

COVID-19 mRNA Pfizer- BioNTech Vaccine Analysis Print

Report Run Date: 14-Oct-2021
Data Lock Date: 13-Oct-2021 18:30:20

All UK spontaneous reports received between 09/12/2020 and 13/10/2021 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 24.0

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Blood disorders | | |
| <i>Anaemia deficiencies</i> | | |
| Anaemia folate deficiency | 1 | 0 |
| Anaemia vitamin B12 deficiency | 3 | 0 |
| Deficiency anaemia | 1 | 0 |
| Iron deficiency anaemia | 8 | 0 |
| <i>Anaemias NEC</i> | | |
| Anaemia | 102 | 0 |
| Anaemia macrocytic | 2 | 0 |
| Anaemia megaloblastic | 1 | 0 |
| Autoimmune anaemia | 2 | 0 |
| Blood loss anaemia | 1 | 0 |
| Microcytic anaemia | 1 | 0 |
| <i>Anaemias haemolytic NEC</i> | | |
| Coombs negative haemolytic anaemia | 1 | 0 |
| Haemolytic anaemia | 6 | 0 |
| <i>Anaemias haemolytic immune</i> | | |
| Autoimmune haemolytic anaemia | 14 | 0 |
| Evans syndrome | 1 | 0 |
| <i>Anaemias haemolytic mechanical factor</i> | | |
| Microangiopathic haemolytic anaemia | 1 | 0 |
| <i>Bleeding tendencies</i> | | |
| Haemorrhagic diathesis | 1 | 0 |
| Increased tendency to bruise | 41 | 0 |
| Spontaneous haematoma | 2 | 0 |
| <i>Coagulation factor deficiencies</i> | | |
| Acquired haemophilia | 2 | 0 |
| <i>Coagulopathies</i> | | |
| Abnormal clotting factor | 4 | 0 |
| Antiphospholipid syndrome | 5 | 0 |
| Coagulopathy | 22 | 1 |
| Disseminated intravascular coagulation | 2 | 0 |
| Hypercoagulation | 3 | 0 |
| Thrombotic microangiopathy | 2 | 0 |
| <i>Eosinophilic disorders</i> | | |
| Eosinophilia | 12 | 0 |
| <i>Haematological disorders</i> | | |
| Blood disorder | 3 | 0 |
| Hypergammaglobulinaemia | 1 | 0 |
| Hyperviscosity syndrome | 1 | 0 |
| Mast cell activation syndrome | 6 | 0 |
| Methaemoglobinaemia | 1 | 0 |
| <i>Haemolyses NEC</i> | | |
| Haemolysis | 6 | 0 |
| Intravascular haemolysis | 1 | 0 |
| <i>Leukocytoses NEC</i> | | |
| Leukocytosis | 1 | 0 |
| Lymphocytosis | 6 | 0 |
| Neutrophilia | 9 | 0 |
| <i>Leukopenias NEC</i> | | |
| Leukopenia | 4 | 1 |
| Lymphopenia | 4 | 0 |
| <i>Lymphatic system disorders NEC</i> | | |
| Abdominal lymphadenopathy | 3 | 0 |

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|--|--------------|----------|
| Blood disorders Blood disorders cont'd | | |
| Hilar lymphadenopathy | 2 | 0 |
| Lymph node pain | 1499 | 0 |
| Lymph node ulcer | 1 | 0 |
| Lymphadenitis | 125 | 0 |
| Lymphadenopathy | 9501 | 0 |
| Lymphatic disorder | 1 | 0 |
| Lymphatic insufficiency | 1 | 0 |
| Necrotic lymphadenopathy | 3 | 0 |
| Pseudolymphoma | 10 | 0 |
| Retroperitoneal lymphadenopathy | 1 | 0 |
| <i>Marrow depression and hypoplastic anaemias</i> | | |
| Aplasia pure red cell | 2 | 0 |
| Hypoplastic anaemia | 1 | 0 |
| Myelosuppression | 1 | 0 |
| Pancytopenia | 7 | 0 |
| <i>Neutropenias</i> | | |
| Autoimmune neutropenia | 2 | 0 |
| Neutropenia | 36 | 0 |
| <i>Platelet disorders NEC</i> | | |
| Platelet anisocytosis | 1 | 0 |
| Platelet disorder | 4 | 0 |
| <i>Polycythaemia (excl rubra vera)</i> | | |
| Polycythaemia | 1 | 0 |
| <i>Purpuras (excl thrombocytopenic)</i> | | |
| Purpura non-thrombocytopenic | 1 | 0 |
| <i>Red blood cell abnormal findings NEC</i> | | |
| Macrocytosis | 1 | 0 |
| Polychromasia | 2 | 0 |
| Red blood cell abnormality | 2 | 0 |
| <i>Spleen disorders</i> | | |
| Spleen atrophy | 1 | 0 |
| Splenic infarction | 2 | 0 |
| Splenic thrombosis | 1 | 0 |
| Splenic vein thrombosis | 1 | 0 |
| Splenomegaly | 11 | 0 |
| <i>Thrombocytopenias</i> | | |
| Immune thrombocytopenia | 67 | 0 |
| Thrombocytopenia | 186 | 1 |
| Thrombocytopenic purpura | 6 | 0 |
| Thrombotic thrombocytopenic purpura | 6 | 0 |
| <i>Thrombocytoses</i> | | |
| Thrombocytosis | 6 | 0 |
| Blood disorders SOC TOTAL | 11779 | 3 |

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| Cardiac disorders | | |
| <i>Aortic valvular disorders</i> | | |
| Aortic valve incompetence | 1 | 0 |
| <i>Cardiac conduction disorders</i> | | |
| Atrioventricular block | 12 | 1 |
| Atrioventricular block complete | 2 | 1 |
| Atrioventricular block first degree | 1 | 0 |
| Atrioventricular block second degree | 2 | 0 |
| Bundle branch block | 2 | 0 |
| Bundle branch block left | 1 | 0 |
| Bundle branch block right | 1 | 0 |
| <i>Cardiac disorders NEC</i> | | |
| Acute cardiac event | 3 | 0 |
| Cardiac disorder | 47 | 0 |
| Cardiac dysfunction | 1 | 0 |
| Cardiovascular deconditioning | 1 | 0 |
| Cardiovascular disorder | 5 | 0 |
| Intracardiac thrombus | 5 | 0 |
| <i>Cardiac hypertensive complications</i> | | |
| Hypertensive heart disease | 1 | 0 |
| <i>Cardiac infections and inflammations NEC</i> | | |
| Carditis | 3 | 0 |
| <i>Cardiac neoplasms NEC</i> | | |
| Pericardial cyst | 1 | 0 |
| <i>Cardiac signs and symptoms NEC</i> | | |
| Cardiac discomfort | 16 | 0 |
| Cardiovascular symptom | 1 | 0 |
| Palpitations | 2904 | 1 |
| <i>Cardiac valve disorders NEC</i> | | |
| Cardiac valve disease | 2 | 0 |
| Heart valve incompetence | 1 | 0 |
| <i>Cardiomyopathies</i> | | |
| Cardiomyopathy | 4 | 0 |
| Congestive cardiomyopathy | 4 | 0 |
| Stress cardiomyopathy | 2 | 0 |
| <i>Coronary artery disorders NEC</i> | | |
| Coronary artery disease | 6 | 3 |
| Coronary artery occlusion | 2 | 0 |
| Coronary artery thrombosis | 1 | 1 |
| <i>Endocarditis NEC</i> | | |
| Endocarditis noninfective | 1 | 1 |
| <i>Heart failures NEC</i> | | |
| Cardiac failure | 61 | 8 |
| Cardiac failure acute | 3 | 0 |
| Cardiac failure chronic | 2 | 0 |
| Cardiac failure congestive | 3 | 1 |
| Cardiogenic shock | 4 | 1 |
| Cardiopulmonary failure | 1 | 1 |
| <i>Ischaemic coronary artery disorders</i> | | |
| Acute coronary syndrome | 3 | 0 |
| Acute myocardial infarction | 18 | 1 |
| Angina pectoris | 174 | 0 |
| Angina unstable | 2 | 0 |
| Arteriospasm coronary | 3 | 0 |

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| Cardiac disorders Cardiac disorders cont'd | | |
| Microvascular coronary artery disease | 2 | 0 |
| Myocardial infarction | 183 | 31 |
| Myocardial ischaemia | 8 | 4 |
| Left ventricular failures | | |
| Acute left ventricular failure | 1 | 1 |
| Left ventricular failure | 7 | 2 |
| Mitral valvular disorders | | |
| Mitral valve incompetence | 4 | 0 |
| Mitral valve prolapse | 1 | 0 |
| Myocardial disorders NEC | | |
| Cardiac amyloidosis | 1 | 0 |
| Cardiomegaly | 26 | 2 |
| Left atrial dilatation | 1 | 0 |
| Left ventricular dysfunction | 5 | 0 |
| Left ventricular enlargement | 1 | 0 |
| Left ventricular hypertrophy | 1 | 0 |
| Myocardial fibrosis | 4 | 0 |
| Myocardial haemorrhage | 1 | 0 |
| Myocardial oedema | 4 | 0 |
| Myocardial rupture | 1 | 0 |
| Right ventricular enlargement | 1 | 0 |
| Ventricular hypertrophy | 1 | 0 |
| Noninfectious myocarditis | | |
| Myocarditis | 337 | 1 |
| Noninfectious pericarditis | | |
| Pericarditis | 265 | 1 |
| Pericardial disorders NEC | | |
| Pericardial effusion | 28 | 0 |
| Pericardial fibrosis | 1 | 0 |
| Pericardial haemorrhage | 3 | 3 |
| Pericardial rub | 2 | 0 |
| Rate and rhythm disorders NEC | | |
| Arrhythmia | 110 | 0 |
| Bradycardia | 54 | 0 |
| Bradycardia foetal | 2 | 1 |
| Cardiac flutter | 365 | 0 |
| Extrasystoles | 136 | 0 |
| Paroxysmal arrhythmia | 1 | 0 |
| Postural orthostatic tachycardia syndrome | 17 | 0 |
| Tachyarrhythmia | 1 | 0 |
| Tachycardia | 664 | 0 |
| Tachycardia foetal | 1 | 0 |
| Tachycardia paroxysmal | 1 | 0 |
| Right ventricular failures | | |
| Cor pulmonale | 1 | 0 |
| Supraventricular arrhythmias | | |
| Arrhythmia supraventricular | 10 | 0 |
| Atrial fibrillation | 170 | 0 |
| Atrial flutter | 20 | 0 |
| Atrial tachycardia | 6 | 0 |
| Nodal arrhythmia | 1 | 0 |
| Sinus arrest | 1 | 0 |
| Sinus arrhythmia | 2 | 0 |

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| Cardiac disorders Cardiac disorders cont'd | | |
| Sinus bradycardia | 9 | 0 |
| Sinus node dysfunction | 1 | 0 |
| Sinus tachycardia | 49 | 0 |
| Supraventricular extrasystoles | 2 | 0 |
| Supraventricular tachycardia | 35 | 0 |
| <i>Tricuspid valvular disorders</i> | | |
| Tricuspid valve incompetence | 3 | 0 |
| <i>Ventricular arrhythmias and cardiac arrest</i> | | |
| Cardiac arrest | 89 | 34 |
| Cardio-respiratory arrest | 1 | 1 |
| Pulseless electrical activity | 3 | 0 |
| Ventricular arrhythmia | 5 | 0 |
| Ventricular extrasystoles | 18 | 0 |
| Ventricular fibrillation | 6 | 1 |
| Ventricular tachycardia | 10 | 0 |
| Cardiac disorders SOC TOTAL | 5990 | 102 |

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|---|-------|-------|
| Congenital disorders | | |
| <i>Autosomal chromosomal abnormalities</i> | | |
| Trisomy 8 | 1 | 0 |
| <i>Cardiac disorders congenital NEC</i> | | |
| Heart disease congenital | 12 | 0 |
| <i>Cardiac septal defects congenital</i> | | |
| Atrial septal defect | 1 | 0 |
| Hypertrophic cardiomyopathy | 1 | 0 |
| <i>Cardiac valve disorders congenital</i> | | |
| Bicuspid aortic valve | 1 | 0 |
| <i>Central nervous system disorders congenital NEC</i> | | |
| Spina bifida | 1 | 0 |
| Syringomyelia | 1 | 0 |
| <i>Cerebellar disorders congenital</i> | | |
| Arnold-Chiari malformation | 1 | 0 |
| Hereditary ataxia | 1 | 0 |
| <i>Cerebral disorders congenital</i> | | |
| Anencephaly | 2 | 0 |
| Cerebral palsy | 3 | 0 |
| <i>Coagulation disorders congenital</i> | | |
| Haemophilia | 2 | 0 |
| <i>Congenital disorders NEC</i> | | |
| Foetal malformation | 1 | 0 |
| Multiple congenital abnormalities | 1 | 0 |
| Young's syndrome | 1 | 0 |
| <i>Connective tissue disorders congenital</i> | | |
| Ehlers-Danlos syndrome | 2 | 0 |
| <i>Gastrointestinal tract disorders congenital NEC</i> | | |
| Gastroschisis | 2 | 0 |
| <i>Great vessel disorders congenital</i> | | |
| Transposition of the great vessels | 1 | 0 |
| <i>Haematological disorders congenital NEC</i> | | |
| Amegakaryocytic thrombocytopenia | 1 | 0 |
| Neonatal alloimmune thrombocytopenia | 1 | 0 |
| <i>Haemoglobinopathies congenital</i> | | |
| Congenital methaemoglobinaemia | 1 | 0 |
| <i>Inborn errors of metabolism NEC</i> | | |
| Alpha-1 antitrypsin deficiency | 1 | 0 |
| <i>Inborn errors of porphyrin metabolism</i> | | |
| Porphyria | 1 | 0 |
| <i>Lymphatic system disorders congenital</i> | | |
| Cystic lymphangioma | 3 | 0 |
| <i>Male reproductive tract disorders congenital</i> | | |
| Cryptorchism | 1 | 0 |
| Micropenis | 3 | 0 |
| Phimosis | 1 | 0 |
| <i>Musculoskeletal and connective tissue disorders of limbs congenital</i> | | |
| Developmental hip dysplasia | 1 | 0 |
| <i>Musculoskeletal and connective tissue disorders of spine congenital</i> | | |
| Brachyolmia | 1 | 0 |
| <i>Neurological disorders congenital NEC</i> | | |
| Familial hemiplegic migraine | 2 | 0 |
| Familial periodic paralysis | 1 | 0 |
| Moebius II syndrome | 1 | 0 |

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| Congenital disorders Congenital disorders cont'd | | |
| Tourette's disorder | 2 | 0 |
| Ocular disorders congenital NEC | | |
| Colour blindness | 4 | 0 |
| Palate disorders congenital | | |
| Cleft lip and palate | 2 | 0 |
| Peripheral nervous system disorders congenital NEC | | |
| Hereditary neuropathy with liability to pressure palsies | 1 | 0 |
| Paroxysmal extreme pain disorder | 1 | 0 |
| Pulmonary and bronchial disorders congenital | | |
| Congenital cystic lung | 1 | 0 |
| Retinal disorders congenital | | |
| Retinitis pigmentosa | 1 | 0 |
| Skin and subcutaneous tissue disorders congenital NEC | | |
| Acral peeling skin syndrome | 1 | 0 |
| Tongue disorders congenital | | |
| Ankyloglossia congenital | 1 | 0 |
| Congenital disorders SOC TOTAL | 68 | 0 |

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|---|-------|-------|
| Ear disorders | | |
| <i>Ear disorders NEC</i> | | |
| Ear canal erythema | 1 | 0 |
| Ear congestion | 28 | 0 |
| Ear discomfort | 85 | 0 |
| Ear disorder | 14 | 0 |
| Ear haemorrhage | 9 | 0 |
| Ear pain | 866 | 0 |
| Ear pruritus | 9 | 0 |
| Ear swelling | 31 | 0 |
| Otorrhoea | 4 | 0 |
| <i>Eustachian tube disorders</i> | | |
| Eustachian tube disorder | 4 | 0 |
| Eustachian tube dysfunction | 8 | 0 |
| Eustachian tube obstruction | 4 | 0 |
| <i>External ear disorders NEC</i> | | |
| Auricular swelling | 1 | 0 |
| Excessive cerumen production | 8 | 0 |
| External ear pain | 2 | 0 |
| Red ear syndrome | 2 | 0 |
| <i>External ear infections and inflammations</i> | | |
| External ear inflammation | 2 | 0 |
| <i>Hearing disorders NEC</i> | | |
| Auditory disorder | 7 | 0 |
| Diplacusis | 2 | 0 |
| <i>Hearing losses</i> | | |
| Conductive deafness | 1 | 0 |
| Deafness | 211 | 0 |
| Deafness bilateral | 6 | 0 |
| Deafness neurosensory | 17 | 0 |
| Deafness transitory | 6 | 0 |
| Deafness unilateral | 29 | 0 |
| Hypoacusis | 161 | 0 |
| Sudden hearing loss | 39 | 0 |
| <i>Hyperacusia</i> | | |
| Hyperacusis | 49 | 0 |
| Misophonia | 3 | 0 |
| <i>Inner ear disorders NEC</i> | | |
| Acute vestibular syndrome | 1 | 0 |
| Inner ear disorder | 12 | 0 |
| Meniere's disease | 11 | 0 |
| Vestibular disorder | 10 | 0 |
| <i>Inner ear infections and inflammations</i> | | |
| Inner ear inflammation | 8 | 0 |
| <i>Inner ear signs and symptoms</i> | | |
| Motion sickness | 53 | 0 |
| Tinnitus | 1717 | 0 |
| Vertigo | 1219 | 0 |
| Vertigo labyrinthine | 9 | 0 |
| Vertigo positional | 68 | 0 |
| <i>Mastoid disorders</i> | | |
| Mastoid effusion | 1 | 0 |
| <i>Middle ear disorders NEC</i> | | |
| Middle ear disorder | 3 | 0 |

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|---|-------------|----------|
| Ear disorders Ear disorders cont'd | | |
| Middle ear effusion | 1 | 0 |
| <i>Middle ear infections and inflammations</i> | | |
| Middle ear inflammation | 1 | 0 |
| <i>Tympanic membrane disorders (excl infections)</i> | | |
| Tympanic membrane perforation | 3 | 0 |
| Ear disorders SOC TOTAL | 4726 | 0 |

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|---|------------|----------|
| Endocrine disorders | | |
| <i>Acute and chronic thyroiditis</i> | | |
| Autoimmune thyroiditis | 2 | 0 |
| Thyroiditis | 15 | 0 |
| Thyroiditis acute | 2 | 0 |
| Thyroiditis subacute | 3 | 0 |
| <i>Adrenal cortical hypofunctions</i> | | |
| Addison's disease | 2 | 0 |
| Adrenal insufficiency | 2 | 0 |
| Adrenocortical insufficiency acute | 13 | 0 |
| <i>Adrenal gland disorders NEC</i> | | |
| Adrenal haemorrhage | 2 | 0 |
| <i>Anterior pituitary hyperfunction</i> | | |
| Pituitary-dependent Cushing's syndrome | 1 | 0 |
| <i>Anterior pituitary hypofunction</i> | | |
| Hypopituitarism | 1 | 0 |
| <i>Endocrine abnormalities of gonadal function NEC</i> | | |
| Oestrogen deficiency | 1 | 0 |
| <i>Endocrine abnormalities of puberty</i> | | |
| Delayed menarche | 4 | 0 |
| Premature menarche | 16 | 0 |
| <i>Female gonadal function disorders</i> | | |
| Anovulatory cycle | 44 | 0 |
| Ovulation delayed | 30 | 0 |
| <i>Thyroid disorders NEC</i> | | |
| Autoimmune thyroid disorder | 1 | 0 |
| Goitre | 12 | 0 |
| Thyroid disorder | 7 | 0 |
| Thyroid mass | 1 | 0 |
| Thyroid pain | 6 | 0 |
| <i>Thyroid hyperfunction disorders</i> | | |
| Basedow's disease | 8 | 0 |
| Hyperthyroidism | 30 | 0 |
| Thyrotoxic crisis | 3 | 0 |
| <i>Thyroid hypofunction disorders</i> | | |
| Autoimmune hypothyroidism | 1 | 0 |
| Hypothyroidism | 24 | 0 |
| Myxoedema | 1 | 0 |
| Endocrine disorders SOC TOTAL | 232 | 0 |

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| Eye disorders | | |
| <i>Amblyopic vision impairment</i> | | |
| Amblyopia | 6 | 0 |
| <i>Cataract conditions</i> | | |
| Cataract | 11 | 0 |
| <i>Choroid and vitreous haemorrhages and vascular disorders</i> | | |
| Choroidal haemorrhage | 1 | 0 |
| Choroidal neovascularisation | 1 | 0 |
| Vitreous haemorrhage | 3 | 0 |
| <i>Choroid and vitreous structural change, deposit and degeneration</i> | | |
| Chorioretinopathy | 5 | 0 |
| Vitreous detachment | 17 | 0 |
| Vitreous floaters | 77 | 0 |
| <i>Colour blindness (incl acquired)</i> | | |
| Dyschromatopsia | 8 | 0 |
| <i>Conjunctival and corneal bleeding and vascular disorders</i> | | |
| Conjunctival haemorrhage | 35 | 0 |
| <i>Conjunctival infections, irritations and inflammations</i> | | |
| Conjunctival hyperaemia | 2 | 0 |
| Conjunctival irritation | 1 | 0 |
| Conjunctival oedema | 3 | 0 |
| Conjunctivitis allergic | 1 | 0 |
| <i>Corneal infections, oedemas and inflammations</i> | | |
| Corneal oedema | 2 | 0 |
| Keratitis | 6 | 0 |
| Ulcerative keratitis | 5 | 0 |
| <i>Eyelid movement disorders</i> | | |
| Blepharospasm | 134 | 0 |
| Excessive eye blinking | 5 | 0 |
| Eyelid function disorder | 3 | 0 |
| Eyelid myokymia | 4 | 0 |
| Eyelid ptosis | 40 | 0 |
| Paralytic lagophthalmos | 2 | 0 |
| <i>Glaucomas (excl congenital)</i> | | |
| Angle closure glaucoma | 2 | 0 |
| Glaucoma | 6 | 0 |
| <i>Iris and ciliary body structural change, deposit and degeneration</i> | | |
| Eye colour change | 2 | 0 |
| <i>Iris and uveal tract infections, irritations and inflammations</i> | | |
| Autoimmune uveitis | 1 | 0 |
| Iridocyclitis | 14 | 0 |
| Iritis | 6 | 0 |
| Uveitis | 43 | 0 |
| <i>Lacrimation disorders</i> | | |
| Dry eye | 130 | 0 |
| Lacrimation increased | 118 | 0 |
| <i>Lid bleeding and vascular disorders</i> | | |
| Eyelid bleeding | 1 | 0 |
| <i>Lid, lash and lacrimal infections, irritations and inflammations</i> | | |
| Blepharitis | 13 | 0 |
| Chalazion | 7 | 0 |
| Eczema eyelids | 7 | 0 |
| Erythema of eyelid | 8 | 0 |
| Eyelid cyst | 4 | 0 |

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| Eye disorders Eye disorders cont'd | | |
| Eyelid irritation | 2 | 0 |
| Eyelid margin crusting | 4 | 0 |
| Eyelid oedema | 5 | 0 |
| Eyelid rash | 16 | 0 |
| Swelling of eyelid | 111 | 0 |
| Swollen tear duct | 1 | 0 |
| Lid, lash and lacrimal structural disorders | | |
| 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 |
| Ocular bleeding and vascular disorders NEC | | |
| Eye haematoma | 4 | 0 |
| Eye haemorrhage | 25 | 0 |
| Ocular vascular disorder | 1 | 0 |
| Ophthalmic vein thrombosis | 1 | 0 |
| Ocular disorders NEC | | |
| Dark circles under eyes | 6 | 0 |
| Eye disorder | 31 | 0 |
| Eye oedema | 15 | 0 |
| Eye pain | 937 | 0 |
| Eye swelling | 448 | 0 |
| Eye symptom | 9 | 0 |
| Eye ulcer | 3 | 0 |
| Eyelid disorder | 11 | 0 |
| Eyelid pain | 11 | 0 |
| Eyelids pruritus | 6 | 0 |
| Ocular discomfort | 25 | 0 |
| Periorbital oedema | 17 | 0 |
| Periorbital pain | 1 | 0 |
| Periorbital swelling | 108 | 0 |
| Retinal disorder | 2 | 0 |
| Vitreous disorder | 1 | 0 |
| Ocular infections, inflammations and associated manifestations | | |
| Eye allergy | 12 | 0 |
| Eye discharge | 25 | 0 |
| Eye inflammation | 23 | 0 |
| Eye irritation | 82 | 0 |
| Eye pruritus | 211 | 0 |
| Limbal swelling | 2 | 0 |
| Ocular hyperaemia | 192 | 0 |
| Ocular nerve and muscle disorders | | |
| Binocular eye movement disorder | 1 | 0 |
| Extraocular muscle disorder | 1 | 0 |
| Extraocular muscle paresis | 1 | 0 |
| Eye movement disorder | 30 | 0 |
| Gaze palsy | 1 | 0 |
| Ocular myasthenia | 1 | 0 |

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| Eye disorders Eye disorders cont'd | | |
| Ophthalmoplegia | 4 | 0 |
| Strabismus | 5 | 0 |
| Ocular sensation disorders | | |
| Abnormal sensation in eye | 17 | 0 |
| Asthenopia | 136 | 0 |
| Eye paraesthesia | 2 | 0 |
| Eyelid sensory disorder | 1 | 0 |
| Foreign body sensation in eyes | 16 | 0 |
| Hypoaesthesia eye | 14 | 0 |
| Photophobia | 403 | 0 |
| Optic disc abnormalities NEC | | |
| Papilloedema | 5 | 0 |
| Optic nerve bleeding and vascular disorders | | |
| Optic disc haemorrhage | 1 | 0 |
| Optic ischaemic neuropathy | 2 | 0 |
| Orbital infections, inflammations and irritations | | |
| Parophthalmia | 1 | 0 |
| Orbital structural change, deposit and degeneration | | |
| Orbital oedema | 2 | 0 |
| Pupil disorders | | |
| Miosis | 2 | 0 |
| Mydriasis | 21 | 0 |
| Pupil fixed | 2 | 0 |
| Pupils unequal | 12 | 0 |
| Refractive and accommodative disorders | | |
| Accommodation disorder | 1 | 0 |
| Altered visual depth perception | 2 | 0 |
| Astigmatism | 2 | 0 |
| Hypermetropia | 2 | 0 |
| Myopia | 1 | 0 |
| Retinal bleeding and vascular disorders (excl retinopathy) | | |
| Retinal artery occlusion | 9 | 0 |
| Retinal artery thrombosis | 1 | 0 |
| Retinal haemorrhage | 7 | 0 |
| Retinal vascular thrombosis | 1 | 0 |
| Retinal vein occlusion | 30 | 0 |
| Retinal vein thrombosis | 2 | 0 |
| Retinal structural change, deposit and degeneration | | |
| Macular degeneration | 4 | 0 |
| Macular hole | 2 | 0 |
| Macular rupture | 1 | 0 |
| Maculopathy | 1 | 0 |
| Neovascular age-related macular degeneration | 2 | 0 |
| Retinal degeneration | 1 | 0 |
| Retinal detachment | 4 | 0 |
| Retinal tear | 2 | 0 |
| Retinal toxicity | 3 | 0 |
| Retinal, choroid and vitreous infections and inflammations | | |
| Birdshot chorioretinopathy | 2 | 0 |
| Cystoid macular oedema | 1 | 0 |
| Macular oedema | 4 | 0 |
| Retinal vasculitis | 3 | 0 |
| Retinopathies NEC | | |

