

COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

All UK spontaneous reports received between 9/12/20 and 11/08/21 for mRNA Pfizer/BioNTech vaccine analysis print

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: 12-Aug-2021

Data Lock Date: 11-Aug-2021 18:30:09

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemia deficiencies</i>		
Anaemia folate deficiency	1	0
Anaemia vitamin B12 deficiency	2	0
Deficiency anaemia	1	0
Iron deficiency anaemia	6	0
<i>Anaemias NEC</i>		
Anaemia	82	0
Anaemia macrocytic	1	0
Anaemia megaloblastic	1	0
Autoimmune anaemia	2	0
Microcytic anaemia	1	0
<i>Anaemias haemolytic NEC</i>		
Haemolytic anaemia	5	0
<i>Anaemias haemolytic immune</i>		
Autoimmune haemolytic anaemia	9	0
<i>Anaemias haemolytic mechanical factor</i>		
Microangiopathic haemolytic anaemia	1	0
<i>Bleeding tendencies</i>		
Haemorrhagic diathesis	1	0
Increased tendency to bruise	31	0
Spontaneous haematoma	2	0
<i>Coagulation factor deficiencies</i>		
Acquired haemophilia	2	0
<i>Coagulopathies</i>		
Abnormal clotting factor	3	0
Antiphospholipid syndrome	5	0
Coagulopathy	15	1
Disseminated intravascular coagulation	2	0
Hypercoagulation	3	0
Thrombotic microangiopathy	2	0
<i>Eosinophilic disorders</i>		
Eosinophilia	12	0
<i>Haematological disorders</i>		
Blood disorder	3	0
Hypergammaglobulinaemia	1	0
Hyperviscosity syndrome	1	0
Mast cell activation syndrome	6	0
Methaemoglobinaemia	1	0
<i>Haemolyses NEC</i>		
Haemolysis	6	0
Intravascular haemolysis	1	0
<i>Leukocytoses NEC</i>		
Leukocytosis	1	0
Lymphocytosis	5	0
Neutrophilia	7	0
<i>Leukopenias NEC</i>		
Leukopenia	4	1
Lymphopenia	4	0
<i>Lymphatic system disorders NEC</i>		
Abdominal lymphadenopathy	1	0
Hilar lymphadenopathy	2	0
Lymph node pain	1225	0
Lymph node ulcer	1	0

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Reaction Name	Total	Fatal
Blood disorders Blood disorders cont'd		
Lymphadenitis	107	0
Lymphadenopathy	8032	0
Lymphatic disorder	1	0
Necrotic lymphadenopathy	3	0
Pseudolymphoma	10	0
Retroperitoneal lymphadenopathy	1	0
<i>Marrow depression and hypoplastic anaemias</i>		
Aplasia pure red cell	2	0
Hypoplastic anaemia	1	0
Myelosuppression	2	0
Pancytopenia	6	0
<i>Neutropenias</i>		
Autoimmune neutropenia	2	0
Neutropenia	36	0
<i>Platelet disorders NEC</i>		
Platelet anisocytosis	1	0
Platelet disorder	2	0
<i>Purpuras (excl thrombocytopenic)</i>		
Purpura non-thrombocytopenic	1	0
<i>Red blood cell abnormal findings NEC</i>		
Polychromasia	2	0
Red blood cell abnormality	2	0
<i>Spleen disorders</i>		
Spleen atrophy	1	0
Splenic infarction	2	0
Splenic thrombosis	1	0
Splenic vein thrombosis	1	0
Splenomegaly	10	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	69	0
Thrombocytopenia	165	1
Thrombocytopenic purpura	4	0
Thrombotic thrombocytopenic purpura	5	0
<i>Thrombocytoses</i>		
Thrombocytosis	5	0
Blood disorders SOC TOTAL	9933	3

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac conduction disorders</i>		
Atrioventricular block	9	1
Atrioventricular block complete	2	1
Atrioventricular block first degree	1	0
Atrioventricular block second degree	2	0
Bundle branch block	2	0
Bundle branch block right	1	0
<i>Cardiac disorders NEC</i>		
Acute cardiac event	3	0
Cardiac disorder	39	0
Cardiac dysfunction	1	0
Cardiovascular deconditioning	1	0
Cardiovascular disorder	5	0
Intracardiac thrombus	4	0
<i>Cardiac hypertensive complications</i>		
Hypertensive heart disease	2	0
<i>Cardiac infections and inflammations NEC</i>		
Carditis	2	0
<i>Cardiac signs and symptoms NEC</i>		
Cardiac discomfort	9	0
Cardiovascular symptom	1	0
Palpitations	2233	0
<i>Cardiac valve disorders NEC</i>		
Cardiac valve disease	1	0
Heart valve incompetence	1	0
<i>Cardiomyopathies</i>		
Cardiomyopathy	4	0
Congestive cardiomyopathy	5	0
Stress cardiomyopathy	2	0
<i>Coronary artery disorders NEC</i>		
Coronary artery disease	5	2
Coronary artery occlusion	2	0
Coronary artery thrombosis	1	1
<i>Endocarditis NEC</i>		
Endocarditis noninfective	1	1
<i>Heart failures NEC</i>		
Cardiac failure	53	7
Cardiac failure acute	2	0
Cardiac failure chronic	1	0
Cardiac failure congestive	3	1
Cardiogenic shock	4	1
Cardiopulmonary failure	1	1
<i>Ischaemic coronary artery disorders</i>		
Acute coronary syndrome	3	0
Acute myocardial infarction	17	1
Angina pectoris	126	0
Angina unstable	2	0
Arteriospasm coronary	1	0
Microvascular coronary artery disease	2	0
Myocardial infarction	161	29
Myocardial ischaemia	6	2
<i>Left ventricular failures</i>		
Acute left ventricular failure	1	1

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Reaction Name	Total	Fatal
Cardiac disorders Cardiac disorders cont'd		
Left ventricular failure	6	2
Mitral valvular disorders		
Mitral valve incompetence	4	0
Mitral valve prolapse	1	0
Myocardial disorders NEC		
Cardiac amyloidosis	1	0
Cardiomegaly	17	1
Left atrial dilatation	1	0
Left ventricular dysfunction	5	0
Left ventricular enlargement	1	0
Left ventricular hypertrophy	1	0
Myocardial fibrosis	1	0
Myocardial haemorrhage	1	0
Myocardial oedema	3	0
Myocardial rupture	1	0
Right ventricular enlargement	1	0
Ventricular hypertrophy	2	0
Noninfectious myocarditis		
Myocarditis	182	1
Noninfectious pericarditis		
Pericarditis	153	1
Pericardial disorders NEC		
Pericardial effusion	19	0
Pericardial haemorrhage	3	3
Pericardial rub	1	0
Rate and rhythm disorders NEC		
Arrhythmia	90	0
Bradycardia	50	0
Bradycardia foetal	1	1
Cardiac flutter	271	0
Extrasystoles	107	0
Paroxysmal arrhythmia	1	0
Postural orthostatic tachycardia syndrome	13	0
Tachyarrhythmia	1	0
Tachycardia	597	0
Tachycardia paroxysmal	1	0
Right ventricular failures		
Cor pulmonale	1	0
Supraventricular arrhythmias		
Arrhythmia supraventricular	8	0
Atrial fibrillation	153	0
Atrial flutter	12	0
Atrial tachycardia	4	0
Nodal arrhythmia	1	0
Sinus arrest	1	0
Sinus arrhythmia	2	0
Sinus bradycardia	6	0
Sinus tachycardia	41	0
Supraventricular extrasystoles	2	0
Supraventricular tachycardia	30	0
Tricuspid valvular disorders		
Tricuspid valve incompetence	1	0
Ventricular arrhythmias and cardiac arrest		

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Reaction Name	Total	Fatal
Cardiac disorders Cardiac disorders cont'd		
Cardiac arrest	83	32
Cardio-respiratory arrest	1	1
Pulseless electrical activity	3	0
Ventricular arrhythmia	4	0
Ventricular extrasystoles	13	0
Ventricular fibrillation	6	1
Ventricular tachycardia	10	0
Cardiac disorders SOC TOTAL	4640	92

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Cardiac disorders congenital NEC</i>		
Heart disease congenital	11	0
<i>Cardiac septal defects congenital</i>		
Hypertrophic cardiomyopathy	1	0
<i>Central nervous system disorders congenital NEC</i>		
Spina bifida	1	0
<i>Cerebellar disorders congenital</i>		
Arnold-Chiari malformation	1	0
Hereditary ataxia	1	0
<i>Cerebral disorders congenital</i>		
Anencephaly	2	0
Cerebral palsy	2	0
<i>Chemically-induced congenital syndromes</i>		
Foetal warfarin syndrome	1	0
<i>Coagulation disorders congenital</i>		
Haemophilia	1	0
<i>Congenital disorders NEC</i>		
Foetal malformation	1	0
Young's syndrome	1	0
<i>Connective tissue disorders congenital</i>		
Ehlers-Danlos syndrome	2	0
<i>External ear disorders congenital</i>		
Anotia	1	0
<i>Gastrointestinal tract disorders congenital NEC</i>		
Gastroschisis	1	0
<i>Great vessel disorders congenital</i>		
Transposition of the great vessels	1	0
<i>Haematological disorders congenital NEC</i>		
Amegakaryocytic thrombocytopenia	1	0
Neonatal alloimmune thrombocytopenia	1	0
<i>Haemoglobinopathies congenital</i>		
Congenital methaemoglobinaemia	1	0
<i>Lymphatic system disorders congenital</i>		
Cystic lymphangioma	3	0
<i>Male reproductive tract disorders congenital</i>		
Cryptorchism	1	0
Micropenis	2	0
Phimosis	1	0
<i>Musculoskeletal and connective tissue disorders of limbs congenital</i>		
Developmental hip dysplasia	1	0
<i>Musculoskeletal and connective tissue disorders of spine congenital</i>		
Brachyolmia	1	0
<i>Musculoskeletal disorders congenital NEC</i>		
Congenital multiplex arthrogyposis	1	0
<i>Neurological disorders congenital NEC</i>		
Familial hemiplegic migraine	2	0
Familial periodic paralysis	1	0
Moebius II syndrome	1	0
Tourette's disorder	2	0
<i>Ocular disorders congenital NEC</i>		
Colour blindness	2	0
<i>Palate disorders congenital</i>		
Cleft lip and palate	1	0

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Reaction Name	Total	Fatal
Congenital disorders Congenital disorders cont'd		
<i>Peripheral nervous system disorders congenital NEC</i>		
Hereditary neuropathy with liability to pressure palsies	1	0
Paroxysmal extreme pain disorder	1	0
<i>Pulmonary and bronchial disorders congenital</i>		
Congenital cystic lung	1	0
<i>Retinal disorders congenital</i>		
Retinitis pigmentosa	1	0
<i>Skin and subcutaneous tissue disorders congenital NEC</i>		
Acral peeling skin syndrome	1	0
<i>Tongue disorders congenital</i>		
Ankyloglossia congenital	1	0
Congenital disorders SOC TOTAL	56	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear canal erythema	1	0
Ear congestion	23	0
Ear discomfort	76	0
Ear disorder	14	0
Ear haemorrhage	9	0
Ear pain	741	0
Ear pruritus	8	0
Ear swelling	27	0
Otorrhoea	3	0
<i>Eustachian tube disorders</i>		
Eustachian tube disorder	4	0
Eustachian tube dysfunction	7	0
Eustachian tube obstruction	3	0
<i>External ear disorders NEC</i>		
Auricular swelling	1	0
Excessive cerumen production	5	0
External ear pain	2	0
Red ear syndrome	2	0
<i>External ear infections and inflammations</i>		
External ear inflammation	2	0
<i>Hearing disorders NEC</i>		
Auditory disorder	7	0
Diplacusis	2	0
<i>Hearing losses</i>		
Conductive deafness	1	0
Deafness	181	0
Deafness bilateral	6	0
Deafness neurosensory	13	0
Deafness transitory	4	0
Deafness unilateral	25	0
Hypoacusis	136	0
Sudden hearing loss	30	0
<i>Hyperacusia</i>		
Hyperacusis	40	0
Misophonia	3	0
<i>Inner ear disorders NEC</i>		
Acute vestibular syndrome	1	0
Inner ear disorder	9	0
Meniere's disease	9	0
Vestibular disorder	8	0
<i>Inner ear infections and inflammations</i>		
Inner ear inflammation	6	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	39	0
Tinnitus	1466	0
Vertigo	1043	0
Vertigo labyrinthine	9	0
Vertigo positional	61	0
<i>Mastoid disorders</i>		
Mastoid effusion	1	0
<i>Middle ear disorders NEC</i>		
Middle ear disorder	3	0

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Reaction Name	Total	Fatal
Ear disorders Ear disorders cont'd		
Middle ear effusion	1	0
<i>Middle ear infections and inflammations</i>		
Middle ear inflammation	1	0
<i>Tympanic membrane disorders (excl infections)</i>		
Tympanic membrane perforation	2	0
Ear disorders SOC TOTAL	4035	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Autoimmune thyroiditis	1	0
Thyroiditis	10	0
Thyroiditis acute	2	0
Thyroiditis subacute	2	0
<i>Adrenal cortical hypofunctions</i>		
Addison's disease	2	0
Adrenocortical insufficiency acute	10	0
<i>Adrenal gland disorders NEC</i>		
Adrenal haemorrhage	2	0
<i>Anterior pituitary hyperfunction</i>		
Pituitary-dependent Cushing's syndrome	1	0
<i>Anterior pituitary hypofunction</i>		
Hypopituitarism	1	0
<i>Endocrine abnormalities of gonadal function NEC</i>		
Oestrogen deficiency	1	0
<i>Endocrine abnormalities of puberty</i>		
Delayed menarche	3	0
Premature menarche	14	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	31	0
Ovulation delayed	21	0
<i>Thyroid disorders NEC</i>		
Autoimmune thyroid disorder	1	0
Goitre	10	0
Thyroid disorder	6	0
Thyroid mass	1	0
Thyroid pain	3	0
<i>Thyroid hyperfunction disorders</i>		
Basedow's disease	3	0
Hyperthyroidism	21	0
Thyrotoxic crisis	3	0
<i>Thyroid hypofunction disorders</i>		
Autoimmune hypothyroidism	1	0
Hypothyroidism	21	0
Myxoedema	1	0
Endocrine disorders SOC TOTAL	172	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Amblyopic vision impairment</i>		
Amblyopia	5	0
<i>Cataract conditions</i>		
Cataract	10	0
<i>Choroid and vitreous haemorrhages and vascular disorders</i>		
Choroidal haemorrhage	1	0
Choroidal neovascularisation	1	0
Vitreous haemorrhage	3	0
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Chorioretinopathy	2	0
Vitreous detachment	17	0
Vitreous floaters	58	0
<i>Colour blindness (incl acquired)</i>		
Dyschromatopsia	5	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	32	0
<i>Conjunctival infections, irritations and inflammations</i>		
Conjunctival hyperaemia	2	0
Conjunctival irritation	1	0
Conjunctival oedema	3	0
<i>Corneal infections, oedemas and inflammations</i>		
Keratitis	6	0
Ulcerative keratitis	4	0
<i>Eyelid movement disorders</i>		
Blepharospasm	107	0
Excessive eye blinking	4	0
Eyelid function disorder	3	0
Eyelid myokymia	3	0
Eyelid ptosis	37	0
Paralytic lagophthalmos	2	0
<i>Glaucomas (excl congenital)</i>		
Angle closure glaucoma	2	0
Glaucoma	5	0
<i>Iris and ciliary body structural change, deposit and degeneration</i>		
Eye colour change	2	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Autoimmune uveitis	1	0
Iridocyclitis	9	0
Iritis	5	0
Uveitis	32	0
<i>Lacrimation disorders</i>		
Dry eye	112	0
Lacrimation increased	104	0
<i>Lid bleeding and vascular disorders</i>		
Eyelid bleeding	1	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Blepharitis	7	0
Chalazion	6	0
Eczema eyelids	4	0
Erythema of eyelid	7	0
Eyelid cyst	4	0
Eyelid irritation	2	0
Eyelid margin crusting	3	0

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Eye disorders Eye disorders cont'd		
Eyelid oedema	3	0
Eyelid rash	12	0
Swelling of eyelid	101	0
Lid, lash and lacrimal structural disorders		
Dermatochalasis	1	0
Eyelash changes	1	0
Eyelid exfoliation	2	0
Eyelid skin dryness	2	0
Floppy eyelid syndrome	1	0
Growth of eyelashes	2	0
Lagophthalmos	2	0
Ocular bleeding and vascular disorders NEC		
Eye haematoma	4	0
Eye haemorrhage	21	0
Ocular vascular disorder	1	0
Ophthalmic vein thrombosis	1	0
Ocular disorders NEC		
Dark circles under eyes	6	0
Eye disorder	27	0
Eye oedema	10	0
Eye pain	794	0
Eye swelling	386	0
Eye symptom	8	0
Eye ulcer	2	0
Eyelid disorder	10	0
Eyelid pain	10	0
Eyelids pruritus	5	0
Ocular discomfort	24	0
Periorbital oedema	16	0
Periorbital pain	1	0
Periorbital swelling	98	0
Retinal disorder	2	0
Vitreous disorder	1	0
Ocular infections, inflammations and associated manifestations		
Eye allergy	9	0
Eye discharge	18	0
Eye inflammation	19	0
Eye irritation	77	0
Eye pruritus	194	0
Limbal swelling	2	0
Ocular hyperaemia	166	0
Ocular nerve and muscle disorders		
Binocular eye movement disorder	1	0
Extraocular muscle disorder	1	0
Extraocular muscle paresis	1	0
Eye movement disorder	23	0
Gaze palsy	1	0
Ocular myasthenia	1	0
Ophthalmoplegia	3	0
Strabismus	5	0
Ocular sensation disorders		
Abnormal sensation in eye	13	0
Asthenopia	120	0

