

COVID-19 mRNA Pfizer- BioNTech Vaccine Analysis Úrint

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All UK spontaneous reports received between 9/12/20Á and 27/07/22
for mRNA Pfizer/BioNTech vacci} ^É

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

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

Report Run Date: 27-Jul-2022

Data Lock Date: 27-Jul-2022 18:30:07

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemia deficiencies</i>		
Anaemia folate deficiency	1	0
Anaemia vitamin B12 deficiency	7	0
Deficiency anaemia	1	0
Iron deficiency anaemia	8	0
Pernicious anaemia	2	0
<i>Anaemias NEC</i>		
Anaemia	151	0
Anaemia macrocytic	2	0
Anaemia megaloblastic	1	0
Autoimmune anaemia	3	0
Blood loss anaemia	1	0
Microcytic anaemia	1	0
Normocytic anaemia	1	0
<i>Anaemias haemolytic NEC</i>		
Coombs negative haemolytic anaemia	1	0
Haemolytic anaemia	7	0
<i>Anaemias haemolytic immune</i>		
Autoimmune haemolytic anaemia	19	0
Cold type haemolytic anaemia	1	0
Evans syndrome	1	0
Warm autoimmune haemolytic anaemia	1	0
<i>Anaemias haemolytic mechanical factor</i>		
Microangiopathic haemolytic anaemia	2	0
<i>Bleeding tendencies</i>		
Haemorrhagic diathesis	1	0
Increased tendency to bruise	57	0
Spontaneous haematoma	2	0
<i>Coagulation factor deficiencies</i>		
Acquired factor VIII deficiency	1	0
Acquired haemophilia	4	0
<i>Coagulopathies</i>		
Abnormal clotting factor	4	0
Antiphospholipid syndrome	7	0
Coagulopathy	32	1
Disseminated intravascular coagulation	3	0
Hypercoagulation	4	0
Thrombotic microangiopathy	5	0
<i>Eosinophilic disorders</i>		
Eosinophilia	13	0
<i>Haematological disorders</i>		
Blood disorder	7	0
Bone marrow disorder	1	0
Bone marrow oedema	1	0
Hypergammaglobulinaemia	1	0
Hyperviscosity syndrome	1	0
Mast cell activation syndrome	15	0
Methaemoglobinaemia	1	0
<i>Haemolyses NEC</i>		
Haemolysis	6	0
Intravascular haemolysis	1	0
Jaundice acholuric	1	0
<i>Leukocytoses NEC</i>		

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Reaction Name	Total	Fatal
Blood disorders Blood disorders cont'd		
Leukocytosis	3	0
Lymphocytic infiltration	1	0
Lymphocytosis	6	0
Neutrophilia	12	0
Leukopenias NEC		
Leukopenia	4	1
Lymphopenia	4	0
Lymphatic system disorders NEC		
Abdominal lymphadenopathy	4	0
Hilar lymphadenopathy	3	0
Lymph node pain	2288	0
Lymph node ulcer	1	0
Lymphadenitis	193	0
Lymphadenopathy	13828	0
Lymphadenopathy mediastinal	1	0
Lymphatic disorder	3	0
Lymphatic insufficiency	1	0
Lymphoid tissue hyperplasia	1	0
Necrotic lymphadenopathy	4	0
Pseudolymphoma	9	0
Retroperitoneal lymphadenopathy	1	0
Marrow depression and hypoplastic anaemias		
Aplasia pure red cell	2	0
Aplastic anaemia	1	1
Hypoplastic anaemia	2	0
Myelosuppression	1	0
Pancytopenia	9	0
Neutropenias		
Autoimmune neutropenia	2	0
Neutropenia	44	0
Platelet disorders NEC		
Platelet anisocytosis	1	0
Platelet disorder	4	0
Polycythaemia (excl rubra vera)		
Polycythaemia	3	0
Purpuras (excl thrombocytopenic)		
Purpura non-thrombocytopenic	1	0
Red blood cell abnormal findings NEC		
Macrocytosis	2	0
Polychromasia	2	0
Red blood cell abnormality	2	0
Spleen disorders		
Spleen atrophy	1	0
Splenic infarction	4	0
Splenic lesion	1	0
Splenic thrombosis	2	0
Splenic vein thrombosis	3	0
Splenomegaly	12	0
Thrombocytopenias		
Acquired amegakaryocytic thrombocytopenia	1	0
Immune thrombocytopenia	89	0
Thrombocytopenia	244	2
Thrombocytopenic purpura	9	0

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Reaction Name	Total	Fatal
Blood disorders Blood disorders cont'd		
Thrombosis with thrombocytopenia syndrome	1	0
Thrombotic thrombocytopenic purpura	9	0
Thrombocytoses		
Thrombocytosis	7	0
Thymus disorders		
Thymus enlargement	1	0
Blood disorders SOC TOTAL	17206	5

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Aortic valvular disorders</i>		
Aortic valve incompetence	2	0
<i>Cardiac conduction disorders</i>		
Atrioventricular block	35	1
Atrioventricular block complete	3	1
Atrioventricular block first degree	3	0
Atrioventricular block second degree	5	0
Bundle branch block	2	0
Bundle branch block left	6	0
Bundle branch block right	6	0
Trifascicular block	1	0
<i>Cardiac disorders NEC</i>		
Acute cardiac event	7	0
Atrial thrombosis	1	0
Cardiac disorder	110	3
Cardiac dysfunction	2	0
Cardiac ventricular thrombosis	3	0
Cardiovascular deconditioning	1	0
Cardiovascular disorder	10	0
Intracardiac thrombus	8	1
<i>Cardiac hypertensive complications</i>		
Hypertensive heart disease	3	2
<i>Cardiac infections and inflammations NEC</i>		
Carditis	10	0
<i>Cardiac neoplasms NEC</i>		
Pericardial cyst	1	0
<i>Cardiac signs and symptoms NEC</i>		
Cardiac discomfort	40	0
Cardiovascular symptom	4	0
Palpitations	6342	1
<i>Cardiac valve disorders NEC</i>		
Cardiac valve disease	4	0
Heart valve incompetence	3	0
<i>Cardiomyopathies</i>		
Cardiomyopathy	18	2
Congestive cardiomyopathy	9	0
Stress cardiomyopathy	4	0
<i>Coronary artery disorders NEC</i>		
Arteriosclerosis coronary artery	3	0
Coronary artery disease	10	3
Coronary artery dissection	1	0
Coronary artery occlusion	4	0
Coronary artery thrombosis	8	2
<i>Endocarditis NEC</i>		
Endocarditis noninfective	1	1
<i>Heart failures NEC</i>		
Cardiac failure	90	12
Cardiac failure acute	10	2
Cardiac failure chronic	2	0
Cardiac failure congestive	7	4
Cardiogenic shock	6	2
Cardiopulmonary failure	2	1
<i>Ischaemic coronary artery disorders</i>		

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Reaction Name	Total	Fatal
Cardiac disorders Cardiac disorders cont'd		
Acute coronary syndrome	11	1
Acute myocardial infarction	32	5
Angina pectoris	350	1
Angina unstable	5	0
Arteriospasm coronary	4	0
Microvascular coronary artery disease	3	0
Myocardial infarction	308	46
Myocardial ischaemia	14	8
Left ventricular failures		
Acute left ventricular failure	2	2
Left ventricular failure	7	2
Mitral valvular disorders		
Mitral valve incompetence	8	0
Mitral valve prolapse	2	0
Myocardial disorders NEC		
Cardiac amyloidosis	1	0
Cardiac aneurysm	1	1
Cardiac ventricular scarring	2	0
Cardiomegaly	58	3
Dilatation ventricular	1	0
Left atrial dilatation	1	0
Left ventricular dysfunction	19	0
Left ventricular enlargement	3	0
Left ventricular hypertrophy	2	0
Myocardial fibrosis	11	0
Myocardial haemorrhage	1	0
Myocardial injury	27	0
Myocardial necrosis	1	0
Myocardial oedema	7	0
Myocardial rupture	1	0
Right atrial enlargement	1	0
Right ventricular dilatation	1	0
Right ventricular dysfunction	2	0
Right ventricular enlargement	1	0
Systolic dysfunction	1	0
Ventricular dysfunction	2	0
Ventricular hypertrophy	2	0
Ventricular hypokinesia	4	0
Noninfectious myocarditis		
Eosinophilic myocarditis	1	0
Hypersensitivity myocarditis	1	0
Myocarditis	722	5
Myocarditis post infection	1	0
Myopericarditis	94	0
Noninfectious pericarditis		
Pericarditis	553	2
Pericarditis constrictive	1	0
Pericarditis lupus	1	0
Pleuropericarditis	1	0
Pericardial disorders NEC		
Cardiac tamponade	2	1
Pericardial effusion	52	2
Pericardial fibrosis	1	0

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Cardiac disorders Cardiac disorders cont'd		
Pericardial haemorrhage	4	3
Pericardial rub	2	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	197	1
Arrhythmia neonatal	1	0
Bradycardia	81	0
Bradycardia foetal	2	0
Cardiac flutter	633	0
Extrasystoles	228	0
Heart alternation	4	0
Paroxysmal arrhythmia	1	0
Postural orthostatic tachycardia syndrome	52	0
Tachyarrhythmia	11	0
Tachycardia	2546	0
Tachycardia foetal	1	0
Tachycardia paroxysmal	1	0
<i>Right ventricular failures</i>		
Cor pulmonale	1	0
Right ventricular failure	1	0
<i>Supraventricular arrhythmias</i>		
Arrhythmia supraventricular	17	0
Atrial fibrillation	310	1
Atrial flutter	47	0
Atrial tachycardia	14	0
Nodal arrhythmia	1	0
Sinus arrest	1	0
Sinus arrhythmia	10	0
Sinus bradycardia	16	0
Sinus node dysfunction	1	0
Sinus tachycardia	87	0
Supraventricular extrasystoles	6	0
Supraventricular tachycardia	52	0
<i>Tricuspid valvular disorders</i>		
Tricuspid valve incompetence	6	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	135	47
Cardio-respiratory arrest	1	1
Pulseless electrical activity	8	0
Ventricular arrhythmia	6	0
Ventricular extrasystoles	32	0
Ventricular fibrillation	10	1
Ventricular tachycardia	19	0
Cardiac disorders SOC TOTAL	13658	171

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Autosomal chromosomal abnormalities</i>		
Trisomy 8	1	0
<i>Cardiac disorders congenital NEC</i>		
Heart disease congenital	20	0
<i>Cardiac hypoplasias congenital</i>		
Ventricular hypoplasia	1	0
<i>Cardiac septal defects congenital</i>		
Atrial septal defect	2	0
Hypertrophic cardiomyopathy	1	0
Ventricular septal defect	1	0
<i>Cardiac valve disorders congenital</i>		
Bicuspid aortic valve	2	0
<i>Central nervous system disorders congenital NEC</i>		
Spina bifida	2	1
Syringomyelia	1	0
<i>Cerebellar disorders congenital</i>		
Arnold-Chiari malformation	1	0
Hereditary ataxia	2	0
<i>Cerebral disorders congenital</i>		
Anencephaly	2	0
Cerebral palsy	4	0
Congenital hydrocephalus	1	0
<i>Chromosomal abnormalities NEC</i>		
Cytogenetic abnormality	1	0
<i>Coagulation disorders congenital</i>		
Factor IX deficiency	1	0
Haemophilia	2	0
<i>Congenital disorders NEC</i>		
Congenital anomaly	1	0
Foetal malformation	1	0
Heterotaxia	1	0
<i>Connective tissue disorders congenital</i>		
Ehlers-Danlos syndrome	5	0
<i>Diaphragmatic disorders congenital</i>		
Congenital diaphragmatic hernia	1	0
<i>Gastrointestinal tract disorders congenital NEC</i>		
Gastroschisis	3	0
<i>Genetic polymorphisms</i>		
Genetic polymorphism	1	0
<i>Great vessel disorders congenital</i>		
Congenital great vessel anomaly	1	0
Transposition of the great vessels	1	0
<i>Haematological disorders congenital NEC</i>		
Amegakaryocytic thrombocytopenia	1	0
Neonatal alloimmune thrombocytopenia	1	0
<i>Haemoglobinopathies congenital</i>		
Congenital methaemoglobinaemia	1	0
<i>Immune system abnormalities congenital</i>		
Combined immunodeficiency	1	0
<i>Inborn errors of bilirubin metabolism</i>		
Gilbert's syndrome	1	0
<i>Inborn errors of lipid metabolism</i>		
Short-chain acyl-coenzyme A dehydrogenase deficiency	1	0

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Congenital disorders Congenital disorders cont'd		
<i>Inborn errors of metabolism NEC</i>		
Acetylcholinesterase deficiency	1	0
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	4	0
Penoscrotal fusion	1	0
Phimosis	1	0
<i>Musculoskeletal and connective tissue disorders of limbs congenital</i>		
Congenital musculoskeletal disorder of limbs	1	0
Developmental hip dysplasia	1	0
<i>Musculoskeletal and connective tissue disorders of skull congenital</i>		
Platybasia	1	0
<i>Musculoskeletal and connective tissue disorders of spine congenital</i>		
Block vertebra	1	0
Brachyolmia	1	0
<i>Neurological disorders congenital NEC</i>		
Familial hemiplegic migraine	2	0
Familial periodic paralysis	1	0
Moebius II syndrome	1	0
Neurofibromatosis	1	0
Tourette's disorder	4	0
<i>Ocular disorders congenital NEC</i>		
Colour blindness	4	0
Congenital eye disorder	1	0
<i>Palate disorders congenital</i>		
Cleft lip and palate	2	0
<i>Peripheral nervous system disorders congenital NEC</i>		
Hereditary neuropathy with liability to pressure palsies	1	0
Paroxysmal extreme pain disorder	2	0
<i>Pulmonary and bronchial disorders congenital</i>		
Congenital cystic lung	1	0
Cystic fibrosis	1	0
<i>Retinal disorders congenital</i>		
Retinitis pigmentosa	1	0
<i>Sex chromosomal abnormalities</i>		
Turner's syndrome	1	0
<i>Skin and subcutaneous tissue disorders congenital NEC</i>		
Acral peeling skin syndrome	1	0
<i>Tongue disorders congenital</i>		
Ankyloglossia congenital	1	0
<i>Vascular anomalies congenital NEC</i>		
Congenital LUMBAR syndrome	1	0
<i>Venous disorders congenital</i>		
Anomalous pulmonary venous connection	1	0
Congenital disorders SOC TOTAL	111	1

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear canal erythema	1	0
Ear congestion	39	0
Ear discomfort	112	0
Ear disorder	24	0
Ear haemorrhage	15	0
Ear inflammation	3	0
Ear pain	1195	0
Ear pruritus	12	0
Ear swelling	39	0
Otorrhoea	8	0
Ototoxicity	1	0
Paraesthesia ear	1	0
<i>Eustachian tube disorders</i>		
Eustachian tube disorder	5	0
Eustachian tube dysfunction	12	0
Eustachian tube obstruction	7	0
<i>External ear disorders NEC</i>		
Auricular swelling	2	0
Excessive cerumen production	12	0
External ear pain	6	0
Red ear syndrome	2	0
<i>External ear infections and inflammations</i>		
Chondrodermatitis nodularis chronica heliis	1	0
External ear inflammation	2	0
<i>Hearing disorders NEC</i>		
Auditory disorder	6	0
Diplacusis	2	0
Dysacusis	1	0
<i>Hearing losses</i>		
Conductive deafness	1	0
Deafness	310	0
Deafness bilateral	13	0
Deafness neurosensory	27	0
Deafness transitory	10	0
Deafness unilateral	42	0
Hypoacusis	237	0
Mixed deafness	1	0
Sudden hearing loss	53	0
<i>Hyperacusia</i>		
Hyperacusis	85	0
Misophonia	3	0
<i>Inner ear disorders NEC</i>		
Acute vestibular syndrome	2	0
Inner ear disorder	13	0
Meniere's disease	16	0
Vestibular disorder	15	0
<i>Inner ear infections and inflammations</i>		
Autoimmune inner ear disease	1	0
Inner ear inflammation	11	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	70	0
Phobic postural vertigo	1	0

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Reaction Name	Total	Fatal
Ear disorders Ear disorders cont'd		
Tinnitus	2579	0
Vertigo	1690	0
Vertigo labyrinthine	13	0
Vertigo positional	90	0
<i>Mastoid disorders</i>		
Mastoid effusion	1	0
<i>Middle ear disorders NEC</i>		
Middle ear disorder	3	0
Middle ear effusion	1	0
<i>Middle ear infections and inflammations</i>		
Middle ear inflammation	1	0
<i>Tympanic membrane disorders (excl infections)</i>		
Tympanic membrane perforation	4	0
Ear disorders SOC TOTAL	6801	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Autoimmune thyroiditis	5	0
Thyroiditis	24	0
Thyroiditis acute	4	0
Thyroiditis subacute	9	0
<i>Adrenal cortical hyperfunctions</i>		
Cushingoid	1	0
<i>Adrenal cortical hypofunctions</i>		
Addison's disease	4	0
Adrenal insufficiency	4	0
Adrenocortical insufficiency acute	16	0
<i>Adrenal gland disorders NEC</i>		
Adrenal disorder	3	0
Adrenal haemorrhage	4	0
Adrenal mass	1	0
Adrenal thrombosis	1	0
<i>Anterior pituitary hyperfunction</i>		
Pituitary-dependent Cushing's syndrome	1	0
<i>Anterior pituitary hypofunction</i>		
Hypopituitarism	2	0
Luteal phase deficiency	1	0
<i>Endocrine abnormalities of gonadal function NEC</i>		
Oestrogen deficiency	1	0
<i>Endocrine abnormalities of puberty</i>		
Delayed menarche	5	0
Premature menarche	21	0
<i>Endocrine disorders NEC</i>		
Endocrine disorder	1	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	68	0
Ovulation delayed	35	0
<i>Male gonadal function disorders</i>		
Androgen deficiency	1	0
<i>Thyroid disorders NEC</i>		
Autoimmune thyroid disorder	1	0
Goitre	18	0
Thyroid disorder	15	0
Thyroid mass	3	0
Thyroid pain	12	0
<i>Thyroid hyperfunction disorders</i>		
Basedow's disease	14	0
Hyperthyroidism	60	0
Primary hyperthyroidism	1	0
Thyrotoxic crisis	6	0
<i>Thyroid hypofunction disorders</i>		
Autoimmune hypothyroidism	1	0
Hypothyroidic goitre	1	0
Hypothyroidism	49	0
Immune-mediated hypothyroidism	1	0
Myxoedema	1	0
<i>Thyroid neoplasms</i>		
Thyroid cyst	1	0
Endocrine disorders SOC TOTAL	396	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Amblyopic vision impairment</i>		
Amblyopia	7	0
<i>Anterior chamber bleeding and vascular disorders</i>		
Spontaneous hyphaema	1	0
<i>Cataract conditions</i>		
Cataract	18	0
<i>Choroid and vitreous haemorrhages and vascular disorders</i>		
Choroidal haemorrhage	1	0
Choroidal neovascularisation	1	0
Vitreous haemorrhage	4	0
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Vitreous detachment	23	0
Vitreous floaters	125	0
<i>Colour blindness (incl acquired)</i>		
Colour blindness acquired	2	0
Dyschromatopsia	16	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	54	0
Scleral haemorrhage	1	0
<i>Conjunctival infections, irritations and inflammations</i>		
Conjunctival hyperaemia	2	0
Conjunctival irritation	1	0
Conjunctival oedema	3	0
Conjunctival ulcer	1	0
Conjunctivitis allergic	2	0
<i>Corneal infections, oedemas and inflammations</i>		
Corneal oedema	3	0
Keratitis	7	0
Ulcerative keratitis	6	0
<i>Corneal structural change, deposit and degeneration</i>		
Corneal scar	1	0
<i>Eyelid movement disorders</i>		
Blepharospasm	173	0
Excessive eye blinking	7	0
Eyelid function disorder	3	0
Eyelid myokymia	4	0
Eyelid ptosis	54	0
Paralytic lagophthalmos	2	0
<i>Glaucomas (excl congenital)</i>		
Angle closure glaucoma	2	0
Glaucoma	9	0
Ocular hypertension	1	0
<i>Iris and ciliary body structural change, deposit and degeneration</i>		
Eye colour change	3	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Autoimmune uveitis	3	0
Iridocyclitis	21	0
Iritis	13	0
Uveitis	58	0
Vogt-Koyanagi-Harada disease	1	0
<i>Lacrimation disorders</i>		
Dry eye	183	0
Lacrimation decreased	1	0

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Eye disorders Eye disorders cont'd		
Lacrimation increased	171	0
Lid bleeding and vascular disorders		
Eyelid bleeding	1	0
Lid, lash and lacrimal infections, irritations and inflammations		
Blepharitis	21	0
Blepharitis allergic	1	0
Chalazion	8	0
Eczema eyelids	11	0
Erythema of eyelid	11	0
Eyelid cyst	7	0
Eyelid irritation	4	0
Eyelid margin crusting	5	0
Eyelid oedema	16	0
Eyelid rash	20	0
Meibomian gland dysfunction	1	0
Swelling of eyelid	149	0
Swollen tear duct	2	0
Lid, lash and lacrimal structural disorders		
Dacryostenosis acquired	2	0
Dermatochalasis	1	0
Ectropion	1	0
Eyelash changes	1	0
Eyelid exfoliation	3	0
Eyelid skin dryness	2	0
Eyelid thickening	1	0
Floppy eyelid syndrome	1	0
Growth of eyelashes	3	0
Lacrimal gland enlargement	1	0
Lagophthalmos	5	0
Ocular bleeding and vascular disorders NEC		
Eye haematoma	4	0
Eye haemorrhage	39	0
Ocular vascular disorder	2	0
Ophthalmic vein thrombosis	1	0
Ocular disorders NEC		
Dark circles under eyes	10	0
Eye disorder	45	0
Eye oedema	19	0
Eye pain	1318	0
Eye swelling	666	0
Eye symptom	10	0
Eye ulcer	6	0
Eyelid disorder	16	0
Eyelid pain	16	0
Eyelids pruritus	8	0
Ocular discomfort	37	0
Periorbital oedema	22	0
Periorbital pain	5	0
Periorbital swelling	137	0
Retinal disorder	2	0
Vitreous disorder	1	0
Ocular infections, inflammations and associated manifestations		
Eye allergy	22	0