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| Reaction Name | Total | Fatal |
|---|-------------|----------|
| Eye disorders Eye disorders cont'd | | |
| Acute macular outer retinopathy | 1 | 0 |
| Retinal exudates | 2 | 0 |
| Retinopathy | 2 | 0 |
| <i>Scleral infections, irritations and inflammations</i> | | |
| Episcleritis | 7 | 0 |
| Scleritis | 3 | 0 |
| <i>Scleral structural change, deposit and degeneration</i> | | |
| Scleral discolouration | 2 | 0 |
| <i>Structural change, deposit and degeneration of eye NEC</i> | | |
| Exophthalmos | 1 | 0 |
| <i>Visual colour distortions</i> | | |
| Chloropsia | 2 | 0 |
| Chromatopsia | 1 | 0 |
| Cyanopsia | 2 | 0 |
| Erythropsia | 2 | 0 |
| Xanthopsia | 1 | 0 |
| <i>Visual disorders NEC</i> | | |
| Charles Bonnet syndrome | 2 | 0 |
| Diplopia | 142 | 0 |
| Glare | 1 | 0 |
| Halo vision | 7 | 0 |
| Heteronymous diplopia | 1 | 0 |
| Metamorphopsia | 17 | 0 |
| Oscillopsia | 2 | 0 |
| Photopsia | 116 | 0 |
| Scintillating scotoma | 4 | 0 |
| Vision blurred | 1054 | 0 |
| Visual brightness | 3 | 0 |
| Visual snow syndrome | 7 | 0 |
| <i>Visual field disorders</i> | | |
| Visual field defect | 24 | 0 |
| <i>Visual impairment and blindness (excl colour blindness)</i> | | |
| Amaurosis fugax | 2 | 0 |
| Blindness | 112 | 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 | 21 | 0 |
| Visual acuity reduced transiently | 1 | 0 |
| Visual impairment | 308 | 0 |
| <i>Visual pathway disorders</i> | | |
| Optic nerve disorder | 1 | 0 |
| Eye disorders SOC TOTAL | 5749 | 0 |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Gastrointestinal disorders | | |
| <i>Abdominal findings abnormal</i> | | |
| Abdominal mass | 2 | 0 |
| Gastrointestinal sounds abnormal | 16 | 0 |
| <i>Abdominal hernias NEC</i> | | |
| Abdominal hernia | 2 | 0 |
| <i>Abdominal wall conditions NEC</i> | | |
| Abdominal wall haematoma | 1 | 0 |
| <i>Acute and chronic pancreatitis</i> | | |
| Alcoholic pancreatitis | 1 | 0 |
| Obstructive pancreatitis | 1 | 0 |
| Pancreatitis | 13 | 0 |
| Pancreatitis acute | 13 | 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 | 9 | 0 |
| <i>Anal and rectal signs and symptoms</i> | | |
| Anal hypoaesthesia | 1 | 0 |
| Anal spasm | 1 | 0 |
| Anorectal discomfort | 4 | 0 |
| Anorectal swelling | 1 | 0 |
| Rectal discharge | 1 | 0 |
| Rectal tenesmus | 1 | 0 |
| <i>Benign oral cavity neoplasms</i> | | |
| Mouth cyst | 5 | 0 |
| Tongue cyst | 4 | 0 |
| <i>Colitis (excl infective)</i> | | |
| Autoimmune colitis | 1 | 0 |
| Colitis | 38 | 1 |
| Colitis ischaemic | 1 | 0 |
| Colitis microscopic | 1 | 0 |
| Colitis ulcerative | 62 | 0 |
| Crohn's disease | 37 | 0 |
| Eosinophilic colitis | 1 | 0 |
| Inflammatory bowel disease | 5 | 0 |
| <i>Dental and periodontal infections and inflammations</i> | | |
| Dental caries | 1 | 0 |
| <i>Dental disorders NEC</i> | | |
| Loose tooth | 1 | 0 |
| Malpositioned teeth | 2 | 0 |
| Periodontal disease | 1 | 0 |
| Teeth brittle | 3 | 0 |
| Teething | 6 | 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 | 137 | 0 |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Gastrointestinal disorders | | |
| <i>Gastrointestinal disorders cont'd</i> | | |
| <i>Dental surface disorders</i> | | |
| Tooth discolouration | 9 | 0 |
| <i>Diaphragmatic hernias</i> | | |
| Hiatus hernia | 5 | 0 |
| <i>Diarrhoea (excl infective)</i> | | |
| Diarrhoea | 4578 | 2 |
| Diarrhoea haemorrhagic | 19 | 0 |
| <i>Diverticula</i> | | |
| Diverticulum | 4 | 0 |
| Diverticulum intestinal | 1 | 0 |
| <i>Duodenal and small intestinal stenosis and obstruction</i> | | |
| Small intestinal obstruction | 1 | 0 |
| <i>Duodenal ulcers and perforation</i> | | |
| Duodenal ulcer haemorrhage | 1 | 0 |
| Duodenal ulcer perforation | 3 | 0 |
| <i>Dyspeptic signs and symptoms</i> | | |
| Dyspepsia | 371 | 0 |
| Epigastric discomfort | 13 | 0 |
| Eructation | 43 | 0 |
| <i>Faecal abnormalities NEC</i> | | |
| Abnormal faeces | 19 | 0 |
| Faecaloma | 4 | 0 |
| Faeces discoloured | 55 | 0 |
| Faeces hard | 2 | 0 |
| Faeces pale | 3 | 0 |
| Faeces soft | 10 | 0 |
| Mucous stools | 9 | 0 |
| <i>Flatulence, bloating and distension</i> | | |
| Abdominal distension | 463 | 0 |
| Aerophagia | 3 | 0 |
| Flatulence | 163 | 0 |
| <i>Gastric and oesophageal haemorrhages</i> | | |
| Gastric haemorrhage | 5 | 1 |
| Mallory-Weiss syndrome | 1 | 0 |
| Oesophageal varices haemorrhage | 1 | 0 |
| <i>Gastric ulcers and perforation</i> | | |
| Gastric ulcer | 6 | 0 |
| <i>Gastritis (excl infective)</i> | | |
| Chronic gastritis | 2 | 0 |
| Gastritis | 46 | 0 |
| Reflux gastritis | 5 | 0 |
| <i>Gastrointestinal and abdominal pains (excl oral and throat)</i> | | |
| Abdominal migraine | 2 | 0 |
| Abdominal pain | 1244 | 0 |
| Abdominal pain lower | 115 | 0 |
| Abdominal pain upper | 2054 | 0 |
| Abdominal rigidity | 22 | 0 |
| Abdominal tenderness | 10 | 0 |
| Gastrointestinal pain | 114 | 0 |
| Oesophageal pain | 7 | 0 |
| <i>Gastrointestinal atonic and hypomotility disorders NEC</i> | | |
| Constipation | 222 | 0 |
| Duodenogastric reflux | 4 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Gastrointestinal disorders | | |
| <i>Gastrointestinal disorders cont'd</i> | | |
| Gastric dilatation | 7 | 0 |
| Gastroesophageal reflux disease | 128 | 0 |
| Impaired gastric emptying | 8 | 0 |
| Infrequent bowel movements | 3 | 0 |
| Intestinal dilatation | 1 | 0 |
| Intestinal pseudo-obstruction | 2 | 0 |
| <i>Gastrointestinal disorders NEC</i> | | |
| Appendix disorder | 1 | 0 |
| Food poisoning | 7 | 0 |
| Functional gastrointestinal disorder | 9 | 0 |
| Gastric disorder | 7 | 0 |
| Gastrointestinal disorder | 19 | 0 |
| Stomach mass | 4 | 0 |
| <i>Gastrointestinal dyskinetic disorders</i> | | |
| Bowel movement irregularity | 6 | 0 |
| Change of bowel habit | 5 | 0 |
| Dyschezia | 2 | 0 |
| Gastrointestinal motility disorder | 2 | 0 |
| Oesophageal achalasia | 1 | 0 |
| <i>Gastrointestinal fistulae</i> | | |
| Diverticular fistula | 2 | 0 |
| <i>Gastrointestinal inflammatory disorders NEC</i> | | |
| Duodenitis | 1 | 0 |
| Enteritis | 6 | 0 |
| Epiploic appendagitis | 2 | 0 |
| Gastrointestinal inflammation | 3 | 0 |
| Intestinal angioedema | 2 | 0 |
| <i>Gastrointestinal mucosal dystrophies and secretion disorders</i> | | |
| Hyperchlorhydria | 4 | 0 |
| <i>Gastrointestinal signs and symptoms NEC</i> | | |
| Abdominal discomfort | 526 | 0 |
| Abdominal symptom | 1 | 0 |
| Acute abdomen | 5 | 0 |
| Anal incontinence | 19 | 0 |
| Breath odour | 17 | 0 |
| Dysphagia | 184 | 1 |
| Odynophagia | 30 | 0 |
| <i>Gastrointestinal spastic and hypermotility disorders</i> | | |
| Cardiospasm | 1 | 0 |
| Defaecation urgency | 9 | 0 |
| Frequent bowel movements | 23 | 0 |
| Gastrointestinal hypermotility | 1 | 0 |
| Irritable bowel syndrome | 76 | 0 |
| Oesophageal spasm | 3 | 0 |
| Pylorospasm | 1 | 0 |
| <i>Gastrointestinal stenosis and obstruction NEC</i> | | |
| Intestinal obstruction | 3 | 0 |
| Neonatal intestinal obstruction | 1 | 0 |
| <i>Gastrointestinal vascular malformations</i> | | |
| Gastric antral vascular ectasia | 10 | 0 |
| <i>Gastrointestinal vascular occlusion and infarction</i> | | |
| Intestinal ischaemia | 5 | 2 |
| Mesenteric vein thrombosis | 6 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Gastrointestinal disorders | | |
| <i>Gastrointestinal disorders cont'd</i> | | |
| Omental infarction | 1 | 0 |
| Thrombosis mesenteric vessel | 2 | 0 |
| Visceral venous thrombosis | 1 | 0 |
| <i>Gingival disorders, signs and symptoms NEC</i> | | |
| Gingival blister | 11 | 0 |
| Gingival discomfort | 5 | 0 |
| Gingival disorder | 3 | 0 |
| Gingival erythema | 2 | 0 |
| Gingival hypertrophy | 1 | 0 |
| Gingival oedema | 1 | 0 |
| Gingival pain | 94 | 0 |
| Gingival pruritus | 1 | 0 |
| Gingival swelling | 31 | 0 |
| Gingival ulceration | 1 | 0 |
| Gingivitis ulcerative | 1 | 0 |
| Noninfective gingivitis | 7 | 0 |
| <i>Gingival haemorrhages</i> | | |
| Gingival bleeding | 56 | 0 |
| <i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i> | | |
| Gastric varices | 1 | 0 |
| Haemorrhoidal haemorrhage | 1 | 0 |
| Haemorrhoids | 28 | 0 |
| Haemorrhoids thrombosed | 1 | 0 |
| <i>Inguinal hernias</i> | | |
| Inguinal hernia | 1 | 0 |
| <i>Intestinal haemorrhages</i> | | |
| Anal haemorrhage | 17 | 1 |
| Intestinal haemorrhage | 1 | 0 |
| Rectal haemorrhage | 62 | 0 |
| Small intestinal haemorrhage | 5 | 0 |
| <i>Intestinal ulcers and perforation NEC</i> | | |
| Intestinal perforation | 5 | 2 |
| Large intestinal ulcer | 1 | 0 |
| Large intestine perforation | 1 | 0 |
| <i>Malabsorption syndromes</i> | | |
| Bile acid malabsorption | 2 | 0 |
| Coeliac disease | 9 | 0 |
| Malabsorption | 1 | 0 |
| Steatorrhoea | 4 | 0 |
| <i>Nausea and vomiting symptoms</i> | | |
| Discoloured vomit | 12 | 0 |
| Infantile vomiting | 7 | 0 |
| Nausea | 11923 | 0 |
| Regurgitation | 1 | 0 |
| Retching | 90 | 0 |
| Vomiting | 3680 | 1 |
| Vomiting projectile | 53 | 0 |
| <i>Non-mechanical ileus</i> | | |
| Ileus paralytic | 1 | 0 |
| <i>Non-site specific gastrointestinal haemorrhages</i> | | |
| Gastrointestinal haemorrhage | 14 | 1 |
| Haematemesis | 26 | 2 |
| Haematochezia | 48 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Gastrointestinal disorders | | |
| <i>Gastrointestinal disorders cont'd</i> | | |
| Melaena | 8 | 0 |
| Upper gastrointestinal haemorrhage | 6 | 0 |
| <i>Oesophageal stenosis and obstruction</i> | | |
| Oesophageal stenosis | 3 | 0 |
| <i>Oesophagitis (excl infective)</i> | | |
| Eosinophilic oesophagitis | 1 | 0 |
| Oesophagitis | 3 | 0 |
| <i>Oral dryness and saliva altered</i> | | |
| Aptyalism | 3 | 0 |
| Dry mouth | 435 | 0 |
| Lip dry | 36 | 0 |
| Saliva altered | 6 | 0 |
| Salivary hypersecretion | 44 | 0 |
| <i>Oral soft tissue disorders NEC</i> | | |
| Angina bullosa haemorrhagica | 1 | 0 |
| Chapped lips | 19 | 0 |
| Cheilitis | 23 | 0 |
| Enlarged uvula | 14 | 0 |
| Leukoplakia oral | 2 | 0 |
| Lip blister | 26 | 0 |
| Lip disorder | 4 | 0 |
| Oral disorder | 15 | 0 |
| Oral lichen planus | 10 | 0 |
| Oral mucosal hypertrophy | 1 | 0 |
| Oral papule | 1 | 0 |
| Uvulitis | 2 | 0 |
| <i>Oral soft tissue haemorrhages</i> | | |
| Mouth haemorrhage | 12 | 0 |
| Oral blood blister | 10 | 0 |
| Oral purpura | 2 | 0 |
| <i>Oral soft tissue infections</i> | | |
| Angular cheilitis | 2 | 0 |
| <i>Oral soft tissue signs and symptoms</i> | | |
| Anaesthesia oral | 2 | 0 |
| Burning mouth syndrome | 6 | 0 |
| Coating in mouth | 1 | 0 |
| Hypoaesthesia oral | 422 | 0 |
| Lip discolouration | 7 | 0 |
| Lip erythema | 2 | 0 |
| Lip exfoliation | 5 | 0 |
| Lip pain | 47 | 0 |
| Lip pruritus | 14 | 0 |
| Lip scab | 1 | 0 |
| Oral discomfort | 73 | 0 |
| Oral dysaesthesia | 1 | 0 |
| Oral mucosal blistering | 13 | 0 |
| Oral mucosal discolouration | 1 | 0 |
| Oral mucosal eruption | 13 | 0 |
| Oral mucosal erythema | 5 | 0 |
| Oral mucosal exfoliation | 8 | 0 |
| Oral mucosal roughening | 3 | 0 |
| Oral mucosal scab | 1 | 0 |
| Oral pain | 147 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Gastrointestinal disorders | | |
| Gastrointestinal disorders cont'd | | |
| Oral pruritus | 20 | 0 |
| Paraesthesia oral | 826 | 0 |
| Pigmentation lip | 1 | 0 |
| Oral soft tissue swelling and oedema | | |
| Lip oedema | 4 | 0 |
| Lip swelling | 641 | 0 |
| Mouth swelling | 79 | 0 |
| Oedema mouth | 4 | 0 |
| Palatal oedema | 3 | 0 |
| Palatal swelling | 2 | 0 |
| Pancreatic disorders NEC | | |
| Pancreatic mass | 1 | 0 |
| Peptic ulcers and perforation | | |
| Peptic ulcer | 1 | 0 |
| Peptic ulcer haemorrhage | 11 | 0 |
| Peritoneal and retroperitoneal disorders | | |
| Ascites | 1 | 0 |
| Peritoneal and retroperitoneal fibrosis and adhesions | | |
| Abdominal adhesions | 1 | 0 |
| Peritoneal and retroperitoneal haemorrhages | | |
| Haemoperitoneum | 1 | 0 |
| Retroperitoneal haemorrhage | 1 | 1 |
| Rectal inflammations NEC | | |
| Proctitis | 3 | 0 |
| Proctitis ulcerative | 1 | 0 |
| Salivary gland disorders NEC | | |
| Salivary gland disorder | 1 | 0 |
| Salivary gland pain | 12 | 0 |
| Salivary gland enlargements | | |
| Parotid gland enlargement | 9 | 0 |
| Salivary gland enlargement | 5 | 0 |
| Submaxillary gland enlargement | 7 | 0 |
| Salivary gland infections and inflammations | | |
| Noninfective sialoadenitis | 1 | 0 |
| Stomatitis and ulceration | | |
| Aphthous ulcer | 43 | 0 |
| Lip ulceration | 16 | 0 |
| Mouth ulceration | 387 | 0 |
| Oral mucosa erosion | 1 | 0 |
| Palatal ulcer | 1 | 0 |
| Stomatitis | 57 | 0 |
| Tongue disorders | | |
| Glossitis | 17 | 0 |
| Hypertrophy of tongue papillae | 1 | 0 |
| Plicated tongue | 3 | 0 |
| Tongue disorder | 34 | 0 |
| Tongue geographic | 1 | 0 |
| Tongue haemorrhage | 3 | 0 |
| Tongue ulceration | 29 | 0 |
| Trichoglossia | 4 | 0 |
| Tongue signs and symptoms | | |
| Glossodynia | 181 | 0 |
| Scalloped tongue | 5 | 0 |

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| Reaction Name | Total | Fatal |
|---|--------------|-----------|
| Gastrointestinal disorders | | |
| <i>Gastrointestinal disorders cont'd</i> | | |
| Stiff tongue | 4 | 0 |
| Swollen tongue | 423 | 0 |
| Tongue blistering | 16 | 0 |
| Tongue coated | 16 | 0 |
| Tongue discolouration | 33 | 0 |
| Tongue discomfort | 38 | 0 |
| Tongue dry | 13 | 0 |
| Tongue eruption | 9 | 0 |
| Tongue erythema | 9 | 0 |
| Tongue exfoliation | 1 | 0 |
| Tongue movement disturbance | 6 | 0 |
| Tongue oedema | 20 | 0 |
| Tongue pruritus | 2 | 0 |
| Tongue rough | 4 | 0 |
| Tongue spasm | 8 | 0 |
| <i>Tooth missing</i> | | |
| Tooth loss | 6 | 0 |
| Gastrointestinal disorders SOC TOTAL | 31924 | 16 |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| General disorders | | |
| <i>Administration site reactions NEC</i> | | |
| Administration site bruise | 6 | 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 | 15 | 0 |
| Administration site rash | 4 | 0 |
| Administration site reaction | 1 | 0 |
| Administration site swelling | 3 | 0 |
| Administration site urticaria | 2 | 0 |
| Administration site warmth | 2 | 0 |
| Puncture site bruise | 32 | 0 |
| Puncture site pain | 6 | 0 |
| Puncture site reaction | 1 | 0 |
| Puncture site swelling | 2 | 0 |
| Vessel puncture site bruise | 2 | 0 |
| Vessel puncture site erythema | 1 | 0 |
| Vessel puncture site pain | 1 | 0 |
| <i>Adverse effect absent</i> | | |
| No adverse event | 3 | 0 |
| <i>Application and instillation site reactions</i> | | |
| Application site acne | 2 | 0 |
| Application site bruise | 8 | 0 |
| Application site burn | 1 | 0 |
| Application site erythema | 13 | 0 |
| Application site haemorrhage | 1 | 0 |
| Application site hypoaesthesia | 1 | 0 |
| Application site irritation | 1 | 0 |
| Application site joint erythema | 1 | 0 |
| Application site joint pain | 1 | 0 |
| Application site mass | 1 | 0 |
| Application site odour | 2 | 0 |
| Application site pain | 12 | 0 |
| Application site pruritus | 4 | 0 |
| Application site rash | 2 | 0 |
| Application site reaction | 1 | 0 |
| Application site swelling | 2 | 0 |
| Application site vesicles | 6 | 0 |
| Application site warmth | 1 | 0 |
| Instillation site warmth | 5 | 0 |
| <i>Asthenic conditions</i> | | |
| Asthenia | 1587 | 0 |
| Chronic fatigue syndrome | 65 | 0 |
| Decreased activity | 9 | 0 |
| Fatigue | 19043 | 0 |
| Malaise | 4291 | 0 |
| Sluggishness | 12 | 0 |
| <i>Body temperature altered</i> | | |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| General disorders General disorders cont'd | | |
| Hyperthermia | 5 | 0 |
| Hypothermia | 21 | 0 |
| Temperature regulation disorder | 10 | 0 |
| Breast complications associated with device | | |
| Breast implant palpable | 1 | 0 |
| Capsular contracture associated with breast implant | 1 | 0 |
| Cardiac complications associated with device | | |
| Prosthetic cardiac valve thrombosis | 2 | 0 |
| Complications associated with device NEC | | |
| Capsular contracture associated with implant | 1 | 0 |
| Complication of device removal | 3 | 0 |
| Injury associated with device | 3 | 0 |
| Medical device pain | 1 | 0 |
| Medical device site swelling | 1 | 0 |
| Phantom shocks | 1 | 0 |
| Death and sudden death | | |
| Brain death | 3 | 2 |
| Cardiac death | 1 | 1 |
| Clinical death | 1 | 1 |
| Death | 150 | 150 |
| Drowning | 1 | 0 |
| Sudden death | 26 | 26 |
| Febrile disorders | | |
| Hyperpyrexia | 9 | 0 |
| Pyrexia | 12371 | 0 |
| Feelings and sensations NEC | | |
| Chills | 7845 | 0 |
| Feeling abnormal | 1355 | 0 |
| Feeling cold | 951 | 0 |
| Feeling drunk | 71 | 0 |
| Feeling hot | 980 | 0 |
| Feeling jittery | 21 | 0 |
| Feeling of body temperature change | 281 | 0 |
| Feeling of relaxation | 3 | 0 |
| Hangover | 74 | 0 |
| Hunger | 40 | 0 |
| Sensation of blood flow | 3 | 0 |
| Sensation of foreign body | 47 | 0 |
| Temperature intolerance | 37 | 0 |
| Thirst | 291 | 0 |
| Fibrosis NEC | | |
| Fibrosis | 1 | 0 |
| Gait disturbances | | |
| Gait disturbance | 194 | 0 |
| Gait inability | 64 | 0 |
| Loss of control of legs | 17 | 0 |
| General signs and symptoms NEC | | |
| Adhesion | 1 | 0 |
| Chronic disease | 1 | 0 |
| Condition aggravated | 183 | 0 |
| Crepitations | 1 | 0 |
| Crying | 138 | 0 |
| Deformity | 2 | 0 |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| General disorders General disorders cont'd | | |
| Discharge | 10 | 0 |
| Disease progression | 2 | 0 |
| Disease recurrence | 25 | 0 |
| Effusion | 3 | 0 |
| Energy increased | 19 | 0 |
| Exercise tolerance decreased | 20 | 0 |
| Foaming at mouth | 1 | 0 |
| General physical health deterioration | 15 | 2 |
| General symptom | 3 | 0 |
| Glassy eyes | 4 | 0 |
| High-pitched crying | 3 | 0 |
| Illness | 1542 | 0 |
| Induration | 14 | 0 |
| Influenza like illness | 1941 | 0 |
| Irritability postvaccinal | 2 | 0 |
| Local reaction | 69 | 0 |
| Moaning | 3 | 0 |
| Multiple organ dysfunction syndrome | 9 | 4 |
| Nonspecific reaction | 1 | 0 |
| Organ failure | 1 | 1 |
| Perforation | 2 | 0 |
| Peripheral swelling | 2963 | 0 |
| Physical deconditioning | 2 | 0 |
| Pre-existing condition improved | 8 | 0 |
| Prolapse | 1 | 0 |
| Screaming | 19 | 0 |
| Secretion discharge | 18 | 0 |
| Swelling | 2407 | 0 |
| Swelling face | 697 | 0 |
| Symptom recurrence | 1 | 0 |
| Terminal state | 1 | 0 |
| Tissue irritation | 1 | 0 |
| Implant and catheter site reactions | | |
| Implant site discolouration | 2 | 0 |
| Implant site pain | 2 | 0 |
| Implant site rash | 1 | 0 |
| Implant site swelling | 1 | 0 |
| Implant site urticaria | 1 | 0 |
| Implant site warmth | 3 | 0 |
| Inflammations | | |
| Granuloma | 1 | 0 |
| Inflammation | 385 | 0 |
| Papillitis | 1 | 0 |
| Serositis | 1 | 0 |
| Systemic inflammatory response syndrome | 2 | 0 |
| Infusion site reactions | | |
| Infusion site coldness | 1 | 0 |
| Infusion site joint effusion | 1 | 0 |
| Infusion site joint pain | 2 | 0 |
| Infusion site mass | 1 | 0 |
| Infusion site nerve damage | 1 | 0 |
| Infusion site pain | 1 | 0 |
| Infusion site pruritus | 1 | 0 |

Case Series Drug Analysis Print

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

Report Run Date: 14-Oct-2021

Data Lock Date: 13-Oct-2021 18:30:20

MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|---|-------|-------|
| General disorders General disorders cont'd | | |
| Infusion site swelling | 1 | 0 |
| Infusion site urticaria | 1 | 0 |
| Infusion site warmth | 1 | 0 |
| <i>Injection site reactions</i> | | |
| Injected limb mobility decreased | 26 | 0 |
| Injection site bruising | 59 | 0 |
| Injection site coldness | 1 | 0 |
| Injection site cyst | 2 | 0 |
| Injection site discolouration | 5 | 0 |
| Injection site discomfort | 9 | 0 |
| Injection site eczema | 1 | 0 |
| Injection site erythema | 319 | 0 |
| Injection site haemorrhage | 6 | 0 |
| Injection site hypersensitivity | 2 | 0 |
| Injection site hypoaesthesia | 8 | 0 |
| Injection site indentation | 9 | 0 |
| Injection site induration | 3 | 0 |
| Injection site inflammation | 31 | 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 | 13 | 0 |
| Injection site lymphadenopathy | 1 | 0 |
| Injection site macule | 1 | 0 |
| Injection site mass | 437 | 0 |
| Injection site movement impairment | 1 | 0 |
| Injection site necrosis | 3 | 0 |
| Injection site nerve damage | 1 | 0 |
| Injection site oedema | 13 | 0 |
| Injection site pain | 2518 | 0 |
| Injection site paraesthesia | 12 | 0 |
| Injection site pruritus | 159 | 0 |
| Injection site rash | 138 | 0 |
| Injection site reaction | 24 | 0 |
| Injection site scab | 4 | 0 |
| Injection site scar | 5 | 0 |
| Injection site swelling | 255 | 0 |
| Injection site urticaria | 26 | 0 |
| Injection site vesicles | 9 | 0 |
| Injection site warmth | 164 | 0 |
| <i>Interactions</i> | | |
| Alcohol interaction | 3 | 0 |
| Drug interaction | 25 | 0 |
| Inhibitory drug interaction | 3 | 0 |
| <i>Mass conditions NEC</i> | | |
| Cyst | 38 | 0 |
| Mass | 60 | 0 |
| Nodule | 31 | 0 |
| <i>Mucosal findings abnormal</i> | | |
| Mucosa vesicle | 1 | 0 |
| Mucosal dryness | 1 | 0 |
| Mucosal haemorrhage | 8 | 0 |

Case Series Drug Analysis Print

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

Report Run Date: 14-Oct-2021

Data Lock Date: 13-Oct-2021 18:30:20

MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|---|-------|-------|
| General disorders General disorders cont'd | | |
| Mucosal inflammation | 2 | 0 |
| Oedema mucosal | 1 | 0 |
| Polyp | 5 | 0 |
| Necrosis NEC | | |
| Fat necrosis | 3 | 0 |
| Necrosis | 4 | 0 |
| Oedema NEC | | |
| Face oedema | 27 | 0 |
| Generalised oedema | 3 | 0 |
| Localised oedema | 15 | 0 |
| Oedema | 59 | 0 |
| Oedema peripheral | 75 | 0 |
| Pain and discomfort NEC | | |
| Axillary pain | 2547 | 0 |
| Chest discomfort | 1408 | 0 |
| Chest pain | 3385 | 0 |
| Discomfort | 398 | 0 |
| Facial discomfort | 19 | 0 |
| Facial pain | 180 | 0 |
| Inflammatory pain | 11 | 0 |
| Non-cardiac chest pain | 24 | 0 |
| Pain | 7378 | 0 |
| Suprapubic pain | 1 | 0 |
| Tenderness | 567 | 0 |
| Visceral pain | 2 | 0 |
| Therapeutic and nontherapeutic responses | | |
| Adverse drug reaction | 35 | 0 |
| Adverse event | 1 | 0 |
| Adverse food reaction | 2 | 0 |
| Drug ineffective | 260 | 1 |
| Drug intolerance | 3 | 0 |
| Immediate post-injection reaction | 2 | 0 |
| Inadequate analgesia | 8 | 0 |
| No reaction on previous exposure to drug | 29 | 0 |
| Product intolerance | 1 | 0 |
| Therapeutic product effect decreased | 1 | 0 |
| Therapeutic product effect delayed | 2 | 0 |
| Therapeutic product effect increased | 1 | 0 |
| Therapeutic product ineffective | 2 | 0 |
| Therapeutic response decreased | 2 | 0 |
| Therapeutic response unexpected | 70 | 0 |
| Therapy non-responder | 1 | 0 |
| Treatment failure | 6 | 0 |
| Vaccination failure | 32 | 0 |
| Trophic disorders | | |
| Atrophy | 2 | 0 |
| Calcinosis | 1 | 0 |
| Hyperplasia | 1 | 0 |
| Ulcers NEC | | |
| Ulcer | 30 | 0 |
| Ulcer haemorrhage | 1 | 0 |
| Vaccination site reactions | | |
| Extensive swelling of vaccinated limb | 11 | 0 |