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Eye disorders Eye disorders cont'd		
Eye paraesthesia	1	0
Foreign body sensation in eyes	16	0
Hypoaesthesia eye	13	0
Photophobia	321	0
Optic disc abnormalities NEC		
Papilloedema	4	0
Optic nerve bleeding and vascular disorders		
Optic disc haemorrhage	1	0
Optic ischaemic neuropathy	2	0
Orbital infections, inflammations and irritations		
Parophthalmia	1	0
Orbital structural change, deposit and degeneration		
Orbital oedema	2	0
Pupil disorders		
Miosis	2	0
Mydriasis	17	0
Pupil fixed	2	0
Pupils unequal	8	0
Refractive and accommodative disorders		
Accommodation disorder	1	0
Altered visual depth perception	2	0
Astigmatism	1	0
Myopia	1	0
Retinal bleeding and vascular disorders (excl retinopathy)		
Retinal artery occlusion	9	0
Retinal artery thrombosis	1	0
Retinal haemorrhage	5	0
Retinal vein occlusion	27	0
Retinal vein thrombosis	2	0
Retinal structural change, deposit and degeneration		
Macular degeneration	3	0
Macular hole	2	0
Macular rupture	1	0
Maculopathy	1	0
Neovascular age-related macular degeneration	2	0
Retinal detachment	3	0
Retinal tear	2	0
Retinal toxicity	3	0
Retinal, choroid and vitreous infections and inflammations		
Birdshot chorioretinopathy	1	0
Cystoid macular oedema	1	0
Macular oedema	3	0
Retinal vasculitis	3	0
Retinopathies NEC		
Acute macular outer retinopathy	1	0
Retinal exudates	2	0
Retinopathy	1	0
Scleral infections, irritations and inflammations		
Episcleritis	7	0
Scleritis	3	0
Scleral structural change, deposit and degeneration		
Scleral discolouration	2	0
Visual colour distortions		

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Eye disorders Eye disorders cont'd		
Chloropsia	3	0
Cyanopsia	1	0
Erythropsia	2	0
Xanthopsia	1	0
Visual disorders NEC		
Charles Bonnet syndrome	1	0
Diplopia	126	0
Glare	1	0
Halo vision	7	0
Heteronymous diplopia	1	0
Metamorphopsia	15	0
Oscillopsia	2	0
Photopsia	96	0
Scintillating scotoma	3	0
Vision blurred	892	0
Visual brightness	3	0
Visual snow syndrome	5	0
Visual field disorders		
Visual field defect	16	0
Visual impairment and blindness (excl colour blindness)		
Amaurosis fugax	2	0
Blindness	96	0
Blindness transient	10	0
Blindness unilateral	10	0
Central vision loss	3	0
Sudden visual loss	3	0
Visual acuity reduced	16	0
Visual acuity reduced transiently	1	0
Visual impairment	255	0
Visual pathway disorders		
Optic nerve disorder	1	0
Eye disorders SOC TOTAL	4872	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Abdominal findings abnormal</i>		
Abdominal mass	1	0
Gastrointestinal sounds abnormal	16	0
<i>Abdominal hernias NEC</i>		
Abdominal hernia	1	0
<i>Abdominal wall conditions NEC</i>		
Abdominal wall haematoma	2	0
<i>Acute and chronic pancreatitis</i>		
Obstructive pancreatitis	1	0
Pancreatitis	10	0
Pancreatitis acute	10	0
Pancreatitis necrotising	1	0
<i>Anal and rectal disorders NEC</i>		
Anal fissure	2	0
Anal sphincter atony	1	0
<i>Anal and rectal pains</i>		
Proctalgia	8	0
<i>Anal and rectal signs and symptoms</i>		
Anal hypoaesthesia	1	0
Anal spasm	1	0
Anorectal discomfort	3	0
Anorectal swelling	1	0
Rectal discharge	1	0
Rectal tenesmus	1	0
<i>Benign oral cavity neoplasms</i>		
Mouth cyst	4	0
Tongue cyst	4	0
<i>Colitis (excl infective)</i>		
Autoimmune colitis	1	0
Colitis	32	1
Colitis ischaemic	1	0
Colitis microscopic	1	0
Colitis ulcerative	55	0
Crohn's disease	35	0
Eosinophilic colitis	1	0
Inflammatory bowel disease	4	0
<i>Dental and periodontal infections and inflammations</i>		
Dental caries	1	0
<i>Dental disorders NEC</i>		
Loose tooth	1	0
Teeth brittle	3	0
Teething	4	0
Tooth disorder	2	0
Tooth socket haemorrhage	1	0
<i>Dental pain and sensation disorders</i>		
Dental discomfort	6	0
Dental paraesthesia	10	0
Hyperaesthesia teeth	29	0
Toothache	121	0
<i>Dental surface disorders</i>		
Tooth discolouration	9	0
<i>Diaphragmatic hernias</i>		
Hiatus hernia	5	0

Case Series Drug Analysis Print

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

Report Run Date: 12-Aug-2021

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	4010	2
Diarrhoea haemorrhagic	20	0
<i>Diverticula</i>		
Diverticulum	4	0
Diverticulum intestinal	1	0
<i>Duodenal and small intestinal stenosis and obstruction</i>		
Small intestinal obstruction	1	0
<i>Duodenal ulcers and perforation</i>		
Duodenal ulcer haemorrhage	1	0
Duodenal ulcer perforation	3	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	309	0
Epigastric discomfort	13	0
Eructation	36	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	15	0
Faecaloma	3	0
Faeces discoloured	43	0
Faeces hard	1	0
Faeces pale	3	0
Faeces soft	10	0
Mucous stools	7	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	358	0
Aerophagia	3	0
Flatulence	136	0
<i>Gastric and oesophageal haemorrhages</i>		
Gastric haemorrhage	5	1
Mallory-Weiss syndrome	1	0
Oesophageal varices haemorrhage	1	0
<i>Gastric ulcers and perforation</i>		
Gastric ulcer	6	0
<i>Gastritis (excl infective)</i>		
Chronic gastritis	2	0
Gastritis	35	0
Reflux gastritis	4	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal migraine	2	0
Abdominal pain	1030	0
Abdominal pain lower	89	0
Abdominal pain upper	1717	0
Abdominal rigidity	17	0
Abdominal tenderness	9	0
Gastrointestinal pain	100	0
Oesophageal pain	4	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	186	0
Duodenogastric reflux	3	0
Gastric dilatation	6	0
Gastrooesophageal reflux disease	99	0
Impaired gastric emptying	6	0
Infrequent bowel movements	2	0

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

Report Run Date: 12-Aug-2021

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Intestinal dilatation	1	0
Intestinal pseudo-obstruction	2	0
<i>Gastrointestinal disorders NEC</i>		
Food poisoning	3	0
Functional gastrointestinal disorder	6	0
Gastric disorder	6	0
Gastrointestinal disorder	17	0
Stomach mass	3	0
<i>Gastrointestinal dyskinetic disorders</i>		
Bowel movement irregularity	2	0
Change of bowel habit	5	0
Dyschezia	2	0
Gastrointestinal motility disorder	1	0
Oesophageal achalasia	1	0
<i>Gastrointestinal fistulae</i>		
Diverticular fistula	1	0
<i>Gastrointestinal inflammatory disorders NEC</i>		
Duodenitis	1	0
Enteritis	5	0
Epiploic appendagitis	2	0
Gastrointestinal inflammation	3	0
Intestinal angioedema	2	0
<i>Gastrointestinal mucosal dystrophies and secretion disorders</i>		
Hyperchlorhydria	4	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	471	0
Abdominal symptom	1	0
Acute abdomen	4	0
Anal incontinence	18	0
Breath odour	15	0
Dysphagia	158	1
Odynophagia	25	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Cardiospasm	1	0
Defaecation urgency	8	0
Frequent bowel movements	21	0
Irritable bowel syndrome	64	0
Oesophageal spasm	3	0
Pylorospasm	1	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Intestinal obstruction	2	0
Neonatal intestinal obstruction	1	0
<i>Gastrointestinal vascular malformations</i>		
Gastric antral vascular ectasia	5	0
<i>Gastrointestinal vascular occlusion and infarction</i>		
Intestinal ischaemia	5	2
Mesenteric vein thrombosis	6	0
Omental infarction	1	0
Thrombosis mesenteric vessel	1	0
Visceral venous thrombosis	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival blister	11	0
Gingival discomfort	2	0

Case Series Drug Analysis Print

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

Report Run Date: 12-Aug-2021

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Gingival disorder	3	0
Gingival erythema	2	0
Gingival oedema	1	0
Gingival pain	83	0
Gingival pruritus	1	0
Gingival swelling	28	0
Gingival ulceration	1	0
Gingivitis ulcerative	1	0
Noninfective gingivitis	5	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	48	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Gastric varices	1	0
Haemorrhoids	23	0
Haemorrhoids thrombosed	1	0
<i>Intestinal haemorrhages</i>		
Anal haemorrhage	13	0
Intestinal haemorrhage	1	0
Rectal haemorrhage	49	0
Small intestinal haemorrhage	6	0
<i>Intestinal ulcers and perforation NEC</i>		
Intestinal perforation	5	2
Large intestinal ulcer	1	0
Large intestine perforation	1	0
<i>Malabsorption syndromes</i>		
Bile acid malabsorption	1	0
Coeliac disease	8	0
Steatorrhoea	4	0
<i>Nausea and vomiting symptoms</i>		
Discoloured vomit	10	0
Infantile vomiting	5	0
Nausea	10588	1
Regurgitation	1	0
Retching	79	0
Vomiting	3107	0
Vomiting projectile	44	0
<i>Non-mechanical ileus</i>		
Ileus paralytic	1	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Gastrointestinal haemorrhage	12	0
Haematemesis	25	2
Haematochezia	42	0
Melaena	8	0
Upper gastrointestinal haemorrhage	5	0
<i>Oesophageal stenosis and obstruction</i>		
Oesophageal stenosis	3	0
<i>Oesophagitis (excl infective)</i>		
Eosinophilic oesophagitis	1	0
Oesophagitis	3	0
<i>Oral dryness and saliva altered</i>		
Aptyalism	2	0
Dry mouth	395	0
Lip dry	33	0

Case Series Drug Analysis Print

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

Report Run Date: 12-Aug-2021

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Saliva altered	4	0
Salivary hypersecretion	41	0
Oral soft tissue disorders NEC		
Angina bullosa haemorrhagica	1	0
Chapped lips	18	0
Cheilitis	21	0
Enlarged uvula	13	0
Leukoplakia oral	1	0
Lip blister	23	0
Lip disorder	4	0
Oral disorder	11	0
Oral lichen planus	8	0
Oral mucosal hypertrophy	1	0
Oral papule	1	0
Uvulitis	2	0
Oral soft tissue haemorrhages		
Mouth haemorrhage	11	0
Oral blood blister	10	0
Oral purpura	2	0
Oral soft tissue infections		
Angular cheilitis	1	0
Oral soft tissue signs and symptoms		
Anaesthesia oral	1	0
Burning mouth syndrome	5	0
Coating in mouth	1	0
Hypoaesthesia oral	382	0
Lip discolouration	7	0
Lip erythema	2	0
Lip exfoliation	5	0
Lip pain	43	0
Lip pruritus	12	0
Lip scab	1	0
Oral discomfort	66	0
Oral dysaesthesia	1	0
Oral mucosal blistering	12	0
Oral mucosal discolouration	1	0
Oral mucosal eruption	11	0
Oral mucosal erythema	5	0
Oral mucosal exfoliation	7	0
Oral mucosal roughening	3	0
Oral pain	136	0
Oral pruritus	19	0
Paraesthesia oral	772	0
Pigmentation lip	1	0
Oral soft tissue swelling and oedema		
Lip oedema	4	0
Lip swelling	560	0
Mouth swelling	72	0
Oedema mouth	4	0
Palatal oedema	2	0
Palatal swelling	2	0
Peptic ulcers and perforation		
Peptic ulcer	1	0

Case Series Drug Analysis Print

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

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Peptic ulcer haemorrhage	9	0
<i>Peritoneal and retroperitoneal disorders</i>		
Ascites	1	0
<i>Peritoneal and retroperitoneal fibrosis and adhesions</i>		
Abdominal adhesions	1	0
<i>Peritoneal and retroperitoneal haemorrhages</i>		
Haemoperitoneum	1	0
Retroperitoneal haemorrhage	1	1
<i>Rectal inflammations NEC</i>		
Proctitis	1	0
Proctitis ulcerative	1	0
<i>Salivary gland disorders NEC</i>		
Salivary gland disorder	1	0
Salivary gland pain	12	0
<i>Salivary gland enlargements</i>		
Parotid gland enlargement	9	0
Salivary gland enlargement	4	0
Submaxillary gland enlargement	6	0
<i>Salivary gland infections and inflammations</i>		
Noninfective sialoadenitis	1	0
<i>Stomatitis and ulceration</i>		
Aphthous ulcer	36	0
Lip ulceration	15	0
Mouth ulceration	346	0
Oral mucosa erosion	1	0
Palatal ulcer	1	0
Stomatitis	50	0
<i>Tongue disorders</i>		
Glossitis	14	0
Hypertrophy of tongue papillae	1	0
Plicated tongue	3	0
Tongue disorder	30	0
Tongue geographic	1	0
Tongue haemorrhage	2	0
Tongue ulceration	26	0
Trichoglossia	4	0
<i>Tongue signs and symptoms</i>		
Glossodynia	165	0
Scalloped tongue	5	0
Stiff tongue	3	0
Swollen tongue	387	0
Tongue blistering	15	0
Tongue coated	15	0
Tongue discolouration	28	0
Tongue discomfort	34	0
Tongue dry	12	0
Tongue eruption	9	0
Tongue erythema	7	0
Tongue exfoliation	1	0
Tongue movement disturbance	5	0
Tongue oedema	19	0
Tongue pruritus	2	0
Tongue rough	3	0

Case Series Drug Analysis Print

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

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Tongue spasm	8	0
<i>Tooth missing</i>		
Tooth loss	4	0
Gastrointestinal disorders SOC TOTAL	27846	13

Case Series Drug Analysis Print

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

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site bruise	5	0
Administration site erythema	3	0
Administration site extravasation	3	0
Administration site haematoma	3	0
Administration site inflammation	1	0
Administration site irritation	1	0
Administration site joint discomfort	1	0
Administration site joint movement impairment	1	0
Administration site nerve damage	1	0
Administration site pain	12	0
Administration site rash	3	0
Administration site reaction	1	0
Administration site swelling	2	0
Administration site urticaria	1	0
Administration site warmth	2	0
Puncture site bruise	23	0
Puncture site pain	5	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	12	0
<i>Application and instillation site reactions</i>		
Application site acne	2	0
Application site bruise	6	0
Application site burn	1	0
Application site erythema	11	0
Application site haemorrhage	1	0
Application site hypoaesthesia	1	0
Application site irritation	1	0
Application site joint erythema	1	0
Application site joint pain	1	0
Application site mass	1	0
Application site odour	1	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	5	0
Instillation site warmth	4	0
<i>Asthenic conditions</i>		
Asthenia	1327	1
Chronic fatigue syndrome	61	0
Decreased activity	7	0
Fatigue	16844	0
Malaise	3754	0
Sluggishness	12	0
<i>Body temperature altered</i>		
Hyperthermia	5	0

