

COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

All UK spontaneous reports received between 9/12/20 and 15/12/21 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: 20-Dec-2021

Data Lock Date: 15-Dec-2021 18:32:39

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemia deficiencies</i>		
Anaemia folate deficiency	1	0
Anaemia vitamin B12 deficiency	3	0
Deficiency anaemia	1	0
Iron deficiency anaemia	8	0
Pernicious anaemia	1	0
<i>Anaemias NEC</i>		
Anaemia	121	0
Anaemia macrocytic	2	0
Anaemia megaloblastic	1	0
Autoimmune anaemia	3	0
Blood loss anaemia	1	0
Microcytic anaemia	1	0
<i>Anaemias haemolytic NEC</i>		
Coombs negative haemolytic anaemia	1	0
Haemolytic anaemia	7	0
<i>Anaemias haemolytic immune</i>		
Autoimmune haemolytic anaemia	15	0
Cold type haemolytic anaemia	1	0
Evans syndrome	1	0
Warm type haemolytic anaemia	1	0
<i>Anaemias haemolytic mechanical factor</i>		
Microangiopathic haemolytic anaemia	1	0
<i>Bleeding tendencies</i>		
Haemorrhagic diathesis	1	0
Increased tendency to bruise	47	0
Spontaneous haematoma	2	0
<i>Coagulation factor deficiencies</i>		
Acquired haemophilia	2	0
<i>Coagulopathies</i>		
Abnormal clotting factor	4	0
Antiphospholipid syndrome	6	0
Coagulopathy	24	1
Disseminated intravascular coagulation	2	0
Hypercoagulation	3	0
Thrombotic microangiopathy	2	0
<i>Eosinophilic disorders</i>		
Eosinophilia	13	0
<i>Haematological disorders</i>		
Blood disorder	4	0
Hypergammaglobulinaemia	1	0
Hyperviscosity syndrome	1	0
Mast cell activation syndrome	7	0
Methaemoglobinaemia	1	0
<i>Haemolyses NEC</i>		
Haemolysis	6	0
Intravascular haemolysis	1	0
Jaundice acholuric	1	0
<i>Leukocytoses NEC</i>		
Leukocytosis	2	0
Lymphocytic infiltration	1	0
Lymphocytosis	6	0
Neutrophilia	11	0

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Reaction Name	Total	Fatal
Blood disorders Blood disorders cont'd		
<i>Leukopenias NEC</i>		
Leukopenia	4	1
Lymphopenia	4	0
<i>Lymphatic system disorders NEC</i>		
Abdominal lymphadenopathy	3	0
Hilar lymphadenopathy	2	0
Lymph node pain	1897	0
Lymph node ulcer	1	0
Lymphadenitis	156	0
Lymphadenopathy	11601	0
Lymphatic disorder	2	0
Lymphatic insufficiency	1	0
Necrotic lymphadenopathy	3	0
Pseudolymphoma	11	0
Retroperitoneal lymphadenopathy	1	0
<i>Marrow depression and hypoplastic anaemias</i>		
Aplasia pure red cell	2	0
Aplastic anaemia	1	1
Hypoplastic anaemia	2	0
Myelosuppression	1	0
Pancytopenia	8	0
<i>Neutropenias</i>		
Autoimmune neutropenia	2	0
Neutropenia	39	0
<i>Platelet disorders NEC</i>		
Platelet anisocytosis	1	0
Platelet disorder	3	0
<i>Polycythaemia (excl rubra vera)</i>		
Polycythaemia	3	0
<i>Purpuras (excl thrombocytopenic)</i>		
Purpura non-thrombocytopenic	1	0
<i>Red blood cell abnormal findings NEC</i>		
Macrocytosis	1	0
Polychromasia	2	0
Red blood cell abnormality	2	0
<i>Spleen disorders</i>		
Spleen atrophy	1	0
Splenic infarction	3	0
Splenic thrombosis	1	0
Splenic vein thrombosis	2	0
Splenomegaly	11	0
<i>Thrombocytopenias</i>		
Acquired amegakaryocytic thrombocytopenia	1	0
Immune thrombocytopenia	78	0
Thrombocytopenia	222	1
Thrombocytopenic purpura	8	0
Thrombotic thrombocytopenic purpura	6	0
<i>Thrombocytoses</i>		
Thrombocytosis	6	0
Blood disorders SOC TOTAL	14411	4

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Aortic valvular disorders</i>		
Aortic valve incompetence	1	0
<i>Cardiac conduction disorders</i>		
Atrioventricular block	24	1
Atrioventricular block complete	3	1
Atrioventricular block first degree	2	0
Atrioventricular block second degree	3	0
Bundle branch block	2	0
Bundle branch block left	3	0
Bundle branch block right	2	0
<i>Cardiac disorders NEC</i>		
Acute cardiac event	5	0
Cardiac disorder	70	2
Cardiac dysfunction	1	0
Cardiac ventricular thrombosis	1	0
Cardiovascular deconditioning	1	0
Cardiovascular disorder	7	0
Intracardiac thrombus	6	0
<i>Cardiac hypertensive complications</i>		
Hypertensive heart disease	2	1
<i>Cardiac infections and inflammations NEC</i>		
Carditis	5	0
<i>Cardiac neoplasms NEC</i>		
Pericardial cyst	1	0
<i>Cardiac signs and symptoms NEC</i>		
Cardiac discomfort	27	0
Cardiovascular symptom	1	0
Palpitations	4355	1
<i>Cardiac valve disorders NEC</i>		
Cardiac valve disease	2	0
Heart valve incompetence	3	0
<i>Cardiomyopathies</i>		
Cardiomyopathy	11	0
Congestive cardiomyopathy	6	0
Stress cardiomyopathy	3	0
<i>Coronary artery disorders NEC</i>		
Arteriosclerosis coronary artery	1	0
Coronary artery disease	7	3
Coronary artery dissection	1	0
Coronary artery occlusion	3	0
Coronary artery thrombosis	2	1
<i>Endocarditis NEC</i>		
Endocarditis noninfective	1	1
<i>Heart failures NEC</i>		
Cardiac failure	72	9
Cardiac failure acute	5	1
Cardiac failure chronic	2	0
Cardiac failure congestive	4	1
Cardiogenic shock	4	1
Cardiopulmonary failure	1	1
<i>Ischaemic coronary artery disorders</i>		
Acute coronary syndrome	7	1
Acute myocardial infarction	23	1

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Cardiac disorders Cardiac disorders cont'd		
Angina pectoris	248	1
Angina unstable	3	0
Arteriospasm coronary	3	0
Microvascular coronary artery disease	2	0
Myocardial infarction	242	36
Myocardial ischaemia	11	6
Left ventricular failures		
Acute left ventricular failure	1	1
Left ventricular failure	7	2
Mitral valvular disorders		
Mitral valve incompetence	7	0
Mitral valve prolapse	1	0
Myocardial disorders NEC		
Cardiac amyloidosis	1	0
Cardiac aneurysm	1	1
Cardiomegaly	35	2
Left atrial dilatation	1	0
Left ventricular dysfunction	13	0
Left ventricular enlargement	2	0
Left ventricular hypertrophy	2	0
Myocardial fibrosis	5	0
Myocardial haemorrhage	1	0
Myocardial injury	12	0
Myocardial necrosis	1	0
Myocardial oedema	5	0
Myocardial rupture	1	0
Right atrial enlargement	1	0
Right ventricular dysfunction	1	0
Right ventricular enlargement	1	0
Ventricular dysfunction	2	0
Ventricular hypertrophy	1	0
Ventricular hypokinesia	1	0
Noninfectious myocarditis		
Eosinophilic myocarditis	1	0
Hypersensitivity myocarditis	1	0
Myocarditis	543	1
Noninfectious pericarditis		
Pericarditis	378	2
Pericarditis constrictive	1	0
Pericardial disorders NEC		
Cardiac tamponade	1	1
Pericardial effusion	37	1
Pericardial fibrosis	1	0
Pericardial haemorrhage	4	3
Pericardial rub	2	0
Rate and rhythm disorders NEC		
Arrhythmia	148	0
Bradycardia	62	0
Bradycardia foetal	2	1
Cardiac flutter	473	0
Extrasystoles	176	0
Heart alternation	2	0
Paroxysmal arrhythmia	1	0

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Cardiac disorders Cardiac disorders cont'd		
Postural orthostatic tachycardia syndrome	21	0
Tachyarrhythmia	7	0
Tachycardia	1427	0
Tachycardia foetal	1	0
Tachycardia paroxysmal	1	0
Right ventricular failures		
Cor pulmonale	1	0
Right ventricular failure	1	0
Supraventricular arrhythmias		
Arrhythmia supraventricular	13	0
Atrial fibrillation	233	0
Atrial flutter	34	0
Atrial tachycardia	10	0
Nodal arrhythmia	1	0
Sinus arrest	1	0
Sinus arrhythmia	6	0
Sinus bradycardia	13	0
Sinus node dysfunction	1	0
Sinus tachycardia	60	0
Supraventricular extrasystoles	4	0
Supraventricular tachycardia	41	0
Tricuspid valvular disorders		
Tricuspid valve incompetence	6	0
Ventricular arrhythmias and cardiac arrest		
Cardiac arrest	112	42
Cardio-respiratory arrest	1	1
Pulseless electrical activity	4	0
Ventricular arrhythmia	5	0
Ventricular extrasystoles	28	0
Ventricular fibrillation	9	1
Ventricular tachycardia	13	0
Cardiac disorders SOC TOTAL	9179	128

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Autosomal chromosomal abnormalities</i>		
Trisomy 8	1	0
<i>Cardiac disorders congenital NEC</i>		
Heart disease congenital	14	0
<i>Cardiac hypoplasias congenital</i>		
Ventricular hypoplasia	1	0
<i>Cardiac septal defects congenital</i>		
Atrial septal defect	2	0
Hypertrophic cardiomyopathy	1	0
Ventricular septal defect	1	0
<i>Cardiac valve disorders congenital</i>		
Bicuspid aortic valve	1	0
<i>Central nervous system disorders congenital NEC</i>		
Spina bifida	2	1
Syringomyelia	2	0
<i>Cerebellar disorders congenital</i>		
Arnold-Chiari malformation	1	0
Hereditary ataxia	1	0
<i>Cerebral disorders congenital</i>		
Anencephaly	2	0
Cerebral palsy	3	0
<i>Coagulation disorders congenital</i>		
Haemophilia	2	0
<i>Congenital disorders NEC</i>		
Foetal malformation	1	0
Heterotaxia	1	0
<i>Connective tissue disorders congenital</i>		
Ehlers-Danlos syndrome	2	0
<i>Gastrointestinal tract disorders congenital NEC</i>		
Gastroschisis	3	0
<i>Great vessel disorders congenital</i>		
Congenital great vessel anomaly	1	0
Transposition of the great vessels	1	0
<i>Haematological disorders congenital NEC</i>		
Amegakaryocytic thrombocytopenia	1	0
Neonatal alloimmune thrombocytopenia	1	0
<i>Haemoglobinopathies congenital</i>		
Congenital methaemoglobinaemia	1	0
<i>Inborn errors of bilirubin metabolism</i>		
Gilbert's syndrome	1	0
<i>Inborn errors of lipid metabolism</i>		
Short-chain acyl-coenzyme A dehydrogenase deficiency	1	0
<i>Inborn errors of metabolism NEC</i>		
Alpha-1 antitrypsin deficiency	1	0
<i>Inborn errors of porphyrin metabolism</i>		
Porphyria	1	0
<i>Laryngeal and tracheal disorders congenital</i>		
Laryngomalacia	1	0
<i>Lymphatic system disorders congenital</i>		
Cystic lymphangioma	3	0
<i>Male reproductive tract disorders congenital</i>		
Cryptorchism	1	0
Micropenis	3	0

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Reaction Name	Total	Fatal
Congenital disorders Congenital disorders cont'd		
Phimosis	1	0
Musculoskeletal and connective tissue disorders of limbs congenital		
Developmental hip dysplasia	1	0
Musculoskeletal and connective tissue disorders of skull congenital		
Platybasia	1	0
Musculoskeletal and connective tissue disorders of spine congenital		
Block vertebra	1	0
Brachyolmia	1	0
Neurological disorders congenital NEC		
Familial hemiplegic migraine	2	0
Familial periodic paralysis	1	0
Moebius II syndrome	1	0
Tourette's disorder	2	0
Ocular disorders congenital NEC		
Colour blindness	4	0
Congenital eye disorder	1	0
Palate disorders congenital		
Cleft lip and palate	2	0
Peripheral nervous system disorders congenital NEC		
Hereditary neuropathy with liability to pressure palsies	1	0
Paroxysmal extreme pain disorder	1	0
Pulmonary and bronchial disorders congenital		
Congenital cystic lung	1	0
Retinal disorders congenital		
Retinitis pigmentosa	1	0
Sex chromosomal abnormalities		
Turner's syndrome	1	0
Skin and subcutaneous tissue disorders congenital NEC		
Acral peeling skin syndrome	1	0
Tongue disorders congenital		
Ankyloglossia congenital	1	0
Vascular anomalies congenital NEC		
Congenital LUMBAR syndrome	1	0
Venous disorders congenital		
Anomalous pulmonary venous connection	1	0
Congenital disorders SOC TOTAL	85	1

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear canal erythema	1	0
Ear congestion	32	0
Ear discomfort	97	0
Ear disorder	19	0
Ear haemorrhage	12	0
Ear inflammation	1	0
Ear pain	994	0
Ear pruritus	11	0
Ear swelling	36	0
Otorrhoea	5	0
Paraesthesia ear	1	0
<i>Eustachian tube disorders</i>		
Eustachian tube disorder	4	0
Eustachian tube dysfunction	9	0
Eustachian tube obstruction	4	0
<i>External ear disorders NEC</i>		
Auricular swelling	2	0
Excessive cerumen production	10	0
External ear pain	4	0
Red ear syndrome	2	0
<i>External ear infections and inflammations</i>		
External ear inflammation	2	0
<i>Hearing disorders NEC</i>		
Auditory disorder	6	0
Diplacusic	2	0
<i>Hearing losses</i>		
Conductive deafness	1	0
Deafness	256	0
Deafness bilateral	9	0
Deafness neurosensory	18	0
Deafness transitory	9	0
Deafness unilateral	34	0
Hypoacusis	193	0
Sudden hearing loss	47	0
<i>Hyperacusia</i>		
Hyperacusis	62	0
Misophonia	3	0
<i>Inner ear disorders NEC</i>		
Acute vestibular syndrome	2	0
Inner ear disorder	13	0
Meniere's disease	11	0
Vestibular disorder	11	0
<i>Inner ear infections and inflammations</i>		
Inner ear inflammation	10	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	63	0
Tinnitus	2066	0
Vertigo	1444	0
Vertigo labyrinthine	12	0
Vertigo positional	78	0
<i>Mastoid disorders</i>		
Mastoid effusion	1	0

