scalloped tongue	5	0
Stiff tongue	4	0
Swollen tongue	451	0
Tongue blistering	17	0
Tongue coated	16	0
Tongue discolouration	36	0
Tongue discomfort	39	0
Tongue dry	13	0
Tongue eruption	9	0
Tongue erythema	10	0
Tongue exfoliation	1	0
Tongue movement disturbance	6	0
Tongue oedema	21	0
Tongue pruritus	2	0
Tongue rough	4	0
Tongue spasm	9	0
<b><i>Tooth missing</i></b>		
Tooth loss	6	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>34836</b>	<b>18</b>

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Reaction Name	Total	Fatal
<b>General disorders</b>		
<b><i>Administration site reactions NEC</i></b>		
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	35	0
Puncture site pain	6	0
Puncture site reaction	1	0
Puncture site swelling	2	0
Vessel puncture site bruise	2	0
Vessel puncture site erythema	1	0
Vessel puncture site pain	1	0
<b><i>Adverse effect absent</i></b>		
No adverse event	4	0
<b><i>Application and instillation site reactions</i></b>		
Application site acne	2	0
Application site bruise	8	0
Application site burn	1	0
Application site erythema	15	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
<b><i>Asthenic conditions</i></b>		
Asthenia	1789	0
Chronic fatigue syndrome	71	0
Decreased activity	9	0
Fatigue	20835	0
Malaise	4787	0
Sluggishness	13	0
<b><i>Body temperature altered</i></b>		

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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Hyperthermia	7	0
Hypothermia	23	0
Temperature regulation disorder	12	0
<b>Breast complications associated with device</b>		
Breast implant palpable	1	0
Capsular contracture associated with breast implant	1	0
<b>Cardiac complications associated with device</b>		
Prosthetic cardiac valve thrombosis	2	0
<b>Complications associated with device NEC</b>		
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
<b>Death and sudden death</b>		
Brain death	3	2
Cardiac death	2	2
Clinical death	1	1
Death	165	165
Decapitation	1	1
Drowning	1	0
Sudden death	26	26
<b>Febrile disorders</b>		
Hyperpyrexia	9	0
Pyrexia	13620	0
<b>Feelings and sensations NEC</b>		
Chills	8676	0
Feeling abnormal	1495	0
Feeling cold	1093	0
Feeling drunk	76	0
Feeling hot	1070	0
Feeling jittery	26	0
Feeling of body temperature change	304	0
Feeling of relaxation	3	0
Hangover	75	0
Hunger	44	0
Sensation of blood flow	3	0
Sensation of foreign body	50	0
Temperature intolerance	41	0
Thirst	318	0
<b>Fibrosis NEC</b>		
Fibrosis	1	0
<b>Gait disturbances</b>		
Gait disturbance	211	0
Gait inability	82	0
Loss of control of legs	20	0
<b>General signs and symptoms NEC</b>		
Adhesion	1	0
Chronic disease	1	0
Condition aggravated	203	0
Crepitations	3	0
Crying	145	0



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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Deformity	2	0
Discharge	11	0
Disease progression	2	0
Disease recurrence	27	0
Effusion	3	0
Energy increased	20	0
Exercise tolerance decreased	24	0
Foaming at mouth	2	0
General physical health deterioration	15	2
General symptom	3	0
Glassy eyes	4	0
High-pitched crying	3	0
Illness	1755	0
Induration	15	0
Influenza like illness	2181	0
Irritability postvaccinal	2	0
Local reaction	78	0
Moaning	3	0
Multiple organ dysfunction syndrome	10	4
Nonspecific reaction	1	0
Organ failure	2	1
Perforation	2	0
Peripheral swelling	3342	0
Physical deconditioning	2	0
Pre-existing condition improved	8	0
Prolapse	1	0
Screaming	20	0
Secretion discharge	23	0
Swelling	2700	0
Swelling face	762	0
Symptom recurrence	1	0
Terminal state	1	0
Tissue irritation	1	0
<b>Healing abnormal NEC</b>		
Impaired healing	1	0
<b>Implant and catheter site reactions</b>		
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
<b>Inflammations</b>		
Granuloma	1	0
Inflammation	441	0
Papillitis	1	0
Scar inflammation	3	0
Serositis	1	0
Systemic inflammatory response syndrome	2	0
<b>Infusion site reactions</b>		
Infusion site coldness	1	0
Infusion site discolouration	1	0
Infusion site erythema	1	0

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Reaction Name	Total	Fatal
<b>General disorders</b> 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	3	0
Infusion site pruritus	1	0
Infusion site swelling	2	0
Infusion site urticaria	1	0
Infusion site warmth	2	0
<b>Injection site reactions</b>		
Injected limb mobility decreased	30	0
Injection site bruising	62	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	351	0
Injection site extravasation	1	0
Injection site haemorrhage	6	0
Injection site hypersensitivity	2	0
Injection site hypoaesthesia	9	0
Injection site indentation	9	0
Injection site induration	3	0
Injection site inflammation	38	0
Injection site irritation	1	0
Injection site joint discomfort	2	0
Injection site joint erythema	2	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	492	0
Injection site movement impairment	1	0
Injection site necrosis	4	0
Injection site nerve damage	1	0
Injection site oedema	15	0
Injection site pain	2725	0
Injection site paraesthesia	12	0
Injection site pruritus	184	0
Injection site rash	159	0
Injection site reaction	31	0
Injection site scab	4	0
Injection site scar	5	0
Injection site swelling	269	0
Injection site urticaria	28	0
Injection site vesicles	10	0
Injection site warmth	174	0
<b>Interactions</b>		
Alcohol interaction	4	0
Drug interaction	25	0
Inhibitory drug interaction	3	0
<b>Mass conditions NEC</b>		

## Case Series Drug Analysis Print

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

Report Run Date: 18-Nov-2021

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Cyst	40	0
Mass	64	0
Nodule	35	0
<b><i>Mucosal findings abnormal</i></b>		
Mucosa vesicle	1	0
Mucosal dryness	1	0
Mucosal haemorrhage	9	0
Mucosal inflammation	2	0
Oedema mucosal	1	0
Polyp	5	0
<b><i>Necrosis NEC</i></b>		
Fat necrosis	3	0
Necrosis	4	0
<b><i>Oedema NEC</i></b>		
Face oedema	28	0
Generalised oedema	3	0
Localised oedema	17	0
Oedema	71	0
Oedema peripheral	85	0
<b><i>Pain and discomfort NEC</i></b>		
Axillary pain	2815	0
Chest discomfort	1566	0
Chest pain	4116	0
Discomfort	438	0
Facial discomfort	19	0
Facial pain	194	0
Inflammatory pain	13	0
Non-cardiac chest pain	27	0
Pain	8061	0
Suprapubic pain	1	0
Tenderness	616	0
Visceral pain	2	0
<b><i>Therapeutic and nontherapeutic responses</i></b>		
Adverse drug reaction	50	0
Adverse event	2	0
Adverse food reaction	3	0
Adverse reaction	2	0
Drug ineffective	294	1
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	38	0
Product intolerance	1	0
Therapeutic product effect decreased	1	0
Therapeutic product effect delayed	2	0
Therapeutic product effect increased	1	0
Therapeutic product ineffective	2	0
Therapeutic response decreased	2	0
Therapeutic response unexpected	71	0
Therapy non-responder	1	0
Treatment failure	8	0
Vaccination failure	38	0

## Case Series Drug Analysis Print

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

Report Run Date: 18-Nov-2021

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
<b><i>Trophic disorders</i></b>		
Atrophy	2	0
Calcinosis	2	0
Hyperplasia	1	0
<b><i>Ulcers NEC</i></b>		
Ulcer	30	0
Ulcer haemorrhage	1	0
<b><i>Vaccination site reactions</i></b>		
Extensive swelling of vaccinated limb	14	0
Shoulder injury related to vaccine administration	28	0
Vaccination site anaesthesia	1	0
Vaccination site bruising	118	0
Vaccination site coldness	3	0
Vaccination site cyst	5	0
Vaccination site dermatitis	1	0
Vaccination site discolouration	14	0
Vaccination site discomfort	47	0
Vaccination site dryness	1	0
Vaccination site eczema	1	0
Vaccination site erythema	589	0
Vaccination site granuloma	5	0
Vaccination site haematoma	2	0
Vaccination site haemorrhage	21	0
Vaccination site hypersensitivity	3	0
Vaccination site hypoaesthesia	16	0
Vaccination site induration	71	0
Vaccination site inflammation	53	0
Vaccination site irritation	12	0
Vaccination site joint discomfort	2	0
Vaccination site joint erythema	11	0
Vaccination site joint inflammation	1	0
Vaccination site joint movement impairment	17	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	266	0
Vaccination site movement impairment	85	0
Vaccination site nerve damage	1	0
Vaccination site nodule	3	0
Vaccination site oedema	3	0
Vaccination site pain	2035	0
Vaccination site paraesthesia	8	0
Vaccination site phlebitis	1	0
Vaccination site pruritus	154	0
Vaccination site rash	124	0
Vaccination site reaction	33	0
Vaccination site scab	2	0
Vaccination site scar	1	0
Vaccination site swelling	539	0
Vaccination site thrombosis	1	0
Vaccination site ulcer	1	0

## Case Series Drug Analysis Print

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

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Vaccination site urticaria	10	0
Vaccination site vesicles	9	0
Vaccination site warmth	258	0
<b><i>Vascular complications associated with device</i></b>		
Vascular stent thrombosis	1	0
<b><i>Withdrawal and rebound effects</i></b>		
Drug withdrawal syndrome	4	0
Withdrawal syndrome	40	0
<b>General disorders SOC TOTAL</b>	<b>95174</b>	<b>205</b>

## Case Series Drug Analysis Print

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

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Hepatic disorders</b>		
<i><b>Bile duct infections and inflammations</b></i>		
Biliary colic	12	0
Cholangitis	1	0
<i><b>Cholecystitis and cholelithiasis</b></i>		
Cholecystitis	3	0
Cholecystitis acute	2	0
Cholelithiasis	10	0
<i><b>Cholestasis and jaundice</b></i>		
Cholestasis	2	0
Jaundice	22	0
Jaundice cholestatic	10	0
Ocular icterus	2	0
<i><b>Gallbladder disorders NEC</b></i>		
Gallbladder disorder	1	0
<i><b>Hepatic and hepatobiliary disorders NEC</b></i>		
Liver disorder	13	0
<i><b>Hepatic enzymes and function abnormalities</b></i>		
Hepatic function abnormal	7	0
<i><b>Hepatic failure and associated disorders</b></i>		
Acute hepatic failure	1	0
Hepatic failure	2	1
<i><b>Hepatic fibrosis and cirrhosis</b></i>		
Hepatic cirrhosis	1	0
<i><b>Hepatic vascular disorders</b></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><b>Hepatobiliary signs and symptoms</b></i>		
Hepatic pain	26	0
Hepatomegaly	2	0
Liver tenderness	3	0
<i><b>Hepatocellular damage and hepatitis NEC</b></i>		
Autoimmune hepatitis	8	0
Drug-induced liver injury	3	0
Hepatic steatosis	2	0
Hepatitis	9	0
Immune-mediated hepatic disorder	1	0
Liver injury	20	0
<b>Hepatic disorders SOC TOTAL</b>	<b>179</b>	<b>1</b>

## Case Series Drug Analysis Print

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

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i><b>Acute and chronic sarcoidosis</b></i>		
Sarcoidosis	15	0
<i><b>Allergic conditions NEC</b></i>		
Allergic oedema	15	0
Allergy to animal	1	0
Allergy to arthropod bite	6	0
Allergy to arthropod sting	2	0
Allergy to metals	1	0
Allergy to sting	1	0
Hypersensitivity	903	0
Infusion related hypersensitivity reaction	4	0
Mite allergy	3	0
Multiple allergies	9	0
Serum sickness	2	0
Serum sickness-like reaction	6	0
Type I hypersensitivity	1	0
Type III immune complex mediated reaction	4	0
Type IV hypersensitivity reaction	6	0
<i><b>Allergies to foods, food additives, drugs and other chemicals</b></i>		
Allergic reaction to excipient	5	0
Allergy to chemicals	3	0
Allergy to vaccine	36	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	9	0
Reaction to preservatives	5	0
Rubber sensitivity	1	0
Smoke sensitivity	1	0
<i><b>Anaphylactic and anaphylactoid responses</b></i>		
Anaphylactic reaction	478	2
Anaphylactic shock	53	0
Anaphylactoid reaction	20	0
Anaphylactoid shock	4	0
<i><b>Atopic disorders</b></i>		
Atopy	1	0
Seasonal allergy	104	0
<i><b>Autoimmune disorders NEC</b></i>		
Autoimmune disorder	42	0
<i><b>Immune and associated conditions NEC</b></i>		
Anamnestic reaction	1	0
Bacille Calmette-Guerin scar reactivation	52	0
Cytokine storm	1	0
Decreased immune responsiveness	2	0
Graft versus host disease	2	0
Haemophagocytic lymphohistiocytosis	2	0
Immune reconstitution inflammatory syndrome	1	0
Immune system disorder	23	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: 18-Nov-2021

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i>Immune system disorders cont'd</i>		
Multisystem inflammatory syndrome in children	2	0
Sensitisation	5	0
Systemic immune activation	2	0
<b><i>Immunodeficiency disorders NEC</i></b>		
Hypogammaglobulinaemia	1	0
Immunodeficiency	1	0
Immunosuppression	4	0
<b><i>Primary immunodeficiency syndromes</i></b>		
Selective IgA immunodeficiency	1	0
<b><i>Transplant rejections</i></b>		
Corneal graft rejection	8	0
Kidney transplant rejection	1	0
Solid organ transplant rejection	1	0
Transplant rejection	1	0
<b>Immune system disorders SOC TOTAL</b>	<b>1921</b>	<b>2</b>



## Case Series Drug Analysis Print

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

Report Run Date: 18-Nov-2021

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Infections</b>		
<b><i>Abdominal and gastrointestinal infections</i></b>		
Abdominal abscess	2	0
Abdominal infection	1	0
Anal abscess	3	0
Appendicitis	38	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
<b><i>Adenoviral infections</i></b>		
Adenoviral conjunctivitis	1	0
<b><i>Aspergillus infections</i></b>		
Bronchopulmonary aspergillosis	1	0
<b><i>Bacterial infections NEC</i></b>		
Abscess bacterial	2	0
Arthritis bacterial	4	0
Bacterial colitis	1	0
Bacterial diarrhoea	1	0
Bacterial infection	13	0
Bacterial sepsis	1	0
Cellulitis	172	0
Conjunctivitis bacterial	1	0
Ear infection bacterial	1	0
Folliculitis	16	0
Gangrene	1	0
Injection site cellulitis	2	0
Meningitis bacterial	3	0
Paronychia	3	0
Perichondritis	1	0
Periorbital cellulitis	1	0
Pneumonia bacterial	1	0
Sinusitis bacterial	1	0
Skin bacterial infection	2	0
Tonsillitis bacterial	3	0
Urinary tract infection bacterial	1	0
Vaccination site cellulitis	19	0
Zoonotic bacterial infection	1	1
<b><i>Bartonella infections</i></b>		
Cat scratch disease	1	0
<b><i>Bone and joint infections</i></b>		
Abscess jaw	1	0
Arthritis infective	1	0
Osteomyelitis	2	0
<b><i>Borrelial infections</i></b>		
Lyme disease	2	0
Relapsing fever	2	0
<b><i>Breast infections</i></b>		
Breast abscess	3	0
Mastitis	75	0

## Case Series Drug Analysis Print

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

Report Run Date: 18-Nov-2021

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Infections</b> Infections cont'd		
<b><i>Caliciviral infections</i></b>		
Gastroenteritis norovirus	3	0
<b><i>Campylobacter infections</i></b>		
Campylobacter gastroenteritis	1	0
Campylobacter infection	1	0
<b><i>Candida infections</i></b>		
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	45	0
<b><i>Cardiac infections</i></b>		
Cardiac infection	1	0
Cardiac valve vegetation	1	0
Pericarditis infective	2	0
<b><i>Central nervous system and spinal infections</i></b>		
Brain abscess	1	0
CNS ventriculitis	1	0
Cavernous sinus thrombosis	1	0
Encephalitis	19	0
Encephalomyelitis	1	0
Meningitis	7	0
Meningitis aseptic	3	0
Myelitis	6	0
Subdural abscess	1	0
<b><i>Clostridia infections</i></b>		
Clostridium difficile infection	2	0
<b><i>Coronavirus infections</i></b>		
Asymptomatic COVID-19	15	0
COVID-19	1365	42
COVID-19 pneumonia	49	14
Coronavirus infection	7	0
Post-acute COVID-19 syndrome	2	0
Severe acute respiratory syndrome	2	0
Suspected COVID-19	67	4
<b><i>Corynebacteria infections</i></b>		
Diphtheria	1	0
<b><i>Coxiella infections</i></b>		
Q fever	11	0
<b><i>Cytomegaloviral infections</i></b>		
Cytomegalovirus infection	2	0
Cytomegalovirus syndrome	1	0
<b><i>Dental and oral soft tissue infections</i></b>		
Abscess oral	6	0
Gingivitis	10	0
Oral infection	1	0
Parotitis	10	0
Pericoronitis	2	0
Pulpitis dental	1	0