Case Series Drug Analysis Print

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

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Hypothermia	19	0
Temperature regulation disorder	9	0
Breast complications associated with device		
Capsular contracture associated with breast implant	1	0
Cardiac complications associated with device		
Prosthetic cardiac valve thrombosis	2	0
Complications associated with device NEC		
Capsular contracture associated with implant	1	0
Complication of device removal	3	0
Injury associated with device	3	0
Medical device pain	1	0
Medical device site swelling	1	0
Phantom shocks	1	0
Death and sudden death		
Brain death	2	2
Clinical death	1	1
Death	131	131
Drowning	1	1
Sudden death	25	25
Febrile disorders		
Hyperpyrexia	7	0
Pyrexia	10939	0
Feelings and sensations NEC		
Chills	7032	0
Feeling abnormal	1145	0
Feeling cold	860	0
Feeling drunk	64	0
Feeling hot	853	0
Feeling jittery	17	0
Feeling of body temperature change	243	0
Feeling of relaxation	2	0
Hangover	63	0
Hunger	31	0
Sensation of blood flow	2	0
Sensation of foreign body	39	0
Temperature intolerance	30	0
Thirst	256	0
Fibrosis NEC		
Fibrosis	2	0
Gait disturbances		
Gait disturbance	150	0
Gait inability	52	0
Loss of control of legs	13	0
General signs and symptoms NEC		
Adhesion	1	0
Chronic disease	1	0
Condition aggravated	140	0
Crepitations	1	0
Crying	110	0
Deformity	2	0
Discharge	9	0
Disease progression	2	0
Disease recurrence	24	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Effusion	2	0
Energy increased	16	0
Exercise tolerance decreased	12	0
Foaming at mouth	1	0
General physical health deterioration	14	1
General symptom	2	0
Glassy eyes	3	0
High-pitched crying	2	0
Illness	1301	0
Induration	12	0
Influenza like illness	1736	0
Irritability postvaccinal	2	0
Local reaction	67	0
Moaning	3	0
Multiple organ dysfunction syndrome	6	4
Nonspecific reaction	1	0
Organ failure	1	1
Perforation	2	0
Peripheral swelling	2561	0
Pre-existing condition improved	8	0
Prolapse	1	0
Screaming	17	0
Secretion discharge	10	0
Swelling	2044	0
Swelling face	606	0
Symptom recurrence	1	0
Terminal state	1	0
Implant and catheter site reactions		
Implant site discolouration	2	0
Implant site pain	1	0
Implant site rash	1	0
Implant site swelling	1	0
Implant site urticaria	1	0
Implant site warmth	1	0
Inflamations		
Granuloma	1	0
Inflammation	299	0
Papillitis	1	0
Serositis	1	0
Systemic inflammatory response syndrome	2	0
Infusion site reactions		
Infusion site coldness	1	0
Infusion site joint pain	2	0
Infusion site mass	1	0
Infusion site pain	1	0
Infusion site swelling	1	0
Infusion site urticaria	1	0
Infusion site warmth	1	0
Injection site reactions		
Injected limb mobility decreased	24	0
Injection site bruising	52	0
Injection site coldness	1	0
Injection site cyst	2	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Injection site discolouration	5	0
Injection site discomfort	9	0
Injection site eczema	1	0
Injection site erythema	286	0
Injection site haemorrhage	6	0
Injection site hypersensitivity	2	0
Injection site hypoaesthesia	8	0
Injection site indentation	8	0
Injection site induration	3	0
Injection site inflammation	28	0
Injection site joint discomfort	1	0
Injection site joint erythema	1	0
Injection site joint movement impairment	1	0
Injection site joint pain	12	0
Injection site lymphadenopathy	1	0
Injection site macule	1	0
Injection site mass	380	0
Injection site movement impairment	1	0
Injection site necrosis	3	0
Injection site oedema	12	0
Injection site pain	2298	0
Injection site paraesthesia	11	0
Injection site pruritus	140	0
Injection site rash	120	0
Injection site reaction	22	0
Injection site scab	2	0
Injection site scar	4	0
Injection site swelling	231	0
Injection site urticaria	21	0
Injection site vesicles	8	0
Injection site warmth	144	0
Interactions		
Alcohol interaction	2	0
Drug interaction	20	0
Inhibitory drug interaction	3	0
Mass conditions NEC		
Cyst	28	0
Mass	52	0
Nodule	27	0
Mucosal findings abnormal		
Mucosa vesicle	1	0
Mucosal dryness	1	0
Mucosal haemorrhage	9	0
Mucosal inflammation	2	0
Oedema mucosal	1	0
Polyp	2	0
Necrosis NEC		
Fat necrosis	2	0
Necrosis	3	0
Oedema NEC		
Face oedema	25	0
Generalised oedema	2	0
Localised oedema	15	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Oedema	49	0
Oedema peripheral	67	0
<i>Pain and discomfort NEC</i>		
Axillary pain	2042	0
Chest discomfort	1150	0
Chest pain	2520	1
Discomfort	318	0
Facial discomfort	14	0
Facial pain	165	0
Inflammatory pain	8	0
Non-cardiac chest pain	21	0
Pain	6292	0
Suprapubic pain	1	0
Tenderness	497	0
Visceral pain	1	0
<i>Therapeutic and nontherapeutic responses</i>		
Adverse drug reaction	10	0
Adverse event	1	0
Adverse food reaction	1	0
Drug ineffective	194	1
Drug intolerance	2	0
Immediate post-injection reaction	2	0
Inadequate analgesia	7	0
No reaction on previous exposure to drug	35	0
Product intolerance	1	0
Therapeutic product effect delayed	2	0
Therapeutic product effect increased	1	0
Therapeutic product ineffective	2	0
Therapeutic response decreased	2	0
Therapeutic response unexpected	62	0
Therapy non-responder	1	0
Treatment failure	6	0
Vaccination failure	13	0
<i>Trophic disorders</i>		
Atrophy	1	0
Calcinosis	1	0
Hyperplasia	1	0
<i>Ulcers NEC</i>		
Ulcer	21	0
Ulcer haemorrhage	1	0
<i>Vaccination site reactions</i>		
Extensive swelling of vaccinated limb	9	0
Shoulder injury related to vaccine administration	18	0
Vaccination site bruising	92	0
Vaccination site coldness	2	0
Vaccination site cyst	5	0
Vaccination site dermatitis	1	0
Vaccination site discolouration	11	0
Vaccination site discomfort	38	0
Vaccination site dryness	1	0
Vaccination site eczema	1	0
Vaccination site erythema	469	0
Vaccination site granuloma	1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site haematoma	1	0
Vaccination site haemorrhage	15	0
Vaccination site hypersensitivity	2	0
Vaccination site hypoaesthesia	14	0
Vaccination site induration	67	0
Vaccination site inflammation	47	0
Vaccination site irritation	11	0
Vaccination site joint discomfort	2	0
Vaccination site joint erythema	7	0
Vaccination site joint inflammation	1	0
Vaccination site joint movement impairment	16	0
Vaccination site joint pain	27	0
Vaccination site joint swelling	3	0
Vaccination site joint warmth	1	0
Vaccination site lymphadenopathy	4	0
Vaccination site macule	1	0
Vaccination site mass	202	0
Vaccination site movement impairment	65	0
Vaccination site nerve damage	1	0
Vaccination site nodule	2	0
Vaccination site oedema	3	0
Vaccination site pain	1744	0
Vaccination site paraesthesia	6	0
Vaccination site phlebitis	1	0
Vaccination site pruritus	123	0
Vaccination site rash	102	0
Vaccination site reaction	27	0
Vaccination site scab	2	0
Vaccination site scar	1	0
Vaccination site swelling	448	0
Vaccination site ulcer	1	0
Vaccination site urticaria	11	0
Vaccination site vesicles	7	0
Vaccination site warmth	222	0
<i>Vascular complications associated with device</i>		
Vascular stent thrombosis	1	0
<i>Withdrawal and rebound effects</i>		
Drug withdrawal syndrome	5	0
Withdrawal syndrome	26	0
General disorders SOC TOTAL	74619	169

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	11	0
Cholangitis	1	0
<i>Cholecystitis and cholelithiasis</i>		
Cholecystitis	2	0
Cholecystitis acute	2	0
Cholelithiasis	7	0
<i>Cholestasis and jaundice</i>		
Cholestasis	2	0
Jaundice	15	0
Jaundice cholestatic	7	0
<i>Gallbladder disorders NEC</i>		
Gallbladder disorder	1	0
<i>Hepatic and hepatobiliary disorders NEC</i>		
Liver disorder	9	0
<i>Hepatic enzymes and function abnormalities</i>		
Hepatic function abnormal	2	0
<i>Hepatic failure and associated disorders</i>		
Acute hepatic failure	1	0
Hepatic failure	2	1
<i>Hepatic fibrosis and cirrhosis</i>		
Hepatic cirrhosis	1	0
<i>Hepatic vascular disorders</i>		
Congestive hepatopathy	2	0
Hepatic artery embolism	1	0
Hepatic haemorrhage	2	0
Hepatic vein thrombosis	5	0
Portal vein thrombosis	6	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	20	0
Hepatomegaly	1	0
Liver tenderness	3	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Autoimmune hepatitis	5	0
Drug-induced liver injury	2	0
Hepatitis	9	0
Immune-mediated hepatic disorder	1	0
Liver injury	8	0
Hepatic disorders SOC TOTAL	128	1

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	10	0
<i>Allergic conditions NEC</i>		
Allergic oedema	11	0
Allergy to animal	1	0
Allergy to arthropod bite	5	0
Allergy to arthropod sting	1	0
Allergy to metals	1	0
Allergy to sting	1	0
Hypersensitivity	717	0
Infusion related hypersensitivity reaction	2	0
Mite allergy	1	0
Multiple allergies	6	0
Serum sickness	2	0
Serum sickness-like reaction	3	0
Type I hypersensitivity	1	0
Type III immune complex mediated reaction	1	0
Type IV hypersensitivity reaction	6	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergic reaction to excipient	4	0
Allergy to chemicals	2	0
Allergy to vaccine	32	0
Contrast media reaction	2	0
Drug hypersensitivity	19	0
Food allergy	19	0
Oral allergy syndrome	2	0
Reaction to colouring	1	0
Reaction to excipient	8	0
Reaction to preservatives	4	0
Rubber sensitivity	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	399	2
Anaphylactic shock	39	0
Anaphylactoid reaction	19	0
Anaphylactoid shock	4	0
<i>Atopic disorders</i>		
Atopy	1	0
Seasonal allergy	84	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	30	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	39	0
Graft versus host disease	1	0
Immune system disorder	17	0
Immune-mediated adverse reaction	6	0
Immunisation reaction	1	0
Sensitisation	4	0
Systemic immune activation	2	0
<i>Immunodeficiency disorders NEC</i>		
Hypogammaglobulinaemia	1	0
Immunodeficiency	1	0
Immunosuppression	2	0
<i>Transplant rejections</i>		

Case Series Drug Analysis Print

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

Report Run Date: 12-Aug-2021

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Immune system disorders		
Immune system disorders cont'd		
Corneal graft rejection	5	0
Kidney transplant rejection	1	0
Solid organ transplant rejection	1	0
Immune system disorders SOC TOTAL	1520	2

Case Series Drug Analysis Print

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

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Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Abdominal abscess	1	0
Abdominal infection	1	0
Anal abscess	3	0
Appendicitis	25	0
Appendicitis perforated	3	0
Diverticulitis	8	0
Dysentery	1	0
Gastric infection	2	0
Gastroenteritis	22	0
Mesenteric abscess	1	0
Peritonitis	1	1
Rectal abscess	1	0
<i>Adenoviral infections</i>		
Adenoviral conjunctivitis	1	0
<i>Aspergillus infections</i>		
Bronchopulmonary aspergillosis	1	0
<i>Bacterial infections NEC</i>		
Abscess bacterial	1	0
Arthritis bacterial	3	0
Bacterial colitis	1	0
Bacterial diarrhoea	1	0
Bacterial infection	9	0
Cellulitis	138	0
Conjunctivitis bacterial	1	0
Ear infection bacterial	1	0
Folliculitis	12	0
Gangrene	1	0
Injection site cellulitis	2	0
Meningitis bacterial	3	0
Paronychia	2	0
Perichondritis	1	0
Periorbital cellulitis	1	0
Sinusitis bacterial	1	0
Skin bacterial infection	2	0
Tonsillitis bacterial	3	0
Urinary tract infection bacterial	1	0
Vaccination site cellulitis	16	0
Zoonotic bacterial infection	1	1
<i>Bartonella infections</i>		
Cat scratch disease	1	0
<i>Bone and joint infections</i>		
Abscess jaw	1	0
Arthritis infective	1	0
Osteomyelitis	1	0
<i>Borrelial infections</i>		
Lyme disease	1	0
Relapsing fever	1	0
<i>Breast infections</i>		
Breast abscess	2	0
Mastitis	59	0
<i>Caliciviral infections</i>		
Gastroenteritis norovirus	2	0

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Reaction Name	Total	Fatal
Infections Infections cont'd		
<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	46	0
Oral candidiasis	34	0
Respiratory moniliasis	1	0
Skin candida	1	0
Systemic candida	1	0
Vulvovaginal candidiasis	38	0
<i>Cardiac infections</i>		
Pericarditis infective	1	0
<i>Central nervous system and spinal infections</i>		
CNS ventriculitis	1	0
Cavernous sinus thrombosis	1	0
Encephalitis	14	0
Meningitis	5	0
Meningitis aseptic	1	0
Myelitis	4	0
<i>Clostridia infections</i>		
Clostridium difficile infection	2	0
<i>Coronavirus infections</i>		
Asymptomatic COVID-19	11	0
COVID-19	928	35
COVID-19 pneumonia	37	13
Coronavirus infection	6	0
Post-acute COVID-19 syndrome	1	0
Severe acute respiratory syndrome	1	0
Suspected COVID-19	46	1
<i>Coxiella infections</i>		
Q fever	9	0
<i>Cytomegaloviral infections</i>		
Cytomegalovirus infection	2	0
Cytomegalovirus syndrome	1	0
<i>Dental and oral soft tissue infections</i>		
Abscess oral	4	0
Gingivitis	9	0
Oral infection	1	0
Parotitis	9	0
Pulpitis dental	1	0
Sialoadenitis	3	0
Tooth abscess	8	0
Tooth infection	8	0
<i>Ear infections</i>		
Ear infection	63	0
Labyrinthitis	73	0
Mastoiditis	1	0
Otitis media	4	0
Otitis media acute	1	0
<i>Ectoparasitic infestations</i>		
Acarodermatitis	4	0

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Bed bug infestation	1	0
<i>Epstein-Barr viral infections</i>		
Epstein-Barr virus infection	3	0
Infectious mononucleosis	21	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	58	0
Eye abscess	1	0
Eye infection	16	0
Eyelid boil	1	0
Eyelid infection	2	0
Hordeolum	20	0
Periorbital infection	2	0
<i>Female reproductive tract infections</i>		
Bartholin's abscess	1	0
Bartholinitis	1	0
Endometritis	3	0
Funisitis	1	0
Pelvic inflammatory disease	1	0
Vaginal infection	1	0
Vulval abscess	1	0
Vulvitis	1	0
<i>Fungal infections NEC</i>		
Fungal infection	10	0
Fungal skin infection	4	0
Onychomycosis	1	0
Oral fungal infection	1	0
Pneumonia fungal	2	0
Vulvovaginal mycotic infection	6	0
<i>Hepatitis virus infections</i>		
Hepatitis A	1	0
Hepatitis E	1	0
<i>Hepatobiliary and spleen infections</i>		
Biliary sepsis	2	0
Cholecystitis infective	1	0
<i>Herpes viral infections</i>		
Disseminated varicella zoster virus infection	1	0
Eczema herpeticum	2	0
Genital herpes	69	0
Genital herpes simplex	6	0
Herpes ophthalmic	3	0
Herpes simplex	22	0
Herpes simplex encephalitis	1	1
Herpes simplex reactivation	2	0
Herpes virus infection	9	0
Herpes zoster	1153	0
Herpes zoster meningoencephalitis	1	0
Herpes zoster oticus	11	0
Herpes zoster reactivation	1	0
Nasal herpes	3	0
Ophthalmic herpes zoster	3	0
Oral herpes	249	0
Varicella	20	0
Varicella zoster virus infection	1	0

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Reaction Name	Total	Fatal
Infections Infections cont'd		
<i>Infections NEC</i>		
Abscess	29	0
Abscess limb	6	0
Abscess soft tissue	1	0
Genital abscess	1	0
Infected bite	3	0
Infected cyst	2	0
Infection	178	0
Injection site abscess	1	0
Injection site infection	5	0
Localised infection	20	0
Lymph gland infection	7	0
Lymph node abscess	4	0
Opportunistic infection	1	0
Respiratory tract infection	9	0
Vaccination site abscess	6	0
Vaccination site infection	13	0
Vaccine breakthrough infection	23	0
Vestibulitis	2	0
Wound infection	1	0
<i>Infectious transmissions</i>		
Secondary transmission	9	0
Vaccine virus shedding	1	0
<i>Influenza viral infections</i>		
Influenza	1139	0
<i>Klebsiella infections</i>		
Klebsiella infection	1	0
<i>Lower respiratory tract and lung infections</i>		
Bronchitis	17	0
Infectious pleural effusion	1	0
Lower respiratory tract infection	156	7
Pneumonia	92	11
Sputum purulent	1	0
<i>Male reproductive tract infections</i>		
Epididymitis	4	0
Orchitis	3	0
Prostate infection	1	0
<i>Mumps viral infections</i>		
Mumps	6	0
<i>Muscle and soft tissue infections</i>		
Abscess neck	1	0
Infective tenosynovitis	1	0
Necrotising fasciitis	2	0
Soft tissue infection	1	0
<i>Neisseria infections</i>		
Gonorrhoea	1	0
<i>Plasmodia infections</i>		
Malaria	1	0
<i>Pneumocystis infections</i>		
Pneumocystis jirovecii pneumonia	2	0
<i>Retroviral infections</i>		
Acquired immunodeficiency syndrome	1	0
HIV infection	1	0

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Reaction Name	Total	Fatal
Infections Infections cont'd		
<i>Rotaviral infections</i>		
Gastroenteritis rotavirus	1	0
<i>Rubeola viral infections</i>		
Measles	4	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Bacteraemia	1	0
Neutropenic sepsis	3	1
Sepsis	37	5
Sepsis syndrome	1	0
Septic rash	1	0
Septic shock	5	1
Urosepsis	5	0
<i>Skin structures and soft tissue infections</i>		
Abscess sweat gland	1	0
Acne pustular	1	0
Blister infected	1	0
Dermatitis infected	2	0
Impetigo	8	0
Infected skin ulcer	1	0
Injection site pustule	1	0
Nail infection	1	0
Pustule	10	0
Rash pustular	9	0
Skin infection	26	0
Subcutaneous abscess	6	0
Sweat gland infection	1	0
Vaccination site pustule	4	0
<i>Staphylococcal infections</i>		
Furuncle	30	0
Pneumonia staphylococcal	1	0
Staphylococcal abscess	1	0
Staphylococcal infection	3	0
Staphylococcal sepsis	1	0
<i>Streptococcal infections</i>		
Meningitis pneumococcal	1	0
Pharyngitis streptococcal	5	0
Streptococcal abscess	1	0
Streptococcal endocarditis	1	0
Streptococcal infection	1	0
Streptococcal sepsis	1	0
<i>Tinea infections</i>		
Body tinea	1	0
Tinea infection	1	0
Tinea pedis	2	0
Tinea versicolour	2	0
<i>Treponema infections</i>		
Syphilis	2	0
<i>Trypanosomal infections</i>		
African trypanosomiasis	2	0
<i>Tuberculous infections</i>		
Lymph node tuberculosis	1	0
Pulmonary tuberculosis	1	0
Tuberculosis	1	0

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Tuberculosis of central nervous system	1	0
Upper respiratory tract infections		
Acute sinusitis	4	0
Croup infectious	1	0
Epiglottitis	1	0
Laryngitis	24	0
Nasopharyngitis	725	0
Peritonsillar abscess	2	0
Pharyngitis	23	0
Rhinitis	36	0
Sinusitis	114	0
Tonsillitis	77	0
Tracheitis	4	0
Tracheostomy infection	1	0
Upper respiratory tract infection	6	0
Urinary tract infections		
Cystitis	58	0
Kidney infection	29	0
Pyelonephritis	1	0
Urinary tract infection	138	0
Vascular infections		
Haematoma infection	1	0
Infected lymphocele	1	0
Infusion site infection	1	0
Lymphangitis	7	0
Viral infections NEC		
Arthritis viral	1	0
Conjunctivitis viral	2	0
Encephalitis viral	4	1
Eye infection viral	2	0
Gastroenteritis viral	20	0
Hepatitis viral	2	0
Meningitis viral	8	0
Meningoencephalitis viral	1	0
Oral viral infection	1	0
Pleurisy viral	1	0
Pneumonia viral	2	1
Post viral fatigue syndrome	35	0
Sweating fever	72	0
Vestibular neuronitis	22	0
Viral diarrhoea	2	0
Viral infection	37	0
Viral labyrinthitis	3	0
Viral pericarditis	3	0
Viral pharyngitis	13	0
Viral rash	40	0
Viral sinusitis	1	0
Viral tonsillitis	1	0
Infections SOC TOTAL	6920	79