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Eye discharge	35	0
Eye inflammation	43	0
Eye irritation	110	0
Eye pruritus	287	0
Limbal swelling	4	0
Ocular hyperaemia	271	0
Ocular vasculitis	1	0
Ocular nerve and muscle disorders		
Binocular eye movement disorder	1	0
Extraocular muscle disorder	1	0
Eye movement disorder	46	0
Gaze palsy	3	0
Ocular myasthenia	1	0
Ophthalmoplegia	9	0
Strabismus	10	0
Ocular sensation disorders		
Abnormal sensation in eye	26	0
Asthenopia	176	0
Eye paraesthesia	2	0
Eyelid sensory disorder	3	0
Foreign body sensation in eyes	19	0
Hypoaesthesia eye	19	0
Photophobia	532	0
Optic disc abnormalities NEC		
Optic disc disorder	1	0
Papilloedema	8	0
Optic nerve bleeding and vascular disorders		
Optic disc haemorrhage	1	0
Optic ischaemic neuropathy	4	0
Orbital infections, inflammations and irritations		
Parophthalmia	1	0
Orbital structural change, deposit and degeneration		
Orbital oedema	2	0
Pupil disorders		
Anisocoria	15	0
Miosis	2	0
Mydriasis	24	0
Pupil fixed	4	0
Pupillary disorder	1	0
Refractive and accommodative disorders		
Accommodation disorder	1	0
Altered visual depth perception	5	0
Astigmatism	3	0
Hypermetropia	4	0
Myopia	4	0
Retinal bleeding and vascular disorders (excl retinopathy)		
Papillophlebitis	1	0
Retinal artery occlusion	18	0
Retinal artery thrombosis	2	0
Retinal haemorrhage	12	0
Retinal ischaemia	1	0
Retinal vascular thrombosis	1	0
Retinal vein occlusion	49	0

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Retinal vein thrombosis	2	0
Retinal structural change, deposit and degeneration		
Age-related macular degeneration	1	0
Chorioretinal disorder	1	0
Dry age-related macular degeneration	1	0
Epiretinal membrane	1	0
Macular degeneration	5	0
Macular hole	4	0
Macular rupture	1	0
Maculopathy	1	0
Neovascular age-related macular degeneration	4	0
Retinal degeneration	1	0
Retinal detachment	9	0
Retinal tear	3	0
Retinal toxicity	3	0
Retinal, choroid and vitreous infections and inflammations		
Birdshot chorioretinopathy	2	0
Choroiditis	1	0
Cystoid macular oedema	1	0
Macular oedema	8	0
Retinal oedema	2	0
Retinal vasculitis	3	0
Retinopathies NEC		
Acute macular neuroretinopathy	3	0
Central serous chorioretinopathy	8	0
Diabetic retinopathy	1	0
Retinal exudates	3	0
Retinopathy	4	0
Scleral infections, irritations and inflammations		
Episcleritis	9	0
Scleritis	6	0
Scleral structural change, deposit and degeneration		
Scleral discolouration	2	0
Structural change, deposit and degeneration of eye NEC		
Endocrine ophthalmopathy	2	0
Exophthalmos	4	0
Visual colour distortions		
Chloropsia	2	0
Chromatopsia	1	0
Cyanopsia	5	0
Erythroptopsia	2	0
Xanthopsia	1	0
Visual disorders NEC		
Charles Bonnet syndrome	2	0
Diplopia	197	0
Dysmetropsia	1	0
Glare	1	0
Halo vision	10	0
Heteronymous diplopia	1	0
Metamorphopsia	25	0
Oscillopsia	3	0
Photopsia	170	0
Scintillating scotoma	4	0

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Vision blurred	1481	0
Visual brightness	3	0
Visual snow syndrome	8	0
Visual field disorders		
Visual field defect	42	0
Visual impairment and blindness (excl colour blindness)		
Amaurosis fugax	4	0
Blindness	172	0
Blindness cortical	1	0
Blindness transient	23	0
Blindness unilateral	20	0
Central vision loss	6	0
Sudden visual loss	5	0
Visual acuity reduced	31	0
Visual acuity reduced transiently	1	0
Visual impairment	492	0
Visual pathway disorders		
Optic nerve disorder	1	0
Eye disorders SOC TOTAL	8226	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Abdominal findings abnormal</i>		
Abdominal mass	2	0
Gastrointestinal sounds abnormal	18	0
<i>Abdominal hernias NEC</i>		
Abdominal hernia	2	0
<i>Abdominal wall conditions NEC</i>		
Abdominal wall haematoma	2	0
<i>Acute and chronic pancreatitis</i>		
Alcoholic pancreatitis	1	0
Autoimmune pancreatitis	1	0
Obstructive pancreatitis	1	0
Pancreatitis	19	0
Pancreatitis acute	17	1
Pancreatitis chronic	1	0
Pancreatitis necrotising	2	0
<i>Anal and rectal disorders NEC</i>		
Anal fissure	2	0
Anal sphincter atony	1	0
Rectal prolapse	1	0
<i>Anal and rectal pains</i>		
Proctalgia	16	0
<i>Anal and rectal signs and symptoms</i>		
Anal blister	1	0
Anal eczema	1	0
Anal erythema	1	0
Anal hypoaesthesia	2	0
Anal pruritus	2	0
Anal rash	1	0
Anal spasm	1	0
Anorectal discomfort	5	0
Anorectal swelling	1	0
Rectal discharge	2	0
Rectal spasm	1	0
Rectal tenesmus	1	0
<i>Anal and rectal ulcers and perforation</i>		
Anal ulcer	1	0
<i>Benign oral cavity neoplasms</i>		
Mouth cyst	6	0
Tongue cyst	4	0
Tongue polyp	2	0
<i>Colitis (excl infective)</i>		
Autoimmune colitis	2	0
Colitis	62	1
Colitis ischaemic	1	0
Colitis microscopic	4	0
Colitis ulcerative	84	0
Crohn's disease	53	0
Eosinophilic colitis	1	0
Inflammatory bowel disease	13	0
<i>Dental and periodontal infections and inflammations</i>		
Dental caries	2	0
Periodontal inflammation	1	0
<i>Dental developmental disorders and anomalies</i>		

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Tooth impacted	1	0
Dental disorders NEC		
Loose tooth	5	0
Malpositioned teeth	2	0
Periodontal disease	1	0
Teeth brittle	3	0
Teething	9	0
Tooth disorder	2	0
Tooth erosion	1	0
Tooth socket haemorrhage	1	0
Dental pain and sensation disorders		
Dental discomfort	7	0
Dental paraesthesia	14	0
Hyperaesthesia teeth	39	0
Toothache	198	0
Dental surface disorders		
Tooth discolouration	10	0
Diaphragmatic hernias		
Hiatus hernia	8	0
Diarrhoea (excl infective)		
Diarrhoea	6182	0
Diarrhoea haemorrhagic	29	0
Diverticula		
Diverticulum	7	0
Diverticulum intestinal	1	0
Duodenal and small intestinal stenosis and obstruction		
Small intestinal obstruction	4	0
Duodenal ulcers and perforation		
Duodenal ulcer	1	0
Duodenal ulcer haemorrhage	1	0
Duodenal ulcer perforation	3	0
Dyspeptic signs and symptoms		
Dyspepsia	555	0
Epigastric discomfort	15	0
Eructation	67	0
Faecal abnormalities NEC		
Abnormal faeces	23	0
Faecaloma	7	0
Faeces discoloured	63	0
Faeces hard	3	0
Faeces pale	5	0
Faeces soft	14	0
Mucous stools	13	0
Flatulence, bloating and distension		
Abdominal distension	610	0
Aerophagia	3	0
Flatulence	206	0
Gastric and oesophageal haemorrhages		
Gastric haemorrhage	5	1
Mallory-Weiss syndrome	1	0
Oesophageal varices haemorrhage	1	0
Gastric ulcers and perforation		
Gastric ulcer	7	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Gastritis (excl infective)</i>		
Chronic gastritis	4	0
Gastritis	74	0
Reflux gastritis	9	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal migraine	2	0
Abdominal pain	1729	0
Abdominal pain lower	157	0
Abdominal pain upper	2855	0
Abdominal rigidity	27	0
Abdominal tenderness	15	0
Gastrointestinal pain	174	0
Oesophageal pain	14	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	285	0
Duodenogastric reflux	5	0
Gastric dilatation	8	0
Gastrooesophageal reflux disease	202	0
Impaired gastric emptying	10	0
Infrequent bowel movements	3	0
Intestinal dilatation	1	0
Intestinal pseudo-obstruction	2	0
<i>Gastrointestinal disorders NEC</i>		
Appendicolith	1	0
Appendix disorder	2	0
Food poisoning	7	0
Functional gastrointestinal disorder	11	0
Gastric disorder	11	0
Gastrointestinal disorder	31	0
Stomach mass	4	0
<i>Gastrointestinal dyskinetic disorders</i>		
Bowel movement irregularity	9	0
Change of bowel habit	14	0
Dyschezia	4	0
Gastrointestinal motility disorder	5	0
Oesophageal achalasia	1	0
<i>Gastrointestinal fistulae</i>		
Diverticular fistula	2	0
<i>Gastrointestinal inflammatory disorders NEC</i>		
Appendicitis noninfective	1	0
Duodenitis	1	0
Enteritis	6	0
Epiploic appendagitis	2	0
Gastrointestinal inflammation	6	0
Gastrointestinal tract irritation	1	0
Intestinal angioedema	2	0
<i>Gastrointestinal mucosal dystrophies and secretion disorders</i>		
Barrett's oesophagus	2	0
Hyperchlorhydria	4	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	718	0
Abdominal symptom	2	0
Acute abdomen	8	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Anal incontinence	24	0
Breath odour	23	0
Dysphagia	255	1
Gastrointestinal wall thickening	1	0
Odynophagia	48	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Cardiospasm	1	0
Defaecation urgency	12	0
Frequent bowel movements	35	0
Gastrointestinal hypermotility	1	0
Irritable bowel syndrome	106	0
Oesophageal spasm	5	0
Pylorospasm	1	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Ileus	2	0
Intestinal obstruction	8	0
Neonatal intestinal obstruction	1	0
Volvulus	1	0
<i>Gastrointestinal vascular malformations</i>		
Gastric antral vascular ectasia	11	0
<i>Gastrointestinal vascular occlusion and infarction</i>		
Intestinal infarction	1	0
Intestinal ischaemia	11	2
Mesenteric vein thrombosis	10	0
Omental infarction	1	0
Thrombosis mesenteric vessel	2	0
Visceral venous thrombosis	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival blister	13	0
Gingival discomfort	8	0
Gingival disorder	5	0
Gingival erythema	2	0
Gingival hypertrophy	1	0
Gingival oedema	2	0
Gingival pain	138	0
Gingival pruritus	2	0
Gingival recession	1	0
Gingival swelling	43	0
Gingival ulceration	3	0
Gingivitis ulcerative	1	0
Noninfective gingivitis	15	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	86	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Gastric varices	1	0
Haemorrhoidal haemorrhage	1	0
Haemorrhoids	35	1
Haemorrhoids thrombosed	1	0
<i>Inguinal hernias</i>		
Inguinal hernia	1	0
<i>Intestinal haemorrhages</i>		
Anal haemorrhage	24	1
Intestinal haemorrhage	1	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Rectal haemorrhage	84	0
Small intestinal haemorrhage	5	0
<i>Intestinal ulcers and perforation NEC</i>		
Intestinal perforation	7	2
Large intestinal ulcer	1	0
Large intestinal ulcer haemorrhage	1	0
Large intestine perforation	1	0
<i>Large intestinal stenosis and obstruction</i>		
Large intestinal obstruction	2	2
<i>Malabsorption syndromes</i>		
Bile acid malabsorption	5	0
Celiac disease	14	0
Malabsorption	1	0
Steatorrhoea	4	0
<i>Nausea and vomiting symptoms</i>		
Cyclic vomiting syndrome	1	0
Discoloured vomit	13	0
Infantile vomiting	7	0
Nausea	15501	0
Regurgitation	1	0
Retching	117	0
Vomiting	5333	1
Vomiting projectile	76	0
<i>Non-mechanical ileus</i>		
Ileus paralytic	2	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Gastrointestinal haemorrhage	19	1
Haematemesis	42	2
Haematochezia	62	0
Melaena	11	0
Upper gastrointestinal haemorrhage	14	1
<i>Oesophageal disorders NEC</i>		
Oesophageal disorder	1	0
<i>Oesophageal stenosis and obstruction</i>		
Oesophageal stenosis	3	0
<i>Oesophagitis (excl infective)</i>		
Eosinophilic oesophagitis	2	0
Oesophagitis	6	0
<i>Oral dryness and saliva altered</i>		
Aptyalism	5	0
Dry mouth	551	0
Lip dry	51	0
Saliva altered	8	0
Salivary hypersecretion	55	0
<i>Oral soft tissue disorders NEC</i>		
Angina bullosa haemorrhagica	1	0
Chapped lips	29	0
Cheilitis	33	0
Enlarged uvula	15	0
Leukoplakia oral	2	0
Lip blister	36	0
Lip disorder	7	0
Oral disorder	25	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Oral lichen planus	17	0
Oral mucosal hypertrophy	1	0
Oral papule	1	0
Uvulitis	7	0
Oral soft tissue haemorrhages		
Lip haemorrhage	2	0
Mouth haemorrhage	23	0
Oral blood blister	19	0
Oral purpura	2	0
Oral soft tissue infections		
Angular cheilitis	5	0
Oral soft tissue signs and symptoms		
Anaesthesia oral	3	0
Burning mouth syndrome	7	0
Coating in mouth	1	0
Hypoaesthesia oral	523	0
Lip discolouration	11	0
Lip erythema	4	0
Lip exfoliation	6	0
Lip pain	67	0
Lip pruritus	18	0
Lip scab	1	0
Oral discomfort	91	0
Oral dysaesthesia	1	0
Oral mucosal blistering	19	0
Oral mucosal discolouration	2	0
Oral mucosal eruption	22	0
Oral mucosal erythema	10	0
Oral mucosal exfoliation	10	0
Oral mucosal roughening	3	0
Oral mucosal scab	2	0
Oral pain	193	0
Oral pruritus	24	0
Paraesthesia oral	983	0
Pigmentation lip	1	0
Oral soft tissue swelling and oedema		
Lip oedema	5	0
Lip swelling	908	0
Mouth swelling	120	0
Oedema mouth	4	0
Palatal oedema	4	0
Palatal swelling	5	0
Pancreatic disorders NEC		
Pancreatic disorder	3	0
Pancreatic failure	1	0
Pancreatic mass	1	0
Peptic ulcers and perforation		
Peptic ulcer	1	0
Peptic ulcer haemorrhage	14	0
Peritoneal and retroperitoneal disorders		
Ascites	3	0
Peritoneal disorder	1	0
Peritoneal and retroperitoneal fibrosis and adhesions		

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Abdominal adhesions	2	0
Peritoneal and retroperitoneal haemorrhages		
Haemoperitoneum	1	0
Retroperitoneal haematoma	1	0
Retroperitoneal haemorrhage	2	1
Rectal inflammations NEC		
Proctitis	4	0
Proctitis ulcerative	1	0
Salivary gland disorders NEC		
Salivary gland disorder	1	0
Salivary gland mucocoele	1	0
Salivary gland pain	13	0
Salivary gland enlargements		
Parotid gland enlargement	12	0
Salivary gland enlargement	5	0
Submaxillary gland enlargement	7	0
Salivary gland infections and inflammations		
Noninfective sialoadenitis	2	0
Stomatitis and ulceration		
Aphthous ulcer	62	0
Lip ulceration	23	0
Mouth ulceration	498	0
Oral mucosa erosion	1	0
Palatal ulcer	1	0
Stomatitis	69	0
Tongue disorders		
Glossitis	23	0
Hypertrophy of tongue papillae	2	0
Plicated tongue	4	0
Tongue disorder	45	0
Tongue geographic	8	0
Tongue haemorrhage	3	0
Tongue ulceration	34	0
Trichoglossia	4	0
Tongue signs and symptoms		
Glossodynia	234	0
Scalloped tongue	5	0
Stiff tongue	4	0
Swollen tongue	562	0
Tongue blistering	19	0
Tongue coated	20	0
Tongue discolouration	42	0
Tongue discomfort	48	0
Tongue dry	17	0
Tongue eruption	11	0
Tongue erythema	13	0
Tongue exfoliation	2	0
Tongue movement disturbance	8	0
Tongue oedema	24	0
Tongue pruritus	2	0
Tongue rough	5	0
Tongue spasm	12	0
Tooth missing		

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Tooth loss	6	0
Gastrointestinal disorders SOC TOTAL	43010	18

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site bruise	9	0
Administration site erythema	4	0
Administration site extravasation	3	0
Administration site haematoma	3	0
Administration site inflammation	1	0
Administration site irritation	1	0
Administration site joint discomfort	2	0
Administration site joint movement impairment	2	0
Administration site joint pain	1	0
Administration site nerve damage	1	0
Administration site pain	21	0
Administration site rash	5	0
Administration site reaction	1	0
Administration site swelling	5	0
Administration site urticaria	2	0
Administration site warmth	2	0
Puncture site bruise	43	0
Puncture site pain	9	0
Puncture site reaction	1	0
Puncture site swelling	2	0
Vessel puncture site bruise	2	0
Vessel puncture site erythema	1	0
Vessel puncture site pain	1	0
<i>Adverse effect absent</i>		
No adverse event	10	0
<i>Application and instillation site reactions</i>		
Application site acne	2	0
Application site bruise	12	0
Application site burn	1	0
Application site dryness	2	0
Application site erythema	18	0
Application site haemorrhage	1	0
Application site hypoaesthesia	2	0
Application site irritation	1	0
Application site joint erythema	1	0
Application site joint pain	1	0
Application site mass	1	0
Application site odour	2	0
Application site pain	12	0
Application site pruritus	4	0
Application site rash	2	0
Application site reaction	1	0
Application site swelling	2	0
Application site vesicles	7	0
Application site warmth	1	0
Instillation site warmth	9	0
<i>Asthenic conditions</i>		
Asthenia	2481	0
Chronic fatigue syndrome	90	0
Decreased activity	10	0
Fatigue	26531	1
Malaise	6008	2

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Sluggishness	19	0
Body temperature altered		
Hyperthermia	8	0
Hyperthermia malignant	1	0
Hypothermia	27	0
Temperature regulation disorder	17	0
Breast complications associated with device		
Breast implant palpable	1	0
Capsular contracture associated with breast implant	2	0
Cardiac complications associated with device		
Prosthetic cardiac valve thrombosis	2	0
Complications associated with device NEC		
Capsular contracture associated with implant	1	0
Complication of device removal	3	0
Injury associated with device	5	0
Medical device pain	1	0
Medical device site swelling	1	0
Phantom shocks	2	0
Death and sudden death		
Brain death	4	3
Cardiac death	3	2
Clinical death	1	1
Death	199	199
Sudden cardiac death	2	2
Sudden death	30	30
Febrile disorders		
Hyperpyrexia	10	0
Pyrexia	17138	0
Feelings and sensations NEC		
Chills	10613	0
Feeling abnormal	1883	0
Feeling cold	1395	0
Feeling drunk	83	0
Feeling hot	1328	0
Feeling jittery	34	0
Feeling of body temperature change	373	0
Feeling of relaxation	3	0
Hangover	87	0
Hunger	52	0
Sensation of blood flow	5	0
Sensation of foreign body	65	0
Sense of oppression	1	0
Temperature intolerance	57	0
Thirst	387	0
Thirst decreased	2	0
Fibrosis NEC		
Fibrosis	3	0
Gait disturbances		
Gait deviation	1	0
Gait disturbance	303	0
Gait inability	123	0
Loss of control of legs	29	0
General signs and symptoms NEC		

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Adhesion	2	0
Chronic disease	1	0
Concomitant disease progression	1	1
Condition aggravated	369	0
Crepitations	5	0
Crying	169	0
Deformity	2	0
Developmental delay	1	0
Discharge	13	0
Disease progression	2	0
Disease recurrence	32	0
Effusion	3	0
Energy increased	27	0
Exercise tolerance decreased	47	0
Exercise tolerance increased	2	0
Fat tissue increased	1	0
Foaming at mouth	3	0
General physical health deterioration	18	3
General symptom	3	0
Glassy eyes	8	0
High-pitched crying	3	0
Illness	2321	0
Induration	18	0
Influenza like illness	2715	0
Irritability postvaccinal	2	0
Local reaction	93	0
Moaning	4	0
Multiple organ dysfunction syndrome	16	6
Nonspecific reaction	2	0
Organ failure	5	2
Perforation	2	0
Peripheral swelling	4499	0
Physical deconditioning	2	0
Pre-existing condition improved	9	0
Prolapse	1	0
Screaming	24	0
Secretion discharge	27	0
Stenosis	1	0
Swelling	3626	0
Swelling face	997	0
Symptom recurrence	1	0
Terminal state	1	0
Tissue irritation	1	0
Tissue rupture	1	0
Unevaluable event	1	0
Healing abnormal NEC		
Impaired healing	7	0
Implant and catheter site reactions		
Catheter site pain	1	0
Implant site discolouration	2	0
Implant site pain	3	0
Implant site rash	1	0
Implant site reaction	1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Implant site swelling	2	0
Implant site urticaria	1	0
Implant site warmth	3	0
Inflammations		
Chronic inflammatory response syndrome	1	0
Foreign body reaction	1	0
Granuloma	1	0
Inflammation	681	0
Papillitis	1	0
Scar inflammation	3	0
Serositis	1	0
Soft tissue inflammation	1	0
Systemic inflammatory response syndrome	7	0
Infusion site reactions		
Infusion site coldness	1	0
Infusion site discolouration	1	0
Infusion site joint effusion	1	0
Infusion site joint pain	2	0
Infusion site mass	1	0
Infusion site nerve damage	1	0
Infusion site pain	5	0
Infusion site pruritus	3	0
Infusion site swelling	2	0
Infusion site urticaria	1	0
Infusion site warmth	2	0
Injection site reactions		
Injected limb mobility decreased	37	0
Injection site bruising	73	0
Injection site coldness	1	0
Injection site cyst	3	0
Injection site discolouration	6	0
Injection site discomfort	10	0
Injection site eczema	1	0
Injection site erythema	447	0
Injection site extravasation	1	0
Injection site haematoma	2	0
Injection site haemorrhage	10	0
Injection site hypersensitivity	3	0
Injection site hypoaesthesia	17	0
Injection site indentation	10	0
Injection site induration	4	0
Injection site inflammation	50	0
Injection site injury	2	0
Injection site irritation	3	0
Injection site joint discomfort	2	0
Injection site joint erythema	5	0
Injection site joint movement impairment	1	0
Injection site joint pain	15	0
Injection site lymphadenopathy	1	0
Injection site macule	1	0
Injection site mass	648	0
Injection site movement impairment	1	0
Injection site muscle atrophy	1	0