Case Series Drug Analysis Print

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

Report Run Date: 14-Oct-2021

Data Lock Date: 13-Oct-2021 18:30:20

MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|--|--------------|------------|
| General disorders General disorders cont'd | | |
| Shoulder injury related to vaccine administration | 23 | 0 |
| Vaccination site anaesthesia | 1 | 0 |
| Vaccination site bruising | 107 | 0 |
| Vaccination site coldness | 2 | 0 |
| Vaccination site cyst | 5 | 0 |
| Vaccination site dermatitis | 1 | 0 |
| Vaccination site discolouration | 14 | 0 |
| Vaccination site discomfort | 42 | 0 |
| Vaccination site dryness | 1 | 0 |
| Vaccination site eczema | 1 | 0 |
| Vaccination site erythema | 531 | 0 |
| Vaccination site granuloma | 3 | 0 |
| Vaccination site haematoma | 2 | 0 |
| Vaccination site haemorrhage | 18 | 0 |
| Vaccination site hypersensitivity | 3 | 0 |
| Vaccination site hypoaesthesia | 15 | 0 |
| Vaccination site induration | 70 | 0 |
| Vaccination site inflammation | 51 | 0 |
| Vaccination site irritation | 12 | 0 |
| Vaccination site joint discomfort | 2 | 0 |
| Vaccination site joint erythema | 7 | 0 |
| Vaccination site joint inflammation | 1 | 0 |
| Vaccination site joint movement impairment | 17 | 0 |
| Vaccination site joint pain | 30 | 0 |
| Vaccination site joint swelling | 4 | 0 |
| Vaccination site joint warmth | 1 | 0 |
| Vaccination site lymphadenopathy | 5 | 0 |
| Vaccination site macule | 1 | 0 |
| Vaccination site mass | 233 | 0 |
| Vaccination site movement impairment | 74 | 0 |
| Vaccination site nerve damage | 1 | 0 |
| Vaccination site nodule | 2 | 0 |
| Vaccination site oedema | 3 | 0 |
| Vaccination site pain | 1922 | 0 |
| Vaccination site paraesthesia | 7 | 0 |
| Vaccination site phlebitis | 1 | 0 |
| Vaccination site pruritus | 141 | 0 |
| Vaccination site rash | 112 | 0 |
| Vaccination site reaction | 31 | 0 |
| Vaccination site scab | 2 | 0 |
| Vaccination site scar | 1 | 0 |
| Vaccination site swelling | 492 | 0 |
| Vaccination site thrombosis | 1 | 0 |
| Vaccination site ulcer | 1 | 0 |
| Vaccination site urticaria | 10 | 0 |
| Vaccination site vesicles | 9 | 0 |
| Vaccination site warmth | 243 | 0 |
| Vascular complications associated with device | | |
| Vascular stent thrombosis | 1 | 0 |
| Withdrawal and rebound effects | | |
| Drug withdrawal syndrome | 4 | 0 |
| Withdrawal syndrome | 33 | 0 |
| General disorders SOC TOTAL | 85952 | 188 |

Case Series Drug Analysis Print

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

Report Run Date: 14-Oct-2021

Data Lock Date: 13-Oct-2021 18:30:20

MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|--|------------|----------|
| Hepatic disorders | | |
| <i>Bile duct infections and inflammations</i> | | |
| Biliary colic | 11 | 0 |
| Cholangitis | 1 | 0 |
| <i>Cholecystitis and cholelithiasis</i> | | |
| Cholecystitis | 3 | 0 |
| Cholecystitis acute | 2 | 0 |
| Cholelithiasis | 9 | 0 |
| <i>Cholestasis and jaundice</i> | | |
| Cholestasis | 2 | 0 |
| Jaundice | 20 | 0 |
| Jaundice cholestatic | 10 | 0 |
| Ocular icterus | 2 | 0 |
| <i>Gallbladder disorders NEC</i> | | |
| Gallbladder disorder | 1 | 0 |
| <i>Hepatic and hepatobiliary disorders NEC</i> | | |
| Liver disorder | 12 | 0 |
| <i>Hepatic enzymes and function abnormalities</i> | | |
| Hepatic function abnormal | 4 | 0 |
| <i>Hepatic failure and associated disorders</i> | | |
| Acute hepatic failure | 1 | 0 |
| Hepatic failure | 2 | 1 |
| <i>Hepatic fibrosis and cirrhosis</i> | | |
| Hepatic cirrhosis | 1 | 0 |
| <i>Hepatic vascular disorders</i> | | |
| Congestive hepatopathy | 2 | 0 |
| Hepatic artery embolism | 1 | 0 |
| Hepatic haemorrhage | 2 | 0 |
| Hepatic vein thrombosis | 5 | 0 |
| Portal vein thrombosis | 6 | 0 |
| <i>Hepatobiliary signs and symptoms</i> | | |
| Hepatic pain | 23 | 0 |
| Hepatomegaly | 2 | 0 |
| Liver tenderness | 3 | 0 |
| <i>Hepatocellular damage and hepatitis NEC</i> | | |
| Autoimmune hepatitis | 7 | 0 |
| Drug-induced liver injury | 2 | 0 |
| Hepatic steatosis | 1 | 0 |
| Hepatitis | 9 | 0 |
| Immune-mediated hepatic disorder | 1 | 0 |
| Liver injury | 14 | 0 |
| Hepatic disorders SOC TOTAL | 159 | 1 |

Case Series Drug Analysis Print

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

Report Run Date: 14-Oct-2021

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MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Immune system disorders | | |
| <i>Acute and chronic sarcoidosis</i> | | |
| Sarcoidosis | 12 | 0 |
| <i>Allergic conditions NEC</i> | | |
| Allergic oedema | 14 | 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 | 828 | 0 |
| Infusion related hypersensitivity reaction | 2 | 0 |
| Mite allergy | 3 | 0 |
| Multiple allergies | 9 | 0 |
| Serum sickness | 2 | 0 |
| Serum sickness-like reaction | 4 | 0 |
| Type I hypersensitivity | 1 | 0 |
| Type III immune complex mediated reaction | 2 | 0 |
| Type IV hypersensitivity reaction | 6 | 0 |
| <i>Allergies to foods, food additives, drugs and other chemicals</i> | | |
| Allergic reaction to excipient | 5 | 0 |
| Allergy to chemicals | 3 | 0 |
| Allergy to vaccine | 34 | 0 |
| Contrast media reaction | 2 | 0 |
| Drug hypersensitivity | 24 | 0 |
| Food allergy | 26 | 0 |
| Milk allergy | 2 | 0 |
| Oral allergy syndrome | 2 | 0 |
| Reaction to colouring | 1 | 0 |
| Reaction to excipient | 8 | 0 |
| Reaction to preservatives | 5 | 0 |
| Rubber sensitivity | 1 | 0 |
| Smoke sensitivity | 1 | 0 |
| <i>Anaphylactic and anaphylactoid responses</i> | | |
| Anaphylactic reaction | 433 | 2 |
| Anaphylactic shock | 44 | 0 |
| Anaphylactoid reaction | 20 | 0 |
| Anaphylactoid shock | 4 | 0 |
| <i>Atopic disorders</i> | | |
| Atopy | 1 | 0 |
| Seasonal allergy | 101 | 0 |
| <i>Autoimmune disorders NEC</i> | | |
| Autoimmune disorder | 38 | 0 |
| <i>Immune and associated conditions NEC</i> | | |
| Anamnestic reaction | 1 | 0 |
| Bacille Calmette-Guerin scar reactivation | 47 | 0 |
| Cytokine storm | 1 | 0 |
| Decreased immune responsiveness | 1 | 0 |
| Graft versus host disease | 1 | 0 |
| Haemophagocytic lymphohistiocytosis | 2 | 0 |
| Immune reconstitution inflammatory syndrome | 1 | 0 |
| Immune system disorder | 20 | 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: 14-Oct-2021

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MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|--|-------------|----------|
| Immune system disorders | | |
| Immune system disorders cont'd | | |
| Multisystem inflammatory syndrome in children | 1 | 0 |
| Sensitisation | 4 | 0 |
| Systemic immune activation | 2 | 0 |
| <i>Immunodeficiency disorders NEC</i> | | |
| Hypogammaglobulinaemia | 1 | 0 |
| Immunodeficiency | 1 | 0 |
| Immunosuppression | 3 | 0 |
| <i>Primary immunodeficiency syndromes</i> | | |
| Selective IgA immunodeficiency | 1 | 0 |
| <i>Transplant rejections</i> | | |
| Corneal graft rejection | 6 | 0 |
| Kidney transplant rejection | 1 | 0 |
| Solid organ transplant rejection | 1 | 0 |
| Transplant rejection | 1 | 0 |
| Immune system disorders SOC TOTAL | 1753 | 2 |

Case Series Drug Analysis Print

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

Report Run Date: 14-Oct-2021

Data Lock Date: 13-Oct-2021 18:30:20

MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Infections | | |
| <i>Abdominal and gastrointestinal infections</i> | | |
| Abdominal abscess | 1 | 0 |
| Abdominal infection | 1 | 0 |
| Anal abscess | 3 | 0 |
| Appendicitis | 35 | 0 |
| Appendicitis perforated | 7 | 0 |
| Diverticulitis | 11 | 0 |
| Dysentery | 1 | 0 |
| Gastric infection | 2 | 0 |
| Gastroenteritis | 24 | 0 |
| Mesenteric abscess | 1 | 0 |
| Peritonitis | 2 | 1 |
| Rectal abscess | 1 | 0 |
| <i>Adenoviral infections</i> | | |
| Adenoviral conjunctivitis | 1 | 0 |
| <i>Aspergillus infections</i> | | |
| Bronchopulmonary aspergillosis | 1 | 0 |
| <i>Bacterial infections NEC</i> | | |
| Abscess bacterial | 1 | 0 |
| Arthritis bacterial | 3 | 0 |
| Bacterial colitis | 1 | 0 |
| Bacterial diarrhoea | 1 | 0 |
| Bacterial infection | 13 | 0 |
| Bacterial sepsis | 1 | 0 |
| Cellulitis | 154 | 0 |
| Conjunctivitis bacterial | 1 | 0 |
| Ear infection bacterial | 1 | 0 |
| Folliculitis | 15 | 0 |
| Gangrene | 1 | 0 |
| Injection site cellulitis | 2 | 0 |
| Meningitis bacterial | 3 | 0 |
| Paronychia | 3 | 0 |
| Perichondritis | 1 | 0 |
| Periorbital cellulitis | 1 | 0 |
| Sinusitis bacterial | 1 | 0 |
| Skin bacterial infection | 2 | 0 |
| Tonsillitis bacterial | 3 | 0 |
| Urinary tract infection bacterial | 1 | 0 |
| Vaccination site cellulitis | 19 | 0 |
| Zoonotic bacterial infection | 1 | 1 |
| <i>Bartonella infections</i> | | |
| Cat scratch disease | 1 | 0 |
| <i>Bone and joint infections</i> | | |
| Abscess jaw | 1 | 0 |
| Arthritis infective | 1 | 0 |
| Osteomyelitis | 2 | 0 |
| <i>Borrelial infections</i> | | |
| Lyme disease | 2 | 0 |
| Relapsing fever | 2 | 0 |
| <i>Breast infections</i> | | |
| Breast abscess | 3 | 0 |
| Mastitis | 67 | 0 |
| <i>Caliciviral infections</i> | | |

Case Series Drug Analysis Print

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

Report Run Date: 14-Oct-2021

Data Lock Date: 13-Oct-2021 18:30:20

MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Infections Infections cont'd | | |
| Gastroenteritis norovirus | 3 | 0 |
| <i>Campylobacter infections</i> | | |
| Campylobacter gastroenteritis | 1 | 0 |
| Campylobacter infection | 1 | 0 |
| <i>Candida infections</i> | | |
| Anal candidiasis | 3 | 0 |
| Balanitis candida | 1 | 0 |
| Candida infection | 58 | 0 |
| Oral candidiasis | 36 | 0 |
| Respiratory moniliasis | 1 | 0 |
| Skin candida | 1 | 0 |
| Systemic candida | 1 | 0 |
| Urinary tract candidiasis | 1 | 0 |
| Vulvovaginal candidiasis | 43 | 0 |
| <i>Cardiac infections</i> | | |
| Pericarditis infective | 2 | 0 |
| <i>Central nervous system and spinal infections</i> | | |
| Brain abscess | 1 | 0 |
| CNS ventriculitis | 1 | 0 |
| Cavernous sinus thrombosis | 1 | 0 |
| Encephalitis | 18 | 0 |
| Encephalomyelitis | 1 | 0 |
| Meningitis | 7 | 0 |
| Meningitis aseptic | 3 | 0 |
| Myelitis | 6 | 0 |
| Subdural abscess | 1 | 0 |
| <i>Clostridia infections</i> | | |
| Clostridium difficile infection | 2 | 0 |
| <i>Coronavirus infections</i> | | |
| Asymptomatic COVID-19 | 14 | 0 |
| COVID-19 | 1202 | 39 |
| COVID-19 pneumonia | 46 | 13 |
| Coronavirus infection | 7 | 0 |
| Post-acute COVID-19 syndrome | 1 | 0 |
| Severe acute respiratory syndrome | 2 | 0 |
| Suspected COVID-19 | 60 | 4 |
| <i>Coxiella infections</i> | | |
| Q fever | 9 | 0 |
| <i>Cytomegaloviral infections</i> | | |
| Cytomegalovirus infection | 2 | 0 |
| Cytomegalovirus syndrome | 1 | 0 |
| <i>Dental and oral soft tissue infections</i> | | |
| Abscess oral | 5 | 0 |
| Gingivitis | 10 | 0 |
| Oral infection | 1 | 0 |
| Parotitis | 9 | 0 |
| Pericoronitis | 2 | 0 |
| Pulpitis dental | 1 | 0 |
| Sialoadenitis | 3 | 0 |
| Tongue abscess | 1 | 0 |
| Tooth abscess | 8 | 0 |
| Tooth infection | 8 | 0 |
| <i>Ear infections</i> | | |

Case Series Drug Analysis Print

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Report Run Date: 14-Oct-2021

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MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Infections | | |
| Infections cont'd | | |
| Ear infection | 74 | 0 |
| Labyrinthitis | 90 | 0 |
| Mastoiditis | 1 | 0 |
| Otitis externa | 2 | 0 |
| Otitis media | 6 | 0 |
| Otitis media acute | 1 | 0 |
| <i>Ectoparasitic infestations</i> | | |
| Acarodermatitis | 4 | 0 |
| Bed bug infestation | 1 | 0 |
| <i>Epstein-Barr viral infections</i> | | |
| Epstein-Barr virus infection | 3 | 0 |
| Infectious mononucleosis | 23 | 0 |
| <i>Escherichia infections</i> | | |
| Escherichia bacteraemia | 1 | 0 |
| <i>Eye and eyelid infections</i> | | |
| Conjunctivitis | 61 | 0 |
| Eye abscess | 1 | 0 |
| Eye infection | 17 | 0 |
| Eyelid boil | 2 | 0 |
| Eyelid infection | 2 | 0 |
| Hordeolum | 25 | 0 |
| Periorbital infection | 2 | 0 |
| <i>Female reproductive tract infections</i> | | |
| Bartholin's abscess | 1 | 0 |
| Bartholinitis | 1 | 0 |
| Endometritis | 3 | 0 |
| Funisitis | 1 | 0 |
| Pelvic inflammatory disease | 1 | 0 |
| Vaginal infection | 1 | 0 |
| Vulval abscess | 1 | 0 |
| Vulvitis | 1 | 0 |
| <i>Fungal infections NEC</i> | | |
| Fungal infection | 15 | 0 |
| Fungal skin infection | 5 | 0 |
| Onychomycosis | 1 | 0 |
| Oral fungal infection | 2 | 0 |
| Pneumonia fungal | 2 | 0 |
| Vulvovaginal mycotic infection | 6 | 0 |
| <i>Hepatitis virus infections</i> | | |
| Hepatitis A | 1 | 0 |
| Hepatitis E | 1 | 0 |
| <i>Hepatobiliary and spleen infections</i> | | |
| Biliary sepsis | 2 | 0 |
| Cholecystitis infective | 1 | 0 |
| <i>Herpes viral infections</i> | | |
| Disseminated varicella zoster virus infection | 1 | 0 |
| Eczema herpeticum | 2 | 0 |
| Genital herpes | 77 | 0 |
| Genital herpes simplex | 6 | 0 |
| Herpes ophthalmic | 3 | 0 |
| Herpes simplex | 25 | 0 |
| Herpes simplex encephalitis | 1 | 1 |
| Herpes simplex reactivation | 2 | 0 |

Case Series Drug Analysis Print

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

Report Run Date: 14-Oct-2021

Data Lock Date: 13-Oct-2021 18:30:20

MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Infections | | |
| Infections cont'd | | |
| Herpes virus infection | 10 | 0 |
| Herpes zoster | 1244 | 0 |
| Herpes zoster meningoencephalitis | 1 | 0 |
| Herpes zoster oticus | 13 | 0 |
| Herpes zoster reactivation | 1 | 0 |
| Nasal herpes | 3 | 0 |
| Ophthalmic herpes simplex | 2 | 0 |
| Ophthalmic herpes zoster | 3 | 0 |
| Oral herpes | 272 | 0 |
| Varicella | 23 | 0 |
| Varicella zoster virus infection | 1 | 0 |
| Infections NEC | | |
| Abscess | 35 | 0 |
| Abscess limb | 7 | 0 |
| Abscess soft tissue | 1 | 0 |
| Catheter site infection | 1 | 0 |
| Genital abscess | 2 | 0 |
| Infected bite | 3 | 0 |
| Infected cyst | 2 | 0 |
| Infection | 205 | 0 |
| Infection susceptibility increased | 1 | 0 |
| Injection site abscess | 1 | 0 |
| Injection site infection | 5 | 0 |
| Localised infection | 24 | 0 |
| Lymph gland infection | 9 | 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 | 6 | 0 |
| Vaccination site infection | 13 | 0 |
| Vaccine breakthrough infection | 23 | 0 |
| Vestibulitis | 2 | 0 |
| Wound infection | 1 | 0 |
| Infectious transmissions | | |
| Secondary transmission | 8 | 0 |
| Vaccine virus shedding | 1 | 0 |
| Influenza viral infections | | |
| Influenza | 1311 | 0 |
| Klebsiella infections | | |
| Klebsiella infection | 1 | 0 |
| Lower respiratory tract and lung infections | | |
| Bronchitis | 20 | 0 |
| Infectious pleural effusion | 1 | 0 |
| Lower respiratory tract infection | 184 | 7 |
| Pneumonia | 114 | 12 |
| Sputum purulent | 1 | 0 |
| Male reproductive tract infections | | |
| Epididymitis | 7 | 0 |
| Orchitis | 4 | 0 |
| Prostate infection | 2 | 0 |
| Molluscum contagiosum viral infections | | |

Case Series Drug Analysis Print

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Report Run Date: 14-Oct-2021

Data Lock Date: 13-Oct-2021 18:30:20

MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Infections Infections cont'd | | |
| Molluscum contagiosum | 1 | 0 |
| Mumps viral infections | | |
| Mumps | 6 | 0 |
| Muscle and soft tissue infections | | |
| Abscess neck | 1 | 0 |
| Infective tenosynovitis | 1 | 0 |
| Necrotising fasciitis | 2 | 0 |
| Psoas abscess | 1 | 0 |
| Soft tissue infection | 1 | 0 |
| Neisseria infections | | |
| Gonorrhoea | 1 | 0 |
| Meningococcal bacteraemia | 1 | 0 |
| Plasmodia infections | | |
| Malaria | 2 | 0 |
| Pneumocystis infections | | |
| Pneumocystis jirovecii pneumonia | 2 | 0 |
| Prion-associated disorders | | |
| Creutzfeldt-Jakob disease | 1 | 0 |
| Retroviral infections | | |
| Acquired immunodeficiency syndrome | 1 | 0 |
| HIV infection | 1 | 0 |
| Rotaviral infections | | |
| Gastroenteritis rotavirus | 1 | 0 |
| Rubeola viral infections | | |
| Measles | 4 | 0 |
| Sepsis, bacteraemia, viraemia and fungaemia NEC | | |
| Neutropenic sepsis | 3 | 1 |
| Sepsis | 45 | 7 |
| Sepsis syndrome | 1 | 0 |
| Septic rash | 1 | 0 |
| Septic shock | 5 | 1 |
| Urosepsis | 5 | 0 |
| Skin structures and soft tissue infections | | |
| Abscess sweat gland | 1 | 0 |
| Acne pustular | 1 | 0 |
| Blister infected | 1 | 0 |
| Dermatitis infected | 2 | 0 |
| Impetigo | 10 | 0 |
| Infected skin ulcer | 1 | 0 |
| Injection site pustule | 1 | 0 |
| Nail infection | 1 | 0 |
| Pustule | 15 | 0 |
| Rash pustular | 9 | 0 |
| Skin infection | 29 | 0 |
| Subcutaneous abscess | 8 | 0 |
| Sweat gland infection | 1 | 0 |
| Vaccination site pustule | 4 | 0 |
| Staphylococcal infections | | |
| Furuncle | 37 | 1 |
| Pneumonia staphylococcal | 1 | 0 |
| Staphylococcal abscess | 1 | 0 |
| Staphylococcal infection | 3 | 0 |
| Staphylococcal sepsis | 1 | 0 |

Case Series Drug Analysis Print

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

Report Run Date: 14-Oct-2021

Data Lock Date: 13-Oct-2021 18:30:20

MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Infections Infections cont'd | | |
| <i>Streptococcal infections</i> | | |
| Meningitis pneumococcal | 1 | 0 |
| Pharyngitis streptococcal | 5 | 0 |
| Streptococcal abscess | 1 | 0 |
| Streptococcal endocarditis | 1 | 0 |
| Streptococcal infection | 1 | 0 |
| Streptococcal sepsis | 1 | 0 |
| <i>Tinea infections</i> | | |
| Body tinea | 3 | 0 |
| Tinea infection | 1 | 0 |
| Tinea pedis | 2 | 0 |
| Tinea versicolour | 3 | 0 |
| <i>Treponema infections</i> | | |
| Syphilis | 2 | 0 |
| <i>Trypanosomal infections</i> | | |
| African trypanosomiasis | 2 | 0 |
| <i>Tuberculous infections</i> | | |
| Lymph node tuberculosis | 1 | 0 |
| Pulmonary tuberculosis | 1 | 0 |
| Tuberculosis | 1 | 0 |
| Tuberculosis of central nervous system | 1 | 0 |
| <i>Upper respiratory tract infections</i> | | |
| Acute sinusitis | 4 | 0 |
| Chronic sinusitis | 1 | 0 |
| Croup infectious | 1 | 0 |
| Epiglottitis | 1 | 0 |
| Laryngitis | 26 | 0 |
| Nasopharyngitis | 886 | 0 |
| Peritonsillar abscess | 3 | 0 |
| Pharyngitis | 29 | 0 |
| Rhinitis | 38 | 0 |
| Sinusitis | 134 | 0 |
| Tonsillitis | 102 | 0 |
| Tracheitis | 4 | 0 |
| Tracheostomy infection | 1 | 0 |
| Upper respiratory tract infection | 8 | 0 |
| <i>Urinary tract infections</i> | | |
| Cystitis | 69 | 0 |
| Kidney infection | 42 | 0 |
| Pyelonephritis | 2 | 0 |
| Urethritis | 1 | 0 |
| Urinary tract infection | 167 | 0 |
| <i>Vascular infections</i> | | |
| Haematoma infection | 1 | 0 |
| Infected lymphocele | 2 | 0 |
| Infusion site infection | 1 | 0 |
| Lymphangitis | 7 | 0 |
| <i>Viral infections NEC</i> | | |
| Arthritis viral | 1 | 0 |
| Conjunctivitis viral | 2 | 0 |
| Encephalitis viral | 4 | 1 |
| Eye infection viral | 2 | 0 |
| Gastroenteritis viral | 24 | 0 |

Case Series Drug Analysis Print

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

Report Run Date: 14-Oct-2021

Data Lock Date: 13-Oct-2021 18:30:20

MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|-------------------------------------|-------------|-----------|
| Infections Infections cont'd | | |
| Hepatitis viral | 2 | 0 |
| Meningitis viral | 8 | 0 |
| Meningoencephalitis viral | 1 | 0 |
| Oral viral infection | 1 | 0 |
| Pleurisy viral | 1 | 0 |
| Pneumonia viral | 2 | 1 |
| Post viral fatigue syndrome | 41 | 0 |
| Sweating fever | 88 | 0 |
| Vestibular neuronitis | 26 | 0 |
| Viral diarrhoea | 2 | 0 |
| Viral infection | 46 | 0 |
| Viral labyrinthitis | 4 | 0 |
| Viral myocarditis | 2 | 0 |
| Viral pericarditis | 4 | 0 |
| Viral pharyngitis | 15 | 0 |
| Viral rash | 49 | 0 |
| Viral sinusitis | 1 | 0 |
| Viral tonsillitis | 1 | 0 |
| Infections SOC TOTAL | 8147 | 90 |

Case Series Drug Analysis Print

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

Report Run Date: 14-Oct-2021

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MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Injuries | | |
| <i>Abdominal and gastrointestinal injuries NEC</i> | | |
| Mouth injury | 3 | 0 |
| Oral contusion | 3 | 0 |
| Palate injury | 1 | 0 |
| Rectal injury | 1 | 0 |
| Splenic rupture | 6 | 0 |
| Tongue injury | 2 | 0 |
| Tooth fracture | 1 | 0 |
| Tooth injury | 1 | 0 |
| <i>Accidental exposures to product</i> | | |
| Accidental exposure to product | 18 | 0 |
| <i>Anaesthetic and allied procedural complications</i> | | |
| Airway complication of anaesthesia | 1 | 0 |
| Delayed recovery from anaesthesia | 2 | 0 |
| Sedation complication | 1 | 0 |
| <i>Atmospheric pressure injuries</i> | | |
| Barotitis media | 1 | 0 |
| Hypobarism | 1 | 0 |
| <i>Bone and joint injuries NEC</i> | | |
| Bursa injury | 2 | 0 |
| Joint injury | 8 | 0 |
| Meniscus injury | 1 | 0 |
| <i>Cardiac and vascular procedural complications</i> | | |
| Shunt blood flow excessive | 1 | 0 |
| <i>Cardiovascular injuries</i> | | |
| Heart injury | 8 | 0 |
| Vascular injury | 6 | 0 |
| <i>Cerebral injuries NEC</i> | | |
| Brain contusion | 3 | 0 |
| Brain herniation | 1 | 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 |
| <i>Chemical injuries</i> | | |
| Chemical burn of skin | 3 | 0 |
| Chemical cystitis | 1 | 0 |
| <i>Chest and respiratory tract injuries NEC</i> | | |
| Chest crushing | 8 | 0 |
| Foreign body in throat | 1 | 0 |
| <i>Conditions caused by cold</i> | | |
| Chillblains | 51 | 0 |
| Cold shock response | 1 | 0 |
| Frostbite | 1 | 0 |
| <i>Cranial nerve injuries</i> | | |
| Vth nerve injury | 1 | 0 |
| <i>Ear injuries NEC</i> | | |
| Ear injury | 1 | 0 |
| <i>Exposures associated with pregnancy, delivery and lactation</i> | | |
| Exposure during pregnancy | 10 | 0 |
| Exposure via breast milk | 126 | 0 |