## Case Series Drug Analysis Print

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

Report Run Date: 18-Nov-2021

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Reaction Name	Total	Fatal
<b>Infections</b>		
Infections cont'd		
Sialoadenitis	3	0
Tongue abscess	1	0
Tooth abscess	8	0
Tooth infection	9	0
<b>Ear infections</b>		
Ear infection	83	0
Labyrinthitis	98	0
Mastoiditis	1	0
Otitis externa	2	0
Otitis media	2	0
Otitis media acute	1	0
Otitis media chronic	4	0
<b>Ectoparasitic infestations</b>		
Acarodermatitis	4	0
Bed bug infestation	1	0
<b>Epstein-Barr viral infections</b>		
Epstein-Barr virus infection	3	0
Infectious mononucleosis	24	0
<b>Escherichia infections</b>		
Escherichia bacteraemia	1	0
<b>Eye and eyelid infections</b>		
Conjunctivitis	67	0
Eye abscess	1	0
Eye infection	19	0
Eyelid boil	2	0
Eyelid infection	2	0
Hordeolum	27	0
Keratouveitis	1	0
Periorbital infection	2	0
<b>Female reproductive tract infections</b>		
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
<b>Fungal infections NEC</b>		
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
<b>Hepatitis virus infections</b>		
Hepatitis A	1	0
Hepatitis E	1	0
<b>Hepatobiliary and spleen infections</b>		
Biliary sepsis	2	0
Cholecystitis infective	2	0
Hepatic infection	1	0
<b>Herpes viral infections</b>		

## Case Series Drug Analysis Print

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

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Reaction Name	Total	Fatal
<b>Infections</b>		
Infections cont'd		
Eczema herpeticum	2	0
Genital herpes	79	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	10	0
Herpes zoster	1345	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	3	0
Oral herpes	292	0
Varicella	27	0
Varicella zoster virus infection	2	0
<b>Infections NEC</b>		
Abscess	36	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	222	0
Infection susceptibility increased	1	0
Injection site abscess	1	0
Injection site infection	5	0
Localised infection	28	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	8	0
Vaccination site infection	13	0
Vaccine breakthrough infection	23	0
Vestibulitis	2	0
Wound infection	2	0
<b>Infectious transmissions</b>		
Secondary transmission	8	0
Vaccine virus shedding	1	0
<b>Influenza viral infections</b>		
Influenza	1456	0
<b>Klebsiella infections</b>		
Klebsiella infection	1	0
<b>Lower respiratory tract and lung infections</b>		
Bronchitis	20	0
Infectious pleural effusion	1	0

## Case Series Drug Analysis Print

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

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Infections</b>		
Infections cont'd		
Lower respiratory tract infection	212	8
Pneumonia	126	12
Pneumonia aspiration	9	6
Sputum purulent	1	0
<b>Male reproductive tract infections</b>		
Epididymitis	7	0
Orchitis	5	0
Prostate infection	2	0
<b>Molluscum contagiosum viral infections</b>		
Molluscum contagiosum	1	0
<b>Mumps viral infections</b>		
Mumps	7	0
<b>Muscle and soft tissue infections</b>		
Abscess neck	1	0
Infective tenosynovitis	1	0
Necrotising fasciitis	2	0
Psoas abscess	1	0
Soft tissue infection	2	0
<b>Neisseria infections</b>		
Gonorrhoea	1	0
Meningococcal bacteraemia	1	0
<b>Orthopox viral infections</b>		
Vaccinia virus infection	1	0
<b>Plasmodia infections</b>		
Malaria	2	0
<b>Pneumocystis infections</b>		
Pneumocystis jirovecii pneumonia	2	0
<b>Prion-associated disorders</b>		
Creutzfeldt-Jakob disease	1	0
<b>Retroviral infections</b>		
Acquired immunodeficiency syndrome	1	0
HIV infection	2	0
Persistent generalised lymphadenopathy	1	0
<b>Rotaviral infections</b>		
Gastroenteritis rotavirus	1	0
<b>Rubeola viral infections</b>		
Measles	4	0
<b>Sepsis, bacteraemia, viraemia and fungaemia NEC</b>		
Neutropenic sepsis	3	1
Sepsis	49	7
Sepsis syndrome	1	0
Septic rash	1	0
Septic shock	5	1
Urosepsis	5	0
<b>Skin structures and soft tissue infections</b>		
Abscess sweat gland	1	0
Acne pustular	1	0
Blister infected	1	0
Dermatitis infected	2	0
Impetigo	10	0
Infected skin ulcer	1	0
Injection site pustule	2	0
Nail infection	2	0

## Case Series Drug Analysis Print

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

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Infections</b>		
Infections cont'd		
Pustule	19	0
Rash pustular	10	0
Skin infection	30	0
Subcutaneous abscess	12	0
Sweat gland infection	1	0
Vaccination site pustule	4	0
<b><i>Staphylococcal infections</i></b>		
Furuncle	38	1
Pneumonia staphylococcal	1	0
Staphylococcal abscess	1	0
Staphylococcal infection	3	0
Staphylococcal sepsis	1	0
<b><i>Streptococcal infections</i></b>		
Meningitis pneumococcal	1	0
Pharyngitis streptococcal	6	0
Streptococcal abscess	1	0
Streptococcal endocarditis	1	0
Streptococcal infection	1	0
Streptococcal sepsis	1	0
<b><i>Tinea infections</i></b>		
Body tinea	3	0
Tinea infection	1	0
Tinea pedis	2	0
Tinea versicolour	3	0
<b><i>Treponema infections</i></b>		
Syphilis	2	0
<b><i>Trypanosomal infections</i></b>		
African trypanosomiasis	2	0
<b><i>Tuberculous infections</i></b>		
Lymph node tuberculosis	1	0
Pulmonary tuberculosis	1	0
Tuberculosis	1	0
Tuberculosis of central nervous system	1	0
<b><i>Upper respiratory tract infections</i></b>		
Acute sinusitis	4	0
Chronic sinusitis	2	0
Croup infectious	1	0
Epiglottitis	1	0
Laryngitis	28	0
Nasopharyngitis	965	0
Peritonsillar abscess	3	0
Pharyngitis	30	0
Rhinitis	41	0
Sinusitis	149	0
Tonsillitis	109	0
Tracheitis	4	0
Tracheostomy infection	1	0
Upper respiratory tract infection	10	0
<b><i>Urinary tract infections</i></b>		
Cystitis	75	0
Kidney infection	43	0
Pyelonephritis	2	0
Urethritis	1	0

## Case Series Drug Analysis Print

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

Report Run Date: 18-Nov-2021

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Infections</b>		
Infections cont'd		
Urinary tract infection	185	0
<b>Vascular infections</b>		
Haematoma infection	1	0
Infected lymphocele	2	0
Infusion site infection	1	0
Lymphangitis	8	0
<b>Viral infections NEC</b>		
Arthritis viral	1	0
Conjunctivitis viral	2	0
Ear infection viral	1	0
Encephalitis viral	6	1
Eye infection viral	2	0
Gastroenteritis viral	28	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	46	0
Sweating fever	95	0
Vestibular neuronitis	30	0
Viral diarrhoea	2	0
Viral infection	50	0
Viral labyrinthitis	4	0
Viral myocarditis	3	0
Viral pericarditis	3	0
Viral pharyngitis	18	0
Viral rash	54	0
Viral sinusitis	1	0
Viral tonsillitis	2	0
<b>Infections SOC TOTAL</b>	<b>8959</b>	<b>101</b>

## Case Series Drug Analysis Print

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

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Injuries</b>		
<b><i>Abdominal and gastrointestinal injuries NEC</i></b>		
Liver contusion	1	0
Mouth injury	3	0
Oral contusion	4	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
<b><i>Accidental exposures to product</i></b>		
Accidental exposure to product	20	0
<b><i>Anaesthetic and allied procedural complications</i></b>		
Airway complication of anaesthesia	1	0
Delayed recovery from anaesthesia	2	0
Sedation complication	1	0
<b><i>Atmospheric pressure injuries</i></b>		
Barotitis media	1	0
Hypobarism	1	0
<b><i>Bone and joint injuries NEC</i></b>		
Bursa injury	2	0
Joint injury	8	0
Meniscus injury	1	0
<b><i>Cardiac and vascular procedural complications</i></b>		
Shunt blood flow excessive	1	0
Vascular pseudoaneurysm	1	0
<b><i>Cardiovascular injuries</i></b>		
Vascular injury	7	0
<b><i>Cerebral injuries NEC</i></b>		
Brain contusion	4	0
Brain herniation	2	0
Concussion	4	0
Cranio-cerebral injury	1	0
Subarachnoid haematoma	1	0
Subdural haematoma	5	0
Subdural haemorrhage	5	0
Traumatic intracranial haemorrhage	1	1
<b><i>Chemical injuries</i></b>		
Chemical burn of skin	5	0
Chemical cystitis	1	0
<b><i>Chest and respiratory tract injuries NEC</i></b>		
Bronchial injury	1	0
Chest crushing	10	0
Foreign body in throat	1	0
Traumatic lung injury	1	0
<b><i>Conditions caused by cold</i></b>		
Chillblains	53	0
Cold shock response	1	0
Frostbite	1	0
<b><i>Cranial nerve injuries</i></b>		
Vth nerve injury	1	0
<b><i>Ear injuries NEC</i></b>		
Deafness traumatic	1	0



## Case Series Drug Analysis Print

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

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Injuries</b>		
Injuries cont'd		
Ear injury	1	0
<b>Exposures associated with pregnancy, delivery and lactation</b>		
Exposure during pregnancy	9	0
Exposure via breast milk	132	0
Foetal exposure during pregnancy	44	0
Maternal exposure before pregnancy	15	0
Maternal exposure during breast feeding	1596	0
Maternal exposure during pregnancy	868	0
Maternal exposure timing unspecified	10	0
Paternal exposure before pregnancy	3	0
<b>Exposures to agents or circumstances NEC</b>		
Exposure to SARS-CoV-2	3	0
Exposure to vaccinated person	4	0
<b>Eye and ear procedural complications</b>		
Toxic anterior segment syndrome	1	0
<b>Eye injuries NEC</b>		
Corneal abrasion	1	0
Eye contusion	13	0
Eye injury	20	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
<b>Foetal and neonatal conditions associated with product exposure</b>		
Intoxication by breast feeding	1	0
<b>Fractures and dislocations NEC</b>		
Bone fragmentation	1	0
Fracture	3	0
Joint dislocation	3	0
Multiple fractures	1	0
<b>Gastrointestinal and hepatobiliary procedural complications</b>		
Post procedural constipation	1	0
Postoperative ileus	1	0
Procedural nausea	9	0
Procedural vomiting	2	0
<b>Heat injuries (excl thermal burns)</b>		
Heat cramps	2	0
Heat exhaustion	3	0
Heat illness	1	0
Heat oedema	12	0
Heat stroke	3	0
<b>Intentional product use issues</b>		
Intentional dose omission	1	0
Intentional product use issue	1	0
<b>Limb fractures and dislocations</b>		
Atypical femur fracture	3	0
Clavicle fracture	25	0
Femoral neck fracture	1	0
Femur fracture	1	0
Fibula fracture	1	0
Hip fracture	2	0
Tibia fracture	1	0

## Case Series Drug Analysis Print

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

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Injuries</b>		
Injuries cont'd		
Upper limb fracture	1	0
Wrist fracture	1	0
<b>Medication errors, product use errors and issues NEC</b>		
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	20	0
Prescription drug used without a prescription	2	0
Product use complaint	1	0
Product use issue	23	0
Vaccination error	5	0
Wrong dose	4	0
Wrong drug	11	0
Wrong technique in product usage process	5	0
<b>Muscle, tendon and ligament injuries</b>		
Epicondylitis	18	0
Ligament injury	2	0
Ligament sprain	9	0
Mallet finger	1	0
Muscle injury	27	0
Muscle rupture	8	0
Muscle strain	29	0
Post-traumatic neck syndrome	2	0
Tendon injury	7	0
Tendon rupture	19	0
<b>Musculoskeletal procedural complications</b>		
Periprosthetic osteolysis	1	0
Post laminectomy syndrome	1	0
<b>Nerve injuries NEC</b>		
Nerve injury	89	0
<b>Neurological and psychiatric procedural complications</b>		
Post lumbar puncture syndrome	1	0
Post procedural stroke	1	0
Procedural dizziness	11	0
<b>Non-occupational environmental exposures</b>		
Exposure to extreme temperature	2	0
<b>Non-site specific injuries NEC</b>		
Animal scratch	1	0
Arthropod bite	5	0
Arthropod sting	5	0
Bite	1	0
Electric shock	18	0
Fall	176	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
Wound complication	10	0
Wound haematoma	1	0
Wound haemorrhage	2	0

## Case Series Drug Analysis Print

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

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Injuries</b>		
Injuries cont'd		
Wound secretion	5	0
<b>Non-site specific procedural complications</b>		
Incision site pain	3	0
Infusion related reaction	7	0
Injection related reaction	53	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
<b>Occupational exposures</b>		
Occupational exposure to SARS-CoV-2	1	0
Occupational exposure to product	2	0
<b>Off label uses</b>		
Off label use	177	0
<b>Overdoses NEC</b>		
Overdose	47	0
<b>Pathways and sources of exposure</b>		
Exposure via unknown route	1	0
<b>Pelvic fractures and dislocations</b>		
Pelvic fracture	1	0
<b>Peripheral nerve injuries</b>		
Axillary nerve injury	1	0
Brachial plexus injury	1	0
Sciatic nerve injury	1	0
Ulnar nerve injury	4	0
<b>Poisoning and toxicity</b>		
Alcohol poisoning	1	0
Poisoning	11	0
Toxicity to various agents	3	0
<b>Product administration errors and issues</b>		
Accidental overdose	7	0
Contraindicated product administered	1	0
Expired product administered	13	0
Extra dose administered	1	0
Inappropriate schedule of product administration	541	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	4	0
Lack of vaccination site rotation	1	0
Poor quality product administered	3	0
Product administered at inappropriate site	17	0
Product administered to patient of inappropriate age	1	0
Product administration error	7	0
Product dose omission issue	5	0
Wrong product administered	20	0
<b>Product confusion errors and issues</b>		
Product dosage form confusion	1	0
Product label confusion	1	0
<b>Product dispensing errors and issues</b>		

## Case Series Drug Analysis Print

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

Report Run Date: 18-Nov-2021

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Injuries</b> <span style="float: right;">Injuries cont'd</span>		
Product dispensing error	4	0
<b>Product monitoring errors and issues</b>		
Drug monitoring procedure incorrectly performed	1	0
<b>Product preparation errors and issues</b>		
Product preparation error	2	0
Product preparation issue	6	0
<b>Product prescribing errors and issues</b>		
Contraindicated product prescribed	2	0
Product prescribing error	2	0
<b>Product selection errors and issues</b>		
Product selection error	2	0
<b>Radiation injuries</b>		
Radiation sickness syndrome	1	0
Sunburn	21	0
<b>Renal and urinary tract injuries NEC</b>		
Bladder injury	1	0
Foreign body in urogenital tract	1	0
<b>Reproductive system and breast injuries</b>		
Penis injury	1	0
<b>Site specific injuries NEC</b>		
Back injury	2	0
Face crushing	3	0
Face injury	1	0
Head injury	33	0
Limb crushing injury	4	0
Limb injury	112	0
Nasal injury	1	0
Neck crushing	1	0
Neck injury	1	0
<b>Site specific procedural complications NEC</b>		
Axillary web syndrome	1	0
<b>Skin injuries NEC</b>		
Contusion	1135	0
Hair injury	1	0
Nail avulsion	1	0
Scar	21	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
<b>Skin procedural complications</b>		
Dermal filler overcorrection	1	0
Recall phenomenon	1	0
<b>Skull fractures, facial bone fractures and dislocations</b>		
Facial bones fracture	1	0
Fractured skull depressed	1	0
<b>Spinal cord injuries NEC</b>		
Spinal cord injury cervical	1	0
<b>Spinal fractures and dislocations</b>		
Spinal fracture	4	0

## Case Series Drug Analysis Print

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Report Run Date: 18-Nov-2021