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Reaction Name	Total	Fatal
Injuries		
<i>Abdominal and gastrointestinal injuries NEC</i>		
Mouth injury	3	0
Oral contusion	3	0
Palate injury	1	0
Rectal injury	1	0
Splenic rupture	6	0
Tongue injury	1	0
Tooth fracture	1	0
Tooth injury	1	0
<i>Accidental exposures to product</i>		
Accidental exposure to product	15	0
<i>Anaesthetic and allied procedural complications</i>		
Airway complication of anaesthesia	1	0
Delayed recovery from anaesthesia	2	0
Sedation complication	1	0
<i>Atmospheric pressure injuries</i>		
Barotitis media	1	0
Hypobarism	1	0
<i>Bone and joint injuries NEC</i>		
Bursa injury	1	0
Joint injury	6	0
<i>Cardiovascular injuries</i>		
Heart injury	4	0
Vascular injury	5	0
<i>Cerebral injuries NEC</i>		
Brain contusion	1	0
Brain herniation	1	0
Concussion	2	0
Cranio-cerebral injury	1	0
Subarachnoid haematoma	1	0
Subdural haematoma	5	0
Subdural haemorrhage	5	0
Traumatic intracranial haemorrhage	1	1
<i>Chemical injuries</i>		
Chemical burn of skin	1	0
Chemical cystitis	1	0
<i>Chest and respiratory tract injuries NEC</i>		
Chest crushing	8	0
Foreign body in throat	1	0
<i>Conditions caused by cold</i>		
Chillblains	49	0
<i>Cranial nerve injuries</i>		
Vth nerve injury	1	0
<i>Ear injuries NEC</i>		
Ear injury	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	8	0
Exposure via breast milk	35	0
Foetal exposure during pregnancy	27	0
Maternal exposure before pregnancy	2	0
Maternal exposure during breast feeding	1171	0
Maternal exposure during pregnancy	582	0
Maternal exposure timing unspecified	2	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Paternal exposure before pregnancy	2	0
Exposures to agents or circumstances NEC		
Exposure to SARS-CoV-2	2	0
Exposure to vaccinated person	3	0
Eye and ear procedural complications		
Toxic anterior segment syndrome	1	0
Eye injuries NEC		
Eye contusion	13	0
Eye injury	15	0
Foreign body in eye	2	0
Injury corneal	1	0
Periorbital haematoma	1	0
Retinal injury	2	0
Superficial injury of eye	1	0
Foetal and neonatal conditions associated with product exposure		
Intoxication by breast feeding	1	0
Fractures and dislocations NEC		
Bone fragmentation	1	0
Fracture	1	0
Joint dislocation	2	0
Multiple fractures	1	0
Gastrointestinal and hepatobiliary procedural complications		
Post procedural constipation	1	0
Postoperative ileus	1	0
Procedural nausea	6	0
Procedural vomiting	1	0
Heat injuries (excl thermal burns)		
Heat cramps	2	0
Heat exhaustion	2	0
Heat illness	1	0
Heat oedema	7	0
Heat stroke	3	0
Intentional product use issues		
Intentional dose omission	1	0
Intentional product use issue	1	0
Limb fractures and dislocations		
Atypical femur fracture	1	0
Clavicle fracture	22	0
Femoral neck fracture	1	0
Hip fracture	1	0
Upper limb fracture	1	0
Wrist fracture	1	0
Medication errors, product use errors and issues NEC		
Circumstance or information capable of leading to medication error	1	0
Dose calculation error	1	0
Inadequate aseptic technique in use of product	1	0
Medication error	17	0
Prescription drug used without a prescription	2	0
Product use complaint	1	0
Product use issue	13	0
Vaccination error	6	0
Wrong dose	3	0
Wrong drug	11	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Wrong technique in product usage process	4	0
Muscle, tendon and ligament injuries		
Epicondylitis	13	0
Ligament injury	2	0
Ligament sprain	8	0
Mallet finger	1	0
Muscle injury	14	0
Muscle rupture	6	0
Muscle strain	24	0
Post-traumatic neck syndrome	1	0
Tendon injury	5	0
Tendon rupture	9	0
Musculoskeletal procedural complications		
Periprosthetic osteolysis	2	0
Post laminectomy syndrome	1	0
Nerve injuries NEC		
Nerve injury	60	0
Neurological and psychiatric procedural complications		
Post procedural stroke	1	0
Procedural dizziness	11	0
Non-occupational environmental exposures		
Exposure to extreme temperature	1	0
Non-site specific injuries NEC		
Arthropod bite	4	0
Arthropod sting	4	0
Bite	1	0
Electric shock	13	0
Fall	125	1
Foreign body	2	0
Injury	7	0
Nervous system injury	1	0
Post concussion syndrome	1	0
Traumatic haematoma	1	0
Wound	5	0
Wound complication	8	0
Wound haematoma	1	0
Wound haemorrhage	2	0
Wound secretion	3	0
Non-site specific procedural complications		
Incision site pain	2	0
Infusion related reaction	6	0
Injection related reaction	37	0
Post procedural complication	3	0
Procedural pain	2	0
Seroma	1	0
Occupational exposures		
Occupational exposure to SARS-CoV-2	1	0
Occupational exposure to product	1	0
Off label uses		
Off label use	46	0
Overdoses NEC		
Overdose	35	0
Pathways and sources of exposure		

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Exposure via unknown route	1	0
Pelvic fractures and dislocations		
Pelvic fracture	1	0
Peripheral nerve injuries		
Brachial plexus injury	1	0
Ulnar nerve injury	4	0
Poisoning and toxicity		
Alcohol poisoning	1	0
Poisoning	9	0
Toxicity to various agents	2	0
Product administration errors and issues		
Accidental overdose	5	0
Contraindicated product administered	1	0
Expired product administered	10	0
Inappropriate schedule of product administration	364	0
Incomplete course of vaccination	1	0
Incorrect dose administered	51	0
Incorrect drug administration rate	1	0
Incorrect product formulation administered	2	0
Incorrect route of product administration	4	0
Poor quality product administered	3	0
Product administered at inappropriate site	11	0
Product administered to patient of inappropriate age	1	0
Product administration error	6	0
Product dose omission issue	4	0
Wrong product administered	19	0
Product confusion errors and issues		
Product label confusion	1	0
Product dispensing errors and issues		
Product dispensing error	3	0
Product monitoring errors and issues		
Drug monitoring procedure incorrectly performed	1	0
Product preparation errors and issues		
Product preparation error	1	0
Product preparation issue	5	0
Product prescribing errors and issues		
Contraindicated product prescribed	2	0
Product prescribing error	1	0
Product selection errors and issues		
Product selection error	2	0
Radiation injuries		
Sunburn	19	0
Renal and urinary tract injuries NEC		
Foreign body in urogenital tract	1	0
Site specific injuries NEC		
Face crushing	1	0
Face injury	1	0
Head injury	30	0
Limb crushing injury	2	0
Limb injury	77	0
Nasal injury	2	0
Neck crushing	1	0
Neck injury	1	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
<i>Skin injuries NEC</i>		
Contusion	865	0
Nail avulsion	1	0
Scar	15	0
Scratch	7	0
Skin abrasion	5	0
Skin injury	3	0
Skin laceration	3	0
Skin wound	2	0
Subcutaneous haematoma	2	0
<i>Skin procedural complications</i>		
Recall phenomenon	1	0
<i>Skull fractures, facial bone fractures and dislocations</i>		
Facial bones fracture	1	0
Fractured skull depressed	1	0
<i>Spinal cord injuries NEC</i>		
Spinal cord injury cervical	1	0
<i>Spinal fractures and dislocations</i>		
Spinal fracture	3	0
<i>Stoma complications</i>		
Gastrointestinal stoma complication	1	0
Stoma site discharge	1	0
Stoma site extravasation	1	0
Stoma site haemorrhage	1	0
<i>Thermal burns</i>		
Airway burns	1	0
Burn oesophageal	2	0
Burn of internal organs	2	0
Burn oral cavity	2	0
Burns second degree	4	0
Thermal burn	16	0
Thermal burns of eye	9	0
<i>Underdoses NEC</i>		
Underdose	6	0
<i>Vaccination related complications</i>		
Vaccination complication	41	0
Injuries SOC TOTAL	4243	2

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Reaction Name	Total	Fatal
Investigations		
Adrenal cortex tests		
Cortisol decreased	3	0
Adrenal medulla tests		
Epinephrine abnormal	1	0
Epinephrine increased	1	0
Auditory and vestibular diagnostic procedures		
Acoustic stimulation tests	5	0
Audiogram abnormal	1	0
Autoimmunity analyses		
Antinuclear antibody	1	0
Antinuclear antibody increased	1	0
Antinuclear antibody positive	2	0
Rheumatoid factor	3	0
Bacteria identification and serology (excl mycobacteria)		
Klebsiella test positive	1	0
Blood counts NEC		
Blood count	4	0
Blood count abnormal	2	0
Blood gas and acid base analyses		
Acid base balance abnormal	1	0
Blood lactic acid	3	0
Blood lactic acid decreased	1	0
Blood lactic acid increased	4	0
Blood pH	6	0
Blood pH increased	6	0
Oxygen consumption decreased	2	0
Oxygen saturation	8	0
Oxygen saturation decreased	52	0
PO2 decreased	1	0
Bone marrow and immune tissue histopathology procedures		
Aspiration bone marrow	1	0
Biopsy lymph gland	1	0
Bone marrow and immune tissue imaging procedures		
Lymph nodes scan abnormal	1	0
Scan lymph nodes	4	0
Carbohydrate tolerance analyses (incl diabetes)		
Blood glucose	6	0
Blood glucose abnormal	10	0
Blood glucose decreased	27	0
Blood glucose fluctuation	14	0
Blood glucose increased	84	0
Blood glucose normal	1	0
Glycosylated haemoglobin increased	1	0
Cardiac auscultatory investigations		
Cardiac murmur	23	0
Heart sounds	2	0
Heart sounds abnormal	3	0
Cardiac function diagnostic procedures		
Cardiac monitoring	1	0
Cardiac output	1	0
Central venous pressure	1	0
Echocardiogram	1	0
Myocardial strain	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Stroke volume decreased	1	0
Cardiac imaging procedures		
Magnetic resonance imaging heart	1	0
Scan myocardial perfusion abnormal	1	0
Cell marker analyses		
HLA-B*27 positive	1	0
Prostatic specific antigen increased	2	0
Central nervous system imaging procedures		
Computerised tomogram head	5	0
Magnetic resonance imaging head	11	0
Magnetic resonance imaging head abnormal	1	0
Cerebrospinal fluid tests (excl microbiology)		
CSF pressure	1	0
Chemistry analyses NEC		
Histamine abnormal	1	0
Histamine level increased	1	0
Inflammatory marker increased	3	0
Renin	1	0
Cholesterol analyses		
Blood cholesterol increased	5	0
Remnant-like lipoprotein particles	3	0
Coagulation and bleeding analyses		
Activated partial thromboplastin time prolonged	15	0
Activated partial thromboplastin time shortened	1	0
Bleeding time	1	0
Bleeding time abnormal	1	0
Bleeding time prolonged	5	0
Blood thromboplastin	1	0
Clot retraction	1	1
Coagulation factor VIII level decreased	1	0
Coagulation time prolonged	9	0
Coagulation time shortened	2	0
Fibrin D dimer increased	7	0
International normalised ratio abnormal	5	0
International normalised ratio decreased	18	0
International normalised ratio fluctuation	1	0
International normalised ratio increased	47	0
Prothrombin time shortened	1	0
Digestive enzymes		
Amylase increased	1	0
ECG investigations		
Electrocardiogram	2	0
Electrocardiogram QRS complex prolonged	1	0
Electrocardiogram QT prolonged	3	0
Electrocardiogram ST segment depression	1	0
Electrocardiogram ST segment elevation	4	0
Electrocardiogram ST-T segment abnormal	1	0
Electrocardiogram T wave inversion	4	0
Electrocardiogram abnormal	12	0
Electrocardiogram normal	2	0
Electrocardiogram repolarisation abnormality	1	0
QRS axis abnormal	1	0
Endocrine analyses and imaging NEC		

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Hormone level abnormal	31	0
Faecal analyses NEC		
Faecal calprotectin	2	0
Faecal calprotectin increased	4	0
Fertility analyses		
Infertility tests	1	0
Semen analysis abnormal	1	0
Foetal and neonatal diagnostic procedures		
Foetal heart rate abnormal	2	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
Gastrointestinal function diagnostic procedures		
Gastric pH decreased	1	0
Gastrointestinal, pancreatic and APUD hormone analyses		
Blood insulin	1	0
Blood insulin decreased	1	0
Haematological analyses NEC		
Blood viscosity abnormal	1	0
Plasma viscosity	1	0
Red blood cell sedimentation rate increased	5	0
Heart rate and pulse investigations		
Carotid pulse	1	0
Heart rate	314	0
Heart rate abnormal	44	0
Heart rate decreased	51	0
Heart rate increased	618	0
Heart rate irregular	122	0
Maximum heart rate	1	0
Pulse abnormal	14	0
Pulse pressure increased	1	0
Radial pulse abnormal	1	0
Sinus rhythm	5	0
Imaging procedures NEC		
Computerised tomogram	3	0
Magnetic resonance imaging	3	0
Magnetic resonance imaging abnormal	1	0
Scan	2	0
X-ray	1	0
Immunoglobulin analyses		
Blood immunoglobulin G increased	1	0
Blood immunoglobulin M	1	0
Blood immunoglobulin M increased	1	0
Immunology analyses NEC		
Antibody test	4	0
Immunology test	9	0
Immunology skin tests NEC		
Skin test positive	1	0
Investigations NEC		
Blood test	16	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Blood test abnormal	37	0
False positive investigation result	1	0
Laboratory test	1	0
Polymerase chain reaction positive	33	0
Quality of life decreased	2	0
Systemic lupus erythematosus disease activity index increased	1	0
Liver function analyses		
Alanine aminotransferase increased	19	0
Aspartate aminotransferase	1	0
Aspartate aminotransferase increased	2	0
Blood bilirubin increased	3	0
Gamma-glutamyltransferase increased	4	0
Hepatic enzyme increased	4	0
Liver function test	1	0
Liver function test abnormal	23	0
Liver function test increased	17	0
Transaminases increased	3	0
Metabolism tests NEC		
Blood ketone body	3	0
Blood ketone body increased	1	0
Blood ketone body present	1	0
Blood uric acid increased	2	0
Brain natriuretic peptide increased	1	0
Ubiquinone	1	0
Urine ketone body present	1	0
Microbiology and serology tests NEC		
Culture negative	1	0
Mineral and electrolyte analyses		
Blood copper increased	1	0
Blood iron	1	0
Blood iron decreased	7	0
Blood magnesium decreased	1	0
Blood phosphorus decreased	1	0
Blood phosphorus increased	1	0
Blood potassium abnormal	1	0
Blood potassium decreased	4	0
Blood potassium increased	2	0
Blood sodium decreased	8	0
Serum ferritin	1	0
Serum ferritin decreased	4	0
Serum ferritin increased	1	0
Musculoskeletal and soft tissue imaging procedures		
Skull X-ray	6	0
Musculoskeletal and soft tissue tests NEC		
Swollen joint count increased	1	0
Mycobacteria identification and serology		
Tuberculin test positive	1	0
Neurologic diagnostic procedures		
Coma scale abnormal	3	0
Hoover's sign of leg paresis	1	0
Lumbar puncture	4	0
Temperature perception test abnormal	1	0
Temperature perception test increased	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
<i>Ophthalmic function diagnostic procedures</i>		
Corneal reflex decreased	1	0
Intraocular pressure increased	7	0
Intraocular pressure test	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature	198	0
Body temperature abnormal	32	0
Body temperature decreased	33	0
Body temperature fluctuation	29	0
Body temperature increased	324	0
Body temperature normal	1	0
Breath sounds abnormal	1	0
General physical condition abnormal	1	0
Grip strength	2	0
Grip strength decreased	14	0
Head lag	5	0
Lymph node palpable	32	0
Menstruation normal	2	0
Muscle strength abnormal	1	0
Ophthalmological examination	2	0
Palpatory finding abnormal	1	0
Product residue present	2	0
Psoriasis area severity index decreased	1	0
Respiratory rate	7	0
Respiratory rate decreased	13	0
Respiratory rate increased	30	0
Skin temperature	30	0
Temperature difference of extremities	7	0
Weight	1	0
Weight decreased	74	0
Weight increased	23	0
<i>Pituitary analyses anterior</i>		
Blood corticotrophin	1	0
Blood follicle stimulating hormone	1	0
Blood growth hormone	3	0
Blood prolactin	2	0
Blood prolactin increased	2	0
Blood thyroid stimulating hormone decreased	1	0
Blood thyroid stimulating hormone increased	3	0
<i>Platelet analyses</i>		
Mean platelet volume decreased	1	0
Mean platelet volume increased	1	0
Platelet count	2	0
Platelet count decreased	58	0
Platelet count increased	2	0
<i>Protein analyses NEC</i>		
Alpha 1 globulin decreased	1	0
Alpha 2 globulin decreased	1	0
C-reactive protein increased	14	0
<i>Red blood cell analyses</i>		
Haematocrit	1	0
Haematocrit increased	1	0
Haemoglobin	1	0