Case Series Drug Analysis Print

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

Report Run Date: 14-Oct-2021

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MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Injuries Injuries cont'd | | |
| Foetal exposure during pregnancy | 40 | 0 |
| Maternal exposure before pregnancy | 6 | 0 |
| Maternal exposure during breast feeding | 1483 | 0 |
| Maternal exposure during pregnancy | 809 | 0 |
| Maternal exposure timing unspecified | 10 | 0 |
| Paternal exposure before pregnancy | 3 | 0 |
| Exposures to agents or circumstances NEC | | |
| Exposure to SARS-CoV-2 | 3 | 0 |
| Exposure to vaccinated person | 4 | 0 |
| Eye and ear procedural complications | | |
| Toxic anterior segment syndrome | 1 | 0 |
| Eye injuries NEC | | |
| Corneal abrasion | 1 | 0 |
| Eye contusion | 13 | 0 |
| Eye injury | 17 | 0 |
| Foreign body in eye | 3 | 0 |
| Injury corneal | 1 | 0 |
| Periorbital haematoma | 1 | 0 |
| Retinal injury | 2 | 0 |
| Superficial injury of eye | 1 | 0 |
| Foetal and neonatal conditions associated with product exposure | | |
| Intoxication by breast feeding | 1 | 0 |
| Fractures and dislocations NEC | | |
| Bone fragmentation | 1 | 0 |
| Fracture | 2 | 0 |
| Joint dislocation | 3 | 0 |
| Multiple fractures | 1 | 0 |
| Gastrointestinal and hepatobiliary procedural complications | | |
| Post procedural constipation | 1 | 0 |
| Postoperative ileus | 1 | 0 |
| Procedural nausea | 8 | 0 |
| Procedural vomiting | 1 | 0 |
| Heat injuries (excl thermal burns) | | |
| Heat cramps | 2 | 0 |
| Heat exhaustion | 3 | 0 |
| Heat illness | 1 | 0 |
| Heat oedema | 8 | 0 |
| Heat stroke | 3 | 0 |
| Intentional product use issues | | |
| Intentional dose omission | 1 | 0 |
| Intentional product use issue | 1 | 0 |
| Limb fractures and dislocations | | |
| Atypical femur fracture | 3 | 0 |
| Clavicle fracture | 23 | 0 |
| Femoral neck fracture | 1 | 0 |
| Femur fracture | 1 | 0 |
| Fibula fracture | 1 | 0 |
| Hip fracture | 2 | 0 |
| Tibia fracture | 1 | 0 |
| Upper limb fracture | 1 | 0 |
| Wrist fracture | 1 | 0 |
| Medication errors, product use errors and issues NEC | | |
| Circumstance or information capable of leading to medication error | 1 | 0 |

Case Series Drug Analysis Print

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

Report Run Date: 14-Oct-2021

Data Lock Date: 13-Oct-2021 18:30:20

MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Injuries Injuries cont'd | | |
| Dose calculation error | 1 | 0 |
| Inadequate aseptic technique in use of product | 1 | 0 |
| Medication error | 18 | 0 |
| Prescription drug used without a prescription | 2 | 0 |
| Product use complaint | 1 | 0 |
| Product use issue | 20 | 0 |
| Vaccination error | 5 | 0 |
| Wrong dose | 3 | 0 |
| Wrong drug | 11 | 0 |
| Wrong technique in product usage process | 4 | 0 |
| Muscle, tendon and ligament injuries | | |
| Epicondylitis | 18 | 0 |
| Ligament injury | 2 | 0 |
| Ligament sprain | 9 | 0 |
| Mallet finger | 1 | 0 |
| Muscle injury | 17 | 0 |
| Muscle rupture | 8 | 0 |
| Muscle strain | 27 | 0 |
| Post-traumatic neck syndrome | 2 | 0 |
| Tendon injury | 5 | 0 |
| Tendon rupture | 16 | 0 |
| Musculoskeletal procedural complications | | |
| Periprosthetic osteolysis | 1 | 0 |
| Post laminectomy syndrome | 1 | 0 |
| Nerve injuries NEC | | |
| Nerve injury | 75 | 0 |
| Neurological and psychiatric procedural complications | | |
| Post procedural stroke | 1 | 0 |
| Procedural dizziness | 11 | 0 |
| Non-occupational environmental exposures | | |
| Exposure to extreme temperature | 1 | 0 |
| Non-site specific injuries NEC | | |
| Animal scratch | 1 | 0 |
| Arthropod bite | 5 | 0 |
| Arthropod sting | 5 | 0 |
| Bite | 1 | 0 |
| Electric shock | 18 | 0 |
| Fall | 159 | 0 |
| Foreign body | 2 | 0 |
| Injury | 10 | 0 |
| Multiple injuries | 2 | 0 |
| Nervous system injury | 1 | 0 |
| Post concussion syndrome | 1 | 0 |
| Traumatic haematoma | 1 | 0 |
| Wound | 7 | 0 |
| Wound complication | 9 | 0 |
| Wound haematoma | 1 | 0 |
| Wound haemorrhage | 2 | 0 |
| Wound secretion | 5 | 0 |
| Non-site specific procedural complications | | |
| Incision site pain | 3 | 0 |
| Infusion related reaction | 6 | 0 |
| Injection related reaction | 39 | 0 |

Case Series Drug Analysis Print

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

Report Run Date: 14-Oct-2021

Data Lock Date: 13-Oct-2021 18:30:20

MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Injuries Injuries cont'd | | |
| Post procedural complication | 3 | 0 |
| Post procedural erythema | 1 | 0 |
| Procedural pain | 2 | 0 |
| Seroma | 1 | 0 |
| Occupational exposures | | |
| Occupational exposure to SARS-CoV-2 | 1 | 0 |
| Occupational exposure to product | 1 | 0 |
| Off label uses | | |
| Off label use | 64 | 0 |
| Overdoses NEC | | |
| Overdose | 40 | 0 |
| Pathways and sources of exposure | | |
| Exposure via unknown route | 1 | 0 |
| Pelvic fractures and dislocations | | |
| Pelvic fracture | 1 | 0 |
| Peripheral nerve injuries | | |
| Axillary nerve injury | 1 | 0 |
| Brachial plexus injury | 1 | 0 |
| Ulnar nerve injury | 4 | 0 |
| Poisoning and toxicity | | |
| Alcohol poisoning | 1 | 0 |
| Poisoning | 11 | 0 |
| Toxicity to various agents | 2 | 0 |
| Product administration errors and issues | | |
| Accidental overdose | 6 | 0 |
| Contraindicated product administered | 1 | 0 |
| Expired product administered | 12 | 0 |
| Extra dose administered | 1 | 0 |
| Inappropriate schedule of product administration | 482 | 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 |
| Poor quality product administered | 3 | 0 |
| Product administered at inappropriate site | 14 | 0 |
| Product administered to patient of inappropriate age | 1 | 0 |
| Product administration error | 6 | 0 |
| Product dose omission issue | 5 | 0 |
| Wrong product administered | 19 | 0 |
| Product confusion errors and issues | | |
| Product label confusion | 1 | 0 |
| Product dispensing errors and issues | | |
| Product dispensing error | 3 | 0 |
| Product monitoring errors and issues | | |
| Drug monitoring procedure incorrectly performed | 1 | 0 |
| Product preparation errors and issues | | |
| Product preparation error | 2 | 0 |
| Product preparation issue | 4 | 0 |
| Product prescribing errors and issues | | |
| Contraindicated product prescribed | 2 | 0 |
| Product prescribing error | 1 | 0 |
| Product selection errors and issues | | |

Case Series Drug Analysis Print

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

Report Run Date: 14-Oct-2021

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MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Injuries Injuries cont'd | | |
| Product selection error | 2 | 0 |
| Radiation injuries | | |
| Radiation sickness syndrome | 1 | 0 |
| Sunburn | 20 | 0 |
| Renal and urinary tract injuries NEC | | |
| Foreign body in urogenital tract | 1 | 0 |
| Reproductive system and breast injuries | | |
| Penis injury | 1 | 0 |
| Site specific injuries NEC | | |
| Face crushing | 2 | 0 |
| Face injury | 1 | 0 |
| Head injury | 33 | 0 |
| Limb crushing injury | 3 | 0 |
| Limb injury | 94 | 0 |
| Nasal injury | 1 | 0 |
| Neck crushing | 1 | 0 |
| Neck injury | 1 | 0 |
| Skin injuries NEC | | |
| Contusion | 1030 | 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 |
| Subcutaneous haematoma | 2 | 0 |
| Skin procedural complications | | |
| Dermal filler overcorrection | 1 | 0 |
| Recall phenomenon | 1 | 0 |
| Skull fractures, facial bone fractures and dislocations | | |
| Facial bones fracture | 1 | 0 |
| Fractured skull depressed | 1 | 0 |
| Spinal cord injuries NEC | | |
| Spinal cord injury cervical | 1 | 0 |
| Spinal fractures and dislocations | | |
| Spinal fracture | 3 | 0 |
| Stoma complications | | |
| Gastrointestinal stoma complication | 2 | 0 |
| Stoma site discharge | 1 | 0 |
| Stoma site extravasation | 1 | 0 |
| Stoma site haemorrhage | 1 | 0 |
| Thermal burns | | |
| Airway burns | 1 | 0 |
| Burn oesophageal | 2 | 0 |
| Burn of internal organs | 2 | 0 |
| Burn oral cavity | 4 | 0 |
| Burns second degree | 5 | 0 |
| Burns third degree | 1 | 0 |
| Thermal burn | 19 | 0 |
| Thermal burns of eye | 11 | 0 |
| Underdoses NEC | | |
| Underdose | 6 | 0 |

Case Series Drug Analysis Print

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

Report Run Date: 14-Oct-2021

Data Lock Date: 13-Oct-2021 18:30:20

MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|--|-------------|----------|
| Injuries Injuries cont'd | | |
| <i>Vaccination related complications</i> | | |
| Vaccination complication | 45 | 0 |
| Injuries SOC TOTAL | 5408 | 1 |

Case Series Drug Analysis Print

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

Report Run Date: 14-Oct-2021

Data Lock Date: 13-Oct-2021 18:30:20

MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Investigations | | |
| <i>Adrenal cortex tests</i> | | |
| Cortisol decreased | 4 | 0 |
| <i>Adrenal medulla tests</i> | | |
| Epinephrine abnormal | 1 | 0 |
| Epinephrine increased | 1 | 0 |
| <i>Auditory and vestibular diagnostic procedures</i> | | |
| Acoustic stimulation tests | 5 | 0 |
| Audiogram abnormal | 1 | 0 |
| <i>Autoimmunity analyses</i> | | |
| Antinuclear antibody | 1 | 0 |
| Antinuclear antibody increased | 1 | 0 |
| Antinuclear antibody positive | 2 | 0 |
| Rheumatoid factor | 3 | 0 |
| <i>Bacteria identification and serology (excl mycobacteria)</i> | | |
| Bacterial test positive | 1 | 0 |
| Klebsiella test positive | 1 | 0 |
| <i>Blood counts NEC</i> | | |
| Blood count | 5 | 0 |
| Blood count abnormal | 2 | 0 |
| <i>Blood gas and acid base analyses</i> | | |
| Acid base balance abnormal | 1 | 0 |
| Blood lactic acid | 4 | 0 |
| Blood lactic acid decreased | 1 | 0 |
| Blood lactic acid increased | 4 | 0 |
| Blood pH | 8 | 0 |
| Blood pH increased | 7 | 0 |
| Oxygen consumption decreased | 2 | 0 |
| Oxygen saturation | 9 | 0 |
| Oxygen saturation decreased | 58 | 0 |
| PO2 decreased | 1 | 0 |
| <i>Bone marrow and immune tissue histopathology procedures</i> | | |
| Aspiration bone marrow | 1 | 0 |
| Biopsy lymph gland | 1 | 0 |
| <i>Bone marrow and immune tissue imaging procedures</i> | | |
| Lymph nodes scan abnormal | 1 | 0 |
| Scan lymph nodes | 4 | 0 |
| <i>Carbohydrate tolerance analyses (incl diabetes)</i> | | |
| Blood glucose | 8 | 0 |
| Blood glucose abnormal | 11 | 0 |
| Blood glucose decreased | 27 | 0 |
| Blood glucose fluctuation | 15 | 0 |
| Blood glucose increased | 89 | 0 |
| Blood glucose normal | 1 | 0 |
| Glycosylated haemoglobin increased | 1 | 0 |
| <i>Cardiac auscultatory investigations</i> | | |
| Cardiac murmur | 31 | 0 |
| Heart sounds | 4 | 0 |
| Heart sounds abnormal | 4 | 0 |
| <i>Cardiac function diagnostic procedures</i> | | |
| Cardiac monitoring | 1 | 0 |
| Cardiac output | 1 | 0 |
| Central venous pressure | 1 | 0 |
| Echocardiogram | 1 | 0 |

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Investigations | | |
| Investigations cont'd | | |
| Ejection fraction decreased | 1 | 0 |
| Myocardial strain | 1 | 0 |
| Stroke volume decreased | 1 | 0 |
| Cardiac imaging procedures | | |
| Magnetic resonance imaging heart | 1 | 0 |
| Scan myocardial perfusion abnormal | 1 | 0 |
| Cell marker analyses | | |
| HLA-B*27 positive | 1 | 0 |
| Prostatic specific antigen increased | 2 | 0 |
| Central nervous system imaging procedures | | |
| Computerised tomogram head | 5 | 0 |
| Magnetic resonance imaging head | 12 | 0 |
| Magnetic resonance imaging head abnormal | 1 | 0 |
| Cerebrospinal fluid tests (excl microbiology) | | |
| CSF pressure | 1 | 0 |
| Chemistry analyses NEC | | |
| Histamine abnormal | 1 | 0 |
| Histamine level | 1 | 0 |
| Histamine level increased | 1 | 0 |
| Inflammatory marker decreased | 1 | 0 |
| Inflammatory marker increased | 3 | 0 |
| Renin | 1 | 0 |
| Cholesterol analyses | | |
| Blood cholesterol increased | 7 | 0 |
| Remnant-like lipoprotein particles | 3 | 0 |
| Coagulation and bleeding analyses | | |
| Activated partial thromboplastin time prolonged | 15 | 0 |
| Activated partial thromboplastin time shortened | 1 | 0 |
| Bleeding time | 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 | 9 | 0 |
| International normalised ratio abnormal | 6 | 0 |
| International normalised ratio decreased | 20 | 0 |
| International normalised ratio fluctuation | 2 | 0 |
| International normalised ratio increased | 49 | 0 |
| Prothrombin time shortened | 1 | 0 |
| Digestive enzymes | | |
| Amylase increased | 1 | 0 |
| ECG investigations | | |
| Electrocardiogram | 3 | 0 |
| Electrocardiogram QRS complex prolonged | 1 | 0 |
| Electrocardiogram QT prolonged | 6 | 0 |
| Electrocardiogram ST segment depression | 1 | 0 |
| Electrocardiogram ST segment elevation | 7 | 0 |
| Electrocardiogram ST-T segment abnormal | 1 | 0 |
| Electrocardiogram T wave inversion | 4 | 0 |
| Electrocardiogram abnormal | 17 | 0 |

Case Series Drug Analysis Print

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Investigations Investigations cont'd | | |
| Electrocardiogram change | 1 | 0 |
| Electrocardiogram normal | 2 | 0 |
| Electrocardiogram repolarisation abnormality | 1 | 0 |
| QRS axis abnormal | 1 | 0 |
| Endocrine analyses and imaging NEC | | |
| Hormone level abnormal | 47 | 0 |
| Faecal analyses NEC | | |
| Faecal calprotectin | 2 | 0 |
| Faecal calprotectin increased | 4 | 0 |
| Fertility analyses | | |
| Infertility tests | 1 | 0 |
| Semen analysis abnormal | 1 | 0 |
| Sperm concentration | 3 | 0 |
| Foetal and neonatal diagnostic procedures | | |
| Foetal heart rate abnormal | 3 | 2 |
| Foetal heart rate increased | 1 | 0 |
| Foetal monitoring | 1 | 0 |
| Foetal non-stress test | 1 | 0 |
| Gastrointestinal and abdominal imaging procedures | | |
| Computerised tomogram abdomen | 1 | 0 |
| Sigmoidoscopy abnormal | 1 | 0 |
| X-ray with contrast upper gastrointestinal tract | 1 | 0 |
| Gastrointestinal function diagnostic procedures | | |
| Gastric pH decreased | 1 | 0 |
| Gastrointestinal, pancreatic and APUD hormone analyses | | |
| Blood insulin | 1 | 0 |
| Blood insulin decreased | 1 | 0 |
| Haematological analyses NEC | | |
| Blood viscosity abnormal | 1 | 0 |
| Plasma viscosity | 1 | 0 |
| Plasma viscosity abnormal | 1 | 0 |
| Red blood cell sedimentation rate increased | 6 | 0 |
| Heart rate and pulse investigations | | |
| Carotid pulse | 1 | 0 |
| Heart rate | 386 | 0 |
| Heart rate abnormal | 52 | 0 |
| Heart rate decreased | 66 | 0 |
| Heart rate increased | 735 | 0 |
| Heart rate irregular | 157 | 0 |
| Heart rate normal | 1 | 0 |
| Maximum heart rate | 2 | 0 |
| Pulse abnormal | 17 | 0 |
| Pulse pressure increased | 1 | 0 |
| Radial pulse abnormal | 1 | 0 |
| Sinus rhythm | 6 | 0 |
| Imaging procedures NEC | | |
| Computerised tomogram | 3 | 0 |
| Magnetic resonance imaging | 4 | 0 |
| Magnetic resonance imaging abnormal | 1 | 0 |
| Scan | 2 | 0 |
| X-ray | 1 | 0 |
| Immune response protein analyses NEC | | |
| Cytokine test | 1 | 0 |

Case Series Drug Analysis Print

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Investigations Investigations cont'd | | |
| <i>Immunoglobulin analyses</i> | | |
| Blood immunoglobulin G increased | 1 | 0 |
| Blood immunoglobulin M | 1 | 0 |
| Blood immunoglobulin M increased | 1 | 0 |
| Immunoglobulins | 1 | 0 |
| <i>Immunology analyses NEC</i> | | |
| Antibody test | 4 | 0 |
| Immunology test | 10 | 0 |
| <i>Immunology skin tests NEC</i> | | |
| Allergy alert test | 1 | 0 |
| Skin test positive | 1 | 0 |
| <i>Investigations NEC</i> | | |
| Blood test | 21 | 0 |
| Blood test abnormal | 45 | 0 |
| False positive investigation result | 1 | 0 |
| Laboratory test | 1 | 0 |
| Polymerase chain reaction positive | 33 | 0 |
| Quality of life decreased | 2 | 0 |
| Systemic lupus erythematosus disease activity index increased | 1 | 0 |
| <i>Liver function analyses</i> | | |
| Alanine aminotransferase increased | 21 | 0 |
| Aspartate aminotransferase | 1 | 0 |
| Aspartate aminotransferase abnormal | 1 | 0 |
| Aspartate aminotransferase increased | 2 | 0 |
| Blood bilirubin increased | 3 | 0 |
| Gamma-glutamyltransferase increased | 4 | 0 |
| Hepatic enzyme increased | 6 | 0 |
| Liver function test | 1 | 0 |
| Liver function test abnormal | 26 | 0 |
| Liver function test increased | 22 | 0 |
| Transaminases increased | 5 | 0 |
| <i>Metabolism tests NEC</i> | | |
| Blood ketone body | 3 | 0 |
| Blood ketone body increased | 1 | 0 |
| Blood ketone body present | 1 | 0 |
| Blood uric acid increased | 2 | 0 |
| Brain natriuretic peptide increased | 1 | 0 |
| Ubiquinone | 1 | 0 |
| Urine ketone body present | 1 | 0 |
| <i>Microbiology and serology tests NEC</i> | | |
| Culture negative | 1 | 0 |
| Culture urine | 1 | 0 |
| <i>Mineral and electrolyte analyses</i> | | |
| Blood copper increased | 1 | 0 |
| Blood iron | 1 | 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 |

Case Series Drug Analysis Print

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

Report Run Date: 14-Oct-2021

Data Lock Date: 13-Oct-2021 18:30:20

MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Investigations Investigations cont'd | | |
| Serum ferritin | 1 | 0 |
| Serum ferritin decreased | 4 | 0 |
| Serum ferritin increased | 1 | 0 |
| Sweat test | 1 | 0 |
| Urine copper | 1 | 0 |
| <i>Musculoskeletal and soft tissue imaging procedures</i> | | |
| Skull X-ray | 6 | 0 |
| <i>Musculoskeletal and soft tissue tests NEC</i> | | |
| Swollen joint count increased | 1 | 0 |
| <i>Mycobacteria identification and serology</i> | | |
| Tuberculin test positive | 1 | 0 |
| <i>Neurologic diagnostic procedures</i> | | |
| Coma scale abnormal | 4 | 0 |
| Hoover's sign of leg paresis | 1 | 0 |
| Joint position sense decreased | 1 | 0 |
| Lumbar puncture | 7 | 0 |
| Temperature perception test abnormal | 1 | 0 |
| Temperature perception test increased | 1 | 0 |
| <i>Ophthalmic function diagnostic procedures</i> | | |
| Corneal reflex decreased | 1 | 0 |
| Intraocular pressure increased | 7 | 0 |
| Intraocular pressure test | 1 | 0 |
| <i>Physical examination procedures and organ system status</i> | | |
| Body temperature | 226 | 0 |
| Body temperature abnormal | 39 | 0 |
| Body temperature decreased | 37 | 0 |
| Body temperature fluctuation | 43 | 0 |
| Body temperature increased | 361 | 0 |
| Body temperature normal | 1 | 0 |
| Breath sounds abnormal | 2 | 0 |
| General physical condition abnormal | 1 | 0 |
| Grip strength | 2 | 0 |
| Grip strength decreased | 20 | 0 |
| Head lag | 6 | 0 |
| Lymph node palpable | 38 | 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 |
| Respiratory rate | 10 | 0 |
| Respiratory rate decreased | 16 | 0 |
| Respiratory rate increased | 33 | 0 |
| Skin temperature | 35 | 0 |
| Temperature difference of extremities | 9 | 0 |
| Weight | 1 | 0 |
| Weight decreased | 91 | 0 |
| Weight increased | 32 | 0 |
| <i>Pituitary analyses anterior</i> | | |
| Blood corticotrophin | 1 | 0 |
| Blood follicle stimulating hormone increased | 1 | 0 |

Case Series Drug Analysis Print

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

Report Run Date: 14-Oct-2021

Data Lock Date: 13-Oct-2021 18:30:20

MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Investigations Investigations cont'd | | |
| Blood growth hormone | 3 | 0 |
| Blood prolactin | 2 | 0 |
| Blood prolactin increased | 2 | 0 |
| Blood thyroid stimulating hormone decreased | 1 | 0 |
| Blood thyroid stimulating hormone increased | 4 | 0 |
| Platelet analyses | | |
| Mean platelet volume decreased | 1 | 0 |
| Mean platelet volume increased | 1 | 0 |
| Platelet count | 3 | 0 |
| Platelet count decreased | 63 | 0 |
| Platelet count increased | 3 | 0 |
| Protein analyses NEC | | |
| Alpha 1 globulin decreased | 1 | 0 |
| Alpha 2 globulin decreased | 1 | 0 |
| C-reactive protein increased | 17 | 0 |
| Red blood cell analyses | | |
| Haematocrit | 1 | 0 |
| Haematocrit decreased | 1 | 0 |
| Haematocrit increased | 1 | 0 |
| Haemoglobin | 1 | 0 |
| Haemoglobin decreased | 10 | 0 |
| Haemoglobin increased | 1 | 0 |
| Red blood cell count decreased | 2 | 0 |
| Renal function analyses | | |
| Blood creatinine increased | 2 | 0 |
| Glomerular filtration rate decreased | 3 | 0 |
| Reproductive hormone analyses | | |
| 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 |
| Reproductive organ and breast histopathology procedures | | |
| Biopsy endometrium | 1 | 0 |
| Smear cervix | 1 | 0 |
| Reproductive organ and breast imaging procedures | | |
| Breast scan | 1 | 0 |
| Hysteroscopy | 2 | 0 |
| Respiratory and pulmonary function diagnostic procedures | | |
| Forced expiratory volume increased | 2 | 0 |
| Fractional exhaled nitric oxide normal | 1 | 0 |
| Maximal voluntary ventilation | 1 | 0 |
| Peak expiratory flow rate | 1 | 0 |
| Peak expiratory flow rate decreased | 4 | 0 |
| Pulmonary function test | 3 | 0 |
| Total lung capacity decreased | 3 | 0 |
| Vital capacity | 1 | 0 |
| Respiratory tract and thoracic histopathology procedures | | |
| Sputum abnormal | 3 | 0 |

Case Series Drug Analysis Print

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

Report Run Date: 14-Oct-2021

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MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Investigations Investigations cont'd | | |
| <i>Respiratory tract and thoracic imaging procedures</i> | | |
| 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 |
| <i>Skeletal and cardiac muscle analyses</i> | | |
| Blood creatine phosphokinase increased | 4 | 0 |
| Muscle enzyme | 1 | 0 |
| Myocardial necrosis marker | 1 | 0 |
| Myocardial necrosis marker increased | 1 | 0 |
| Troponin T increased | 1 | 0 |
| Troponin increased | 13 | 0 |
| <i>Therapeutic drug monitoring analyses</i> | | |
| Analgesic drug level | 4 | 0 |
| Anticoagulation drug level above therapeutic | 1 | 0 |
| Anticoagulation drug level below therapeutic | 5 | 0 |
| Anticoagulation drug level increased | 1 | 0 |
| Drug level decreased | 1 | 0 |
| <i>Thyroid analyses</i> | | |
| Anti-thyroid antibody | 1 | 0 |
| Thyroid function test abnormal | 4 | 0 |
| Thyroxine free increased | 2 | 0 |
| Tri-iodothyronine | 1 | 0 |
| Tri-iodothyronine decreased | 5 | 0 |
| <i>Tissue enzyme analyses NEC</i> | | |
| Blood alkaline phosphatase increased | 4 | 0 |
| Enzyme level increased | 1 | 0 |
| <i>Toxicology laboratory analyses</i> | | |
| Blood caffeine decreased | 1 | 0 |
| Blood lead | 1 | 0 |
| Drug screen positive | 2 | 0 |
| Opiates | 1 | 0 |
| <i>Urinalysis NEC</i> | | |
| Blood urine | 14 | 0 |
| Blood urine present | 44 | 0 |
| 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 |
| <i>Urinary tract function analyses NEC</i> | | |
| Urine output | 13 | 0 |
| Urine output decreased | 11 | 0 |
| Urine output increased | 6 | 0 |
| <i>Urinary tract histopathology procedures</i> | | |
| Urine cytology | 1 | 0 |
| <i>Urinary tract imaging procedures</i> | | |
| Cystoscopy | 2 | 0 |
| Ultrasound kidney normal | 1 | 0 |
| <i>Vascular imaging procedures NEC</i> | | |

Case Series Drug Analysis Print

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

Report Run Date: 14-Oct-2021

Data Lock Date: 13-Oct-2021 18:30:20

MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|--|-------------|----------|
| Investigations Investigations cont'd | | |
| Venogram | 2 | 0 |
| <i>Vascular tests NEC (incl blood pressure)</i> | | |
| Blood pressure abnormal | 6 | 0 |
| Blood pressure decreased | 64 | 0 |
| Blood pressure diastolic | 2 | 0 |
| Blood pressure diastolic decreased | 1 | 0 |
| Blood pressure diastolic increased | 2 | 0 |
| Blood pressure increased | 199 | 0 |
| Blood pressure measurement | 32 | 0 |
| Blood pressure normal | 2 | 0 |
| Blood pressure systolic | 1 | 0 |
| Blood pressure systolic decreased | 3 | 0 |
| Blood pressure systolic increased | 1 | 0 |
| <i>Virus identification and serology</i> | | |
| Coronavirus test | 11 | 0 |
| Coronavirus test positive | 4 | 0 |
| HIV test | 1 | 0 |
| SARS-CoV-1 test | 1 | 0 |
| SARS-CoV-1 test positive | 1 | 0 |
| SARS-CoV-2 antibody test | 11 | 0 |
| SARS-CoV-2 antibody test negative | 13 | 0 |
| SARS-CoV-2 antibody test positive | 4 | 0 |
| SARS-CoV-2 test | 27 | 0 |
| SARS-CoV-2 test false negative | 2 | 0 |
| SARS-CoV-2 test false positive | 4 | 0 |
| SARS-CoV-2 test negative | 8 | 0 |
| SARS-CoV-2 test positive | 95 | 0 |
| Viral test | 4 | 0 |
| Viral test positive | 1 | 0 |
| <i>Vitamin analyses</i> | | |
| Blood folate decreased | 6 | 0 |
| Vitamin B12 | 1 | 0 |
| Vitamin B12 abnormal | 2 | 0 |
| Vitamin B12 decreased | 2 | 0 |
| Vitamin D | 2 | 0 |
| Vitamin D decreased | 3 | 0 |
| <i>Water and electrolyte analyses NEC</i> | | |
| Urine osmolarity | 1 | 0 |
| Volume blood | 1 | 0 |
| <i>White blood cell analyses</i> | | |
| Eosinophil count | 1 | 0 |
| Eosinophil count decreased | 1 | 0 |
| Eosinophil count increased | 3 | 0 |
| Lymphocyte count | 2 | 0 |
| Lymphocyte count decreased | 2 | 0 |
| Monocyte count increased | 1 | 0 |
| Neutrophil count | 3 | 0 |
| Neutrophil count decreased | 8 | 0 |
| Neutrophil count increased | 2 | 0 |
| White blood cell count | 2 | 0 |
| White blood cell count decreased | 10 | 0 |
| White blood cell count increased | 8 | 0 |
| Investigations SOC TOTAL | 4314 | 3 |