Case Series Drug Analysis Print

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

Report Run Date: 27-Jul-2022

Data Lock Date: 27-Jul-2022 18:30:07

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Injection site muscle weakness	1	0
Injection site necrosis	4	0
Injection site nerve damage	1	0
Injection site nodule	1	0
Injection site oedema	19	0
Injection site pain	3233	0
Injection site pallor	1	0
Injection site paraesthesia	15	0
Injection site pruritus	250	0
Injection site rash	207	0
Injection site reaction	58	0
Injection site scab	4	0
Injection site scar	4	0
Injection site swelling	354	0
Injection site urticaria	36	0
Injection site vesicles	10	0
Injection site warmth	211	0
Interactions		
Alcohol interaction	5	0
Drug interaction	33	0
Drug-device interaction	2	0
Inhibitory drug interaction	3	0
Mass conditions NEC		
Cyst	60	0
Mass	93	0
Nodule	46	0
Mucosal findings abnormal		
Mucosa vesicle	1	0
Mucosal dryness	1	0
Mucosal haemorrhage	10	0
Mucosal inflammation	3	0
Mucosal ulceration	1	0
Oedema mucosal	2	0
Polyp	5	0
Necrosis NEC		
Fat necrosis	4	0
Necrosis	5	0
Oedema NEC		
Face oedema	37	0
Generalised oedema	7	0
Localised oedema	21	0
Oedema	99	0
Oedema peripheral	107	0
Pain and discomfort NEC		
Axillary pain	4095	0
Breakthrough pain	1	0
Chest discomfort	2116	0
Chest pain	7009	0
Discomfort	597	0
Facial discomfort	21	0
Facial pain	245	0
First bite syndrome	1	0
Inflammatory pain	22	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Non-cardiac chest pain	36	0
Pain	10251	0
Suprapubic pain	1	0
Tenderness	749	0
Visceral pain	2	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	124	1
Adverse food reaction	4	0
Adverse reaction	2	0
Drug ineffective	631	0
Drug intolerance	4	0
Drug resistance	1	0
Immediate post-injection reaction	5	0
Inadequate analgesia	9	0
No reaction on previous exposure to drug	28	0
Product intolerance	1	0
Therapeutic product effect decreased	2	0
Therapeutic product effect delayed	2	0
Therapeutic product effect increased	1	0
Therapeutic product ineffective	3	0
Therapeutic response decreased	2	0
Therapeutic response unexpected	100	0
Therapy non-responder	1	0
Treatment failure	12	0
Vaccination failure	144	0
Trophic disorders		
Abnormal organ growth	1	0
Atrophy	3	0
Calcinosis	2	0
Hyperplasia	1	0
Hypertrophy	2	0
Ulcers NEC		
Ulcer	39	0
Ulcer haemorrhage	1	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	25	0
Shoulder injury related to vaccine administration	75	0
Vaccination site anaesthesia	1	0
Vaccination site bruising	144	0
Vaccination site coldness	4	0
Vaccination site cyst	7	0
Vaccination site dermatitis	2	0
Vaccination site discharge	1	0
Vaccination site discolouration	17	0
Vaccination site discomfort	54	0
Vaccination site dryness	2	0
Vaccination site eczema	1	0
Vaccination site erythema	688	0
Vaccination site granuloma	5	0
Vaccination site haematoma	2	0
Vaccination site haemorrhage	34	0
Vaccination site hypersensitivity	5	0
Vaccination site hypoaesthesia	20	0

Case Series Drug Analysis Print

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

Report Run Date: 27-Jul-2022

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MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site induration	82	0
Vaccination site inflammation	66	0
Vaccination site injury	1	0
Vaccination site irritation	16	0
Vaccination site joint discomfort	3	0
Vaccination site joint erythema	11	0
Vaccination site joint inflammation	1	0
Vaccination site joint movement impairment	22	0
Vaccination site joint pain	37	0
Vaccination site joint swelling	4	0
Vaccination site joint warmth	1	0
Vaccination site lymphadenopathy	8	0
Vaccination site macule	1	0
Vaccination site mass	342	0
Vaccination site movement impairment	99	0
Vaccination site necrosis	1	0
Vaccination site nerve damage	1	0
Vaccination site nodule	6	0
Vaccination site oedema	3	0
Vaccination site pain	2434	0
Vaccination site papule	2	0
Vaccination site paraesthesia	10	0
Vaccination site phlebitis	1	0
Vaccination site photosensitivity reaction	1	0
Vaccination site pruritus	190	0
Vaccination site rash	156	0
Vaccination site reaction	37	0
Vaccination site scab	4	0
Vaccination site scar	3	0
Vaccination site swelling	660	0
Vaccination site thrombosis	1	0
Vaccination site ulcer	3	0
Vaccination site urticaria	11	0
Vaccination site vesicles	13	0
Vaccination site warmth	307	0
<i>Vascular complications associated with device</i>		
Vascular stent thrombosis	1	0
<i>Withdrawal and rebound effects</i>		
Drug withdrawal syndrome	4	0
Withdrawal syndrome	48	0
General disorders SOC TOTAL	123715	253

Case Series Drug Analysis Print

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Report Run Date: 27-Jul-2022

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MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	19	0
Cholangitis	1	0
<i>Cholecystitis and cholelithiasis</i>		
Cholecystitis	4	0
Cholecystitis acute	2	0
Cholelithiasis	13	0
<i>Cholestasis and jaundice</i>		
Cholestasis	2	0
Cholestasis of pregnancy	1	0
Jaundice	29	0
Jaundice cholestatic	10	0
Ocular icterus	2	0
<i>Gallbladder disorders NEC</i>		
Gallbladder disorder	4	0
Gallbladder enlargement	2	0
<i>Hepatic and hepatobiliary disorders NEC</i>		
Hepatic cyst	1	0
Hepatic lesion	1	0
Liver disorder	18	0
<i>Hepatic enzymes and function abnormalities</i>		
Hepatic function abnormal	10	0
Hypertransaminasaemia	5	0
<i>Hepatic failure and associated disorders</i>		
Acute hepatic failure	2	0
Hepatic failure	3	1
<i>Hepatic fibrosis and cirrhosis</i>		
Hepatic cirrhosis	4	0
<i>Hepatic vascular disorders</i>		
Congestive hepatopathy	2	0
Hepatic artery embolism	1	0
Hepatic haemorrhage	2	0
Hepatic vein thrombosis	5	0
Portal vein thrombosis	11	0
Portosplenomesenteric venous thrombosis	1	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	38	0
Hepatomegaly	7	0
Liver tenderness	3	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Autoimmune hepatitis	16	0
Drug-induced liver injury	3	0
Hepatic steatosis	6	0
Hepatitis	20	0
Hepatitis acute	5	0
Hepatitis toxic	2	0
Hepatotoxicity	1	0
Immune-mediated hepatic disorder	1	0
Liver injury	29	0
<i>Obstructive bile duct disorders (excl neoplasms)</i>		
Bile duct stenosis	1	0
Hepatic disorders SOC TOTAL	287	1

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Immune system disorders		
<i>Acute and chronic sarcoidosis</i>		
Loefgren syndrome	1	0
Sarcoidosis	21	0
<i>Allergic conditions NEC</i>		
Allergic oedema	19	0
Allergy to animal	2	0
Allergy to arthropod bite	7	0
Allergy to arthropod sting	2	0
Allergy to metals	3	0
Allergy to sting	1	0
Hypersensitivity	1188	0
Infusion related hypersensitivity reaction	3	0
Mite allergy	2	0
Multiple allergies	17	0
Serum sickness	3	0
Serum sickness-like reaction	6	0
Type I hypersensitivity	1	0
Type III immune complex mediated reaction	4	0
Type IV hypersensitivity reaction	7	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergic reaction to excipient	7	0
Allergy to chemicals	8	0
Allergy to vaccine	50	0
Contrast media reaction	2	0
Drug hypersensitivity	45	0
Food allergy	49	0
Milk allergy	3	0
Oral allergy syndrome	3	0
Polymers allergy	1	0
Reaction to colouring	1	0
Reaction to excipient	11	0
Reaction to preservatives	5	0
Rubber sensitivity	1	0
Smoke sensitivity	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	570	2
Anaphylactic shock	67	0
Anaphylactoid reaction	25	0
Anaphylactoid shock	4	0
<i>Atopic disorders</i>		
Atopy	3	0
Seasonal allergy	118	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	68	0
<i>Autoinflammatory diseases</i>		
Autoinflammatory disease	1	0
<i>Immune and associated conditions NEC</i>		
Anamnestic reaction	1	0
Bacille Calmette-Guerin scar reactivation	68	0
Cytokine release syndrome	1	0
Cytokine storm	1	0
Decreased immune responsiveness	4	0
Graft versus host disease	2	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Immune system disorders		
Immune system disorders cont'd		
Haemophagocytic lymphohistiocytosis	4	0
Immune reconstitution inflammatory syndrome	1	0
Immune system disorder	40	0
Immune-mediated adverse reaction	7	0
Immunisation reaction	58	0
Multisystem inflammatory syndrome in children	6	0
Sensitisation	9	0
Systemic immune activation	2	0
Immunodeficiency disorders NEC		
Hypogammaglobulinaemia	1	0
Immunodeficiency	7	0
Immunosuppression	5	0
Transplant rejections		
Corneal graft rejection	10	0
Kidney transplant rejection	2	0
Solid organ transplant rejection	1	0
Transplant rejection	2	0
Vasculitides		
Anti-neutrophil cytoplasmic antibody positive vasculitis	1	0
Immune system disorders SOC TOTAL	2563	2

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MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Abdominal abscess	3	0
Abdominal infection	2	0
Anal abscess	3	0
Anorectal infection	1	0
Appendicitis	51	0
Appendicitis perforated	7	0
Complicated appendicitis	1	0
Diarrhoea infectious	1	0
Diverticulitis	20	0
Dysentery	1	0
Gastric infection	2	0
Gastroenteritis	36	0
Gastrointestinal infection	1	0
Mesenteric abscess	1	0
Peritonitis	3	1
Rectal abscess	1	0
<i>Adenoviral infections</i>		
Adenoviral conjunctivitis	1	0
Adenovirus infection	1	0
<i>Aspergillus infections</i>		
Bronchopulmonary aspergillosis	1	0
<i>Bacterial infections NEC</i>		
Abscess bacterial	2	0
Administration site cellulitis	2	0
Arthritis bacterial	4	0
Bacterial colitis	1	0
Bacterial diarrhoea	1	0
Bacterial infection	17	0
Bacterial sepsis	1	0
Bacterial vaginosis	2	0
Cellulitis	209	0
Cellulitis orbital	2	0
Conjunctivitis bacterial	1	0
Ear infection bacterial	1	0
External ear cellulitis	1	0
Folliculitis	20	0
Gangrene	2	0
Gastrointestinal bacterial overgrowth	1	0
Injection site cellulitis	2	0
Meningitis bacterial	3	0
Myocarditis bacterial	1	0
Paronychia	3	0
Perichondritis	3	0
Periorbital cellulitis	3	0
Pneumonia bacterial	5	0
Sinusitis bacterial	2	0
Skin bacterial infection	4	0
Small intestine gangrene	1	0
Tonsillitis bacterial	3	0
Urinary tract infection bacterial	1	0
Vaccination site cellulitis	21	0
Zoonotic bacterial infection	1	1

Case Series Drug Analysis Print

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

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MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Infections Infections cont'd		
<i>Bartonella infections</i>		
Cat scratch disease	1	0
<i>Bone and joint infections</i>		
Abscess jaw	1	0
Arthritis infective	3	0
Intervertebral discitis	1	0
Joint abscess	1	0
Osteomyelitis	3	0
Osteomyelitis acute	2	0
Osteomyelitis chronic	1	0
<i>Bordetella infections</i>		
Pertussis	1	0
<i>Borrelial infections</i>		
Lyme disease	5	0
Relapsing fever	1	0
<i>Breast infections</i>		
Breast abscess	3	0
Mastitis	87	0
<i>Caliciviral infections</i>		
Gastroenteritis norovirus	3	0
<i>Campylobacter infections</i>		
Campylobacter gastroenteritis	1	0
Campylobacter infection	1	0
<i>Candida infections</i>		
Anal candidiasis	3	0
Balanitis candida	1	0
Candida infection	75	0
Oral candidiasis	44	0
Respiratory moniliasis	1	0
Skin candida	2	0
Systemic candida	1	0
Urinary tract candidiasis	1	0
Vulvovaginal candidiasis	57	0
<i>Cardiac infections</i>		
Cardiac infection	1	0
Cardiac valve vegetation	1	0
Endocarditis	3	0
Myocarditis infectious	1	0
Myocarditis septic	1	0
Pericarditis infective	4	0
<i>Central nervous system and spinal infections</i>		
Brain abscess	2	0
CNS ventriculitis	1	0
Cavernous sinus thrombosis	1	0
Encephalitis	24	0
Encephalomyelitis	1	0
Meningitis	11	0
Meningitis aseptic	4	0
Myelitis	15	0
Subdural abscess	1	0
<i>Clostridia infections</i>		
Clostridium difficile infection	2	0
<i>Coronavirus infections</i>		

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Asymptomatic COVID-19	21	0
COVID-19	3114	42
COVID-19 pneumonia	57	18
Coronavirus infection	7	0
Coronavirus pneumonia	1	0
Post-acute COVID-19 syndrome	17	0
Severe acute respiratory syndrome	4	0
Suspected COVID-19	114	4
<i>Corynebacteria infections</i>		
Diphtheria	2	0
<i>Coxiella infections</i>		
Q fever	13	0
<i>Cytomegaloviral infections</i>		
Cytomegalovirus colitis	1	0
Cytomegalovirus hepatitis	1	0
Cytomegalovirus infection	3	0
Cytomegalovirus syndrome	1	0
<i>Dental and oral soft tissue infections</i>		
Abscess oral	6	0
Gingival abscess	1	0
Gingivitis	15	0
Ludwig angina	1	0
Oral infection	1	0
Parotitis	15	0
Pericoronitis	3	0
Periodontitis	1	0
Pulpitis dental	2	0
Sialoadenitis	3	0
Tongue abscess	1	0
Tooth abscess	8	0
Tooth infection	10	0
<i>Ear infections</i>		
Ear infection	105	0
Labyrinthitis	120	0
Mastoiditis	3	0
Otitis externa	7	0
Otitis media	4	0
Otitis media acute	1	0
Otitis media chronic	5	0
<i>Ectoparasitic infestations</i>		
Acarodermatitis	6	0
Bed bug infestation	1	0
Demodicidosis	1	0
Lice infestation	1	0
<i>Enteroviral infections NEC</i>		
Enterovirus infection	1	0
<i>Epstein-Barr viral infections</i>		
Epstein-Barr virus infection	6	0
Epstein-Barr virus infection reactivation	2	0
Infectious mononucleosis	31	0
<i>Escherichia infections</i>		
Escherichia bacteraemia	1	0
Escherichia infection	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Infections Infections cont'd		
<i>Eye and eyelid infections</i>		
Conjunctivitis	89	0
Eye abscess	1	0
Eye infection	31	0
Eye infection intraocular	1	0
Eyelid boil	2	0
Eyelid infection	2	0
Hordeolum	30	0
Keratouveitis	1	0
Orbital infection	1	0
Periorbital infection	2	0
<i>Female reproductive tract infections</i>		
Bartholin's abscess	1	0
Bartholinitis	1	0
Endometritis	3	0
Fallopian tube abscess	1	0
Funisitis	1	0
Ovarian abscess	1	0
Pelvic inflammatory disease	2	0
Vaginal infection	3	0
Vulval abscess	1	0
Vulvitis	1	0
<i>Fungal infections NEC</i>		
Fungal infection	21	0
Fungal skin infection	7	0
Mycotoxicosis	1	0
Myocarditis mycotic	2	0
Onychomycosis	3	0
Oral fungal infection	2	0
Pneumonia fungal	4	0
Severe asthma with fungal sensitisation	2	0
Vulvovaginal mycotic infection	8	0
<i>Helminthic infections NEC</i>		
Helminthic infection	1	0
<i>Hepatitis virus infections</i>		
Hepatitis A	2	0
Hepatitis E	1	0
<i>Hepatobiliary and spleen infections</i>		
Biliary sepsis	3	0
Cholecystitis infective	2	0
Hepatic infection	1	0
Liver abscess	1	0
<i>Herpes viral infections</i>		
Eczema herpeticum	4	0
Genital herpes	97	0
Genital herpes simplex	6	0
Genital herpes zoster	1	0
Herpes ophthalmic	3	0
Herpes simplex	36	0
Herpes simplex encephalitis	1	1
Herpes simplex reactivation	3	0
Herpes virus infection	13	0
Herpes zoster	1671	0

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Herpes zoster disseminated	1	0
Herpes zoster meningoencephalitis	1	0
Herpes zoster oticus	18	0
Herpes zoster reactivation	5	0
Meningitis herpes	1	0
Nasal herpes	5	0
Ophthalmic herpes simplex	3	0
Ophthalmic herpes zoster	6	0
Oral herpes	351	0
Varicella	39	0
Varicella zoster virus infection	6	0
<i>Infections NEC</i>		
Abscess	40	0
Abscess limb	9	0
Abscess soft tissue	1	0
Catheter site infection	1	0
Device related infection	1	0
Genital abscess	2	0
Groin abscess	2	0
Groin infection	1	0
Infected bite	3	0
Infected cyst	2	0
Infection	296	0
Infection susceptibility increased	2	0
Injection site abscess	1	0
Injection site infection	5	0
Localised infection	41	0
Lymph gland infection	19	0
Lymph node abscess	7	0
Opportunistic infection	1	0
Pathogen resistance	1	0
Purulent discharge	1	0
Respiratory tract infection	15	0
Superinfection	1	0
Vaccination site abscess	12	0
Vaccination site infection	13	0
Vaccine breakthrough infection	23	0
Vestibulitis	2	0
Wound infection	2	0
<i>Infectious transmissions</i>		
Nosocomial infection	1	0
Secondary transmission	8	0
Vaccine virus shedding	1	0
<i>Influenza viral infections</i>		
H1N1 influenza	1	0
Influenza	1820	0
<i>Klebsiella infections</i>		
Klebsiella infection	1	0
<i>Lower respiratory tract and lung infections</i>		
Bronchitis	30	0
Infectious pleural effusion	1	0
Lower respiratory tract infection	317	10
Lung abscess	1	0

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Pneumonia	193	17
Pneumonia aspiration	11	7
Sputum purulent	1	0
Male reproductive tract infections		
Epididymitis	10	0
Orchitis	7	0
Prostate infection	2	0
Molluscum contagiosum viral infections		
Molluscum contagiosum	2	0
Mumps viral infections		
Mumps	9	0
Muscle and soft tissue infections		
Abscess neck	1	0
Infective tenosynovitis	1	0
Necrotising fasciitis	2	0
Psoas abscess	1	0
Soft tissue infection	2	0
Neisseria infections		
Gonorrhoea	1	0
Meningococcal bacteraemia	1	0
Meningococcal infection	1	0
Orthopox viral infections		
Smallpox	1	0
Vaccinia virus infection	2	0
Plasmodia infections		
Malaria	2	0
Pneumocystis infections		
Pneumocystis jirovecii pneumonia	2	0
Pseudomonal infections		
Pseudomonas infection	1	0
Retroviral infections		
Acquired immunodeficiency syndrome	1	0
HIV infection	2	0
Persistent generalised lymphadenopathy	1	0
Rhinoviral infections		
Rhinovirus infection	2	0
Rotaviral infections		
Gastroenteritis rotavirus	1	0
Rubeola viral infections		
Measles	5	0
Salmonella infections		
Typhoid fever	1	0
Sepsis, bacteraemia, viraemia and fungaemia NEC		
Neutropenic sepsis	4	1
Sepsis	76	11
Sepsis syndrome	2	0
Septic rash	3	0
Septic shock	9	3
Urosepsis	6	0
Skin structures and soft tissue infections		
Abscess sweat gland	1	0
Acne pustular	1	0
Blister infected	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Dermatitis infected	3	0
Eczema infected	1	0
Impetigo	11	0
Infected skin ulcer	4	0
Injection site pustule	3	0
Nail infection	2	0
Pustule	21	0
Pyoderma	1	0
Rash pustular	13	0
Skin infection	34	0
Subcutaneous abscess	12	0
Sweat gland infection	1	0
Vaccination site pustule	4	0
Staphylococcal infections		
Furuncle	47	1
Pneumonia staphylococcal	1	0
Septic arthritis staphylococcal	1	0
Staphylococcal abscess	1	0
Staphylococcal infection	6	0
Staphylococcal sepsis	1	0
Streptococcal infections		
Meningitis pneumococcal	1	0
Pharyngitis streptococcal	8	0
Pneumonia pneumococcal	1	0
Scarlet fever	1	0
Streptococcal abscess	1	0
Streptococcal endocarditis	1	0
Streptococcal infection	2	0
Streptococcal sepsis	1	0
Tinea infections		
Body tinea	6	0
Tinea capitis	1	0
Tinea infection	1	0
Tinea pedis	3	0
Tinea versicolour	5	0
Toxoplasma infections		
Toxoplasmosis	1	0
Treponema infections		
Syphilis	2	0
Trypanosomal infections		
African trypanosomiasis	5	0
Tuberculous infections		
Disseminated Bacillus Calmette-Guerin infection	1	0
Lymph node tuberculosis	1	0
Pulmonary tuberculosis	1	0
Tuberculosis	1	0
Tuberculosis of central nervous system	1	0
Upper respiratory tract infections		
Acute sinusitis	5	0
Chronic sinusitis	6	0
Croup infectious	1	0
Epiglottitis	3	0
Laryngitis	35	0

Case Series Drug Analysis Print

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

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Nasopharyngitis	1198	1
Peritonsillar abscess	6	0
Pharyngitis	40	0
Rhinitis	58	0
Sinusitis	211	0
Tonsillitis	147	0
Tracheitis	5	0
Tracheostomy infection	1	0
Upper respiratory tract infection	12	0
Urinary tract infections		
Cystitis	87	0
Kidney infection	56	0
Pyelonephritis	3	0
Urethritis	2	0
Urinary tract infection	226	0
Vascular infections		
Haematoma infection	1	0
Infected lymphocele	2	0
Infusion site infection	1	0
Lymphangitis	14	0
Viral infections NEC		
Arthritis viral	1	0
Conjunctivitis viral	2	0
Ear infection viral	1	0
Encephalitis viral	6	1
Eye infection viral	2	0
Gastroenteritis viral	35	0
Gianotti-Crosti syndrome	1	0
Hepatitis viral	4	0
Meningitis viral	9	0
Meningoencephalitis viral	1	0
Oral viral infection	1	0
Pleurisy viral	2	0
Pneumonia viral	5	2
Post viral fatigue syndrome	65	0
Sweating fever	128	0
Vestibular neuronitis	37	0
Viral diarrhoea	2	0
Viral infection	71	0
Viral labyrinthitis	4	0
Viral myocarditis	5	0
Viral pericarditis	4	0
Viral pharyngitis	24	0
Viral rash	69	0
Viral sinusitis	1	0
Viral tonsillitis	2	0
Infections SOC TOTAL	12924	121