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Reaction Name	Total	Fatal
<b>Injuries</b> <span style="float: right;">Injuries cont'd</span>		
<b><i>Stoma complications</i></b>		
Gastrointestinal stoma complication	2	0
Stoma site discharge	1	0
Stoma site extravasation	1	0
Stoma site haemorrhage	1	0
<b><i>Thermal burns</i></b>		
Airway burns	1	0
Burn oesophageal	2	0
Burn of internal organs	2	0
Burn oral cavity	5	0
Burns second degree	6	0
Burns third degree	5	0
Thermal burn	20	0
Thermal burns of eye	12	0
<b><i>Underdoses NEC</i></b>		
Underdose	6	0
<b><i>Vaccination related complications</i></b>		
Vaccination complication	50	0
<b>Injuries SOC TOTAL</b>	<b>6041</b>	<b>1</b>

## Case Series Drug Analysis Print

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

Report Run Date: 18-Nov-2021

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Investigations</b>		
<i><b>Adrenal cortex tests</b></i>		
Cortisol decreased	4	0
<i><b>Adrenal medulla tests</b></i>		
Epinephrine abnormal	1	0
Epinephrine increased	1	0
<i><b>Auditory and vestibular diagnostic procedures</b></i>		
Acoustic stimulation tests	5	0
Audiogram abnormal	1	0
<i><b>Autoimmunity analyses</b></i>		
Antinuclear antibody	1	0
Antinuclear antibody increased	1	0
Antinuclear antibody positive	2	0
Rheumatoid factor	3	0
<i><b>Bacteria identification and serology (excl mycobacteria)</b></i>		
Bacterial test positive	1	0
Klebsiella test positive	1	0
<i><b>Blood counts NEC</b></i>		
Full blood count	5	0
Full blood count abnormal	2	0
<i><b>Blood gas and acid base analyses</b></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	8	0
Blood pH increased	9	0
Oxygen consumption	1	0
Oxygen consumption decreased	2	0
Oxygen saturation	9	0
Oxygen saturation decreased	67	0
PO2 decreased	1	0
<i><b>Bone marrow and immune tissue histopathology procedures</b></i>		
Aspiration bone marrow	1	0
Biopsy lymph gland	1	0
<i><b>Bone marrow and immune tissue imaging procedures</b></i>		
Lymph nodes scan abnormal	1	0
Scan lymph nodes	4	0
<i><b>Carbohydrate tolerance analyses (incl diabetes)</b></i>		
Blood glucose	8	0
Blood glucose abnormal	12	0
Blood glucose decreased	32	0
Blood glucose fluctuation	15	0
Blood glucose increased	99	0
Blood glucose normal	1	0
Glycosylated haemoglobin increased	1	0
<i><b>Cardiac auscultatory investigations</b></i>		
Cardiac murmur	36	0
Heart sounds	6	0
Heart sounds abnormal	4	0
<i><b>Cardiac function diagnostic procedures</b></i>		
Cardiac monitoring	1	0
Cardiac output	1	0
Central venous pressure	1	0

## Case Series Drug Analysis Print

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

Report Run Date: 18-Nov-2021

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Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
Echocardiogram	1	0
Ejection fraction decreased	1	0
Myocardial strain imaging	1	0
Stroke volume decreased	1	0
<b>Cardiac imaging procedures</b>		
Magnetic resonance imaging heart	1	0
Scan myocardial perfusion abnormal	1	0
<b>Cell marker analyses</b>		
Carcinoembryonic antigen increased	1	0
HLA-B*27 positive	1	0
Prostatic specific antigen increased	2	0
<b>Central nervous system imaging procedures</b>		
Computerised tomogram head	7	0
Magnetic resonance imaging head	12	0
Magnetic resonance imaging head abnormal	1	0
<b>Cerebrospinal fluid tests (excl microbiology)</b>		
CSF pressure	1	0
<b>Chemistry analyses NEC</b>		
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
<b>Cholesterol analyses</b>		
Blood cholesterol increased	7	0
Remnant-like lipoprotein particles	3	0
<b>Coagulation and bleeding analyses</b>		
Activated partial thromboplastin time prolonged	15	0
Activated partial thromboplastin time shortened	1	0
Bleeding time	2	0
Bleeding time abnormal	1	0
Bleeding time prolonged	7	0
Blood thromboplastin	1	0
Clot retraction	2	1
Coagulation factor VIII level decreased	1	0
Coagulation time prolonged	9	0
Coagulation time shortened	4	0
Fibrin D dimer increased	13	0
International normalised ratio abnormal	7	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
<b>Digestive enzymes</b>		
Amylase increased	1	0
<b>ECG investigations</b>		
Electrocardiogram	7	0
Electrocardiogram QRS complex prolonged	1	0
Electrocardiogram QT prolonged	9	0
Electrocardiogram ST segment depression	2	0

## Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<b>Investigations</b>		
Investigations cont'd		
Electrocardiogram ST segment elevation	11	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
<b>Endocrine analyses and imaging NEC</b>		
Hormone level abnormal	50	0
<b>Faecal analyses NEC</b>		
Faecal calprotectin	2	0
Faecal calprotectin increased	4	0
<b>Fertility analyses</b>		
Infertility tests	1	0
Semen analysis abnormal	1	0
Sperm concentration	2	0
Sperm concentration decreased	1	0
<b>Foetal and neonatal diagnostic procedures</b>		
Foetal heart rate abnormal	4	2
Foetal heart rate increased	1	0
Foetal monitoring	1	0
Foetal non-stress test	1	0
<b>Gastrointestinal and abdominal imaging procedures</b>		
Colonoscopy	1	0
Computerised tomogram abdomen	1	0
Laparoscopy	1	0
Sigmoidoscopy abnormal	1	0
X-ray gastrointestinal tract abnormal	1	0
X-ray with contrast upper gastrointestinal tract	1	0
<b>Gastrointestinal function diagnostic procedures</b>		
Gastric pH decreased	1	0
<b>Gastrointestinal, pancreatic and APUD hormone analyses</b>		
Blood insulin	1	0
Blood insulin decreased	1	0
<b>Haematological analyses NEC</b>		
Blood viscosity abnormal	1	0
Plasma viscosity	1	0
Plasma viscosity abnormal	1	0
Red blood cell sedimentation rate increased	6	0
<b>Heart rate and pulse investigations</b>		
Carotid pulse	1	0
Heart rate	426	0
Heart rate abnormal	57	0
Heart rate decreased	72	0
Heart rate increased	846	0
Heart rate irregular	196	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	7	0



## Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
<b><i>Imaging procedures NEC</i></b>		
Computerised tomogram	3	0
Magnetic resonance imaging	4	0
Magnetic resonance imaging abnormal	1	0
Scan	2	0
X-ray	1	0
<b><i>Immune response protein analyses NEC</i></b>		
Cytokine test	1	0
<b><i>Immunoglobulin analyses</i></b>		
Blood immunoglobulin G increased	1	0
Blood immunoglobulin M	1	0
Blood immunoglobulin M increased	1	0
Immunoglobulins	1	0
<b><i>Immunology analyses NEC</i></b>		
Antibody test	4	0
Immunology test	10	0
<b><i>Immunology skin tests NEC</i></b>		
Skin test positive	1	0
<b><i>Investigations NEC</i></b>		
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
<b><i>Liver function analyses</i></b>		
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	6	0
Liver function test	1	0
Liver function test abnormal	28	0
Liver function test increased	24	0
Transaminases increased	5	0
<b><i>Metabolism tests NEC</i></b>		
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
<b><i>Microbiology and serology tests NEC</i></b>		
Culture negative	1	0
Culture throat	1	0
Culture urine	1	0
<b><i>Mineral and electrolyte analyses</i></b>		
Blood copper increased	1	0

## Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<b>Investigations</b>		
Investigations cont'd		
Blood iron	2	0
Blood iron decreased	9	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
<b><i>Musculoskeletal and soft tissue imaging procedures</i></b>		
Skull X-ray	6	0
<b><i>Musculoskeletal and soft tissue tests NEC</i></b>		
Swollen joint count increased	1	0
<b><i>Mycobacteria identification and serology</i></b>		
Tuberculin test positive	1	0
<b><i>Neurologic diagnostic procedures</i></b>		
Coma scale abnormal	5	0
Hoover's sign of leg paresis	1	0
Joint position sense decreased	1	0
Lumbar puncture	7	0
Temperature perception test abnormal	1	0
Temperature perception test increased	1	0
<b><i>Ophthalmic function diagnostic procedures</i></b>		
Corneal reflex decreased	1	0
Intraocular pressure increased	7	0
Intraocular pressure test	2	0
Visual acuity tests	1	0
<b><i>Physical examination procedures and organ system status</i></b>		
Body temperature	239	0
Body temperature abnormal	42	0
Body temperature decreased	38	0
Body temperature fluctuation	47	0
Body temperature increased	400	0
Body temperature normal	1	0
Breath sounds	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	39	0
Menstruation normal	2	0
Muscle strength abnormal	1	0
Ophthalmological examination	2	0
Orthopaedic examination	1	0
Palpatory finding abnormal	2	0
Product residue present	2	0
Psoriasis area severity index decreased	2	0

## Case Series Drug Analysis Print

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Report Run Date: 18-Nov-2021

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
Respiratory rate	10	0
Respiratory rate decreased	20	0
Respiratory rate increased	37	0
Skin temperature	41	0
Temperature difference of extremities	10	0
Weight	1	0
Weight abnormal	1	0
Weight decreased	102	0
Weight increased	35	0
<b><i>Pituitary analyses anterior</i></b>		
Blood corticotrophin	1	0
Blood follicle stimulating hormone increased	1	0
Blood growth hormone	3	0
Blood prolactin	2	0
Blood prolactin increased	2	0
Blood thyroid stimulating hormone decreased	2	0
Blood thyroid stimulating hormone increased	5	0
<b><i>Platelet analyses</i></b>		
Mean platelet volume decreased	1	0
Mean platelet volume increased	1	0
Platelet count	3	0
Platelet count abnormal	1	0
Platelet count decreased	69	0
Platelet count increased	5	0
<b><i>Protein analyses NEC</i></b>		
Alpha 1 globulin decreased	1	0
Alpha 2 globulin decreased	1	0
C-reactive protein increased	20	0
<b><i>Red blood cell analyses</i></b>		
Haematocrit	1	0
Haematocrit decreased	1	0
Haematocrit increased	1	0
Haemoglobin	2	0
Haemoglobin decreased	11	0
Haemoglobin increased	1	0
Red blood cell count decreased	2	0
Red blood cell rouleaux formation present	1	0
<b><i>Renal function analyses</i></b>		
Blood creatinine	1	0
Blood creatinine increased	3	0
Glomerular filtration rate decreased	3	0
<b><i>Reproductive hormone analyses</i></b>		
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
<b><i>Reproductive organ and breast histopathology procedures</i></b>		
Biopsy breast	1	0

## Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
Biopsy endometrium	1	0
Smear cervix	2	0
<b><i>Reproductive organ and breast imaging procedures</i></b>		
Breast scan	1	0
Hysteroscopy	2	0
<b><i>Respiratory and pulmonary function diagnostic procedures</i></b>		
Forced expiratory volume increased	2	0
Fractional exhaled nitric oxide normal	1	0
Maximal voluntary ventilation	1	0
Peak expiratory flow rate	1	0
Peak expiratory flow rate decreased	4	0
Pulmonary function test	3	0
Total lung capacity decreased	3	0
Vital capacity	1	0
<b><i>Respiratory tract and thoracic histopathology procedures</i></b>		
Sputum abnormal	3	0
<b><i>Respiratory tract and thoracic imaging procedures</i></b>		
Chest X-ray	18	0
Chest X-ray abnormal	1	0
Chest X-ray normal	2	0
Chest scan	2	0
Computerised tomogram thorax	1	0
<b><i>Skeletal and cardiac muscle analyses</i></b>		
Blood creatine phosphokinase increased	7	0
Muscle enzyme	1	0
Myocardial necrosis marker	1	0
Myocardial necrosis marker increased	3	0
Troponin I increased	1	0
Troponin T increased	1	0
Troponin increased	14	0
<b><i>Therapeutic drug monitoring analyses</i></b>		
Analgesic drug level	5	0
Anticoagulation drug level above therapeutic	1	0
Anticoagulation drug level below therapeutic	5	0
Anticoagulation drug level increased	1	0
Drug level decreased	1	0
<b><i>Thyroid analyses</i></b>		
Anti-thyroid antibody	1	0
Thyroid function test abnormal	5	0
Thyroxine free increased	2	0
Tri-iodothyronine	1	0
Tri-iodothyronine decreased	6	0
<b><i>Tissue enzyme analyses NEC</i></b>		
Blood alkaline phosphatase increased	5	0
Enzyme level increased	1	0
<b><i>Toxicology laboratory analyses</i></b>		
Blood caffeine decreased	1	0
Blood lead	1	0
Drug screen positive	2	0
Opiates	1	0
<b><i>Urinalysis NEC</i></b>		
Blood urine	15	0
Blood urine present	50	0

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Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
Cells in urine	1	0
Glucose urine present	1	0
Protein urine absent	1	0
Urine analysis abnormal	6	0
Urine uric acid increased	1	0
pH urine	5	0
pH urine increased	2	0
<b>Urinary tract function analyses NEC</b>		
Urine output	13	0
Urine output decreased	13	0
Urine output increased	6	0
<b>Urinary tract histopathology procedures</b>		
Urine cytology	1	0
<b>Urinary tract imaging procedures</b>		
Cystoscopy	2	0
Ultrasound kidney normal	1	0
<b>Vascular imaging procedures NEC</b>		
Venogram	2	0
<b>Vascular tests NEC (incl blood pressure)</b>		
Blood pressure abnormal	7	0
Blood pressure decreased	78	0
Blood pressure diastolic	2	0
Blood pressure diastolic decreased	1	0
Blood pressure diastolic increased	2	0
Blood pressure increased	221	0
Blood pressure measurement	37	0
Blood pressure normal	2	0
Blood pressure systolic	1	0
Blood pressure systolic decreased	3	0
Blood pressure systolic increased	1	0
<b>Virus identification and serology</b>		
Coronavirus test	11	0
Coronavirus test positive	4	0
Epstein-Barr virus 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	11	0
SARS-CoV-2 antibody test negative	15	0
SARS-CoV-2 antibody test positive	5	0
SARS-CoV-2 test	35	0
SARS-CoV-2 test false negative	3	0
SARS-CoV-2 test false positive	4	0
SARS-CoV-2 test negative	8	0
SARS-CoV-2 test positive	98	0
Viral test	4	0
Viral test positive	1	0
<b>Vitamin analyses</b>		
Blood folate decreased	6	0
Vitamin B12	1	0
Vitamin B12 abnormal	2	0
Vitamin B12 decreased	2	0
Vitamin D	2	0

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Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
Vitamin D decreased	3	0
<b><i>Water and electrolyte analyses NEC</i></b>		
Urine osmolarity	1	0
Volume blood	1	0
<b><i>White blood cell analyses</i></b>		
Eosinophil count	1	0
Eosinophil count decreased	1	0
Eosinophil count increased	3	0
Lymphocyte count	2	0
Lymphocyte count decreased	3	0
Lymphocyte count increased	1	0
Monocyte count increased	1	0
Neutrophil count	3	0
Neutrophil count decreased	10	0
Neutrophil count increased	3	0
White blood cell count	3	0
White blood cell count decreased	10	0
White blood cell count increased	11	0
<b>Investigations SOC TOTAL</b>	<b>4809</b>	<b>3</b>

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Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<b><i>Appetite disorders</i></b>		
Appetite disorder	17	0
Decreased appetite	1119	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
<b><i>Calcium metabolism disorders</i></b>		
Hypocalcaemia	3	0
Tetany	3	0
<b><i>Diabetes mellitus (incl subtypes)</i></b>		
Diabetes mellitus	48	0
Diabetes mellitus inadequate control	14	1
Increased insulin requirement	2	0
Insulin resistant diabetes	1	0
Latent autoimmune diabetes in adults	2	0
Type 1 diabetes mellitus	15	0
Type 2 diabetes mellitus	4	0
<b><i>Diabetic complications NEC</i></b>		
Diabetic complication	2	0
Diabetic ketoacidosis	11	0
Diabetic ketosis	1	0
<b><i>Disorders of purine metabolism</i></b>		
Gout	93	0
<b><i>Electrolyte imbalance NEC</i></b>		
Electrolyte imbalance	1	0
Fluid imbalance	2	0
<b><i>Fat soluble vitamin deficiencies and disorders</i></b>		
Vitamin D deficiency	4	0
<b><i>Fluid intake decreased</i></b>		
Fluid intake reduced	1	0
<b><i>Fluid intake increased</i></b>		
Polydipsia	6	0
<b><i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i></b>		
Alcohol intolerance	3	0
Breast milk substitute intolerance	1	0
Dairy intolerance	3	0
Food intolerance	16	0
Gluten sensitivity	7	0
Histamine intolerance	4	0
<b><i>General nutritional disorders NEC</i></b>		
Abnormal loss of weight	20	0
Abnormal weight gain	19	0
Cachexia	1	0
Feeding disorder	77	0
Food aversion	8	0
Malnutrition	1	0
Neonatal insufficient breast milk syndrome	3	0
Obesity	1	0