Case Series Drug Analysis Print

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

Report Run Date: 14-Oct-2021

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MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Metabolic disorders | | |
| <i>Appetite disorders</i> | | |
| Appetite disorder | 15 | 0 |
| Decreased appetite | 1020 | 0 |
| Diet refusal | 1 | 0 |
| Eating disorder symptom | 2 | 0 |
| Food craving | 11 | 0 |
| Food refusal | 11 | 0 |
| Hyperphagia | 12 | 0 |
| Hypophagia | 16 | 0 |
| Increased appetite | 29 | 0 |
| Salt craving | 2 | 0 |
| <i>Calcium metabolism disorders</i> | | |
| Hypocalcaemia | 3 | 0 |
| Tetany | 3 | 0 |
| <i>Diabetes mellitus (incl subtypes)</i> | | |
| Diabetes mellitus | 42 | 0 |
| Diabetes mellitus inadequate control | 13 | 1 |
| Increased insulin requirement | 1 | 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 |
| <i>Diabetic complications NEC</i> | | |
| Diabetic complication | 2 | 0 |
| Diabetic ketoacidosis | 11 | 0 |
| Diabetic ketosis | 1 | 0 |
| <i>Disorders of purine metabolism</i> | | |
| Gout | 82 | 0 |
| <i>Electrolyte imbalance NEC</i> | | |
| Electrolyte imbalance | 1 | 0 |
| Fluid imbalance | 1 | 0 |
| <i>Fat soluble vitamin deficiencies and disorders</i> | | |
| Vitamin D deficiency | 4 | 0 |
| <i>Fluid intake increased</i> | | |
| Polydipsia | 6 | 0 |
| <i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i> | | |
| Alcohol intolerance | 3 | 0 |
| Dairy intolerance | 3 | 0 |
| Food intolerance | 13 | 0 |
| Gluten sensitivity | 6 | 0 |
| Histamine intolerance | 4 | 0 |
| <i>General nutritional disorders NEC</i> | | |
| Abnormal loss of weight | 16 | 0 |
| Abnormal weight gain | 19 | 0 |
| Cachexia | 1 | 0 |
| Feeding disorder | 63 | 0 |
| Food aversion | 8 | 0 |
| Malnutrition | 1 | 0 |
| Neonatal insufficient breast milk syndrome | 2 | 0 |
| Obesity | 1 | 0 |
| Overweight | 1 | 0 |
| Poor feeding infant | 15 | 0 |
| Weight loss poor | 3 | 0 |

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|--|-------------|----------|
| Metabolic disorders Metabolic disorders cont'd | | |
| <i>Hyperglycaemic conditions NEC</i> | | |
| Glucose tolerance impaired | 1 | 0 |
| Hyperglycaemia | 62 | 0 |
| Insulin resistance | 4 | 0 |
| <i>Hypoglycaemic conditions NEC</i> | | |
| Glycopenia | 1 | 0 |
| Hypoglycaemia | 71 | 0 |
| Hypoglycaemia unawareness | 1 | 0 |
| Postprandial hypoglycaemia | 1 | 0 |
| <i>Iron deficiencies</i> | | |
| Iron deficiency | 11 | 0 |
| <i>Iron excess</i> | | |
| Haemochromatosis | 1 | 0 |
| Iron overload | 1 | 0 |
| <i>Lipid metabolism and deposit disorders NEC</i> | | |
| Body fat disorder | 1 | 0 |
| <i>Metabolic acidoses (excl diabetic acidoses)</i> | | |
| Ketoacidosis | 5 | 1 |
| Lactic acidosis | 2 | 0 |
| Metabolic acidosis | 2 | 0 |
| <i>Metabolic disorders NEC</i> | | |
| Metabolic disorder | 1 | 0 |
| <i>Mixed acid-base disorders</i> | | |
| Acidosis | 3 | 0 |
| <i>Potassium imbalance</i> | | |
| Hyperkalaemia | 4 | 0 |
| Hypokalaemia | 3 | 0 |
| Hypokalaemic syndrome | 1 | 0 |
| <i>Sodium imbalance</i> | | |
| Hyponatraemia | 8 | 0 |
| Hyponatraemic syndrome | 3 | 0 |
| Salt intoxication | 1 | 0 |
| <i>Sugar intolerance (excl glucose intolerance)</i> | | |
| Lactose intolerance | 1 | 0 |
| <i>Total fluid volume decreased</i> | | |
| Dehydration | 178 | 0 |
| <i>Total fluid volume increased</i> | | |
| Fluid overload | 1 | 0 |
| Fluid retention | 46 | 0 |
| Hypervolaemia | 1 | 0 |
| <i>Vitamin deficiencies NEC</i> | | |
| Hypovitaminosis | 5 | 0 |
| <i>Water soluble vitamin deficiencies</i> | | |
| Folate deficiency | 3 | 0 |
| Vitamin B12 deficiency | 5 | 0 |
| Metabolic disorders SOC TOTAL | 1898 | 2 |

Case Series Drug Analysis Print

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Report Run Date: 14-Oct-2021

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MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Muscle & tissue disorders | | |
| <i>Arthropathies NEC</i> | | |
| Arthritis | 242 | 0 |
| Arthropathy | 23 | 0 |
| Autoimmune arthritis | 6 | 0 |
| Haemarthrosis | 5 | 0 |
| Joint microhaemorrhage | 1 | 0 |
| Palindromic rheumatism | 1 | 0 |
| Polyarthritis | 15 | 0 |
| Rheumatic fever | 1 | 0 |
| Sacroiliitis | 4 | 0 |
| Seronegative arthritis | 2 | 0 |
| <i>Bone disorders NEC</i> | | |
| Bone cyst | 1 | 0 |
| Exostosis | 1 | 0 |
| Jaw disorder | 4 | 0 |
| Medial tibial stress syndrome | 4 | 0 |
| Osteitis | 6 | 0 |
| Osteonecrosis | 1 | 0 |
| Osteonecrosis of jaw | 3 | 0 |
| Spinal disorder | 1 | 0 |
| <i>Bone related signs and symptoms</i> | | |
| Bone pain | 312 | 0 |
| Bone swelling | 7 | 0 |
| Coccydynia | 3 | 0 |
| Metatarsalgia | 1 | 0 |
| Pain in jaw | 309 | 0 |
| Pubic pain | 2 | 0 |
| Spinal pain | 63 | 0 |
| <i>Bursal disorders</i> | | |
| Bursitis | 58 | 0 |
| <i>Cartilage disorders</i> | | |
| Chondritis | 1 | 0 |
| Costochondritis | 74 | 0 |
| Osteochondritis | 1 | 0 |
| Polychondritis | 3 | 0 |
| <i>Connective tissue disorders NEC</i> | | |
| Connective tissue disorder | 1 | 0 |
| Polymyalgia rheumatica | 52 | 0 |
| Reynold's syndrome | 1 | 0 |
| Sjogren's syndrome | 5 | 0 |
| <i>Crystal arthropathic disorders</i> | | |
| Chondrocalcinosis pyrophosphate | 2 | 0 |
| Crystal arthropathy | 1 | 0 |
| <i>Epiphyseal disorders</i> | | |
| Epiphyses premature fusion | 1 | 0 |
| <i>Extremity deformities</i> | | |
| Bone deformity | 1 | 0 |
| Finger deformity | 2 | 0 |
| Foot deformity | 1 | 0 |
| Hand deformity | 2 | 0 |
| Knee deformity | 1 | 0 |
| Limb deformity | 4 | 0 |
| Musculoskeletal deformity | 1 | 0 |

Case Series Drug Analysis Print

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Muscle & tissue disorders | | |
| <i>Muscle & tissue disorders cont'd</i> | | |
| Fractures NEC | | |
| Osteoporotic fracture | 1 | 0 |
| Intervertebral disc disorders NEC | | |
| Intervertebral disc protrusion | 3 | 0 |
| Joint related disorders NEC | | |
| Chondromalacia | 1 | 0 |
| Hypermobility syndrome | 1 | 0 |
| Joint deposit | 1 | 0 |
| Joint destruction | 1 | 0 |
| Joint instability | 1 | 0 |
| Joint laxity | 3 | 0 |
| Joint lock | 23 | 0 |
| Patellofemoral pain syndrome | 1 | 0 |
| Periarthritis | 142 | 0 |
| Rotator cuff syndrome | 26 | 0 |
| Temporomandibular joint syndrome | 8 | 0 |
| Joint related signs and symptoms | | |
| Arthralgia | 7634 | 0 |
| Jaw clicking | 6 | 0 |
| Joint effusion | 15 | 0 |
| Joint noise | 32 | 0 |
| Joint range of motion decreased | 29 | 0 |
| Joint stiffness | 209 | 0 |
| Joint swelling | 459 | 0 |
| Joint vibration | 3 | 0 |
| Joint warmth | 13 | 0 |
| Loose body in joint | 1 | 0 |
| Ligament disorders | | |
| Ligament pain | 2 | 0 |
| Symphysiolysis | 1 | 0 |
| Lupus erythematosus (incl subtypes) | | |
| Lupus-like syndrome | 1 | 0 |
| Systemic lupus erythematosus | 18 | 0 |
| Metabolic bone disorders | | |
| Osteopenia | 3 | 0 |
| Osteoporosis | 2 | 0 |
| Muscle infections and inflammations | | |
| Antisynthetase syndrome | 3 | 0 |
| Immune-mediated myositis | 1 | 0 |
| Myositis | 27 | 0 |
| Polymyositis | 7 | 0 |
| Muscle pains | | |
| Fibromyalgia | 89 | 0 |
| Myalgia | 9315 | 0 |
| Myalgia intercostal | 1 | 0 |
| Myofascial pain syndrome | 11 | 0 |
| Muscle related signs and symptoms NEC | | |
| Haematoma muscle | 1 | 0 |
| Muscle atrophy | 19 | 0 |
| Muscle discomfort | 4 | 0 |
| Muscle disorder | 6 | 0 |
| Muscle fatigue | 303 | 0 |
| Muscle haemorrhage | 1 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Muscle & tissue disorders | | |
| <i>Muscle & tissue disorders cont'd</i> | | |
| Muscle mass | 4 | 0 |
| Muscle oedema | 1 | 0 |
| Muscle spasms | 1815 | 0 |
| Muscle swelling | 27 | 0 |
| Muscle tightness | 79 | 0 |
| Muscle twitching | 423 | 0 |
| <i>Muscle tone abnormalities</i> | | |
| Muscle rigidity | 14 | 0 |
| Nuchal rigidity | 10 | 0 |
| Torticollis | 5 | 0 |
| Trismus | 30 | 0 |
| <i>Muscle weakness conditions</i> | | |
| Muscular weakness | 786 | 0 |
| <i>Musculoskeletal and connective tissue conditions NEC</i> | | |
| Back disorder | 2 | 0 |
| Growth disorder | 2 | 0 |
| Limb mass | 20 | 0 |
| Mandibular mass | 2 | 0 |
| Mastication disorder | 3 | 0 |
| Mobility decreased | 96 | 0 |
| Musculoskeletal disorder | 10 | 0 |
| Musculoskeletal stiffness | 1088 | 0 |
| Posture abnormal | 1 | 0 |
| Sacroiliac joint dysfunction | 1 | 0 |
| Weight bearing difficulty | 2 | 0 |
| <i>Musculoskeletal and connective tissue deformities of skull, face and buccal cavity</i> | | |
| Head deformity | 2 | 0 |
| <i>Musculoskeletal and connective tissue infections and inflammations NEC</i> | | |
| Dactylitis | 2 | 0 |
| Dupuytren's contracture | 1 | 0 |
| Fasciitis | 1 | 0 |
| Plantar fasciitis | 8 | 0 |
| <i>Musculoskeletal and connective tissue pain and discomfort</i> | | |
| Back pain | 2051 | 0 |
| Flank pain | 56 | 0 |
| Limb discomfort | 1316 | 0 |
| Musculoskeletal chest pain | 188 | 0 |
| Musculoskeletal discomfort | 81 | 0 |
| Musculoskeletal pain | 39 | 0 |
| Neck pain | 1610 | 0 |
| Pain in extremity | 10914 | 0 |
| Rheumatic disorder | 13 | 0 |
| <i>Myopathies</i> | | |
| Myopathy | 6 | 0 |
| Rhabdomyolysis | 11 | 0 |
| <i>Osteoarthropathies</i> | | |
| Nodal osteoarthritis | 1 | 0 |
| Osteoarthritis | 37 | 0 |
| Spinal osteoarthritis | 1 | 0 |
| <i>Psoriatic arthropathies</i> | | |
| Psoriatic arthropathy | 16 | 0 |
| <i>Rheumatoid arthropathies</i> | | |

Case Series Drug Analysis Print

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| Reaction Name | Total | Fatal |
|--|--------------|----------|
| Muscle & tissue disorders | | |
| <i>Muscle & tissue disorders cont'd</i> | | |
| Juvenile idiopathic arthritis | 1 | 0 |
| Rheumatoid arthritis | 103 | 0 |
| Still's disease | 2 | 0 |
| Soft tissue disorders NEC | | |
| Axillary mass | 209 | 0 |
| Fluctuance | 1 | 0 |
| Groin pain | 95 | 0 |
| Neck mass | 29 | 0 |
| Purple glove syndrome | 1 | 0 |
| Soft tissue disorder | 3 | 0 |
| Soft tissue swelling | 6 | 0 |
| Spine and neck deformities | | |
| Kyphosis | 2 | 0 |
| Lordosis | 1 | 0 |
| Neck deformity | 1 | 0 |
| Scoliosis | 1 | 0 |
| Spinal stenosis | 1 | 0 |
| Spondyloarthropathies | | |
| Ankylosing spondylitis | 6 | 0 |
| Arthritis reactive | 39 | 0 |
| Spondylitis | 2 | 0 |
| Spondyloarthropathy | 1 | 0 |
| Synovial disorders | | |
| Synovial cyst | 18 | 0 |
| Synovitis | 8 | 0 |
| Tendon disorders | | |
| Enthesopathy | 2 | 0 |
| Posterior tibial tendon dysfunction | 1 | 0 |
| Tendon disorder | 5 | 0 |
| Tendon pain | 19 | 0 |
| Tendonitis | 35 | 0 |
| Tenosynovitis | 2 | 0 |
| Tenosynovitis stenosaurs | 2 | 0 |
| Trigger finger | 25 | 0 |
| Trunk deformities | | |
| Drooping shoulder syndrome | 1 | 0 |
| Shoulder deformity | 2 | 0 |
| Muscle & tissue disorders SOC TOTAL | 41057 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Neoplasms | | |
| <i>B-cell lymphomas NEC</i> | | |
| B-cell lymphoma | 1 | 1 |
| Follicular lymphoma | 3 | 0 |
| <i>Bone neoplasms malignant (excl sarcomas)</i> | | |
| Bone cancer | 1 | 1 |
| <i>Bone neoplasms unspecified malignancy</i> | | |
| Bone neoplasm | 1 | 0 |
| <i>Breast and nipple neoplasms benign</i> | | |
| Benign breast neoplasm | 1 | 0 |
| <i>Breast and nipple neoplasms malignant</i> | | |
| Breast cancer | 31 | 0 |
| Breast cancer female | 1 | 0 |
| Breast cancer male | 1 | 0 |
| Breast cancer stage I | 1 | 0 |
| Breast cancer stage III | 2 | 0 |
| Invasive ductal breast carcinoma | 1 | 0 |
| Triple negative breast cancer | 2 | 0 |
| <i>Cardiovascular neoplasms benign</i> | | |
| Pericardial lipoma | 1 | 0 |
| <i>Cervix neoplasms malignant</i> | | |
| Cervix carcinoma | 1 | 0 |
| <i>Colorectal neoplasms malignant</i> | | |
| Colon cancer | 1 | 0 |
| Colorectal cancer | 1 | 0 |
| Rectal cancer | 2 | 0 |
| <i>Endocrine neoplasms malignant and unspecified NEC</i> | | |
| Neuroendocrine tumour | 1 | 0 |
| Thyroid neoplasm | 1 | 0 |
| <i>Endometrial neoplasms malignant</i> | | |
| Endometrial cancer | 1 | 0 |
| <i>Follicular lymphomas</i> | | |
| Primary gastrointestinal follicular lymphoma | 1 | 0 |
| <i>Gastric neoplasms malignant</i> | | |
| Gastric cancer | 1 | 1 |
| <i>Gastrointestinal neoplasms malignant NEC</i> | | |
| Gastrointestinal carcinoma | 3 | 0 |
| <i>Hepatobiliary neoplasms malignancy unspecified</i> | | |
| Hepatic neoplasm | 1 | 0 |
| <i>Hodgkin's disease NEC</i> | | |
| Hodgkin's disease | 4 | 0 |
| <i>Islet cell neoplasms and APUDoma NEC</i> | | |
| Pancreatic neuroendocrine tumour | 1 | 0 |
| <i>Leukaemias NEC</i> | | |
| Leukaemia | 4 | 1 |
| <i>Leukaemias acute NEC</i> | | |
| Acute leukaemia | 2 | 0 |
| <i>Leukaemias chronic NEC</i> | | |
| Chronic leukaemia | 1 | 0 |
| <i>Leukaemias chronic lymphocytic</i> | | |
| Chronic lymphocytic leukaemia | 3 | 0 |
| <i>Leukaemias chronic myeloid</i> | | |
| Chronic myeloid leukaemia | 1 | 0 |
| <i>Lip and oral cavity neoplasms malignant</i> | | |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Neoplasms Neoplasms cont'd | | |
| Lip and/or oral cavity cancer recurrent | 1 | 0 |
| Lymphomas unspecified NEC | | |
| Lymphoma | 29 | 1 |
| Metastases to specified sites | | |
| Metastases to liver | 1 | 0 |
| Metastases to lymph nodes | 5 | 0 |
| Metastases to unknown and unspecified sites | | |
| Metastasis | 1 | 0 |
| Myelodysplastic syndromes | | |
| Myelodysplastic syndrome | 3 | 0 |
| Myeloproliferative disorders (excl leukaemias) | | |
| Essential thrombocythaemia | 1 | 0 |
| Neoplasms benign site unspecified NEC | | |
| Adenoma benign | 1 | 0 |
| Neoplasms malignant site unspecified NEC | | |
| Adenocarcinoma metastatic | 1 | 0 |
| Metastatic neoplasm | 2 | 0 |
| Neoplasm malignant | 7 | 0 |
| Second primary malignancy | 1 | 0 |
| Squamous cell carcinoma | 5 | 0 |
| Neoplasms unspecified malignancy and site unspecified NEC | | |
| Neoplasm | 2 | 0 |
| Neoplasm recurrence | 1 | 0 |
| Nervous system neoplasms benign NEC | | |
| Cranial nerve neoplasm benign | 1 | 0 |
| Neurilemmoma benign | 1 | 0 |
| Nervous system neoplasms unspecified malignancy NEC | | |
| Brain neoplasm | 2 | 0 |
| Spinal cord neoplasm | 1 | 0 |
| Neuromas | | |
| Acoustic neuroma | 2 | 0 |
| Non-Hodgkin's lymphomas NEC | | |
| Non-Hodgkin's lymphoma | 2 | 0 |
| Ocular neoplasms benign | | |
| Eye naevus | 1 | 0 |
| Oesophageal neoplasms malignant | | |
| Oesophageal cancer metastatic | 4 | 0 |
| Oncologic complications and emergencies | | |
| Cancer pain | 1 | 0 |
| Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified | | |
| Tonsil cancer | 3 | 0 |
| Ovarian neoplasms malignant (excl germ cell) | | |
| Ovarian cancer | 1 | 0 |
| Pancreatic neoplasms malignant (excl islet cell and carcinoid) | | |
| Pancreatic carcinoma | 4 | 0 |
| Plasma cell myelomas | | |
| POEMS syndrome | 1 | 0 |
| Plasma cell myeloma | 1 | 0 |
| Plasma cell neoplasms NEC | | |
| TEMPI syndrome | 1 | 0 |
| Prostatic neoplasms malignant | | |
| Prostate cancer | 3 | 0 |