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Reaction Name	Total	Fatal
Ear disorders Ear disorders cont'd		
<i>Middle ear disorders NEC</i>		
Middle ear disorder	3	0
Middle ear effusion	1	0
<i>Middle ear infections and inflammations</i>		
Middle ear inflammation	1	0
<i>Tympanic membrane disorders (excl infections)</i>		
Tympanic membrane perforation	3	0
Ear disorders SOC TOTAL	5605	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Autoimmune thyroiditis	2	0
Thyroiditis	20	0
Thyroiditis acute	3	0
Thyroiditis subacute	3	0
<i>Adrenal cortical hypofunctions</i>		
Addison's disease	2	0
Adrenal insufficiency	3	0
Adrenocortical insufficiency acute	16	0
<i>Adrenal gland disorders NEC</i>		
Adrenal haemorrhage	3	0
<i>Anterior pituitary hyperfunction</i>		
Pituitary-dependent Cushing's syndrome	1	0
<i>Anterior pituitary hypofunction</i>		
Hypopituitarism	1	0
<i>Endocrine abnormalities of gonadal function NEC</i>		
Oestrogen deficiency	1	0
<i>Endocrine abnormalities of puberty</i>		
Delayed menarche	4	0
Premature menarche	19	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	50	0
Ovulation delayed	32	0
<i>Male gonadal function disorders</i>		
Androgen deficiency	1	0
<i>Thyroid disorders NEC</i>		
Autoimmune thyroid disorder	1	0
Goitre	14	0
Thyroid disorder	8	0
Thyroid mass	1	0
Thyroid pain	10	0
<i>Thyroid hyperfunction disorders</i>		
Basedow's disease	11	0
Hyperthyroidism	41	0
Thyrotoxic crisis	3	0
<i>Thyroid hypofunction disorders</i>		
Autoimmune hypothyroidism	1	0
Hypothyroidism	32	0
Immune-mediated hypothyroidism	1	0
Myxoedema	1	0
Endocrine disorders SOC TOTAL	285	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Amblyopic vision impairment</i>		
Amblyopia	7	0
<i>Anterior chamber bleeding and vascular disorders</i>		
Spontaneous hyphaema	1	0
<i>Cataract conditions</i>		
Cataract	12	0
<i>Choroid and vitreous haemorrhages and vascular disorders</i>		
Choroidal haemorrhage	1	0
Choroidal neovascularisation	1	0
Vitreous haemorrhage	4	0
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Chorioretinopathy	7	0
Vitreous detachment	17	0
Vitreous floaters	98	0
<i>Colour blindness (incl acquired)</i>		
Dyschromatopsia	9	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	47	0
Scleral haemorrhage	1	0
<i>Conjunctival infections, irritations and inflammations</i>		
Conjunctival hyperaemia	2	0
Conjunctival irritation	1	0
Conjunctival oedema	3	0
Conjunctivitis allergic	1	0
<i>Corneal infections, oedemas and inflammations</i>		
Corneal oedema	2	0
Keratitis	6	0
Ulcerative keratitis	5	0
<i>Corneal structural change, deposit and degeneration</i>		
Corneal scar	1	0
<i>Eyelid movement disorders</i>		
Blepharospasm	146	0
Excessive eye blinking	6	0
Eyelid function disorder	3	0
Eyelid myokymia	4	0
Eyelid ptosis	45	0
Paralytic lagophthalmos	2	0
<i>Glaucomas (excl congenital)</i>		
Angle closure glaucoma	2	0
Glaucoma	6	0
Ocular hypertension	1	0
<i>Iris and ciliary body structural change, deposit and degeneration</i>		
Eye colour change	3	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Autoimmune uveitis	2	0
Iridocyclitis	15	0
Iritis	11	0
Uveitis	48	0
<i>Lacrimation disorders</i>		
Dry eye	156	0
Lacrimation increased	141	0
<i>Lid bleeding and vascular disorders</i>		
Eyelid bleeding	1	0

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Eye disorders Eye disorders cont'd		
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Blepharitis	15	0
Chalazion	7	0
Eczema eyelids	9	0
Erythema of eyelid	9	0
Eyelid cyst	5	0
Eyelid irritation	3	0
Eyelid margin crusting	4	0
Eyelid oedema	10	0
Eyelid rash	16	0
Meibomian gland dysfunction	1	0
Swelling of eyelid	126	0
Swollen tear duct	2	0
<i>Lid, lash and lacrimal structural disorders</i>		
Dacryostenosis acquired	1	0
Dermatochalasis	1	0
Eyelash changes	1	0
Eyelid exfoliation	3	0
Eyelid skin dryness	2	0
Eyelid thickening	1	0
Floppy eyelid syndrome	1	0
Growth of eyelashes	3	0
Lagophthalmos	3	0
<i>Ocular bleeding and vascular disorders NEC</i>		
Eye haematoma	4	0
Eye haemorrhage	31	0
Ocular vascular disorder	2	0
Ophthalmic vein thrombosis	1	0
<i>Ocular disorders NEC</i>		
Dark circles under eyes	8	0
Eye disorder	36	0
Eye oedema	18	0
Eye pain	1130	0
Eye swelling	539	0
Eye symptom	9	0
Eye ulcer	5	0
Eyelid disorder	14	0
Eyelid pain	12	0
Eyelids pruritus	6	0
Ocular discomfort	27	0
Periorbital oedema	18	0
Periorbital pain	1	0
Periorbital swelling	118	0
Retinal disorder	2	0
Vitreous disorder	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye allergy	16	0
Eye discharge	30	0
Eye inflammation	29	0
Eye irritation	95	0
Eye pruritus	247	0
Limbal swelling	4	0
Ocular hyperaemia	228	0

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Eye disorders Eye disorders cont'd		
<i>Ocular nerve and muscle disorders</i>		
Binocular eye movement disorder	1	0
Extraocular muscle disorder	1	0
Extraocular muscle paresis	2	0
Eye movement disorder	36	0
Gaze palsy	1	0
Ocular myasthenia	1	0
Ophthalmoplegia	5	0
Strabismus	9	0
<i>Ocular sensation disorders</i>		
Abnormal sensation in eye	20	0
Asthenopia	156	0
Eye paraesthesia	2	0
Eyelid sensory disorder	2	0
Foreign body sensation in eyes	17	0
Hypoaesthesia eye	16	0
Photophobia	491	0
<i>Optic disc abnormalities NEC</i>		
Papilloedema	6	0
<i>Optic nerve bleeding and vascular disorders</i>		
Optic disc haemorrhage	1	0
Optic ischaemic neuropathy	2	0
<i>Orbital infections, inflammations and irritations</i>		
Parophthalmia	1	0
<i>Orbital structural change, deposit and degeneration</i>		
Orbital oedema	2	0
<i>Pupil disorders</i>		
Miosis	2	0
Mydriasis	22	0
Pupil fixed	2	0
Pupillary disorder	1	0
Pupils unequal	12	0
<i>Refractive and accommodative disorders</i>		
Accommodation disorder	1	0
Altered visual depth perception	5	0
Astigmatism	2	0
Hypermetropia	2	0
Myopia	1	0
<i>Retinal bleeding and vascular disorders (excl retinopathy)</i>		
Retinal artery occlusion	14	0
Retinal artery thrombosis	2	0
Retinal haemorrhage	8	0
Retinal vascular thrombosis	1	0
Retinal vein occlusion	37	0
Retinal vein thrombosis	2	0
<i>Retinal structural change, deposit and degeneration</i>		
Macular degeneration	4	0
Macular hole	3	0
Macular rupture	1	0
Maculopathy	1	0
Neovascular age-related macular degeneration	4	0
Retinal degeneration	1	0
Retinal detachment	6	0

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Eye disorders Eye disorders cont'd		
Retinal tear	2	0
Retinal toxicity	3	0
<i>Retinal, choroid and vitreous infections and inflammations</i>		
Birdshot chorioretinopathy	2	0
Cystoid macular oedema	1	0
Macular oedema	5	0
Retinal oedema	1	0
Retinal vasculitis	3	0
<i>Retinopathies NEC</i>		
Acute macular neuroretinopathy	2	0
Retinal exudates	2	0
Retinopathy	4	0
<i>Scleral infections, irritations and inflammations</i>		
Episcleritis	8	0
Scleritis	6	0
<i>Scleral structural change, deposit and degeneration</i>		
Scleral discolouration	2	0
<i>Structural change, deposit and degeneration of eye NEC</i>		
Endocrine ophthalmopathy	1	0
Exophthalmos	2	0
<i>Visual colour distortions</i>		
Chloropsia	2	0
Chromatopsia	1	0
Cyanopsia	3	0
Erythropsia	2	0
Xanthopsia	1	0
<i>Visual disorders NEC</i>		
Charles Bonnet syndrome	2	0
Diplopia	162	0
Dysmetropsia	1	0
Glare	1	0
Halo vision	7	0
Heteronymous diplopia	1	0
Metamorphopsia	21	0
Oscillopsia	3	0
Photopsia	140	0
Scintillating scotoma	4	0
Vision blurred	1245	0
Visual brightness	3	0
Visual snow syndrome	8	0
<i>Visual field disorders</i>		
Visual field defect	32	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Amaurosis fugax	3	0
Blindness	135	0
Blindness cortical	1	0
Blindness transient	16	0
Blindness unilateral	16	0
Central vision loss	6	0
Sudden visual loss	3	0
Visual acuity reduced	26	0
Visual acuity reduced transiently	1	0
Visual impairment	390	0

Case Series Drug Analysis Print

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Report Run Date: 20-Dec-2021

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
<i>Visual pathway disorders</i>		
Optic nerve disorder	1	0
Eye disorders SOC TOTAL	6859	0

Case Series Drug Analysis Print

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

Report Run Date: 20-Dec-2021

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Abdominal findings abnormal</i>		
Abdominal mass	2	0
Gastrointestinal sounds abnormal	16	0
<i>Abdominal hernias NEC</i>		
Abdominal hernia	2	0
<i>Abdominal wall conditions NEC</i>		
Abdominal wall haematoma	1	0
<i>Acute and chronic pancreatitis</i>		
Alcoholic pancreatitis	1	0
Obstructive pancreatitis	1	0
Pancreatitis	15	0
Pancreatitis acute	16	1
Pancreatitis necrotising	1	0
<i>Anal and rectal disorders NEC</i>		
Anal fissure	3	0
Anal sphincter atony	1	0
Rectal prolapse	1	0
<i>Anal and rectal pains</i>		
Proctalgia	14	0
<i>Anal and rectal signs and symptoms</i>		
Anal erythema	1	0
Anal hypoaesthesia	1	0
Anal pruritus	1	0
Anal spasm	1	0
Anorectal discomfort	5	0
Anorectal swelling	1	0
Rectal discharge	2	0
Rectal tenesmus	1	0
<i>Anal and rectal ulcers and perforation</i>		
Anal ulcer	1	0
<i>Benign oral cavity neoplasms</i>		
Mouth cyst	6	0
Tongue cyst	4	0
<i>Colitis (excl infective)</i>		
Autoimmune colitis	2	0
Colitis	48	1
Colitis ischaemic	1	0
Colitis microscopic	2	0
Colitis ulcerative	70	0
Crohn's disease	40	0
Eosinophilic colitis	1	0
Inflammatory bowel disease	9	0
<i>Dental and periodontal infections and inflammations</i>		
Dental caries	2	0
<i>Dental disorders NEC</i>		
Loose tooth	3	0
Malpositioned teeth	2	0
Periodontal disease	1	0
Teeth brittle	3	0
Teething	8	0
Tooth disorder	2	0
Tooth socket haemorrhage	1	0
<i>Dental pain and sensation disorders</i>		

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Dental discomfort	7	0
Dental paraesthesia	13	0
Hyperaesthesia teeth	36	0
Toothache	168	0
<i>Dental surface disorders</i>		
Tooth discolouration	9	0
<i>Diaphragmatic hernias</i>		
Hiatus hernia	8	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	5508	0
Diarrhoea haemorrhagic	25	0
<i>Diverticula</i>		
Diverticulum	5	0
Diverticulum intestinal	1	0
<i>Duodenal and small intestinal stenosis and obstruction</i>		
Small intestinal obstruction	2	0
<i>Duodenal ulcers and perforation</i>		
Duodenal ulcer haemorrhage	1	0
Duodenal ulcer perforation	3	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	455	0
Epigastric discomfort	14	0
Eructation	53	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	19	0
Faecaloma	4	0
Faeces discoloured	60	0
Faeces hard	2	0
Faeces pale	4	0
Faeces soft	12	0
Mucous stools	10	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	523	0
Aerophagia	3	0
Flatulence	184	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	7	0
<i>Gastritis (excl infective)</i>		
Chronic gastritis	3	0
Gastritis	60	0
Reflux gastritis	6	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal migraine	2	0
Abdominal pain	1473	0
Abdominal pain lower	133	0
Abdominal pain upper	2451	0
Abdominal rigidity	24	0
Abdominal tenderness	13	0
Gastrointestinal pain	141	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Oesophageal pain	13	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	252	0
Duodenogastric reflux	4	0
Gastric dilatation	7	0
Gastrooesophageal reflux disease	155	0
Impaired gastric emptying	9	0
Infrequent bowel movements	3	0
Intestinal dilatation	1	0
Intestinal pseudo-obstruction	2	0
<i>Gastrointestinal disorders NEC</i>		
Appendix disorder	1	0
Food poisoning	7	0
Functional gastrointestinal disorder	10	0
Gastric disorder	10	0
Gastrointestinal disorder	23	0
Stomach mass	4	0
<i>Gastrointestinal dyskinetic disorders</i>		
Bowel movement irregularity	6	0
Change of bowel habit	8	0
Dyschezia	3	0
Gastrointestinal motility disorder	3	0
Oesophageal achalasia	1	0
<i>Gastrointestinal fistulae</i>		
Diverticular fistula	2	0
<i>Gastrointestinal inflammatory disorders NEC</i>		
Duodenitis	1	0
Enteritis	6	0
Epiploic appendagitis	2	0
Gastrointestinal inflammation	3	0
Gastrointestinal tract irritation	1	0
Intestinal angioedema	2	0
<i>Gastrointestinal mucosal dystrophies and secretion disorders</i>		
Barrett's oesophagus	1	0
Hyperchlorhydria	4	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	627	0
Abdominal symptom	1	0
Acute abdomen	6	0
Anal incontinence	19	0
Breath odour	19	0
Dysphagia	208	1
Gastrointestinal wall thickening	1	0
Odynophagia	39	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Cardiospasm	1	0
Defaecation urgency	11	0
Frequent bowel movements	28	0
Gastrointestinal hypermotility	1	0
Irritable bowel syndrome	87	0
Oesophageal spasm	5	0
Pylorospasm	1	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Intestinal obstruction	4	0
Neonatal intestinal obstruction	1	0
<i>Gastrointestinal vascular malformations</i>		
Gastric antral vascular ectasia	11	0
<i>Gastrointestinal vascular occlusion and infarction</i>		
Intestinal ischaemia	7	2
Mesenteric vein thrombosis	7	0
Omental infarction	1	0
Thrombosis mesenteric vessel	2	0
Visceral venous thrombosis	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival blister	13	0
Gingival discomfort	8	0
Gingival disorder	4	0
Gingival erythema	2	0
Gingival hypertrophy	1	0
Gingival oedema	1	0
Gingival pain	113	0
Gingival pruritus	1	0
Gingival recession	1	0
Gingival swelling	36	0
Gingival ulceration	2	0
Gingivitis ulcerative	1	0
Noninfective gingivitis	8	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	67	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Gastric varices	1	0
Haemorrhoidal haemorrhage	1	0
Haemorrhoids	31	1
Haemorrhoids thrombosed	1	0
<i>Inguinal hernias</i>		
Inguinal hernia	1	0
<i>Intestinal haemorrhages</i>		
Anal haemorrhage	21	1
Intestinal haemorrhage	1	0
Rectal haemorrhage	73	0
Small intestinal haemorrhage	5	0
<i>Intestinal ulcers and perforation NEC</i>		
Intestinal perforation	5	2
Large intestinal ulcer	1	0
Large intestinal ulcer haemorrhage	1	0
Large intestine perforation	1	0
<i>Large intestinal stenosis and obstruction</i>		
Large intestinal obstruction	1	1
<i>Malabsorption syndromes</i>		
Bile acid malabsorption	2	0
Coeliac disease	12	0
Malabsorption	1	0
Steatorrhoea	4	0
<i>Nausea and vomiting symptoms</i>		
Discoloured vomit	12	0
Infantile vomiting	7	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Nausea	13897	0
Regurgitation	1	0
Retching	106	0
Vomiting	4537	1
Vomiting projectile	63	0
Non-mechanical ileus		
Ileus paralytic	2	0
Non-site specific gastrointestinal haemorrhages		
Gastrointestinal haemorrhage	17	1
Haematemesis	34	2
Haematochezia	52	0
Melaena	9	0
Upper gastrointestinal haemorrhage	14	0
Oesophageal stenosis and obstruction		
Oesophageal stenosis	3	0
Oesophagitis (excl infective)		
Eosinophilic oesophagitis	1	0
Oesophagitis	4	0
Oral dryness and saliva altered		
Aptyalism	3	0
Dry mouth	499	0
Lip dry	41	0
Saliva altered	8	0
Salivary hypersecretion	50	0
Oral soft tissue disorders NEC		
Angina bullosa haemorrhagica	1	0
Chapped lips	24	0
Cheilitis	25	0
Enlarged uvula	14	0
Leukoplakia oral	2	0
Lip blister	30	0
Lip disorder	5	0
Oral disorder	20	0
Oral lichen planus	13	0
Oral mucosal hypertrophy	1	0
Oral papule	1	0
Uvulitis	5	0
Oral soft tissue haemorrhages		
Lip haemorrhage	1	0
Mouth haemorrhage	16	0
Oral blood blister	15	0
Oral purpura	2	0
Oral soft tissue infections		
Angular cheilitis	4	0
Oral soft tissue signs and symptoms		
Anaesthesia oral	3	0
Burning mouth syndrome	6	0
Coating in mouth	1	0
Hypoaesthesia oral	476	0
Lip discolouration	7	0
Lip erythema	4	0
Lip exfoliation	5	0
Lip pain	54	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Lip pruritus	15	0
Lip scab	1	0
Oral discomfort	82	0
Oral dysaesthesia	1	0
Oral mucosal blistering	16	0
Oral mucosal discolouration	1	0
Oral mucosal eruption	17	0
Oral mucosal erythema	7	0
Oral mucosal exfoliation	9	0
Oral mucosal roughening	3	0
Oral mucosal scab	1	0
Oral pain	170	0
Oral pruritus	23	0
Paraesthesia oral	889	0
Pigmentation lip	1	0
<i>Oral soft tissue swelling and oedema</i>		
Lip oedema	4	0
Lip swelling	766	0
Mouth swelling	96	0
Oedema mouth	4	0
Palatal oedema	4	0
Palatal swelling	2	0
<i>Pancreatic disorders NEC</i>		
Pancreatic disorder	1	0
Pancreatic failure	1	0
Pancreatic mass	1	0
<i>Peptic ulcers and perforation</i>		
Peptic ulcer	1	0
Peptic ulcer haemorrhage	13	0
<i>Peritoneal and retroperitoneal disorders</i>		
Ascites	1	0
<i>Peritoneal and retroperitoneal fibrosis and adhesions</i>		
Abdominal adhesions	2	0
<i>Peritoneal and retroperitoneal haemorrhages</i>		
Haemoperitoneum	1	0
Retroperitoneal haemorrhage	1	1
<i>Rectal inflammations NEC</i>		
Proctitis	3	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	10	0
Salivary gland enlargement	5	0
Submaxillary gland enlargement	7	0
<i>Salivary gland infections and inflammations</i>		
Noninfective sialoadenitis	1	0
<i>Stomatitis and ulceration</i>		
Aphthous ulcer	53	0
Lip ulceration	19	0
Mouth ulceration	445	0
Oral mucosa erosion	1	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Palatal ulcer	1	0
Stomatitis	65	0
<i>Tongue disorders</i>		
Glossitis	20	0
Hypertrophy of tongue papillae	1	0
Plicated tongue	4	0
Tongue disorder	41	0
Tongue geographic	7	0
Tongue haemorrhage	3	0
Tongue ulceration	30	0
Trichoglossia	4	0
<i>Tongue signs and symptoms</i>		
Glossodynia	211	0
Scalloped tongue	5	0
Stiff tongue	4	0
Swollen tongue	483	0
Tongue blistering	19	0
Tongue coated	17	0
Tongue discolouration	38	0
Tongue discomfort	41	0
Tongue dry	15	0
Tongue eruption	9	0
Tongue erythema	13	0
Tongue exfoliation	1	0
Tongue movement disturbance	6	0
Tongue oedema	23	0
Tongue pruritus	2	0
Tongue rough	5	0
Tongue spasm	10	0
<i>Tooth missing</i>		
Tooth loss	6	0
Gastrointestinal disorders SOC TOTAL	37666	16