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Reaction Name	Total	Fatal
<b>Metabolic disorders</b> Metabolic disorders cont'd		
Overweight	1	0
Poor feeding infant	15	0
Weight loss poor	3	0
<b>Hyperglycaemic conditions NEC</b>		
Glucose tolerance impaired	1	0
Hyperglycaemia	66	0
Insulin resistance	4	0
<b>Hypoglycaemic conditions NEC</b>		
Glycopenia	1	0
Hypoglycaemia	76	0
Hypoglycaemia unawareness	1	0
Postprandial hypoglycaemia	1	0
<b>Iron deficiencies</b>		
Iron deficiency	11	0
<b>Iron excess</b>		
Haemochromatosis	1	0
Iron overload	1	0
<b>Lipid metabolism and deposit disorders NEC</b>		
Body fat disorder	1	0
<b>Metabolic acidoses (excl diabetic acidoses)</b>		
Ketoacidosis	5	1
Lactic acidosis	2	0
Metabolic acidosis	2	0
<b>Metabolic disorders NEC</b>		
Hypercatabolism	1	0
Metabolic disorder	1	0
<b>Mixed acid-base disorders</b>		
Acidosis	4	0
<b>Potassium imbalance</b>		
Hyperkalaemia	6	0
Hypokalaemia	3	0
Hypokalaemic syndrome	1	0
<b>Sodium imbalance</b>		
Hyponatraemia	9	0
Hyponatraemic syndrome	3	0
Salt intoxication	1	0
<b>Sugar intolerance (excl glucose intolerance)</b>		
Lactose intolerance	2	0
<b>Total fluid volume decreased</b>		
Dehydration	193	0
<b>Total fluid volume increased</b>		
Fluid retention	50	0
Hypervolaemia	5	0
<b>Vitamin deficiencies NEC</b>		
Hypovitaminosis	6	0
<b>Water soluble vitamin deficiencies</b>		
Folate deficiency	5	0
Vitamin B12 deficiency	5	0
<b>Metabolic disorders SOC TOTAL</b>	<b>2097</b>	<b>2</b>



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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<b><i>Arthropathies NEC</i></b>		
Arthritis	284	0
Arthropathy	26	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
<b><i>Bone disorders NEC</i></b>		
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
<b><i>Bone related signs and symptoms</i></b>		
Bone pain	345	0
Bone swelling	7	0
Coccydynia	3	0
Metatarsalgia	1	0
Pain in jaw	352	0
Pubic pain	2	0
Spinal pain	71	0
<b><i>Bursal disorders</i></b>		
Bursitis	67	0
<b><i>Cartilage disorders</i></b>		
Chondritis	1	0
Costochondritis	87	0
Osteochondritis	1	0
Polychondritis	3	0
<b><i>Connective tissue disorders NEC</i></b>		
Connective tissue disorder	1	0
Polymyalgia rheumatica	55	0
Reynold's syndrome	1	0
Sjogren's syndrome	5	0
Systemic scleroderma	1	0
<b><i>Crystal arthropathic disorders</i></b>		
Chondrocalcinosis pyrophosphate	3	0
Crystal arthropathy	1	0
<b><i>Epiphyseal disorders</i></b>		
Epiphyses premature fusion	1	0
<b><i>Extremity deformities</i></b>		
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
<b>Muscle &amp; tissue disorders</b>		
Muscle & tissue disorders cont'd		
Musculoskeletal deformity	1	0
<b>Fractures NEC</b>		
Osteoporotic fracture	1	0
<b>Intervertebral disc disorders NEC</b>		
Intervertebral disc protrusion	3	0
<b>Joint related disorders NEC</b>		
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	24	0
Patellofemoral pain syndrome	1	0
Periarthritis	169	0
Rotator cuff syndrome	29	0
Temporomandibular joint syndrome	8	0
<b>Joint related signs and symptoms</b>		
Arthralgia	8378	0
Jaw clicking	6	0
Joint effusion	16	0
Joint noise	34	0
Joint range of motion decreased	30	0
Joint stiffness	223	0
Joint swelling	500	0
Joint vibration	3	0
Joint warmth	14	0
Loose body in joint	1	0
<b>Ligament disorders</b>		
Ligament pain	2	0
Symphysiolysis	1	0
<b>Lupus erythematosus (incl subtypes)</b>		
Lupus-like syndrome	1	0
Systemic lupus erythematosus	21	0
<b>Metabolic bone disorders</b>		
Osteopenia	3	0
Osteoporosis	4	0
<b>Muscle infections and inflammations</b>		
Antisynthetase syndrome	3	0
Immune-mediated myositis	1	0
Myositis	36	0
Polymyositis	8	0
<b>Muscle pains</b>		
Fibromyalgia	105	0
Myalgia	9998	0
Myalgia intercostal	2	0
Myofascial pain syndrome	11	0
<b>Muscle related signs and symptoms NEC</b>		
Haematoma muscle	1	0
Muscle atrophy	22	0
Muscle discomfort	7	0
Muscle disorder	7	0

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i>Muscle &amp; tissue disorders cont'd</i>		
Muscle fatigue	329	0
Muscle haemorrhage	1	0
Muscle mass	5	0
Muscle oedema	3	0
Muscle spasms	1957	0
Muscle swelling	32	0
Muscle tightness	82	0
Muscle twitching	451	0
<b>Muscle tone abnormalities</b>		
Muscle rigidity	15	0
Nuchal rigidity	11	0
Torticollis	7	0
Trismus	31	0
<b>Muscle weakness conditions</b>		
Muscular weakness	872	0
<b>Musculoskeletal and connective tissue conditions NEC</b>		
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	108	0
Muscle contracture	1	0
Musculoskeletal disorder	11	0
Musculoskeletal stiffness	1178	0
Posture abnormal	2	0
Sacroiliac joint dysfunction	1	0
Weight bearing difficulty	3	0
<b>Musculoskeletal and connective tissue deformities of skull, face and buccal cavity</b>		
Head deformity	2	0
<b>Musculoskeletal and connective tissue infections and inflammations NEC</b>		
Dactylitis	2	0
Dupuytren's contracture	1	0
Fasciitis	1	0
Plantar fasciitis	10	0
<b>Musculoskeletal and connective tissue pain and discomfort</b>		
Back pain	2242	0
Flank pain	68	0
Limb discomfort	1413	0
Musculoskeletal chest pain	222	0
Musculoskeletal discomfort	92	0
Musculoskeletal pain	113	0
Neck pain	1777	0
Pain in extremity	11872	2
Rheumatic disorder	15	0
Sacral pain	3	0
<b>Myopathies</b>		
Mitochondrial myopathy acquired	1	0
Myopathy	6	0
Rhabdomyolysis	12	0
<b>Osteoarthropathies</b>		

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i>Muscle &amp; tissue disorders cont'd</i>		
Nodal osteoarthritis	1	0
Osteoarthritis	44	0
Spinal osteoarthritis	1	0
<b><i>Psoriatic arthropathies</i></b>		
Psoriatic arthropathy	17	0
<b><i>Rheumatoid arthropathies</i></b>		
Juvenile idiopathic arthritis	1	0
Rheumatoid arthritis	112	0
Still's disease	2	0
<b><i>Soft tissue disorders NEC</i></b>		
Axillary mass	239	0
Fluctuance	1	0
Groin pain	102	0
Neck mass	34	0
Purple glove syndrome	1	0
Soft tissue disorder	3	0
Soft tissue swelling	6	0
<b><i>Spine and neck deformities</i></b>		
Kyphosis	2	0
Lordosis	1	0
Neck deformity	1	0
Scoliosis	1	0
Spinal stenosis	2	0
<b><i>Spondyloarthropathies</i></b>		
Ankylosing spondylitis	7	0
Arthritis reactive	43	0
Spondylitis	3	0
Spondyloarthropathy	1	0
<b><i>Synovial disorders</i></b>		
Synovial cyst	18	0
Synovitis	10	0
<b><i>Tendon disorders</i></b>		
Enthesopathy	2	0
Posterior tibial tendon dysfunction	1	0
Tendon disorder	5	0
Tendon pain	20	0
Tendonitis	41	0
Tenosynovitis	3	0
Tenosynovitis stenans	2	0
Trigger finger	28	0
<b><i>Trunk deformities</i></b>		
Drooping shoulder syndrome	2	0
Shoulder deformity	2	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>44817</b>	<b>2</b>

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Reaction Name	Total	Fatal
<b>Neoplasms</b>		
<b><i>Angioimmunoblastic T-cell lymphomas</i></b>		
Angioimmunoblastic T-cell lymphoma	1	0
<b><i>B-cell lymphomas NEC</i></b>		
B-cell lymphoma	2	1
Follicular lymphoma	4	0
<b><i>Bone neoplasms malignant (excl sarcomas)</i></b>		
Bone cancer	1	1
<b><i>Bone neoplasms unspecified malignancy</i></b>		
Bone neoplasm	1	0
<b><i>Breast and nipple neoplasms benign</i></b>		
Benign breast neoplasm	1	0
Fibroadenoma of breast	1	0
<b><i>Breast and nipple neoplasms malignant</i></b>		
Breast cancer	37	0
Breast cancer female	1	0
Breast cancer male	1	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
<b><i>Cardiovascular neoplasms benign</i></b>		
Haemangioma	1	0
Pericardial lipoma	1	0
<b><i>Cervix neoplasms malignant</i></b>		
Cervix carcinoma	1	0
<b><i>Colorectal neoplasms malignant</i></b>		
Colon cancer	2	0
Colorectal cancer	1	0
Rectal cancer	2	0
<b><i>Endocrine neoplasms malignant and unspecified NEC</i></b>		
Neuroendocrine tumour	1	0
Thyroid neoplasm	1	0
<b><i>Endometrial neoplasms malignant</i></b>		
Endometrial cancer	1	0
<b><i>Follicular lymphomas</i></b>		
Primary gastrointestinal follicular lymphoma	1	0
<b><i>Gastric neoplasms malignant</i></b>		
Gastric cancer	1	1
<b><i>Gastrointestinal neoplasms malignant NEC</i></b>		
Gastrointestinal carcinoma	3	0
<b><i>Hepatic neoplasms malignant</i></b>		
Hepatocellular carcinoma	1	0
<b><i>Hepatobiliary neoplasms malignancy unspecified</i></b>		
Hepatic neoplasm	1	0
<b><i>Hodgkin's disease NEC</i></b>		
Hodgkin's disease	5	0
<b><i>Islet cell neoplasms and APUDoma NEC</i></b>		
Pancreatic neuroendocrine tumour	1	0
<b><i>Leukaemias NEC</i></b>		
Leukaemia	4	1
<b><i>Leukaemias acute NEC</i></b>		
Acute leukaemia	2	0
<b><i>Leukaemias chronic NEC</i></b>		

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Reaction Name	Total	Fatal
<b>Neoplasms</b> Neoplasms cont'd		
Chronic leukaemia	1	0
<b>Leukaemias chronic lymphocytic</b>		
Chronic lymphocytic leukaemia	3	0
<b>Leukaemias chronic myeloid</b>		
Chronic myeloid leukaemia	1	0
<b>Lip and oral cavity neoplasms malignant</b>		
Lip and/or oral cavity cancer recurrent	1	0
<b>Lymphomas unspecified NEC</b>		
Lymphoma	33	1
<b>Metastases to specified sites</b>		
Metastases to bone	1	0
Metastases to liver	1	0
Metastases to lymph nodes	5	0
<b>Metastases to unknown and unspecified sites</b>		
Metastasis	1	0
<b>Mycoses fungoides</b>		
Cutaneous T-cell lymphoma	1	0
<b>Myelodysplastic syndromes</b>		
Myelodysplastic syndrome	3	0
<b>Myeloproliferative disorders (excl leukaemias)</b>		
Essential thrombocythaemia	1	0
<b>Neoplasms malignant site unspecified NEC</b>		
Adenocarcinoma metastatic	1	0
Metastatic neoplasm	2	0
Neoplasm malignant	8	0
Second primary malignancy	1	0
Squamous cell carcinoma	5	0
<b>Neoplasms unspecified malignancy and site unspecified NEC</b>		
Neoplasm	1	0
Neoplasm recurrence	1	0
<b>Nervous system neoplasms benign NEC</b>		
Cranial nerve neoplasm benign	1	0
Neurilemmoma benign	1	0
<b>Nervous system neoplasms unspecified malignancy NEC</b>		
Brain neoplasm	2	0
Spinal cord neoplasm	1	0
<b>Neuromas</b>		
Acoustic neuroma	2	0
<b>Non-Hodgkin's lymphomas NEC</b>		
Non-Hodgkin's lymphoma	2	0
<b>Ocular neoplasms benign</b>		
Eye naevus	1	0
<b>Oesophageal neoplasms malignant</b>		
Oesophageal cancer metastatic	4	0
<b>Oncologic complications and emergencies</b>		
Cancer pain	1	0
Tumour haemorrhage	1	0
<b>Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified</b>		
Tonsil cancer	3	0
<b>Ovarian neoplasms malignant (excl germ cell)</b>		
Ovarian cancer	1	0
<b>Pancreatic neoplasms malignant (excl islet cell and carcinoid)</b>		

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Reaction Name	Total	Fatal
<b>Neoplasms</b> <span style="float: right;">Neoplasms cont'd</span>		
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
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
<b>Neoplasms SOC TOTAL</b>	<b>283</b>	<b>6</b>

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<b><i>Abnormal reflexes</i></b>		
Areflexia	7	0
Extensor plantar response	2	0
Hoffmann's sign	1	0
Hyperreflexia	4	0
Hyporeflexia	7	0
Reflexes abnormal	2	0
<b><i>Abnormal sleep-related events</i></b>		
Sleep paralysis	25	0
<b><i>Absence seizures</i></b>		
Petit mal epilepsy	26	0
<b><i>Acute polyneuropathies</i></b>		
Acute motor axonal neuropathy	1	0
Acute motor-sensory axonal neuropathy	1	0
Guillain-Barre syndrome	66	1
Miller Fisher syndrome	1	0
Subacute inflammatory demyelinating polyneuropathy	1	0
<b><i>Autonomic nervous system disorders</i></b>		
Anticholinergic syndrome	1	0
Autonomic nervous system imbalance	9	0
Autonomic neuropathy	2	0
Horner's syndrome	1	0
Orthostatic intolerance	2	0
<b><i>Central nervous system aneurysms and dissections</i></b>		
Carotid artery dissection	1	0
Intracranial aneurysm	2	1
<b><i>Central nervous system haemorrhages and cerebrovascular accidents</i></b>		
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	47	9
Cerebral infarction	27	2
Cerebral thrombosis	13	0
Cerebrovascular accident	392	16
Embolic stroke	6	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	51	2
Lacunar infarction	2	0
Lacunar stroke	4	0