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| Reaction Name | Total | Fatal |
|---|------------|----------|
| Neoplasms Neoplasms cont'd | | |
| <i>Renal neoplasms malignant</i> | | |
| Renal cancer | 2 | 0 |
| <i>Reproductive neoplasms female benign NEC</i> | | |
| Benign hydatidiform mole | 1 | 0 |
| <i>Respiratory tract and pleural neoplasms malignant cell type unspecified NEC</i> | | |
| Bronchial carcinoma | 1 | 0 |
| Lung neoplasm malignant | 9 | 0 |
| <i>Skin melanomas (excl ocular)</i> | | |
| Malignant melanoma | 1 | 0 |
| <i>Skin neoplasms benign</i> | | |
| Acrochordon | 3 | 0 |
| Anogenital warts | 7 | 0 |
| Haemangioma of skin | 4 | 0 |
| Melanocytic naevus | 6 | 0 |
| Pyogenic granuloma | 1 | 0 |
| Skin papilloma | 15 | 0 |
| <i>Skin neoplasms malignant and unspecified (excl melanoma)</i> | | |
| Basal cell carcinoma | 2 | 0 |
| Bowen's disease | 1 | 0 |
| Neoplasm skin | 2 | 0 |
| Squamous cell carcinoma of skin | 1 | 0 |
| <i>Soft tissue neoplasms benign NEC</i> | | |
| Lipoma | 6 | 0 |
| Lymphangioma | 1 | 0 |
| <i>Soft tissue sarcomas histology unspecified</i> | | |
| Sarcoma | 1 | 0 |
| <i>Thyroid neoplasms malignant</i> | | |
| Papillary thyroid cancer | 2 | 0 |
| Thyroid cancer | 1 | 0 |
| <i>Uterine neoplasms benign</i> | | |
| Uterine leiomyoma | 9 | 0 |
| Neoplasms SOC TOTAL | 243 | 5 |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Nervous system disorders | | |
| <i>Abnormal reflexes</i> | | |
| Areflexia | 6 | 0 |
| Extensor plantar response | 2 | 0 |
| Hoffmann's sign | 1 | 0 |
| Hyperreflexia | 4 | 0 |
| Hyporeflexia | 7 | 0 |
| Reflexes abnormal | 2 | 0 |
| <i>Abnormal sleep-related events</i> | | |
| Sleep paralysis | 24 | 0 |
| <i>Absence seizures</i> | | |
| Petit mal epilepsy | 24 | 0 |
| <i>Acute polyneuropathies</i> | | |
| Acute motor axonal neuropathy | 1 | 0 |
| Guillain-Barre syndrome | 59 | 1 |
| Miller Fisher syndrome | 1 | 0 |
| Subacute inflammatory demyelinating polyneuropathy | 1 | 0 |
| <i>Autonomic nervous system disorders</i> | | |
| Anticholinergic syndrome | 1 | 0 |
| Autonomic nervous system imbalance | 8 | 0 |
| Autonomic neuropathy | 2 | 0 |
| Horner's syndrome | 1 | 0 |
| <i>Central nervous system aneurysms and dissections</i> | | |
| Carotid artery dissection | 1 | 0 |
| Intracranial aneurysm | 2 | 1 |
| <i>Central nervous system haemorrhages and cerebrovascular accidents</i> | | |
| Brain stem infarction | 1 | 1 |
| Brain stem stroke | 1 | 0 |
| Carotid artery occlusion | 1 | 0 |
| Carotid artery thrombosis | 3 | 0 |
| Cerebellar haemorrhage | 2 | 0 |
| Cerebellar infarction | 2 | 0 |
| Cerebellar ischaemia | 1 | 0 |
| Cerebellar stroke | 8 | 1 |
| Cerebral artery embolism | 3 | 1 |
| Cerebral artery occlusion | 1 | 0 |
| Cerebral artery thrombosis | 3 | 0 |
| Cerebral haemorrhage | 42 | 8 |
| Cerebral infarction | 25 | 1 |
| Cerebral thrombosis | 13 | 0 |
| Cerebrovascular accident | 339 | 14 |
| Embolic stroke | 6 | 0 |
| Haemorrhage intracranial | 9 | 2 |
| Haemorrhagic cerebral infarction | 1 | 0 |
| Haemorrhagic stroke | 9 | 3 |
| Internal capsule infarction | 1 | 0 |
| Intracranial haematoma | 1 | 0 |
| Ischaemic cerebral infarction | 1 | 0 |
| Ischaemic stroke | 41 | 2 |
| Lacunar infarction | 2 | 0 |
| Lacunar stroke | 3 | 0 |
| Lateral medullary syndrome | 1 | 0 |
| Pseudostroke | 1 | 0 |
| Subarachnoid haemorrhage | 14 | 6 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Nervous system disorders | | |
| <i>Nervous system disorders cont'd</i> | | |
| Thalamic infarction | 1 | 0 |
| Thrombotic stroke | 3 | 1 |
| Central nervous system inflammatory disorders NEC | | |
| Arachnoiditis | 1 | 0 |
| Gliosis | 1 | 0 |
| Central nervous system vascular disorders NEC | | |
| Brain hypoxia | 2 | 1 |
| Carotid arteriosclerosis | 1 | 0 |
| Central nervous system vasculitis | 1 | 0 |
| Cerebral amyloid angiopathy | 1 | 0 |
| Cerebral congestion | 3 | 0 |
| Cerebral small vessel ischaemic disease | 1 | 0 |
| Cerebrovascular disorder | 1 | 0 |
| Post cardiac arrest syndrome | 1 | 0 |
| Reversible cerebral vasoconstriction syndrome | 1 | 0 |
| Cerebrovascular venous and sinus thrombosis | | |
| Cerebral venous sinus thrombosis | 44 | 3 |
| Cerebral venous thrombosis | 5 | 0 |
| Superior sagittal sinus thrombosis | 5 | 0 |
| Transverse sinus thrombosis | 1 | 0 |
| Cervical spinal cord and nerve root disorders | | |
| Cervical radiculopathy | 1 | 0 |
| Cervicobrachial syndrome | 3 | 0 |
| Choreiform movements | | |
| Chorea | 2 | 0 |
| Chronic polyneuropathies | | |
| Demyelinating polyneuropathy | 1 | 0 |
| Coma states | | |
| Coma | 10 | 0 |
| Diabetic coma | 1 | 0 |
| Hypoglycaemic coma | 1 | 0 |
| Coordination and balance disturbances | | |
| Ataxia | 12 | 0 |
| Balance disorder | 330 | 0 |
| Cerebellar ataxia | 1 | 0 |
| Coordination abnormal | 47 | 0 |
| Dysdiadochokinesis | 1 | 0 |
| Dysstasia | 52 | 0 |
| Nystagmus | 10 | 0 |
| Cortical dysfunction NEC | | |
| Alexia | 2 | 0 |
| Aphasia | 72 | 0 |
| Apraxia | 1 | 0 |
| Dyslexia | 1 | 0 |
| Dyspraxia | 1 | 0 |
| Neurologic neglect syndrome | 1 | 0 |
| Sensory processing disorder | 2 | 0 |
| Visuospatial deficit | 1 | 0 |
| Cranial nerve disorders NEC | | |
| Cranial nerve disorder | 2 | 0 |
| Cranial nerve paralysis | 1 | 0 |
| Dementia (excl Alzheimer's type) | | |
| Dementia | 15 | 0 |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Nervous system disorders | | |
| Nervous system disorders cont'd | | |
| Dementia with Lewy bodies | 1 | 0 |
| Senile dementia | 1 | 0 |
| Demyelinating disorders NEC | | |
| Acute disseminated encephalomyelitis | 5 | 0 |
| Clinically isolated syndrome | 1 | 0 |
| Demyelination | 8 | 0 |
| Neuromyelitis optica spectrum disorder | 2 | 0 |
| Disturbances in consciousness NEC | | |
| Altered state of consciousness | 11 | 0 |
| Consciousness fluctuating | 2 | 0 |
| Depressed level of consciousness | 41 | 0 |
| Infant sedation | 1 | 0 |
| Lethargy | 1949 | 0 |
| Loss of consciousness | 555 | 0 |
| Postictal state | 4 | 0 |
| Sedation | 8 | 0 |
| Somnolence | 887 | 0 |
| Stupor | 4 | 0 |
| Syncope | 1846 | 0 |
| Disturbances in sleep phase rhythm | | |
| Circadian rhythm sleep disorder | 1 | 0 |
| Irregular sleep phase | 2 | 0 |
| Irregular sleep wake rhythm disorder | 1 | 0 |
| Dyskinesias and movement disorders NEC | | |
| Akathisia | 5 | 0 |
| Bradykinesia | 18 | 0 |
| Clumsiness | 17 | 0 |
| Dyskinesia | 57 | 0 |
| Extrapyramidal disorder | 2 | 0 |
| Fine motor skill dysfunction | 11 | 0 |
| Foetal movement disorder | 3 | 0 |
| Hyperkinesia | 3 | 0 |
| Hypokinesia | 63 | 0 |
| Motor dysfunction | 2 | 0 |
| Movement disorder | 50 | 0 |
| Psychomotor hyperactivity | 21 | 0 |
| Synkinesis | 2 | 0 |
| Tardive dyskinesia | 2 | 0 |
| Dystonias | | |
| Dystonia | 15 | 0 |
| Writer's cramp | 1 | 0 |
| Encephalitis NEC | | |
| Encephalitis autoimmune | 1 | 0 |
| Limbic encephalitis | 1 | 0 |
| Noninfective encephalitis | 5 | 0 |
| Encephalopathies NEC | | |
| Autoimmune encephalopathy | 1 | 1 |
| Encephalopathy | 4 | 0 |
| Hashimoto's encephalopathy | 1 | 0 |
| Posterior reversible encephalopathy syndrome | 1 | 0 |
| Eye movement disorders | | |
| IIIrd nerve disorder | 1 | 0 |
| IIIrd nerve paralysis | 6 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Nervous system disorders <small>Nervous system disorders cont'd</small> | | |
| IVth nerve paralysis | 1 | 0 |
| Microvascular cranial nerve palsy | 1 | 0 |
| VIth nerve disorder | 1 | 0 |
| VIth nerve paralysis | 10 | 0 |
| Facial cranial nerve disorders | | |
| Bell's palsy | 438 | 0 |
| Facial nerve disorder | 8 | 0 |
| Facial paralysis | 343 | 0 |
| Facial paresis | 85 | 0 |
| Facial spasm | 45 | 0 |
| Generalised tonic-clonic seizures | | |
| Generalised tonic-clonic seizure | 46 | 0 |
| Headaches NEC | | |
| Cervicogenic headache | 3 | 0 |
| Cluster headache | 196 | 0 |
| Cold-stimulus headache | 19 | 0 |
| Drug withdrawal headache | 2 | 0 |
| Exertional headache | 8 | 0 |
| External compression headache | 2 | 0 |
| Headache | 22889 | 0 |
| Medication overuse headache | 2 | 0 |
| New daily persistent headache | 4 | 0 |
| Occipital neuralgia | 10 | 0 |
| Ophthalmoplegic migraine | 1 | 0 |
| Primary cough headache | 4 | 0 |
| Primary headache associated with sexual activity | 5 | 0 |
| Sinus headache | 311 | 0 |
| Tension headache | 491 | 0 |
| Thunderclap headache | 9 | 0 |
| Vascular headache | 15 | 0 |
| Hydrocephalic conditions | | |
| Hydrocephalus | 2 | 0 |
| Hypoglossal nerve disorders | | |
| Tongue paralysis | 1 | 0 |
| Increased intracranial pressure disorders | | |
| Brain compression | 1 | 0 |
| Brain oedema | 6 | 2 |
| Idiopathic intracranial hypertension | 6 | 0 |
| Intracranial pressure increased | 1 | 0 |
| Intellectual disabilities | | |
| Intellectual disability | 3 | 0 |
| Lumbar spinal cord and nerve root disorders | | |
| Sciatica | 76 | 0 |
| Memory loss (excl dementia) | | |
| Amnesia | 155 | 0 |
| Memory impairment | 163 | 0 |
| Transient global amnesia | 7 | 0 |
| Mental impairment (excl dementia and memory loss) | | |
| Cognitive disorder | 74 | 0 |
| Cognitive linguistic deficit | 1 | 0 |
| Disturbance in attention | 281 | 0 |
| Mental impairment | 44 | 0 |
| Migraine headaches | | |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Nervous system disorders | | |
| <i>Nervous system disorders cont'd</i> | | |
| Hemiplegic migraine | 29 | 0 |
| Migraine | 2606 | 0 |
| Migraine with aura | 169 | 0 |
| Migraine without aura | 17 | 0 |
| Ophthalmic migraine | 5 | 0 |
| Retinal migraine | 30 | 0 |
| Typical aura without headache | 7 | 0 |
| Vestibular migraine | 18 | 0 |
| Mixed cranial nerve disorders | | |
| Bulbar palsy | 2 | 0 |
| Mononeuropathies | | |
| Carpal tunnel syndrome | 20 | 0 |
| Cubital tunnel syndrome | 2 | 0 |
| Meralgia paraesthetica | 1 | 0 |
| Mononeuritis | 2 | 0 |
| Mononeuropathy | 3 | 0 |
| Nerve compression | 20 | 0 |
| Peripheral nerve lesion | 1 | 0 |
| Peroneal nerve palsy | 14 | 0 |
| Sciatic nerve neuropathy | 2 | 0 |
| Ulnar nerve palsy | 2 | 0 |
| Ulnar neuritis | 1 | 0 |
| Ulnar tunnel syndrome | 1 | 0 |
| Motor neurone diseases | | |
| Lower motor neurone lesion | 1 | 0 |
| Motor neurone disease | 1 | 0 |
| Multiple sclerosis acute and progressive | | |
| Band sensation | 1 | 0 |
| Multiple sclerosis | 28 | 0 |
| Multiple sclerosis relapse | 20 | 0 |
| Tumefactive multiple sclerosis | 1 | 1 |
| Muscle tone abnormal | | |
| Drop attacks | 1 | 0 |
| Hypertonia | 2 | 0 |
| Hypotonia | 25 | 0 |
| Morvan syndrome | 1 | 0 |
| Muscle tone disorder | 1 | 0 |
| Serotonin syndrome | 1 | 0 |
| Stiff leg syndrome | 1 | 0 |
| Myelitis (incl infective) | | |
| Myelitis transverse | 26 | 0 |
| Narcolepsy and hypersomnia | | |
| Cataplexy | 3 | 0 |
| Hypersomnia | 100 | 0 |
| Narcolepsy | 7 | 0 |
| Nervous system disorders NEC | | |
| Central nervous system lesion | 2 | 0 |
| Cerebral disorder | 1 | 0 |
| Nervous system disorder | 14 | 0 |
| Neurotoxicity | 3 | 0 |
| Neurologic visual problems NEC | | |
| Hemianopia | 1 | 0 |
| Hemianopia homonymous | 2 | 0 |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Nervous system disorders | | |
| <i>Nervous system disorders cont'd</i> | | |
| Quadrantanopia | 1 | 0 |
| Tunnel vision | 17 | 0 |
| Neurological signs and symptoms NEC | | |
| Agitation neonatal | 1 | 0 |
| Clonus | 4 | 0 |
| Decerebrate posture | 1 | 0 |
| Decorticate posture | 1 | 0 |
| Dizziness | 8687 | 0 |
| Dizziness exertional | 39 | 0 |
| Dizziness postural | 650 | 0 |
| Drooling | 21 | 0 |
| Fontanelle bulging | 2 | 0 |
| Head discomfort | 303 | 0 |
| Hyporesponsive to stimuli | 2 | 0 |
| Inability to crawl | 2 | 0 |
| Infant irritability | 9 | 0 |
| Myoclonus | 25 | 0 |
| Neurological symptom | 42 | 0 |
| Patient elopement | 1 | 0 |
| Persistent postural-perceptual dizziness | 14 | 0 |
| Presyncope | 561 | 0 |
| Sensory overload | 4 | 0 |
| Slow response to stimuli | 4 | 0 |
| Tongue biting | 5 | 0 |
| Unresponsive to stimuli | 41 | 0 |
| Neuromuscular disorders NEC | | |
| Muscle contractions involuntary | 17 | 0 |
| Muscle spasticity | 10 | 0 |
| Neuromuscular pain | 3 | 0 |
| Neuromuscular junction dysfunction | | |
| Myasthenia gravis | 7 | 0 |
| Myasthenia gravis crisis | 2 | 0 |
| Olfactory nerve disorders | | |
| Anosmia | 230 | 0 |
| Hyposmia | 16 | 0 |
| Parosmia | 223 | 0 |
| Optic nerve disorders NEC | | |
| Optic neuritis | 26 | 0 |
| Paraesthesias and dysaesthesias | | |
| Burning feet syndrome | 7 | 0 |
| Burning sensation | 472 | 0 |
| Burning sensation mucosal | 2 | 0 |
| Dysaesthesia | 7 | 0 |
| Formication | 37 | 0 |
| Hand-arm vibration syndrome | 3 | 0 |
| Hemianaesthesia | 1 | 0 |
| Hemiparaesthesia | 3 | 0 |
| Hyperaesthesia | 80 | 0 |
| Hypoaesthesia | 2609 | 0 |
| Paraesthesia | 3572 | 0 |
| Reversed hot-cold sensation | 4 | 0 |
| Synaesthesia | 1 | 0 |
| Paralysis and paresis (excl cranial nerve) | | |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Nervous system disorders | | |
| <i>Nervous system disorders cont'd</i> | | |
| Diplegia | 12 | 0 |
| Hemiparesis | 42 | 0 |
| Hemiplegia | 37 | 0 |
| Locked-in syndrome | 1 | 0 |
| Monoparesis | 52 | 0 |
| Monoplegia | 71 | 0 |
| Paralysis | 115 | 0 |
| Paraparesis | 3 | 0 |
| Paraplegia | 1 | 0 |
| Paresis | 6 | 0 |
| Quadriparesis | 1 | 0 |
| Quadriplegia | 1 | 0 |
| <i>Parkinson's disease and parkinsonism</i> | | |
| Freezing phenomenon | 8 | 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 | 10 | 0 |
| <i>Partial complex seizures</i> | | |
| Dreamy state | 6 | 0 |
| Focal dyscognitive seizures | 3 | 0 |
| Temporal lobe epilepsy | 2 | 0 |
| <i>Partial simple seizures NEC</i> | | |
| Autonomic seizure | 1 | 0 |
| <i>Peripheral neuropathies NEC</i> | | |
| Axonal neuropathy | 2 | 0 |
| Neuralgic amyotrophy | 3 | 0 |
| Neuritis | 7 | 0 |
| Neuropathy peripheral | 98 | 0 |
| Peripheral sensorimotor neuropathy | 1 | 0 |
| Peripheral sensory neuropathy | 11 | 0 |
| Polyneuropathy | 3 | 0 |
| Thoracic outlet syndrome | 1 | 0 |
| <i>Seizures and seizure disorders NEC</i> | | |
| Atonic seizures | 4 | 0 |
| Change in seizure presentation | 2 | 0 |
| Clonic convulsion | 3 | 0 |
| Convulsions local | 1 | 0 |
| Epilepsy | 143 | 0 |
| Epileptic aura | 2 | 0 |
| Epileptic encephalopathy | 1 | 0 |
| Febrile convulsion | 14 | 0 |
| Idiopathic generalised epilepsy | 1 | 0 |
| Partial seizures | 17 | 0 |
| Post stroke seizure | 1 | 0 |
| Psychogenic seizure | 7 | 0 |
| Seizure | 525 | 0 |
| Seizure anoxic | 2 | 0 |
| Seizure cluster | 6 | 0 |
| Seizure like phenomena | 2 | 0 |
| Status epilepticus | 41 | 0 |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Nervous system disorders | | |
| <i>Nervous system disorders cont'd</i> | | |
| Tonic clonic movements | 3 | 0 |
| Tonic convulsion | 24 | 0 |
| Tonic posturing | 1 | 0 |
| Sensory abnormalities NEC | | |
| Ageusia | 465 | 0 |
| Allodynia | 24 | 0 |
| Aura | 20 | 0 |
| Complex regional pain syndrome | 5 | 0 |
| Dysgeusia | 1053 | 0 |
| Electric shock sensation | 35 | 0 |
| Hypergeusia | 1 | 0 |
| Hypogeusia | 7 | 0 |
| Intercostal neuralgia | 1 | 0 |
| Loss of proprioception | 3 | 0 |
| Morton's neuralgia | 1 | 0 |
| Neuralgia | 470 | 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 | 124 | 0 |
| Sensory disturbance | 93 | 0 |
| Sensory loss | 66 | 0 |
| Taste disorder | 235 | 0 |
| Visual perseveration | 3 | 0 |
| Sleep disturbances NEC | | |
| Sleep deficit | 9 | 0 |
| Sudden onset of sleep | 1 | 0 |
| Speech and language abnormalities | | |
| Dysarthria | 169 | 0 |
| Incoherent | 9 | 0 |
| Language disorder | 2 | 0 |
| Repetitive speech | 3 | 0 |
| Slow speech | 18 | 0 |
| Speech disorder | 60 | 0 |
| Spinal cord and nerve root disorders NEC | | |
| Cauda equina syndrome | 1 | 0 |
| Myelopathy | 1 | 0 |
| Radiculitis brachial | 10 | 0 |
| Radiculopathy | 5 | 0 |
| Structural brain disorders NEC | | |
| Brain injury | 6 | 2 |
| Hyperintensity in brain deep nuclei | 1 | 0 |
| Transient cerebrovascular events | | |
| Transient ischaemic attack | 134 | 3 |
| Tremor (excl congenital) | | |
| Essential tremor | 3 | 0 |
| Head titubation | 12 | 0 |
| Resting tremor | 4 | 0 |
| Tremor | 1465 | 0 |
| Trigeminal disorders | | |
| Facial neuralgia | 17 | 0 |
| Numb chin syndrome | 2 | 0 |

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| Reaction Name | Total | Fatal |
|---|--------------|-----------|
| Nervous system disorders | | |
| Nervous system disorders cont'd | | |
| Trigeminal nerve disorder | 3 | 0 |
| Trigeminal neuralgia | 41 | 0 |
| Trigeminal neuritis | 1 | 0 |
| <i>Vagus nerve disorders</i> | | |
| Vocal cord paralysis | 1 | 0 |
| <i>Vertigos NEC</i> | | |
| Cervicogenic vertigo | 1 | 0 |
| Vertigo CNS origin | 3 | 0 |
| Nervous system disorders SOC TOTAL | 59600 | 55 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Pregnancy conditions | | |
| <i>Abortion related conditions and complications</i> | | |
| Anembryonic gestation | 2 | 0 |
| <i>Abortions not specified as induced or spontaneous</i> | | |
| Abortion | 1 | 0 |
| Abortion missed | 4 | 1 |
| <i>Abortions spontaneous</i> | | |
| Abortion spontaneous | 354 | 9 |
| Abortion threatened | 2 | 0 |
| <i>Amniotic fluid and cavity disorders of pregnancy NEC</i> | | |
| Amniorrhoea | 1 | 0 |
| <i>Foetal complications NEC</i> | | |
| Foetal cardiac disorder | 1 | 0 |
| Foetal damage | 1 | 1 |
| Foetal distress syndrome | 1 | 0 |
| Foetal hypokinesia | 10 | 0 |
| <i>Foetal growth complications</i> | | |
| Foetal growth restriction | 6 | 0 |
| <i>Gestational age and weight conditions</i> | | |
| Premature baby | 4 | 1 |
| <i>Haemorrhagic complications of pregnancy</i> | | |
| Haemorrhage in pregnancy | 2 | 0 |
| Premature separation of placenta | 3 | 0 |
| Subchorionic haematoma | 2 | 0 |
| Subchorionic haemorrhage | 1 | 0 |
| <i>Hypertension associated disorders of pregnancy</i> | | |
| Pre-eclampsia | 1 | 0 |
| <i>Labour onset and length abnormalities</i> | | |
| Induced labour | 1 | 0 |
| Premature delivery | 1 | 0 |
| Premature labour | 5 | 0 |
| Premature rupture of membranes | 2 | 0 |
| Threatened labour | 1 | 0 |
| <i>Maternal complications of labour NEC</i> | | |
| Uterine contractions abnormal | 1 | 0 |
| Uterine hypertonus | 8 | 0 |
| <i>Maternal complications of pregnancy NEC</i> | | |
| Biochemical pregnancy | 1 | 0 |
| Complication of pregnancy | 2 | 0 |
| Decidual cast | 4 | 0 |
| Ectopic pregnancy | 7 | 0 |
| Hyperemesis gravidarum | 1 | 0 |
| Morning sickness | 15 | 0 |
| Preterm premature rupture of membranes | 3 | 0 |
| Ruptured ectopic pregnancy | 1 | 0 |
| Somatic symptom disorder of pregnancy | 3 | 0 |
| <i>Newborn complications NEC</i> | | |
| Neonatal disorder | 1 | 0 |
| <i>Normal newborn status</i> | | |
| Normal newborn | 1 | 0 |
| <i>Normal pregnancy, labour and delivery</i> | | |
| Labour pain | 1 | 0 |
| Live birth | 4 | 0 |
| Pregnancy | 35 | 0 |

Case Series Drug Analysis Print

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Report Run Date: 14-Oct-2021

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MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|--|------------|-----------|
| Pregnancy conditions <small>Pregnancy conditions cont'd</small> | | |
| Uterine contractions during pregnancy | 4 | 0 |
| Placental abnormalities (excl neoplasms) | | |
| Placental disorder | 1 | 0 |
| Placental insufficiency | 1 | 0 |
| Postpartum complications NEC | | |
| Postpartum haemorrhage | 3 | 0 |
| Pregnancy complicated by maternal disorders | | |
| Gestational diabetes | 2 | 0 |
| Peripartum cardiomyopathy | 1 | 0 |
| Stillbirth and foetal death | | |
| Foetal death | 3 | 2 |
| Stillbirth | 6 | 4 |
| Unintended pregnancies | | |
| Pregnancy after post coital contraception | 2 | 0 |
| Pregnancy on contraceptive | 2 | 0 |
| Pregnancy on oral contraceptive | 2 | 0 |
| Pregnancy with contraceptive device | 1 | 0 |
| Pregnancy with implant contraceptive | 1 | 0 |
| Unintended pregnancy | 2 | 0 |
| Unwanted pregnancy | 1 | 0 |
| Pregnancy conditions SOC TOTAL | 526 | 18 |

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MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|--|-----------|----------|
| <i>Device issues NEC</i> | | |
| Device connection issue | 1 | 0 |
| Device failure | 1 | 0 |
| Device issue | 2 | 0 |
| <i>Device malfunction events NEC</i> | | |
| Device infusion issue | 1 | 0 |
| Device malfunction | 1 | 0 |
| Device pacing issue | 1 | 0 |
| Device stimulation issue | 1 | 0 |
| Oversensing | 15 | 0 |
| Thrombosis in device | 9 | 0 |
| <i>Device physical property and chemical issues</i> | | |
| Device breakage | 1 | 0 |
| Device defective | 7 | 0 |
| Device kink | 1 | 0 |
| Needle issue | 2 | 0 |
| <i>Product contamination and sterility issues</i> | | |
| Product contamination | 11 | 0 |
| Product contamination physical | 6 | 0 |
| <i>Product packaging issues</i> | | |
| Product closure issue | 1 | 0 |
| <i>Product physical issues</i> | | |
| Liquid product physical issue | 9 | 0 |
| Product deposit | 1 | 0 |
| Product odour abnormal | 2 | 0 |
| Product physical issue | 2 | 0 |
| Product taste abnormal | 9 | 0 |
| <i>Product quality issues NEC</i> | | |
| Product complaint | 1 | 0 |
| Product origin unknown | 6 | 0 |
| <i>Product supply and availability issues</i> | | |
| Product availability issue | 1 | 0 |
| null SOC TOTAL | 92 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Psychiatric disorders | | |
| <i>Abnormal behaviour NEC</i> | | |
| Abnormal behaviour | 24 | 0 |
| Behaviour disorder | 1 | 0 |
| Breath holding | 6 | 0 |
| Staring | 7 | 0 |
| <i>Adjustment disorders</i> | | |
| Adjustment disorder with depressed mood | 4 | 0 |
| <i>Affect alterations NEC</i> | | |
| Affect lability | 12 | 0 |
| Constricted affect | 3 | 0 |
| Flat affect | 8 | 0 |
| Inappropriate affect | 19 | 0 |
| <i>Amnesic symptoms</i> | | |
| Paramnesia | 5 | 0 |
| <i>Anxiety disorders NEC</i> | | |
| Anxiety disorder | 1 | 0 |
| Generalised anxiety disorder | 1 | 0 |
| Neurosis | 1 | 0 |
| <i>Anxiety symptoms</i> | | |
| Agitation | 71 | 0 |
| Anxiety | 748 | 0 |
| Immunisation anxiety related reaction | 2 | 0 |
| Nervousness | 156 | 0 |
| Stress | 93 | 0 |
| Tension | 36 | 0 |
| <i>Attention deficit and disruptive behaviour disorders</i> | | |
| Attention deficit hyperactivity disorder | 5 | 0 |
| <i>Behaviour and socialisation disturbances</i> | | |
| Aggression | 12 | 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 |
| <i>Bipolar disorders</i> | | |
| Bipolar I disorder | 2 | 0 |
| Bipolar disorder | 4 | 0 |
| <i>Cognitive and attention disorders and disturbances NEC</i> | | |
| Daydreaming | 7 | 0 |
| Distractibility | 1 | 0 |
| Mental fatigue | 194 | 0 |
| <i>Communications disorders</i> | | |
| Communication disorder | 5 | 0 |
| Mutism | 3 | 0 |
| <i>Confusion and disorientation</i> | | |
| Confusional state | 789 | 0 |
| Disorientation | 253 | 0 |
| <i>Decreased physical activity levels</i> | | |
| Catatonia | 1 | 0 |

Case Series Drug Analysis Print

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Psychiatric disorders <small>Psychiatric disorders cont'd</small> | | |
| <i>Deliria</i> | | |
| Delirium | 96 | 0 |
| <i>Delusional symptoms</i> | | |
| Delusion | 11 | 0 |
| <i>Depressive disorders</i> | | |
| Agitated depression | 5 | 0 |
| Depression | 304 | 0 |
| Depression suicidal | 13 | 0 |
| Major depression | 9 | 0 |
| Mixed anxiety and depressive disorder | 3 | 0 |
| <i>Dissociative states</i> | | |
| Depersonalisation/derealisation disorder | 9 | 0 |
| Dissociation | 25 | 0 |
| Dissociative amnesia | 2 | 0 |
| Dissociative disorder | 2 | 0 |
| <i>Disturbances in initiating and maintaining sleep</i> | | |
| Initial insomnia | 19 | 0 |
| Insomnia | 1261 | 0 |
| Middle insomnia | 25 | 0 |
| Terminal insomnia | 31 | 0 |
| <i>Dyssomnias</i> | | |
| Breathing-related sleep disorder | 1 | 0 |
| Dyssomnia | 1 | 0 |
| Poor quality sleep | 197 | 0 |
| <i>Eating disorders NEC</i> | | |
| Bulimia nervosa | 1 | 0 |
| Eating disorder | 10 | 0 |
| Selective eating disorder | 1 | 0 |
| <i>Emotional and mood disturbances NEC</i> | | |
| Anger | 34 | 0 |
| Dysphoria | 2 | 0 |
| Emotional disorder | 52 | 0 |
| Emotional distress | 38 | 0 |
| Emotional poverty | 1 | 0 |
| Euphoric mood | 43 | 0 |
| Frustration tolerance decreased | 2 | 0 |
| Irritability | 189 | 0 |
| Mood altered | 53 | 0 |
| <i>Factitious disorders</i> | | |
| Factitious disorder | 4 | 0 |
| <i>Fear symptoms and phobic disorders (incl social phobia)</i> | | |
| Agoraphobia | 2 | 0 |
| Fear | 18 | 0 |
| Fear of death | 1 | 0 |
| Fear of eating | 1 | 0 |
| Fear of falling | 3 | 0 |
| Fear of injection | 6 | 0 |
| Osmophobia | 1 | 0 |
| Phobia | 3 | 0 |
| Phonophobia | 2 | 0 |
| Social anxiety disorder | 1 | 0 |
| Social fear | 1 | 0 |
| <i>Fluctuating mood symptoms</i> | | |

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Psychiatric disorders <small>Psychiatric disorders cont'd</small> | | |
| Mood swings | 130 | 0 |
| Hallucinations (excl sleep-related) | | |
| Hallucination | 174 | 0 |
| Hallucination, auditory | 13 | 0 |
| Hallucination, olfactory | 10 | 0 |
| Hallucination, tactile | 1 | 0 |
| Hallucination, visual | 23 | 0 |
| Hallucinations, mixed | 2 | 0 |
| Increased physical activity levels | | |
| Restlessness | 140 | 0 |
| Infancy, childhood and adolescence psychiatric disorders NEC | | |
| Social (pragmatic) communication disorder | 1 | 0 |
| Learning disorders | | |
| Learning disability | 1 | 0 |
| Learning disorder | 1 | 0 |
| Mental disorders NEC | | |
| Mental disorder | 15 | 0 |
| Mental status changes | 1 | 0 |
| Psychological factor affecting medical condition | 1 | 0 |
| Mood alterations with depressive symptoms | | |
| Anhedonia | 3 | 0 |
| Decreased interest | 9 | 0 |
| Depressed mood | 348 | 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 | 2 | 0 |
| Tearfulness | 35 | 0 |
| Mood alterations with manic symptoms | | |
| Hypomania | 2 | 0 |
| Mania | 11 | 0 |
| Mood disorders NEC | | |
| Affective disorder | 3 | 0 |
| Apathy | 28 | 0 |
| Boredom | 1 | 0 |
| Laziness | 3 | 0 |
| Listless | 17 | 0 |
| Mood disorder due to a general medical condition | 1 | 0 |
| Narcolepsy and associated conditions | | |
| Hypnagogic hallucination | 3 | 0 |
| Hypnopompic hallucination | 2 | 0 |
| Sleep attacks | 3 | 0 |
| Obsessive-compulsive disorders and symptoms | | |
| Obsessive-compulsive symptom | 1 | 0 |
| Orgasmic disorders and disturbances | | |
| Anorgasmia | 4 | 0 |
| Female orgasmic disorder | 2 | 0 |
| Orgasm abnormal | 4 | 0 |
| Orgasmic sensation decreased | 1 | 0 |
| Premature ejaculation | 1 | 0 |