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Haemoglobin decreased	10	0
Haemoglobin increased	1	0
Renal function analyses		
Blood creatinine increased	1	0
Glomerular filtration rate decreased	2	0
Reproductive hormone analyses		
Anti-Muellerian hormone level decreased	1	0
Blood testosterone increased	1	0
False negative pregnancy test	7	0
Female sex hormone level	2	0
Pregnancy test	18	0
Pregnancy test false positive	1	0
Pregnancy test positive	1	0
Reproductive organ and breast histopathology procedures		
Smear cervix	1	0
Reproductive organ and breast imaging procedures		
Hysteroscopy	2	0
Respiratory and pulmonary function diagnostic procedures		
Forced expiratory volume increased	2	0
Maximal voluntary ventilation	1	0
Peak expiratory flow rate	1	0
Peak expiratory flow rate decreased	4	0
Pulmonary function test	2	0
Total lung capacity decreased	1	0
Vital capacity	1	0
Respiratory tract and thoracic histopathology procedures		
Sputum abnormal	3	0
Respiratory tract and thoracic imaging procedures		
Chest X-ray	18	0
Chest X-ray abnormal	1	0
Chest X-ray normal	1	0
Chest scan	1	0
Computerised tomogram thorax	1	0
Skeletal and cardiac muscle analyses		
Blood creatine phosphokinase increased	4	0
Myocardial necrosis marker	1	0
Troponin	1	0
Troponin T increased	1	0
Troponin increased	8	0
Therapeutic drug monitoring analyses		
Analgesic drug level	4	0
Anticoagulation drug level above therapeutic	1	0
Anticoagulation drug level below therapeutic	5	0
Anticoagulation drug level increased	1	0
Drug level decreased	1	0
Thyroid analyses		
Anti-thyroid antibody	1	0
Thyroid function test abnormal	3	0
Thyroxine free increased	2	0
Tri-iodothyronine	1	0
Tri-iodothyronine decreased	4	0
Tissue enzyme analyses NEC		
Blood alkaline phosphatase increased	2	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Enzyme level increased	1	0
Toxicology laboratory analyses		
Blood caffeine decreased	1	0
Drug screen positive	2	0
Opiates	1	0
Urinalysis NEC		
Blood urine	11	0
Blood urine present	37	0
Cells in urine	1	0
Glucose urine present	1	0
Protein urine absent	1	0
Urine analysis abnormal	5	0
Urine uric acid increased	1	0
pH urine	5	0
pH urine increased	2	0
Urinary tract function analyses NEC		
Urine output	11	0
Urine output decreased	8	0
Urine output increased	5	0
Urinary tract imaging procedures		
Cystoscopy	2	0
Vascular imaging procedures NEC		
Venogram	1	0
Vascular tests NEC (incl blood pressure)		
Blood pressure abnormal	6	0
Blood pressure decreased	53	0
Blood pressure diastolic	1	0
Blood pressure diastolic decreased	1	0
Blood pressure diastolic increased	2	0
Blood pressure increased	174	0
Blood pressure measurement	29	0
Blood pressure normal	1	0
Blood pressure systolic	1	0
Blood pressure systolic decreased	3	0
Blood pressure systolic increased	1	0
Virus identification and serology		
Coronavirus test	11	0
Coronavirus test positive	3	0
HIV test	1	0
SARS-CoV-1 test	1	0
SARS-CoV-1 test positive	1	0
SARS-CoV-2 antibody test	9	0
SARS-CoV-2 antibody test negative	13	0
SARS-CoV-2 antibody test positive	2	0
SARS-CoV-2 test	26	0
SARS-CoV-2 test false negative	1	0
SARS-CoV-2 test false positive	2	0
SARS-CoV-2 test negative	7	0
SARS-CoV-2 test positive	89	0
Viral test	4	0
Vitamin analyses		
Blood folate decreased	3	0
Vitamin B12	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Vitamin B12 abnormal	1	0
Vitamin B12 decreased	1	0
Vitamin D	2	0
Vitamin D decreased	3	0
<i>Water and electrolyte analyses NEC</i>		
Urine osmolarity	1	0
Volume blood	1	0
<i>White blood cell analyses</i>		
Eosinophil count increased	3	0
Lymphocyte count	1	0
Lymphocyte count decreased	2	0
Neutrophil count	2	0
Neutrophil count decreased	5	0
White blood cell count	3	0
White blood cell count decreased	9	0
White blood cell count increased	6	0
Investigations SOC TOTAL	3642	3

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	11	0
Decreased appetite	917	0
Diet refusal	1	0
Eating disorder symptom	2	0
Food craving	9	0
Food refusal	9	0
Hyperphagia	9	0
Hypophagia	16	0
Increased appetite	25	0
Salt craving	2	0
<i>Calcium metabolism disorders</i>		
Hypocalcaemia	3	0
Tetany	3	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	35	0
Diabetes mellitus inadequate control	12	1
Increased insulin requirement	1	0
Insulin resistant diabetes	1	0
Latent autoimmune diabetes in adults	2	0
Type 1 diabetes mellitus	14	0
Type 2 diabetes mellitus	3	0
<i>Diabetic complications NEC</i>		
Diabetic complication	2	0
Diabetic ketoacidosis	11	0
Diabetic ketosis	1	0
<i>Disorders of purine metabolism</i>		
Gout	75	0
<i>Electrolyte imbalance NEC</i>		
Fluid imbalance	1	0
<i>Fat soluble vitamin deficiencies and disorders</i>		
Vitamin D deficiency	2	0
<i>Fluid intake increased</i>		
Polydipsia	5	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Alcohol intolerance	2	0
Dairy intolerance	1	0
Food intolerance	8	0
Gluten sensitivity	6	0
Histamine intolerance	3	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	12	0
Abnormal weight gain	11	0
Cachexia	1	0
Feeding disorder	51	0
Food aversion	7	0
Malnutrition	1	0
Neonatal insufficient breast milk syndrome	4	0
Overweight	1	0
Poor feeding infant	11	0
Weight loss poor	2	0
<i>Hyperglycaemic conditions NEC</i>		
Glucose tolerance impaired	1	0

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Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
Hyperglycaemia	59	0
Insulin resistance	4	0
<i>Hypoglycaemic conditions NEC</i>		
Glycopenia	1	0
Hypoglycaemia	71	0
Hypoglycaemia unawareness	1	0
Postprandial hypoglycaemia	1	0
<i>Iron deficiencies</i>		
Iron deficiency	10	0
<i>Iron excess</i>		
Haemochromatosis	1	0
Iron overload	1	0
<i>Lipid metabolism and deposit disorders NEC</i>		
Body fat disorder	1	0
<i>Metabolic acidoses (excl diabetic acidoses)</i>		
Ketoacidosis	4	0
Lactic acidosis	2	0
Metabolic acidosis	2	0
<i>Mixed acid-base disorders</i>		
Acidosis	3	0
<i>Potassium imbalance</i>		
Hyperkalaemia	3	0
Hypokalaemia	3	0
Hypokalaemic syndrome	1	0
<i>Sodium imbalance</i>		
Hyponatraemia	7	0
Hyponatraemic syndrome	3	0
<i>Sugar intolerance (excl glucose intolerance)</i>		
Lactose intolerance	1	0
<i>Total fluid volume decreased</i>		
Dehydration	141	0
<i>Total fluid volume increased</i>		
Fluid overload	1	0
Fluid retention	41	0
Hypervolaemia	1	0
<i>Vitamin deficiencies NEC</i>		
Hypovitaminosis	3	0
<i>Water soluble vitamin deficiencies</i>		
Folate deficiency	3	0
Vitamin B12 deficiency	3	0
Metabolic disorders SOC TOTAL	1666	1

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	195	0
Arthropathy	23	0
Autoimmune arthritis	4	0
Haemarthrosis	5	0
Joint microhaemorrhage	1	0
Palindromic rheumatism	1	0
Polyarthritis	13	0
Rheumatic fever	1	0
Sacroiliitis	4	0
Seronegative arthritis	2	0
<i>Bone disorders NEC</i>		
Jaw disorder	3	0
Medial tibial stress syndrome	4	0
Osteitis	4	0
Osteonecrosis	1	0
Osteonecrosis of jaw	3	0
Spinal disorder	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	278	0
Bone swelling	5	0
Coccydynia	3	0
Metatarsalgia	1	0
Pain in jaw	272	0
Pubic pain	2	0
Spinal pain	52	0
<i>Bursal disorders</i>		
Bursitis	50	0
<i>Cartilage disorders</i>		
Chondritis	1	0
Costochondritis	53	0
Osteochondritis	1	0
Polychondritis	3	0
<i>Connective tissue disorders NEC</i>		
Connective tissue disorder	1	0
Polymyalgia rheumatica	42	0
Reynold's syndrome	1	0
Sjogren's syndrome	5	0
<i>Crystal arthropathic disorders</i>		
Chondrocalcinosis pyrophosphate	2	0
Crystal arthropathy	1	0
<i>Epiphyseal disorders</i>		
Epiphyses premature fusion	1	0
<i>Extremity deformities</i>		
Bone deformity	1	0
Finger deformity	1	0
Foot deformity	1	0
Hand deformity	2	0
Knee deformity	1	0
Limb deformity	4	0
Musculoskeletal deformity	1	0
<i>Intervertebral disc disorders NEC</i>		
Intervertebral disc protrusion	2	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Joint related disorders NEC		
Chondromalacia	1	0
Hypermobility syndrome	1	0
Joint deposit	1	0
Joint destruction	1	0
Joint laxity	3	0
Joint lock	20	0
Patellofemoral pain syndrome	1	0
Periarthritis	103	0
Rotator cuff syndrome	18	0
Temporomandibular joint syndrome	7	0
Joint related signs and symptoms		
Arthralgia	6705	0
Jaw clicking	4	0
Joint effusion	14	0
Joint noise	27	0
Joint range of motion decreased	19	0
Joint stiffness	175	0
Joint swelling	372	0
Joint vibration	2	0
Joint warmth	12	0
Loose body in joint	1	0
Ligament disorders		
Symphysiolysis	1	0
Lupus erythematosus (incl subtypes)		
Lupus-like syndrome	1	0
Systemic lupus erythematosus	17	0
Metabolic bone disorders		
Osteopenia	2	0
Osteoporosis	2	0
Muscle infections and inflammations		
Antisynthetase syndrome	3	0
Myositis	21	0
Polymyositis	5	0
Muscle pains		
Fibromyalgia	72	0
Myalgia	8368	0
Myalgia intercostal	1	0
Myofascial pain syndrome	7	0
Muscle related signs and symptoms NEC		
Haematoma muscle	1	0
Muscle atrophy	15	0
Muscle discomfort	2	0
Muscle disorder	4	0
Muscle fatigue	265	0
Muscle haemorrhage	1	0
Muscle mass	4	0
Muscle oedema	1	0
Muscle spasms	1426	0
Muscle swelling	22	0
Muscle tightness	67	0
Muscle twitching	331	0
Muscle tone abnormalities		

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Muscle rigidity	13	0
Nuchal rigidity	10	0
Torticollis	4	0
Trismus	28	0
Muscle weakness conditions		
Muscular weakness	649	0
Musculoskeletal and connective tissue conditions NEC		
Back disorder	2	0
Growth disorder	1	0
Limb mass	19	0
Mandibular mass	2	0
Mastication disorder	3	0
Mobility decreased	70	0
Musculoskeletal disorder	10	0
Musculoskeletal stiffness	945	0
Posture abnormal	1	0
Sacroiliac joint dysfunction	1	0
Weight bearing difficulty	1	0
Musculoskeletal and connective tissue deformities of skull, face and buccal cavity		
Head deformity	2	0
Musculoskeletal and connective tissue infections and inflammations NEC		
Dactylitis	2	0
Dupuytren's contracture	1	0
Fasciitis	1	0
Plantar fasciitis	6	0
Musculoskeletal and connective tissue pain and discomfort		
Back pain	1719	0
Flank pain	44	0
Limb discomfort	1148	0
Musculoskeletal chest pain	159	0
Musculoskeletal discomfort	71	0
Musculoskeletal pain	34	0
Neck pain	1380	0
Pain in extremity	9585	0
Rheumatic disorder	9	0
Myopathies		
Myopathy	4	0
Rhabdomyolysis	7	0
Osteoarthropathies		
Nodal osteoarthritis	1	0
Osteoarthritis	30	0
Spinal osteoarthritis	1	0
Psoriatic arthropathies		
Psoriatic arthropathy	14	0
Rheumatoid arthropathies		
Rheumatoid arthritis	87	0
Soft tissue disorders NEC		
Axillary mass	176	0
Fluctuance	1	0
Groin pain	86	0
Neck mass	25	0
Purple glove syndrome	1	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Soft tissue disorder	2	0
Soft tissue swelling	3	0
<i>Spine and neck deformities</i>		
Kyphosis	2	0
Lordosis	1	0
Neck deformity	1	0
Scoliosis	1	0
<i>Spondyloarthropathies</i>		
Ankylosing spondylitis	6	0
Arthritis reactive	33	0
Spondylitis	1	0
<i>Synovial disorders</i>		
Synovial cyst	17	0
Synovitis	5	0
<i>Tendon disorders</i>		
Enthesopathy	1	0
Tendon disorder	2	0
Tendon pain	17	0
Tendonitis	28	0
Tenosynovitis	2	0
Tenosynovitis stenosaurs	2	0
Trigger finger	19	0
<i>Trunk deformities</i>		
Drooping shoulder syndrome	1	0
Shoulder deformity	1	0
Muscle & tissue disorders SOC TOTAL	35676	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>B-cell lymphomas NEC</i>		
B-cell lymphoma	1	1
Follicular lymphoma	3	0
<i>Bone neoplasms unspecified malignancy</i>		
Bone neoplasm	2	0
<i>Breast and nipple neoplasms benign</i>		
Benign breast neoplasm	1	0
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	29	0
Breast cancer female	1	0
Breast cancer male	1	0
Breast cancer stage I	1	0
Breast cancer stage III	2	0
Invasive ductal breast carcinoma	1	0
Triple negative breast cancer	2	0
<i>Cardiovascular neoplasms benign</i>		
Pericardial lipoma	1	0
<i>Colorectal neoplasms malignant</i>		
Colon cancer	1	0
Colorectal cancer	1	0
Rectal cancer	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>		
Gastric cancer	1	1
<i>Gastrointestinal neoplasms malignant NEC</i>		
Gastrointestinal carcinoma	3	0
<i>Hodgkin's disease NEC</i>		
Hodgkin's disease	3	0
<i>Islet cell neoplasms and APUDoma NEC</i>		
Pancreatic neuroendocrine tumour	1	0
<i>Leukaemias NEC</i>		
Leukaemia	2	1
<i>Leukaemias acute NEC</i>		
Acute leukaemia	1	0
<i>Leukaemias chronic lymphocytic</i>		
Chronic lymphocytic leukaemia	2	0
<i>Lip and oral cavity neoplasms malignant</i>		
Lip and/or oral cavity cancer recurrent	1	0
<i>Lymphomas unspecified NEC</i>		
Lymphoma	23	1
<i>Metastases to specified sites</i>		
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	2	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
<i>Myeloproliferative disorders (excl leukaemias)</i>		
Essential thrombocythaemia	1	0
<i>Neoplasms benign site unspecified NEC</i>		
Adenoma benign	1	0
<i>Neoplasms malignant site unspecified NEC</i>		
Adenocarcinoma metastatic	1	0
Metastatic neoplasm	1	0
Neoplasm malignant	6	0
Second primary malignancy	1	0
Squamous cell carcinoma	4	0
<i>Neoplasms unspecified malignancy and site unspecified NEC</i>		
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	2	0
Spinal cord neoplasm	1	0
<i>Neuromas</i>		
Acoustic neuroma	2	0
<i>Non-Hodgkin's lymphomas NEC</i>		
Non-Hodgkin's lymphoma	2	0
<i>Oesophageal neoplasms malignant</i>		
Oesophageal cancer metastatic	4	0
<i>Oncologic complications and emergencies</i>		
Cancer pain	1	0
<i>Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified</i>		
Tonsil cancer	2	0
<i>Pancreatic neoplasms malignant (excl islet cell and carcinoid)</i>		
Pancreatic carcinoma	4	0
<i>Plasma cell myelomas</i>		
POEMS syndrome	1	0
Plasma cell myeloma	1	0
<i>Plasma cell neoplasms NEC</i>		
TEMPI syndrome	1	0
<i>Prostatic neoplasms malignant</i>		
Prostate cancer	3	0
<i>Renal neoplasms malignant</i>		
Renal cancer	2	0
<i>Respiratory tract and pleural neoplasms malignant cell type unspecified NEC</i>		
Bronchial carcinoma	1	0
Lung neoplasm malignant	6	0
<i>Skin melanomas (excl ocular)</i>		
Malignant melanoma	1	0
<i>Skin neoplasms benign</i>		
Acrochordon	2	0
Anogenital warts	6	0
Haemangioma of skin	3	0
Melanocytic naevus	4	0
Pyogenic granuloma	1	0

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
Skin papilloma	12	0
<i>Skin neoplasms malignant and unspecified (excl melanoma)</i>		
Basal cell carcinoma	2	0
Bowen's disease	1	0
Neoplasm skin	2	0
Squamous cell carcinoma of skin	1	0
<i>Soft tissue neoplasms benign NEC</i>		
Lipoma	6	0
Lymphangioma	1	0
<i>Soft tissue sarcomas histology unspecified</i>		
Sarcoma	1	0
<i>Thyroid neoplasms malignant</i>		
Papillary thyroid cancer	2	0
Thyroid cancer	1	0
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	9	0
Neoplasms SOC TOTAL	207	4