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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Lateral medullary syndrome	1	0
Pseudostroke	1	0
Subarachnoid haemorrhage	14	6
Thalamic infarction	1	0
Thrombotic stroke	3	1
<b>Central nervous system inflammatory disorders NEC</b>		
Arachnoiditis	1	0
Gliosis	1	0
<b>Central nervous system vascular disorders NEC</b>		
Brain hypoxia	2	1
Carotid arteriosclerosis	1	0
Central nervous system vasculitis	1	0
Cerebral amyloid angiopathy	1	0
Cerebral congestion	4	0
Cerebral small vessel ischaemic disease	1	0
Cerebrovascular disorder	2	0
Post cardiac arrest syndrome	1	0
Reversible cerebral vasoconstriction syndrome	1	0
<b>Cerebrovascular venous and sinus thrombosis</b>		
Cerebral venous sinus thrombosis	49	5
Cerebral venous thrombosis	6	0
Superior sagittal sinus thrombosis	6	0
Transverse sinus thrombosis	1	0
<b>Cervical spinal cord and nerve root disorders</b>		
Cervical radiculopathy	1	0
Cervicobrachial syndrome	3	0
<b>Choreiform movements</b>		
Chorea	2	0
<b>Chronic polyneuropathies</b>		
Chronic inflammatory demyelinating polyradiculoneuropathy	2	0
Demyelinating polyneuropathy	1	0
Diabetic neuropathy	1	0
<b>Coma states</b>		
Coma	14	0
Diabetic coma	1	0
Hypoglycaemic coma	1	0
<b>Coordination and balance disturbances</b>		
Ataxia	14	0
Balance disorder	390	0
Cerebellar ataxia	1	0
Coordination abnormal	56	0
Dysdiadochokinesis	1	0
Dysstasia	57	0
Nystagmus	11	0
<b>Cortical dysfunction NEC</b>		
Alexia	2	0
Aphasia	79	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
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Visuospatial deficit	1	0
<b>Cranial nerve disorders NEC</b>		
Cranial nerve disorder	2	0
Cranial nerve paralysis	1	0
<b>Dementia (excl Alzheimer's type)</b>		
Dementia	18	0
Dementia with Lewy bodies	1	0
Senile dementia	1	0
<b>Demyelinating disorders NEC</b>		
Acute disseminated encephalomyelitis	6	0
Clinically isolated syndrome	1	0
Demyelination	8	0
Neuromyelitis optica spectrum disorder	2	0
<b>Disturbances in consciousness NEC</b>		
Altered state of consciousness	11	0
Consciousness fluctuating	2	0
Depressed level of consciousness	45	0
Infant sedation	1	0
Lethargy	2130	0
Loss of consciousness	633	0
Postictal state	5	0
Sedation	8	0
Somnolence	977	0
Stupor	4	0
Syncope	2113	0
<b>Disturbances in sleep phase rhythm</b>		
Circadian rhythm sleep disorder	1	0
Irregular sleep phase	2	0
Irregular sleep wake rhythm disorder	1	0
<b>Dyskinesias and movement disorders NEC</b>		
Akathisia	5	0
Bradykinesia	18	0
Clumsiness	21	0
Dyskinesia	61	0
Extrapyramidal disorder	2	0
Fine motor skill dysfunction	12	0
Foetal movement disorder	4	0
Hyperkinesia	3	0
Hypokinesia	73	0
Motor dysfunction	4	0
Movement disorder	51	0
Psychomotor hyperactivity	23	0
Synkinesis	2	0
Tardive dyskinesia	2	0
<b>Dystonias</b>		
Dystonia	15	0
Writer's cramp	1	0
<b>Encephalitis NEC</b>		
Encephalitis autoimmune	1	0
Limbic encephalitis	1	0
Noninfective encephalitis	5	0
<b>Encephalopathies NEC</b>		
Autoimmune encephalopathy	1	1

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b> <small>Nervous system disorders cont'd</small>		
Encephalopathy	5	0
Hashimoto's encephalopathy	1	0
Posterior reversible encephalopathy syndrome	1	0
<b>Eye movement disorders</b>		
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
<b>Facial cranial nerve disorders</b>		
Bell's palsy	489	0
Facial nerve disorder	8	0
Facial paralysis	371	0
Facial paresis	90	0
Facial spasm	47	0
<b>Generalised tonic-clonic seizures</b>		
Generalised tonic-clonic seizure	55	0
<b>Headaches NEC</b>		
Cervicogenic headache	3	0
Cluster headache	225	0
Cold-stimulus headache	25	0
Drug withdrawal headache	2	0
Exertional headache	8	0
External compression headache	2	0
Headache	24941	0
Medication overuse headache	2	0
New daily persistent headache	6	0
Occipital neuralgia	12	0
Ophthalmoplegic migraine	1	0
Primary cough headache	4	0
Primary headache associated with sexual activity	8	0
Sinus headache	335	0
Tension headache	539	0
Thunderclap headache	11	0
Vascular headache	15	0
<b>Hydrocephalic conditions</b>		
Hydrocephalus	2	0
<b>Hypoglossal nerve disorders</b>		
Tongue paralysis	1	0
<b>Increased intracranial pressure disorders</b>		
Brain compression	1	0
Brain oedema	8	2
Idiopathic intracranial hypertension	7	0
Intracranial pressure increased	2	0
<b>Intellectual disabilities</b>		
Intellectual disability	3	0
<b>Lumbar spinal cord and nerve root disorders</b>		
Sciatica	90	0
<b>Memory loss (excl dementia)</b>		
Amnesia	179	0
Memory impairment	192	0
Transient global amnesia	9	0

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
<b><i>Mental impairment (excl dementia and memory loss)</i></b>		
Cognitive disorder	85	0
Cognitive linguistic deficit	1	0
Disturbance in attention	310	0
Mental impairment	46	0
<b><i>Migraine headaches</i></b>		
Basilar migraine	1	0
Hemiplegic migraine	29	0
Migraine	2875	0
Migraine with aura	185	0
Migraine without aura	17	0
Ophthalmic migraine	5	0
Retinal migraine	32	0
Typical aura without headache	7	0
Vestibular migraine	18	0
<b><i>Mixed cranial nerve disorders</i></b>		
Bulbar palsy	2	0
<b><i>Mononeuropathies</i></b>		
Carpal tunnel syndrome	23	0
Cubital tunnel syndrome	3	0
Meralgia paraesthetica	1	0
Mononeuritis	2	0
Mononeuropathy	4	0
Nerve compression	24	0
Peripheral nerve lesion	1	0
Peroneal nerve palsy	15	0
Sciatic nerve neuropathy	2	0
Ulnar nerve palsy	2	0
Ulnar neuritis	2	0
Ulnar tunnel syndrome	2	0
<b><i>Motor neurone diseases</i></b>		
Lower motor neurone lesion	1	0
Motor neurone disease	1	0
<b><i>Multiple sclerosis acute and progressive</i></b>		
Band sensation	1	0
Multiple sclerosis	32	0
Multiple sclerosis relapse	23	0
Tumefactive multiple sclerosis	1	1
<b><i>Muscle tone abnormal</i></b>		
Drop attacks	2	0
Hypertonia	2	0
Hypotonia	30	0
Morvan syndrome	1	0
Muscle tone disorder	1	0
Serotonin syndrome	1	0
Stiff leg syndrome	1	0
<b><i>Myelitis (incl infective)</i></b>		
Myelitis transverse	27	0
<b><i>Narcolepsy and hypersomnia</i></b>		
Cataplexy	3	0
Hypersomnia	107	0
Narcolepsy	7	0
<b><i>Nervous system disorders NEC</i></b>		

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b> <small>Nervous system disorders cont'd</small>		
Central nervous system lesion	2	0
Cerebral disorder	1	0
Nervous system disorder	14	0
Neurotoxicity	4	0
Psychomotor skills impaired	1	0
<b>Neurologic visual problems NEC</b>		
Hemianopia	1	0
Hemianopia homonymous	2	0
Quadrantanopia	1	0
Tunnel vision	18	0
<b>Neurological signs and symptoms NEC</b>		
Agitation neonatal	1	0
Clonus	5	0
Decerebrate posture	1	0
Decorticate posture	1	0
Dizziness	9432	0
Dizziness exertional	41	0
Dizziness postural	711	0
Drooling	22	0
Fontanelle bulging	2	0
Head discomfort	321	0
Hyporesponsive to stimuli	2	0
Inability to crawl	2	0
Infant irritability	10	0
Meningism	1	0
Myoclonus	29	0
Neurological symptom	48	0
Patient elopement	1	0
Persistent postural-perceptual dizziness	15	0
Presyncope	609	0
Sensory overload	4	0
Slow response to stimuli	4	0
Tongue biting	7	0
Unresponsive to stimuli	47	0
<b>Neuromuscular disorders NEC</b>		
Muscle contractions involuntary	24	0
Muscle spasticity	10	0
Neuromuscular pain	3	0
<b>Neuromuscular junction dysfunction</b>		
Myasthenia gravis	7	0
Myasthenia gravis crisis	2	0
<b>Olfactory nerve disorders</b>		
Anosmia	262	0
Hyposmia	16	0
Parosmia	242	0
<b>Optic nerve disorders NEC</b>		
Optic neuritis	28	0
<b>Paraesthesias and dysaesthesias</b>		
Burning feet syndrome	7	0
Burning sensation	520	0
Burning sensation mucosal	2	0
Dysaesthesia	7	0
Formication	40	0

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Hand-arm vibration syndrome	3	0
Hemianaesthesia	2	0
Hemiparaesthesia	5	0
Hyperaesthesia	93	0
Hypoaesthesia	2821	0
Paraesthesia	3871	0
Reversed hot-cold sensation	4	0
Synaesthesia	1	0
<b><i>Paralysis and paresis (excl cranial nerve)</i></b>		
Diplegia	12	0
Hemiparesis	48	0
Hemiplegia	38	0
Locked-in syndrome	1	0
Monoparesis	61	0
Monoplegia	79	0
Paralysis	126	0
Paraparesis	3	0
Paraplegia	2	0
Paresis	6	0
Quadriparesis	1	0
Quadriplegia	1	0
<b><i>Parkinson's disease and parkinsonism</i></b>		
Freezing phenomenon	9	0
Hypokinetic dysarthria	1	0
Parkinson's disease	3	0
Parkinsonian gait	1	0
Parkinsonian rest tremor	1	0
Parkinsonism	4	0
Reduced facial expression	11	0
<b><i>Partial complex seizures</i></b>		
Dreamy state	6	0
Focal dyscognitive seizures	3	0
Temporal lobe epilepsy	2	0
<b><i>Partial simple seizures NEC</i></b>		
Autonomic seizure	1	0
<b><i>Peripheral neuropathies NEC</i></b>		
Axonal neuropathy	2	0
Neuralgic amyotrophy	5	0
Neuritis	7	0
Neuropathy peripheral	113	0
Peripheral sensorimotor neuropathy	1	0
Peripheral sensory neuropathy	12	0
Polyneuropathy	3	0
Thoracic outlet syndrome	1	0
<b><i>Seizures and seizure disorders NEC</i></b>		
Atonic seizures	5	0
Change in seizure presentation	2	0
Clonic convulsion	3	0
Convulsions local	1	0
Epilepsy	153	0
Epileptic aura	2	0
Epileptic encephalopathy	1	0
Febrile convulsion	15	0

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Idiopathic generalised epilepsy	1	0
Partial seizures	19	0
Post stroke seizure	1	0
Psychogenic seizure	9	0
Seizure	600	1
Seizure anoxic	2	0
Seizure cluster	6	0
Seizure like phenomena	2	0
Status epilepticus	44	0
Tonic clonic movements	4	0
Tonic convulsion	27	0
Tonic posturing	1	0
<b>Sensory abnormalities NEC</b>		
Ageusia	506	0
Allodynia	24	0
Aura	23	0
Complex regional pain syndrome	5	0
Dysgeusia	1121	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	518	0
Persistent genital arousal disorder	1	0
Phantom limb syndrome	4	0
Post herpetic neuralgia	14	0
Restless arm syndrome	2	0
Restless legs syndrome	136	0
Sensory disturbance	104	0
Sensory loss	76	0
Taste disorder	252	0
Visual perseveration	3	0
<b>Sleep disturbances NEC</b>		
Sleep deficit	9	0
Sudden onset of sleep	1	0
<b>Speech and language abnormalities</b>		
Dysarthria	191	0
Incoherent	12	0
Language disorder	2	0
Repetitive speech	3	0
Slow speech	18	0
Speech disorder	70	0
Speech disorder developmental	1	0
<b>Spinal cord and nerve root disorders NEC</b>		
Cauda equina syndrome	1	0
Myelopathy	1	0
Radiculitis brachial	14	0
Radiculopathy	5	0
<b>Structural brain disorders NEC</b>		
Brain injury	7	2
Cerebral ventricle dilatation	1	0

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
Nervous system disorders cont'd		
Hyperintensity in brain deep nuclei	1	0
<b>Transient cerebrovascular events</b>		
Transient ischaemic attack	148	3
<b>Tremor (excl congenital)</b>		
Essential tremor	5	0
Head titubation	13	0
Resting tremor	4	0
Tremor	1681	0
<b>Trigeminal disorders</b>		
Numb chin syndrome	2	0
Trigeminal nerve disorder	3	0
Trigeminal neuralgia	60	0
Trigeminal neuritis	2	0
<b>Vagus nerve disorders</b>		
Vocal cord paralysis	2	0
<b>Vertigos NEC</b>		
Cervicogenic vertigo	1	0
Vertigo CNS origin	3	0
<b>Nervous system disorders SOC TOTAL</b>	<b>65331</b>	<b>64</b>



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Reaction Name	Total	Fatal
<b>Pregnancy conditions</b>		
<b><i>Abortion related conditions and complications</i></b>		
Anembryonic gestation	2	0
<b><i>Abortions not specified as induced or spontaneous</i></b>		
Abortion	1	0
Abortion missed	5	0
<b><i>Abortions spontaneous</i></b>		
Abortion spontaneous	378	0
Abortion threatened	2	0
<b><i>Amniotic fluid and cavity disorders of pregnancy NEC</i></b>		
Amniorrhoea	1	0
<b><i>Foetal complications NEC</i></b>		
Foetal cardiac disorder	1	0
Foetal distress syndrome	1	0
Foetal hypokinesia	12	0
<b><i>Foetal growth complications</i></b>		
Foetal growth restriction	6	0
<b><i>Gestational age and weight conditions</i></b>		
Premature baby	4	1
<b><i>Haemorrhagic complications of pregnancy</i></b>		
Haemorrhage in pregnancy	2	0
Premature separation of placenta	3	0
Subchorionic haematoma	2	0
Subchorionic haemorrhage	1	0
<b><i>Hypertension associated disorders of pregnancy</i></b>		
Pre-eclampsia	1	0
<b><i>Labour onset and length abnormalities</i></b>		
Induced labour	1	0
Premature delivery	1	0
Premature labour	7	0
Premature rupture of membranes	3	0
Threatened labour	1	0
<b><i>Maternal complications of delivery NEC</i></b>		
Retained placenta or membranes	2	0
<b><i>Maternal complications of labour NEC</i></b>		
Uterine contractions abnormal	1	0
Uterine hypertonus	8	0
<b><i>Maternal complications of pregnancy NEC</i></b>		
Biochemical pregnancy	1	0
Complication of pregnancy	1	0
Decidual cast	4	0
Ectopic pregnancy	9	0
Hyperemesis gravidarum	1	0
Morning sickness	16	0
Preterm premature rupture of membranes	3	0
Ruptured ectopic pregnancy	1	0
Somatic symptom disorder of pregnancy	3	0
<b><i>Normal newborn status</i></b>		
Normal newborn	1	0
<b><i>Normal pregnancy, labour and delivery</i></b>		
Labour pain	1	0
Live birth	5	0
Pregnancy	32	0
Uterine contractions during pregnancy	5	0

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Reaction Name	Total	Fatal
<b>Pregnancy conditions</b> <small>Pregnancy conditions cont'd</small>		
<b><i>Placental abnormalities (excl neoplasms)</i></b>		
Foetal vascular malperfusion	1	0
Placental disorder	1	0
Placental insufficiency	1	0
<b><i>Postpartum complications NEC</i></b>		
Postpartum haemorrhage	3	0
<b><i>Pregnancy complicated by maternal disorders</i></b>		
Gestational diabetes	2	0
Peripartum cardiomyopathy	1	0
<b><i>Stillbirth and foetal death</i></b>		
Foetal death	4	2
Stillbirth	7	5
<b><i>Unintended pregnancies</i></b>		
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
<b>Pregnancy conditions SOC TOTAL</b>	<b>560</b>	<b>8</b>