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MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Psychiatric disorders <small>Psychiatric disorders cont'd</small> | | |
| <i>Panic attacks and disorders</i> | | |
| Panic attack | 174 | 0 |
| Panic disorder | 3 | 0 |
| Panic reaction | 25 | 0 |
| <i>Paraphilias and paraphilic disorders</i> | | |
| Transvestism | 1 | 0 |
| <i>Parasomnias</i> | | |
| Abnormal dreams | 163 | 0 |
| Abnormal sleep-related event | 1 | 0 |
| Confusional arousal | 1 | 0 |
| Exploding head syndrome | 2 | 0 |
| Nightmare | 181 | 0 |
| Parasomnia | 2 | 0 |
| Sleep inertia | 1 | 0 |
| Sleep talking | 6 | 0 |
| Sleep terror | 21 | 0 |
| Somnambulism | 5 | 0 |
| <i>Perception disturbances NEC</i> | | |
| Autoscopy | 16 | 0 |
| Deja vu | 2 | 0 |
| Derealisation | 8 | 0 |
| Flashback | 3 | 0 |
| Illusion | 2 | 0 |
| Near death experience | 1 | 0 |
| Time perception altered | 2 | 0 |
| <i>Personality disorders NEC</i> | | |
| Personality disorder | 1 | 0 |
| <i>Pervasive developmental disorders NEC</i> | | |
| Autism spectrum disorder | 2 | 0 |
| <i>Psychiatric elimination disorders</i> | | |
| Enuresis | 20 | 0 |
| <i>Psychiatric symptoms NEC</i> | | |
| Hypervigilance | 9 | 0 |
| Psychiatric symptom | 4 | 0 |
| Psychological trauma | 2 | 0 |
| Trance | 1 | 0 |
| <i>Psychotic disorder NEC</i> | | |
| Acute psychosis | 1 | 0 |
| Psychotic behaviour | 1 | 0 |
| Psychotic disorder | 22 | 0 |
| <i>Schizophrenia NEC</i> | | |
| Schizophrenia | 1 | 0 |
| <i>Sexual arousal disorders</i> | | |
| Disturbance in sexual arousal | 3 | 0 |
| Sexual inhibition | 1 | 0 |
| <i>Sexual desire disorders</i> | | |
| Hypersexuality | 1 | 0 |
| Libido decreased | 13 | 0 |
| Libido increased | 6 | 0 |
| Loss of libido | 16 | 0 |
| <i>Sexual dysfunction NEC</i> | | |
| Genito-pelvic pain/penetration disorder | 1 | 0 |
| <i>Sleep disorders NEC</i> | | |

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| Reaction Name | Total | Fatal |
|--|-------------|----------|
| Psychiatric disorders <small>Psychiatric disorders cont'd</small> | | |
| Sleep disorder | 183 | 0 |
| Sleep disorder due to general medical condition, insomnia type | 4 | 0 |
| <i>Somatic symptom disorders</i> | | |
| Conversion disorder | 21 | 0 |
| Habit cough | 16 | 0 |
| Somatic symptom disorder | 1 | 0 |
| Vomiting psychogenic | 1 | 0 |
| <i>Speech and language usage disturbances</i> | | |
| Disorganised speech | 7 | 0 |
| Logorrhoea | 2 | 0 |
| <i>Speech articulation and rhythm disturbances</i> | | |
| Dysphemia | 24 | 0 |
| Lack of spontaneous speech | 1 | 0 |
| Pressure of speech | 1 | 0 |
| <i>Stereotypies and automatisms</i> | | |
| Bruxism | 10 | 0 |
| Head banging | 8 | 0 |
| Stereotypy | 1 | 0 |
| <i>Stress disorders</i> | | |
| Burnout syndrome | 2 | 0 |
| Post-traumatic stress disorder | 4 | 0 |
| <i>Substance related and addictive disorders</i> | | |
| Alcohol problem | 1 | 0 |
| Alcoholic hangover | 1 | 0 |
| Alcoholism | 3 | 0 |
| Nicotine dependence | 2 | 0 |
| <i>Suicidal and self-injurious behaviour</i> | | |
| Completed suicide | 1 | 1 |
| Intentional self-injury | 7 | 0 |
| Self-injurious ideation | 2 | 0 |
| Suicidal ideation | 35 | 0 |
| Suicide attempt | 8 | 0 |
| Suicide threat | 1 | 0 |
| <i>Thinking disturbances</i> | | |
| Bradyphrenia | 38 | 0 |
| Intrusive thoughts | 6 | 0 |
| Morbid thoughts | 1 | 0 |
| Tachyphrenia | 5 | 0 |
| Thinking abnormal | 19 | 0 |
| Thought blocking | 1 | 0 |
| <i>Tic disorders</i> | | |
| Tic | 9 | 0 |
| Psychiatric disorders SOC TOTAL | 7163 | 1 |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Renal & urinary disorders | | |
| <i>Bladder and urethral symptoms</i> | | |
| Bladder discomfort | 2 | 0 |
| Bladder irritation | 7 | 0 |
| Bladder pain | 26 | 0 |
| Dysuria | 44 | 0 |
| Incontinence | 22 | 0 |
| Lower urinary tract symptoms | 2 | 0 |
| Micturition disorder | 2 | 0 |
| Micturition urgency | 38 | 0 |
| Pollakiuria | 113 | 0 |
| Stress urinary incontinence | 1 | 0 |
| Urethral pain | 7 | 0 |
| Urge incontinence | 1 | 0 |
| Urinary hesitation | 1 | 0 |
| Urinary incontinence | 46 | 0 |
| Urinary retention | 33 | 0 |
| Urine flow decreased | 12 | 0 |
| <i>Bladder disorders NEC</i> | | |
| Bladder disorder | 8 | 0 |
| Bladder fibrosis | 1 | 0 |
| Bladder prolapse | 1 | 0 |
| Urinary bladder haemorrhage | 2 | 0 |
| <i>Bladder infections and inflammations</i> | | |
| Cystitis interstitial | 5 | 0 |
| Cystitis noninfective | 1 | 0 |
| <i>Genital and urinary tract disorders NEC</i> | | |
| Genitourinary symptom | 1 | 0 |
| Urinary tract disorder | 4 | 0 |
| <i>Glomerulonephritis and nephrotic syndrome</i> | | |
| Glomerulonephritis minimal lesion | 5 | 0 |
| Glomerulonephritis rapidly progressive | 2 | 0 |
| IgA nephropathy | 3 | 0 |
| Nephrotic syndrome | 17 | 0 |
| <i>Myoneurogenic bladder disorders</i> | | |
| Bladder dysfunction | 5 | 0 |
| Hypertonic bladder | 1 | 0 |
| Hypotonic urinary bladder | 1 | 0 |
| Loss of bladder sensation | 2 | 0 |
| Neurogenic bladder | 2 | 0 |
| <i>Nephritis NEC</i> | | |
| Lupus nephritis | 1 | 0 |
| Nephritis | 2 | 0 |
| Tubulointerstitial nephritis | 2 | 0 |
| <i>Nephropathies and tubular disorders NEC</i> | | |
| Nephropathy | 1 | 0 |
| <i>Renal disorders NEC</i> | | |
| Renal disorder | 4 | 1 |
| Renal haemorrhage | 1 | 0 |
| Renal mass | 1 | 0 |
| <i>Renal failure and impairment</i> | | |
| Acute kidney injury | 43 | 4 |
| Anuria | 3 | 0 |
| Chronic kidney disease | 4 | 0 |

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| Reaction Name | Total | Fatal |
|--|------------|----------|
| Renal & urinary disorders | | |
| <i>Renal & urinary disorders cont'd</i> | | |
| Oliguria | 1 | 0 |
| Renal failure | 17 | 1 |
| Renal impairment | 22 | 0 |
| Renal injury | 1 | 0 |
| Renal lithiasis | | |
| Nephrolithiasis | 9 | 0 |
| Renal neoplasms | | |
| Renal cyst | 1 | 0 |
| Renal obstructive disorders | | |
| Hydronephrosis | 2 | 0 |
| Renal structural abnormalities and trauma | | |
| Kidney small | 1 | 0 |
| Renal vascular and ischaemic conditions | | |
| Renal infarct | 1 | 0 |
| Renal tubular necrosis | 1 | 0 |
| Renal vasculitis | 1 | 1 |
| Structural and obstructive urethral disorders (excl congenital) | | |
| Urethral stenosis | 1 | 0 |
| Ureteric disorders NEC | | |
| Ureteric stenosis | 1 | 0 |
| Urinary abnormalities | | |
| Albuminuria | 1 | 0 |
| Chromaturia | 44 | 0 |
| Haematuria | 32 | 0 |
| Ketonuria | 1 | 0 |
| Myoglobinuria | 1 | 0 |
| Proteinuria | 11 | 0 |
| Urine abnormality | 9 | 0 |
| Urine odour abnormal | 8 | 0 |
| Urinary tract lithiasis (excl renal) | | |
| Calculus urinary | 1 | 0 |
| Urinary tract signs and symptoms NEC | | |
| Costovertebral angle tenderness | 1 | 0 |
| Cystitis-like symptom | 1 | 0 |
| Haemorrhage urinary tract | 20 | 0 |
| Nocturia | 3 | 0 |
| Polyuria | 8 | 0 |
| Renal colic | 4 | 0 |
| Renal pain | 247 | 0 |
| Urinary tract discomfort | 1 | 0 |
| Urinary tract pain | 4 | 0 |
| Renal & urinary disorders SOC TOTAL | 936 | 7 |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Reproductive & breast disorders | | |
| <i>Benign and malignant breast neoplasms</i> | | |
| Breast cyst | 11 | 0 |
| <i>Breast disorders NEC</i> | | |
| Breast disorder | 1 | 0 |
| Breast enlargement | 26 | 0 |
| Breast mass | 101 | 0 |
| Gynaecomastia | 3 | 0 |
| Mastoptosis | 1 | 0 |
| Nipple disorder | 1 | 0 |
| <i>Breast infections and inflammations</i> | | |
| Breast inflammation | 2 | 0 |
| Nipple inflammation | 2 | 0 |
| <i>Breast signs and symptoms</i> | | |
| Breast discharge | 3 | 0 |
| Breast discomfort | 9 | 0 |
| Breast engorgement | 8 | 0 |
| Breast haematoma | 1 | 0 |
| Breast oedema | 5 | 0 |
| Breast pain | 567 | 0 |
| Breast swelling | 127 | 0 |
| Breast tenderness | 67 | 0 |
| Nipple pain | 36 | 1 |
| Nipple swelling | 4 | 0 |
| <i>Cervix disorders NEC</i> | | |
| Cervical dysplasia | 2 | 0 |
| Cervix disorder | 1 | 0 |
| Cervix haemorrhage uterine | 5 | 0 |
| Ectropion of cervix | 2 | 0 |
| <i>Cervix infections and inflammations</i> | | |
| Cervix inflammation | 1 | 0 |
| <i>Cervix neoplasms</i> | | |
| Cervical polyp | 1 | 0 |
| <i>Erection and ejaculation conditions and disorders</i> | | |
| Ejaculation disorder | 2 | 0 |
| Ejaculation failure | 3 | 0 |
| Erectile dysfunction | 51 | 0 |
| Erection increased | 2 | 0 |
| Organic erectile dysfunction | 12 | 0 |
| Painful ejaculation | 1 | 0 |
| Spontaneous ejaculation | 1 | 0 |
| Spontaneous penile erection | 1 | 0 |
| <i>Fallopian tube and ovary infections and inflammations</i> | | |
| Noninfective oophoritis | 3 | 0 |
| <i>Lactation disorders</i> | | |
| Breast milk discolouration | 3 | 0 |
| Breast milk odour abnormal | 1 | 0 |
| Galactorrhoea | 5 | 0 |
| Galactostasis | 1 | 0 |
| Lactation disorder | 6 | 0 |
| Lactation puerperal increased | 5 | 0 |
| Suppressed lactation | 41 | 0 |
| <i>Menopausal effects NEC</i> | | |
| Artificial menopause | 1 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Reproductive & breast disorders | | |
| <i>Reproductive & breast disorders cont'd</i> | | |
| Menopausal disorder | 1 | 0 |
| Menopausal symptoms | 22 | 0 |
| Menopause delayed | 1 | 0 |
| Premature menopause | 14 | 0 |
| <i>Menopausal effects on the genitourinary tract</i> | | |
| Atrophic vulvovaginitis | 1 | 0 |
| Postmenopausal haemorrhage | 84 | 0 |
| <i>Menstruation and uterine bleeding NEC</i> | | |
| Abnormal uterine bleeding | 6 | 0 |
| Abnormal withdrawal bleeding | 1 | 0 |
| Dysmenorrhoea | 2519 | 0 |
| Intermenstrual bleeding | 947 | 0 |
| Menstrual discomfort | 24 | 0 |
| Menstrual disorder | 1563 | 0 |
| Menstruation irregular | 2803 | 0 |
| Premenstrual dysphoric disorder | 10 | 0 |
| Premenstrual headache | 7 | 0 |
| Premenstrual pain | 99 | 0 |
| Premenstrual syndrome | 101 | 0 |
| Retrograde menstruation | 1 | 0 |
| Withdrawal bleed | 15 | 0 |
| <i>Menstruation with decreased bleeding</i> | | |
| Amenorrhoea | 504 | 0 |
| Hypomenorrhoea | 574 | 0 |
| Menstruation delayed | 4307 | 0 |
| Oligomenorrhoea | 135 | 0 |
| <i>Menstruation with increased bleeding</i> | | |
| Heavy menstrual bleeding | 4769 | 0 |
| Menometrorrhagia | 17 | 0 |
| Polymenorrhoea | 734 | 0 |
| <i>Ovarian and fallopian tube cysts and neoplasms</i> | | |
| Ovarian cyst | 17 | 0 |
| Ovarian cyst ruptured | 1 | 0 |
| Polycystic ovaries | 41 | 0 |
| <i>Ovarian and fallopian tube disorders NEC</i> | | |
| Adnexal torsion | 1 | 0 |
| Hydrosalpinx | 2 | 0 |
| Ovarian enlargement | 1 | 0 |
| Ovarian haemorrhage | 5 | 0 |
| Ovulation disorder | 2 | 0 |
| Ovulation pain | 57 | 0 |
| Premature ovulation | 4 | 0 |
| <i>Pelvis and broad ligament disorders NEC</i> | | |
| Adnexa uteri mass | 1 | 0 |
| Adnexa uteri pain | 45 | 0 |
| Pelvic congestion | 1 | 0 |
| Pelvic floor muscle weakness | 1 | 0 |
| Pelvic haemorrhage | 17 | 0 |
| <i>Penile and scrotal infections and inflammations</i> | | |
| Balanoposthitis | 2 | 0 |
| <i>Penile disorders NEC (excl erection and ejaculation)</i> | | |
| Penile blister | 1 | 0 |
| Penile discharge | 1 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Reproductive & breast disorders | | |
| <i>Reproductive & breast disorders cont'd</i> | | |
| Penile discomfort | 1 | 0 |
| Penile erythema | 1 | 0 |
| Penile haemorrhage | 2 | 0 |
| Penile pain | 1 | 0 |
| Penile swelling | 5 | 0 |
| Penis disorder | 8 | 0 |
| <i>Prostate and seminal vesicles infections and inflammations</i> | | |
| Prostatitis | 3 | 0 |
| <i>Prostatic signs, symptoms and disorders NEC</i> | | |
| Prostatic pain | 1 | 0 |
| Prostatomegaly | 3 | 0 |
| <i>Reproductive tract disorders NEC (excl neoplasms)</i> | | |
| Genital erosion | 1 | 0 |
| Genital haemorrhage | 22 | 0 |
| Genital hypoaesthesia | 1 | 0 |
| Genital lesion | 2 | 0 |
| Genital paraesthesia | 1 | 0 |
| Genital ulceration | 6 | 0 |
| Perineal ulceration | 1 | 0 |
| <i>Reproductive tract infections and inflammations NEC</i> | | |
| Genital tract inflammation | 1 | 0 |
| <i>Reproductive tract signs and symptoms NEC</i> | | |
| Genital burning sensation | 2 | 0 |
| Genital erythema | 1 | 0 |
| Genital pain | 5 | 0 |
| Genital rash | 4 | 0 |
| Genital swelling | 3 | 0 |
| Pelvic discomfort | 5 | 0 |
| Pelvic pain | 89 | 0 |
| Perineal pain | 2 | 0 |
| Perineal rash | 1 | 0 |
| Pruritus genital | 3 | 0 |
| <i>Scrotal disorders NEC</i> | | |
| Acquired hydrocele | 1 | 0 |
| Scrotal angiokeratoma | 1 | 0 |
| Scrotal discomfort | 1 | 0 |
| Scrotal erythema | 1 | 0 |
| Scrotal exfoliation | 1 | 0 |
| Scrotal pain | 20 | 0 |
| Scrotal swelling | 4 | 0 |
| Varicocele | 1 | 0 |
| <i>Sexual function and fertility disorders NEC</i> | | |
| Dyspareunia | 5 | 0 |
| Infertility | 9 | 0 |
| Infertility female | 2 | 0 |
| Sexual dysfunction | 6 | 0 |
| <i>Spermatogenesis and semen disorders</i> | | |
| Aspermia | 1 | 0 |
| Haematospermia | 6 | 0 |
| Semen discolouration | 1 | 0 |
| <i>Testicular and epididymal disorders NEC</i> | | |
| Testicular disorder | 3 | 0 |
| Testicular pain | 50 | 0 |

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| Reaction Name | Total | Fatal |
|--|--------------|----------|
| Reproductive & breast disorders | | |
| <i>Reproductive & breast disorders cont'd</i> | | |
| Testicular swelling | 8 | 0 |
| Testis discomfort | 2 | 0 |
| <i>Uterine disorders NEC</i> | | |
| Adenomyosis | 7 | 0 |
| Endometrial thickening | 3 | 0 |
| Endometriosis | 72 | 0 |
| Uterine haemorrhage | 30 | 0 |
| Uterine pain | 13 | 0 |
| <i>Uterine infections and inflammations (excl cervix)</i> | | |
| Uterine inflammation | 1 | 0 |
| <i>Uterine neoplasms</i> | | |
| Uterine polyp | 4 | 0 |
| <i>Uterine tone disorders</i> | | |
| Uterine spasm | 29 | 0 |
| <i>Vulvovaginal cysts and neoplasms</i> | | |
| Bartholin's cyst | 1 | 0 |
| Vaginal cyst | 6 | 0 |
| Vaginal polyp | 1 | 0 |
| <i>Vulvovaginal disorders NEC</i> | | |
| Vaginal haemorrhage | 1318 | 0 |
| Vaginal mucosal blistering | 1 | 0 |
| Vaginal ulceration | 1 | 0 |
| Vulval disorder | 1 | 0 |
| Vulval haemorrhage | 23 | 0 |
| Vulval ulceration | 7 | 0 |
| Vulvovaginal ulceration | 3 | 0 |
| <i>Vulvovaginal signs and symptoms</i> | | |
| Clitoral engorgement | 1 | 0 |
| Coital bleeding | 5 | 0 |
| Labia enlarged | 1 | 0 |
| Vaginal discharge | 69 | 0 |
| Vaginal lesion | 1 | 0 |
| Vaginal odour | 2 | 0 |
| Vulval oedema | 1 | 0 |
| Vulvovaginal burning sensation | 4 | 0 |
| Vulvovaginal dryness | 3 | 0 |
| Vulvovaginal erythema | 1 | 0 |
| Vulvovaginal pain | 23 | 0 |
| Vulvovaginal pruritus | 8 | 0 |
| Vulvovaginal rash | 2 | 0 |
| Vulvovaginal swelling | 3 | 0 |
| Reproductive & breast disorders SOC TOTAL | 22528 | 1 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Respiratory disorders | | |
| <i>Breathing abnormalities</i> | | |
| Apnoea | 5 | 0 |
| Apnoeic attack | 1 | 0 |
| Dyspnoea | 3897 | 5 |
| Dyspnoea at rest | 11 | 0 |
| Dyspnoea exertional | 33 | 1 |
| Hyperventilation | 43 | 0 |
| Hypopnoea | 96 | 0 |
| Hypoventilation | 1 | 0 |
| Irregular breathing | 19 | 0 |
| Mouth breathing | 3 | 0 |
| Nocturnal dyspnoea | 2 | 0 |
| Orthopnoea | 3 | 0 |
| Respiration abnormal | 47 | 0 |
| Respiratory arrest | 13 | 0 |
| Respiratory depression | 1 | 0 |
| Respiratory distress | 17 | 0 |
| Sleep apnoea syndrome | 11 | 0 |
| Tachypnoea | 23 | 0 |
| <i>Bronchial conditions NEC</i> | | |
| Bronchial secretion retention | 4 | 0 |
| Bronchiectasis | 12 | 0 |
| <i>Bronchospasm and obstruction</i> | | |
| Asthma | 308 | 0 |
| Asthma late onset | 2 | 0 |
| Bronchospasm | 15 | 0 |
| Chronic obstructive pulmonary disease | 16 | 1 |
| Cough variant asthma | 4 | 0 |
| Obstructive airways disorder | 9 | 0 |
| Reversible airways obstruction | 1 | 0 |
| Wheezing | 355 | 0 |
| <i>Conditions associated with abnormal gas exchange</i> | | |
| Asphyxia | 1 | 0 |
| Cyanosis central | 1 | 0 |
| Hyperoxia | 1 | 0 |
| Hypoxia | 23 | 1 |
| Respiratory acidosis | 2 | 0 |
| <i>Coughing and associated symptoms</i> | | |
| Allergic cough | 6 | 0 |
| Cough | 2137 | 3 |
| Cough decreased | 2 | 0 |
| Haemoptysis | 50 | 0 |
| Productive cough | 142 | 0 |
| Sputum discoloured | 7 | 0 |
| Sputum increased | 2 | 0 |
| <i>Diaphragmatic disorders</i> | | |
| Acquired diaphragmatic eventration | 1 | 0 |
| Diaphragm muscle weakness | 1 | 0 |
| <i>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</i> | | |
| Laryngeal disorder | 1 | 0 |
| Reflux laryngitis | 1 | 0 |
| Vocal cord disorder | 1 | 0 |

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MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Respiratory disorders <small>Respiratory disorders cont'd</small> | | |
| Vocal cord dysfunction | 1 | 0 |
| <i>Laryngeal spasm, oedema and obstruction</i> | | |
| Epiglottic oedema | 1 | 0 |
| Laryngeal obstruction | 1 | 0 |
| Laryngeal oedema | 2 | 0 |
| Laryngospasm | 1 | 0 |
| Stridor | 21 | 0 |
| <i>Lower respiratory tract inflammatory and immunologic conditions</i> | | |
| Alveolitis | 1 | 0 |
| Hypersensitivity pneumonitis | 1 | 0 |
| Lower respiratory tract inflammation | 1 | 0 |
| Pneumonia aspiration | 8 | 5 |
| Pneumonitis | 27 | 1 |
| Pulmonary sarcoidosis | 2 | 0 |
| <i>Lower respiratory tract signs and symptoms</i> | | |
| Hiccups | 27 | 0 |
| Increased bronchial secretion | 2 | 0 |
| Increased viscosity of bronchial secretion | 1 | 0 |
| Lung hyperinflation | 1 | 0 |
| Lung opacity | 2 | 0 |
| Pleuritic pain | 18 | 0 |
| Pulmonary haemorrhage | 1 | 0 |
| Pulmonary pain | 78 | 0 |
| Rales | 4 | 0 |
| Respiratory fremitus | 1 | 0 |
| <i>Mediastinal disorders</i> | | |
| Mediastinal mass | 1 | 0 |
| Pulmonary hilum mass | 1 | 0 |
| <i>Nasal congestion and inflammations</i> | | |
| Nasal congestion | 251 | 0 |
| Nasal inflammation | 2 | 0 |
| Rhinitis allergic | 18 | 0 |
| <i>Nasal disorders NEC</i> | | |
| Epistaxis | 797 | 0 |
| Intranasal hyposaesthesia | 1 | 0 |
| Intranasal paraesthesia | 1 | 0 |
| Nasal crusting | 1 | 0 |
| Nasal disorder | 3 | 0 |
| Nasal dryness | 32 | 0 |
| Nasal mucosal discolouration | 1 | 0 |
| Nasal odour | 6 | 0 |
| Nasal oedema | 6 | 0 |
| Nasal polyps | 1 | 0 |
| Nasal pruritus | 9 | 0 |
| <i>Neonatal hypoxic conditions</i> | | |
| Dry lung syndrome | 1 | 0 |
| Gasping syndrome | 1 | 0 |
| Infantile apnoea | 1 | 0 |
| <i>Paranasal sinus disorders (excl infections and neoplasms)</i> | | |
| Allergic sinusitis | 1 | 0 |
| Paranasal sinus inflammation | 3 | 0 |
| Sinonasal obstruction | 9 | 0 |
| Sinus congestion | 53 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Respiratory disorders <small>Respiratory disorders cont'd</small> | | |
| Sinus disorder | 6 | 0 |
| <i>Parenchymal lung disorders NEC</i> | | |
| Atelectasis | 3 | 0 |
| Combined pulmonary fibrosis and emphysema | 1 | 0 |
| Emphysema | 2 | 0 |
| Interstitial lung disease | 9 | 0 |
| Lung consolidation | 1 | 0 |
| Lung infiltration | 1 | 0 |
| Pulmonary alveolar haemorrhage | 1 | 0 |
| Pulmonary cavitation | 1 | 0 |
| Pulmonary fibrosis | 5 | 0 |
| <i>Pharyngeal disorders (excl infections and neoplasms)</i> | | |
| Pharyngeal enanthema | 1 | 0 |
| Pharyngeal erythema | 6 | 0 |
| Pharyngeal haemorrhage | 2 | 0 |
| Pharyngeal hypoaesthesia | 32 | 0 |
| Pharyngeal inflammation | 4 | 0 |
| Pharyngeal mass | 1 | 0 |
| Pharyngeal oedema | 13 | 0 |
| Pharyngeal paraesthesia | 51 | 0 |
| Pharyngeal swelling | 224 | 0 |
| Pharyngeal ulceration | 14 | 0 |
| Tonsillar erythema | 9 | 0 |
| Tonsillar haemorrhage | 1 | 0 |
| Tonsillar hypertrophy | 68 | 0 |
| Tonsillar inflammation | 3 | 0 |
| Tonsillar ulcer | 1 | 0 |
| Tonsillolith | 1 | 0 |
| <i>Pleural infections and inflammations</i> | | |
| Pleurisy | 30 | 0 |
| <i>Pneumothorax and pleural effusions NEC</i> | | |
| Pleural effusion | 23 | 0 |
| Pneumothorax | 8 | 0 |
| Pneumothorax spontaneous | 2 | 0 |
| <i>Pulmonary hypertensions</i> | | |
| Pulmonary hypertension | 2 | 0 |
| <i>Pulmonary oedemas</i> | | |
| Acute respiratory distress syndrome | 2 | 1 |
| Pulmonary congestion | 12 | 0 |
| Pulmonary oedema | 18 | 1 |
| <i>Pulmonary thrombotic and embolic conditions</i> | | |
| Pulmonary embolism | 385 | 27 |
| Pulmonary infarction | 6 | 0 |
| Pulmonary thrombosis | 6 | 1 |
| <i>Respiratory failures (excl neonatal)</i> | | |
| Acute respiratory failure | 2 | 1 |
| Respiratory failure | 11 | 2 |
| <i>Respiratory signs and symptoms NEC</i> | | |
| Allergic respiratory symptom | 6 | 0 |
| Diaphragmalgia | 6 | 0 |
| Nasal flaring | 1 | 0 |
| Painful respiration | 8 | 1 |
| Pleural rub | 1 | 0 |