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

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Chillblains	75	0
Cold shock response	1	0
Frostbite	1	0
Cranial nerve injuries		
IIIrd nerve injury	1	0
Vth nerve injury	1	0
Ear injuries NEC		
Deafness traumatic	1	0
Ear injury	2	0
Exposures associated with pregnancy, delivery and lactation		
Exposure during pregnancy	11	0
Exposure via breast milk	155	0
Foetal exposure during pregnancy	75	0
Foetal exposure timing unspecified	1	0
Maternal exposure before pregnancy	32	0
Maternal exposure during breast feeding	2027	0
Maternal exposure during pregnancy	1106	0
Maternal exposure timing unspecified	15	0
Paternal exposure before pregnancy	3	0
Exposures to agents or circumstances NEC		
Exposure to SARS-CoV-2	3	0
Exposure to vaccinated person	4	0
Eye and ear procedural complications		
Toxic anterior segment syndrome	1	0
Eye injuries NEC		
Corneal abrasion	1	0
Eye contusion	18	0
Eye injury	33	0
Foreign body in eye	4	0
Injury corneal	1	0
Periorbital haematoma	1	0
Retinal injury	2	0
Superficial injury of eye	1	0
Foetal and neonatal conditions associated with product exposure		
Intoxication by breast feeding	1	0
Fractures and dislocations NEC		
Fracture	3	0
Joint dislocation	4	0
Multiple fractures	1	0
Gastrointestinal and hepatobiliary procedural complications		
Diversion colitis	1	0
Post procedural constipation	1	0
Postoperative ileus	1	0
Procedural nausea	11	0
Procedural vomiting	2	0
Heat injuries (excl thermal burns)		
Heat cramps	2	0
Heat exhaustion	3	0
Heat illness	2	0
Heat oedema	14	0
Heat stroke	3	0
Intentional product use issues		
Intentional product use issue	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
<i>Limb fractures and dislocations</i>		
Ankle fracture	1	0
Atypical femur fracture	1	0
Clavicle fracture	27	0
Femoral neck fracture	1	0
Femur fracture	1	0
Fibula fracture	1	0
Hip fracture	2	0
Lower limb fracture	1	0
Tibia fracture	1	0
Upper limb fracture	1	0
Wrist fracture	1	0
<i>Medication errors, product use errors and issues NEC</i>		
Circumstance or information capable of leading to medication error	2	0
Dose calculation error	1	0
Inadequate aseptic technique in use of product	1	0
Medication error	119	0
Prescription drug used without a prescription	3	0
Product use complaint	2	0
Product use issue	39	0
Vaccination error	6	0
Wrong dose	4	0
Wrong drug	11	0
Wrong schedule	1	0
Wrong technique in product usage process	11	0
<i>Muscle, tendon and ligament injuries</i>		
Epicondylitis	25	0
Ligament injury	2	0
Ligament sprain	11	0
Mallet finger	1	0
Muscle hernia	1	0
Muscle injury	45	0
Muscle rupture	11	0
Muscle strain	38	0
Post-traumatic neck syndrome	3	0
Tendon injury	7	0
Tendon rupture	26	0
<i>Musculoskeletal procedural complications</i>		
Periprosthetic osteolysis	1	0
Post laminectomy syndrome	1	0
<i>Nerve injuries NEC</i>		
Nerve injury	127	0
<i>Neurological and psychiatric procedural complications</i>		
Post lumbar puncture syndrome	1	0
Post procedural stroke	1	0
Procedural dizziness	14	0
<i>Non-occupational environmental exposures</i>		
Exposure to extreme temperature	2	0
<i>Non-site specific injuries NEC</i>		
Accident	2	0
Animal scratch	1	0
Arthropod bite	11	0
Arthropod sting	6	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Bite	1	0
Bone contusion	2	0
Crush injury	1	0
Electric shock	20	0
Fall	230	0
Foreign body	6	0
Injury	15	0
Multiple injuries	2	0
Musculoskeletal injury	1	0
Nervous system injury	3	0
Post concussion syndrome	2	0
Traumatic haematoma	1	0
Wound	7	0
Wound complication	12	0
Wound haematoma	1	0
Wound haemorrhage	4	0
Wound necrosis	1	1
Wound secretion	7	0
<i>Non-site specific procedural complications</i>		
Administration related reaction	1	0
Anastomotic leak	1	0
Incision site pain	3	0
Infusion related reaction	8	0
Injection related reaction	68	0
Post procedural complication	5	0
Post procedural erythema	1	0
Post procedural inflammation	1	0
Post procedural pruritus	1	0
Procedural pain	4	0
Seroma	1	0
<i>Occupational exposures</i>		
Occupational exposure to SARS-CoV-2	1	0
Occupational exposure to product	1	0
<i>Off label uses</i>		
Off label use	529	0
<i>Overdoses NEC</i>		
Intentional overdose	1	0
Overdose	57	0
<i>Pathways and sources of exposure</i>		
Exposure via contaminated device	1	0
Exposure via unknown route	1	0
<i>Pelvic fractures and dislocations</i>		
Pelvic fracture	1	0
<i>Peripheral nerve injuries</i>		
Axillary nerve injury	1	0
Brachial plexus injury	1	0
Radial nerve injury	2	0
Sciatic nerve injury	2	0
Ulnar nerve injury	6	0
<i>Poisoning and toxicity</i>		
Alcohol poisoning	1	0
Poisoning	14	0
Toxicity to various agents	6	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
<i>Product administration errors and issues</i>		
Accidental overdose	8	0
Contraindicated product administered	3	0
Duplicate therapy error	1	0
Expired product administered	14	0
Inappropriate schedule of product administration	750	0
Incomplete course of vaccination	2	0
Incorrect dose administered	72	0
Incorrect drug administration rate	1	0
Incorrect product formulation administered	2	0
Incorrect route of product administration	14	0
Lack of vaccination site rotation	1	0
Poor quality product administered	5	0
Product administered at inappropriate site	26	0
Product administered to patient of inappropriate age	4	0
Product administration error	22	0
Product dose omission issue	6	0
Wrong product administered	20	0
<i>Product confusion errors and issues</i>		
Product dosage form confusion	1	0
Product label confusion	6	0
Product packaging confusion	2	0
<i>Product dispensing errors and issues</i>		
Product dispensing error	4	0
<i>Product monitoring errors and issues</i>		
Drug monitoring procedure incorrectly performed	1	0
<i>Product preparation errors and issues</i>		
Product preparation error	5	0
Product preparation issue	6	0
<i>Product prescribing errors and issues</i>		
Contraindicated product prescribed	2	0
Product prescribing error	2	0
<i>Product selection errors and issues</i>		
Product selection error	2	0
<i>Product storage errors and issues in the product use system</i>		
Product storage error	1	0
<i>Radiation injuries</i>		
Sunburn	24	0
<i>Renal and urinary tract injuries NEC</i>		
Bladder injury	1	0
Foreign body in urogenital tract	1	0
<i>Reproductive system and breast injuries</i>		
Breast injury	1	0
Cervix injury	1	0
Penile contusion	1	0
Penis injury	2	0
Uterine rupture	1	0
<i>Reproductive tract and breast procedural complications</i>		
Failed in vitro fertilisation	1	0
<i>Site specific injuries NEC</i>		
Back injury	4	0
Face crushing	3	0
Face injury	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Head injury	36	0
Limb crushing injury	4	0
Limb injury	214	0
Nasal injury	2	0
Neck crushing	1	0
Neck injury	1	0
Pharyngeal contusion	1	0
Site specific procedural complications NEC		
Axillary web syndrome	3	0
Skin injuries NEC		
Contusion	1412	0
Hair injury	2	0
Nail avulsion	1	0
Scar	38	0
Scratch	9	0
Skin abrasion	7	0
Skin injury	6	0
Skin laceration	4	0
Skin pressure mark	1	0
Skin wound	3	0
Splinter	1	0
Subcutaneous haematoma	2	0
Skin procedural complications		
Dermal filler overcorrection	1	0
Recall phenomenon	1	0
Skin procedural complication	1	0
Skull fractures, facial bone fractures and dislocations		
Facial bones fracture	1	0
Fractured skull depressed	1	0
Spinal cord injuries NEC		
Spinal cord injury cervical	1	0
Spinal fractures and dislocations		
Spinal compression fracture	1	0
Spinal fracture	4	0
Stoma complications		
Gastrointestinal stoma complication	2	0
Stoma site discharge	1	0
Stoma site extravasation	1	0
Stoma site haemorrhage	1	0
Thermal burns		
Airway burns	1	0
Burn oesophageal	4	0
Burn of internal organs	4	0
Burn oral cavity	6	0
Burns second degree	3	0
Burns third degree	1	0
Cold burn	1	0
Thermal burn	29	0
Thermal burns of eye	17	0
Underdoses NEC		
Underdose	6	0
Vaccination related complications		
Adverse event following immunisation	1	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Post vaccination syndrome	1	0
Injuries SOC TOTAL	8246	2

Case Series Drug Analysis Print

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

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Blood glucose fluctuation	17	0
Blood glucose increased	115	0
Blood glucose normal	1	0
Glycosylated haemoglobin increased	1	0
Cardiac auscultatory investigations		
Cardiac murmur	52	0
Heart sounds	10	0
Heart sounds abnormal	6	0
Cardiac function diagnostic procedures		
Cardiac monitoring	1	0
Cardiac output	2	0
Central venous pressure	1	0
Echocardiogram	1	0
Ejection fraction decreased	4	0
Myocardial strain imaging	2	0
Right atrial volume abnormal	1	0
Stroke volume decreased	1	0
Cardiac imaging procedures		
Catheterisation cardiac	1	0
Magnetic resonance imaging heart	1	0
Scan myocardial perfusion abnormal	1	0
Cell marker analyses		
Carbohydrate antigen 15-3 increased	1	0
Carcinoembryonic antigen increased	1	0
HLA-B*27 positive	1	0
Prostatic specific antigen increased	4	0
Central nervous system imaging procedures		
Computerised tomogram head	11	0
Magnetic resonance imaging head	12	0
Magnetic resonance imaging head abnormal	2	0
Cerebrospinal fluid tests (excl microbiology)		
CSF pressure	1	0
CSF protein increased	1	0
Chemistry analyses NEC		
Histamine abnormal	1	0
Histamine level	1	0
Histamine level increased	2	0
Inflammatory marker decreased	1	0
Inflammatory marker increased	5	0
Inflammatory marker test	1	0
Renin	1	0
Cholesterol analyses		
Blood cholesterol abnormal	1	0
Blood cholesterol increased	15	0
Remnant-like lipoprotein particles	4	0
Coagulation and bleeding analyses		
ADAMTS13 activity decreased	1	0
Activated partial thromboplastin time prolonged	15	0
Activated partial thromboplastin time shortened	1	0
Bleeding time	1	0
Bleeding time abnormal	2	0
Bleeding time prolonged	12	0
Blood thromboplastin	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Clot retraction	1	1
Coagulation factor VIII level decreased	1	0
Coagulation time prolonged	9	0
Coagulation time shortened	4	0
Fibrin D dimer increased	26	0
International normalised ratio abnormal	9	0
International normalised ratio decreased	22	0
International normalised ratio fluctuation	3	0
International normalised ratio increased	54	0
Platelet factor 4	1	0
Prothrombin time prolonged	1	0
Prothrombin time shortened	1	0
Digestive enzymes		
Amylase increased	1	0
ECG investigations		
Electrocardiogram	5	0
Electrocardiogram QRS complex prolonged	1	0
Electrocardiogram QT prolonged	11	0
Electrocardiogram ST segment depression	2	0
Electrocardiogram ST segment elevation	12	0
Electrocardiogram ST-T segment abnormal	2	0
Electrocardiogram T wave inversion	6	0
Electrocardiogram abnormal	25	0
Electrocardiogram change	1	0
Electrocardiogram normal	3	0
Electrocardiogram repolarisation abnormality	1	0
QRS axis abnormal	1	0
Endocrine analyses and imaging NEC		
Hormone level abnormal	87	0
Faecal analyses NEC		
Faecal calprotectin	2	0
Faecal calprotectin increased	4	0
Fertility analyses		
Infertility tests	1	0
Semen analysis abnormal	1	0
Semen volume increased	1	0
Sperm concentration	2	0
Sperm concentration decreased	2	0
Spermatozoa abnormal	1	0
Foetal and neonatal diagnostic procedures		
Amniocentesis abnormal	1	0
Foetal heart rate abnormal	5	2
Foetal heart rate increased	1	0
Foetal monitoring	1	0
Foetal non-stress test	1	0
Gastrointestinal and abdominal imaging procedures		
Computerised tomogram abdomen	1	0
Sigmoidoscopy abnormal	1	0
X-ray with contrast upper gastrointestinal tract	1	0
Gastrointestinal function diagnostic procedures		
Gastric pH decreased	4	0
Gastrointestinal, pancreatic and APUD hormone analyses		
Blood insulin	2	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Blood insulin decreased	1	0
Gene analyses		
EGFR status assay	1	0
Haematological analyses NEC		
Blood viscosity abnormal	1	0
Blood viscosity decreased	1	0
Blood viscosity increased	2	0
Plasma viscosity	1	0
Plasma viscosity abnormal	1	0
Red blood cell sedimentation rate increased	8	0
Heart rate and pulse investigations		
Carotid pulse	2	0
Carotid pulse abnormal	1	0
Heart rate	607	0
Heart rate abnormal	82	0
Heart rate decreased	109	0
Heart rate increased	1228	0
Heart rate irregular	307	0
Heart rate normal	1	0
Heart rate variability decreased	1	0
Heart rate variability increased	1	0
Maximum heart rate	5	0
Maximum heart rate increased	2	0
Pulse abnormal	24	0
Pulse absent	1	0
Pulse pressure increased	3	0
Radial pulse abnormal	1	0
Sinus rhythm	8	0
Hepatobiliary function diagnostic procedures		
Alanine aminotransferase increased	29	0
Aspartate aminotransferase	1	0
Aspartate aminotransferase abnormal	1	0
Aspartate aminotransferase increased	2	0
Blood bilirubin decreased	1	0
Blood bilirubin increased	7	0
Gamma-glutamyltransferase	2	0
Gamma-glutamyltransferase increased	5	0
Hepatic enzyme	1	0
Hepatic enzyme increased	10	0
Liver function test	1	0
Liver function test abnormal	37	0
Liver function test increased	30	0
Hepatobiliary imaging procedures		
Computerised tomogram liver	1	0
Liver scan	1	0
Imaging procedures NEC		
Computerised tomogram	4	0
Magnetic resonance imaging	6	0
Magnetic resonance imaging abnormal	1	0
Positron emission tomogram abnormal	1	0
Scan	2	0
X-ray	2	0
Immune response protein analyses NEC		

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Cytokine test	1	0
<i>Immunoglobulin analyses</i>		
Blood immunoglobulin E increased	2	0
Blood immunoglobulin G increased	1	0
Blood immunoglobulin M	1	0
Blood immunoglobulin M increased	2	0
<i>Immunology analyses NEC</i>		
Antibody test	4	0
Antibody test positive	1	0
Immunology test	14	0
<i>Immunology skin tests NEC</i>		
Allergy alert test	2	0
Allergy alert test positive	1	0
Skin test positive	2	0
<i>Investigations NEC</i>		
Blood test	27	0
Blood test abnormal	49	0
Blood test normal	1	0
False positive investigation result	1	0
Laboratory test	1	0
Polymerase chain reaction	1	0
Polymerase chain reaction positive	33	0
Quality of life decreased	1	0
Systemic lupus erythematosus disease activity index increased	1	0
<i>Metabolism tests NEC</i>		
Blood ketone body	3	0
Blood ketone body increased	1	0
Blood ketone body present	1	0
Blood uric acid increased	3	0
Brain natriuretic peptide increased	1	0
N-terminal prohormone brain natriuretic peptide increased	1	0
Ubiquinone	1	0
Urine ketone body	1	0
Urine ketone body present	1	0
<i>Microbiology and serology tests NEC</i>		
Culture negative	1	0
Culture urine	1	0
Nasopharyngeal swab	1	0
Vaccine induced antibody absent	1	0
<i>Mineral and electrolyte analyses</i>		
Blood calcium increased	1	0
Blood copper increased	1	0
Blood iron	4	0
Blood iron decreased	15	0
Blood iron increased	1	0
Blood magnesium decreased	1	0
Blood phosphorus decreased	1	0
Blood phosphorus increased	1	0
Blood potassium abnormal	1	0
Blood potassium decreased	5	0
Blood potassium increased	3	0
Blood sodium decreased	11	0
Serum ferritin	2	0

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Serum ferritin abnormal	1	0
Serum ferritin decreased	5	0
Serum ferritin increased	3	0
Sweat test	2	0
Urine copper	2	0
<i>Musculoskeletal and soft tissue histopathology procedures</i>		
Biopsy bone	1	0
<i>Musculoskeletal and soft tissue imaging procedures</i>		
Skull X-ray	6	0
<i>Musculoskeletal and soft tissue tests NEC</i>		
Swollen joint count	1	0
Swollen joint count increased	1	0
<i>Mycobacteria identification and serology</i>		
Tuberculin test positive	1	0
<i>Neurologic diagnostic procedures</i>		
Balance test	1	0
Coma scale abnormal	5	0
Hoover's sign of leg paresis	1	0
Joint position sense decreased	1	0
Lumbar puncture	6	0
Magnetic resonance neurography	1	0
Nerve conduction studies	1	0
Pain threshold decreased	1	0
Sensory level	2	0
Temperature perception test abnormal	1	0
Temperature perception test increased	1	0
<i>Ophthalmic function diagnostic procedures</i>		
Corneal reflex decreased	1	0
Intraocular pressure increased	9	0
Intraocular pressure test	3	0
Pupil dilation procedure	1	0
Visual acuity tests	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature	302	0
Body temperature abnormal	55	0
Body temperature decreased	49	0
Body temperature fluctuation	70	0
Body temperature increased	546	0
Body temperature normal	1	0
Breath sounds abnormal	2	0
General physical condition abnormal	1	0
Grip strength	3	0
Grip strength decreased	28	0
Gynaecological examination	1	0
Head lag	9	0
Intelligence test	1	0
Lymph node palpable	46	0
Male genital examination abnormal	1	0
Menstruation normal	4	0
Muscle strength abnormal	5	0
Ophthalmological examination	3	0
Orthopaedic examination	1	0
Palpatory finding abnormal	2	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Product residue present	2	0
Psoriasis area severity index decreased	2	0
Psoriasis area severity index increased	1	0
Respiratory rate	9	0
Respiratory rate decreased	28	0
Respiratory rate increased	49	0
Skin temperature	49	0
Temperature difference of extremities	13	0
Weight	1	0
Weight abnormal	1	0
Weight decreased	150	0
Weight increased	57	0
<i>Pituitary analyses anterior</i>		
Blood corticotrophin	1	0
Blood follicle stimulating hormone increased	3	0
Blood growth hormone	3	0
Blood prolactin	3	0
Blood prolactin increased	4	0
Blood thyroid stimulating hormone decreased	1	0
Blood thyroid stimulating hormone increased	11	0
<i>Platelet analyses</i>		
Mean platelet volume decreased	1	0
Mean platelet volume increased	1	0
Platelet count	3	0
Platelet count abnormal	1	0
Platelet count decreased	90	0
Platelet count increased	6	0
<i>Protein analyses NEC</i>		
Alpha 1 globulin decreased	1	0
Alpha 2 globulin decreased	1	0
C-reactive protein increased	32	0
Protein total abnormal	1	0
<i>Red blood cell analyses</i>		
Haematocrit	1	0
Haematocrit decreased	1	0
Haematocrit increased	1	0
Haemoglobin decreased	16	0
Haemoglobin increased	2	0
Red blood cell count decreased	1	0
Red blood cell count increased	1	0
Red blood cell rouleaux formation present	1	0
<i>Renal function analyses</i>		
Blood creatine decreased	1	0
Blood creatinine	2	0
Blood creatinine decreased	1	0
Blood creatinine increased	5	0
Glomerular filtration rate decreased	4	0
Glomerular filtration rate increased	1	0
<i>Reproductive hormone analyses</i>		
Blood oestrogen	2	0
Blood oestrogen decreased	2	0
Blood testosterone decreased	3	0
Blood testosterone increased	2	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
False negative pregnancy test	9	0
Female sex hormone level	3	0
Human chorionic gonadotropin increased	1	0
Pregnancy test	18	0
Pregnancy test false positive	1	0
Pregnancy test positive	1	0
Progesterone decreased	2	0
<i>Reproductive organ and breast histopathology procedures</i>		
Biopsy breast	2	0
Biopsy endometrium	1	0
Smear cervix	3	0
<i>Reproductive organ and breast imaging procedures</i>		
Breast scan	1	0
Hysteroscopy	2	0
<i>Respiratory and pulmonary function diagnostic procedures</i>		
Airway peak pressure increased	1	0
Forced expiratory volume	1	0
Forced expiratory volume increased	3	0
Fractional exhaled nitric oxide normal	1	0
Maximal voluntary ventilation	2	0
Peak expiratory flow rate	2	0
Peak expiratory flow rate decreased	7	0
Pulmonary function test	3	0
Spirometry abnormal	1	0
Total lung capacity decreased	4	0
Vital capacity	1	0
<i>Respiratory tract and thoracic histopathology procedures</i>		
Sputum abnormal	3	0
<i>Respiratory tract and thoracic imaging procedures</i>		
Chest X-ray	19	0
Chest X-ray abnormal	1	0
Chest X-ray normal	2	0
Chest scan	2	0
Computerised tomogram thorax	2	0
Ventilation/perfusion scan	2	0
<i>Skeletal and cardiac muscle analyses</i>		
Blood creatine phosphokinase increased	12	0
Muscle enzyme	1	0
Myocardial necrosis marker	1	0
Myocardial necrosis marker increased	3	0
Troponin I increased	2	0
Troponin T increased	2	0
Troponin abnormal	1	0
Troponin increased	32	0
<i>Therapeutic drug monitoring analyses</i>		
Analgesic drug level	9	0
Anticoagulation drug level above therapeutic	1	0
Anticoagulation drug level below therapeutic	5	0
Anticoagulation drug level increased	1	0
Drug level decreased	1	0
<i>Thyroid analyses</i>		
Anti-thyroid antibody	1	0
Thyroid function test abnormal	1	0