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site bruise	7	0
Administration site erythema	4	0
Administration site extravasation	3	0
Administration site haematoma	3	0
Administration site inflammation	1	0
Administration site irritation	1	0
Administration site joint discomfort	1	0
Administration site joint movement impairment	1	0
Administration site nerve damage	1	0
Administration site pain	19	0
Administration site rash	5	0
Administration site reaction	1	0
Administration site swelling	4	0
Administration site urticaria	2	0
Administration site warmth	2	0
Puncture site bruise	38	0
Puncture site pain	7	0
Puncture site reaction	1	0
Puncture site swelling	2	0
Vessel puncture site bruise	2	0
Vessel puncture site erythema	1	0
Vessel puncture site pain	1	0
<i>Adverse effect absent</i>		
No adverse event	6	0
<i>Application and instillation site reactions</i>		
Application site acne	2	0
Application site bruise	10	0
Application site burn	1	0
Application site dryness	1	0
Application site erythema	17	0
Application site haemorrhage	1	0
Application site hypoaesthesia	1	0
Application site irritation	1	0
Application site joint erythema	1	0
Application site joint pain	1	0
Application site mass	1	0
Application site odour	2	0
Application site pain	12	0
Application site pruritus	4	0
Application site rash	2	0
Application site reaction	1	0
Application site swelling	2	0
Application site vesicles	7	0
Application site warmth	1	0
Instillation site warmth	8	0
<i>Asthenic conditions</i>		
Asthenia	2013	0
Chronic fatigue syndrome	76	0
Decreased activity	10	0
Fatigue	22727	0
Malaise	5264	1
Sluggishness	18	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
<i>Body temperature altered</i>		
Hyperthermia	7	0
Hypothermia	25	0
Temperature regulation disorder	13	0
<i>Breast complications associated with device</i>		
Breast implant palpable	1	0
Capsular contracture associated with breast implant	1	0
<i>Cardiac complications associated with device</i>		
Prosthetic cardiac valve thrombosis	2	0
<i>Complications associated with device NEC</i>		
Capsular contracture associated with implant	1	0
Complication of device removal	3	0
Injury associated with device	5	0
Medical device pain	1	0
Medical device site swelling	1	0
Phantom shocks	2	0
<i>Death and sudden death</i>		
Brain death	3	3
Cardiac death	3	3
Clinical death	1	1
Death	186	186
Sudden death	27	27
<i>Febrile disorders</i>		
Hyperpyrexia	9	0
Pyrexia	14892	0
<i>Feelings and sensations NEC</i>		
Chills	9493	0
Feeling abnormal	1632	0
Feeling cold	1229	0
Feeling drunk	77	0
Feeling hot	1159	0
Feeling jittery	29	0
Feeling of body temperature change	322	0
Feeling of relaxation	3	0
Hangover	77	0
Hunger	47	0
Sensation of blood flow	4	0
Sensation of foreign body	55	0
Temperature intolerance	45	0
Thirst	343	0
Thirst decreased	1	0
<i>Fibrosis NEC</i>		
Fibrosis	1	0
<i>Gait disturbances</i>		
Gait disturbance	234	0
Gait inability	91	0
Loss of control of legs	23	0
<i>General signs and symptoms NEC</i>		
Adhesion	1	0
Chronic disease	1	0
Concomitant disease progression	1	1
Condition aggravated	248	0
Crepitations	3	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Crying	151	0
Deformity	2	0
Discharge	12	0
Disease progression	2	0
Disease recurrence	29	0
Effusion	3	0
Energy increased	23	0
Exercise tolerance decreased	25	0
Exercise tolerance increased	1	0
Fat tissue increased	1	0
Foaming at mouth	3	0
General physical health deterioration	17	2
General symptom	3	0
Glassy eyes	6	0
High-pitched crying	3	0
Illness	1930	0
Induration	16	0
Influenza like illness	2406	0
Irritability postvaccinal	2	0
Local reaction	84	0
Moaning	3	0
Multiple organ dysfunction syndrome	10	4
Nonspecific reaction	2	0
Organ failure	2	1
Perforation	2	0
Peripheral swelling	3758	0
Physical deconditioning	2	0
Pre-existing condition improved	8	0
Prolapse	1	0
Screaming	21	0
Secretion discharge	24	0
Swelling	3035	0
Swelling face	834	0
Symptom recurrence	1	0
Terminal state	1	0
Tissue irritation	1	0
Healing abnormal NEC		
Impaired healing	3	0
Implant and catheter site reactions		
Implant site discolouration	2	0
Implant site pain	3	0
Implant site rash	1	0
Implant site swelling	2	0
Implant site urticaria	1	0
Implant site warmth	3	0
Inflammations		
Granuloma	1	0
Inflammation	512	0
Papillitis	1	0
Scar inflammation	3	0
Serositis	1	0
Systemic inflammatory response syndrome	3	0
Infusion site reactions		

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Infusion site coldness	1	0
Infusion site discolouration	1	0
Infusion site joint effusion	1	0
Infusion site joint pain	2	0
Infusion site mass	1	0
Infusion site nerve damage	1	0
Infusion site pain	4	0
Infusion site pruritus	2	0
Infusion site swelling	2	0
Infusion site urticaria	1	0
Infusion site warmth	2	0
Injection site reactions		
Injected limb mobility decreased	33	0
Injection site bruising	65	0
Injection site coldness	1	0
Injection site cyst	2	0
Injection site discolouration	5	0
Injection site discomfort	11	0
Injection site eczema	1	0
Injection site erythema	377	0
Injection site extravasation	1	0
Injection site haematoma	1	0
Injection site haemorrhage	6	0
Injection site hypersensitivity	2	0
Injection site hypoaesthesia	12	0
Injection site indentation	9	0
Injection site induration	4	0
Injection site inflammation	42	0
Injection site irritation	1	0
Injection site joint discomfort	2	0
Injection site joint erythema	3	0
Injection site joint movement impairment	1	0
Injection site joint pain	14	0
Injection site lymphadenopathy	1	0
Injection site macule	1	0
Injection site mass	551	0
Injection site movement impairment	1	0
Injection site muscle weakness	1	0
Injection site necrosis	4	0
Injection site nerve damage	1	0
Injection site nodule	1	0
Injection site oedema	17	0
Injection site pain	2913	0
Injection site paraesthesia	12	0
Injection site pruritus	203	0
Injection site rash	178	0
Injection site reaction	49	0
Injection site scab	4	0
Injection site scar	5	0
Injection site swelling	294	0
Injection site urticaria	30	0
Injection site vesicles	10	0
Injection site warmth	186	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
<i>Interactions</i>		
Alcohol interaction	4	0
Drug interaction	28	0
Inhibitory drug interaction	3	0
<i>Mass conditions NEC</i>		
Cyst	45	0
Mass	71	0
Nodule	37	0
<i>Mucosal findings abnormal</i>		
Mucosa vesicle	1	0
Mucosal dryness	1	0
Mucosal haemorrhage	9	0
Mucosal inflammation	2	0
Oedema mucosal	1	0
Polyp	5	0
<i>Necrosis NEC</i>		
Fat necrosis	4	0
Necrosis	4	0
<i>Oedema NEC</i>		
Face oedema	33	0
Generalised oedema	4	0
Localised oedema	21	0
Oedema	75	0
Oedema peripheral	90	0
<i>Pain and discomfort NEC</i>		
Axillary pain	3225	0
Breakthrough pain	1	0
Chest discomfort	1719	0
Chest pain	4912	0
Discomfort	474	0
Facial discomfort	19	0
Facial pain	206	0
Inflammatory pain	17	0
Non-cardiac chest pain	30	0
Pain	8791	0
Suprapubic pain	1	0
Tenderness	668	0
Visceral pain	2	0
<i>Therapeutic and nontherapeutic responses</i>		
Adverse drug reaction	61	0
Adverse event	2	0
Adverse food reaction	3	0
Adverse reaction	7	0
Drug ineffective	309	0
Drug intolerance	4	0
Drug resistance	1	0
Immediate post-injection reaction	3	0
Inadequate analgesia	8	0
No reaction on previous exposure to drug	40	0
Product intolerance	1	0
Therapeutic product effect decreased	1	0
Therapeutic product effect delayed	2	0
Therapeutic product effect increased	1	0

Case Series Drug Analysis Print

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

Report Run Date: 20-Dec-2021

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Therapeutic product ineffective	2	0
Therapeutic response decreased	2	0
Therapeutic response unexpected	75	0
Therapy non-responder	1	0
Treatment failure	8	0
Vaccination failure	43	0
Trophic disorders		
Atrophy	2	0
Calcinosis	2	0
Hyperplasia	1	0
Ulcers NEC		
Ulcer	35	0
Ulcer haemorrhage	1	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	15	0
Shoulder injury related to vaccine administration	37	0
Vaccination site anaesthesia	1	0
Vaccination site bruising	134	0
Vaccination site coldness	3	0
Vaccination site cyst	6	0
Vaccination site dermatitis	1	0
Vaccination site discolouration	16	0
Vaccination site discomfort	50	0
Vaccination site dryness	1	0
Vaccination site eczema	1	0
Vaccination site erythema	652	0
Vaccination site granuloma	5	0
Vaccination site haematoma	2	0
Vaccination site haemorrhage	25	0
Vaccination site hypersensitivity	4	0
Vaccination site hypoaesthesia	18	0
Vaccination site induration	75	0
Vaccination site inflammation	59	0
Vaccination site irritation	13	0
Vaccination site joint discomfort	3	0
Vaccination site joint erythema	11	0
Vaccination site joint inflammation	1	0
Vaccination site joint movement impairment	19	0
Vaccination site joint pain	32	0
Vaccination site joint swelling	4	0
Vaccination site joint warmth	1	0
Vaccination site lymphadenopathy	8	0
Vaccination site macule	1	0
Vaccination site mass	293	0
Vaccination site movement impairment	92	0
Vaccination site nerve damage	1	0
Vaccination site nodule	4	0
Vaccination site oedema	3	0
Vaccination site pain	2183	0
Vaccination site paraesthesia	9	0
Vaccination site phlebitis	1	0
Vaccination site photosensitivity reaction	1	0
Vaccination site pruritus	171	0

Case Series Drug Analysis Print

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

Report Run Date: 20-Dec-2021

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site rash	139	0
Vaccination site reaction	35	0
Vaccination site scab	2	0
Vaccination site scar	1	0
Vaccination site swelling	597	0
Vaccination site thrombosis	1	0
Vaccination site ulcer	1	0
Vaccination site urticaria	10	0
Vaccination site vesicles	11	0
Vaccination site warmth	277	0
<i>Vascular complications associated with device</i>		
Vascular stent thrombosis	1	0
<i>Withdrawal and rebound effects</i>		
Drug withdrawal syndrome	4	0
Withdrawal syndrome	48	0
General disorders SOC TOTAL	104833	229

Case Series Drug Analysis Print

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

Report Run Date: 20-Dec-2021

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	13	0
Cholangitis	1	0
<i>Cholecystitis and cholelithiasis</i>		
Cholecystitis	4	0
Cholecystitis acute	2	0
Cholelithiasis	11	0
<i>Cholestasis and jaundice</i>		
Cholestasis	2	0
Jaundice	25	0
Jaundice cholestatic	10	0
Ocular icterus	2	0
<i>Gallbladder disorders NEC</i>		
Gallbladder disorder	2	0
<i>Hepatic and hepatobiliary disorders NEC</i>		
Liver disorder	14	0
<i>Hepatic enzymes and function abnormalities</i>		
Hepatic function abnormal	6	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	7	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	30	0
Hepatomegaly	3	0
Liver tenderness	3	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Autoimmune hepatitis	12	0
Drug-induced liver injury	3	0
Hepatic steatosis	6	0
Hepatitis	13	0
Hepatitis acute	2	0
Immune-mediated hepatic disorder	1	0
Liver injury	22	0
Hepatic disorders SOC TOTAL	208	1

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Immune system disorders		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	17	0
<i>Allergic conditions NEC</i>		
Allergic oedema	15	0
Allergy to animal	2	0
Allergy to arthropod bite	6	0
Allergy to arthropod sting	2	0
Allergy to metals	3	0
Allergy to sting	1	0
Hypersensitivity	985	0
Infusion related hypersensitivity reaction	3	0
Mite allergy	2	0
Multiple allergies	12	0
Serum sickness	2	0
Serum sickness-like reaction	5	0
Type I hypersensitivity	1	0
Type III immune complex mediated reaction	4	0
Type IV hypersensitivity reaction	6	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergic reaction to excipient	6	0
Allergy to chemicals	4	0
Allergy to vaccine	42	0
Contrast media reaction	2	0
Drug hypersensitivity	30	0
Food allergy	28	0
Milk allergy	2	0
Oral allergy syndrome	2	0
Reaction to colouring	1	0
Reaction to excipient	9	0
Reaction to preservatives	5	0
Rubber sensitivity	1	0
Smoke sensitivity	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	509	1
Anaphylactic shock	58	0
Anaphylactoid reaction	21	0
Anaphylactoid shock	4	0
<i>Atopic disorders</i>		
Atopy	3	0
Seasonal allergy	106	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	45	0
<i>Immune and associated conditions NEC</i>		
Anamnestic reaction	1	0
Bacille Calmette-Guerin scar reactivation	54	0
Cytokine storm	1	0
Decreased immune responsiveness	3	0
Graft versus host disease	2	0
Haemophagocytic lymphohistiocytosis	3	0
Immune reconstitution inflammatory syndrome	1	0
Immune system disorder	29	0
Immune-mediated adverse reaction	7	0
Immunisation reaction	1	0