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Areflexia	5	0
Extensor plantar response	1	0
Hyperreflexia	3	0
Hyporeflexia	7	0
<i>Abnormal sleep-related events</i>		
Sleep paralysis	19	0
<i>Absence seizures</i>		
Petit mal epilepsy	22	0
<i>Acute polyneuropathies</i>		
Acute motor axonal neuropathy	1	0
Guillain-Barre syndrome	42	1
Subacute inflammatory demyelinating polyneuropathy	1	0
<i>Autonomic nervous system disorders</i>		
Anticholinergic syndrome	1	0
Autonomic nervous system imbalance	7	0
Autonomic neuropathy	2	0
Horner's syndrome	1	0
<i>Central nervous system aneurysms and dissections</i>		
Carotid artery dissection	1	0
Intracranial aneurysm	2	1
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Brain stem infarction	1	1
Brain stem stroke	1	0
Carotid artery thrombosis	3	0
Cerebellar haemorrhage	2	0
Cerebellar infarction	2	0
Cerebellar ischaemia	1	0
Cerebellar stroke	5	0
Cerebral artery embolism	3	1
Cerebral artery occlusion	1	0
Cerebral artery thrombosis	3	0
Cerebral haemorrhage	40	7
Cerebral infarction	23	1
Cerebral thrombosis	9	0
Cerebrovascular accident	310	13
Embolic stroke	6	0
Haemorrhage intracranial	9	2
Haemorrhagic cerebral infarction	1	0
Haemorrhagic stroke	10	4
Internal capsule infarction	1	0
Intracranial haematoma	1	0
Ischaemic cerebral infarction	1	0
Ischaemic stroke	32	1
Lacunar infarction	2	0
Lacunar stroke	3	0
Lateral medullary syndrome	1	0
Pseudostroke	1	0
Subarachnoid haemorrhage	13	6
Thalamic infarction	1	0
Thrombotic stroke	3	1
<i>Central nervous system inflammatory disorders NEC</i>		
Gliosis	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Central nervous system vascular disorders NEC		
Brain hypoxia	1	1
Central nervous system vasculitis	1	0
Cerebral amyloid angiopathy	1	0
Cerebral congestion	2	0
Cerebral small vessel ischaemic disease	1	0
Cerebrovascular disorder	1	0
Post cardiac arrest syndrome	1	0
Reversible cerebral vasoconstriction syndrome	1	0
Cerebrovascular venous and sinus thrombosis		
Cerebral venous sinus thrombosis	35	2
Cerebral venous thrombosis	4	0
Superior sagittal sinus thrombosis	3	0
Transverse sinus thrombosis	1	0
Cervical spinal cord and nerve root disorders		
Cervical radiculopathy	1	0
Cervicobrachial syndrome	3	0
Choreiform movements		
Chorea	2	0
Chronic polyneuropathies		
Demyelinating polyneuropathy	1	0
Coma states		
Coma	9	0
Diabetic coma	1	0
Hypoglycaemic coma	1	0
Coordination and balance disturbances		
Ataxia	9	0
Balance disorder	290	0
Coordination abnormal	39	0
Dysdiadochokinesis	1	0
Dysstasia	42	0
Nystagmus	10	0
Cortical dysfunction NEC		
Alexia	2	0
Aphasia	58	0
Apraxia	1	0
Dyspraxia	1	0
Neurologic neglect syndrome	1	0
Sensory processing disorder	2	0
Visuospatial deficit	1	0
Cranial nerve disorders NEC		
Cranial nerve disorder	2	0
Dementia (excl Alzheimer's type)		
Dementia	12	0
Dementia with Lewy bodies	1	0
Senile dementia	1	0
Demyelinating disorders NEC		
Acute disseminated encephalomyelitis	4	0
Clinically isolated syndrome	1	0
Demyelination	8	0
Neuromyelitis optica spectrum disorder	2	0
Disturbances in consciousness NEC		
Altered state of consciousness	10	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Consciousness fluctuating	2	0
Depressed level of consciousness	37	1
Infant sedation	1	0
Lethargy	1738	0
Loss of consciousness	456	0
Postictal state	4	0
Sedation	8	0
Somnolence	789	0
Stupor	4	0
Syncope	1516	0
<i>Disturbances in sleep phase rhythm</i>		
Irregular sleep phase	2	0
Irregular sleep wake rhythm disorder	1	0
<i>Dyskinesias and movement disorders NEC</i>		
Akathisia	3	0
Bradykinesia	12	0
Clumsiness	13	0
Dyskinesia	47	0
Extrapyramidal disorder	2	0
Fine motor skill dysfunction	7	0
Foetal movement disorder	1	0
Hyperkinesia	3	0
Hypokinesia	52	0
Motor dysfunction	2	0
Movement disorder	40	0
Psychomotor hyperactivity	18	0
Synkinesis	2	0
Tardive dyskinesia	2	0
<i>Dystonias</i>		
Dystonia	15	0
Writer's cramp	1	0
<i>Encephalitis NEC</i>		
Encephalitis autoimmune	1	0
Limbic encephalitis	1	0
Noninfective encephalitis	4	0
<i>Encephalopathies NEC</i>		
Encephalopathy	3	0
Hashimoto's encephalopathy	1	0
Posterior reversible encephalopathy syndrome	1	0
<i>Eye movement disorders</i>		
IIIrd nerve disorder	1	0
IIIrd nerve paralysis	5	0
IVth nerve paralysis	1	0
Microvascular cranial nerve palsy	1	0
VIth nerve paralysis	9	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	381	0
Facial nerve disorder	8	0
Facial paralysis	294	0
Facial paresis	75	0
Facial spasm	33	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	37	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Headaches NEC		
Cervicogenic headache	3	0
Cluster headache	170	0
Cold-stimulus headache	16	0
Drug withdrawal headache	2	0
Exertional headache	7	0
External compression headache	1	0
Headache	20246	0
Medication overuse headache	2	0
New daily persistent headache	4	0
Occipital neuralgia	9	0
Ophthalmoplegic migraine	1	0
Primary cough headache	4	0
Primary headache associated with sexual activity	4	0
Sinus headache	276	0
Tension headache	428	0
Thunderclap headache	7	0
Vascular headache	13	0
Hydrocephalic conditions		
Hydrocephalus	2	0
Hypoglossal nerve disorders		
Tongue paralysis	1	0
Increased intracranial pressure disorders		
Brain compression	1	0
Brain oedema	5	1
Idiopathic intracranial hypertension	6	0
Intracranial pressure increased	1	0
Intellectual disabilities		
Intellectual disability	2	0
Lumbar spinal cord and nerve root disorders		
Sciatica	64	0
Memory loss (excl dementia)		
Amnesia	125	0
Memory impairment	131	0
Transient global amnesia	7	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	65	0
Cognitive linguistic deficit	1	0
Disturbance in attention	240	0
Mental impairment	38	0
Migraine headaches		
Hemiplegic migraine	22	0
Migraine	2168	0
Migraine with aura	143	0
Migraine without aura	15	0
Ophthalmic migraine	5	0
Retinal migraine	25	0
Typical aura without headache	7	0
Vestibular migraine	15	0
Mixed cranial nerve disorders		
Bulbar palsy	2	0
Mononeuropathies		
Carpal tunnel syndrome	16	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Cubital tunnel syndrome	1	0
Meralgia paraesthetica	1	0
Mononeuritis	2	0
Mononeuropathy	2	0
Nerve compression	17	0
Peripheral nerve lesion	1	0
Peroneal nerve palsy	11	0
Sciatic nerve neuropathy	2	0
Ulnar nerve palsy	1	0
Ulnar neuritis	1	0
Ulnar tunnel syndrome	1	0
Motor neurone diseases		
Lower motor neurone lesion	1	0
Motor neurone disease	1	0
Multiple sclerosis acute and progressive		
Band sensation	1	0
Multiple sclerosis	25	0
Multiple sclerosis relapse	20	0
Tumefactive multiple sclerosis	1	1
Muscle tone abnormal		
Drop attacks	1	0
Hypotonia	13	0
Muscle tone disorder	1	0
Serotonin syndrome	1	0
Stiff leg syndrome	1	0
Myelitis (incl infective)		
Myelitis transverse	26	0
Narcolepsy and hypersomnia		
Cataplexy	1	0
Hypersomnia	83	0
Narcolepsy	6	0
Nervous system disorders NEC		
Central nervous system lesion	1	0
Cerebral disorder	1	0
Nervous system disorder	10	0
Neurotoxicity	2	0
Neurologic visual problems NEC		
Hemianopia	1	0
Hemianopia homonymous	1	0
Quadrantanopia	1	0
Tunnel vision	14	0
Neurological signs and symptoms NEC		
Clonus	3	0
Decerebrate posture	1	0
Dizziness	7519	0
Dizziness exertional	35	0
Dizziness postural	581	0
Drooling	21	0
Fontanelle bulging	2	0
Head discomfort	239	0
Hyporesponsive to stimuli	2	0
Inability to crawl	2	0
Infant irritability	6	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Myoclonus	20	0
Neurological symptom	37	0
Patient elopement	1	0
Persistent postural-perceptual dizziness	12	0
Presyncope	463	0
Sensory overload	3	0
Slow response to stimuli	3	0
Tongue biting	4	0
Unresponsive to stimuli	36	0
Neuromuscular disorders NEC		
Muscle contractions involuntary	16	0
Muscle spasticity	9	0
Neuromuscular pain	3	0
Neuromuscular junction dysfunction		
Myasthenia gravis	7	0
Myasthenia gravis crisis	2	0
Olfactory nerve disorders		
Anosmia	198	0
Hyposmia	14	0
Parosmia	187	0
Optic nerve disorders NEC		
Optic neuritis	22	0
Paraesthesias and dysaesthesias		
Burning feet syndrome	6	0
Burning sensation	389	0
Burning sensation mucosal	2	0
Dysaesthesia	5	0
Formication	32	0
Hand-arm vibration syndrome	3	0
Hemianaesthesia	1	0
Hemiparaesthesia	2	0
Hyperaesthesia	70	0
Hypoaesthesia	2175	0
Paraesthesia	3041	0
Reversed hot-cold sensation	4	0
Synaesthesia	1	0
Paralysis and paresis (excl cranial nerve)		
Diplegia	10	1
Hemiparesis	37	0
Hemiplegia	32	0
Locked-in syndrome	1	0
Monoparesis	46	0
Monoplegia	58	0
Paralysis	101	0
Paraparesis	3	0
Paresis	6	0
Quadriparesis	1	0
Quadriplegia	1	0
Parkinson's disease and parkinsonism		
Freezing phenomenon	8	0
Parkinson's disease	3	0
Parkinsonian gait	1	0
Parkinsonian rest tremor	1	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Parkinsonism	4	0
Reduced facial expression	8	0
Partial complex seizures		
Dreamy state	6	0
Focal dyscognitive seizures	2	0
Temporal lobe epilepsy	2	0
Partial simple seizures NEC		
Autonomic seizure	1	0
Peripheral neuropathies NEC		
Axonal neuropathy	2	0
Neuralgic amyotrophy	2	0
Neuritis	6	0
Neuropathy peripheral	74	0
Peripheral sensorimotor neuropathy	1	0
Peripheral sensory neuropathy	10	0
Polyneuropathy	1	0
Thoracic outlet syndrome	1	0
Seizures and seizure disorders NEC		
Atonic seizures	5	0
Change in seizure presentation	1	0
Clonic convulsion	3	0
Convulsions local	1	0
Epilepsy	129	0
Epileptic aura	2	0
Epileptic encephalopathy	1	0
Febrile convulsion	14	0
Partial seizures	17	0
Post stroke seizure	1	0
Psychogenic seizure	7	0
Seizure	439	0
Seizure anoxic	1	0
Seizure cluster	5	0
Seizure like phenomena	2	0
Status epilepticus	36	0
Tonic clonic movements	2	0
Tonic convulsion	19	0
Tonic posturing	1	0
Sensory abnormalities NEC		
Ageusia	403	0
Allodynia	15	0
Aura	14	0
Complex regional pain syndrome	3	0
Dysgeusia	982	0
Electric shock sensation	28	0
Hypergeusia	1	0
Hypogeusia	4	0
Intercostal neuralgia	1	0
Loss of proprioception	3	0
Neuralgia	392	0
Persistent genital arousal disorder	1	0
Phantom limb syndrome	4	0
Post herpetic neuralgia	14	0
Restless arm syndrome	2	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Restless legs syndrome	99	0
Sensory disturbance	76	0
Sensory loss	57	0
Taste disorder	210	0
Visual perseveration	2	0
Sleep disturbances NEC		
Sleep deficit	3	0
Sudden onset of sleep	1	0
Speech and language abnormalities		
Dysarthria	143	0
Incoherent	9	0
Language disorder	1	0
Repetitive speech	2	0
Slow speech	11	0
Speech disorder	50	0
Spinal cord and nerve root disorders NEC		
Radiculitis brachial	7	0
Radiculopathy	4	0
Structural brain disorders NEC		
Brain injury	6	2
Hyperintensity in brain deep nuclei	1	0
Transient cerebrovascular events		
Transient ischaemic attack	121	3
Tremor (excl congenital)		
Action tremor	1	0
Essential tremor	3	0
Head titubation	9	0
Resting tremor	3	0
Tremor	1231	0
Trigeminal disorders		
Facial neuralgia	15	0
Numb chin syndrome	2	0
Trigeminal nerve disorder	2	0
Trigeminal neuralgia	35	0
Vagus nerve disorders		
Vocal cord paralysis	1	0
Vertigos NEC		
Cervicogenic vertigo	1	0
Vertigo CNS origin	1	0
Nervous system disorders SOC TOTAL	51628	51

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions not specified as induced or spontaneous</i>		
Abortion	1	0
Abortion missed	2	0
<i>Abortions spontaneous</i>		
Abortion spontaneous	258	4
Abortion threatened	2	0
<i>Amniotic fluid and cavity disorders of pregnancy NEC</i>		
Amniorrhoea	1	0
<i>Foetal complications NEC</i>		
Foetal disorder	1	0
Foetal hypokinesia	5	0
<i>Foetal growth complications</i>		
Foetal growth restriction	1	0
<i>Foetal position and presentation abnormalities</i>		
Oblique presentation	1	0
<i>Gestational age and weight conditions</i>		
Premature baby	2	1
Term baby	1	0
<i>Haemorrhagic complications of pregnancy</i>		
Haemorrhage in pregnancy	1	0
Premature separation of placenta	2	0
Subchorionic haematoma	1	0
Subchorionic haemorrhage	1	0
<i>Labour onset and length abnormalities</i>		
Premature delivery	1	0
Premature labour	3	0
Premature rupture of membranes	1	0
Threatened labour	1	0
<i>Maternal complications of labour NEC</i>		
Uterine contractions abnormal	1	0
Uterine hypertonus	6	0
<i>Maternal complications of pregnancy NEC</i>		
Decidual cast	4	0
Ectopic pregnancy	4	0
Morning sickness	10	0
Preterm premature rupture of membranes	3	0
Somatic symptom disorder of pregnancy	3	0
<i>Neonatal hepatobiliary disorders</i>		
Jaundice neonatal	1	0
<i>Newborn complications NEC</i>		
Neonatal disorder	1	0
<i>Normal newborn status</i>		
Normal newborn	1	0
<i>Normal pregnancy, labour and delivery</i>		
Labour pain	1	0
Live birth	1	0
Pregnancy	47	0
Uterine contractions during pregnancy	1	0
<i>Placental abnormalities (excl neoplasms)</i>		
Placental disorder	1	0
<i>Postpartum complications NEC</i>		
Postpartum haemorrhage	4	0
<i>Pregnancy complicated by maternal disorders</i>		

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Reaction Name	Total	Fatal
Pregnancy conditions <small>Pregnancy conditions cont'd</small>		
Gestational diabetes	2	0
Peripartum cardiomyopathy	1	0
<i>Stillbirth and foetal death</i>		
Foetal death	3	2
Stillbirth	3	2
<i>Unintended pregnancies</i>		
Pregnancy after post coital contraception	2	0
Pregnancy on contraceptive	2	0
Pregnancy on oral contraceptive	1	0
Pregnancy with contraceptive device	1	0
Unintended pregnancy	1	0
Pregnancy conditions SOC TOTAL	391	9

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Reaction Name	Total	Fatal
<i>Device issues NEC</i>		
Device connection issue	1	0
Device failure	1	0
Device issue	2	0
<i>Device malfunction events NEC</i>		
Device infusion issue	1	0
Device malfunction	1	0
Device pacing issue	1	0
Device stimulation issue	1	0
Oversensing	15	0
Thrombosis in device	9	0
<i>Device physical property and chemical issues</i>		
Device breakage	1	0
Device defective	7	0
Device kink	1	0
Needle issue	2	0
<i>Product contamination and sterility issues</i>		
Product contamination	10	0
Product contamination physical	2	0
<i>Product packaging issues</i>		
Product closure issue	1	0
<i>Product physical issues</i>		
Liquid product physical issue	7	0
Product odour abnormal	1	0
Product physical issue	2	0
Product taste abnormal	9	0
<i>Product quality issues NEC</i>		
Product complaint	1	0
Product origin unknown	6	0
<i>Product supply and availability issues</i>		
Product availability issue	1	0
null SOC TOTAL	83	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	19	0
Behaviour disorder	1	0
Breath holding	6	0
Sexually inappropriate behaviour	1	0
Staring	5	0
<i>Adjustment disorders</i>		
Adjustment disorder with depressed mood	2	0
<i>Affect alterations NEC</i>		
Affect lability	9	0
Constricted affect	3	0
Flat affect	4	0
Inappropriate affect	15	0
<i>Amnesic symptoms</i>		
Paramnesia	4	0
<i>Anxiety disorders NEC</i>		
Anxiety disorder	1	0
Generalised anxiety disorder	1	0
Neurosis	1	0
<i>Anxiety symptoms</i>		
Agitation	61	0
Anxiety	601	0
Immunisation anxiety related reaction	2	0
Nervousness	135	0
Stress	70	0
Tension	32	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	5	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	10	0
Aversion	1	0
Disinhibition	1	0
Indifference	6	0
Paranoia	18	0
Personality change	3	0
Social avoidant behaviour	5	0
Soliloquy	2	0
Suspiciousness	1	0
<i>Bipolar disorders</i>		
Bipolar I disorder	2	0
Bipolar disorder	4	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Daydreaming	7	0
Distractibility	1	0
Mental fatigue	171	0
<i>Communications disorders</i>		
Communication disorder	5	0
Mutism	2	0
<i>Confusion and disorientation</i>		
Confusional state	685	0
Disorientation	222	0
<i>Decreased physical activity levels</i>		
Catatonia	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Deliria</i>		
Delirium	83	0
<i>Delusional symptoms</i>		
Delusion	9	0
<i>Depressive disorders</i>		
Agitated depression	3	0
Depression	242	0
Depression suicidal	8	0
Major depression	6	0
Mixed anxiety and depressive disorder	1	0
<i>Dissociative states</i>		
Depersonalisation/derealisation disorder	8	0
Dissociation	23	0
Dissociative amnesia	2	0
Dissociative disorder	2	0
<i>Disturbances in initiating and maintaining sleep</i>		
Initial insomnia	15	0
Insomnia	1013	0
Middle insomnia	23	0
Terminal insomnia	28	0
<i>Dyssomnias</i>		
Dyssomnia	1	0
Poor quality sleep	162	0
<i>Eating disorders NEC</i>		
Bulimia nervosa	1	0
Eating disorder	9	0
Selective eating disorder	1	0
<i>Emotional and mood disturbances NEC</i>		
Anger	26	0
Dysphoria	2	0
Emotional disorder	44	0
Emotional distress	32	0
Emotional poverty	1	0
Euphoric mood	37	0
Frustration tolerance decreased	3	0
Irritability	161	0
Mood altered	46	0
<i>Factitious disorders</i>		
Factitious disorder	3	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Agoraphobia	1	0
Fear	14	0
Fear of falling	3	0
Fear of injection	4	0
Osmophobia	1	0
Phobia	2	0
Phonophobia	2	0
Social anxiety disorder	1	0
Social fear	1	0
<i>Fluctuating mood symptoms</i>		
Mood swings	94	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	147	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Hallucination, auditory	12	0
Hallucination, olfactory	9	0
Hallucination, tactile	1	0
Hallucination, visual	23	0
Hallucinations, mixed	2	0
Increased physical activity levels		
Restlessness	119	0
Infancy, childhood and adolescence psychiatric disorders NEC		
Social (pragmatic) communication disorder	1	0
Learning disorders		
Learning disability	1	0
Learning disorder	1	0
Mental disorders NEC		
Mental disorder	13	0
Mental status changes	1	0
Mood alterations with depressive symptoms		
Anhedonia	2	0
Decreased interest	9	0
Depressed mood	282	0
Depressive symptom	1	0
Feeling of despair	3	0
Feelings of worthlessness	1	0
Negative thoughts	1	0
Psychomotor retardation	1	0
Sense of a foreshortened future	2	0
Tearfulness	32	0
Mood alterations with manic symptoms		
Hypomania	2	0
Mania	9	0
Mood disorders NEC		
Affective disorder	2	0
Apathy	22	0
Boredom	1	0
Laziness	1	0
Listless	14	0
Mood disorder due to a general medical condition	1	0
Narcolepsy and associated conditions		
Hypnagogic hallucination	3	0
Hypnopompic hallucination	2	0
Sleep attacks	3	0
Obsessive-compulsive disorders and symptoms		
Obsessive-compulsive symptom	1	0
Orgasmic disorders and disturbances		
Anorgasmia	4	0
Female orgasmic disorder	2	0
Orgasm abnormal	3	0
Orgasmic sensation decreased	1	0
Premature ejaculation	1	0
Panic attacks and disorders		
Panic attack	134	0
Panic disorder	3	0
Panic reaction	20	0
Parasomnias		