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Reaction Name	Total	Fatal
Investigations		
Thyroxine	1	0
Thyroxine decreased	1	0
Thyroxine free increased	2	0
Tri-iodothyronine	1	0
Tri-iodothyronine decreased	5	0
Tissue enzyme analyses NEC		
Blood alkaline phosphatase abnormal	1	0
Blood alkaline phosphatase increased	6	0
Blood lactate dehydrogenase	1	0
Blood lactate dehydrogenase increased	1	0
Enzyme level increased	1	0
Toxicology laboratory analyses		
Blood caffeine decreased	1	0
Blood lead	1	0
Drug screen positive	2	0
Opiates	1	0
Toxicologic test abnormal	1	0
Urinalysis NEC		
Blood urine	19	0
Blood urine present	81	0
Cells in urine	1	0
Glucose urine present	1	0
Protein urine	1	0
Protein urine absent	1	0
Protein urine present	1	0
Red blood cells urine	1	0
Urine analysis abnormal	6	0
Urine leukocyte esterase positive	1	0
Urine uric acid increased	1	0
White blood cells urine	1	0
pH urine	6	0
pH urine increased	2	0
Urinary tract function analyses NEC		
Urine output	14	0
Urine output decreased	15	0
Urine output increased	7	0
Urinary tract histopathology procedures		
Biopsy kidney	1	0
Urine cytology	1	0
Urinary tract imaging procedures		
Bladder scan	1	0
Cystoscopy	2	0
Ultrasound kidney normal	1	0
Vascular imaging procedures NEC		
Venogram	2	0
Vascular tests NEC (incl blood pressure)		
Blood pressure abnormal	14	0
Blood pressure ambulatory increased	1	0
Blood pressure decreased	92	0
Blood pressure diastolic	2	0
Blood pressure diastolic decreased	1	0
Blood pressure diastolic increased	4	0
Blood pressure difference of extremities	1	0

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Blood pressure increased	308	0
Blood pressure measurement	49	0
Blood pressure normal	2	0
Blood pressure orthostatic	1	0
Blood pressure systolic	1	0
Blood pressure systolic decreased	4	0
Blood pressure systolic increased	1	0
<i>Virus identification and serology</i>		
Coronavirus test	11	0
Coronavirus test positive	4	0
Cytomegalovirus test positive	1	0
HIV antibody positive	1	0
HIV test	1	0
Respiratory syncytial virus test positive	1	0
SARS-CoV-1 test	1	0
SARS-CoV-1 test positive	1	0
SARS-CoV-2 antibody test	10	0
SARS-CoV-2 antibody test negative	15	0
SARS-CoV-2 antibody test positive	6	0
SARS-CoV-2 test	36	0
SARS-CoV-2 test false negative	2	0
SARS-CoV-2 test false positive	4	0
SARS-CoV-2 test negative	10	0
SARS-CoV-2 test positive	112	0
Viral load	2	0
Viral test	4	0
Viral test positive	1	0
<i>Vitamin analyses</i>		
Blood folate decreased	8	0
Vitamin B12	1	0
Vitamin B12 abnormal	2	0
Vitamin B12 decreased	3	0
Vitamin D	4	0
Vitamin D decreased	6	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	1	0
Lymphocyte count decreased	3	0
Lymphocyte count increased	1	0
Monocyte count increased	2	0
Neutrophil count	4	0
Neutrophil count decreased	14	0
Neutrophil count increased	4	0
White blood cell count	5	0
White blood cell count decreased	17	0
White blood cell count increased	13	0
Investigations SOC TOTAL	6590	3

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	24	0
Decreased appetite	1568	0
Diet refusal	1	0
Eating disorder symptom	4	0
Food craving	14	0
Food refusal	16	0
Hyperphagia	15	0
Hypophagia	21	0
Increased appetite	38	0
Salt craving	2	0
<i>Calcium metabolism disorders</i>		
Hypercalcaemia	1	0
Hypocalcaemia	3	0
Tetany	5	0
<i>Copper metabolism disorders</i>		
Copper deficiency	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	67	0
Diabetes mellitus inadequate control	18	1
Fulminant type 1 diabetes mellitus	1	0
Increased insulin requirement	2	0
Insulin resistant diabetes	1	0
Latent autoimmune diabetes in adults	2	0
Type 1 diabetes mellitus	18	0
Type 2 diabetes mellitus	7	0
<i>Diabetic complications NEC</i>		
Diabetic complication	2	0
Diabetic ketoacidosis	12	0
Diabetic ketosis	1	0
<i>Disorders of purine metabolism</i>		
Gout	112	0
<i>Electrolyte imbalance NEC</i>		
Electrolyte imbalance	1	0
Fluid imbalance	2	0
Tumour lysis syndrome	1	0
<i>Elevated cholesterol</i>		
Hypercholesterolaemia	1	0
<i>Fat soluble vitamin deficiencies and disorders</i>		
Vitamin D deficiency	11	0
<i>Fluid intake decreased</i>		
Fluid intake reduced	2	0
<i>Fluid intake increased</i>		
Polydipsia	7	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Alcohol intolerance	9	0
Breast milk substitute intolerance	1	0
Dairy intolerance	4	0
Food intolerance	26	0
Gluten sensitivity	7	0
Histamine intolerance	7	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	46	0

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Reaction Name	Total	Fatal
Metabolic disorders <small>Metabolic disorders cont'd</small>		
Abnormal weight gain	22	0
Cachexia	1	0
Feeding disorder	115	0
Food aversion	14	0
Malnutrition	3	0
Neonatal insufficient breast milk syndrome	7	0
Obesity	1	0
Overweight	1	0
Poor feeding infant	17	0
Weight loss poor	3	0
Hyperglycaemic conditions NEC		
Glucose tolerance impaired	2	0
Hyperglycaemia	69	0
Insulin resistance	5	0
Hyperlipidaemias NEC		
Hyperlipidaemia	1	0
Hypoglycaemic conditions NEC		
Glycopenia	1	0
Hypoglycaemia	85	0
Hypoglycaemia unawareness	1	0
Postprandial hypoglycaemia	3	0
Iron deficiencies		
Iron deficiency	13	0
Iron excess		
Haemochromatosis	2	0
Iron overload	1	0
Lipid metabolism and deposit disorders NEC		
Body fat disorder	1	0
Magnesium metabolism disorders		
Hypomagnesaemia	2	0
Magnesium deficiency	1	0
Metabolic acidoses (excl diabetic acidoses)		
Ketoacidosis	7	1
Lactic acidosis	3	0
Metabolic acidosis	4	0
Metabolic disorders NEC		
Hypercarotinaemia	1	0
Hypercatabolism	1	0
Hypometabolism	1	0
Metabolic disorder	1	0
Mixed acid-base disorders		
Acidosis	4	0
Phosphorus metabolism disorders		
Hypophosphataemia	1	0
Potassium imbalance		
Hyperkalaemia	6	0
Hypokalaemia	5	0
Hypokalaemic syndrome	1	0
Sodium imbalance		
Hypernatraemia	1	0
Hyponatraemia	13	0
Hyponatraemic syndrome	3	0
Salt intoxication	1	0

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Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
<i>Sugar intolerance (excl glucose intolerance)</i>		
Lactose intolerance	5	0
<i>Total fluid volume decreased</i>		
Dehydration	246	0
<i>Total fluid volume increased</i>		
Fluid retention	70	0
Hypervolaemia	6	0
<i>Vitamin deficiencies NEC</i>		
Hypovitaminosis	6	0
<i>Water soluble vitamin deficiencies</i>		
Folate deficiency	11	0
Vitamin B complex deficiency	1	0
Vitamin B12 deficiency	8	0
Metabolic disorders SOC TOTAL	2858	2

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	426	0
Arthropathy	36	0
Autoimmune arthritis	11	0
Haemarthrosis	5	0
Joint microhaemorrhage	1	0
Palindromic rheumatism	3	0
Polyarthritis	17	0
Rheumatic fever	2	0
Sacroiliitis	6	0
Seronegative arthritis	5	0
<i>Bone disorders NEC</i>		
Bone cyst	2	0
Bone disorder	1	0
Exostosis	1	0
Jaw disorder	4	0
Medial tibial stress syndrome	7	0
Osteitis	9	0
Osteonecrosis	1	0
Osteonecrosis of jaw	3	0
Spinal disorder	4	0
<i>Bone related signs and symptoms</i>		
Bone pain	462	0
Bone swelling	10	0
Coccydynia	5	0
Metatarsalgia	1	0
Pain in jaw	439	0
Pubic pain	2	0
Spinal pain	105	0
<i>Bursal disorders</i>		
Bursitis	110	0
<i>Cartilage disorders</i>		
Chondritis	1	0
Chondropathy	1	0
Costochondritis	147	0
Osteochondritis	1	0
Polychondritis	3	0
<i>Connective tissue disorders NEC</i>		
Connective tissue disorder	3	0
Polymyalgia rheumatica	98	0
Reynold's syndrome	3	0
Scleroderma	2	0
Sjogren's syndrome	10	0
Systemic scleroderma	1	0
<i>Crystal arthropathic disorders</i>		
Chondrocalcinosis pyrophosphate	3	0
Crystal arthropathy	2	0
Gouty arthritis	2	0
<i>Epiphyseal disorders</i>		
Epiphyses premature fusion	1	0
<i>Extremity deformities</i>		
Bone deformity	1	0
Finger deformity	3	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Foot deformity	4	0
Hand deformity	5	0
Knee deformity	1	0
Limb deformity	6	0
Musculoskeletal deformity	1	0
Fractures NEC		
Osteoporotic fracture	2	0
Intervertebral disc disorders NEC		
Intervertebral disc protrusion	3	0
Joint related disorders NEC		
Carpal collapse	1	0
Chondromalacia	1	0
Greater trochanteric pain syndrome	2	0
Hypermobility syndrome	1	0
Joint ankylosis	1	0
Joint deposit	1	0
Joint destruction	1	0
Joint instability	2	0
Joint laxity	3	0
Joint lock	36	0
Ligament laxity	1	0
Patellofemoral pain syndrome	2	0
Periarthritis	292	0
Rotator cuff syndrome	46	0
Temporomandibular joint syndrome	17	0
Joint related signs and symptoms		
Arthralgia	10718	0
Jaw clicking	7	0
Joint effusion	17	0
Joint noise	46	0
Joint range of motion decreased	40	0
Joint stiffness	317	0
Joint swelling	700	0
Joint vibration	4	0
Joint warmth	17	0
Loose body in joint	1	0
Ligament disorders		
Ligament pain	4	0
Ligamentitis	3	0
Symphysiolysis	1	0
Lupus erythematosus (incl subtypes)		
Lupus-like syndrome	1	0
Systemic lupus erythematosus	32	0
Metabolic bone disorders		
Osteopenia	4	0
Osteoporosis	8	0
Muscle infections and inflammations		
Antisynthetase syndrome	3	0
Autoimmune myositis	1	0
Immune-mediated myositis	2	0
Myositis	54	0
Polymyositis	9	0
Muscle pains		

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Fibromyalgia	149	0
Myalgia	11981	0
Myalgia intercostal	2	0
Myofascial pain syndrome	13	0
<i>Muscle related signs and symptoms NEC</i>		
Haematoma muscle	1	0
Muscle atrophy	37	0
Muscle discomfort	9	0
Muscle disorder	13	0
Muscle fatigue	409	0
Muscle haemorrhage	1	0
Muscle mass	5	0
Muscle oedema	5	0
Muscle spasms	2391	0
Muscle swelling	45	0
Muscle tightness	117	0
Muscle twitching	574	0
Myofascial spasm	1	0
<i>Muscle tone abnormalities</i>		
Muscle rigidity	26	0
Nuchal rigidity	13	0
Torticollis	7	0
Trismus	42	0
<i>Muscle weakness conditions</i>		
Muscular weakness	1220	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Back disorder	5	0
Chest wall mass	1	0
Growth disorder	2	0
Limb mass	24	0
Mandibular mass	3	0
Mastication disorder	8	0
Mobility decreased	169	0
Muscle contracture	1	0
Musculoskeletal disorder	13	0
Musculoskeletal stiffness	1542	0
Pelvic misalignment	1	0
Posture abnormal	2	0
Sacroiliac joint dysfunction	1	0
Weight bearing difficulty	6	0
<i>Musculoskeletal and connective tissue deformities of skull, face and buccal cavity</i>		
Facial asymmetry	1	0
Head deformity	2	0
Nose deformity	1	0
<i>Musculoskeletal and connective tissue infections and inflammations NEC</i>		
Connective tissue inflammation	1	0
Dactylitis	3	0
Dupuytren's contracture	1	0
Fasciitis	1	0
Plantar fasciitis	18	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	2932	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Muscle & tissue disorders cont'd		
Flank pain	87	0
Growing pains	1	0
Limb discomfort	1698	0
Musculoskeletal chest pain	317	0
Musculoskeletal discomfort	131	0
Musculoskeletal pain	146	0
Neck pain	2281	0
Pain in extremity	14861	1
Rheumatic disorder	17	0
Sacral pain	4	0
Myopathies		
Compartment syndrome	1	0
Mitochondrial myopathy acquired	1	0
Myopathy	9	0
Rhabdomyolysis	14	0
Osteoarthropathies		
Nodal osteoarthritis	1	0
Osteoarthritis	70	0
Spinal osteoarthritis	2	0
Psoriatic arthropathies		
Psoriatic arthropathy	31	0
Rheumatoid arthropathies		
Juvenile idiopathic arthritis	1	0
Rheumatoid arthritis	156	0
Rheumatoid nodule	1	0
Still's disease	2	0
Soft tissue disorders NEC		
Axillary mass	326	0
Fistula	1	0
Fistula discharge	1	0
Fluctuance	1	0
Groin pain	129	0
Neck mass	47	0
Purple glove syndrome	1	0
Soft tissue disorder	3	0
Soft tissue necrosis	1	0
Soft tissue swelling	7	0
Spine and neck deformities		
Kyphosis	2	0
Lordosis	1	0
Neck deformity	1	0
Scoliosis	1	0
Spinal stenosis	3	0
Spondyloarthropathies		
Ankylosing spondylitis	11	0
Arthritis reactive	80	0
Axial spondyloarthritis	1	0
Spondylitis	4	0
Spondyloarthropathy	2	0
Synovial disorders		
Synovial cyst	23	0
Synovitis	15	0
Tendon disorders		

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Enthesopathy	3	0
Posterior tibial tendon dysfunction	1	0
Tendon disorder	7	0
Tendon pain	28	0
Tendonitis	66	0
Tenosynovitis	4	0
Tenosynovitis stenosaurs	2	0
Trigger finger	35	0
Trunk deformities		
Deformity thorax	1	0
Drooping shoulder syndrome	3	0
Shoulder deformity	4	0
Muscle & tissue disorders SOC TOTAL	56824	1

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Reaction Name	Total	Fatal
Neoplasms		
<i>Adrenal neoplasms malignant</i>		
Adrenal gland cancer	1	0
<i>Angioimmunoblastic T-cell lymphomas</i>		
Angioimmunoblastic T-cell lymphoma	1	0
<i>B-cell lymphomas NEC</i>		
B-cell lymphoma	2	1
Follicular lymphoma	4	0
<i>Bile duct neoplasms malignant</i>		
Bile duct cancer	1	0
<i>Bladder neoplasms malignant</i>		
Bladder cancer	2	0
<i>Bone neoplasms malignant (excl sarcomas)</i>		
Bone cancer	1	1
<i>Bone neoplasms unspecified malignancy</i>		
Bone neoplasm	1	0
<i>Breast and nipple neoplasms benign</i>		
Benign breast neoplasm	3	0
Fibroadenoma of breast	2	0
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	46	0
Breast cancer female	1	0
Breast cancer male	2	0
Breast cancer stage I	1	0
Breast cancer stage III	3	0
HER2 positive breast cancer	1	0
Inflammatory carcinoma of the breast	1	0
Invasive ductal breast carcinoma	1	0
Triple negative breast cancer	4	0
<i>Cardiovascular neoplasms benign</i>		
Haemangioma	2	0
Pericardial lipoma	1	0
<i>Cardiovascular neoplasms malignant and unspecified</i>		
Cardiac neoplasm unspecified	1	0
<i>Cartilage sarcomas</i>		
Chondrosarcoma	1	0
<i>Central nervous system neoplasms malignant NEC</i>		
Brain cancer metastatic	1	0
<i>Cervix neoplasms malignant</i>		
Cervix carcinoma	3	0
<i>Colorectal neoplasms malignant</i>		
Colon cancer	2	0
Colorectal cancer	2	0
Rectal cancer	2	0
<i>Endocrine neoplasms benign NEC</i>		
Pituitary tumour benign	1	0
<i>Endocrine neoplasms malignant and unspecified NEC</i>		
Neuroendocrine tumour	1	0
Thyroid neoplasm	1	0
<i>Endometrial neoplasms malignant</i>		
Endometrial cancer	2	0
<i>Follicular lymphomas</i>		
Primary gastrointestinal follicular lymphoma	1	0
<i>Gastric neoplasms malignant</i>		

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
Gastric cancer	1	1
<i>Gastrointestinal neoplasms malignant NEC</i>		
Gastrointestinal carcinoma	4	0
<i>Hepatic neoplasms malignant</i>		
Hepatic cancer	1	1
Hepatocellular carcinoma	1	0
<i>Hepatobiliary neoplasms benign</i>		
Haemangioma of liver	1	0
<i>Hepatobiliary neoplasms malignancy unspecified</i>		
Hepatic neoplasm	1	0
<i>Hodgkin's disease NEC</i>		
Hodgkin's disease	4	0
<i>Islet cell neoplasms and APUDoma NEC</i>		
Pancreatic neuroendocrine tumour	1	0
<i>Kaposi's sarcomas</i>		
Kaposi's sarcoma	1	0
<i>Leukaemias NEC</i>		
Leukaemia	7	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>		
Lip and/or oral cavity cancer recurrent	1	0
<i>Lymphomas unspecified NEC</i>		
Lymphoma	48	1
<i>Lymphoproliferative disorders NEC (excl leukaemias and lymphomas)</i>		
Histiocytic necrotising lymphadenitis	1	0
<i>Mantle cell lymphomas</i>		
Mantle cell lymphoma	2	0
<i>Metastases to specified sites</i>		
Metastases to bone	1	0
Metastases to liver	1	0
Metastases to lymph nodes	5	0
<i>Metastases to unknown and unspecified sites</i>		
Metastasis	1	0
<i>Myelodysplastic syndromes</i>		
Myelodysplastic syndrome	4	0
<i>Myeloproliferative disorders (excl leukaemias)</i>		
Essential thrombocythaemia	2	0
<i>Neoplasms benign site unspecified NEC</i>		
Papilloma	1	0
<i>Neoplasms malignant site unspecified NEC</i>		
Adenocarcinoma metastatic	1	0
Metastatic neoplasm	2	0
Neoplasm malignant	16	3
Second primary malignancy	1	0
Squamous cell carcinoma	5	0
<i>Neoplasms unspecified malignancy and site unspecified NEC</i>		

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

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
Malignant melanoma	3	0
Metastatic malignant melanoma	1	0
<i>Skin neoplasms benign</i>		
Acrochordon	7	0
Anogenital warts	7	0
Fibrous histiocytoma	1	0
Haemangioma of skin	7	0
Melanocytic naevus	10	0
Pyogenic granuloma	1	0
Seborrheic keratosis	2	0
Skin papilloma	22	0
<i>Skin neoplasms malignant and unspecified (excl melanoma)</i>		
Basal cell carcinoma	3	0
Bowen's disease	1	0
Neoplasm skin	3	0
Skin cancer	1	0
Squamous cell carcinoma of skin	1	0
<i>Soft tissue neoplasms benign NEC</i>		
Lipoma	7	0
Lymphangioma	1	0
<i>Soft tissue sarcomas histology unspecified</i>		
Sarcoma	1	0
<i>Thyroid neoplasms malignant</i>		
Anaplastic thyroid cancer	1	0
Huerthle cell carcinoma	1	0
Papillary thyroid cancer	2	0
Thyroid cancer	1	0
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	18	0
Neoplasms SOC TOTAL	402	13

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Areflexia	9	0
Extensor plantar response	2	0
Hoffmann's sign	1	0
Hyperreflexia	5	0
Hyporeflexia	11	0
Reflexes abnormal	2	0
<i>Abnormal sleep-related events</i>		
Sleep paralysis	32	0
<i>Absence seizures</i>		
Petit mal epilepsy	32	0
<i>Acute polyneuropathies</i>		
Acute motor axonal neuropathy	1	0
Acute motor-sensory axonal neuropathy	1	0
Guillain-Barre syndrome	107	2
Miller Fisher syndrome	6	0
Subacute inflammatory demyelinating polyneuropathy	1	0
<i>Alzheimer's disease (incl subtypes)</i>		
Dementia Alzheimer's type	3	2
<i>Auditory nerve disorders</i>		
Auditory nerve disorder	1	0
<i>Autonomic nervous system disorders</i>		
Anticholinergic syndrome	1	0
Autonomic nervous system imbalance	17	0
Autonomic neuropathy	4	0
Horner's syndrome	2	0
Orthostatic intolerance	2	0
<i>Central nervous system aneurysms and dissections</i>		
Carotid artery dissection	2	0
Intracranial aneurysm	2	1
Vertebral artery dissection	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Basal ganglia haemorrhage	1	0
Basal ganglia infarction	1	0
Brain stem haemorrhage	4	3
Brain stem infarction	1	1
Brain stem stroke	3	0
Carotid artery occlusion	1	0
Carotid artery thrombosis	4	0
Cerebellar artery thrombosis	1	0
Cerebellar haemorrhage	3	0
Cerebellar infarction	3	0
Cerebellar ischaemia	1	0
Cerebellar stroke	8	1
Cerebral artery embolism	3	1
Cerebral artery occlusion	2	0
Cerebral artery thrombosis	5	0
Cerebral haematoma	2	0
Cerebral haemorrhage	70	18
Cerebral infarction	33	3
Cerebral ischaemia	1	0
Cerebral thrombosis	16	0
Cerebrovascular accident	520	22