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Reaction Name	Total	Fatal
<b><i>Device issues NEC</i></b>		
Device connection issue	1	0
Device failure	1	0
Device issue	2	0
<b><i>Device malfunction events NEC</i></b>		
Device infusion issue	1	0
Device malfunction	1	0
Device pacing issue	1	0
Device stimulation issue	1	0
Oversensing	15	0
Thrombosis in device	11	0
<b><i>Device physical property and chemical issues</i></b>		
Device breakage	1	0
Device defective	9	0
Device kink	1	0
Needle issue	2	0
<b><i>Product contamination and sterility issues</i></b>		
Product contamination	11	0
Product contamination physical	6	0
<b><i>Product packaging issues</i></b>		
Packaging design issue	1	0
Product closure issue	1	0
<b><i>Product physical issues</i></b>		
Liquid product physical issue	9	0
Product after taste	2	0
Product deposit	1	0
Product odour abnormal	2	0
Product physical issue	2	0
Product taste abnormal	9	0
<b><i>Product quality issues NEC</i></b>		
Product complaint	1	0
Product origin unknown	6	0
<b><i>Product supply and availability issues</i></b>		
Product availability issue	1	0
<b>null SOC TOTAL</b>	<b>99</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<b><i>Abnormal behaviour NEC</i></b>		
Abnormal behaviour	27	0
Behaviour disorder	1	0
Breath holding	6	0
Staring	7	0
<b><i>Adjustment disorders</i></b>		
Adjustment disorder	1	0
Adjustment disorder with depressed mood	4	0
<b><i>Affect alterations NEC</i></b>		
Affect lability	14	0
Constricted affect	3	0
Flat affect	11	0
Inappropriate affect	22	0
<b><i>Amnesic symptoms</i></b>		
Paramnesia	7	0
<b><i>Anxiety disorders NEC</i></b>		
Anxiety disorder	1	0
Generalised anxiety disorder	1	0
Neurosis	1	0
<b><i>Anxiety symptoms</i></b>		
Agitation	78	0
Anxiety	839	0
Immunisation anxiety related reaction	2	0
Nervousness	173	0
Stress	99	0
Tension	38	0
<b><i>Attention deficit and disruptive behaviour disorders</i></b>		
Attention deficit hyperactivity disorder	7	0
<b><i>Behaviour and socialisation disturbances</i></b>		
Aggression	14	0
Attention-seeking behaviour	1	0
Aversion	1	0
Disinhibition	2	0
Indifference	6	0
Paranoia	24	0
Personality change	4	0
Social avoidant behaviour	5	0
Soliloquy	2	0
Suspiciousness	1	0
<b><i>Bipolar disorders</i></b>		
Bipolar I disorder	2	0
Bipolar disorder	4	0
<b><i>Cognitive and attention disorders and disturbances NEC</i></b>		
Daydreaming	8	0
Distractibility	1	0
Mental fatigue	203	0
<b><i>Communications disorders</i></b>		
Communication disorder	5	0
Mutism	3	0
<b><i>Confusion and disorientation</i></b>		
Confusional state	873	0
Disorientation	278	0
<b><i>Decreased physical activity levels</i></b>		

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Catatonia	1	0
<b>Deliria</b>		
Delirium	116	0
<b>Delusional symptoms</b>		
Delusion	13	0
<b>Depressive disorders</b>		
Agitated depression	5	0
Depression	331	0
Depression suicidal	15	0
Major depression	11	0
Mixed anxiety and depressive disorder	3	0
<b>Dissociative states</b>		
Depersonalisation/derealisation disorder	11	0
Dissociation	30	0
Dissociative amnesia	2	0
Dissociative disorder	2	0
<b>Disturbances in initiating and maintaining sleep</b>		
Initial insomnia	23	0
Insomnia	1434	0
Middle insomnia	32	0
Terminal insomnia	32	0
<b>Dyssomnias</b>		
Breathing-related sleep disorder	1	0
Dyssomnia	1	0
Poor quality sleep	213	0
<b>Eating disorders NEC</b>		
Bulimia nervosa	1	0
Eating disorder	10	0
Selective eating disorder	1	0
<b>Emotional and mood disturbances NEC</b>		
Anger	37	0
Dysphoria	2	0
Emotional disorder	56	0
Emotional distress	43	0
Emotional poverty	1	0
Euphoric mood	43	0
Frustration tolerance decreased	2	0
Irritability	199	0
Mood altered	55	0
<b>Factitious disorders</b>		
Factitious disorder	4	0
<b>Fear symptoms and phobic disorders (incl social phobia)</b>		
Agoraphobia	2	0
Fear	19	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	1	0
Social fear	1	0

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
<i><b>Fluctuating mood symptoms</b></i>		
Mood swings	139	0
<i><b>Hallucinations (excl sleep-related)</b></i>		
Hallucination	201	0
Hallucination, auditory	16	0
Hallucination, olfactory	11	0
Hallucination, tactile	1	0
Hallucination, visual	25	0
Hallucinations, mixed	2	0
<i><b>Increased physical activity levels</b></i>		
Restlessness	149	0
<i><b>Infancy, childhood and adolescence psychiatric disorders NEC</b></i>		
Social (pragmatic) communication disorder	1	0
<i><b>Learning disorders</b></i>		
Learning disability	1	0
Learning disorder	1	0
<i><b>Mental disorders NEC</b></i>		
Mental disorder	15	0
Mental status changes	1	0
Psychological factor affecting medical condition	1	0
<i><b>Mood alterations with depressive symptoms</b></i>		
Anhedonia	3	0
Decreased interest	9	0
Depressed mood	387	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	41	0
<i><b>Mood alterations with manic symptoms</b></i>		
Hypomania	2	0
Mania	11	0
<i><b>Mood disorders NEC</b></i>		
Affective disorder	3	0
Apathy	30	0
Boredom	1	0
Laziness	3	0
Listless	20	0
Mood disorder due to a general medical condition	1	0
<i><b>Narcolepsy and associated conditions</b></i>		
Hypnagogic hallucination	4	0
Hypnopompic hallucination	2	0
Sleep attacks	3	0
<i><b>Obsessive-compulsive disorders and symptoms</b></i>		
Obsessive-compulsive symptom	1	0
<i><b>Orgasmic disorders and disturbances</b></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
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Premature ejaculation	1	0
<b><i>Panic attacks and disorders</i></b>		
Panic attack	192	0
Panic disorder	4	0
Panic reaction	28	0
<b><i>Paraphilias and paraphilic disorders</i></b>		
Transvestism	1	0
<b><i>Parasomnias</i></b>		
Abnormal dreams	179	0
Abnormal sleep-related event	1	0
Confusional arousal	1	0
Exploding head syndrome	2	0
Nightmare	192	0
Parasomnia	4	0
Sleep inertia	1	0
Sleep talking	6	0
Sleep terror	21	0
Somnambulism	6	0
<b><i>Perception disturbances NEC</i></b>		
Autoscopy	17	0
Deja vu	2	0
Derealisation	9	0
Flashback	3	0
Illusion	2	0
Near death experience	1	0
Time perception altered	2	0
<b><i>Personality disorders NEC</i></b>		
Personality disorder	1	0
<b><i>Pervasive developmental disorders NEC</i></b>		
Autism spectrum disorder	2	0
<b><i>Psychiatric elimination disorders</i></b>		
Enuresis	23	0
<b><i>Psychiatric symptoms NEC</i></b>		
Helplessness	1	0
Hypervigilance	9	0
Psychiatric symptom	5	0
Psychological trauma	3	0
Trance	1	0
<b><i>Psychotic disorder NEC</i></b>		
Acute psychosis	1	0
Psychotic behaviour	1	0
Psychotic disorder	24	0
<b><i>Schizophrenia NEC</i></b>		
Schizophrenia	1	0
<b><i>Sexual and gender identity disorders NEC</i></b>		
Gender dysphoria	1	0
<b><i>Sexual arousal disorders</i></b>		
Disturbance in sexual arousal	3	0
Sexual inhibition	1	0
<b><i>Sexual desire disorders</i></b>		
Hypersexuality	1	0
Libido decreased	15	0
Libido increased	6	0

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Loss of libido	17	0
<b>Sexual dysfunction NEC</b>		
Genito-pelvic pain/penetration disorder	1	0
<b>Sleep disorders NEC</b>		
Sleep disorder	207	0
Sleep disorder due to general medical condition, insomnia type	5	0
<b>Somatic symptom disorders</b>		
Conversion disorder	21	0
Habit cough	17	0
Somatic symptom disorder	2	0
Vomiting psychogenic	1	0
<b>Speech and language usage disturbances</b>		
Disorganised speech	7	0
Logorrhoea	2	0
<b>Speech articulation and rhythm disturbances</b>		
Dysphemia	24	0
Lack of spontaneous speech	1	0
Pressure of speech	1	0
<b>Stereotypies and automatisms</b>		
Automatism	1	0
Bruxism	13	0
Head banging	10	0
Stereotypy	1	0
<b>Stress disorders</b>		
Burnout syndrome	2	0
Post-traumatic stress disorder	4	0
<b>Substance related and addictive disorders</b>		
Alcohol problem	1	0
Alcoholic hangover	1	0
Alcoholism	4	0
Nicotine dependence	2	0
<b>Suicidal and self-injurious behaviour</b>		
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
<b>Thinking disturbances</b>		
Bradyphrenia	40	0
Intrusive thoughts	7	0
Morbid thoughts	1	0
Tachyphrenia	6	0
Thinking abnormal	19	0
Thought blocking	1	0
<b>Tic disorders</b>		
Tic	11	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>7922</b>	<b>1</b>



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Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i><b>Bladder and urethral symptoms</b></i>		
Bladder discomfort	2	0
Bladder irritation	8	0
Bladder pain	28	0
Dysuria	48	0
Incontinence	28	0
Lower urinary tract symptoms	3	0
Micturition disorder	2	0
Micturition urgency	42	0
Pollakiuria	132	0
Stress urinary incontinence	1	0
Urethral pain	7	0
Urge incontinence	2	0
Urinary hesitation	2	0
Urinary incontinence	56	0
Urinary retention	38	0
Urine flow decreased	14	0
<i><b>Bladder disorders NEC</b></i>		
Bladder disorder	9	0
Bladder fibrosis	1	0
Bladder prolapse	1	0
Urinary bladder haemorrhage	3	0
<i><b>Bladder infections and inflammations</b></i>		
Cystitis interstitial	5	0
Cystitis noninfective	1	0
<i><b>Genital and urinary tract disorders NEC</b></i>		
Genitourinary symptom	1	0
Urinary tract disorder	4	0
<i><b>Glomerulonephritis and nephrotic syndrome</b></i>		
Glomerulonephritis minimal lesion	5	0
Glomerulonephritis rapidly progressive	2	0
IgA nephropathy	4	0
Nephrotic syndrome	17	0
<i><b>Myoneurogenic bladder disorders</b></i>		
Bladder dysfunction	5	0
Hypertonic bladder	2	0
Hypotonic urinary bladder	1	0
Loss of bladder sensation	2	0
Neurogenic bladder	2	0
<i><b>Nephritis NEC</b></i>		
Lupus nephritis	1	0
Nephritis	3	0
Tubulointerstitial nephritis	2	0
<i><b>Nephropathies and tubular disorders NEC</b></i>		
Nephropathy	1	0
<i><b>Renal disorders NEC</b></i>		
Renal disorder	5	1
Renal haemorrhage	1	0
Renal mass	1	0
<i><b>Renal failure and impairment</b></i>		
Acute kidney injury	47	4
Anuria	3	0
Chronic kidney disease	4	0

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Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
Renal & urinary disorders cont'd		
Oliguria	1	0
Renal failure	20	1
Renal impairment	23	0
Renal injury	2	0
<b>Renal lithiasis</b>		
Nephrolithiasis	9	0
<b>Renal neoplasms</b>		
Renal cyst	1	0
<b>Renal obstructive disorders</b>		
Hydronephrosis	2	0
<b>Renal structural abnormalities and trauma</b>		
Kidney small	1	0
<b>Renal vascular and ischaemic conditions</b>		
Renal aneurysm	1	0
Renal infarct	1	0
Renal tubular necrosis	1	0
Renal vasculitis	1	1
<b>Structural and obstructive urethral disorders (excl congenital)</b>		
Urethral stenosis	1	0
<b>Ureteric disorders NEC</b>		
Ureteric stenosis	1	0
<b>Urinary abnormalities</b>		
Albuminuria	1	0
Chromaturia	53	0
Haematuria	37	0
Ketonuria	1	0
Myoglobinuria	1	0
Proteinuria	12	0
Urine abnormality	11	0
Urine odour abnormal	8	0
<b>Urinary tract lithiasis (excl renal)</b>		
Calculus urinary	1	0
<b>Urinary tract signs and symptoms NEC</b>		
Costovertebral angle tenderness	1	0
Cystitis-like symptom	1	0
Haemorrhage urinary tract	23	0
Nocturia	3	0
Polyuria	9	0
Renal colic	4	0
Renal pain	276	0
Urinary tract discomfort	1	0
Urinary tract pain	6	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>1060</b>	<b>7</b>

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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i><b>Benign and malignant breast neoplasms</b></i>		
Breast cyst	13	0
<i><b>Breast disorders NEC</b></i>		
Breast disorder	1	0
Breast enlargement	26	0
Breast mass	112	0
Gynaecomastia	4	0
Mastoptosis	1	0
Nipple disorder	1	0
<i><b>Breast infections and inflammations</b></i>		
Breast inflammation	3	0
Nipple inflammation	2	0
<i><b>Breast signs and symptoms</b></i>		
Breast discharge	4	0
Breast discomfort	10	0
Breast engorgement	11	0
Breast haematoma	1	0
Breast oedema	5	0
Breast pain	632	0
Breast swelling	139	0
Breast tenderness	78	0
Nipple pain	37	1
Nipple swelling	4	0
<i><b>Cervix disorders NEC</b></i>		
Cervical dysplasia	2	0
Cervix disorder	1	0
Cervix haemorrhage uterine	5	0
Ectropion of cervix	4	0
<i><b>Cervix infections and inflammations</b></i>		
Cervix inflammation	1	0
<i><b>Cervix neoplasms</b></i>		
Cervical polyp	1	0
<i><b>Erection and ejaculation conditions and disorders</b></i>		
Ejaculation disorder	2	0
Ejaculation failure	3	0
Erectile dysfunction	63	0
Erection increased	2	0
Organic erectile dysfunction	16	0
Painful ejaculation	1	0
Spontaneous ejaculation	1	0
Spontaneous penile erection	2	0
<i><b>Fallopian tube and ovary infections and inflammations</b></i>		
Noninfective oophoritis	4	0
<i><b>Lactation disorders</b></i>		
Breast milk discolouration	3	0
Breast milk odour abnormal	2	0
Galactorrhoea	5	0
Galactostasis	1	0
Lactation disorder	7	0
Lactation puerperal increased	5	0
Suppressed lactation	43	0
<i><b>Menopausal effects NEC</b></i>		
Artificial menopause	1	0

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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i>Reproductive &amp; breast disorders cont'd</i>		
Menopausal disorder	1	0
Menopausal symptoms	26	0
Menopause delayed	1	0
Premature menopause	17	0
<b><i>Menopausal effects on the genitourinary tract</i></b>		
Atrophic vulvovaginitis	1	0
Postmenopausal haemorrhage	90	0
<b><i>Menstruation and uterine bleeding NEC</i></b>		
Abnormal uterine bleeding	6	0
Abnormal withdrawal bleeding	1	0
Bleeding anovulatory	1	0
Dysmenorrhoea	2677	0
Intermenstrual bleeding	1020	0
Menstrual discomfort	27	0
Menstrual disorder	1724	0
Menstruation irregular	3035	0
Premenstrual dysphoric disorder	11	0
Premenstrual headache	10	0
Premenstrual pain	113	0
Premenstrual syndrome	103	0
Retrograde menstruation	1	0
Withdrawal bleed	15	0
<b><i>Menstruation with decreased bleeding</i></b>		
Amenorrhoea	551	0
Hypomenorrhoea	619	0
Menstruation delayed	4589	0
Oligomenorrhoea	149	0
<b><i>Menstruation with increased bleeding</i></b>		
Heavy menstrual bleeding	5068	0
Menometrorrhagia	17	0
Polymenorrhoea	791	0
<b><i>Ovarian and fallopian tube cysts and neoplasms</i></b>		
Haemorrhagic ovarian cyst	1	0
Ovarian cyst	22	0
Ovarian cyst ruptured	1	0
Polycystic ovaries	43	0
<b><i>Ovarian and fallopian tube disorders NEC</i></b>		
Adnexal torsion	1	0
Hydrosalpinx	2	0
Ovarian enlargement	1	0
Ovarian haemorrhage	6	0
Ovulation disorder	2	0
Ovulation pain	62	0
Premature ovulation	4	0
<b><i>Pelvic prolapse conditions</i></b>		
Vaginal prolapse	1	0
<b><i>Pelvis and broad ligament disorders NEC</i></b>		
Adnexa uteri mass	1	0
Adnexa uteri pain	46	0
Pelvic congestion	1	0
Pelvic floor muscle weakness	1	0
Pelvic haemorrhage	18	0
<b><i>Penile and scrotal infections and inflammations</i></b>		