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Abnormal dreams	140	0
Abnormal sleep-related event	1	0
Confusional arousal	1	0
Exploding head syndrome	2	0
Nightmare	160	0
Parasomnia	1	0
Sleep inertia	1	0
Sleep talking	4	0
Sleep terror	15	0
Somnambulism	4	0
Perception disturbances NEC		
Autoscopy	14	0
Deja vu	2	0
Derealisation	7	0
Flashback	3	0
Illusion	1	0
Near death experience	1	0
Time perception altered	1	0
Personality disorders NEC		
Personality disorder	1	0
Pervasive developmental disorders NEC		
Autism spectrum disorder	3	0
Psychiatric elimination disorders		
Enuresis	17	0
Psychiatric symptoms NEC		
Hypervigilance	8	0
Psychiatric symptom	3	0
Psychological trauma	2	0
Trance	1	0
Psychotic disorder NEC		
Psychotic behaviour	1	0
Psychotic disorder	16	0
Schizophrenia NEC		
Schizophrenia	1	0
Sexual arousal disorders		
Disturbance in sexual arousal	2	0
Sexual desire disorders		
Libido decreased	8	0
Libido increased	4	0
Loss of libido	12	0
Sleep disorders NEC		
Sleep disorder	158	0
Sleep disorder due to general medical condition, insomnia type	2	0
Somatic symptom disorders		
Conversion disorder	14	0
Habit cough	13	0
Somatic symptom disorder	1	0
Vomiting psychogenic	1	0
Speech and language usage disturbances		
Disorganised speech	6	0
Logorrhoea	2	0
Speech articulation and rhythm disturbances		
Dysphemia	18	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Lack of spontaneous speech	1	0
Pressure of speech	1	0
<i>Stereotypies and automatisms</i>		
Bruxism	10	0
Head banging	6	0
Stereotypy	1	0
<i>Stress disorders</i>		
Burnout syndrome	1	0
Post-traumatic stress disorder	2	0
<i>Substance related and addictive disorders</i>		
Alcohol problem	1	0
Alcoholic hangover	1	0
Alcoholism	2	0
Nicotine dependence	1	0
<i>Suicidal and self-injurious behaviour</i>		
Completed suicide	1	1
Intentional self-injury	6	0
Self-injurious ideation	2	0
Suicidal ideation	24	0
Suicide attempt	13	0
Suicide threat	1	0
<i>Thinking disturbances</i>		
Bradyphrenia	32	0
Intrusive thoughts	4	0
Morbid thoughts	1	0
Tachyphrenia	4	0
Thinking abnormal	16	0
Thought blocking	1	0
<i>Tic disorders</i>		
Tic	9	0
Psychiatric disorders SOC TOTAL	5929	1

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder discomfort	2	0
Bladder irritation	5	0
Bladder pain	21	0
Dysuria	40	0
Incontinence	21	0
Lower urinary tract symptoms	2	0
Micturition disorder	1	0
Micturition urgency	29	0
Pollakiuria	84	0
Urethral pain	6	0
Urge incontinence	1	0
Urinary hesitation	1	0
Urinary incontinence	44	0
Urinary retention	32	0
Urine flow decreased	8	0
<i>Bladder disorders NEC</i>		
Bladder disorder	5	0
Bladder fibrosis	1	0
Urinary bladder haemorrhage	2	0
<i>Bladder infections and inflammations</i>		
Cystitis interstitial	4	0
<i>Genital and urinary tract disorders NEC</i>		
Genitourinary symptom	1	0
Urinary tract disorder	3	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
Glomerulonephritis	1	0
Glomerulonephritis minimal lesion	5	0
Glomerulonephritis rapidly progressive	1	0
IgA nephropathy	1	0
Nephrotic syndrome	15	0
<i>Myoneurogenic bladder disorders</i>		
Bladder dysfunction	5	0
Hypertonic bladder	1	0
Hypotonic urinary bladder	1	0
Loss of bladder sensation	1	0
Neurogenic bladder	1	0
<i>Nephritis NEC</i>		
Lupus nephritis	1	0
Nephritis	2	0
Tubulointerstitial nephritis	2	0
<i>Nephropathies and tubular disorders NEC</i>		
Nephropathy	1	0
<i>Renal disorders NEC</i>		
Renal disorder	4	1
Renal haemorrhage	1	0
Renal mass	1	0
<i>Renal failure and impairment</i>		
Acute kidney injury	40	4
Anuria	3	0
Chronic kidney disease	4	0
Oliguria	1	0
Renal failure	14	1

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Reaction Name	Total	Fatal
Renal & urinary disorders		
Renal & urinary disorders cont'd		
Renal impairment	15	0
Renal injury	1	0
Renal lithiasis		
Nephrolithiasis	6	0
Renal neoplasms		
Renal cyst	1	0
Renal obstructive disorders		
Hydronephrosis	2	0
Renal structural abnormalities and trauma		
Kidney small	1	0
Renal vascular and ischaemic conditions		
Renal infarct	1	0
Renal tubular necrosis	1	0
Renal vasculitis	1	1
Structural and obstructive urethral disorders (excl congenital)		
Urethral stenosis	1	0
Ureteric disorders NEC		
Ureteric stenosis	1	0
Urinary abnormalities		
Albuminuria	1	0
Chromaturia	40	0
Haematuria	27	0
Proteinuria	7	0
Urine abnormality	8	0
Urine odour abnormal	5	0
Urinary tract signs and symptoms NEC		
Costovertebral angle tenderness	1	0
Cystitis-like symptom	1	0
Haemorrhage urinary tract	17	0
Nocturia	3	0
Polyuria	6	0
Renal colic	4	0
Renal pain	203	0
Urinary tract pain	2	0
Renal & urinary disorders SOC TOTAL	775	7

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Benign and malignant breast neoplasms</i>		
Breast cyst	9	0
<i>Breast disorders NEC</i>		
Breast disorder	1	0
Breast enlargement	16	0
Breast mass	85	0
Gynaecomastia	3	0
Mastoptosis	1	0
<i>Breast infections and inflammations</i>		
Breast inflammation	1	0
Nipple inflammation	1	0
<i>Breast signs and symptoms</i>		
Breast discharge	2	0
Breast discomfort	8	0
Breast engorgement	6	0
Breast haematoma	1	0
Breast oedema	4	0
Breast pain	443	0
Breast swelling	92	0
Breast tenderness	51	0
Nipple pain	27	1
Nipple swelling	3	0
<i>Cervix disorders NEC</i>		
Cervical dysplasia	2	0
Cervix disorder	1	0
Cervix haemorrhage uterine	2	0
Ectropion of cervix	2	0
<i>Cervix neoplasms</i>		
Cervical polyp	1	0
<i>Erection and ejaculation conditions and disorders</i>		
Ejaculation disorder	2	0
Ejaculation failure	1	0
Erectile dysfunction	35	0
Erection increased	2	0
Organic erectile dysfunction	9	0
Painful ejaculation	1	0
Spontaneous ejaculation	1	0
<i>Fallopian tube and ovary infections and inflammations</i>		
Noninfective oophoritis	2	0
<i>Lactation disorders</i>		
Breast milk discolouration	3	0
Breast milk odour abnormal	1	0
Galactorrhoea	5	0
Lactation disorder	6	0
Lactation puerperal increased	4	0
Suppressed lactation	16	0
<i>Menopausal effects NEC</i>		
Artificial menopause	1	0
Menopausal symptoms	11	0
Menopause delayed	1	0
Premature menopause	12	0
<i>Menopausal effects on the genitourinary tract</i>		
Atrophic vulvovaginitis	1	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Postmenopausal haemorrhage	87	0
<i>Menstruation and uterine bleeding NEC</i>		
Abnormal uterine bleeding	5	0
Dysmenorrhoea	1808	0
Intermenstrual bleeding	710	0
Menstrual discomfort	17	0
Menstrual disorder	1103	0
Menstruation irregular	1937	0
Premenstrual dysphoric disorder	7	0
Premenstrual headache	5	0
Premenstrual pain	68	0
Premenstrual syndrome	83	0
Withdrawal bleed	11	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	380	0
Hypomenorrhoea	436	0
Menstruation delayed	3124	0
Oligomenorrhoea	92	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	3515	0
Menometrorrhagia	15	0
Polymenorrhoea	498	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>		
Ovarian cyst	8	0
Polycystic ovaries	31	0
<i>Ovarian and fallopian tube disorders NEC</i>		
Adnexal torsion	1	0
Hydrosalpinx	2	0
Ovarian haemorrhage	4	0
Ovulation disorder	1	0
Ovulation pain	37	0
Premature ovulation	4	0
<i>Pelvis and broad ligament disorders NEC</i>		
Adnexa uteri mass	1	0
Adnexa uteri pain	32	0
Pelvic floor muscle weakness	1	0
Pelvic haemorrhage	13	0
<i>Penile and scrotal infections and inflammations</i>		
Balanoposthitis	2	0
<i>Penile disorders NEC (excl erection and ejaculation)</i>		
Penile discomfort	1	0
Penile erythema	1	0
Penile haemorrhage	2	0
Penile pain	1	0
Penile size reduced	2	0
Penile swelling	4	0
Penis disorder	6	0
<i>Prostate and seminal vesicles infections and inflammations</i>		
Prostatitis	3	0
<i>Prostatic signs, symptoms and disorders NEC</i>		
Prostatic pain	1	0
Prostatomegaly	3	0
<i>Reproductive tract disorders NEC (excl neoplasms)</i>		

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Genital haemorrhage	14	0
Genital hypoaesthesia	1	0
Genital lesion	1	0
Genital paraesthesia	1	0
Genital ulceration	5	0
Perineal ulceration	1	0
<i>Reproductive tract infections and inflammations NEC</i>		
Genital tract inflammation	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Genital burning sensation	2	0
Genital pain	3	0
Genital rash	2	0
Genital swelling	2	0
Pelvic discomfort	4	0
Pelvic pain	74	0
Perineal pain	2	0
Pruritus genital	3	0
<i>Scrotal disorders NEC</i>		
Scrotal angiokeratoma	1	0
Scrotal discomfort	1	0
Scrotal erythema	1	0
Scrotal exfoliation	1	0
Scrotal pain	8	0
Scrotal swelling	4	0
Varicocele	1	0
<i>Sexual function and fertility disorders NEC</i>		
Dyspareunia	3	0
Infertility	4	0
Sexual dysfunction	3	0
<i>Spermatogenesis and semen disorders</i>		
Aspermia	1	0
Haematospermia	6	0
Semen discolouration	1	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular disorder	2	0
Testicular pain	36	0
Testicular swelling	5	0
Testis discomfort	1	0
<i>Uterine disorders NEC</i>		
Adenomyosis	7	0
Endometrial thickening	2	0
Endometriosis	63	0
Uterine haemorrhage	23	0
Uterine pain	12	0
<i>Uterine infections and inflammations (excl cervix)</i>		
Uterine inflammation	1	0
<i>Uterine neoplasms</i>		
Uterine polyp	4	0
<i>Uterine tone disorders</i>		
Uterine spasm	21	0
<i>Vulvovaginal cysts and neoplasms</i>		
Bartholin's cyst	1	0
Vaginal cyst	5	0

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Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	947	0
Vulval disorder	1	0
Vulval haemorrhage	16	0
Vulval ulceration	5	0
Vulvovaginal ulceration	3	0
<i>Vulvovaginal signs and symptoms</i>		
Clitoral engorgement	1	0
Coital bleeding	2	0
Labia enlarged	1	0
Vaginal discharge	51	0
Vaginal odour	1	0
Vulval oedema	1	0
Vulvovaginal burning sensation	3	0
Vulvovaginal dryness	3	0
Vulvovaginal erythema	1	0
Vulvovaginal pain	19	0
Vulvovaginal pruritus	6	0
Vulvovaginal rash	1	0
Vulvovaginal swelling	2	0
Reproductive & breast disorders SOC TOTAL	16336	1

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	4	0
Apnoeic attack	1	0
Dyspnoea	3176	6
Dyspnoea at rest	9	0
Dyspnoea exertional	29	1
Hyperventilation	36	0
Hypopnoea	81	0
Hypoventilation	1	0
Irregular breathing	16	0
Mouth breathing	3	0
Nocturnal dyspnoea	2	0
Orthopnoea	3	0
Respiration abnormal	41	0
Respiratory arrest	14	0
Respiratory depression	1	0
Respiratory distress	15	0
Sleep apnoea syndrome	9	0
Tachypnoea	23	0
<i>Bronchial conditions NEC</i>		
Bronchial secretion retention	2	0
Bronchiectasis	11	0
<i>Bronchospasm and obstruction</i>		
Asthma	261	0
Asthma late onset	2	0
Bronchospasm	14	0
Chronic obstructive pulmonary disease	14	1
Cough variant asthma	4	0
Obstructive airways disorder	8	0
Reversible airways obstruction	1	0
Wheezing	314	0
<i>Conditions associated with abnormal gas exchange</i>		
Asphyxia	1	0
Cyanosis central	1	0
Hyperoxia	1	0
Hypoxia	22	1
Respiratory acidosis	2	0
<i>Coughing and associated symptoms</i>		
Allergic cough	5	0
Cough	1797	2
Cough decreased	2	0
Haemoptysis	43	0
Productive cough	121	0
Sputum discoloured	4	0
Sputum increased	2	0
<i>Diaphragmatic disorders</i>		
Diaphragm muscle weakness	1	0
<i>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</i>		
Laryngeal disorder	1	0
Reflux laryngitis	1	0
Vocal cord disorder	1	0
Vocal cord dysfunction	1	0

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
<i>Laryngeal spasm, oedema and obstruction</i>		
Epiglottic oedema	1	0
Laryngeal obstruction	1	0
Laryngeal oedema	1	0
Laryngospasm	1	0
Stridor	19	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Alveolitis	1	0
Hypersensitivity pneumonitis	1	0
Lower respiratory tract inflammation	1	0
Pneumonia aspiration	8	5
Pneumonitis	23	1
Pulmonary sarcoidosis	2	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	25	0
Increased bronchial secretion	1	0
Lung opacity	2	0
Pleuritic pain	15	0
Pulmonary haemorrhage	1	0
Pulmonary pain	69	0
Rales	4	0
Respiratory fremitus	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	215	0
Nasal inflammation	2	0
Rhinitis allergic	14	0
<i>Nasal disorders NEC</i>		
Epistaxis	718	0
Intranasal hyposaesthesia	1	0
Intranasal paraesthesia	1	0
Nasal crusting	1	0
Nasal disorder	3	0
Nasal dryness	27	0
Nasal mucosal discolouration	1	0
Nasal odour	6	0
Nasal oedema	4	0
Nasal polyps	1	0
Nasal pruritus	9	0
<i>Neonatal hypoxic conditions</i>		
Dry lung syndrome	1	0
Gasping syndrome	1	0
Infantile apnoea	1	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Allergic sinusitis	1	0
Paranasal sinus inflammation	2	0
Sinonasal obstruction	9	0
Sinus congestion	45	0
Sinus disorder	5	0
<i>Parenchymal lung disorders NEC</i>		
Atelectasis	1	0
Combined pulmonary fibrosis and emphysema	1	0
Emphysema	2	0
Interstitial lung disease	8	0

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Lung consolidation	1	0
Lung infiltration	1	0
Pulmonary alveolar haemorrhage	1	0
Pulmonary cavitation	1	0
Pulmonary fibrosis	4	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal erythema	6	0
Pharyngeal haemorrhage	2	0
Pharyngeal hypoaesthesia	30	0
Pharyngeal inflammation	4	0
Pharyngeal oedema	12	0
Pharyngeal paraesthesia	49	0
Pharyngeal swelling	193	0
Pharyngeal ulceration	14	0
Tonsillar erythema	7	0
Tonsillar haemorrhage	1	0
Tonsillar hypertrophy	60	0
Tonsillar inflammation	3	0
Tonsillar ulcer	1	0
Tonsillolith	1	0
<i>Pleural infections and inflammations</i>		
Pleurisy	25	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	16	0
Pneumothorax	6	0
Pneumothorax spontaneous	1	0
<i>Pulmonary hypertensions</i>		
Pulmonary hypertension	2	0
<i>Pulmonary oedemas</i>		
Acute respiratory distress syndrome	2	1
Pulmonary congestion	10	0
Pulmonary oedema	17	1
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	344	22
Pulmonary infarction	4	0
Pulmonary thrombosis	5	1
<i>Respiratory failures (excl neonatal)</i>		
Acute respiratory failure	2	1
Respiratory failure	10	2
<i>Respiratory signs and symptoms NEC</i>		
Allergic respiratory symptom	5	0
Diaphragmalgia	5	0
Nasal flaring	1	0
Painful respiration	7	0
Pleural rub	1	0
Respiratory symptom	13	0
Suffocation feeling	2	0
<i>Respiratory tract disorders NEC</i>		
Aspiration	3	2
Lung disorder	3	0
Pulmonary mass	4	0
Respiratory disorder	9	0
Respiratory tract congestion	2	0

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Respiratory tract haemorrhage	1	0
Respiratory tract inflammation	1	0
Respiratory tract irritation	5	0
Respiratory tract oedema	3	0
<i>Thoracic musculoskeletal disorders</i>		
Respiratory muscle weakness	2	0
<i>Tracheal disorders (excl infections and neoplasms)</i>		
Tracheal pain	1	0
<i>Upper respiratory tract neoplasms</i>		
Tonsillar cyst	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	84	0
Catarrh	16	0
Choking	12	1
Choking sensation	3	0
Dry throat	132	0
Dysphonia	127	0
Increased upper airway secretion	4	0
Increased viscosity of upper respiratory secretion	25	0
Nasal discharge discolouration	3	0
Nasal discomfort	41	0
Nasal obstruction	2	0
Oropharyngeal blistering	10	0
Oropharyngeal discomfort	47	0
Oropharyngeal pain	2211	0
Oropharyngeal plaque	2	0
Paranasal sinus discomfort	34	0
Rhinalgia	11	0
Rhinorrhoea	679	0
Sinus pain	156	0
Sneezing	281	0
Snoring	7	0
Throat clearing	8	0
Throat irritation	188	0
Throat tightness	205	0
Upper airway obstruction	2	0
Upper respiratory tract irritation	1	0
Upper-airway cough syndrome	7	0
Yawning	20	0
<i>Vascular pulmonary disorders NEC</i>		
Acute chest syndrome	1	0
Respiratory disorders SOC TOTAL	12581	48