Case Series Drug Analysis Print

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

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Immune system disorders		
<i>Immune system disorders cont'd</i>		
Multisystem inflammatory syndrome in children	3	0
Sensitisation	7	0
Systemic immune activation	2	0
<i>Immunodeficiency disorders NEC</i>		
Hypogammaglobulinaemia	1	0
Immunodeficiency	2	0
Immunosuppression	3	0
<i>Transplant rejections</i>		
Corneal graft rejection	9	0
Kidney transplant rejection	1	0
Solid organ transplant rejection	1	0
Transplant rejection	2	0
Immune system disorders SOC TOTAL	2078	1

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Abdominal abscess	2	0
Abdominal infection	1	0
Anal abscess	3	0
Appendicitis	41	0
Appendicitis perforated	7	0
Diverticulitis	13	0
Dysentery	1	0
Gastric infection	2	0
Gastroenteritis	27	0
Mesenteric abscess	1	0
Peritonitis	3	1
Rectal abscess	1	0
<i>Adenoviral infections</i>		
Adenoviral conjunctivitis	1	0
Adenovirus infection	1	0
<i>Aspergillus infections</i>		
Bronchopulmonary aspergillosis	1	0
<i>Bacterial infections NEC</i>		
Abscess bacterial	2	0
Arthritis bacterial	4	0
Bacterial colitis	1	0
Bacterial diarrhoea	1	0
Bacterial infection	15	0
Bacterial sepsis	1	0
Bacterial vaginosis	1	0
Cellulitis	184	0
Cellulitis orbital	1	0
Conjunctivitis bacterial	1	0
Ear infection bacterial	1	0
External ear cellulitis	1	0
Folliculitis	17	0
Gangrene	1	0
Gastrointestinal bacterial overgrowth	1	0
Injection site cellulitis	2	0
Meningitis bacterial	3	0
Paronychia	3	0
Perichondritis	2	0
Periorbital cellulitis	2	0
Pneumonia bacterial	1	0
Sinusitis bacterial	2	0
Skin bacterial infection	4	0
Tonsillitis bacterial	3	0
Urinary tract infection bacterial	1	0
Vaccination site cellulitis	20	0
Zoonotic bacterial infection	1	1
<i>Bartonella infections</i>		
Cat scratch disease	1	0
<i>Bone and joint infections</i>		
Abscess jaw	1	0
Arthritis infective	2	0
Osteomyelitis	2	0
<i>Borreliac infections</i>		

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Infections Infections cont'd		
Lyme disease	2	0
Relapsing fever	1	0
Breast infections		
Breast abscess	3	0
Mastitis	79	0
Caliciviral infections		
Gastroenteritis norovirus	3	0
Campylobacter infections		
Campylobacter gastroenteritis	1	0
Campylobacter infection	1	0
Candida infections		
Anal candidiasis	3	0
Balanitis candida	1	0
Candida infection	64	0
Oral candidiasis	38	0
Respiratory moniliasis	1	0
Skin candida	2	0
Systemic candida	1	0
Urinary tract candidiasis	1	0
Vulvovaginal candidiasis	48	0
Cardiac infections		
Cardiac infection	1	0
Cardiac valve vegetation	1	0
Pericarditis infective	2	0
Central nervous system and spinal infections		
Brain abscess	1	0
CNS ventriculitis	1	0
Cavernous sinus thrombosis	1	0
Encephalitis	19	0
Encephalomyelitis	1	0
Meningitis	9	0
Meningitis aseptic	3	0
Myelitis	8	0
Subdural abscess	1	0
Clostridia infections		
Clostridium difficile infection	2	0
Coronavirus infections		
Asymptomatic COVID-19	16	0
COVID-19	1501	43
COVID-19 pneumonia	50	14
Coronavirus infection	7	0
Post-acute COVID-19 syndrome	2	0
Severe acute respiratory syndrome	4	0
Suspected COVID-19	71	4
Corynebacteria infections		
Diphtheria	2	0
Coxiella infections		
Q fever	12	0
Cytomegaloviral infections		
Cytomegalovirus infection	2	0
Cytomegalovirus syndrome	1	0
Dental and oral soft tissue infections		
Abscess oral	6	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Gingival abscess	1	0
Gingivitis	12	0
Oral infection	1	0
Parotitis	11	0
Pericoronitis	2	0
Periodontitis	1	0
Pulpitis dental	1	0
Sialoadenitis	3	0
Tongue abscess	1	0
Tooth abscess	8	0
Tooth infection	9	0
Ear infections		
Ear infection	90	0
Labyrinthitis	105	0
Mastoiditis	1	0
Otitis externa	3	0
Otitis media	3	0
Otitis media acute	1	0
Otitis media chronic	4	0
Ectoparasitic infestations		
Acarodermatitis	4	0
Bed bug infestation	1	0
Epstein-Barr viral infections		
Epstein-Barr virus infection	4	0
Epstein-Barr virus infection reactivation	1	0
Infectious mononucleosis	29	0
Escherichia infections		
Escherichia bacteraemia	1	0
Eye and eyelid infections		
Conjunctivitis	73	0
Eye abscess	1	0
Eye infection	25	0
Eye infection intraocular	1	0
Eyelid boil	2	0
Eyelid infection	2	0
Hordeolum	28	0
Keratouveitis	1	0
Periorbital infection	2	0
Female reproductive tract infections		
Bartholin's abscess	1	0
Bartholinitis	1	0
Endometritis	3	0
Funisitis	1	0
Pelvic inflammatory disease	2	0
Vaginal infection	1	0
Vulval abscess	1	0
Vulvitis	1	0
Fungal infections NEC		
Fungal infection	18	0
Fungal skin infection	5	0
Onychomycosis	2	0
Oral fungal infection	2	0
Pneumonia fungal	2	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Vulvovaginal mycotic infection	7	0
Hepatitis virus infections		
Hepatitis A	1	0
Hepatitis E	1	0
Hepatobiliary and spleen infections		
Biliary sepsis	3	0
Cholecystitis infective	2	0
Hepatic infection	1	0
Herpes viral infections		
Eczema herpeticum	2	0
Genital herpes	88	0
Genital herpes simplex	6	0
Genital herpes zoster	1	0
Herpes ophthalmic	3	0
Herpes simplex	29	0
Herpes simplex encephalitis	1	1
Herpes simplex reactivation	2	0
Herpes virus infection	13	0
Herpes zoster	1440	0
Herpes zoster disseminated	1	0
Herpes zoster meningoencephalitis	1	0
Herpes zoster oticus	15	0
Herpes zoster reactivation	1	0
Meningitis herpes	1	0
Nasal herpes	4	0
Ophthalmic herpes simplex	2	0
Ophthalmic herpes zoster	4	0
Oral herpes	312	0
Varicella	30	0
Varicella zoster virus infection	4	0
Infections NEC		
Abscess	35	0
Abscess limb	9	0
Abscess soft tissue	1	0
Catheter site infection	1	0
Genital abscess	2	0
Infected bite	3	0
Infected cyst	2	0
Infection	242	0
Infection susceptibility increased	2	0
Injection site abscess	1	0
Injection site infection	5	0
Localised infection	32	0
Lymph gland infection	15	0
Lymph node abscess	5	0
Opportunistic infection	1	0
Pathogen resistance	1	0
Purulent discharge	1	0
Respiratory tract infection	11	0
Vaccination site abscess	11	0
Vaccination site infection	13	0
Vaccine breakthrough infection	23	0
Vestibulitis	2	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Wound infection	2	0
<i>Infectious transmissions</i>		
Secondary transmission	8	0
Vaccine virus shedding	1	0
<i>Influenza viral infections</i>		
Influenza	1637	0
<i>Klebsiella infections</i>		
Klebsiella infection	1	0
<i>Lower respiratory tract and lung infections</i>		
Bronchitis	22	0
Infectious pleural effusion	1	0
Lower respiratory tract infection	239	8
Pneumonia	145	13
Pneumonia aspiration	10	6
Sputum purulent	1	0
<i>Male reproductive tract infections</i>		
Epididymitis	8	0
Orchitis	5	0
Prostate infection	2	0
<i>Molluscum contagiosum viral infections</i>		
Molluscum contagiosum	1	0
<i>Mumps viral infections</i>		
Mumps	7	0
<i>Muscle and soft tissue infections</i>		
Abscess neck	1	0
Infective tenosynovitis	1	0
Necrotising fasciitis	2	0
Psoas abscess	1	0
Soft tissue infection	2	0
<i>Neisseria infections</i>		
Gonorrhoea	1	0
Meningococcal bacteraemia	1	0
Meningococcal infection	1	0
<i>Orthopox viral infections</i>		
Vaccinia virus infection	2	0
<i>Plasmodia infections</i>		
Malaria	2	0
<i>Pneumocystis infections</i>		
Pneumocystis jirovecii pneumonia	2	0
<i>Retroviral infections</i>		
Acquired immunodeficiency syndrome	1	0
HIV infection	3	0
Persistent generalised lymphadenopathy	1	0
<i>Rhinoviral infections</i>		
Rhinovirus infection	1	0
<i>Rotaviral infections</i>		
Gastroenteritis rotavirus	1	0
<i>Rubeola viral infections</i>		
Measles	4	0
<i>Salmonella infections</i>		
Typhoid fever	1	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Neutropenic sepsis	3	1

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Sepsis	52	7
Sepsis syndrome	2	0
Septic rash	1	0
Septic shock	6	1
Urosepsis	5	0
Skin structures and soft tissue infections		
Abscess sweat gland	1	0
Acne pustular	1	0
Blister infected	1	0
Dermatitis infected	3	0
Impetigo	11	0
Infected skin ulcer	1	0
Injection site pustule	2	0
Nail infection	2	0
Pustule	18	0
Pyoderma	1	0
Rash pustular	12	0
Skin infection	32	0
Subcutaneous abscess	11	0
Sweat gland infection	1	0
Vaccination site pustule	4	0
Staphylococcal infections		
Furuncle	40	1
Pneumonia staphylococcal	1	0
Staphylococcal abscess	1	0
Staphylococcal infection	4	0
Staphylococcal sepsis	1	0
Streptococcal infections		
Meningitis pneumococcal	1	0
Pharyngitis streptococcal	7	0
Pneumonia pneumococcal	1	0
Streptococcal abscess	1	0
Streptococcal endocarditis	1	0
Streptococcal infection	1	0
Streptococcal sepsis	1	0
Tinea infections		
Body tinea	4	0
Tinea infection	1	0
Tinea pedis	3	0
Tinea versicolour	4	0
Treponema infections		
Syphilis	2	0
Trypanosomal infections		
African trypanosomiasis	3	0
Tuberculous infections		
Lymph node tuberculosis	1	0
Pulmonary tuberculosis	1	0
Tuberculosis	1	0
Tuberculosis of central nervous system	1	0
Upper respiratory tract infections		
Acute sinusitis	4	0
Chronic sinusitis	3	0
Croup infectious	1	0

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Epiglottitis	1	0
Laryngitis	30	0
Nasopharyngitis	1055	1
Peritonsillar abscess	4	0
Pharyngitis	30	0
Rhinitis	45	0
Sinusitis	164	0
Tonsillitis	123	0
Tracheitis	4	0
Tracheostomy infection	1	0
Upper respiratory tract infection	12	0
Urinary tract infections		
Cystitis	76	0
Kidney infection	45	0
Pyelonephritis	2	0
Urethritis	1	0
Urinary tract infection	201	0
Vascular infections		
Haematoma infection	1	0
Infected lymphocele	2	0
Infusion site infection	1	0
Lymphangitis	9	0
Viral infections NEC		
Arthritis viral	1	0
Conjunctivitis viral	2	0
Ear infection viral	1	0
Encephalitis viral	6	1
Eye infection viral	2	0
Gastroenteritis viral	30	0
Hepatitis viral	3	0
Meningitis viral	8	0
Meningoencephalitis viral	1	0
Oral viral infection	1	0
Pleurisy viral	1	0
Pneumonia viral	3	1
Post viral fatigue syndrome	48	0
Sweating fever	109	0
Vestibular neuronitis	30	0
Viral diarrhoea	2	0
Viral infection	56	0
Viral labyrinthitis	4	0
Viral myocarditis	3	0
Viral pericarditis	3	0
Viral pharyngitis	20	0
Viral rash	59	0
Viral sinusitis	1	0
Viral tonsillitis	2	0
Infections SOC TOTAL	9805	104

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Reaction Name	Total	Fatal
Injuries		
<i>Abdominal and gastrointestinal injuries NEC</i>		
Gallbladder injury	1	0
Liver contusion	1	0
Mouth injury	3	0
Oral contusion	5	0
Palate injury	1	0
Rectal injury	1	0
Splenic rupture	7	0
Tongue injury	2	0
Tooth fracture	1	0
Tooth injury	1	0
<i>Accidental exposures to product</i>		
Accidental exposure to product	20	0
<i>Anaesthetic and allied procedural complications</i>		
Airway complication of anaesthesia	2	0
Delayed recovery from anaesthesia	2	0
Sedation complication	1	0
<i>Atmospheric pressure injuries</i>		
Barotitis media	1	0
Hypobarism	1	0
<i>Bone and joint injuries NEC</i>		
Bursa injury	2	0
Joint injury	8	0
Meniscus injury	1	0
<i>Cardiac and vascular procedural complications</i>		
Shunt blood flow excessive	1	0
Vascular pseudoaneurysm	1	0
<i>Cardiovascular injuries</i>		
Vascular injury	8	0
<i>Cerebral injuries NEC</i>		
Brain contusion	4	0
Brain herniation	2	0
Concussion	4	0
Craniocerebral injury	1	0
Subarachnoid haematoma	1	0
Subdural haematoma	5	0
Subdural haemorrhage	6	0
Traumatic intracranial haemorrhage	1	1
<i>Chemical injuries</i>		
Chemical burn of skin	9	0
Chemical cystitis	2	0
<i>Chest and respiratory tract injuries NEC</i>		
Bronchial injury	1	0
Chest crushing	11	0
Foreign body in throat	1	0
Traumatic lung injury	1	0
<i>Conditions caused by cold</i>		
Chillblains	61	0
Cold shock response	1	0
Frostbite	1	0
<i>Cranial nerve injuries</i>		
Vth nerve injury	1	0
<i>Ear injuries NEC</i>		