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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i>Reproductive &amp; breast disorders cont'd</i>		
Balanoposthitis	2	0
<b><i>Penile disorders NEC (excl erection and ejaculation)</i></b>		
Penile blister	1	0
Penile discharge	1	0
Penile discomfort	1	0
Penile erythema	1	0
Penile haemorrhage	3	0
Penile pain	1	0
Penile size reduced	1	0
Penile swelling	5	0
Penis disorder	9	0
<b><i>Prostate and seminal vesicles infections and inflammations</i></b>		
Prostatitis	3	0
<b><i>Prostatic neoplasms and hypertrophy</i></b>		
Benign prostatic hyperplasia	1	0
<b><i>Prostatic signs, symptoms and disorders NEC</i></b>		
Prostatic pain	1	0
Prostatomegaly	3	0
<b><i>Reproductive tract disorders NEC (excl neoplasms)</i></b>		
Genital erosion	1	0
Genital haemorrhage	23	0
Genital hypoaesthesia	1	0
Genital lesion	2	0
Genital paraesthesia	1	0
Genital ulceration	6	0
Perineal ulceration	1	0
<b><i>Reproductive tract infections and inflammations NEC</i></b>		
Genital tract inflammation	1	0
<b><i>Reproductive tract signs and symptoms NEC</i></b>		
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	100	0
Perineal pain	2	0
Perineal rash	1	0
Pruritus genital	4	0
<b><i>Scrotal disorders NEC</i></b>		
Acquired hydrocele	1	0
Scrotal angiokeratoma	1	0
Scrotal discomfort	1	0
Scrotal erythema	1	0
Scrotal exfoliation	1	0
Scrotal pain	23	0
Scrotal swelling	4	0
Varicocele	2	0
<b><i>Sexual function and fertility disorders NEC</i></b>		
Dyspareunia	6	0
Infertility	9	0
Infertility female	3	0
Sexual dysfunction	6	0

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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i>Reproductive &amp; breast disorders cont'd</i>		
<b><i>Spermatogenesis and semen disorders</i></b>		
Aspermia	1	0
Haematospermia	6	0
Semen discolouration	1	0
<b><i>Testicular and epididymal disorders NEC</i></b>		
Testicular disorder	3	0
Testicular oedema	1	0
Testicular pain	55	0
Testicular swelling	8	0
Testicular torsion	1	0
Testis discomfort	3	0
<b><i>Uterine disorders NEC</i></b>		
Adenomyosis	7	0
Endometrial thickening	4	0
Endometriosis	80	0
Uterine haemorrhage	34	0
Uterine pain	14	0
<b><i>Uterine infections and inflammations (excl cervix)</i></b>		
Uterine inflammation	1	0
<b><i>Uterine neoplasms</i></b>		
Uterine polyp	4	0
<b><i>Uterine tone disorders</i></b>		
Uterine spasm	29	0
<b><i>Vulvovaginal cysts and neoplasms</i></b>		
Bartholin's cyst	1	0
Vaginal cyst	6	0
Vaginal polyp	1	0
<b><i>Vulvovaginal disorders NEC</i></b>		
Vaginal haemorrhage	1438	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
<b><i>Vulvovaginal signs and symptoms</i></b>		
Clitoral engorgement	1	0
Coital bleeding	6	0
Labia enlarged	1	0
Vaginal discharge	72	0
Vaginal lesion	1	0
Vaginal odour	2	0
Vulval oedema	1	0
Vulvovaginal burning sensation	4	0
Vulvovaginal dryness	5	0
Vulvovaginal erythema	1	0
Vulvovaginal pain	26	0
Vulvovaginal pruritus	8	0
Vulvovaginal rash	2	0
Vulvovaginal swelling	4	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>24262</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Apnoea	6	0
Apnoeic attack	1	0
Dyspnoea	4544	5
Dyspnoea at rest	11	0
Dyspnoea exertional	36	1
Grunting	1	0
Hyperventilation	50	0
Hypopnoea	106	0
Hypoventilation	1	0
Irregular breathing	20	0
Mouth breathing	5	0
Nocturnal dyspnoea	2	0
Orthopnoea	3	0
Respiration abnormal	55	0
Respiratory arrest	15	0
Respiratory depression	1	0
Respiratory distress	17	0
Sleep apnoea syndrome	12	0
Tachypnoea	25	0
<i><b>Bronchial conditions NEC</b></i>		
Bronchial secretion retention	4	0
Bronchiectasis	13	0
<i><b>Bronchospasm and obstruction</b></i>		
Asthma	341	0
Asthma late onset	2	0
Bronchospasm	15	0
Chronic obstructive pulmonary disease	18	1
Cough variant asthma	5	0
Obstructive airways disorder	9	0
Reversible airways obstruction	1	0
Wheezing	385	0
<i><b>Conditions associated with abnormal gas exchange</b></i>		
Asphyxia	2	0
Cyanosis central	1	0
Hyperoxia	1	0
Hypoxia	28	2
Respiratory acidosis	2	0
<i><b>Coughing and associated symptoms</b></i>		
Allergic cough	7	0
Cough	2359	3
Cough decreased	2	0
Haemoptysis	57	0
Productive cough	162	0
Sputum discoloured	7	0
Sputum increased	3	0
<i><b>Diaphragmatic disorders</b></i>		
Acquired diaphragmatic eventration	1	0
Diaphragm muscle weakness	1	0
<i><b>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</b></i>		
Laryngeal disorder	1	0
Reflux laryngitis	2	0

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b> <small>Respiratory disorders cont'd</small>		
Vocal cord disorder	1	0
Vocal cord dysfunction	2	0
<b><i>Laryngeal spasm, oedema and obstruction</i></b>		
Epiglottic oedema	1	0
Laryngeal obstruction	1	0
Laryngeal oedema	3	0
Laryngospasm	1	0
Stridor	23	0
<b><i>Lower respiratory tract inflammatory and immunologic conditions</i></b>		
Alveolitis	1	0
Autoimmune lung disease	1	0
Hypersensitivity pneumonitis	1	0
Lower respiratory tract inflammation	1	0
Pneumonitis	27	1
Pulmonary sarcoidosis	2	0
<b><i>Lower respiratory tract signs and symptoms</i></b>		
Hiccups	31	0
Increased bronchial secretion	2	0
Increased viscosity of bronchial secretion	1	0
Lung hyperinflation	1	0
Lung opacity	2	0
Pleuritic pain	21	0
Pulmonary haemorrhage	1	0
Pulmonary pain	90	0
Rales	5	0
Respiratory fremitus	1	0
<b><i>Mediastinal disorders</i></b>		
Mediastinal mass	1	0
Pulmonary hilum mass	1	0
<b><i>Nasal congestion and inflammations</i></b>		
Nasal congestion	269	0
Nasal inflammation	3	0
Rhinitis allergic	18	0
<b><i>Nasal disorders NEC</i></b>		
Epistaxis	868	0
Intranasal hypoaesthesia	2	0
Intranasal paraesthesia	1	0
Nasal crusting	2	0
Nasal disorder	3	0
Nasal dryness	35	0
Nasal mucosal discolouration	1	0
Nasal odour	6	0
Nasal oedema	8	0
Nasal polyps	1	0
Nasal pruritus	12	0
<b><i>Neonatal hypoxic conditions</i></b>		
Dry lung syndrome	1	0
Gasping syndrome	1	0
Infantile apnoea	1	0
<b><i>Paranasal sinus disorders (excl infections and neoplasms)</i></b>		
Allergic sinusitis	1	0
Paranasal sinus inflammation	4	0
Sinonasal obstruction	10	0



## Case Series Drug Analysis Print

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

Report Run Date: 18-Nov-2021

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Respiratory disorders</b> <small>Respiratory disorders cont'd</small>		
Sinus congestion	60	0
Sinus disorder	6	0
<b><i>Parenchymal lung disorders NEC</i></b>		
Atelectasis	3	0
Combined pulmonary fibrosis and emphysema	1	0
Emphysema	3	0
Interstitial lung disease	9	0
Lung consolidation	1	0
Lung infiltration	1	0
Pulmonary alveolar haemorrhage	1	0
Pulmonary cavitation	1	0
Pulmonary fibrosis	6	0
<b><i>Pharyngeal disorders (excl infections and neoplasms)</i></b>		
Hyperactive pharyngeal reflex	1	0
Pharyngeal enanthema	1	0
Pharyngeal erythema	7	0
Pharyngeal haemorrhage	2	0
Pharyngeal hypoaesthesia	36	0
Pharyngeal inflammation	4	0
Pharyngeal mass	1	0
Pharyngeal oedema	14	0
Pharyngeal paraesthesia	52	0
Pharyngeal swelling	246	0
Pharyngeal ulceration	14	0
Tonsillar erythema	10	0
Tonsillar haemorrhage	1	0
Tonsillar hypertrophy	80	0
Tonsillar inflammation	3	0
Tonsillar ulcer	1	0
Tonsillolith	1	0
<b><i>Pleural infections and inflammations</i></b>		
Pleurisy	32	0
<b><i>Pneumothorax and pleural effusions NEC</i></b>		
Pleural effusion	27	0
Pneumothorax	8	0
Pneumothorax spontaneous	3	0
<b><i>Pulmonary hypertensions</i></b>		
Pulmonary hypertension	3	0
<b><i>Pulmonary oedemas</i></b>		
Acute respiratory distress syndrome	2	1
Pulmonary congestion	14	0
Pulmonary oedema	20	1
<b><i>Pulmonary thrombotic and embolic conditions</i></b>		
Pulmonary artery thrombosis	1	0
Pulmonary embolism	421	31
Pulmonary infarction	6	0
Pulmonary thrombosis	7	1
<b><i>Respiratory failures (excl neonatal)</i></b>		
Acute respiratory failure	2	1
Respiratory failure	11	2
<b><i>Respiratory signs and symptoms NEC</i></b>		
Allergic respiratory symptom	6	0
Diaphragmalgia	7	0

## Case Series Drug Analysis Print

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

Report Run Date: 18-Nov-2021

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Respiratory disorders</b> <small>Respiratory disorders cont'd</small>		
Nasal flaring	1	0
Painful respiration	11	1
Pleural rub	1	0
Respiratory symptom	18	0
Suffocation feeling	2	0
<b>Respiratory tract disorders NEC</b>		
Aspiration	2	0
Lung disorder	6	0
Pulmonary mass	4	0
Respiratory disorder	13	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
<b>Thoracic musculoskeletal disorders</b>		
Respiratory muscle weakness	2	0
<b>Tracheal disorders (excl infections and neoplasms)</b>		
Tracheal disorder	1	0
Tracheal pain	2	0
<b>Upper respiratory tract neoplasms</b>		
Tonsillar cyst	1	0
<b>Upper respiratory tract signs and symptoms</b>		
Aphonia	110	0
Catarrh	26	0
Choking	15	0
Choking sensation	3	0
Dry throat	166	0
Dysphonia	155	0
Increased upper airway secretion	6	0
Increased viscosity of upper respiratory secretion	32	0
Nasal discharge discolouration	3	0
Nasal discomfort	44	0
Nasal obstruction	2	0
Oropharyngeal blistering	10	0
Oropharyngeal discomfort	67	0
Oropharyngeal pain	2729	0
Oropharyngeal plaque	2	0
Paranasal sinus discomfort	43	0
Rhinalgia	11	0
Rhinorrhoea	864	0
Sinus pain	200	0
Sneezing	361	0
Snoring	7	0
Throat clearing	8	0
Throat irritation	221	0
Throat tightness	254	0
Upper airway obstruction	2	0
Upper respiratory tract congestion	2	0
Upper respiratory tract irritation	1	0
Upper-airway cough syndrome	10	0
Yawning	26	0
<b>Vascular pulmonary disorders NEC</b>		

# Case Series Drug Analysis Print

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

Report Run Date: 18-Nov-2021

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Respiratory disorders</b> Respiratory disorders cont'd		
Acute chest syndrome	1	0
<b>Respiratory disorders SOC TOTAL</b>	<b>16409</b>	<b>52</b>

## Case Series Drug Analysis Print

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

Report Run Date: 18-Nov-2021

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<b><i>Acnes</i></b>		
Acne	181	0
Acne cystic	20	0
Dermatitis acneiform	12	0
<b><i>Alopecias</i></b>		
Alopecia	273	0
Alopecia areata	40	0
Alopecia totalis	2	0
Androgenetic alopecia	2	0
Diffuse alopecia	4	0
Hypotrichosis	1	0
Lichen planopilaris	1	0
Madarosis	4	0
<b><i>Angioedemas</i></b>		
Angioedema	206	0
Circumoral swelling	1	0
<b><i>Apocrine and eccrine gland disorders</i></b>		
Anhidrosis	1	0
Bromhidrosis	1	0
Cold sweat	741	0
Hidradenitis	4	0
Hyperhidrosis	2136	0
Hypohidrosis	2	0
Milia	2	0
Miliaria	88	0
Night sweats	597	0
Sweat discolouration	1	0
<b><i>Bullous conditions</i></b>		
Blister	439	0
Blister rupture	1	0
Blood blister	28	0
Dermatitis bullous	12	0
Erythema multiforme	36	0
Fracture blisters	1	0
Herpes gestationis	1	0
Pemphigoid	24	0
Pemphigus	7	0
Stevens-Johnson syndrome	5	0
Toxic epidermal necrolysis	2	1
<b><i>Connective tissue disorders</i></b>		
Cutaneous lupus erythematosus	1	0
Dermatomyositis	7	0
Subacute cutaneous lupus erythematosus	1	0
<b><i>Dermal and epidermal conditions NEC</i></b>		
Acute febrile neutrophilic dermatosis	1	0
Dermatosis	1	0
Dry skin	217	0
Koebner phenomenon	1	0
Macule	5	0
Neutrophilic dermatosis	1	0
Pain of skin	254	0
Papule	101	0
Pathergy reaction	1	0

## Case Series Drug Analysis Print

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

Report Run Date: 18-Nov-2021

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Scab	22	0
Scar pain	14	0
Sensitive skin	165	0
Shagreen skin	1	0
Skin burning sensation	210	0
Skin degenerative disorder	1	0
Skin discolouration	133	0
Skin discomfort	5	0
Skin disorder	26	0
Skin fissures	8	0
Skin indentation	2	0
Skin induration	5	0
Skin lesion	43	0
Skin lesion inflammation	1	0
Skin necrosis	2	0
Skin odour abnormal	20	0
Skin plaque	3	0
Skin reaction	138	0
Skin sensitisation	37	0
Skin swelling	91	0
Skin texture abnormal	2	0
Skin tightness	26	0
Skin warm	286	0
Skin weeping	11	0
Sticky skin	3	0
Target skin lesion	2	0
Transient acantholytic dermatosis	1	0
Yellow skin	25	0
<b><i>Dermatitis and eczema</i></b>		
Dermatitis	126	0
Dermatitis allergic	227	0
Dermatitis atopic	39	0
Dermatitis contact	19	0
Dermatitis diaper	3	0
Dyshidrotic eczema	27	0
Eczema	304	0
Eczema asteatotic	9	0
Eczema infantile	1	0
Eczema nummular	5	0
Eczema weeping	2	0
Hand dermatitis	1	0
Intertrigo	1	0
Perioral dermatitis	2	0
Seborrhoeic dermatitis	5	0
Skin irritation	113	0
Stasis dermatitis	1	0
<b><i>Dermatitis ascribed to specific agent</i></b>		
Drug eruption	31	0
Drug reaction with eosinophilia and systemic symptoms	2	0
Fixed eruption	2	0
Palmar-plantar erythrodysesthesia syndrome	1	0
Toxic skin eruption	2	0
<b><i>Erythemas</i></b>		

## Case Series Drug Analysis Print

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Report Run Date: 18-Nov-2021

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Erythema	2059	0
Palmar erythema	4	0
Red man syndrome	2	0
<b><i>Exfoliative conditions</i></b>		
Dermatitis exfoliative	2	0
Dermatitis exfoliative generalised	5	0
Exfoliative rash	20	0
Keratolysis exfoliativa acquired	2	0
Skin exfoliation	116	0
<b><i>Granulomatous and deep cutaneous inflammatory conditions</i></b>		
Cutaneous sarcoidosis	1	0
Granuloma annulare	5	0
<b><i>Hyperkeratoses</i></b>		
Hyperkeratosis	1	0
Keratosis pilaris	3	0
Lichenoid keratosis	3	0
<b><i>Hyperpigmentation disorders</i></b>		
Argyria	1	0
Chloasma	1	0
Ephelides	1	0
Skin hyperpigmentation	6	0
Solar lentigo	2	0
<b><i>Hypertrichoses</i></b>		
Hirsutism	2	0
<b><i>Hypopigmentation disorders</i></b>		
Skin depigmentation	4	0
Skin hypopigmentation	1	0
Vitiligo	18	0
<b><i>Lipodystrophies</i></b>		
Lipoatrophy	4	0
Lipodystrophy acquired	1	0
<b><i>Nail and nail bed conditions (excl infections and infestations)</i></b>		
Nail discolouration	10	0
Nail disorder	2	0
Nail pigmentation	2	0
Nail ridging	3	0
Onychalgia	8	0
Onychoclasia	5	0
Onychomadesis	2	0
Splinter haemorrhages	3	0
<b><i>Panniculitides</i></b>		
Erythema nodosum	26	0
Panniculitis	1	0
<b><i>Papulosquamous conditions</i></b>		
Erythema annulare	2	0
Lichen planus	16	0
Lichen sclerosus	9	0
Parapsoriasis	3	0
Pityriasis rosea	112	0
<b><i>Photosensitivity and photodermatosis conditions</i></b>		
Photosensitivity reaction	62	0
Polymorphic light eruption	3	0
Solar dermatitis	2	0