Case Series Drug Analysis Print

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

Report Run Date: 12-Aug-2021

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	125	0
Acne cystic	12	0
Dermatitis acneiform	8	0
<i>Alopecias</i>		
Alopecia	156	0
Alopecia areata	25	0
Alopecia totalis	2	0
Androgenetic alopecia	1	0
Hypotrichosis	1	0
Madarosis	3	0
<i>Angioedemas</i>		
Angioedema	161	0
Circumoral swelling	1	0
<i>Apocrine and eccrine gland disorders</i>		
Anhidrosis	1	0
Cold sweat	570	0
Hidradenitis	2	0
Hyperhidrosis	1639	0
Hypohidrosis	1	0
Milia	1	0
Miliaria	71	0
Night sweats	451	0
<i>Bullous conditions</i>		
Blister	359	0
Blister rupture	1	0
Blood blister	21	0
Dermatitis bullous	10	0
Erythema multiforme	26	0
Fracture blisters	1	0
Herpes gestationis	1	0
Pemphigoid	21	0
Pemphigus	5	0
Stevens-Johnson syndrome	4	0
Toxic epidermal necrolysis	2	1
<i>Connective tissue disorders</i>		
Dermatomyositis	4	0
<i>Dermal and epidermal conditions NEC</i>		
Acute febrile neutrophilic dermatosis	1	0
Dermatosis	1	0
Dry skin	167	0
Macule	4	0
Neutrophilic dermatosis	1	0
Pain of skin	202	0
Papule	85	0
Pathergy reaction	1	0
Peau d'orange	2	0
Scab	17	0
Scar pain	11	0
Sensitive skin	127	0
Skin burning sensation	167	0
Skin degenerative disorder	1	0
Skin discolouration	95	0

Case Series Drug Analysis Print

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

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Skin discomfort	3	0
Skin disorder	12	0
Skin fissures	6	0
Skin indentation	2	0
Skin induration	3	0
Skin lesion	34	0
Skin lesion inflammation	1	0
Skin necrosis	1	0
Skin odour abnormal	15	0
Skin plaque	2	0
Skin reaction	110	0
Skin sensitisation	26	0
Skin swelling	65	0
Skin texture abnormal	1	0
Skin tightness	22	0
Skin warm	228	0
Skin weeping	7	0
Sticky skin	1	0
Target skin lesion	2	0
Transient acantholytic dermatosis	1	0
Yellow skin	18	0
<i>Dermatitis and eczema</i>		
Dermatitis	88	0
Dermatitis allergic	176	0
Dermatitis atopic	23	0
Dermatitis contact	12	0
Dermatitis diaper	3	0
Dyshidrotic eczema	20	0
Eczema	208	0
Eczema asteatotic	7	0
Eczema infantile	1	0
Eczema nummular	4	0
Eczema weeping	1	0
Intertrigo	1	0
Perioral dermatitis	1	0
Seborrhoeic dermatitis	2	0
Skin irritation	83	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	27	0
Drug reaction with eosinophilia and systemic symptoms	1	0
Fixed eruption	2	0
Toxic skin eruption	2	0
<i>Erythemas</i>		
Erythema	1674	0
Palmar erythema	4	0
Red man syndrome	1	0
<i>Exfoliative conditions</i>		
Dermatitis exfoliative	2	0
Dermatitis exfoliative generalised	4	0
Exfoliative rash	16	0
Keratolysis exfoliativa acquired	2	0
Skin exfoliation	82	0
<i>Granulomatous and deep cutaneous inflammatory conditions</i>		

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Cutaneous sarcoidosis	1	0
Granuloma annulare	2	0
Hyperkeratoses		
Hyperkeratosis	1	0
Keratosis pilaris	3	0
Lichenoid keratosis	3	0
Hyperpigmentation disorders		
Argyria	1	0
Chloasma	1	0
Ephelides	1	0
Skin hyperpigmentation	3	0
Solar lentigo	2	0
Hypertrichoses		
Hirsutism	1	0
Hypopigmentation disorders		
Skin depigmentation	4	0
Skin hypopigmentation	1	0
Vitiligo	8	0
Lipodystrophies		
Lipoatrophy	4	0
Lipodystrophy acquired	1	0
Nail and nail bed conditions (excl infections and infestations)		
Nail discolouration	7	0
Nail disorder	3	0
Nail pigmentation	2	0
Nail ridging	2	0
Onychalgia	7	0
Onychoclasia	4	0
Onychomadesis	2	0
Splinter haemorrhages	3	0
Panniculitides		
Erythema nodosum	21	0
Papulosquamous conditions		
Erythema annulare	2	0
Lichen planus	11	0
Lichen sclerosus	7	0
Parapsoriasis	2	0
Pityriasis rosea	82	0
Photosensitivity and photodermatosis conditions		
Photosensitivity reaction	51	0
Polymorphic light eruption	2	0
Solar dermatitis	1	0
Pigmentation changes NEC		
Haemosiderin stain	1	0
Pigmentation disorder	9	0
Pilar disorders NEC		
Hair colour changes	8	0
Hair disorder	1	0
Hair growth abnormal	4	0
Hair texture abnormal	4	0
Piloerection	23	0
Pseudofolliculitis	2	0
Trichorrhexis	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
<i>Pruritus NEC</i>		
Itching scar	5	0
Pruritus	4020	0
<i>Psoriatic conditions</i>		
Dermatitis psoriasiform	2	0
Guttate psoriasis	12	0
Nail psoriasis	1	0
Palmoplantar pustulosis	2	0
Psoriasis	123	0
Pustular psoriasis	2	0
<i>Purpura and related conditions</i>		
Henoch-Schonlein purpura	5	0
Petechiae	113	0
Purpura	40	0
<i>Pustular conditions</i>		
Acute generalised exanthematous pustulosis	1	0
<i>Rashes, eruptions and exanthems NEC</i>		
Butterfly rash	4	0
Rash	4290	0
Rash erythematous	910	0
Rash macular	401	0
Rash maculo-papular	48	0
Rash morbilliform	34	0
Rash papular	270	0
Rash pruritic	916	0
Rash vesicular	54	0
Systemic lupus erythematosus rash	6	0
<i>Rosaceas</i>		
Rosacea	23	0
<i>Scaly conditions</i>		
Dandruff	4	0
Pityriasis	17	0
<i>Sebaceous gland disorders</i>		
Seborrhoea	8	0
<i>Skin and subcutaneous conditions NEC</i>		
Cutaneous symptom	4	0
Reactive perforating collagenosis	1	0
Skin mass	16	0
<i>Skin and subcutaneous tissue ulcerations</i>		
Mucocutaneous ulceration	1	0
Scleroderma associated digital ulcer	1	0
Skin erosion	19	0
Skin ulcer	12	0
<i>Skin cysts and polyps</i>		
Dermal cyst	9	0
<i>Skin dystrophies</i>		
Keloid scar	2	0
Skin wrinkling	2	0
<i>Skin haemorrhages</i>		
Haemorrhage subcutaneous	6	0
Skin haemorrhage	12	0
<i>Skin hyperplasias and hypertrophies</i>		
Skin hypertrophy	2	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
<i>Skin hypoplasias and atrophies</i>		
Skin atrophy	1	0
Skin striae	6	0
<i>Skin injuries and mechanical dermatoses</i>		
Decubitus ulcer	2	0
Needle track marks	2	0
<i>Skin preneoplastic conditions NEC</i>		
Actinic keratosis	1	0
<i>Skin vascular conditions NEC</i>		
Skin oedema	4	0
<i>Skin vasculitides</i>		
Capillaritis	2	0
Cutaneous vasculitis	10	0
Hypersensitivity vasculitis	1	0
Vasculitic rash	17	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	19	0
<i>Telangiectasia and related conditions</i>		
Telangiectasia	1	0
<i>Urticarias</i>		
Chronic spontaneous urticaria	3	0
Cold urticaria	3	0
Idiopathic urticaria	1	0
Mechanical urticaria	5	0
Solar urticaria	2	0
Urticaria	1365	0
Urticaria cholinergic	1	0
Urticaria chronic	12	0
Urticaria contact	1	0
Urticaria papular	3	0
Urticaria thermal	4	0
Urticularial vasculitis	3	0
Skin disorders SOC TOTAL	20741	1

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Social circumstances		
<i>Age related issues</i>		
Infant	2	0
Menopause	21	0
Postmenopause	3	0
<i>Bereavement issues</i>		
Death of relative	1	1
<i>Criminal activity</i>		
Verbal abuse	1	0
<i>Dependents</i>		
Sick relative	4	0
<i>Dietary and nutritional issues</i>		
Feeding tube user	1	0
<i>Disability issues</i>		
Bedridden	21	0
Breast prosthesis user	3	0
Disability	2	0
Hearing disability	1	0
Housebound	1	0
Immobile	11	0
Impaired driving ability	3	0
Impaired work ability	7	0
Loss of personal independence in daily activities	29	0
Physical disability	3	0
Sight disability	8	0
Sitting disability	1	0
Walking disability	1	0
Wheelchair user	1	0
<i>Economic circumstances</i>		
High income	1	0
Low income	1	0
<i>Employment issues</i>		
Retirement	4	0
Stress at work	1	0
<i>Family and partner issues</i>		
Bed sharing	1	0
<i>Non-occupational and unspecified environmental problems</i>		
Flooding	1	0
Water pollution	2	0
<i>Pregnancy related circumstances</i>		
Breast feeding	14	0
Multigravida	1	0
<i>Social issues NEC</i>		
Hair dye user	2	0
Impaired quality of life	1	0
<i>Tobacco use</i>		
Ex-tobacco user	1	0
Non-tobacco user	4	0
Tobacco user	1	0
Social circumstances SOC TOTAL	160	1

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Anaesthesia and allied procedures</i>		
Local anaesthesia	1	0
Nerve block	4	0
<i>Antiinfective therapies</i>		
COVID-19 treatment	3	0
<i>Arterial therapeutic procedures (excl aortic)</i>		
Splenic artery embolisation	1	0
<i>Autonomic nerve therapeutic procedures</i>		
Vagotomy	1	0
<i>Blood and blood product treatment</i>		
Transfusion	1	0
<i>Breast therapeutic procedures NEC</i>		
Axillary lymphadenectomy	2	0
Mammoplasty	1	0
<i>Bronchial and pulmonary therapeutic procedures</i>		
Airway secretion clearance therapy	1	0
<i>Cardiac therapeutic procedures NEC</i>		
Cardiac operation	1	0
<i>Contraceptive methods female</i>		
Contraception	1	0
Contraceptive implant	2	0
Oral contraception	1	0
<i>Contraceptive methods male</i>		
Condom	1	0
<i>Dietary and nutritional therapies</i>		
Medical diet	7	0
Nothing by mouth order	5	0
Wheat-free diet	1	0
<i>External ear therapeutic procedures</i>		
Ear irrigation	1	0
<i>Fertility and fertilisation interventions female</i>		
Endometrial scratching	1	0
<i>Gastrointestinal therapeutic procedures NEC</i>		
Intestinal anastomosis	1	0
Prophylaxis of nausea and vomiting	12	0
<i>Gynaecological therapeutic procedures NEC</i>		
Menstrual cycle management	6	0
<i>Haematological therapeutic procedures NEC</i>		
Anticoagulant therapy	1	0
<i>Head, neck and oral cavity therapeutic procedures NEC</i>		
Neck lift	1	0
<i>Hernia repairs</i>		
Hernia repair	1	0
<i>Hormonal therapeutic procedures NEC</i>		
Hormone replacement therapy	1	0
Hormone therapy	7	0
<i>Immunisations</i>		
COVID-19 immunisation	75	1
Immunisation	41	0
<i>Joint therapeutic procedures</i>		
Joint surgery	1	0
Knee arthroplasty	1	0
<i>Large intestine therapeutic procedures</i>		

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Surgical & medical procedures cont'd</i>		
Appendectomy	2	0
Limb therapeutic procedures		
Limb immobilisation	8	0
Limb operation	5	0
Lymphoid tissue therapeutic procedures		
Lymphadenectomy	1	0
Splenectomy	1	0
Mastectomies		
Breast conserving surgery	3	0
Nail therapeutic procedures		
Nail operation	2	0
Nervous system therapeutic procedures NEC		
Multiple sclerosis relapse prophylaxis	2	0
Orbit and globe therapeutic procedures		
Strabismus correction	1	0
Peripheral nerve therapeutic procedures		
Peripheral nerve neurostimulation	1	0
Phototherapies		
UV light therapy	1	0
Prophylactic procedures NEC		
Anaphylaxis prophylaxis	2	0
Immune tolerance induction	1	0
Prophylaxis against transplant rejection	1	0
Reproductive system disorder prophylaxis	1	0
Psychiatric therapies		
Electroconvulsive therapy	1	0
Renal therapeutic procedures		
Dialysis	1	0
Respiratory tract therapeutic procedures NEC		
Asthma prophylaxis	2	0
Retinal therapeutic procedures		
Retinopexy	1	0
Skin and subcutaneous tissue therapeutic procedures NEC		
Dermal filler injection	4	0
Therapeutic bladder catheterisation		
Bladder catheterisation	1	0
Therapeutic procedures NEC		
Abscess drainage	1	0
Anaphylaxis treatment	4	0
Bed rest	2	0
Fatigue management	1	0
Hospitalisation	9	0
Injection	34	0
Interchange of vaccine products	3	0
Localised alternating hot and cold therapy	1	0
Magnetic therapy	1	0
Mass excision	2	0
Medication dilution	2	0
Product used for unknown indication	2	0
Specialist consultation	1	0
Therapeutic procedure	1	0
Therapy change	1	0
Tracheal therapeutic procedures		

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Reaction Name	Total	Fatal
Surgical & medical procedures		
Surgical & medical procedures cont'd		
Tracheostomy	1	0
<i>Uterine therapeutic procedures</i>		
Endometrial ablation	1	0
Surgical & medical procedures SOC TOTAL	293	1

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Accelerated and malignant hypertension</i>		
Hypertensive crisis	10	0
Hypertensive urgency	1	0
Malignant hypertension	3	0
<i>Aneurysms and dissections non-site specific</i>		
Aneurysm	1	0
Artery dissection	1	0
<i>Aortic aneurysms and dissections</i>		
Acute aortic syndrome	1	0
Aortic aneurysm rupture	1	1
Aortic dissection	1	0
<i>Aortic embolism and thrombosis</i>		
Aortic embolus	5	0
Aortic thrombosis	2	0
<i>Arterial infections and inflammations</i>		
Arteritis	1	0
Giant cell arteritis	10	0
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	10	0
Labile blood pressure	3	0
<i>Bruising, ecchymosis and purpura</i>		
Achenbach syndrome	3	0
<i>Circulatory collapse and shock</i>		
CT hypotension complex	2	0
Circulatory collapse	56	0
Hypoperfusion	1	0
Neurogenic shock	21	0
Peripheral circulatory failure	5	0
Shock	16	0
<i>Haemorrhages NEC</i>		
Bloody discharge	13	0
Haematoma	35	0
Haemorrhage	802	2
Internal haemorrhage	6	0
Venous haemorrhage	1	0
<i>Lymphangiopathies</i>		
Lymphangiopathy	1	0
Lymphocele	4	0
<i>Lymphoedemas</i>		
Lymphoedema	150	0
<i>Non-site specific embolism and thrombosis</i>		
Arterial thrombosis	3	0
Embolism	60	0
Embolism venous	5	0
Microembolism	1	0
Thrombosis	333	7
Venous thrombosis	6	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Arterial occlusive disease	2	0
Arterial spasm	1	0
Arteriosclerosis	1	0
Haemorrhagic infarction	1	0
Infarction	3	0

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Vascular disorders <small>Vascular disorders cont'd</small>		
Ischaemia	7	0
Vasospasm	1	0
<i>Non-site specific vascular disorders NEC</i>		
Capillary disorder	1	0
Capillary fragility	1	0
Superficial vein prominence	1	0
Vascular pain	21	0
Vasodilatation	27	0
Vein discolouration	5	0
Vein disorder	6	0
Vein rupture	4	0
<i>Peripheral embolism and thrombosis</i>		
Axillary vein thrombosis	1	0
Blue toe syndrome	22	0
Deep vein thrombosis	229	1
Femoral artery embolism	1	0
Jugular vein thrombosis	3	0
Pelvic venous thrombosis	4	0
Peripheral embolism	1	0
Subclavian vein thrombosis	3	0
Thrombophlebitis	17	0
Thrombophlebitis superficial	10	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	34	0
Erythromelalgia	1	0
Flushing	350	0
Hot flush	881	0
Peripheral vascular disorder	1	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Claudication of jaw muscles	1	0
Extremity necrosis	2	0
Intermittent claudication	2	0
Ischaemic limb pain	1	0
Jugular vein occlusion	1	0
Peripheral arterial occlusive disease	2	0
Peripheral artery occlusion	1	0
Peripheral coldness	248	0
Peripheral ischaemia	12	0
Poor peripheral circulation	12	0
Raynaud's phenomenon	47	0
Vasoconstriction	2	0
<i>Phlebitis NEC</i>		
Phlebitis	23	0
Phlebitis superficial	6	0
<i>Site specific vascular disorders NEC</i>		
Inferior vena cava dilatation	1	0
Pallor	263	0
<i>Varicose veins NEC</i>		
Spider vein	4	0
Varicophlebitis	4	0
Varicose vein	17	0
<i>Vascular hypertensive disorders NEC</i>		
Diastolic hypertension	2	0

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Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
Essential hypertension	3	0
Hypertension	432	1
Labile hypertension	1	0
Orthostatic hypertension	1	0
Secondary hypertension	1	0
Systolic hypertension	4	0
Vascular hypotensive disorders		
Hypotension	303	0
Orthostatic hypotension	27	0
Vasculitides NEC		
Behcet's syndrome	4	0
Diffuse vasculitis	1	0
Granulomatosis with polyangiitis	1	0
MAGIC syndrome	1	0
Thromboangiitis obliterans	1	0
Vasculitis	40	0
Vena caval embolism and thrombosis		
Vena cava embolism	1	0
Vena cava thrombosis	1	0
Vascular disorders SOC TOTAL	4687	12
TOTAL REACTIONS FOR DRUG	293779	501
TOTAL REPORTS	104446	
TOTAL FATAL OUTCOME REPORTS		501