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| Reaction Name | Total | Fatal |
|--|--------------|-----------|
| Respiratory disorders <small>Respiratory disorders cont'd</small> | | |
| Respiratory symptom | 17 | 0 |
| Suffocation feeling | 2 | 0 |
| <i>Respiratory tract disorders NEC</i> | | |
| Aspiration | 3 | 0 |
| Lung disorder | 5 | 0 |
| Pulmonary mass | 4 | 0 |
| Respiratory disorder | 11 | 0 |
| Respiratory tract congestion | 3 | 0 |
| Respiratory tract haemorrhage | 1 | 0 |
| Respiratory tract inflammation | 2 | 0 |
| Respiratory tract irritation | 8 | 0 |
| Respiratory tract oedema | 3 | 0 |
| <i>Thoracic musculoskeletal disorders</i> | | |
| Respiratory muscle weakness | 2 | 0 |
| <i>Tracheal disorders (excl infections and neoplasms)</i> | | |
| Tracheal disorder | 1 | 0 |
| Tracheal pain | 1 | 0 |
| <i>Upper respiratory tract neoplasms</i> | | |
| Tonsillar cyst | 1 | 0 |
| <i>Upper respiratory tract signs and symptoms</i> | | |
| Aphonia | 100 | 0 |
| Catarrh | 19 | 0 |
| Choking | 13 | 0 |
| Choking sensation | 3 | 0 |
| Dry throat | 153 | 0 |
| Dysphonia | 145 | 0 |
| Increased upper airway secretion | 5 | 0 |
| Increased viscosity of upper respiratory secretion | 28 | 0 |
| Nasal discharge discolouration | 3 | 0 |
| Nasal discomfort | 44 | 0 |
| Nasal obstruction | 2 | 0 |
| Oropharyngeal blistering | 9 | 0 |
| Oropharyngeal discomfort | 58 | 0 |
| Oropharyngeal pain | 2550 | 0 |
| Oropharyngeal plaque | 2 | 0 |
| Paranasal sinus discomfort | 41 | 0 |
| Rhinalgia | 11 | 0 |
| Rhinorrhoea | 804 | 0 |
| Sinus pain | 184 | 0 |
| Sneezing | 324 | 0 |
| Snoring | 7 | 0 |
| Throat clearing | 8 | 0 |
| Throat irritation | 216 | 0 |
| Throat tightness | 238 | 0 |
| Upper airway obstruction | 2 | 0 |
| Upper respiratory tract congestion | 2 | 0 |
| Upper respiratory tract irritation | 1 | 0 |
| Upper-airway cough syndrome | 7 | 0 |
| Yawning | 25 | 0 |
| <i>Vascular pulmonary disorders NEC</i> | | |
| Acute chest syndrome | 1 | 0 |
| Respiratory disorders SOC TOTAL | 14792 | 51 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Skin disorders | | |
| <i>Acnes</i> | | |
| Acne | 174 | 0 |
| Acne cystic | 16 | 0 |
| Dermatitis acneiform | 10 | 0 |
| <i>Alopecias</i> | | |
| Alopecia | 220 | 0 |
| Alopecia areata | 36 | 0 |
| Alopecia totalis | 2 | 0 |
| Androgenetic alopecia | 1 | 0 |
| Diffuse alopecia | 4 | 0 |
| Hypotrichosis | 1 | 0 |
| Madarosis | 3 | 0 |
| <i>Angioedemas</i> | | |
| Angioedema | 183 | 0 |
| Circumoral swelling | 1 | 0 |
| <i>Apocrine and eccrine gland disorders</i> | | |
| Anhidrosis | 1 | 0 |
| Bromhidrosis | 1 | 0 |
| Cold sweat | 670 | 0 |
| Hidradenitis | 3 | 0 |
| Hyperhidrosis | 1919 | 0 |
| Hypohidrosis | 2 | 0 |
| Milia | 2 | 0 |
| Miliaria | 79 | 0 |
| Night sweats | 537 | 0 |
| <i>Bullous conditions</i> | | |
| Blister | 406 | 0 |
| Blister rupture | 1 | 0 |
| Blood blister | 23 | 0 |
| Dermatitis bullous | 11 | 0 |
| Erythema multiforme | 36 | 0 |
| Fracture blisters | 1 | 0 |
| Herpes gestationis | 1 | 0 |
| Pemphigoid | 22 | 0 |
| Pemphigus | 7 | 0 |
| Stevens-Johnson syndrome | 5 | 0 |
| Toxic epidermal necrolysis | 2 | 1 |
| <i>Connective tissue disorders</i> | | |
| Cutaneous lupus erythematosus | 1 | 0 |
| Dermatomyositis | 5 | 0 |
| Subacute cutaneous lupus erythematosus | 1 | 0 |
| <i>Dermal and epidermal conditions NEC</i> | | |
| Acute febrile neutrophilic dermatosis | 1 | 0 |
| Dermatosis | 1 | 0 |
| Dry skin | 196 | 0 |
| Macule | 4 | 0 |
| Neutrophilic dermatosis | 1 | 0 |
| Pain of skin | 232 | 0 |
| Papule | 97 | 0 |
| Pathergy reaction | 1 | 0 |
| Peau d'orange | 2 | 0 |
| Scab | 19 | 0 |
| Scar pain | 12 | 0 |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Skin disorders Skin disorders cont'd | | |
| Sensitive skin | 150 | 0 |
| Shagreen skin | 1 | 0 |
| Skin burning sensation | 192 | 0 |
| Skin degenerative disorder | 1 | 0 |
| Skin discolouration | 112 | 0 |
| Skin discomfort | 5 | 0 |
| Skin disorder | 21 | 0 |
| Skin fissures | 8 | 0 |
| Skin indentation | 2 | 0 |
| Skin induration | 4 | 0 |
| Skin lesion | 39 | 0 |
| Skin lesion inflammation | 1 | 0 |
| Skin necrosis | 2 | 0 |
| Skin odour abnormal | 15 | 0 |
| Skin plaque | 3 | 0 |
| Skin reaction | 123 | 0 |
| Skin sensitisation | 35 | 0 |
| Skin swelling | 74 | 0 |
| Skin texture abnormal | 2 | 0 |
| Skin tightness | 25 | 0 |
| Skin warm | 261 | 0 |
| Skin weeping | 10 | 0 |
| Sticky skin | 2 | 0 |
| Target skin lesion | 2 | 0 |
| Transient acantholytic dermatosis | 1 | 0 |
| Yellow skin | 25 | 0 |
| <i>Dermatitis and eczema</i> | | |
| Dermatitis | 113 | 0 |
| Dermatitis allergic | 203 | 0 |
| Dermatitis atopic | 29 | 0 |
| Dermatitis contact | 17 | 0 |
| Dermatitis diaper | 3 | 0 |
| Dyshidrotic eczema | 25 | 0 |
| Eczema | 274 | 0 |
| Eczema asteatotic | 9 | 0 |
| Eczema infantile | 1 | 0 |
| Eczema nummular | 5 | 0 |
| Eczema weeping | 1 | 0 |
| Hand dermatitis | 1 | 0 |
| Intertrigo | 1 | 0 |
| Perioral dermatitis | 1 | 0 |
| Seborrhoeic dermatitis | 3 | 0 |
| Skin irritation | 103 | 0 |
| Stasis dermatitis | 1 | 0 |
| <i>Dermatitis ascribed to specific agent</i> | | |
| Drug eruption | 30 | 0 |
| Drug reaction with eosinophilia and systemic symptoms | 1 | 0 |
| Fixed eruption | 2 | 0 |
| Palmar-plantar erythrodysesthesia syndrome | 1 | 0 |
| Toxic skin eruption | 2 | 0 |
| <i>Erythemas</i> | | |
| Erythema | 1871 | 0 |
| Palmar erythema | 4 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Skin disorders Skin disorders cont'd | | |
| Red man syndrome | 2 | 0 |
| Exfoliative conditions | | |
| Dermatitis exfoliative | 2 | 0 |
| Dermatitis exfoliative generalised | 5 | 0 |
| Exfoliative rash | 18 | 0 |
| Keratolysis exfoliativa acquired | 2 | 0 |
| Skin exfoliation | 102 | 0 |
| Granulomatous and deep cutaneous inflammatory conditions | | |
| Cutaneous sarcoidosis | 1 | 0 |
| Granuloma annulare | 5 | 0 |
| Hyperkeratoses | | |
| Hyperkeratosis | 1 | 0 |
| Keratosis pilaris | 3 | 0 |
| Lichenoid keratosis | 3 | 0 |
| Hyperpigmentation disorders | | |
| Argyria | 1 | 0 |
| Chloasma | 1 | 0 |
| Ephelides | 1 | 0 |
| Skin hyperpigmentation | 3 | 0 |
| Solar lentigo | 2 | 0 |
| Hypertrichoses | | |
| Hirsutism | 2 | 0 |
| Hypopigmentation disorders | | |
| Skin depigmentation | 4 | 0 |
| Skin hypopigmentation | 1 | 0 |
| Vitiligo | 18 | 0 |
| Lipodystrophies | | |
| Lipoatrophy | 4 | 0 |
| Lipodystrophy acquired | 1 | 0 |
| Nail and nail bed conditions (excl infections and infestations) | | |
| Nail discolouration | 9 | 0 |
| Nail disorder | 2 | 0 |
| Nail pigmentation | 2 | 0 |
| Nail ridging | 3 | 0 |
| Onychalgia | 7 | 0 |
| Onychoclasia | 4 | 0 |
| Onychomadesis | 2 | 0 |
| Splinter haemorrhages | 3 | 0 |
| Panniculitides | | |
| Erythema nodosum | 22 | 0 |
| Panniculitis | 1 | 0 |
| Papulosquamous conditions | | |
| Erythema annulare | 2 | 0 |
| Lichen planus | 16 | 0 |
| Lichen sclerosus | 9 | 0 |
| Parapsoriasis | 2 | 0 |
| Pityriasis rosea | 103 | 0 |
| Photosensitivity and photodermatosis conditions | | |
| Photosensitivity reaction | 57 | 0 |
| Polymorphic light eruption | 2 | 0 |
| Solar dermatitis | 1 | 0 |
| Pigmentation changes NEC | | |
| Haemosiderin stain | 1 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Skin disorders Skin disorders cont'd | | |
| Pigmentation disorder | 13 | 0 |
| <i>Pilar disorders NEC</i> | | |
| Hair colour changes | 8 | 0 |
| Hair disorder | 1 | 0 |
| Hair growth abnormal | 5 | 0 |
| Hair texture abnormal | 5 | 0 |
| Piloerection | 25 | 0 |
| Pseudofolliculitis | 3 | 0 |
| Trichorrhexis | 2 | 0 |
| <i>Pruritus NEC</i> | | |
| Itching scar | 5 | 0 |
| Pruritus | 4614 | 0 |
| <i>Psoriatic conditions</i> | | |
| Dermatitis psoriasiform | 3 | 0 |
| Guttate psoriasis | 14 | 0 |
| Nail psoriasis | 1 | 0 |
| Palmoplantar pustulosis | 2 | 0 |
| Psoriasis | 158 | 0 |
| Pustular psoriasis | 2 | 0 |
| <i>Purpura and related conditions</i> | | |
| Ecchymosis | 1 | 0 |
| Henoch-Schonlein purpura | 9 | 0 |
| Petechiae | 126 | 0 |
| Purpura | 45 | 0 |
| <i>Pustular conditions</i> | | |
| Acute generalised exanthematous pustulosis | 1 | 0 |
| <i>Rashes, eruptions and exanthems NEC</i> | | |
| Butterfly rash | 4 | 0 |
| Rash | 4887 | 1 |
| Rash erythematous | 1021 | 0 |
| Rash macular | 451 | 0 |
| Rash maculo-papular | 57 | 0 |
| Rash morbilliform | 42 | 0 |
| Rash papular | 301 | 0 |
| Rash pruritic | 1031 | 0 |
| Rash vesicular | 67 | 0 |
| Systemic lupus erythematosus rash | 6 | 0 |
| <i>Rosaceas</i> | | |
| Rosacea | 27 | 0 |
| <i>Scaly conditions</i> | | |
| Dandruff | 4 | 0 |
| Pityriasis | 21 | 0 |
| <i>Sebaceous gland disorders</i> | | |
| Seborrhoea | 10 | 0 |
| <i>Skin and subcutaneous conditions NEC</i> | | |
| Cutaneous symptom | 5 | 0 |
| Reactive perforating collagenosis | 1 | 0 |
| Skin mass | 18 | 0 |
| <i>Skin and subcutaneous tissue ulcerations</i> | | |
| Ischaemic skin ulcer | 1 | 0 |
| Mucocutaneous ulceration | 1 | 0 |
| Pyoderma gangrenosum | 1 | 0 |
| Scleroderma associated digital ulcer | 1 | 0 |

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| Reaction Name | Total | Fatal |
|--|--------------|----------|
| Skin disorders Skin disorders cont'd | | |
| Skin erosion | 21 | 0 |
| Skin ulcer | 17 | 0 |
| Skin cysts and polyps | | |
| Dermal cyst | 13 | 0 |
| Skin dystrophies | | |
| Keloid scar | 3 | 0 |
| Skin wrinkling | 2 | 0 |
| Skin haemorrhages | | |
| Haemorrhage subcutaneous | 8 | 0 |
| Skin haemorrhage | 15 | 0 |
| Skin hyperplasias and hypertrophies | | |
| Skin hypertrophy | 2 | 0 |
| Skin hypoplasias and atrophies | | |
| Skin atrophy | 2 | 0 |
| Skin striae | 7 | 0 |
| Skin injuries and mechanical dermatoses | | |
| Decubitus ulcer | 2 | 0 |
| Needle track marks | 3 | 0 |
| Skin preneoplastic conditions NEC | | |
| Actinic keratosis | 1 | 0 |
| Skin vascular conditions NEC | | |
| Skin oedema | 4 | 0 |
| Skin vasculitides | | |
| Capillaritis | 2 | 0 |
| Cutaneous vasculitis | 13 | 0 |
| Hypersensitivity vasculitis | 1 | 0 |
| Vasculitic rash | 18 | 0 |
| Skin vasomotor conditions | | |
| Livedo reticularis | 20 | 0 |
| Telangiectasia and related conditions | | |
| Spider naevus | 1 | 0 |
| Telangiectasia | 1 | 0 |
| Urticarias | | |
| Chronic spontaneous urticaria | 6 | 0 |
| Cold urticaria | 5 | 0 |
| Idiopathic urticaria | 1 | 0 |
| Mechanical urticaria | 7 | 0 |
| Solar urticaria | 2 | 0 |
| Urticaria | 1598 | 0 |
| Urticaria cholinergic | 1 | 0 |
| Urticaria chronic | 16 | 0 |
| Urticaria contact | 1 | 0 |
| Urticaria papular | 4 | 0 |
| Urticaria thermal | 4 | 0 |
| Urticularial vasculitis | 3 | 0 |
| Skin disorders SOC TOTAL | 24004 | 2 |

Case Series Drug Analysis Print

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

Report Run Date: 14-Oct-2021

Data Lock Date: 13-Oct-2021 18:30:20

MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|---|------------|----------|
| Social circumstances | | |
| <i>Age related issues</i> | | |
| Infant | 3 | 0 |
| Menarche | 1 | 0 |
| Menopause | 32 | 0 |
| Postmenopause | 3 | 0 |
| <i>Criminal activity</i> | | |
| Verbal abuse | 1 | 0 |
| <i>Dependents</i> | | |
| Sick relative | 2 | 0 |
| <i>Dietary and nutritional issues</i> | | |
| Feeding tube user | 1 | 0 |
| <i>Disability issues</i> | | |
| Bedridden | 22 | 0 |
| Breast prosthesis user | 3 | 0 |
| Disability | 2 | 0 |
| Hearing disability | 1 | 0 |
| Housebound | 1 | 0 |
| Immobile | 13 | 0 |
| Impaired driving ability | 4 | 0 |
| Impaired work ability | 11 | 0 |
| Loss of personal independence in daily activities | 39 | 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> | | |
| Retirement | 4 | 0 |
| Stress at work | 1 | 0 |
| <i>Family and partner issues</i> | | |
| Bed sharing | 1 | 0 |
| <i>Non-occupational and unspecified environmental problems</i> | | |
| Flooding | 1 | 0 |
| Water pollution | 2 | 0 |
| <i>Pregnancy related circumstances</i> | | |
| Breast feeding | 14 | 0 |
| Multigravida | 1 | 0 |
| Parity | 1 | 0 |
| <i>Social issues NEC</i> | | |
| Exercise adequate | 1 | 0 |
| Hair dye user | 2 | 0 |
| Impaired quality of life | 2 | 0 |
| <i>Tobacco use</i> | | |
| Ex-tobacco user | 1 | 0 |
| Non-tobacco user | 3 | 0 |
| Tobacco user | 1 | 0 |
| Social circumstances SOC TOTAL | 198 | 0 |

Case Series Drug Analysis Print

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Report Run Date: 14-Oct-2021

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MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Surgical & medical procedures | | |
| <i>Anaesthesia and allied procedures</i> | | |
| Local anaesthesia | 2 | 0 |
| Nerve block | 4 | 0 |
| <i>Analgesia supportive care</i> | | |
| Analgesic therapy | 1 | 0 |
| <i>Antiinfective therapies</i> | | |
| COVID-19 prophylaxis | 1 | 0 |
| COVID-19 treatment | 3 | 0 |
| <i>Arterial therapeutic procedures (excl aortic)</i> | | |
| Splenic artery embolisation | 1 | 0 |
| <i>Blood and blood product treatment</i> | | |
| Transfusion | 2 | 0 |
| <i>Breast therapeutic procedures NEC</i> | | |
| Axillary lymphadenectomy | 3 | 0 |
| Mammoplasty | 1 | 0 |
| <i>Bronchial and pulmonary therapeutic procedures</i> | | |
| Airway secretion clearance therapy | 1 | 0 |
| <i>Cardiac device therapeutic procedures</i> | | |
| Cardiac pacemaker insertion | 1 | 0 |
| <i>Cardiac therapeutic procedures NEC</i> | | |
| Cardiac operation | 1 | 0 |
| <i>Contraceptive methods female</i> | | |
| Contraception | 1 | 0 |
| Contraceptive implant | 3 | 0 |
| Oral contraception | 1 | 0 |
| <i>Contraceptive methods male</i> | | |
| Condom | 1 | 0 |
| <i>Dietary and nutritional therapies</i> | | |
| Medical diet | 8 | 0 |
| Nothing by mouth order | 7 | 0 |
| Wheat-free diet | 1 | 0 |
| <i>External ear therapeutic procedures</i> | | |
| Ear irrigation | 1 | 0 |
| <i>Fertility and fertilisation interventions female</i> | | |
| Endometrial scratching | 1 | 0 |
| <i>Gastrointestinal therapeutic procedures NEC</i> | | |
| Intestinal anastomosis | 1 | 0 |
| Prophylaxis of nausea and vomiting | 14 | 0 |
| <i>Gynaecological therapeutic procedures NEC</i> | | |
| Menstrual cycle management | 12 | 0 |
| <i>Haematological therapeutic procedures NEC</i> | | |
| Anticoagulant therapy | 1 | 0 |
| <i>Head, neck and oral cavity therapeutic procedures NEC</i> | | |
| Neck lift | 1 | 0 |
| <i>Hernia repairs</i> | | |
| Hernia repair | 1 | 0 |
| <i>Hormonal therapeutic procedures NEC</i> | | |
| Hormone replacement therapy | 1 | 0 |
| Hormone therapy | 8 | 0 |
| <i>Immunisations</i> | | |
| COVID-19 immunisation | 89 | 0 |
| Immunisation | 72 | 1 |
| <i>Induced abortions</i> | | |

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Surgical & medical procedures | | |
| Surgical & medical procedures cont'd | | |
| Abortion induced | 1 | 0 |
| Joint therapeutic procedures | | |
| Joint injection | 2 | 0 |
| Joint surgery | 1 | 0 |
| Knee arthroplasty | 1 | 0 |
| Large intestine therapeutic procedures | | |
| Appendectomy | 4 | 0 |
| Limb therapeutic procedures | | |
| Limb immobilisation | 8 | 0 |
| Limb operation | 5 | 0 |
| Lymphoid tissue therapeutic procedures | | |
| Lymphadenectomy | 2 | 0 |
| Splenectomy | 1 | 0 |
| Mastectomies | | |
| Breast conserving surgery | 4 | 0 |
| Nail therapeutic procedures | | |
| Nail operation | 3 | 0 |
| Nervous system therapeutic procedures NEC | | |
| Multiple sclerosis relapse prophylaxis | 2 | 0 |
| Obstetric therapeutic procedures | | |
| Labour stimulation | 1 | 0 |
| Orbit and globe therapeutic procedures | | |
| Strabismus correction | 1 | 0 |
| Peripheral nerve therapeutic procedures | | |
| Neurolysis | 1 | 0 |
| Peripheral nerve neurostimulation | 1 | 0 |
| Phototherapies | | |
| UV light therapy | 1 | 0 |
| Prophylactic procedures NEC | | |
| Anaphylaxis prophylaxis | 2 | 0 |
| Immune tolerance induction | 1 | 0 |
| Prophylaxis against transplant rejection | 1 | 0 |
| Reproductive system disorder prophylaxis | 1 | 0 |
| Psychiatric therapies | | |
| Electroconvulsive therapy | 1 | 0 |
| Renal therapeutic procedures | | |
| Dialysis | 1 | 0 |
| Respiratory tract therapeutic procedures NEC | | |
| Asthma prophylaxis | 3 | 0 |
| Retinal therapeutic procedures | | |
| Retinopexy | 1 | 0 |
| Skin and subcutaneous tissue therapeutic procedures NEC | | |
| Dermal filler injection | 4 | 0 |
| Therapeutic skin care topical | 1 | 0 |
| Skull and brain therapeutic procedures | | |
| Cerebrovascular operation | 1 | 0 |
| Posterior fossa decompression | 1 | 0 |
| Therapeutic bladder catheterisation | | |
| Bladder catheterisation | 2 | 0 |
| Therapeutic procedures NEC | | |
| Abscess drainage | 1 | 0 |
| Anaphylaxis treatment | 5 | 0 |
| Bed rest | 2 | 0 |

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|--|------------|----------|
| Surgical & medical procedures | | |
| Surgical & medical procedures cont'd | | |
| Fatigue management | 1 | 0 |
| Hospitalisation | 10 | 0 |
| Injection | 40 | 0 |
| Interchange of vaccine products | 10 | 0 |
| Localised alternating hot and cold therapy | 1 | 0 |
| Magnetic therapy | 1 | 0 |
| Mass excision | 2 | 0 |
| Medical procedure | 1 | 0 |
| Medication dilution | 2 | 0 |
| Physical fitness training | 1 | 0 |
| Product used for unknown indication | 2 | 0 |
| Specialist consultation | 1 | 0 |
| Therapeutic procedure | 1 | 0 |
| Therapy change | 1 | 0 |
| Tracheal therapeutic procedures | | |
| Tracheostomy | 1 | 0 |
| Uterine therapeutic procedures | | |
| Endometrial ablation | 3 | 0 |
| Surgical & medical procedures SOC TOTAL | 390 | 1 |

Case Series Drug Analysis Print

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Report Run Date: 14-Oct-2021

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MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Vascular disorders | | |
| <i>Accelerated and malignant hypertension</i> | | |
| Hypertensive crisis | 10 | 0 |
| Hypertensive urgency | 1 | 0 |
| Malignant hypertension | 3 | 0 |
| <i>Aneurysms and dissections non-site specific</i> | | |
| Aneurysm | 2 | 0 |
| Artery dissection | 1 | 0 |
| <i>Aortic aneurysms and dissections</i> | | |
| Acute aortic syndrome | 1 | 0 |
| Aortic aneurysm rupture | 1 | 1 |
| Aortic dissection | 1 | 0 |
| <i>Aortic embolism and thrombosis</i> | | |
| Aortic embolus | 5 | 0 |
| Aortic thrombosis | 2 | 0 |
| <i>Aortic necrosis and vascular insufficiency</i> | | |
| Aortic occlusion | 1 | 0 |
| <i>Arterial infections and inflammations</i> | | |
| Arteritis | 1 | 0 |
| Giant cell arteritis | 11 | 0 |
| <i>Blood pressure disorders NEC</i> | | |
| Blood pressure fluctuation | 10 | 0 |
| Labile blood pressure | 3 | 0 |
| <i>Bruising, ecchymosis and purpura</i> | | |
| Achenbach syndrome | 3 | 0 |
| <i>Circulatory collapse and shock</i> | | |
| CT hypotension complex | 2 | 0 |
| Circulatory collapse | 59 | 0 |
| Hypoperfusion | 2 | 0 |
| Hypovolaemic shock | 1 | 1 |
| Neurogenic shock | 21 | 0 |
| Peripheral circulatory failure | 5 | 0 |
| Shock | 18 | 0 |
| <i>Haemorrhages NEC</i> | | |
| Arterial haemorrhage | 1 | 0 |
| Bloody discharge | 20 | 0 |
| Haematoma | 40 | 0 |
| Haemorrhage | 1079 | 2 |
| Internal haemorrhage | 7 | 0 |
| Venous haemorrhage | 2 | 0 |
| <i>Lymphangiopathies</i> | | |
| Lymphangiopathy | 1 | 0 |
| Lymphocele | 4 | 0 |
| <i>Lymphoedemas</i> | | |
| Lymphoedema | 173 | 0 |
| <i>Non-site specific embolism and thrombosis</i> | | |
| Arterial thrombosis | 4 | 0 |
| Embolism | 60 | 0 |
| Embolism venous | 5 | 0 |
| Microembolism | 1 | 0 |
| Thrombosis | 371 | 8 |
| Venous thrombosis | 6 | 0 |
| <i>Non-site specific necrosis and vascular insufficiency NEC</i> | | |
| Arterial occlusive disease | 2 | 0 |

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Vascular disorders <small>Vascular disorders cont'd</small> | | |
| Arterial spasm | 1 | 0 |
| Arteriosclerosis | 2 | 0 |
| Haemorrhagic infarction | 1 | 0 |
| Infarction | 3 | 0 |
| Ischaemia | 9 | 0 |
| Peripheral venous disease | 1 | 0 |
| Vascular occlusion | 1 | 0 |
| Vasospasm | 1 | 0 |
| <i>Non-site specific vascular disorders NEC</i> | | |
| Capillary disorder | 1 | 0 |
| Capillary fragility | 1 | 0 |
| Superficial vein prominence | 1 | 0 |
| Vascular pain | 29 | 0 |
| Vascular wall hypertrophy | 1 | 0 |
| Vasodilatation | 34 | 0 |
| Vein discolouration | 5 | 0 |
| Vein disorder | 6 | 0 |
| Vein rupture | 5 | 0 |
| <i>Peripheral embolism and thrombosis</i> | | |
| Axillary vein thrombosis | 1 | 0 |
| Blue toe syndrome | 24 | 0 |
| Deep vein thrombosis | 246 | 1 |
| Femoral artery embolism | 1 | 0 |
| Jugular vein thrombosis | 3 | 0 |
| Pelvic venous thrombosis | 4 | 0 |
| Peripheral artery thrombosis | 1 | 0 |
| Peripheral embolism | 1 | 0 |
| Subclavian vein thrombosis | 3 | 0 |
| Thrombophlebitis | 19 | 0 |
| Thrombophlebitis superficial | 16 | 0 |
| <i>Peripheral vascular disorders NEC</i> | | |
| Cyanosis | 38 | 0 |
| Erythromelalgia | 1 | 0 |
| Flushing | 381 | 0 |
| Hot flush | 1030 | 0 |
| Peripheral vascular disorder | 1 | 0 |
| Vein wall hypertrophy | 1 | 0 |
| <i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i> | | |
| Claudication of jaw muscles | 1 | 0 |
| Extremity necrosis | 3 | 0 |
| Iliac artery occlusion | 1 | 0 |
| Intermittent claudication | 3 | 0 |
| Ischaemic limb pain | 1 | 0 |
| Jugular vein occlusion | 1 | 0 |
| Peripheral arterial occlusive disease | 2 | 0 |
| Peripheral artery occlusion | 1 | 0 |
| Peripheral coldness | 277 | 0 |
| Peripheral ischaemia | 12 | 0 |
| Poor peripheral circulation | 14 | 0 |
| Raynaud's phenomenon | 52 | 0 |
| Subclavian vein occlusion | 1 | 0 |
| Vasoconstriction | 2 | 0 |
| <i>Phlebitis NEC</i> | | |

Case Series Drug Analysis Print

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Report Run Date: 14-Oct-2021

Data Lock Date: 13-Oct-2021 18:30:20

MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|--|---------------|------------|
| Vascular disorders <small>Vascular disorders cont'd</small> | | |
| Phlebitis | 29 | 0 |
| Phlebitis superficial | 6 | 0 |
| Site specific vascular disorders NEC | | |
| Inferior vena cava dilatation | 1 | 0 |
| Pallor | 322 | 0 |
| Varicose veins NEC | | |
| Spider vein | 6 | 0 |
| Varicophlebitis | 4 | 0 |
| Varicose vein | 27 | 0 |
| Vascular hypertensive disorders NEC | | |
| Diastolic hypertension | 2 | 0 |
| Essential hypertension | 3 | 0 |
| Hypertension | 494 | 1 |
| Labile hypertension | 1 | 0 |
| Orthostatic hypertension | 1 | 0 |
| Secondary hypertension | 1 | 0 |
| Systolic hypertension | 5 | 0 |
| White coat hypertension | 1 | 0 |
| Vascular hypotensive disorders | | |
| Hypotension | 354 | 1 |
| Orthostatic hypotension | 30 | 0 |
| Vasculitides NEC | | |
| Behcet's syndrome | 3 | 0 |
| Diffuse vasculitis | 1 | 0 |
| Granulomatosis with polyangiitis | 2 | 0 |
| MAGIC syndrome | 1 | 0 |
| Thromboangiitis obliterans | 1 | 0 |
| Vasculitis | 43 | 0 |
| Vena caval embolism and thrombosis | | |
| Vena cava embolism | 1 | 0 |
| Vena cava thrombosis | 1 | 0 |
| Vascular disorders SOC TOTAL | 5524 | 15 |
| TOTAL REACTIONS FOR DRUG | 345152 | 564 |
| TOTAL REPORTS | 122542 | |
| TOTAL FATAL OUTCOME REPORTS | | 564 |