## Case Series Drug Analysis Print

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

Report Run Date: 18-Nov-2021

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
<b><i>Pigmentation changes NEC</i></b>		
Haemosiderin stain	1	0
Pigmentation disorder	14	0
<b><i>Pilar disorders NEC</i></b>		
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
<b><i>Pruritus NEC</i></b>		
Itching scar	7	0
Pruritus	5098	0
<b><i>Psoriatic conditions</i></b>		
Dermatitis psoriasiform	5	0
Guttate psoriasis	15	0
Nail psoriasis	2	0
Palmoplantar pustulosis	2	0
Psoriasis	184	0
Pustular psoriasis	2	0
Rebound psoriasis	1	0
<b><i>Purpura and related conditions</i></b>		
Ecchymosis	1	0
Henoch-Schonlein purpura	10	0
Petechiae	141	0
Purpura	53	0
<b><i>Pustular conditions</i></b>		
Acute generalised exanthematous pustulosis	2	0
<b><i>Rashes, eruptions and exanthems NEC</i></b>		
Butterfly rash	4	0
Rash	5368	1
Rash erythematous	1127	0
Rash macular	480	0
Rash maculo-papular	61	0
Rash morbilliform	43	0
Rash papular	326	0
Rash pruritic	1124	0
Rash vesicular	71	0
Systemic lupus erythematosus rash	7	0
<b><i>Rosaceas</i></b>		
Rosacea	32	0
<b><i>Scaly conditions</i></b>		
Dandruff	4	0
Pityriasis	23	0
<b><i>Sebaceous gland disorders</i></b>		
Seborrhoea	10	0
<b><i>Skin and subcutaneous conditions NEC</i></b>		
Cellulite	2	0
Cutaneous symptom	5	0
Reactive perforating collagenosis	1	0
Skin mass	20	0
<b><i>Skin and subcutaneous tissue ulcerations</i></b>		

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

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
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	18	0
<b>Skin cysts and polyps</b>		
Dermal cyst	13	0
<b>Skin dystrophies</b>		
Keloid scar	3	0
Skin wrinkling	2	0
<b>Skin haemorrhages</b>		
Haemorrhage subcutaneous	14	0
Skin haemorrhage	19	0
<b>Skin hyperplasias and hypertrophies</b>		
Skin hypertrophy	2	0
<b>Skin hypoplasias and atrophies</b>		
Skin atrophy	3	0
Skin striae	7	0
<b>Skin injuries and mechanical dermatoses</b>		
Decubitus ulcer	2	0
Needle track marks	4	0
<b>Skin preneoplastic conditions NEC</b>		
Actinic keratosis	1	0
<b>Skin vascular conditions NEC</b>		
Skin oedema	4	0
<b>Skin vasculitides</b>		
Capillaritis	2	0
Cutaneous vasculitis	14	0
Hypersensitivity vasculitis	1	0
Vasculitic rash	19	0
<b>Skin vasomotor conditions</b>		
Livedo reticularis	22	0
<b>Telangiectasia and related conditions</b>		
Spider naevus	1	0
Telangiectasia	1	0
<b>Urticarias</b>		
Chronic spontaneous urticaria	9	0
Cold urticaria	6	0
Idiopathic urticaria	1	0
Mechanical urticaria	8	0
Solar urticaria	2	0
Urticaria	1777	0
Urticaria cholinergic	1	0
Urticaria chronic	19	0
Urticaria contact	1	0
Urticaria papular	4	0
Urticaria thermal	6	0
Urticularial vasculitis	5	0
<b>Skin disorders SOC TOTAL</b>	<b>26526</b>	<b>2</b>



## Case Series Drug Analysis Print

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Report Run Date: 18-Nov-2021

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Reaction Name	Total	Fatal
<b>Social circumstances</b>		
<i>Age related issues</i>		
Infant	3	0
Menarche	2	0
Menopause	38	0
Postmenopause	3	0
<i>Alcohol product use</i>		
Alcoholic	1	0
<i>Criminal activity</i>		
Verbal abuse	1	0
<i>Dependents</i>		
Sick relative	6	0
<i>Dietary and nutritional issues</i>		
Feeding tube user	1	0
<i>Disability issues</i>		
Bedridden	26	0
Blood product transfusion dependent	1	0
Breast prosthesis user	3	0
Disability	2	0
Hearing disability	1	0
Housebound	1	0
Immobile	14	0
Impaired driving ability	4	0
Impaired work ability	13	0
Loss of personal independence in daily activities	38	0
Physical disability	5	0
Sight disability	10	0
Sitting disability	3	0
Walking disability	1	0
Wheelchair user	1	0
<i>Economic circumstances</i>		
High income	1	0
Low income	1	0
<i>Educational issues</i>		
Educational problem	1	0
Illiteracy	1	0
<i>Employment issues</i>		
Job dissatisfaction	1	0
Retirement	4	0
Stress at work	2	0
<i>Family and partner issues</i>		
Bed sharing	1	0
<i>Non-occupational and unspecified environmental problems</i>		
Flooding	1	0
Water pollution	2	0
<i>Pregnancy related circumstances</i>		
Breast feeding	15	0
Multigravida	1	0
Parity	1	0
<i>Social issues NEC</i>		
Exercise adequate	2	0
Hair dye user	2	0
Impaired quality of life	3	0
<i>Tobacco use</i>		

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Social circumstances</b> Social circumstances cont'd		
Ex-tobacco user	1	0
Non-tobacco user	3	0
Tobacco user	1	0
<b>Social circumstances SOC TOTAL</b>	<b>222</b>	<b>0</b>

## Case Series Drug Analysis Print

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

Report Run Date: 18-Nov-2021

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
<b><i>Anaesthesia and allied procedures</i></b>		
Local anaesthesia	2	0
Nerve block	4	0
<b><i>Analgesia supportive care</i></b>		
Analgesic therapy	1	0
<b><i>Antiinfective therapies</i></b>		
COVID-19 prophylaxis	1	0
COVID-19 treatment	4	0
<b><i>Arterial therapeutic procedures (excl aortic)</i></b>		
Splenic artery embolisation	1	0
<b><i>Blood and blood product treatment</i></b>		
Transfusion	2	0
<b><i>Breast therapeutic procedures NEC</i></b>		
Axillary lymphadenectomy	3	0
Mammoplasty	1	0
<b><i>Bronchial and pulmonary therapeutic procedures</i></b>		
Airway secretion clearance therapy	1	0
<b><i>Cardiac device therapeutic procedures</i></b>		
Cardiac pacemaker insertion	1	0
<b><i>Cardiac therapeutic procedures NEC</i></b>		
Cardiac operation	1	0
<b><i>Contraceptive methods female</i></b>		
Contraception	1	0
Contraceptive implant	3	0
Oral contraception	1	0
<b><i>Contraceptive methods male</i></b>		
Condom	1	0
<b><i>Dietary and nutritional therapies</i></b>		
Medical diet	8	0
Nothing by mouth order	11	0
Wheat-free diet	1	0
<b><i>External ear therapeutic procedures</i></b>		
Ear irrigation	1	0
<b><i>Fertility and fertilisation interventions female</i></b>		
Endometrial scratching	1	0
<b><i>Gastrointestinal therapeutic procedures NEC</i></b>		
Intestinal anastomosis	1	0
Prophylaxis of nausea and vomiting	16	0
<b><i>Gynaecological therapeutic procedures NEC</i></b>		
Menstrual cycle management	13	0
<b><i>Haematological therapeutic procedures NEC</i></b>		
Anticoagulant therapy	1	0
<b><i>Head, neck and oral cavity therapeutic procedures NEC</i></b>		
Neck lift	1	0
<b><i>Hernia repairs</i></b>		
Hernia repair	1	0
<b><i>Hormonal therapeutic procedures NEC</i></b>		
Hormone replacement therapy	1	0
Hormone therapy	8	0
<b><i>Immunisations</i></b>		
COVID-19 immunisation	95	0
Immunisation	184	1
Influenza immunisation	2	0

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

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Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
<i>Surgical &amp; medical procedures cont'd</i>		
<b><i>Induced abortions</i></b>		
Abortion induced	2	0
<b><i>Joint therapeutic procedures</i></b>		
Joint injection	4	0
Joint surgery	1	0
Knee arthroplasty	1	0
<b><i>Large intestine therapeutic procedures</i></b>		
Appendectomy	4	0
<b><i>Limb therapeutic procedures</i></b>		
Arm amputation	1	0
Limb immobilisation	10	0
Limb operation	6	0
<b><i>Lymphoid tissue therapeutic procedures</i></b>		
Lymphadenectomy	2	0
Splenectomy	1	0
<b><i>Mastectomies</i></b>		
Breast conserving surgery	4	0
<b><i>Nail therapeutic procedures</i></b>		
Nail operation	3	0
<b><i>Nervous system therapeutic procedures NEC</i></b>		
Multiple sclerosis relapse prophylaxis	2	0
<b><i>Obstetric therapeutic procedures</i></b>		
Caesarean section	1	0
Labour stimulation	1	0
<b><i>Orbit and globe therapeutic procedures</i></b>		
Strabismus correction	1	0
<b><i>Ovarian therapeutic procedures</i></b>		
Ovarian operation	1	0
<b><i>Peripheral nerve therapeutic procedures</i></b>		
Neurolysis	1	0
Peripheral nerve neurostimulation	1	0
<b><i>Phototherapies</i></b>		
UV light therapy	1	0
<b><i>Prophylactic procedures NEC</i></b>		
Anaphylaxis prophylaxis	2	0
Immune tolerance induction	1	0
Prophylaxis against transplant rejection	1	0
Reproductive system disorder prophylaxis	1	0
<b><i>Psychiatric therapies</i></b>		
Electroconvulsive therapy	1	0
<b><i>Renal therapeutic procedures</i></b>		
Dialysis	1	0
<b><i>Respiratory tract therapeutic procedures NEC</i></b>		
Asthma prophylaxis	3	0
<b><i>Retinal therapeutic procedures</i></b>		
Retinopexy	1	0
<b><i>Skin and subcutaneous tissue therapeutic procedures NEC</i></b>		
Dermal filler injection	5	0
Therapeutic skin care topical	1	0
<b><i>Skull and brain therapeutic procedures</i></b>		
Cerebrovascular operation	1	0
Posterior fossa decompression	1	0
<b><i>Small intestine therapeutic procedures</i></b>		

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

Report Run Date: 18-Nov-2021

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
Ileostomy	1	0
<b>Therapeutic bladder catheterisation</b>		
Bladder catheterisation	2	0
<b>Therapeutic procedures NEC</b>		
Abscess drainage	1	0
Anaphylaxis treatment	7	0
Bed rest	4	0
Fatigue management	1	0
Hospitalisation	14	0
Injection	55	0
Interchange of vaccine products	39	0
Localised alternating hot and cold therapy	2	0
Magnetic therapy	1	0
Mass excision	2	0
Medical procedure	1	0
Medication dilution	2	0
Physical fitness training	1	0
Product used for unknown indication	2	0
Promotion of wound healing	1	0
Specialist consultation	1	0
Stent placement	1	0
Stoma care	1	0
Therapeutic procedure	1	0
Therapy change	1	0
<b>Tracheal therapeutic procedures</b>		
Tracheostomy	1	0
<b>Uterine therapeutic procedures</b>		
Endometrial ablation	3	0
<b>Vascular therapeutic procedures NEC</b>		
Vasodilation procedure	1	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>586</b>	<b>1</b>

## Case Series Drug Analysis Print

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

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<b><i>Accelerated and malignant hypertension</i></b>		
Hypertensive crisis	12	0
Hypertensive urgency	2	0
Malignant hypertension	4	0
<b><i>Aneurysms and dissections non-site specific</i></b>		
Aneurysm	2	0
Artery dissection	2	0
<b><i>Aortic aneurysms and dissections</i></b>		
Acute aortic syndrome	1	0
Aortic aneurysm rupture	1	1
Aortic dissection	1	0
<b><i>Aortic embolism and thrombosis</i></b>		
Aortic embolus	5	0
Aortic thrombosis	3	0
<b><i>Aortic infections and inflammations</i></b>		
Aortitis	1	0
<b><i>Aortic necrosis and vascular insufficiency</i></b>		
Aortic occlusion	1	0
<b><i>Arterial infections and inflammations</i></b>		
Arteritis	1	0
Giant cell arteritis	13	0
<b><i>Blood pressure disorders NEC</i></b>		
Blood pressure fluctuation	11	0
Labile blood pressure	3	0
<b><i>Bruising, ecchymosis and purpura</i></b>		
Achenbach syndrome	3	0
<b><i>Circulatory collapse and shock</i></b>		
CT hypotension complex	2	0
Circulatory collapse	68	0
Hypoperfusion	2	0
Hypovolaemic shock	1	1
Neurogenic shock	21	0
Peripheral circulatory failure	6	0
Shock	19	0
<b><i>Haemorrhages NEC</i></b>		
Arterial haemorrhage	1	0
Bloody discharge	24	0
Haematoma	47	0
Haemorrhage	1149	2
Internal haemorrhage	9	0
Venous haemorrhage	2	0
<b><i>Lymphangiopathies</i></b>		
Lymphangiopathy	1	0
Lymphocele	5	0
Lymphorrhoea	1	0
<b><i>Lymphoedemas</i></b>		
Lymphoedema	200	0
<b><i>Non-site specific embolism and thrombosis</i></b>		
Arterial thrombosis	4	0
Embolism	61	0
Embolism venous	6	0
Microembolism	1	0
Thrombosis	407	8

## Case Series Drug Analysis Print

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Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Vascular disorders</b> <small>Vascular disorders cont'd</small>		
Venous thrombosis	7	0
<b><i>Non-site specific necrosis and vascular insufficiency NEC</i></b>		
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
<b><i>Non-site specific vascular disorders NEC</i></b>		
Capillary disorder	1	0
Capillary fragility	3	0
Superficial vein prominence	2	0
Vascular pain	31	0
Vascular wall hypertrophy	1	0
Vasodilatation	36	0
Vein discolouration	5	0
Vein disorder	6	0
Vein rupture	5	0
<b><i>Peripheral aneurysms and dissections</i></b>		
Peripheral artery aneurysm	1	0
<b><i>Peripheral embolism and thrombosis</i></b>		
Axillary vein thrombosis	1	0
Blue toe syndrome	26	0
Deep vein thrombosis	276	1
Femoral artery embolism	1	0
Jugular vein thrombosis	3	0
Pelvic venous thrombosis	4	0
Peripheral artery thrombosis	1	0
Peripheral embolism	1	0
Subclavian artery embolism	1	0
Subclavian vein thrombosis	3	0
Superficial vein thrombosis	17	0
Thrombophlebitis	25	0
<b><i>Peripheral vascular disorders NEC</i></b>		
Cyanosis	42	0
Erythromelalgia	2	0
Flushing	408	0
Hot flush	1093	0
Peripheral vascular disorder	1	0
Vein wall hypertrophy	1	0
<b><i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i></b>		
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	316	0

## Case Series Drug Analysis Print

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Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Vascular disorders</b> Vascular disorders cont'd		
Peripheral ischaemia	12	0
Poor peripheral circulation	16	0
Raynaud's phenomenon	55	0
Subclavian vein occlusion	1	0
Vasoconstriction	2	0
<b>Phlebitis NEC</b>		
Phlebitis	32	0
Phlebitis superficial	8	0
<b>Site specific vascular disorders NEC</b>		
Aortic dilatation	1	0
Inferior vena cava dilatation	1	0
Pallor	365	0
<b>Varicose veins NEC</b>		
Spider vein	6	0
Varicophlebitis	4	0
Varicose vein	30	0
<b>Vascular hypertensive disorders NEC</b>		
Diastolic hypertension	3	0
Essential hypertension	3	0
Hypertension	564	1
Labile hypertension	1	0
Orthostatic hypertension	1	0
Secondary hypertension	1	0
Systolic hypertension	6	0
White coat hypertension	1	0
<b>Vascular hypotensive disorders</b>		
Diastolic hypotension	1	0
Hypotension	380	1
Orthostatic hypotension	31	0
<b>Vasculitides NEC</b>		
Behcet's syndrome	4	0
Diffuse vasculitis	1	0
Granulomatosis with polyangiitis	2	0
MAGIC syndrome	1	0
Thromboangiitis obliterans	1	0
Vasculitis	47	0
<b>Vena caval embolism and thrombosis</b>		
Vena cava embolism	1	0
Vena cava thrombosis	1	0
<b>Vascular disorders SOC TOTAL</b>	<b>6043</b>	<b>15</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>380236</b>	<b>611</b>
<b>TOTAL REPORTS</b>	<b>133951</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>611</b>