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Embolic stroke	8	0
Haemorrhage intracranial	16	4
Haemorrhagic cerebral infarction	1	0
Haemorrhagic stroke	13	5
Internal capsule infarction	1	0
Intracranial haematoma	2	0
Ischaemic cerebral infarction	1	0
Ischaemic stroke	68	3
Lacunar infarction	4	0
Lacunar stroke	6	0
Lateral medullary syndrome	2	0
Pseudostroke	3	0
Ruptured cerebral aneurysm	1	0
Spinal cord infarction	1	0
Spinal stroke	1	0
Stroke in evolution	1	0
Subarachnoid haemorrhage	19	8
Thalamic infarction	1	0
Thrombotic stroke	6	1
Vertebrobasilar stroke	1	0
Central nervous system inflammatory disorders NEC		
Arachnoiditis	1	0
Gliosis	3	0
Central nervous system vascular disorders NEC		
Brain hypoxia	5	1
Carotid arteriosclerosis	1	0
Central nervous system vasculitis	1	0
Cerebral amyloid angiopathy	2	0
Cerebral congestion	5	0
Cerebral small vessel ischaemic disease	4	0
Cerebrovascular disorder	3	0
Post cardiac arrest syndrome	1	0
Reversible cerebral vasoconstriction syndrome	1	0
Cerebrovascular venous and sinus thrombosis		
Cerebral venous sinus thrombosis	61	5
Cerebral venous thrombosis	9	0
Superior sagittal sinus thrombosis	6	0
Transverse sinus thrombosis	3	0
Cervical spinal cord and nerve root disorders		
Cervical radiculopathy	2	0
Cervicobrachial syndrome	7	0
Choreiform movements		
Chorea	3	0
Chronic polyneuropathies		
Chronic inflammatory demyelinating polyradiculoneuropathy	3	0
Demyelinating polyneuropathy	3	0
Diabetic neuropathy	1	0
Coma states		
Coma	18	0
Diabetic coma	1	0
Hypoglycaemic coma	1	0
Coordination and balance disturbances		
Ataxia	24	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Balance disorder	535	0
Cerebellar ataxia	1	0
Cerebellar syndrome	1	0
Coordination abnormal	77	0
Dysdiadochokinesis	1	0
Dysstasia	76	0
Nystagmus	17	0
Cortical dysfunction NEC		
Alexia	2	0
Aphasia	111	0
Apraxia	1	0
Dysgraphia	4	0
Dyslexia	2	0
Dyspraxia	2	0
Neurologic neglect syndrome	1	0
Sensory processing disorder	3	0
Visuospatial deficit	1	0
Cranial nerve disorders NEC		
Cranial nerve disorder	3	0
Cranial nerve paralysis	1	0
Dementia (excl Alzheimer's type)		
Dementia	19	0
Dementia with Lewy bodies	2	0
Senile dementia	1	0
Demyelinating disorders NEC		
Acute disseminated encephalomyelitis	9	0
Clinically isolated syndrome	1	0
Demyelination	13	0
Neuromyelitis optica spectrum disorder	2	0
Disturbances in consciousness NEC		
Altered state of consciousness	14	0
Consciousness fluctuating	4	0
Depressed level of consciousness	59	0
Infant sedation	1	0
Lethargy	2598	0
Loss of consciousness	842	1
Postictal state	6	0
Sedation	9	0
Sedation complication	1	0
Somnolence	1237	0
Stupor	5	0
Syncope	2903	0
Disturbances in sleep phase rhythm		
Circadian rhythm sleep disorder	2	0
Irregular sleep phase	2	0
Irregular sleep wake rhythm disorder	2	0
Non-24-hour sleep-wake disorder	1	0
Dyskinesias and movement disorders NEC		
Akathisia	7	0
Ballismus	1	0
Bradykinesia	26	0
Clumsiness	26	0
Dyskinesia	87	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Extrapyramidal disorder	3	0
Fine motor skill dysfunction	14	0
Foetal movement disorder	7	0
Hyperkinesia	4	0
Hypokinesia	117	0
Micrographia	1	0
Motor dysfunction	5	0
Movement disorder	74	0
Psychomotor hyperactivity	31	0
Synkinesis	2	0
Tardive dyskinesia	2	0
Dystonias		
Dystonia	17	0
Writer's cramp	1	0
Encephalitis NEC		
Encephalitis autoimmune	2	0
Limbic encephalitis	1	0
Noninfective encephalitis	8	0
Encephalopathies NEC		
Autoimmune encephalopathy	2	1
Encephalopathy	6	0
Hashimoto's encephalopathy	2	0
Posterior reversible encephalopathy syndrome	2	0
Eye movement disorders		
IIIrd nerve disorder	1	0
IIIrd nerve paralysis	7	0
IVth nerve paralysis	1	0
Microvascular cranial nerve palsy	2	0
VIth nerve disorder	1	0
VIth nerve paralysis	13	0
Facial cranial nerve disorders		
Bell's palsy	657	0
Facial nerve disorder	9	0
Facial paralysis	490	0
Facial paresis	112	0
Facial spasm	57	0
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	88	0
Glossopharyngeal nerve disorders		
Glossopharyngeal neuralgia	1	0
Headaches NEC		
Cervicogenic headache	3	0
Cluster headache	299	0
Cold-stimulus headache	37	0
Drug withdrawal headache	3	0
Exertional headache	10	0
External compression headache	2	0
Headache	30632	1
Medication overuse headache	2	0
New daily persistent headache	10	0
Occipital neuralgia	17	0
Ophthalmoplegic migraine	1	0
Primary cough headache	4	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Primary headache associated with sexual activity	10	0
Sinus headache	405	0
Tension headache	643	0
Thunderclap headache	25	0
Vascular headache	22	0
Hydrocephalic conditions		
Hydrocephalus	5	0
Hypoglossal nerve disorders		
Tongue paralysis	1	0
Increased intracranial pressure disorders		
Brain compression	2	0
Brain oedema	15	2
Idiopathic intracranial hypertension	12	0
Intracranial pressure increased	6	0
Intellectual disabilities		
Intellectual disability	4	0
Lumbar spinal cord and nerve root disorders		
Cauda equina syndrome	1	0
Sciatica	140	0
Memory loss (excl dementia)		
Amnesia	248	0
Memory impairment	267	0
Retrograde amnesia	1	0
Transient global amnesia	10	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	115	0
Cognitive linguistic deficit	1	0
Disturbance in attention	414	0
Mental impairment	66	0
Migraine headaches		
Basilar migraine	1	0
Hemiplegic migraine	44	0
Migraine	3588	0
Migraine with aura	235	0
Migraine without aura	22	0
Ophthalmic migraine	7	0
Retinal migraine	39	0
Typical aura without headache	9	0
Vestibular migraine	32	0
Mixed cranial nerve disorders		
Bulbar palsy	2	0
Mononeuropathies		
Carpal tunnel syndrome	38	0
Cubital tunnel syndrome	4	0
Meralgia paraesthetica	2	0
Mononeuritis	2	0
Mononeuropathy	4	0
Nerve compression	32	0
Peripheral nerve lesion	2	0
Peroneal nerve palsy	21	0
Piriformis syndrome	2	0
Pudendal canal syndrome	3	0
Radial nerve palsy	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Sciatic nerve neuropathy	2	0
Ulnar nerve palsy	2	0
Ulnar neuritis	3	0
Ulnar tunnel syndrome	2	0
Motor neurone diseases		
Amyotrophic lateral sclerosis	2	0
Lower motor neurone lesion	2	0
Motor neurone disease	7	3
Progressive bulbar palsy	1	0
Upper motor neurone lesion	1	0
Multiple sclerosis acute and progressive		
Band sensation	1	0
Multiple sclerosis	40	0
Multiple sclerosis relapse	26	0
Relapsing-remitting multiple sclerosis	1	0
Tumefactive multiple sclerosis	1	1
Muscle tone abnormal		
Drop attacks	3	0
Hypertonia	2	0
Hypotonia	40	0
Morvan syndrome	1	0
Muscle tone disorder	1	0
Serotonin syndrome	1	0
Stiff leg syndrome	1	0
Myelitis (incl infective)		
Myelitis transverse	40	0
Narcolepsy and hypersomnia		
Cataplexy	3	0
Hypersomnia	126	0
Narcolepsy	7	0
Nervous system disorders NEC		
Central nervous system lesion	3	0
Cerebral disorder	3	0
Nervous system disorder	29	0
Neurotoxicity	4	0
Psychomotor skills impaired	1	0
Neurologic visual problems NEC		
Hemianopia	2	0
Hemianopia homonymous	3	0
Quadrantanopia	2	0
Tunnel vision	24	0
Neurological signs and symptoms NEC		
Agitation neonatal	1	0
Cerebrospinal fluid leakage	1	0
Clonus	5	0
Decerebrate posture	1	0
Decorticate posture	1	0
Dizziness	11563	0
Dizziness exertional	54	0
Dizziness postural	866	0
Drooling	27	0
Fontanelle bulging	2	0
Head discomfort	423	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Hyporesponsive to stimuli	2	0
Inability to crawl	3	0
Infant irritability	10	0
Meningism	2	0
Myoclonus	35	0
Neurological symptom	83	0
Patient elopement	1	0
Persistent postural-perceptual dizziness	20	0
Presyncope	736	0
Sensory overload	5	0
Slow response to stimuli	4	0
Tongue biting	9	0
Unresponsive to stimuli	68	0
Neuromuscular disorders NEC		
Muscle contractions involuntary	34	0
Muscle spasticity	21	0
Neuromuscular pain	3	0
Neuromuscular junction dysfunction		
Myasthenia gravis	18	0
Myasthenia gravis crisis	2	0
Myasthenic syndrome	1	0
Olfactory nerve disorders		
Anosmia	337	0
Hyposmia	19	0
Parosmia	342	0
Optic nerve disorders NEC		
Optic neuritis	46	0
Paraesthesias and dysaesthesias		
Burning feet syndrome	15	0
Burning sensation	692	0
Burning sensation mucosal	2	0
Dysaesthesia	8	0
Formication	49	0
Hemianaesthesia	1	0
Hemihypoaesthesia	4	0
Hemiparaesthesia	6	0
Hyperaesthesia	126	0
Hypoaesthesia	3616	0
Lhermitte's sign	1	0
Paraesthesia	4932	0
Reversed hot-cold sensation	4	0
Synaesthesia	2	0
Vibration syndrome	3	0
Paralysis and paresis (excl cranial nerve)		
Diplegia	23	0
Hemiparesis	74	0
Hemiplegia	52	0
Locked-in syndrome	1	0
Monoparesis	94	0
Monoplegia	106	0
Paralysis	166	1
Paraparesis	4	0
Paraplegia	3	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Paresis	10	0
Quadriparesis	1	0
Quadriplegia	1	0
Parkinson's disease and parkinsonism		
Freezing phenomenon	18	0
Hypokinetic dysarthria	1	0
Parkinson's disease	4	0
Parkinsonian gait	1	0
Parkinsonian rest tremor	1	0
Parkinsonism	4	0
Reduced facial expression	11	0
Partial complex seizures		
Dreamy state	6	0
Focal dyscognitive seizures	6	0
Temporal lobe epilepsy	2	0
Partial simple seizures NEC		
Autonomic seizure	1	0
Peripheral neuropathies NEC		
Axonal neuropathy	2	0
Brachial plexopathy	2	0
Neuralgic amyotrophy	13	0
Neuritis	12	0
Neuropathy peripheral	173	0
Peripheral sensorimotor neuropathy	2	0
Peripheral sensory neuropathy	13	0
Polyneuropathy	5	0
Small fibre neuropathy	4	0
Thoracic outlet syndrome	2	0
Seizures and seizure disorders NEC		
Atonic seizures	11	0
Change in seizure presentation	2	0
Clonic convulsion	6	0
Convulsions local	1	0
Convulsive threshold lowered	1	0
Epilepsy	181	0
Epileptic aura	3	0
Epileptic encephalopathy	2	0
Febrile convulsion	21	0
Idiopathic generalised epilepsy	1	0
Neonatal epileptic seizure	1	0
Partial seizures	30	0
Partial seizures with secondary generalisation	1	0
Post stroke seizure	1	0
Psychogenic seizure	11	0
Seizure	785	2
Seizure anoxic	3	0
Seizure cluster	7	0
Seizure like phenomena	4	0
Status epilepticus	41	0
Tonic clonic movements	7	0
Tonic convulsion	40	0
Tonic posturing	1	0
Sensory abnormalities NEC		

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Ageusia	614	0
Allodynia	33	0
Aura	31	0
Central pain syndrome	1	0
Complex regional pain syndrome	6	0
Dysgeusia	1341	0
Electric shock sensation	62	0
Hypergeusia	1	0
Hypogeusia	9	0
Intercostal neuralgia	3	0
Loss of proprioception	3	0
Morton's neuralgia	4	0
Neuralgia	761	0
Persistent genital arousal disorder	2	0
Phantom limb syndrome	8	0
Post herpetic neuralgia	19	0
Post-traumatic neuralgia	1	0
Restless arm syndrome	4	0
Restless legs syndrome	165	0
Sensory disturbance	133	0
Sensory loss	120	0
Taste disorder	321	0
Visual perseveration	3	0
Sleep disturbances NEC		
Microsleep	1	0
Sleep deficit	13	0
Sudden onset of sleep	1	0
Speech and language abnormalities		
Dysarthria	256	0
Incoherent	17	0
Language disorder	2	0
Repetitive speech	5	0
Slow speech	25	0
Speech disorder	86	0
Speech disorder developmental	4	0
Spinal cord and nerve root disorders NEC		
Acquired syringomyelia	1	0
Myelopathy	1	0
Radiculitis brachial	19	0
Radiculopathy	8	0
Structural brain disorders NEC		
Brain injury	13	2
Cerebral ventricle dilatation	2	0
Hyperintensity in brain deep nuclei	1	0
Intracranial mass	1	0
White matter lesion	2	0
Transient cerebrovascular events		
Transient ischaemic attack	207	3
Tremor (excl congenital)		
Essential tremor	6	0
Head titubation	15	0
Resting tremor	4	0
Tremor	2217	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
<i>Trigeminal disorders</i>		
Numb chin syndrome	2	0
Trigeminal nerve disorder	3	0
Trigeminal neuralgia	90	0
Trigeminal neuritis	3	0
<i>Vagus nerve disorders</i>		
Vagus nerve disorder	1	0
Vocal cord paralysis	4	0
<i>Vertigos NEC</i>		
Cervicogenic vertigo	1	0
Vertigo CNS origin	3	0
Nervous system disorders SOC TOTAL	82466	98

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortion related conditions and complications</i>		
Anembryonic gestation	3	0
<i>Abortions not specified as induced or spontaneous</i>		
Abortion	2	0
Abortion missed	7	0
<i>Abortions spontaneous</i>		
Abortion spontaneous	500	1
Abortion threatened	2	0
<i>Amniotic fluid and cavity disorders of pregnancy NEC</i>		
Amniorrhoea	2	0
Oligohydramnios	1	0
<i>Foetal complications NEC</i>		
Foetal cardiac disorder	1	0
Foetal distress syndrome	3	0
Foetal hypokinesia	14	0
<i>Foetal conditions due to maternal conditions</i>		
Maternal condition affecting foetus	1	0
<i>Foetal growth complications</i>		
Foetal growth restriction	8	1
<i>Gestational age and weight conditions</i>		
Low birth weight baby	1	0
Premature baby	9	1
Small for dates baby	1	0
<i>Haemorrhagic complications of pregnancy</i>		
Haemorrhage in pregnancy	3	0
Premature separation of placenta	3	0
Retroplacental haematoma	1	0
Subchorionic haematoma	3	0
Subchorionic haemorrhage	1	0
<i>High risk pregnancies</i>		
Risk of future pregnancy miscarriage	1	0
<i>Hypertension associated disorders of pregnancy</i>		
Pre-eclampsia	4	0
<i>Labour onset and length abnormalities</i>		
Induced labour	1	0
Obstructed labour	1	0
Premature delivery	1	0
Premature labour	9	0
Premature rupture of membranes	3	0
Threatened labour	1	0
<i>Maternal complications of delivery NEC</i>		
Retained placenta or membranes	2	0
<i>Maternal complications of labour NEC</i>		
Uterine contractions abnormal	1	0
Uterine hypertonus	8	0
<i>Maternal complications of pregnancy NEC</i>		
Biochemical pregnancy	4	0
Complication of pregnancy	1	0
Decidual cast	8	0
Ectopic pregnancy	15	0
Hyperemesis gravidarum	1	0
Morning sickness	17	0
Preterm premature rupture of membranes	3	0

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Reaction Name	Total	Fatal
Pregnancy conditions <small>Pregnancy conditions cont'd</small>		
Ruptured ectopic pregnancy	1	0
Somatic symptom disorder of pregnancy	3	0
Neonatal hepatobiliary disorders		
Jaundice neonatal	1	0
Normal newborn status		
Normal newborn	1	0
Normal pregnancy, labour and delivery		
Labour pain	1	0
Live birth	8	0
Pregnancy	35	0
Term birth	1	0
Uterine contractions during pregnancy	6	0
Placental abnormalities (excl neoplasms)		
Foetal vascular malperfusion	2	0
Placental calcification	1	0
Placental disorder	4	0
Placental insufficiency	1	0
Small size placenta	2	0
Postpartum complications NEC		
Postpartum haemorrhage	5	0
Pregnancy complicated by maternal disorders		
Gestational diabetes	2	0
Peripartum cardiomyopathy	1	0
Stillbirth and foetal death		
Foetal death	2	2
Stillbirth	12	12
Umbilical cord complications		
Umbilical cord abnormality	1	0
Umbilical cord thrombosis	1	0
Unintended pregnancies		
Pregnancy after post coital contraception	2	0
Pregnancy on contraceptive	3	0
Pregnancy on oral contraceptive	2	0
Pregnancy with contraceptive device	2	0
Pregnancy with implant contraceptive	1	0
Unintended pregnancy	4	0
Unwanted pregnancy	1	0
Pregnancy conditions SOC TOTAL	753	17

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Reaction Name	Total	Fatal
<i>Device electrical issues</i>		
Electromagnetic interference	1	0
<i>Device issues NEC</i>		
Device connection issue	1	0
Device failure	1	0
Device issue	3	0
<i>Device malfunction events NEC</i>		
Device infusion issue	1	0
Device malfunction	1	0
Device pacing issue	1	0
Device stimulation issue	1	0
Oversensing	21	0
Thrombosis in device	16	0
Undersensing	1	0
<i>Device physical property and chemical issues</i>		
Device breakage	1	0
Device defective	9	0
Device kink	1	0
Needle issue	3	0
<i>Manufacturing materials issues</i>		
Manufacturing materials contamination	1	0
<i>Product contamination and sterility issues</i>		
Product contamination	17	0
Product contamination physical	11	0
<i>Product packaging issues</i>		
Packaging design issue	1	0
Product closure issue	1	0
<i>Product physical issues</i>		
Liquid product physical issue	12	0
Product after taste	3	0
Product deposit	1	0
Product odour abnormal	3	0
Product physical issue	2	0
Product taste abnormal	10	0
<i>Product quality issues NEC</i>		
Product complaint	2	0
Product origin unknown	5	0
<i>Product supply and availability issues</i>		
Product availability issue	1	0
null SOC TOTAL	132	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	28	0
Behaviour disorder	2	0
Breath holding	7	0
Staring	8	0
<i>Adjustment disorders</i>		
Adjustment disorder	1	0
Adjustment disorder with depressed mood	5	0
<i>Affect alterations NEC</i>		
Affect lability	16	0
Constricted affect	9	0
Flat affect	12	0
Inappropriate affect	23	0
<i>Amnesic symptoms</i>		
Paramnesia	7	0
<i>Anxiety disorders NEC</i>		
Anxiety disorder	3	0
Generalised anxiety disorder	3	0
Neurosis	1	0
<i>Anxiety symptoms</i>		
Agitation	102	0
Anxiety	1138	0
Immunisation stress-related response	4	0
Nervousness	220	0
Stress	145	0
Tension	47	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	7	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	18	0
Attention-seeking behaviour	1	0
Aversion	1	0
Disinhibition	3	0
Indifference	7	0
Paranoia	33	0
Personality change	8	0
Social avoidant behaviour	6	0
Soliloquy	2	0
Suspiciousness	1	0
<i>Bipolar disorders</i>		
Bipolar I disorder	2	0
Bipolar disorder	5	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Daydreaming	9	0
Distractibility	4	0
Mental fatigue	256	0
<i>Communications disorders</i>		
Communication disorder	9	0
Mutism	4	0
Speech sound disorder	1	0
<i>Confusion and disorientation</i>		
Confusional state	1090	0
Disorientation	335	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Decreased physical activity levels</i>		
Catatonia	1	0
<i>Deliria</i>		
Delirium	160	0
Delirium febrile	1	0
<i>Delusional symptoms</i>		
Delusion	20	0
<i>Depressive disorders</i>		
Agitated depression	6	0
Depression	444	0
Depression suicidal	20	0
Major depression	15	0
Mixed anxiety and depressive disorder	5	0
<i>Dissociative states</i>		
Depersonalisation/derealisation disorder	13	0
Dissociation	42	0
Dissociative amnesia	4	0
Dissociative disorder	2	0
<i>Disturbances in initiating and maintaining sleep</i>		
Initial insomnia	30	0
Insomnia	2027	0
Middle insomnia	34	0
Terminal insomnia	35	0
<i>Dyssomnias</i>		
Breathing-related sleep disorder	1	0
Dyssomnia	1	0
Poor quality sleep	273	0
<i>Eating disorders NEC</i>		
Bulimia nervosa	1	0
Eating disorder	16	0
Selective eating disorder	1	0
<i>Emotional and mood disturbances NEC</i>		
Anger	51	0
Dysphoria	3	0
Emotional disorder	78	0
Emotional distress	67	0
Emotional poverty	2	0
Euphoric mood	51	0
Frustration tolerance decreased	2	0
Irritability	246	0
Mood altered	68	0
Morose	1	0
<i>Factitious disorders</i>		
Factitious disorder	4	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Agoraphobia	2	0
Claustrophobia	1	0
Fear	34	0
Fear of death	2	0
Fear of eating	1	0
Fear of falling	3	0
Fear of injection	6	0
Osmophobia	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Performance fear	1	0
Phobia	3	0
Phonophobia	3	0
Social anxiety disorder	2	0
Social fear	1	0
Fluctuating mood symptoms		
Mood swings	175	0
Hallucinations (excl sleep-related)		
Hallucination	269	0
Hallucination, auditory	24	0
Hallucination, olfactory	16	0
Hallucination, tactile	1	0
Hallucination, visual	33	0
Hallucinations, mixed	4	0
Increased physical activity levels		
Restlessness	180	0
Infancy, childhood and adolescence psychiatric disorders NEC		
Social (pragmatic) communication disorder	1	0
Learning disorders		
Learning disability	1	0
Learning disorder	1	0
Reading disorder	2	0
Mental disorders NEC		
Mental disorder	25	0
Mental status changes	1	0
Psychological factor affecting medical condition	1	0
Mood alterations with depressive symptoms		
Anhedonia	3	0
Decreased interest	13	0
Depressed mood	463	0
Depressive symptom	2	0
Feeling guilty	1	0
Feeling of despair	5	0
Feelings of worthlessness	2	0
Negative thoughts	3	0
Psychomotor retardation	2	0
Sense of a foreshortened future	3	0
Tearfulness	50	0
Mood alterations with manic symptoms		
Hypomania	2	0
Mania	11	0
Mood disorders NEC		
Affective disorder	4	0
Apathy	39	0
Boredom	1	0
Laziness	3	0
Listless	26	0
Mood disorder due to a general medical condition	1	0
Narcolepsy and associated conditions		
Hypnagogic hallucination	4	0
Hypnopompic hallucination	2	0
Sleep attacks	3	0
Obsessive-compulsive disorders and symptoms		