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Deafness traumatic	1	0
Ear injury	1	0
Exposures associated with pregnancy, delivery and lactation		
Exposure during pregnancy	11	0
Exposure via breast milk	142	0
Foetal exposure during pregnancy	51	0
Foetal exposure timing unspecified	1	0
Maternal exposure before pregnancy	17	0
Maternal exposure during breast feeding	1684	0
Maternal exposure during delivery	1	0
Maternal exposure during pregnancy	920	0
Maternal exposure timing unspecified	11	0
Paternal exposure before pregnancy	3	0
Exposures to agents or circumstances NEC		
Exposure to SARS-CoV-2	3	0
Exposure to vaccinated person	4	0
Eye and ear procedural complications		
Toxic anterior segment syndrome	1	0
Eye injuries NEC		
Corneal abrasion	1	0
Eye contusion	14	0
Eye injury	24	0
Foreign body in eye	3	0
Injury corneal	1	0
Periorbital haematoma	1	0
Retinal injury	2	0
Superficial injury of eye	1	0
Foetal and neonatal conditions associated with product exposure		
Intoxication by breast feeding	1	0
Fractures and dislocations NEC		
Bone fragmentation	1	0
Fracture	3	0
Joint dislocation	3	0
Multiple fractures	1	0
Gastrointestinal and hepatobiliary procedural complications		
Post procedural constipation	1	0
Postoperative ileus	1	0
Procedural nausea	10	0
Procedural vomiting	2	0
Heat injuries (excl thermal burns)		
Heat cramps	2	0
Heat exhaustion	3	0
Heat illness	1	0
Heat oedema	14	0
Heat stroke	3	0
Intentional product use issues		
Intentional dose omission	1	0
Intentional product use issue	1	0
Limb fractures and dislocations		
Atypical femur fracture	1	0
Clavicle fracture	27	0
Femoral neck fracture	1	0
Femur fracture	1	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Fibula fracture	1	0
Hip fracture	2	0
Tibia fracture	1	0
Upper limb fracture	1	0
Wrist fracture	1	0
Medication errors, product use errors and issues NEC		
Circumstance or information capable of leading to medication error	2	0
Dose calculation error	1	0
Inadequate aseptic technique in use of product	1	0
Medication error	22	0
Prescription drug used without a prescription	3	0
Product use complaint	1	0
Product use issue	26	0
Vaccination error	5	0
Wrong dose	4	0
Wrong drug	11	0
Wrong schedule	1	0
Wrong technique in product usage process	5	0
Muscle, tendon and ligament injuries		
Epicondylitis	20	0
Ligament injury	2	0
Ligament sprain	9	0
Mallet finger	1	0
Muscle hernia	1	0
Muscle injury	30	0
Muscle rupture	9	0
Muscle strain	30	0
Post-traumatic neck syndrome	2	0
Tendon injury	7	0
Tendon rupture	22	0
Musculoskeletal procedural complications		
Periprosthetic osteolysis	1	0
Post laminectomy syndrome	1	0
Nerve injuries NEC		
Nerve injury	97	0
Neurological and psychiatric procedural complications		
Post lumbar puncture syndrome	1	0
Post procedural stroke	1	0
Procedural dizziness	11	0
Non-occupational environmental exposures		
Exposure to extreme temperature	2	0
Non-site specific injuries NEC		
Animal scratch	1	0
Arthropod bite	6	0
Arthropod sting	6	0
Bite	1	0
Bone contusion	1	0
Crush injury	1	0
Electric shock	18	0
Fall	191	0
Foreign body	2	0
Injury	11	0
Multiple injuries	2	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Nervous system injury	2	0
Post concussion syndrome	2	0
Traumatic haematoma	1	0
Wound	7	0
Wound complication	10	0
Wound haematoma	1	0
Wound haemorrhage	2	0
Wound secretion	5	0
<i>Non-site specific procedural complications</i>		
Incision site pain	3	0
Infusion related reaction	7	0
Injection related reaction	63	0
Post procedural complication	5	0
Post procedural erythema	1	0
Post procedural inflammation	1	0
Post procedural pruritus	1	0
Procedural pain	2	0
Seroma	1	0
<i>Occupational exposures</i>		
Occupational exposure to SARS-CoV-2	1	0
Occupational exposure to product	1	0
<i>Off label uses</i>		
Off label use	304	0
<i>Overdoses NEC</i>		
Intentional overdose	1	0
Overdose	52	0
<i>Pathways and sources of exposure</i>		
Exposure via unknown route	1	0
<i>Pelvic fractures and dislocations</i>		
Pelvic fracture	1	0
<i>Peripheral nerve injuries</i>		
Axillary nerve injury	1	0
Brachial plexus injury	1	0
Sciatic nerve injury	2	0
Ulnar nerve injury	4	0
<i>Poisoning and toxicity</i>		
Alcohol poisoning	1	0
Poisoning	13	0
Toxicity to various agents	4	0
<i>Product administration errors and issues</i>		
Accidental overdose	8	0
Contraindicated product administered	1	0
Duplicate therapy error	1	0
Expired product administered	12	0
Extra dose administered	1	0
Inappropriate schedule of product administration	607	0
Incomplete course of vaccination	2	0
Incorrect dose administered	52	0
Incorrect drug administration rate	1	0
Incorrect product formulation administered	2	0
Incorrect route of product administration	6	0
Lack of vaccination site rotation	1	0
Poor quality product administered	3	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Product administered at inappropriate site	20	0
Product administered to patient of inappropriate age	1	0
Product administration error	9	0
Product dose omission issue	6	0
Wrong product administered	20	0
Product confusion errors and issues		
Product dosage form confusion	1	0
Product label confusion	4	0
Product dispensing errors and issues		
Product dispensing error	4	0
Product monitoring errors and issues		
Drug monitoring procedure incorrectly performed	1	0
Product preparation errors and issues		
Product preparation error	3	0
Product preparation issue	6	0
Product prescribing errors and issues		
Contraindicated product prescribed	2	0
Product prescribing error	2	0
Product selection errors and issues		
Product selection error	2	0
Radiation injuries		
Sunburn	22	0
Renal and urinary tract injuries NEC		
Bladder injury	1	0
Foreign body in urogenital tract	1	0
Reproductive system and breast injuries		
Penile contusion	1	0
Penis injury	1	0
Site specific injuries NEC		
Back injury	2	0
Face crushing	3	0
Face injury	1	0
Head injury	34	0
Limb crushing injury	4	0
Limb injury	127	0
Nasal injury	1	0
Neck crushing	1	0
Neck injury	1	0
Pharyngeal contusion	1	0
Site specific procedural complications NEC		
Axillary web syndrome	2	0
Skin injuries NEC		
Contusion	1213	0
Hair injury	1	0
Nail avulsion	1	0
Scar	24	0
Scratch	7	0
Skin abrasion	6	0
Skin injury	4	0
Skin laceration	4	0
Skin wound	3	0
Splinter	1	0
Subcutaneous haematoma	2	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
<i>Skin procedural complications</i>		
Dermal filler overcorrection	1	0
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	5	0
<i>Stoma complications</i>		
Gastrointestinal stoma complication	2	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	4	0
Burn of internal organs	4	0
Burn oral cavity	5	0
Burns second degree	5	0
Burns third degree	1	0
Thermal burn	21	0
Thermal burns of eye	16	0
<i>Underdoses NEC</i>		
Underdose	6	0
<i>Vaccination related complications</i>		
Adverse event following immunisation	1	0
Post vaccination syndrome	1	0
Vaccination complication	50	0
Injuries SOC TOTAL	6613	1

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Reaction Name	Total	Fatal
Investigations		
<i>Adrenal cortex tests</i>		
Cortisol decreased	4	0
<i>Adrenal medulla tests</i>		
Epinephrine abnormal	1	0
Epinephrine increased	1	0
<i>Auditory and vestibular diagnostic procedures</i>		
Acoustic stimulation tests	5	0
Audiogram abnormal	1	0
<i>Autoimmunity analyses</i>		
Antinuclear antibody	1	0
Antinuclear antibody increased	1	0
Antinuclear antibody positive	2	0
Rheumatoid factor	3	0
<i>Bacteria identification and serology (excl mycobacteria)</i>		
Bacterial test positive	1	0
Klebsiella test positive	1	0
<i>Blood counts NEC</i>		
Full blood count	5	0
Full blood count abnormal	2	0
<i>Blood gas and acid base analyses</i>		
Acid base balance abnormal	1	0
Blood lactic acid	4	0
Blood lactic acid decreased	1	0
Blood lactic acid increased	5	0
Blood pH	7	0
Blood pH abnormal	1	0
Blood pH increased	12	0
Oxygen consumption	1	0
Oxygen consumption decreased	2	0
Oxygen saturation	8	0
Oxygen saturation abnormal	2	0
Oxygen saturation decreased	81	0
PO2 decreased	1	0
Venous oxygen saturation decreased	1	0
<i>Bone marrow and immune tissue histopathology procedures</i>		
Aspiration bone marrow	1	0
Biopsy lymph gland	1	0
<i>Bone marrow and immune tissue imaging procedures</i>		
Lymph nodes scan abnormal	1	0
Scan lymph nodes	4	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose	9	0
Blood glucose abnormal	13	0
Blood glucose decreased	35	0
Blood glucose fluctuation	17	0
Blood glucose increased	104	0
Blood glucose normal	1	0
Glycosylated haemoglobin increased	1	0
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	41	0
Heart sounds	6	0
Heart sounds abnormal	5	0
<i>Cardiac function diagnostic procedures</i>		

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Cardiac monitoring	1	0
Cardiac output	1	0
Central venous pressure	1	0
Echocardiogram	1	0
Ejection fraction decreased	2	0
Myocardial strain imaging	1	0
Right atrial volume abnormal	1	0
Stroke volume decreased	1	0
Cardiac imaging procedures		
Magnetic resonance imaging heart	1	0
Scan myocardial perfusion abnormal	1	0
Cell marker analyses		
Carcinoembryonic antigen increased	1	0
HLA-B*27 positive	1	0
Prostatic specific antigen increased	2	0
Central nervous system imaging procedures		
Computerised tomogram head	7	0
Magnetic resonance imaging head	12	0
Magnetic resonance imaging head abnormal	1	0
Cerebrospinal fluid tests (excl microbiology)		
CSF pressure	1	0
Chemistry analyses NEC		
Histamine abnormal	1	0
Histamine level	1	0
Histamine level increased	1	0
Inflammatory marker decreased	1	0
Inflammatory marker increased	4	0
Inflammatory marker test	1	0
Renin	1	0
Cholesterol analyses		
Blood cholesterol increased	11	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	10	0
Blood thromboplastin	1	0
Clot retraction	1	1
Coagulation factor VIII level decreased	1	0
Coagulation time prolonged	9	0
Coagulation time shortened	4	0
Fibrin D dimer increased	18	0
International normalised ratio abnormal	8	0
International normalised ratio decreased	22	0
International normalised ratio fluctuation	3	0
International normalised ratio increased	52	0
Platelet factor 4	1	0
Prothrombin time prolonged	1	0
Prothrombin time shortened	1	0
Digestive enzymes		
Amylase increased	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
<i>ECG investigations</i>		
Electrocardiogram	5	0
Electrocardiogram QRS complex prolonged	1	0
Electrocardiogram QT prolonged	11	0
Electrocardiogram ST segment depression	2	0
Electrocardiogram ST segment elevation	10	0
Electrocardiogram ST-T segment abnormal	3	0
Electrocardiogram T wave inversion	5	0
Electrocardiogram abnormal	19	0
Electrocardiogram change	1	0
Electrocardiogram normal	2	0
Electrocardiogram repolarisation abnormality	1	0
QRS axis abnormal	1	0
<i>Endocrine analyses and imaging NEC</i>		
Hormone level abnormal	56	0
<i>Faecal analyses NEC</i>		
Faecal calprotectin	2	0
Faecal calprotectin increased	4	0
<i>Fertility analyses</i>		
Infertility tests	1	0
Semen analysis abnormal	1	0
Sperm concentration	2	0
Sperm concentration decreased	1	0
Spermatozoa abnormal	1	0
<i>Foetal and neonatal diagnostic procedures</i>		
Foetal heart rate abnormal	4	2
Foetal heart rate increased	1	0
Foetal monitoring	1	0
Foetal non-stress test	1	0
<i>Gastrointestinal and abdominal imaging procedures</i>		
Computerised tomogram abdomen	1	0
Sigmoidoscopy abnormal	1	0
X-ray with contrast upper gastrointestinal tract	1	0
<i>Gastrointestinal function diagnostic procedures</i>		
Gastric pH decreased	1	0
<i>Gastrointestinal, pancreatic and APUD hormone analyses</i>		
Blood insulin	2	0
Blood insulin decreased	1	0
<i>Haematological analyses NEC</i>		
Blood viscosity abnormal	1	0
Blood viscosity decreased	1	0
Plasma viscosity	1	0
Plasma viscosity abnormal	1	0
Red blood cell sedimentation rate increased	6	0
<i>Heart rate and pulse investigations</i>		
Carotid pulse	1	0
Heart rate	450	0
Heart rate abnormal	64	0
Heart rate decreased	88	0
Heart rate increased	980	0
Heart rate irregular	234	0
Heart rate normal	1	0
Heart rate variability decreased	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Maximum heart rate	2	0
Pulse abnormal	19	0
Pulse absent	1	0
Pulse pressure increased	1	0
Radial pulse abnormal	1	0
Sinus rhythm	7	0
Hepatobiliary imaging procedures		
Liver scan	1	0
Imaging procedures NEC		
Computerised tomogram	4	0
Magnetic resonance imaging	4	0
Magnetic resonance imaging abnormal	1	0
Scan	2	0
X-ray	1	0
Immune response protein analyses NEC		
Cytokine test	1	0
Immunoglobulin analyses		
Blood immunoglobulin E increased	1	0
Blood immunoglobulin G increased	1	0
Blood immunoglobulin M	1	0
Blood immunoglobulin M increased	1	0
Immunology analyses NEC		
Antibody test	4	0
Antibody test positive	1	0
Immunology test	12	0
Immunology skin tests NEC		
Allergy alert test	1	0
Skin test positive	1	0
Investigations NEC		
Blood test	25	0
Blood test abnormal	45	0
False positive investigation result	1	0
Laboratory test	1	0
Polymerase chain reaction	1	0
Polymerase chain reaction positive	33	0
Quality of life decreased	1	0
Systemic lupus erythematosus disease activity index increased	1	0
Liver function analyses		
Alanine aminotransferase increased	27	0
Aspartate aminotransferase	1	0
Aspartate aminotransferase abnormal	1	0
Aspartate aminotransferase increased	2	0
Blood bilirubin increased	4	0
Gamma-glutamyltransferase increased	5	0
Hepatic enzyme increased	8	0
Liver function test	1	0
Liver function test abnormal	30	0
Liver function test increased	26	0
Transaminases increased	5	0
Metabolism tests NEC		
Blood ketone body	3	0
Blood ketone body increased	1	0
Blood ketone body present	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
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
Culture throat	1	0
Culture urine	1	0
Vaccine induced antibody absent	1	0
Mineral and electrolyte analyses		
Blood calcium increased	1	0
Blood copper increased	1	0
Blood iron	1	0
Blood iron decreased	9	0
Blood iron increased	1	0
Blood magnesium decreased	1	0
Blood phosphorus decreased	1	0
Blood phosphorus increased	1	0
Blood potassium abnormal	1	0
Blood potassium decreased	4	0
Blood potassium increased	3	0
Blood sodium decreased	10	0
Serum ferritin	1	0
Serum ferritin decreased	4	0
Serum ferritin increased	1	0
Sweat test	1	0
Urine copper	2	0
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	5	0
Hoover's sign of leg paresis	1	0
Joint position sense decreased	1	0
Lumbar puncture	6	0
Magnetic resonance neurography	1	0
Temperature perception test abnormal	1	0
Temperature perception test increased	1	0
Ophthalmic function diagnostic procedures		
Corneal reflex decreased	1	0
Intraocular pressure increased	7	0
Intraocular pressure test	3	0
Visual acuity tests	1	0
Physical examination procedures and organ system status		
Body temperature	254	0
Body temperature abnormal	48	0
Body temperature decreased	44	0
Body temperature fluctuation	53	0
Body temperature increased	445	0
Body temperature normal	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Breath sounds abnormal	2	0
General physical condition abnormal	1	0
Grip strength	2	0
Grip strength decreased	22	0
Gynaecological examination	1	0
Head lag	8	0
Lymph node palpable	42	0
Male genital examination abnormal	1	0
Menstruation normal	2	0
Muscle strength abnormal	1	0
Ophthalmological examination	2	0
Orthopaedic examination	1	0
Palpatory finding abnormal	2	0
Product residue present	2	0
Psoriasis area severity index decreased	2	0
Respiratory rate	9	0
Respiratory rate decreased	25	0
Respiratory rate increased	42	0
Skin temperature	42	0
Temperature difference of extremities	10	0
Weight	1	0
Weight abnormal	1	0
Weight decreased	112	0
Weight increased	41	0
<i>Pituitary analyses anterior</i>		
Blood corticotrophin	1	0
Blood follicle stimulating hormone increased	3	0
Blood growth hormone	3	0
Blood prolactin	3	0
Blood prolactin increased	3	0
Blood thyroid stimulating hormone decreased	1	0
Blood thyroid stimulating hormone increased	8	0
<i>Platelet analyses</i>		
Mean platelet volume decreased	1	0
Mean platelet volume increased	1	0
Platelet count	3	0
Platelet count abnormal	1	0
Platelet count decreased	73	0
Platelet count increased	6	0
<i>Protein analyses NEC</i>		
Alpha 1 globulin decreased	1	0
Alpha 2 globulin decreased	1	0
C-reactive protein increased	22	0
<i>Red blood cell analyses</i>		
Haematocrit	1	0
Haematocrit decreased	1	0
Haematocrit increased	1	0
Haemoglobin decreased	12	0
Haemoglobin increased	2	0
Red blood cell count decreased	1	0
Red blood cell rouleaux formation present	1	0
<i>Renal function analyses</i>		
Blood creatinine	1	0