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Obsessive-compulsive symptom	1	0
Orgasmic disorders and disturbances		
Anorgasmia	5	0
Female orgasmic disorder	2	0
Orgasm abnormal	4	0
Orgasmic sensation decreased	1	0
Premature ejaculation	1	0
Panic attacks and disorders		
Limited symptom panic attack	1	0
Panic attack	276	0
Panic disorder	10	0
Panic reaction	32	0
Paraphilias and paraphilic disorders		
Transvestism	1	0
Parasomnias		
Abnormal dreams	214	0
Abnormal sleep-related event	1	0
Confusional arousal	1	0
Exploding head syndrome	3	0
Nightmare	241	0
Parasomnia	5	0
Sleep inertia	1	0
Sleep talking	6	0
Sleep terror	30	0
Somnambulism	10	0
Perception disturbances NEC		
Autoscopy	20	0
Deja vu	3	0
Derealisation	14	0
Flashback	4	0
Illusion	6	0
Near death experience	1	0
Time perception altered	2	0
Personality disorders NEC		
Personality disorder	1	0
Self esteem decreased	1	0
Pervasive developmental disorders NEC		
Autism spectrum disorder	5	0
Psychiatric elimination disorders		
Enuresis	31	0
Psychiatric symptoms NEC		
Helplessness	1	0
Hypervigilance	9	0
Psychiatric symptom	13	0
Psychological trauma	4	0
Trance	1	0
Psychotic disorder NEC		
Acute psychosis	1	0
Psychotic behaviour	1	0
Psychotic disorder	37	1
Schizophrenia NEC		
Schizophrenia	2	0
Sexual and gender identity disorders NEC		

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Gender dysphoria	1	0
Sexual arousal disorders		
Disturbance in sexual arousal	4	0
Sexual inhibition	1	0
Sexual desire disorders		
Hypersexuality	1	0
Libido decreased	20	0
Libido disorder	2	0
Libido increased	8	0
Loss of libido	22	0
Sexual dysfunction NEC		
Genito-pelvic pain/penetration disorder	2	0
Sleep disorders NEC		
Sleep disorder	294	0
Sleep disorder due to general medical condition, insomnia type	5	0
Somatic symptom disorders		
Conversion disorder	34	0
Habit cough	22	0
Somatic symptom disorder	2	0
Vomiting psychogenic	1	0
Speech and language usage disturbances		
Disorganised speech	10	0
Logorrhoea	2	0
Speech articulation and rhythm disturbances		
Dysphemia	29	0
Lack of spontaneous speech	1	0
Pressure of speech	1	0
Stereotypies and automatisms		
Automatism	1	0
Bruxism	16	0
Head banging	13	0
Stereotypy	1	0
Stress disorders		
Burnout syndrome	2	0
Post-traumatic stress disorder	6	0
Substance related and addictive disorders		
Alcohol problem	1	0
Alcoholic hangover	1	0
Alcoholism	5	0
Dependence	1	0
Nicotine dependence	2	0
Suicidal and self-injurious behaviour		
Completed suicide	2	2
Intentional self-injury	6	0
Self-injurious ideation	2	0
Suicidal ideation	57	0
Suicide attempt	10	0
Suicide threat	2	0
Thinking disturbances		
Bradyphrenia	45	0
Flight of ideas	1	0
Intrusive thoughts	8	0
Morbid thoughts	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Tachyphrenia	8	0
Thinking abnormal	23	0
Thought blocking	3	0
<i>Tic disorders</i>		
Tic	21	0
Psychiatric disorders SOC TOTAL	10448	3

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder discomfort	6	0
Bladder irritation	14	0
Bladder pain	36	0
Bladder spasm	2	0
Dysuria	61	0
Incontinence	48	0
Lower urinary tract symptoms	3	0
Micturition disorder	2	0
Micturition urgency	55	0
Mixed incontinence	1	0
Pollakiuria	166	0
Stress urinary incontinence	2	0
Urethral pain	8	0
Urge incontinence	3	0
Urinary hesitation	4	0
Urinary incontinence	86	0
Urinary retention	57	0
Urine flow decreased	20	0
<i>Bladder disorders NEC</i>		
Bladder dilatation	1	0
Bladder disorder	14	0
Bladder fibrosis	1	0
Bladder prolapse	1	0
Urinary bladder haemorrhage	4	0
<i>Bladder infections and inflammations</i>		
Cystitis haemorrhagic	1	0
Cystitis interstitial	6	0
Cystitis noninfective	1	0
<i>Bladder neoplasms</i>		
Bladder cyst	1	0
<i>Genital and urinary tract disorders NEC</i>		
Genitourinary symptom	2	0
Urinary tract disorder	4	0
Urinary tract obstruction	1	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
Anti-glomerular basement membrane disease	1	0
Focal segmental glomerulosclerosis	1	0
Glomerulonephritis membranous	1	0
Glomerulonephritis minimal lesion	8	0
Glomerulonephritis rapidly progressive	2	0
Goodpasture's syndrome	1	0
IgA nephropathy	4	0
Nephrotic syndrome	22	0
<i>Myoneurogenic bladder disorders</i>		
Automatic bladder	1	0
Bladder dysfunction	8	0
Hypertonic bladder	7	0
Hypotonic urinary bladder	1	0
Loss of bladder sensation	3	0
Neurogenic bladder	2	0
<i>Nephritis NEC</i>		
Lupus nephritis	2	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
Renal & urinary disorders cont'd		
Nephritis	3	0
Tubulointerstitial nephritis	3	0
<i>Nephropathies and tubular disorders NEC</i>		
Nephropathy	1	0
<i>Renal disorders NEC</i>		
Kidney fibrosis	1	0
Renal disorder	12	1
Renal haemorrhage	1	0
Renal mass	1	0
<i>Renal failure and impairment</i>		
Acute kidney injury	60	4
Anuria	5	0
Chronic kidney disease	7	0
End stage renal disease	1	0
Oliguria	1	0
Renal failure	30	2
Renal impairment	36	0
Renal injury	3	0
<i>Renal failure complications</i>		
Azotaemia	1	0
<i>Renal lithiasis</i>		
Nephrolithiasis	13	0
<i>Renal neoplasms</i>		
Renal cyst	1	0
<i>Renal obstructive disorders</i>		
Hydronephrosis	2	0
<i>Renal structural abnormalities and trauma</i>		
Kidney enlargement	1	0
Kidney small	2	0
<i>Renal vascular and ischaemic conditions</i>		
Renal aneurysm	1	0
Renal infarct	4	0
Renal tubular necrosis	2	0
Renal vasculitis	2	1
<i>Structural and obstructive urethral disorders (excl congenital)</i>		
Urethral stenosis	1	0
<i>Ureteric disorders NEC</i>		
Ureteric stenosis	1	0
<i>Urinary abnormalities</i>		
Albuminuria	1	0
Chromaturia	71	0
Haematuria	55	0
Ketonuria	1	0
Myoglobinuria	1	0
Proteinuria	13	0
Urine abnormality	13	0
Urine odour abnormal	11	0
<i>Urinary tract lithiasis (excl renal)</i>		
Calculus bladder	1	0
Calculus urinary	1	0
<i>Urinary tract signs and symptoms NEC</i>		
Costovertebral angle tenderness	1	0
Cystitis-like symptom	1	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
Renal & urinary disorders cont'd		
Haemorrhage urinary tract	31	1
Nocturia	3	0
Polyuria	9	0
Renal colic	5	0
Renal pain	371	0
Urinary tract discomfort	2	0
Urinary tract pain	7	0
Renal & urinary disorders SOC TOTAL	1469	9

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Benign and malignant breast neoplasms</i>		
Breast cyst	18	0
<i>Breast disorders NEC</i>		
Breast atrophy	1	0
Breast disorder	4	0
Breast enlargement	33	0
Breast mass	154	0
Fibrocystic breast disease	1	0
Gynaecomastia	7	0
Mastoptosis	1	0
Nipple disorder	1	0
<i>Breast infections and inflammations</i>		
Breast inflammation	6	0
Nipple inflammation	3	0
<i>Breast signs and symptoms</i>		
Breast discharge	5	0
Breast discomfort	15	0
Breast engorgement	11	0
Breast haematoma	1	0
Breast oedema	10	0
Breast pain	880	0
Breast swelling	197	0
Breast tenderness	107	0
Nipple pain	48	1
Nipple swelling	4	0
<i>Cervix disorders NEC</i>		
Cervical dysplasia	3	0
Cervix disorder	1	0
Cervix haemorrhage uterine	5	0
Ectropion of cervix	5	0
<i>Cervix infections and inflammations</i>		
Cervix inflammation	1	0
<i>Cervix neoplasms</i>		
Cervical polyp	2	0
<i>Erection and ejaculation conditions and disorders</i>		
Ejaculation disorder	3	0
Ejaculation failure	3	0
Erectile dysfunction	81	0
Erection increased	4	0
Organic erectile dysfunction	14	0
Painful ejaculation	1	0
Spontaneous ejaculation	2	0
Spontaneous penile erection	2	0
<i>Fallopian tube and ovary infections and inflammations</i>		
Noninfective oophoritis	6	0
<i>Lactation disorders</i>		
Breast milk discolouration	4	0
Breast milk odour abnormal	2	0
Galactorrhoea	5	0
Galactostasis	1	0
Lactation disorder	11	0
Lactation puerperal increased	6	0
Suppressed lactation	50	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Menopausal effects NEC		
Artificial menopause	1	0
Menopausal disorder	1	0
Menopausal symptoms	47	0
Menopause delayed	1	0
Premature menopause	26	0
Menopausal effects on the genitourinary tract		
Atrophic vulvovaginitis	2	0
Postmenopausal haemorrhage	117	0
Menstruation and uterine bleeding NEC		
Abnormal uterine bleeding	8	0
Abnormal withdrawal bleeding	3	0
Bleeding anovulatory	1	0
Dysmenorrhoea	3361	0
Intermenstrual bleeding	1331	0
Menstrual discomfort	37	0
Menstrual disorder	2329	0
Menstruation irregular	4136	0
Premenstrual dysphoric disorder	14	0
Premenstrual headache	13	0
Premenstrual pain	152	0
Premenstrual syndrome	142	0
Retrograde menstruation	2	0
Withdrawal bleed	16	0
Menstruation with decreased bleeding		
Amenorrhoea	741	0
Hypomenorrhoea	763	0
Menstruation delayed	5798	0
Oligomenorrhoea	236	0
Menstruation with increased bleeding		
Heavy menstrual bleeding	6415	0
Menometrorrhagia	22	0
Polymenorrhoea	1058	0
Ovarian and fallopian tube cysts and neoplasms		
Haemorrhagic ovarian cyst	3	0
Ovarian cyst	33	0
Ovarian cyst ruptured	2	0
Polycystic ovaries	51	0
Ovarian and fallopian tube disorders NEC		
Adnexal torsion	1	0
Hydrosalpinx	2	0
Ovarian enlargement	1	0
Ovarian failure	1	0
Ovarian haemorrhage	8	0
Ovarian hyperstimulation syndrome	1	0
Ovarian mass	2	0
Ovarian necrosis	1	0
Ovulation disorder	4	0
Ovulation pain	85	0
Premature ovulation	4	0
Superovulation	1	0
Pelvic prolapse conditions		
Vaginal prolapse	1	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
<i>Pelvis and broad ligament disorders NEC</i>		
Adnexa uteri mass	1	0
Adnexa uteri pain	72	0
Pelvic congestion	1	0
Pelvic floor muscle weakness	1	0
Pelvic fluid collection	1	0
Pelvic haemorrhage	22	0
<i>Penile and scrotal infections and inflammations</i>		
Balanoposthitis	5	0
<i>Penile disorders NEC (excl erection and ejaculation)</i>		
Foreskin oedema	1	0
Penile blister	1	0
Penile discharge	1	0
Penile discomfort	1	0
Penile erythema	1	0
Penile haemorrhage	3	0
Penile oedema	1	0
Penile pain	2	0
Penile rash	1	0
Penile size reduced	1	0
Penile swelling	6	0
Penis disorder	13	0
Peyronie's disease	1	0
<i>Prostate and seminal vesicles infections and inflammations</i>		
Prostatitis	5	0
<i>Prostatic neoplasms and hypertrophy</i>		
Benign prostatic hyperplasia	2	0
<i>Prostatic signs, symptoms and disorders NEC</i>		
Prostatic pain	1	0
Prostatomegaly	3	0
<i>Reproductive tract disorders NEC (excl neoplasms)</i>		
Genital erosion	1	0
Genital haemorrhage	25	0
Genital hypoaesthesia	2	0
Genital lesion	2	0
Genital paraesthesia	1	0
Genital ulceration	8	0
Perineal ulceration	1	0
<i>Reproductive tract infections and inflammations NEC</i>		
Genital tract inflammation	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Genital burning sensation	3	0
Genital discolouration	1	0
Genital erythema	1	0
Genital pain	7	0
Genital rash	6	0
Genital swelling	5	0
Pelvic discomfort	6	0
Pelvic pain	135	0
Perineal pain	3	0
Perineal rash	1	0
Pruritus genital	8	0
<i>Scrotal disorders NEC</i>		

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Acquired hydrocele	1	0
Scrotal angiokeratoma	1	0
Scrotal discomfort	1	0
Scrotal erythema	2	0
Scrotal exfoliation	2	0
Scrotal pain	22	0
Scrotal swelling	6	0
Scrotum erosion	1	0
Varicocele	2	0
Sexual function and fertility disorders NEC		
Dyspareunia	7	0
Infertility	18	0
Infertility female	5	0
Infertility male	1	0
Sexual dysfunction	10	0
Spermatogenesis and semen disorders		
Aspermia	1	0
Haematospermia	8	0
Semen discolouration	1	0
Testicular and epididymal disorders NEC		
Testicular atrophy	1	0
Testicular disorder	4	0
Testicular oedema	1	0
Testicular pain	74	0
Testicular swelling	15	0
Testicular torsion	1	0
Testis discomfort	3	0
Testicular and epididymal neoplasms		
Testicular cyst	1	0
Uterine disorders NEC		
Adenomyosis	11	0
Endometrial thickening	4	0
Endometriosis	98	0
Uterine haemorrhage	49	0
Uterine mass	1	0
Uterine pain	19	0
Uterine infections and inflammations (excl cervix)		
Uterine inflammation	1	0
Uterine neoplasms		
Uterine polyp	6	0
Uterine tone disorders		
Uterine spasm	42	0
Vaginal and vulval infections and inflammations		
Vulvovaginal inflammation	2	0
Vulvovaginal cysts and neoplasms		
Bartholin's cyst	2	0
Vaginal cyst	8	0
Vaginal polyp	1	0
Vulva cyst	1	0
Vulvovaginal disorders NEC		
Vaginal haemorrhage	1822	0
Vaginal mucosal blistering	1	0
Vaginal ulceration	6	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Vulval disorder	2	0
Vulval haemorrhage	34	0
Vulval ulceration	8	0
Vulvovaginal ulceration	6	0
<i>Vulvovaginal signs and symptoms</i>		
Clitoral engorgement	1	0
Coital bleeding	8	0
Labia enlarged	2	0
Vaginal discharge	90	0
Vaginal lesion	1	0
Vaginal odour	4	0
Vaginal oedema	1	0
Vulval eczema	1	0
Vulval oedema	2	0
Vulvovaginal burning sensation	9	0
Vulvovaginal discomfort	2	0
Vulvovaginal dryness	6	0
Vulvovaginal erythema	3	0
Vulvovaginal pain	33	0
Vulvovaginal pruritus	11	0
Vulvovaginal rash	2	0
Vulvovaginal swelling	6	0
Reproductive & breast disorders SOC TOTAL	31552	1

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Agonal respiration	1	0
Apnoea	7	0
Apnoeic attack	1	0
Dyspnoea	7166	5
Dyspnoea at rest	11	0
Dyspnoea exertional	49	1
Grunting	1	0
Hyperventilation	67	0
Hypopnoea	136	0
Hypoventilation	1	0
Irregular breathing	29	0
Mouth breathing	7	0
Nocturnal dyspnoea	2	0
Obstructive sleep apnoea syndrome	1	0
Orthopnoea	4	0
Respiration abnormal	74	0
Respiratory arrest	23	0
Respiratory depression	1	0
Respiratory distress	21	0
Sleep apnoea syndrome	17	0
Tachypnoea	33	0
<i>Bronchial conditions NEC</i>		
Bronchial secretion retention	4	0
Bronchiectasis	16	0
<i>Bronchospasm and obstruction</i>		
Asthma	443	1
Asthma exercise induced	1	0
Asthma late onset	3	0
Bronchospasm	19	0
Chronic obstructive pulmonary disease	29	1
Cough variant asthma	8	0
Obstructive airways disorder	14	0
Reversible airways obstruction	1	0
Wheezing	491	0
<i>Conditions associated with abnormal gas exchange</i>		
Asphyxia	2	0
Cyanosis central	1	0
Hyperoxia	1	0
Hypoxia	36	2
Respiratory acidosis	2	0
<i>Coughing and associated symptoms</i>		
Allergic cough	9	0
Atopic cough	1	0
Cough	3069	1
Cough decreased	2	0
Haemoptysis	77	0
Productive cough	202	0
Sputum discoloured	11	0
Sputum increased	4	0
<i>Diaphragmatic disorders</i>		
Acquired diaphragmatic eventration	1	0
Diaphragm muscle weakness	1	0

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Diaphragmatic disorder	1	0
Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)		
Laryngeal disorder	1	0
Reflux laryngitis	3	0
Vocal cord disorder	2	0
Vocal cord dysfunction	3	0
Laryngeal spasm, oedema and obstruction		
Epiglottic oedema	1	0
Laryngeal obstruction	1	0
Laryngeal oedema	4	0
Laryngospasm	3	0
Stridor	28	0
Lower respiratory tract inflammatory and immunologic conditions		
Alveolitis	1	0
Autoimmune lung disease	1	0
Eosinophilic pneumonia	1	1
Hypersensitivity pneumonitis	1	0
Lower respiratory tract inflammation	1	0
Pneumonitis	36	2
Pulmonary sarcoidosis	3	0
Lower respiratory tract signs and symptoms		
Hiccups	37	0
Increased bronchial secretion	3	0
Increased viscosity of bronchial secretion	1	0
Lung hyperinflation	2	0
Lung opacity	4	0
Pleuritic pain	27	0
Pulmonary haemorrhage	1	0
Pulmonary pain	122	0
Rales	7	0
Respiratory fremitus	1	0
Mediastinal disorders		
Mediastinal mass	1	0
Pulmonary hilum mass	1	0
Nasal congestion and inflammations		
Nasal congestion	345	0
Nasal inflammation	5	0
Rhinitis allergic	28	0
Nasal disorders NEC		
Epistaxis	1123	0
Intranasal hypoaesthesia	2	0
Intranasal paraesthesia	1	0
Nasal crusting	2	0
Nasal disorder	4	0
Nasal dryness	36	0
Nasal mucosal discolouration	1	0
Nasal odour	7	0
Nasal oedema	8	0
Nasal polyps	2	0
Nasal pruritus	13	0
Nasal ulcer	3	0
Neonatal hypoxic conditions		

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Dry lung syndrome	1	0
Gaspings syndrome	1	0
Infantile apnoea	2	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Allergic sinusitis	3	0
Paranasal sinus inflammation	5	0
Sinonasal obstruction	15	0
Sinus congestion	75	0
Sinus disorder	9	0
<i>Parenchymal lung disorders NEC</i>		
Atelectasis	5	0
Combined pulmonary fibrosis and emphysema	1	0
Emphysema	3	0
Interstitial lung disease	13	1
Lung consolidation	7	0
Lung infiltration	2	1
Organising pneumonia	2	0
Pulmonary alveolar haemorrhage	1	0
Pulmonary cavitation	1	0
Pulmonary fibrosis	11	0
Pulmonary toxicity	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Hyperactive pharyngeal reflex	1	0
Pharyngeal enanthema	1	0
Pharyngeal erythema	10	0
Pharyngeal haemorrhage	2	0
Pharyngeal hypoaesthesia	40	0
Pharyngeal inflammation	5	0
Pharyngeal lesion	1	0
Pharyngeal mass	1	0
Pharyngeal oedema	15	0
Pharyngeal paraesthesia	57	0
Pharyngeal swelling	305	0
Pharyngeal ulceration	19	0
Tonsillar erythema	14	0
Tonsillar exudate	1	0
Tonsillar haemorrhage	1	0
Tonsillar hypertrophy	99	0
Tonsillar inflammation	4	0
Tonsillar ulcer	1	0
Tonsilloolith	1	0
<i>Pleural infections and inflammations</i>		
Pleurisy	41	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	44	0
Pneumothorax	15	0
Pneumothorax spontaneous	5	0
<i>Pulmonary hypertensions</i>		
Pulmonary hypertension	3	0
<i>Pulmonary oedemas</i>		
Acute respiratory distress syndrome	3	1
Pulmonary congestion	22	0
Pulmonary oedema	26	2

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary artery thrombosis	2	0
Pulmonary embolism	580	42
Pulmonary infarction	8	0
Pulmonary thrombosis	13	1
<i>Respiratory failures (excl neonatal)</i>		
Acute respiratory failure	3	1
Respiratory failure	15	2
<i>Respiratory signs and symptoms NEC</i>		
Allergic respiratory symptom	6	0
Diaphragmalgia	10	0
Nasal flaring	1	0
Painful respiration	20	1
Pleural rub	1	0
Respiratory symptom	22	0
Suffocation feeling	2	0
Use of accessory respiratory muscles	2	0
<i>Respiratory tract disorders NEC</i>		
Allergic respiratory disease	1	0
Aspiration	4	0
Lung disorder	13	0
Pulmonary mass	7	0
Respiratory disorder	17	1
Respiratory tract congestion	6	0
Respiratory tract haemorrhage	2	0
Respiratory tract inflammation	2	0
Respiratory tract irritation	9	0
Respiratory tract oedema	4	0
<i>Thoracic musculoskeletal disorders</i>		
Respiratory muscle weakness	2	0
<i>Tracheal disorders (excl infections and neoplasms)</i>		
Tracheal disorder	1	0
Tracheal pain	2	0
<i>Upper respiratory tract neoplasms</i>		
Tonsillar cyst	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	150	0
Catarrh	34	0
Choking	21	0
Choking sensation	7	0
Dry throat	188	0
Dysphonia	191	0
Increased upper airway secretion	6	0
Increased viscosity of upper respiratory secretion	37	0
Laryngeal pain	1	0
Nasal discharge discolouration	4	0
Nasal discomfort	59	0
Nasal obstruction	3	0
Oropharyngeal blistering	11	0
Oropharyngeal discolouration	1	0
Oropharyngeal discomfort	72	0
Oropharyngeal pain	3333	0
Oropharyngeal plaque	2	0