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Blood creatinine decreased	1	0
Blood creatinine increased	4	0
Glomerular filtration rate decreased	4	0
Glomerular filtration rate increased	1	0
Reproductive hormone analyses		
Blood oestrogen decreased	2	0
Blood testosterone decreased	1	0
Blood testosterone increased	1	0
False negative pregnancy test	7	0
Female sex hormone level	3	0
Human chorionic gonadotropin increased	1	0
Pregnancy test	18	0
Pregnancy test false positive	1	0
Pregnancy test positive	1	0
Reproductive organ and breast histopathology procedures		
Biopsy breast	2	0
Biopsy endometrium	1	0
Smear cervix	2	0
Reproductive organ and breast imaging procedures		
Breast scan	1	0
Hysteroscopy	2	0
Respiratory and pulmonary function diagnostic procedures		
Forced expiratory volume increased	2	0
Fractional exhaled nitric oxide normal	1	0
Maximal voluntary ventilation	2	0
Peak expiratory flow rate	1	0
Peak expiratory flow rate decreased	5	0
Pulmonary function test	3	0
Total lung capacity decreased	3	0
Vital capacity	1	0
Respiratory tract and thoracic histopathology procedures		
Sputum abnormal	3	0
Respiratory tract and thoracic imaging procedures		
Chest X-ray	19	0
Chest X-ray abnormal	1	0
Chest X-ray normal	2	0
Chest scan	2	0
Computerised tomogram thorax	1	0
Skeletal and cardiac muscle analyses		
Blood creatine phosphokinase increased	8	0
Muscle enzyme	1	0
Myocardial necrosis marker	1	0
Myocardial necrosis marker increased	3	0
Troponin I increased	2	0
Troponin T increased	1	0
Troponin increased	15	0
Therapeutic drug monitoring analyses		
Analgesic drug level	8	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		

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Anti-thyroid antibody	1	0
Thyroid function test abnormal	5	0
Thyroxine	1	0
Thyroxine free increased	2	0
Tri-iodothyronine	1	0
Tri-iodothyronine decreased	5	0
Tissue enzyme analyses NEC		
Blood alkaline phosphatase abnormal	1	0
Blood alkaline phosphatase increased	5	0
Enzyme level increased	1	0
Toxicology laboratory analyses		
Blood caffeine decreased	1	0
Blood lead	1	0
Drug screen positive	2	0
Opiates	1	0
Urinalysis NEC		
Blood urine	15	0
Blood urine present	63	0
Cells in urine	1	0
Glucose urine present	1	0
Protein urine absent	1	0
Protein urine present	1	0
Red blood cells urine	1	0
Urine analysis abnormal	6	0
Urine leukocyte esterase positive	1	0
Urine uric acid increased	1	0
pH urine	6	0
pH urine increased	2	0
Urinary tract function analyses NEC		
Urine output	12	0
Urine output decreased	13	0
Urine output increased	7	0
Urinary tract histopathology procedures		
Urine cytology	1	0
Urinary tract imaging procedures		
Bladder scan	1	0
Cystoscopy	2	0
Ultrasound kidney normal	1	0
Vascular imaging procedures NEC		
Venogram	2	0
Vascular tests NEC (incl blood pressure)		
Blood pressure abnormal	7	0
Blood pressure ambulatory increased	1	0
Blood pressure decreased	84	0
Blood pressure diastolic	1	0
Blood pressure diastolic decreased	1	0
Blood pressure diastolic increased	4	0
Blood pressure difference of extremities	1	0
Blood pressure increased	253	0
Blood pressure measurement	40	0
Blood pressure normal	2	0
Blood pressure systolic	1	0
Blood pressure systolic decreased	4	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Blood pressure systolic increased	1	0
<i>Virus identification and serology</i>		
Coronavirus test	11	0
Coronavirus test positive	4	0
Cytomegalovirus test positive	1	0
HIV test	2	0
SARS-CoV-1 test	1	0
SARS-CoV-1 test positive	1	0
SARS-CoV-2 antibody test	10	0
SARS-CoV-2 antibody test negative	15	0
SARS-CoV-2 antibody test positive	6	0
SARS-CoV-2 test	33	0
SARS-CoV-2 test false negative	2	0
SARS-CoV-2 test false positive	4	0
SARS-CoV-2 test negative	10	0
SARS-CoV-2 test positive	99	0
Viral load	1	0
Viral test	4	0
Viral test positive	1	0
<i>Vitamin analyses</i>		
Blood folate decreased	6	0
Vitamin B12	1	0
Vitamin B12 abnormal	2	0
Vitamin B12 decreased	2	0
Vitamin B12 increased	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	1	0
Eosinophil count decreased	1	0
Eosinophil count increased	3	0
Lymphocyte count	1	0
Lymphocyte count decreased	3	0
Lymphocyte count increased	1	0
Monocyte count increased	1	0
Neutrophil count	3	0
Neutrophil count decreased	9	0
Neutrophil count increased	3	0
White blood cell count	3	0
White blood cell count decreased	11	0
White blood cell count increased	10	0
Investigations SOC TOTAL	5311	3

Case Series Drug Analysis Print

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

Report Run Date: 20-Dec-2021

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	17	0
Decreased appetite	1268	0
Diet refusal	1	0
Eating disorder symptom	2	0
Food craving	12	0
Food refusal	15	0
Hyperphagia	15	0
Hypophagia	18	0
Increased appetite	32	0
Salt craving	2	0
<i>Calcium metabolism disorders</i>		
Hypocalcaemia	3	0
Tetany	3	0
<i>Copper metabolism disorders</i>		
Copper deficiency	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	51	0
Diabetes mellitus inadequate control	16	1
Increased insulin requirement	2	0
Insulin resistant diabetes	1	0
Latent autoimmune diabetes in adults	2	0
Type 1 diabetes mellitus	16	0
Type 2 diabetes mellitus	4	0
<i>Diabetic complications NEC</i>		
Diabetic complication	2	0
Diabetic ketoacidosis	12	0
Diabetic ketosis	1	0
<i>Disorders of purine metabolism</i>		
Gout	96	0
<i>Electrolyte imbalance NEC</i>		
Electrolyte imbalance	1	0
Fluid imbalance	2	0
<i>Fat soluble vitamin deficiencies and disorders</i>		
Vitamin D deficiency	7	0
<i>Fluid intake decreased</i>		
Fluid intake reduced	2	0
<i>Fluid intake increased</i>		
Polydipsia	6	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Alcohol intolerance	5	0
Breast milk substitute intolerance	1	0
Dairy intolerance	3	0
Food intolerance	17	0
Gluten sensitivity	7	0
Histamine intolerance	4	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	27	0
Abnormal weight gain	20	0
Cachexia	1	0
Feeding disorder	92	0
Food aversion	8	0
Malnutrition	1	0

Case Series Drug Analysis Print

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

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
Neonatal insufficient breast milk syndrome	3	0
Obesity	1	0
Overweight	1	0
Poor feeding infant	15	0
Weight loss poor	3	0
Hyperglycaemic conditions NEC		
Glucose tolerance impaired	1	0
Hyperglycaemia	67	0
Insulin resistance	4	0
Hyperlipidaemias NEC		
Hyperlipidaemia	1	0
Hypoglycaemic conditions NEC		
Glycopenia	1	0
Hypoglycaemia	78	0
Hypoglycaemia unawareness	1	0
Postprandial hypoglycaemia	1	0
Iron deficiencies		
Iron deficiency	12	0
Iron excess		
Haemochromatosis	1	0
Iron overload	1	0
Lipid metabolism and deposit disorders NEC		
Body fat disorder	1	0
Magnesium metabolism disorders		
Hypomagnesaemia	1	0
Magnesium deficiency	1	0
Metabolic acidoses (excl diabetic acidoses)		
Ketoacidosis	5	1
Lactic acidosis	2	0
Metabolic acidosis	2	0
Metabolic disorders NEC		
Hypercatabolism	1	0
Metabolic disorder	1	0
Mixed acid-base disorders		
Acidosis	4	0
Phosphorus metabolism disorders		
Hypophosphataemia	1	0
Potassium imbalance		
Hyperkalaemia	6	0
Hypokalaemia	3	0
Hypokalaemic syndrome	1	0
Sodium imbalance		
Hyponatraemia	10	0
Hyponatraemic syndrome	3	0
Salt intoxication	1	0
Sugar intolerance (excl glucose intolerance)		
Lactose intolerance	2	0
Total fluid volume decreased		
Dehydration	212	0
Total fluid volume increased		
Fluid retention	55	0
Hypervolaemia	5	0
Vitamin deficiencies NEC		

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
Hypovitaminosis	6	0
<i>Water soluble vitamin deficiencies</i>		
Folate deficiency	5	0
Vitamin B complex deficiency	1	0
Vitamin B12 deficiency	6	0
Metabolic disorders SOC TOTAL	2322	2

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	321	0
Arthropathy	27	0
Autoimmune arthritis	7	0
Haemarthrosis	5	0
Joint microhaemorrhage	1	0
Palindromic rheumatism	1	0
Polyarthritis	15	0
Rheumatic fever	3	0
Sacroiliitis	5	0
Seronegative arthritis	2	0
<i>Bone disorders NEC</i>		
Bone cyst	1	0
Exostosis	1	0
Jaw disorder	4	0
Medial tibial stress syndrome	4	0
Osteitis	8	0
Osteonecrosis	1	0
Osteonecrosis of jaw	3	0
Spinal disorder	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	391	0
Bone swelling	10	0
Coccydynia	3	0
Metatarsalgia	1	0
Pain in jaw	380	0
Pubic pain	2	0
Spinal pain	84	0
<i>Bursal disorders</i>		
Bursitis	82	0
<i>Cartilage disorders</i>		
Chondritis	1	0
Costochondritis	105	0
Osteochondritis	1	0
Polychondritis	3	0
<i>Connective tissue disorders NEC</i>		
Connective tissue disorder	1	0
Polymyalgia rheumatica	66	0
Reynold's syndrome	1	0
Sjogren's syndrome	5	0
Systemic scleroderma	1	0
<i>Crystal arthropathic disorders</i>		
Chondrocalcinosis pyrophosphate	3	0
Crystal arthropathy	2	0
Gouty arthritis	1	0
<i>Epiphyseal disorders</i>		
Epiphyses premature fusion	1	0
<i>Extremity deformities</i>		
Bone deformity	1	0
Finger deformity	2	0
Foot deformity	2	0
Hand deformity	2	0
Knee deformity	1	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Limb deformity	5	0
Musculoskeletal deformity	1	0
Fractures NEC		
Osteoporotic fracture	1	0
Intervertebral disc disorders NEC		
Intervertebral disc protrusion	3	0
Joint related disorders NEC		
Carpal collapse	1	0
Chondromalacia	1	0
Hypermobility syndrome	1	0
Joint deposit	1	0
Joint destruction	1	0
Joint instability	2	0
Joint laxity	3	0
Joint lock	29	0
Patellofemoral pain syndrome	1	0
Periarthritis	195	0
Rotator cuff syndrome	35	0
Temporomandibular joint syndrome	10	0
Joint related signs and symptoms		
Arthralgia	9207	0
Jaw clicking	6	0
Joint effusion	16	0
Joint noise	36	0
Joint range of motion decreased	31	0
Joint stiffness	249	0
Joint swelling	563	0
Joint vibration	3	0
Joint warmth	15	0
Loose body in joint	1	0
Ligament disorders		
Ligament pain	4	0
Ligamentitis	1	0
Symphysiolysis	1	0
Lupus erythematosus (incl subtypes)		
Lupus-like syndrome	1	0
Systemic lupus erythematosus	23	0
Metabolic bone disorders		
Osteopenia	3	0
Osteoporosis	5	0
Muscle infections and inflammations		
Antisynthetase syndrome	3	0
Immune-mediated myositis	1	0
Myositis	41	0
Polymyositis	8	0
Muscle pains		
Fibromyalgia	120	0
Myalgia	10726	0
Myalgia intercostal	2	0
Myofascial pain syndrome	12	0
Muscle related signs and symptoms NEC		
Haematoma muscle	1	0
Muscle atrophy	24	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Muscle discomfort	7	0
Muscle disorder	9	0
Muscle fatigue	355	0
Muscle haemorrhage	1	0
Muscle mass	6	0
Muscle oedema	4	0
Muscle spasms	2078	0
Muscle swelling	38	0
Muscle tightness	87	0
Muscle twitching	484	0
<i>Muscle tone abnormalities</i>		
Muscle rigidity	16	0
Nuchal rigidity	12	0
Torticollis	6	0
Trismus	36	0
<i>Muscle weakness conditions</i>		
Muscular weakness	956	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Back disorder	2	0
Chest wall mass	1	0
Growth disorder	2	0
Limb mass	20	0
Mandibular mass	2	0
Mastication disorder	6	0
Mobility decreased	117	0
Muscle contracture	1	0
Musculoskeletal disorder	11	0
Musculoskeletal stiffness	1304	0
Posture abnormal	2	0
Sacroiliac joint dysfunction	1	0
Weight bearing difficulty	4	0
<i>Musculoskeletal and connective tissue deformities of skull, face and buccal cavity</i>		
Facial asymmetry	1	0
Head deformity	2	0
<i>Musculoskeletal and connective tissue infections and inflammations NEC</i>		
Connective tissue inflammation	1	0
Dactylitis	2	0
Dupuytren's contracture	1	0
Fasciitis	1	0
Plantar fasciitis	13	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	2448	0
Flank pain	82	0
Limb discomfort	1499	0
Musculoskeletal chest pain	257	0
Musculoskeletal discomfort	103	0
Musculoskeletal pain	125	0
Neck pain	1929	0
Pain in extremity	12855	2
Rheumatic disorder	14	0
Sacral pain	4	0
<i>Myopathies</i>		

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Muscle & tissue disorders cont'd		
Mitochondrial myopathy acquired	1	0
Myopathy	6	0
Rhabdomyolysis	13	0
Osteoarthropathies		
Nodal osteoarthritis	1	0
Osteoarthritis	49	0
Spinal osteoarthritis	2	0
Psoriatic arthropathies		
Psoriatic arthropathy	18	0
Rheumatoid arthropathies		
Juvenile idiopathic arthritis	1	0
Rheumatoid arthritis	120	0
Rheumatoid nodule	1	0
Still's disease	2	0
Soft tissue disorders NEC		
Axillary mass	263	0
Fluctuance	1	0
Groin pain	114	0
Neck mass	38	0
Purple glove syndrome	1	0
Soft tissue disorder	3	0
Soft tissue swelling	6	0
Spine and neck deformities		
Kyphosis	2	0
Lordosis	1	0
Neck deformity	1	0
Scoliosis	1	0
Spinal stenosis	2	0
Spondyloarthropathies		
Ankylosing spondylitis	8	0
Arthritis reactive	54	0
Spondylitis	4	0
Spondyloarthropathy	1	0
Synovial disorders		
Synovial cyst	19	0
Synovitis	11	0
Tendon disorders		
Enthesopathy	2	0
Posterior tibial tendon dysfunction	1	0
Tendon disorder	5	0
Tendon pain	23	0
Tendonitis	50	0
Tenosynovitis	4	0
Tenosynovitis stenosaurs	2	0
Trigger finger	29	0
Trunk deformities		
Deformity thorax	1	0
Drooping shoulder syndrome	2	0
Shoulder deformity	2	0
Muscle & tissue disorders SOC TOTAL	48725	2