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Paranasal sinus discomfort	55	0
Rhinalgia	15	0
Rhinorrhoea	1101	0
Sinus pain	254	0
Sneezing	468	0
Snoring	8	0
Throat clearing	8	0
Throat irritation	271	0
Throat lesion	1	0
Throat tightness	298	0
Upper airway obstruction	3	0
Upper respiratory tract congestion	2	0
Upper respiratory tract irritation	1	0
Upper-airway cough syndrome	16	0
Yawning	31	0
<i>Vascular pulmonary disorders NEC</i>		
Acute chest syndrome	1	0
Respiratory disorders SOC TOTAL	22282	67

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	222	0
Acne cystic	28	0
Dermatitis acneiform	13	0
Oil acne	1	0
<i>Alopecias</i>		
Alopecia	510	0
Alopecia areata	87	0
Alopecia totalis	4	0
Alopecia universalis	3	0
Androgenetic alopecia	2	0
Diffuse alopecia	4	0
Hypotrichosis	3	0
Lichen planopilaris	4	0
Madarosis	9	0
<i>Angioedemas</i>		
Angioedema	289	0
Circumoral oedema	1	0
Circumoral swelling	1	0
Idiopathic angioedema	1	0
<i>Apocrine and eccrine gland disorders</i>		
Anhidrosis	2	0
Bromhidrosis	1	0
Cold sweat	896	0
Hidradenitis	5	0
Hyperhidrosis	2764	0
Hypohidrosis	3	0
Milia	2	0
Miliaria	121	0
Night sweats	980	0
Sweat discolouration	1	0
<i>Bullous conditions</i>		
Autoimmune blistering disease	1	0
Blister	568	0
Blister rupture	1	0
Blood blister	37	0
Dermatitis bullous	20	0
Erythema multiforme	45	0
Fracture blisters	1	0
Herpes gestationis	1	0
Mucous membrane pemphigoid	1	0
Pemphigoid	38	1
Pemphigus	10	0
Stevens-Johnson syndrome	7	0
Toxic epidermal necrolysis	2	1
<i>Connective tissue disorders</i>		
Chronic cutaneous lupus erythematosus	3	0
Dermatomyositis	14	0
Subacute cutaneous lupus erythematosus	3	0
<i>Dermal and epidermal conditions NEC</i>		
Acute febrile neutrophilic dermatosis	1	0
Dermatosis	2	0
Dry skin	311	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Koebner phenomenon	1	0
Macule	5	0
Neutrophilic dermatosis	1	0
Pain of skin	356	0
Papule	121	0
Pathergy reaction	1	0
Scab	30	0
Scar discomfort	1	0
Scar pain	20	0
Sensitive skin	238	0
Shagreen skin	1	0
Skin burning sensation	276	0
Skin degenerative disorder	2	0
Skin discolouration	170	0
Skin discomfort	6	0
Skin disorder	39	0
Skin fissures	12	0
Skin indentation	3	0
Skin induration	5	0
Skin lesion	55	0
Skin lesion inflammation	1	0
Skin necrosis	3	0
Skin odour abnormal	30	0
Skin plaque	4	0
Skin reaction	176	0
Skin sensitisation	45	0
Skin swelling	117	0
Skin texture abnormal	2	0
Skin tightness	30	0
Skin warm	376	0
Skin weeping	20	0
Sticky skin	3	0
Target skin lesion	3	0
Transient acantholytic dermatosis	1	0
Yellow skin	29	0
<i>Dermatitis and eczema</i>		
Autoimmune dermatitis	2	0
Dermatitis	172	0
Dermatitis allergic	310	0
Dermatitis atopic	66	0
Dermatitis contact	28	0
Dermatitis diaper	4	0
Dyshidrotic eczema	32	0
Eczema	455	0
Eczema asteatotic	18	0
Eczema infantile	1	0
Eczema nummular	8	0
Eczema vesicular	1	0
Eczema weeping	8	0
Hand dermatitis	5	0
Intertrigo	1	0
Neurodermatitis	4	0
Perioral dermatitis	3	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Seborrhoeic dermatitis	10	0
Skin irritation	161	0
Stasis dermatitis	3	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	35	0
Drug reaction with eosinophilia and systemic symptoms	2	0
Fixed eruption	3	0
Palmar-plantar erythrodysesthesia syndrome	3	0
Severe cutaneous adverse reaction	1	0
Toxic skin eruption	2	0
<i>Erythemas</i>		
Erythema	2548	0
Palmar erythema	4	0
Pernio-like erythema	1	0
Vancomycin infusion reaction	2	0
<i>Exfoliative conditions</i>		
Dermatitis exfoliative	2	0
Dermatitis exfoliative generalised	6	0
Exfoliative rash	26	0
Keratolysis exfoliativa acquired	2	0
Skin exfoliation	154	0
<i>Granulomatous and deep cutaneous inflammatory conditions</i>		
Cutaneous sarcoidosis	1	0
Granuloma annulare	8	0
Necrobiosis lipoidica diabetorum	1	0
<i>Hyperkeratoses</i>		
Hyperkeratosis	2	0
Keratosis pilaris	3	0
Lichenoid keratosis	5	0
<i>Hyperpigmentation disorders</i>		
Argyria	1	0
Chloasma	2	0
Ephelides	1	0
Skin hyperpigmentation	7	0
Solar lentigo	4	0
<i>Hypertrichoses</i>		
Hirsutism	2	0
Hypertrichosis	2	0
<i>Hypopigmentation disorders</i>		
Skin depigmentation	5	0
Skin hypopigmentation	1	0
Vitiligo	30	0
<i>Lipodystrophies</i>		
Lipoatrophy	4	0
Lipodystrophy acquired	1	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
Ingrowing nail	2	0
Nail bed bleeding	1	0
Nail discolouration	13	0
Nail disorder	8	0
Nail growth abnormal	1	0
Nail pigmentation	2	0
Nail ridging	3	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Onychalgia	10	0
Onychoclasia	10	0
Onychomadesis	3	0
Splinter haemorrhages	4	0
Panniculitides		
Erythema nodosum	35	0
Panniculitis	3	0
Papulosquamous conditions		
Erythema annulare	2	0
Lichen planus	30	0
Lichen sclerosus	13	0
Parapsoriasis	9	0
Pityriasis alba	1	0
Pityriasis rosea	146	0
Pityriasis rubra pilaris	1	0
Photosensitivity and photodermatosis conditions		
Actinic prurigo	1	0
Photosensitivity reaction	74	0
Polymorphic light eruption	4	0
Solar dermatitis	2	0
Pigmentation changes NEC		
Haemosiderin stain	1	0
Pigmentation disorder	18	0
Pilar disorders NEC		
Hair colour changes	11	0
Hair disorder	1	0
Hair growth abnormal	15	0
Hair texture abnormal	7	0
Piloerection	29	0
Pseudofolliculitis	3	0
Trichorrhexis	3	0
Pruritus NEC		
Itching scar	10	0
Polymorphic eruption of pregnancy	1	0
Pruritus	6523	0
Psoriatic conditions		
Dermatitis psoriasiform	6	0
Guttate psoriasis	27	0
Nail psoriasis	3	0
Palmoplantar pustulosis	4	0
Psoriasis	276	0
Pustular psoriasis	5	0
Rebound psoriasis	2	0
Purpura and related conditions		
Ecchymosis	1	0
Henoch-Schonlein purpura	16	0
Petechiae	164	0
Purpura	66	0
Pustular conditions		
Acute generalised exanthematous pustulosis	2	0
Rashes, eruptions and exanthems NEC		
Butterfly rash	8	0
Rash	6860	1

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Rash erythematous	1490	0
Rash macular	592	0
Rash maculo-papular	69	0
Rash morbilliform	51	0
Rash papular	414	0
Rash pruritic	1453	0
Rash scarlatiniform	1	0
Rash vesicular	92	0
Systemic lupus erythematosus rash	9	0
Rosaceas		
Erythematotelangiectatic rosacea	1	0
Papulopustular rosacea	1	0
Rosacea	40	0
Scaly conditions		
Dandruff	5	0
Pityriasis	32	0
Sebaceous gland disorders		
Sebaceous glands overactivity	1	0
Seborrhoea	15	0
Skin and subcutaneous conditions NEC		
Cellulite	2	0
Cutaneous symptom	6	0
Reactive perforating collagenosis	1	0
Skin mass	32	0
Skin and subcutaneous tissue ulcerations		
Ischaemic skin ulcer	1	0
Mucocutaneous ulceration	1	0
Pyoderma gangrenosum	2	0
Scleroderma associated digital ulcer	1	0
Skin erosion	32	0
Skin ulcer	25	0
Skin cysts and polyps		
Dermal cyst	21	0
Skin dystrophies		
Keloid scar	3	0
Skin wrinkling	4	0
Skin haemorrhages		
Haemorrhage subcutaneous	15	0
Skin haemorrhage	25	0
Skin hyperplasias and hypertrophies		
Skin hypertrophy	2	0
Skin hypoplasias and atrophies		
Skin atrophy	3	0
Skin striae	8	0
Skin injuries and mechanical dermatoses		
Decubitus ulcer	3	0
Needle track marks	5	0
Skin preneoplastic conditions NEC		
Actinic keratosis	1	0
Skin vascular conditions NEC		
Angiodermatitis	2	0
Skin oedema	5	0
Vascular skin disorder	1	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
<i>Skin vasculitides</i>		
Capillaritis	4	0
Cutaneous vasculitis	16	0
Hypersensitivity vasculitis	1	0
Vasculitic rash	22	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	32	0
<i>Telangiectasia and related conditions</i>		
Spider naevus	1	0
Telangiectasia	1	0
<i>Urticarias</i>		
Chronic spontaneous urticaria	16	0
Cold urticaria	11	0
Idiopathic urticaria	4	0
Mechanical urticaria	18	0
Solar urticaria	4	0
Urticaria	2385	0
Urticaria cholinergic	2	0
Urticaria chronic	46	0
Urticaria contact	1	0
Urticaria papular	7	0
Urticaria thermal	11	0
Urticarial vasculitis	8	0
Skin disorders SOC TOTAL	34866	3

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Reaction Name	Total	Fatal
Social circumstances		
<i>Age related issues</i>		
Infant	2	0
Menarche	3	0
Menopause	53	0
Postmenopause	5	0
<i>Criminal activity</i>		
Verbal abuse	1	0
<i>Dependents</i>		
Sick relative	7	0
<i>Dietary and nutritional issues</i>		
Feeding tube user	1	0
<i>Disability issues</i>		
Bedridden	40	0
Breast prosthesis user	3	0
Disability	4	0
Hearing disability	4	0
Housebound	1	0
Immobile	14	0
Impaired driving ability	5	0
Impaired work ability	21	0
Loss of personal independence in daily activities	69	0
Mental disability	1	0
Physical disability	7	0
Sight disability	13	0
Sitting disability	6	0
Walking aid user	2	0
Walking disability	3	0
Wheelchair user	1	0
<i>Economic circumstances</i>		
High income	1	0
Low income	1	0
<i>Educational issues</i>		
Educational problem	1	0
Illiteracy	3	0
<i>Employment issues</i>		
Job dissatisfaction	1	0
Retirement	4	0
Sick leave	1	0
Stress at work	3	0
<i>Family and partner issues</i>		
Bed sharing	1	0
Family stress	1	0
<i>Non-occupational and unspecified environmental problems</i>		
Flooding	2	0
Water pollution	2	0
<i>Pregnancy related circumstances</i>		
Breast feeding	17	0
Multigravida	1	0
Parity	1	0
<i>Social issues NEC</i>		
Exercise adequate	2	0
Hair dye user	2	0
Impaired quality of life	4	0

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Reaction Name	Total	Fatal
Social circumstances Social circumstances cont'd		
Patient dissatisfaction with treatment	1	0
Tobacco use		
Ex-tobacco user	1	0
Non-tobacco user	6	0
Tobacco user	1	0
Social circumstances SOC TOTAL	323	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Adrenal gland therapeutic procedures</i>		
Adrenalectomy	1	0
<i>Anaesthesia and allied procedures</i>		
Local anaesthesia	2	0
Nerve block	5	0
<i>Analgesia supportive care</i>		
Analgesic therapy	2	0
<i>Antiinfective therapies</i>		
COVID-19 prophylaxis	1	0
COVID-19 treatment	4	0
<i>Arterial therapeutic procedures (excl aortic)</i>		
Splenic artery embolisation	1	0
<i>Blood and blood product treatment</i>		
Transfusion	2	0
<i>Breast therapeutic procedures NEC</i>		
Axillary lymphadenectomy	3	0
Mammoplasty	1	0
<i>Bronchial and pulmonary therapeutic procedures</i>		
Airway secretion clearance therapy	1	0
Lung transplant	1	0
<i>Cardiac therapeutic procedures NEC</i>		
Cardiac operation	1	0
<i>Contraceptive methods female</i>		
Contraception	1	0
Contraceptive implant	3	0
Oral contraception	1	0
<i>Contraceptive methods male</i>		
Condom	1	0
<i>Dietary and nutritional therapies</i>		
Medical diet	8	0
Nothing by mouth order	13	0
Wheat-free diet	1	0
<i>External ear therapeutic procedures</i>		
Ear irrigation	1	0
<i>Facial therapeutic procedures</i>		
Face lift	1	0
<i>Fertility and fertilisation interventions female</i>		
Endometrial scratching	1	0
Ovulation induction	2	0
<i>Gastric therapeutic procedures</i>		
Gastric operation	1	0
<i>Gastrointestinal therapeutic procedures NEC</i>		
Intestinal anastomosis	1	0
Prophylaxis of nausea and vomiting	16	0
<i>Gynaecological therapeutic procedures NEC</i>		
Menstrual cycle management	15	0
<i>Haematological therapeutic procedures NEC</i>		
Anticoagulant therapy	1	0
<i>Head, neck and oral cavity therapeutic procedures NEC</i>		
Neck lift	1	0
<i>Hernia repairs</i>		
Hernia repair	1	0
<i>Hormonal therapeutic procedures NEC</i>		

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Surgical & medical procedures cont'd</i>		
Hormone replacement therapy	2	0
Hormone therapy	8	0
Immunisations		
COVID-19 immunisation	98	0
Immunisation	506	1
Vaccine coadministration	1	0
Induced abortions		
Abortion induced	1	0
Joint therapeutic procedures		
Joint injection	6	0
Joint surgery	1	0
Knee arthroplasty	1	0
Large intestine therapeutic procedures		
Appendectomy	3	0
Limb therapeutic procedures		
Amputation	1	0
Arm amputation	1	0
Limb immobilisation	12	0
Limb operation	10	0
Lymphoid tissue therapeutic procedures		
Lymphadenectomy	2	0
Splenectomy	1	0
Mastectomies		
Breast conserving surgery	5	0
Nail therapeutic procedures		
Nail operation	3	0
Nervous system therapeutic procedures NEC		
Medical induction of coma	1	0
Multiple sclerosis relapse prophylaxis	3	0
Obstetric therapeutic procedures		
Caesarean section	1	0
Labour stimulation	1	0
Orbit and globe therapeutic procedures		
Strabismus correction	1	0
Ovarian therapeutic procedures		
Ovarian operation	1	0
Peripheral nerve therapeutic procedures		
Neurolysis	1	0
Peripheral nerve neurostimulation	1	0
Phototherapies		
UV light therapy	1	0
Prophylactic procedures NEC		
Anaphylaxis prophylaxis	3	0
Immune tolerance induction	1	0
Prophylaxis against transplant rejection	1	0
Reproductive system disorder prophylaxis	1	0
Psychiatric therapies		
Electroconvulsive therapy	2	0
Renal therapeutic procedures		
Dialysis	1	0
Respiratory tract therapeutic procedures NEC		
Asthma prophylaxis	4	0
Retinal therapeutic procedures		

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Reaction Name	Total	Fatal
Surgical & medical procedures		
Retinopexy	1	0
Skin and subcutaneous tissue therapeutic procedures NEC		
Dermal filler injection	4	0
Therapeutic skin care topical	1	0
Skull and brain therapeutic procedures		
Cerebrovascular operation	1	0
Posterior fossa decompression	1	0
Small intestine therapeutic procedures		
Ileostomy	1	0
Spine and spinal cord therapeutic procedures		
Spinal decompression	1	0
Tendon therapeutic procedures		
Tenodesis	1	0
Therapeutic bladder catheterisation		
Bladder catheterisation	2	0
Therapeutic procedures NEC		
Abscess drainage	1	0
Anaphylaxis treatment	7	0
Bed rest	7	0
Fatigue management	1	0
Hospitalisation	15	0
Injection	54	0
Interchange of vaccine products	352	0
Lesion excision	1	0
Localised alternating hot and cold therapy	2	0
Magnetic therapy	1	0
Mass excision	5	0
Medical procedure	1	0
Medication dilution	2	0
Physical fitness training	1	0
Product used for unknown indication	2	0
Promotion of wound healing	1	0
Specialist consultation	1	0
Stent placement	1	0
Stoma care	1	0
Therapeutic procedure	2	0
Therapy change	2	0
Tracheal therapeutic procedures		
Tracheostomy	1	0
Uterine therapeutic procedures		
Endometrial ablation	2	0
Vascular therapeutic procedures NEC		
Vasodilation procedure	1	0
Surgical & medical procedures SOC TOTAL	1257	1

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Accelerated and malignant hypertension</i>		
Accelerated hypertension	2	0
Hypertensive crisis	16	0
Hypertensive urgency	2	0
Malignant hypertension	4	0
<i>Aneurysms and dissections non-site specific</i>		
Aneurysm	4	0
Aneurysm ruptured	1	0
Artery dissection	2	0
<i>Aortic aneurysms and dissections</i>		
Acute aortic syndrome	1	0
Aortic aneurysm	2	0
Aortic aneurysm rupture	1	1
Aortic dissection	1	0
<i>Aortic embolism and thrombosis</i>		
Aortic embolus	5	0
Aortic thrombosis	4	0
<i>Aortic infections and inflammations</i>		
Aortitis	1	0
<i>Aortic necrosis and vascular insufficiency</i>		
Aortic occlusion	1	0
Aortic stenosis	2	0
<i>Arterial infections and inflammations</i>		
Arteritis	2	0
Giant cell arteritis	25	0
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	20	0
Labile blood pressure	5	0
<i>Bruising, ecchymosis and purpura</i>		
Achenbach syndrome	4	0
<i>Circulatory collapse and shock</i>		
CT hypotension complex	2	0
Circulatory collapse	96	0
Hypoperfusion	2	0
Hypovolaemic shock	2	1
Neurogenic shock	24	0
Peripheral circulatory failure	6	0
Shock	25	0
Shock symptom	4	0
<i>Haemorrhages NEC</i>		
Arterial haemorrhage	1	0
Bloody discharge	26	0
Haematoma	52	0
Haemorrhage	1422	2
Internal haemorrhage	14	1
Venous haemorrhage	2	0
<i>Lymphangiopathies</i>		
Lymphangiopathy	1	0
Lymphocele	7	0
Lymphorrhoea	2	0
Lymphostasis	1	0
<i>Lymphoedemas</i>		
Lymphoedema	253	0

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Reaction Name	Total	Fatal
Vascular disorders <small>Vascular disorders cont'd</small>		
<i>Non-site specific embolism and thrombosis</i>		
Arterial thrombosis	5	0
Embolism	68	0
Embolism arterial	2	0
Embolism venous	9	1
Microembolism	2	0
Thrombosis	559	12
Venous thrombosis	8	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Arterial occlusive disease	2	0
Arterial spasm	1	0
Arteriosclerosis	4	0
Haemorrhagic infarction	1	0
Infarction	3	0
Ischaemia	11	0
Peripheral venous disease	2	0
Vascular compression	1	0
Vascular occlusion	1	0
Vasospasm	1	0
<i>Non-site specific vascular disorders NEC</i>		
Angiopathy	1	0
Capillary disorder	1	0
Capillary fragility	6	0
Endothelial dysfunction	1	0
Haemodynamic instability	1	0
Superficial vein prominence	3	0
Vascular fragility	1	0
Vascular pain	45	0
Vascular wall hypertrophy	1	0
Vasodilatation	47	0
Vein discolouration	8	0
Vein disorder	9	0
Vein rupture	7	0
<i>Peripheral aneurysms and dissections</i>		
Peripheral artery aneurysm	1	0
<i>Peripheral embolism and thrombosis</i>		
Axillary vein thrombosis	1	0
Blue toe syndrome	36	0
Deep vein thrombosis	379	1
Femoral artery embolism	1	0
Jugular vein thrombosis	5	0
Pelvic venous thrombosis	4	0
Peripheral artery thrombosis	4	0
Peripheral embolism	4	0
Subclavian artery thrombosis	1	0
Subclavian vein thrombosis	4	0
Superficial vein thrombosis	31	0
Thrombophlebitis	32	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	61	0
Erythromelalgia	2	0
Flushing	490	0
Hot flush	1282	0

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Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
Peripheral vascular disorder	4	0
Vein wall hypertrophy	1	0
Peripheral vasoconstriction, necrosis and vascular insufficiency		
Claudication of jaw muscles	1	0
Extremity necrosis	3	0
Iliac artery occlusion	1	0
Intermittent claudication	3	0
Ischaemic limb pain	2	0
Jugular vein occlusion	2	0
May-Thurner syndrome	1	0
Peripheral arterial occlusive disease	2	0
Peripheral artery occlusion	1	0
Peripheral coldness	404	0
Peripheral ischaemia	14	0
Poor peripheral circulation	24	0
Raynaud's phenomenon	80	0
Subclavian vein occlusion	1	0
Vasoconstriction	3	0
Phlebitis NEC		
Phlebitis	39	0
Phlebitis superficial	10	0
Site specific embolism and thrombosis NEC		
Brachiocephalic vein thrombosis	1	0
Site specific vascular disorders NEC		
Aortic disorder	1	0
Aortic rupture	2	2
Inferior vena cava dilatation	1	0
Pallor	455	0
Varicose veins NEC		
Spider vein	8	0
Varicophlebitis	4	0
Varicose vein	43	0
Varicose vein ruptured	1	0
Vascular hypertensive disorders NEC		
Diastolic hypertension	7	0
Essential hypertension	6	0
Hypertension	815	0
Labile hypertension	2	0
Orthostatic hypertension	2	0
Secondary hypertension	1	0
Systolic hypertension	7	0
White coat hypertension	1	0
Vascular hypotensive disorders		
Capillary leak syndrome	1	0
Diastolic hypotension	1	0
Hypotension	479	1
Orthostatic hypotension	35	0
Vasculitides NEC		
Behcet's syndrome	5	0
Diffuse vasculitis	1	0
Granulomatosis with polyangiitis	4	1
Lupus vasculitis	1	0
MAGIC syndrome	2	0

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Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
Thromboangiitis obliterans	1	0
Vasculitis	58	0
<i>Vena caval embolism and thrombosis</i>		
Vena cava embolism	1	0
Vena cava thrombosis	1	0
Vascular disorders SOC TOTAL	7739	23
TOTAL REACTIONS FOR DRUG	497104	815
TOTAL REPORTS	172476	
TOTAL FATAL OUTCOME REPORTS		815