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Reaction Name	Total	Fatal
Neoplasms		
<i>Angioimmunoblastic T-cell lymphomas</i>		
Angioimmunoblastic T-cell lymphoma	1	0
<i>B-cell lymphomas NEC</i>		
B-cell lymphoma	2	1
Follicular lymphoma	4	0
<i>Bone neoplasms malignant (excl sarcomas)</i>		
Bone cancer	1	1
<i>Bone neoplasms unspecified malignancy</i>		
Bone neoplasm	1	0
<i>Breast and nipple neoplasms benign</i>		
Benign breast neoplasm	1	0
Fibroadenoma of breast	1	0
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	41	0
Breast cancer female	1	0
Breast cancer male	2	0
Breast cancer stage I	1	0
Breast cancer stage III	3	0
Invasive ductal breast carcinoma	1	0
Triple negative breast cancer	2	0
<i>Cardiovascular neoplasms benign</i>		
Haemangioma	1	0
Pericardial lipoma	1	0
<i>Cartilage sarcomas</i>		
Chondrosarcoma	1	0
<i>Cervix neoplasms malignant</i>		
Cervix carcinoma	1	0
<i>Colorectal neoplasms malignant</i>		
Colon cancer	2	0
Colorectal cancer	1	0
Rectal cancer	2	0
<i>Endocrine neoplasms malignant and unspecified NEC</i>		
Neuroendocrine tumour	1	0
Thyroid neoplasm	1	0
<i>Endometrial neoplasms malignant</i>		
Endometrial cancer	1	0
<i>Follicular lymphomas</i>		
Primary gastrointestinal follicular lymphoma	1	0
<i>Gastric neoplasms malignant</i>		
Gastric cancer	1	1
<i>Gastrointestinal neoplasms malignant NEC</i>		
Gastrointestinal carcinoma	3	0
<i>Hepatic neoplasms malignant</i>		
Hepatocellular carcinoma	1	0
<i>Hepatobiliary neoplasms malignancy unspecified</i>		
Hepatic neoplasm	1	0
<i>Hodgkin's disease NEC</i>		
Hodgkin's disease	4	0
<i>Islet cell neoplasms and APUDoma NEC</i>		
Pancreatic neuroendocrine tumour	1	0
<i>Kaposi's sarcomas</i>		
Kaposi's sarcoma	1	0
<i>Leukaemias NEC</i>		

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
Leukaemia	4	1
Leukaemias acute NEC		
Acute leukaemia	2	0
Leukaemias chronic NEC		
Chronic leukaemia	1	0
Leukaemias chronic lymphocytic		
Chronic lymphocytic leukaemia	3	0
Leukaemias chronic myeloid		
Chronic myeloid leukaemia	1	0
Lip and oral cavity neoplasms malignant		
Lip and/or oral cavity cancer recurrent	1	0
Lymphomas unspecified NEC		
Lymphoma	38	1
Metastases to specified sites		
Metastases to bone	1	0
Metastases to liver	1	0
Metastases to lymph nodes	5	0
Metastases to unknown and unspecified sites		
Metastasis	1	0
Myelodysplastic syndromes		
Myelodysplastic syndrome	3	0
Myeloproliferative disorders (excl leukaemias)		
Essential thrombocythaemia	1	0
Neoplasms malignant site unspecified NEC		
Adenocarcinoma metastatic	1	0
Metastatic neoplasm	2	0
Neoplasm malignant	8	0
Second primary malignancy	1	0
Squamous cell carcinoma	5	0
Neoplasms unspecified malignancy and site unspecified NEC		
Neoplasm	1	0
Neoplasm recurrence	1	0
Nervous system neoplasms benign NEC		
Cranial nerve neoplasm benign	1	0
Neurilemmoma benign	1	0
Nervous system neoplasms unspecified malignancy NEC		
Brain neoplasm	2	0
Meningioma	1	0
Spinal cord neoplasm	1	0
Neuromas		
Acoustic neuroma	2	0
Non-Hodgkin's lymphomas NEC		
Non-Hodgkin's lymphoma	2	0
Ocular neoplasms benign		
Eye naevus	1	0
Oesophageal neoplasms malignant		
Oesophageal cancer metastatic	4	0
Oncologic complications and emergencies		
Cancer pain	1	0
Tumour haemorrhage	1	0
Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified		
Tonsil cancer	4	0

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
<i>Ovarian neoplasms malignant (excl germ cell)</i>		
Ovarian cancer	1	0
<i>Pancreatic neoplasms malignant (excl islet cell and carcinoid)</i>		
Pancreatic carcinoma	4	0
<i>Plasma cell myelomas</i>		
POEMS syndrome	1	0
Plasma cell myeloma	2	0
<i>Plasma cell neoplasms NEC</i>		
TEMPI syndrome	2	0
<i>Prostatic neoplasms malignant</i>		
Prostate cancer	4	0
<i>Renal neoplasms malignant</i>		
Clear cell renal cell carcinoma	1	0
Renal cancer	3	0
<i>Reproductive neoplasms female benign NEC</i>		
Benign hydatidiform mole	2	0
<i>Respiratory tract and pleural neoplasms malignant cell type unspecified NEC</i>		
Bronchial carcinoma	1	0
Lung neoplasm malignant	12	1
<i>Salivary gland neoplasms unspecified malignancy</i>		
Salivary gland neoplasm	2	0
<i>Skin melanomas (excl ocular)</i>		
Malignant melanoma	2	0
<i>Skin neoplasms benign</i>		
Acrochordon	4	0
Anogenital warts	7	0
Fibrous histiocytoma	1	0
Haemangioma of skin	5	0
Melanocytic naevus	6	0
Pyogenic granuloma	1	0
Seborrhoeic keratosis	1	0
Skin papilloma	19	0
<i>Skin neoplasms malignant and unspecified (excl melanoma)</i>		
Basal cell carcinoma	3	0
Bowen's disease	1	0
Neoplasm skin	2	0
Skin cancer	1	0
Squamous cell carcinoma of skin	1	0
<i>Soft tissue neoplasms benign NEC</i>		
Lipoma	7	0
Lymphangioma	1	0
<i>Soft tissue sarcomas histology unspecified</i>		
Sarcoma	1	0
<i>Thyroid neoplasms malignant</i>		
Papillary thyroid cancer	2	0
Thyroid cancer	1	0
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	12	0
Neoplasms SOC TOTAL	302	6

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Areflexia	7	0
Extensor plantar response	2	0
Hoffmann's sign	1	0
Hyperreflexia	4	0
Hyporeflexia	8	0
Reflexes abnormal	2	0
<i>Abnormal sleep-related events</i>		
Sleep paralysis	25	0
<i>Absence seizures</i>		
Petit mal epilepsy	27	0
<i>Acute polyneuropathies</i>		
Acute motor axonal neuropathy	1	0
Acute motor-sensory axonal neuropathy	1	0
Guillain-Barre syndrome	72	2
Miller Fisher syndrome	2	0
Subacute inflammatory demyelinating polyneuropathy	1	0
<i>Autonomic nervous system disorders</i>		
Anticholinergic syndrome	1	0
Autonomic nervous system imbalance	10	0
Autonomic neuropathy	2	0
Horner's syndrome	2	0
Orthostatic intolerance	2	0
<i>Central nervous system aneurysms and dissections</i>		
Carotid artery dissection	1	0
Intracranial aneurysm	2	1
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Basal ganglia haemorrhage	1	0
Brain stem haemorrhage	1	1
Brain stem infarction	1	1
Brain stem stroke	1	0
Carotid artery occlusion	1	0
Carotid artery thrombosis	4	0
Cerebellar artery thrombosis	1	0
Cerebellar haemorrhage	3	0
Cerebellar infarction	3	0
Cerebellar ischaemia	1	0
Cerebellar stroke	8	1
Cerebral artery embolism	3	1
Cerebral artery occlusion	2	0
Cerebral artery thrombosis	4	0
Cerebral haemorrhage	48	10
Cerebral infarction	29	2
Cerebral thrombosis	13	0
Cerebrovascular accident	423	18
Embolic stroke	7	0
Haemorrhage intracranial	10	2
Haemorrhagic cerebral infarction	1	0
Haemorrhagic stroke	11	4
Internal capsule infarction	1	0
Intracranial haematoma	1	0
Ischaemic cerebral infarction	1	0
Ischaemic stroke	56	2

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Lacunar infarction	4	0
Lacunar stroke	5	0
Lateral medullary syndrome	1	0
Pseudostroke	1	0
Ruptured cerebral aneurysm	1	0
Subarachnoid haemorrhage	17	7
Thalamic infarction	1	0
Thrombotic stroke	5	1
Central nervous system inflammatory disorders NEC		
Arachnoiditis	1	0
Gliosis	1	0
Central nervous system vascular disorders NEC		
Brain hypoxia	4	1
Carotid arteriosclerosis	1	0
Central nervous system vasculitis	1	0
Cerebral amyloid angiopathy	1	0
Cerebral congestion	5	0
Cerebral small vessel ischaemic disease	2	0
Cerebrovascular disorder	2	0
Post cardiac arrest syndrome	1	0
Reversible cerebral vasoconstriction syndrome	1	0
Cerebrovascular venous and sinus thrombosis		
Cerebral venous sinus thrombosis	52	5
Cerebral venous thrombosis	6	0
Superior sagittal sinus thrombosis	6	0
Transverse sinus thrombosis	1	0
Cervical spinal cord and nerve root disorders		
Cervical radiculopathy	1	0
Cervicobrachial syndrome	6	0
Choreiform movements		
Chorea	3	0
Chronic polyneuropathies		
Chronic inflammatory demyelinating polyradiculoneuropathy	3	0
Demyelinating polyneuropathy	1	0
Diabetic neuropathy	1	0
Coma states		
Coma	13	0
Diabetic coma	1	0
Hypoglycaemic coma	1	0
Coordination and balance disturbances		
Ataxia	19	0
Balance disorder	430	0
Cerebellar ataxia	1	0
Coordination abnormal	60	0
Dysdiadochokinesis	1	0
Dysstasia	62	0
Nystagmus	14	0
Cortical dysfunction NEC		
Alexia	2	0
Aphasia	85	0
Apraxia	1	0
Dysgraphia	1	0
Dyslexia	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Dyspraxia	1	0
Neurologic neglect syndrome	1	0
Sensory processing disorder	2	0
Visuospatial deficit	1	0
<i>Cranial nerve disorders NEC</i>		
Cranial nerve disorder	2	0
Cranial nerve paralysis	1	0
<i>Dementia (excl Alzheimer's type)</i>		
Dementia	17	0
Dementia with Lewy bodies	1	0
Senile dementia	1	0
<i>Demyelinating disorders NEC</i>		
Acute disseminated encephalomyelitis	6	0
Clinically isolated syndrome	1	0
Demyelination	8	0
Neuromyelitis optica spectrum disorder	2	0
<i>Disturbances in consciousness NEC</i>		
Altered state of consciousness	12	0
Consciousness fluctuating	3	0
Depressed level of consciousness	46	0
Infant sedation	1	0
Lethargy	2293	0
Loss of consciousness	707	1
Postictal state	5	0
Sedation	8	0
Somnolence	1074	0
Stupor	4	0
Syncope	2360	0
<i>Disturbances in sleep phase rhythm</i>		
Circadian rhythm sleep disorder	1	0
Irregular sleep phase	2	0
Irregular sleep wake rhythm disorder	2	0
<i>Dyskinesias and movement disorders NEC</i>		
Akathisia	6	0
Bradykinesia	19	0
Clumsiness	22	0
Dyskinesia	68	0
Extrapyramidal disorder	3	0
Fine motor skill dysfunction	13	0
Foetal movement disorder	4	0
Hyperkinesia	3	0
Hypokinesia	83	0
Motor dysfunction	4	0
Movement disorder	59	0
Psychomotor hyperactivity	26	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

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

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Noninfective encephalitis	7	0
<i>Encephalopathies NEC</i>		
Autoimmune encephalopathy	1	1
Encephalopathy	5	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	7	0
IVth nerve paralysis	1	0
Microvascular cranial nerve palsy	1	0
VIth nerve disorder	1	0
VIth nerve paralysis	11	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	527	0
Facial nerve disorder	9	0
Facial paralysis	402	0
Facial paresis	96	0
Facial spasm	49	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	63	0
<i>Headaches NEC</i>		
Cervicogenic headache	3	0
Cluster headache	248	0
Cold-stimulus headache	26	0
Drug withdrawal headache	3	0
Exertional headache	8	0
External compression headache	2	0
Headache	27002	0
Medication overuse headache	2	0
New daily persistent headache	8	0
Occipital neuralgia	15	0
Ophthalmoplegic migraine	1	0
Primary cough headache	4	0
Primary headache associated with sexual activity	9	0
Sinus headache	360	0
Tension headache	568	0
Thunderclap headache	17	0
Vascular headache	18	0
<i>Hydrocephalic conditions</i>		
Hydrocephalus	4	0
<i>Hypoglossal nerve disorders</i>		
Tongue paralysis	1	0
<i>Increased intracranial pressure disorders</i>		
Brain compression	2	0
Brain oedema	9	2
Idiopathic intracranial hypertension	10	0
Intracranial pressure increased	3	0
<i>Intellectual disabilities</i>		
Intellectual disability	3	0
<i>Lumbar spinal cord and nerve root disorders</i>		
Sciatica	109	0
<i>Memory loss (excl dementia)</i>		

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Amnesia	196	0
Memory impairment	215	0
Transient global amnesia	9	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	90	0
Cognitive linguistic deficit	1	0
Disturbance in attention	339	0
Mental impairment	49	0
Migraine headaches		
Basilar migraine	1	0
Hemiplegic migraine	31	0
Migraine	3086	0
Migraine with aura	203	0
Migraine without aura	20	0
Ophthalmic migraine	5	0
Retinal migraine	35	0
Typical aura without headache	8	0
Vestibular migraine	23	0
Mixed cranial nerve disorders		
Bulbar palsy	2	0
Mononeuropathies		
Carpal tunnel syndrome	23	0
Cubital tunnel syndrome	3	0
Meralgia paraesthetica	2	0
Mononeuritis	2	0
Mononeuropathy	4	0
Nerve compression	25	0
Peripheral nerve lesion	2	0
Peroneal nerve palsy	19	0
Piriformis syndrome	1	0
Pudendal canal syndrome	2	0
Sciatic nerve neuropathy	2	0
Ulnar nerve palsy	2	0
Ulnar neuritis	3	0
Ulnar tunnel syndrome	2	0
Motor neurone diseases		
Lower motor neurone lesion	1	0
Motor neurone disease	2	1
Upper motor neurone lesion	1	0
Multiple sclerosis acute and progressive		
Band sensation	1	0
Multiple sclerosis	35	0
Multiple sclerosis relapse	25	0
Tumefactive multiple sclerosis	1	1
Muscle tone abnormal		
Drop attacks	2	0
Hypertonia	2	0
Hypotonia	33	0
Morvan syndrome	1	0
Muscle tone disorder	1	0
Serotonin syndrome	1	0
Stiff leg syndrome	1	0
Myelitis (incl infective)		

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Myelitis transverse	28	0
<i>Narcolepsy and hypersomnia</i>		
Cataplexy	3	0
Hypersomnia	115	0
Narcolepsy	5	0
<i>Nervous system disorders NEC</i>		
Central nervous system lesion	2	0
Cerebral disorder	1	0
Nervous system disorder	17	0
Neurotoxicity	4	0
Psychomotor skills impaired	1	0
<i>Neurologic visual problems NEC</i>		
Hemianopia	1	0
Hemianopia homonymous	2	0
Quadrantanopia	2	0
Tunnel vision	19	0
<i>Neurological signs and symptoms NEC</i>		
Agitation neonatal	1	0
Clonus	5	0
Decerebrate posture	1	0
Decorticate posture	1	0
Dizziness	10136	0
Dizziness exertional	45	0
Dizziness postural	764	0
Drooling	23	0
Fontanelle bulging	2	0
Head discomfort	352	0
Hyporesponsive to stimuli	2	0
Inability to crawl	3	0
Infant irritability	10	0
Meningism	2	0
Myoclonus	30	0
Neurological symptom	50	0
Patient elopement	1	0
Persistent postural-perceptual dizziness	17	0
Presyncope	655	0
Sensory overload	4	0
Slow response to stimuli	4	0
Tongue biting	8	0
Unresponsive to stimuli	57	0
<i>Neuromuscular disorders NEC</i>		
Muscle contractions involuntary	27	0
Muscle spasticity	15	0
Neuromuscular pain	3	0
<i>Neuromuscular junction dysfunction</i>		
Myasthenia gravis	8	0
Myasthenia gravis crisis	2	0
<i>Olfactory nerve disorders</i>		
Anosmia	285	0
Hyposmia	16	0
Parosmia	268	0
<i>Optic nerve disorders NEC</i>		
Optic neuritis	30	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
<i>Paraesthesias and dysaesthesias</i>		
Burning feet syndrome	9	0
Burning sensation	571	0
Burning sensation mucosal	2	0
Dysaesthesia	8	0
Formication	43	0
Hand-arm vibration syndrome	3	0
Hemianaesthesia	2	0
Hemiparaesthesia	5	0
Hyperaesthesia	104	0
Hypoaesthesia	3032	0
Lhermitte's sign	1	0
Paraesthesia	4215	0
Reversed hot-cold sensation	4	0
Synaesthesia	1	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Diplegia	17	0
Hemiparesis	55	0
Hemiplegia	43	0
Locked-in syndrome	1	0
Monoparesis	78	0
Monoplegia	88	0
Paralysis	132	0
Paraparesis	3	0
Paraplegia	3	0
Paresis	6	0
Quadriparesis	1	0
Quadriplegia	1	0
<i>Parkinson's disease and parkinsonism</i>		
Freezing phenomenon	15	0
Hypokinetic dysarthria	1	0
Parkinson's disease	4	0
Parkinsonian gait	1	0
Parkinsonian rest tremor	1	0
Parkinsonism	4	0
Reduced facial expression	11	0
<i>Partial complex seizures</i>		
Dreamy state	6	0
Focal dyscognitive seizures	4	0
Temporal lobe epilepsy	2	0
<i>Partial simple seizures NEC</i>		
Autonomic seizure	1	0
<i>Peripheral neuropathies NEC</i>		
Axonal neuropathy	2	0
Neuralgic amyotrophy	4	0
Neuritis	7	0
Neuropathy peripheral	130	0
Peripheral sensorimotor neuropathy	1	0
Peripheral sensory neuropathy	12	0
Polyneuropathy	3	0
Thoracic outlet syndrome	2	0
<i>Seizures and seizure disorders NEC</i>		
Atonic seizures	6	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Change in seizure presentation	2	0
Clonic convulsion	3	0
Convulsions local	1	0
Convulsive threshold lowered	1	0
Epilepsy	158	0
Epileptic aura	2	0
Epileptic encephalopathy	1	0
Febrile convulsion	17	0
Idiopathic generalised epilepsy	1	0
Partial seizures	23	0
Post stroke seizure	1	0
Psychogenic seizure	11	0
Seizure	644	1
Seizure anoxic	2	0
Seizure cluster	6	0
Seizure like phenomena	3	0
Status epilepticus	40	0
Tonic clonic movements	4	0
Tonic convulsion	29	0
Tonic posturing	1	0
Sensory abnormalities NEC		
Ageusia	544	0
Allodynia	28	0
Aura	25	0
Central pain syndrome	1	0
Complex regional pain syndrome	5	0
Dysgeusia	1207	0
Electric shock sensation	45	0
Hypergeusia	1	0
Hypogeusia	7	0
Intercostal neuralgia	1	0
Loss of proprioception	3	0
Morton's neuralgia	3	0
Neuralgia	584	0
Persistent genital arousal disorder	2	0
Phantom limb syndrome	5	0
Post herpetic neuralgia	15	0
Restless arm syndrome	2	0
Restless legs syndrome	142	0
Sensory disturbance	112	0
Sensory loss	85	0
Taste disorder	270	0
Visual perseveration	3	0
Sleep disturbances NEC		
Microsleep	1	0
Sleep deficit	12	0
Sudden onset of sleep	1	0
Speech and language abnormalities		
Dysarthria	209	0
Incoherent	14	0
Language disorder	2	0
Repetitive speech	4	0
Slow speech	19	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Speech disorder	77	0
Speech disorder developmental	1	0
Spinal cord and nerve root disorders NEC		
Cauda equina syndrome	1	0
Myelopathy	1	0
Radiculitis brachial	14	0
Radiculopathy	8	0
Structural brain disorders NEC		
Brain injury	8	2
Cerebral ventricle dilatation	1	0
Hyperintensity in brain deep nuclei	1	0
Transient cerebrovascular events		
Transient ischaemic attack	161	3
Tremor (excl congenital)		
Essential tremor	5	0
Head titubation	13	0
Resting tremor	4	0
Tremor	1879	0
Trigeminal disorders		
Numb chin syndrome	2	0
Trigeminal nerve disorder	3	0
Trigeminal neuralgia	70	0
Trigeminal neuritis	3	0
Vagus nerve disorders		
Vocal cord paralysis	2	0
Vertigos NEC		
Cervicogenic vertigo	1	0
Vertigo CNS origin	3	0
Nervous system disorders SOC TOTAL	70891	71

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortion related conditions and complications</i>		
Anembryonic gestation	2	0
<i>Abortions not specified as induced or spontaneous</i>		
Abortion	1	0
Abortion missed	6	0
<i>Abortions spontaneous</i>		
Abortion spontaneous	396	0
Abortion threatened	2	0
<i>Amniotic fluid and cavity disorders of pregnancy NEC</i>		
Amniorrhoea	2	0
<i>Foetal complications NEC</i>		
Foetal cardiac disorder	1	0
Foetal distress syndrome	1	0
Foetal hypokinesia	14	0
<i>Foetal growth complications</i>		
Foetal growth restriction	5	0
<i>Gestational age and weight conditions</i>		
Low birth weight baby	1	0
Premature baby	5	1
<i>Haemorrhagic complications of pregnancy</i>		
Haemorrhage in pregnancy	3	0
Premature separation of placenta	3	0
Subchorionic haematoma	3	0
Subchorionic haemorrhage	1	0
<i>Hypertension associated disorders of pregnancy</i>		
Pre-eclampsia	1	0
<i>Labour onset and length abnormalities</i>		
Induced labour	1	0
Premature delivery	1	0
Premature labour	7	0
Premature rupture of membranes	3	0
Threatened labour	1	0
<i>Maternal complications of delivery NEC</i>		
Retained placenta or membranes	2	0
<i>Maternal complications of labour NEC</i>		
Uterine contractions abnormal	1	0
Uterine hypertonus	9	0
<i>Maternal complications of pregnancy NEC</i>		
Biochemical pregnancy	1	0
Complication of pregnancy	1	0
Decidual cast	4	0
Ectopic pregnancy	11	0
Hyperemesis gravidarum	2	0
Morning sickness	15	0
Preterm premature rupture of membranes	3	0
Ruptured ectopic pregnancy	1	0
Somatic symptom disorder of pregnancy	3	0
<i>Normal newborn status</i>		
Normal newborn	1	0
<i>Normal pregnancy, labour and delivery</i>		
Labour pain	1	0
Live birth	7	0
Pregnancy	32	0

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Reaction Name	Total	Fatal
Pregnancy conditions <small>Pregnancy conditions cont'd</small>		
Uterine contractions during pregnancy	6	0
Placental abnormalities (excl neoplasms)		
Foetal vascular malperfusion	2	0
Placental disorder	1	0
Placental insufficiency	1	0
Small size placenta	1	0
Postpartum complications NEC		
Postpartum haemorrhage	4	0
Pregnancy complicated by maternal disorders		
Gestational diabetes	2	0
Peripartum cardiomyopathy	1	0
Stillbirth and foetal death		
Foetal death	4	4
Stillbirth	8	8
Unintended pregnancies		
Pregnancy after post coital contraception	2	0
Pregnancy on contraceptive	2	0
Pregnancy on oral contraceptive	2	0
Pregnancy with contraceptive device	1	0
Pregnancy with implant contraceptive	1	0
Unintended pregnancy	2	0
Unwanted pregnancy	1	0
Pregnancy conditions SOC TOTAL	595	13

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Reaction Name	Total	Fatal
<i>Device electrical issues</i>		
Electromagnetic interference	1	0
<i>Device issues NEC</i>		
Device connection issue	1	0
Device failure	1	0
Device issue	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	19	0
Thrombosis in device	11	0
Undersensing	1	0
<i>Device physical property and chemical issues</i>		
Device breakage	1	0
Device defective	9	0
Device kink	1	0
Needle issue	3	0
<i>Product contamination and sterility issues</i>		
Product contamination	14	0
Product contamination physical	6	0
<i>Product packaging issues</i>		
Packaging design issue	1	0
Product closure issue	1	0
<i>Product physical issues</i>		
Liquid product physical issue	10	0
Product after taste	2	0
Product deposit	1	0
Product odour abnormal	3	0
Product physical issue	2	0
Product taste abnormal	9	0
<i>Product quality issues NEC</i>		
Product complaint	1	0
Product origin unknown	5	0
<i>Product supply and availability issues</i>		
Product availability issue	1	0
null SOC TOTAL	110	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	28	0
Behaviour disorder	2	0
Breath holding	6	0
Staring	7	0
<i>Adjustment disorders</i>		
Adjustment disorder	1	0
Adjustment disorder with depressed mood	4	0
<i>Affect alterations NEC</i>		
Affect lability	14	0
Constricted affect	3	0
Flat affect	14	0
Inappropriate affect	23	0
<i>Amnesic symptoms</i>		
Paramnesia	7	0
<i>Anxiety disorders NEC</i>		
Anxiety disorder	2	0
Generalised anxiety disorder	2	0
Neurosis	1	0
<i>Anxiety symptoms</i>		
Agitation	86	0
Anxiety	918	0
Immunisation anxiety related reaction	3	0
Nervousness	188	0
Stress	111	0
Tension	39	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	7	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	15	0
Attention-seeking behaviour	1	0
Aversion	1	0
Disinhibition	3	0
Indifference	6	0
Paranoia	25	0
Personality change	4	0
Social avoidant behaviour	5	0
Soliloquy	2	0
Suspiciousness	1	0
<i>Bipolar disorders</i>		
Bipolar I disorder	2	0
Bipolar disorder	4	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Daydreaming	8	0
Distractibility	2	0
Mental fatigue	215	0
<i>Communications disorders</i>		
Communication disorder	5	0
Mutism	3	0
<i>Confusion and disorientation</i>		
Confusional state	938	0
Disorientation	304	0
<i>Decreased physical activity levels</i>		

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Catatonia	1	0
Deliria		
Delirium	134	0
Delusional symptoms		
Delusion	15	0
Depressive disorders		
Agitated depression	6	0
Depression	361	0
Depression suicidal	15	0
Major depression	12	0
Mixed anxiety and depressive disorder	3	0
Dissociative states		
Depersonalisation/derealisation disorder	12	0
Dissociation	33	0
Dissociative amnesia	3	0
Dissociative disorder	2	0
Disturbances in initiating and maintaining sleep		
Initial insomnia	23	0
Insomnia	1604	0
Middle insomnia	32	0
Terminal insomnia	31	0
Dyssomnias		
Breathing-related sleep disorder	1	0
Dyssomnia	1	0
Poor quality sleep	231	0
Eating disorders NEC		
Bulimia nervosa	1	0
Eating disorder	12	0
Selective eating disorder	1	0
Emotional and mood disturbances NEC		
Anger	39	0
Dysphoria	2	0
Emotional disorder	61	0
Emotional distress	46	0
Emotional poverty	1	0
Euphoric mood	46	0
Frustration tolerance decreased	2	0
Irritability	211	0
Mood altered	59	0
Factitious disorders		
Factitious disorder	4	0
Fear symptoms and phobic disorders (incl social phobia)		
Agoraphobia	2	0
Fear	22	0
Fear of death	1	0
Fear of eating	1	0
Fear of falling	3	0
Fear of injection	6	0
Osmophobia	1	0
Phobia	3	0
Phonophobia	3	0
Social anxiety disorder	2	0
Social fear	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Fluctuating mood symptoms</i>		
Mood swings	146	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	226	0
Hallucination, auditory	19	0
Hallucination, olfactory	15	0
Hallucination, tactile	1	0
Hallucination, visual	28	0
Hallucinations, mixed	3	0
<i>Increased physical activity levels</i>		
Restlessness	156	0
<i>Infancy, childhood and adolescence psychiatric disorders NEC</i>		
Social (pragmatic) communication disorder	1	0
<i>Learning disorders</i>		
Learning disability	1	0
Learning disorder	1	0
<i>Mental disorders NEC</i>		
Mental disorder	17	0
Mental status changes	1	0
Psychological factor affecting medical condition	1	0
<i>Mood alterations with depressive symptoms</i>		
Anhedonia	3	0
Decreased interest	9	0
Depressed mood	407	0
Depressive symptom	2	0
Feeling guilty	1	0
Feeling of despair	5	0
Feelings of worthlessness	1	0
Negative thoughts	1	0
Psychomotor retardation	2	0
Sense of a foreshortened future	3	0
Tearfulness	43	0
<i>Mood alterations with manic symptoms</i>		
Hypomania	2	0
Mania	11	0
<i>Mood disorders NEC</i>		
Affective disorder	3	0
Apathy	34	0
Boredom	1	0
Laziness	3	0
Listless	22	0
Mood disorder due to a general medical condition	1	0
<i>Narcolepsy and associated conditions</i>		
Hypnagogic hallucination	4	0
Hypnopompic hallucination	2	0
Sleep attacks	3	0
<i>Obsessive-compulsive disorders and symptoms</i>		
Obsessive-compulsive symptom	1	0
<i>Orgasmic disorders and disturbances</i>		
Anorgasmia	5	0
Female orgasmic disorder	2	0
Orgasm abnormal	4	0
Orgasmic sensation decreased	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Premature ejaculation	1	0
<i>Panic attacks and disorders</i>		
Panic attack	211	0
Panic disorder	5	0
Panic reaction	29	0
<i>Paraphilias and paraphilic disorders</i>		
Transvestism	1	0
<i>Parasomnias</i>		
Abnormal dreams	195	0
Abnormal sleep-related event	1	0
Confusional arousal	1	0
Exploding head syndrome	2	0
Nightmare	209	0
Parasomnia	4	0
Sleep inertia	1	0
Sleep talking	6	0
Sleep terror	26	0
Somnambulism	7	0
<i>Perception disturbances NEC</i>		
Autoscopy	18	0
Deja vu	2	0
Derealisation	9	0
Flashback	4	0
Illusion	5	0
Near death experience	1	0
Time perception altered	2	0
<i>Personality disorders NEC</i>		
Personality disorder	1	0
Self esteem decreased	1	0
<i>Pervasive developmental disorders NEC</i>		
Autism spectrum disorder	3	0
<i>Psychiatric elimination disorders</i>		
Enuresis	30	0
<i>Psychiatric symptoms NEC</i>		
Helplessness	1	0
Hypervigilance	9	0
Psychiatric symptom	10	0
Psychological trauma	4	0
Trance	1	0
<i>Psychotic disorder NEC</i>		
Acute psychosis	1	0
Psychotic behaviour	1	0
Psychotic disorder	26	0
<i>Schizophrenia NEC</i>		
Schizophrenia	1	0
<i>Sexual and gender identity disorders NEC</i>		
Gender dysphoria	1	0
<i>Sexual arousal disorders</i>		
Disturbance in sexual arousal	3	0
Sexual inhibition	1	0
<i>Sexual desire disorders</i>		
Hypersexuality	1	0
Libido decreased	19	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Libido increased	7	0
Loss of libido	19	0
<i>Sexual dysfunction NEC</i>		
Genito-pelvic pain/penetration disorder	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	240	0
Sleep disorder due to general medical condition, insomnia type	5	0
<i>Somatic symptom disorders</i>		
Conversion disorder	24	0
Habit cough	21	0
Somatic symptom disorder	2	0
Vomiting psychogenic	1	0
<i>Speech and language usage disturbances</i>		
Disorganised speech	7	0
Logorrhoea	2	0
<i>Speech articulation and rhythm disturbances</i>		
Dysphemia	25	0
Lack of spontaneous speech	1	0
Pressure of speech	1	0
<i>Stereotypies and automatisms</i>		
Automatism	1	0
Bruxism	14	0
Head banging	11	0
Stereotypy	1	0
<i>Stress disorders</i>		
Burnout syndrome	2	0
Post-traumatic stress disorder	4	0
<i>Substance related and addictive disorders</i>		
Alcohol problem	1	0
Alcoholic hangover	1	0
Alcoholism	5	0
Nicotine dependence	2	0
<i>Suicidal and self-injurious behaviour</i>		
Completed suicide	1	1
Intentional self-injury	6	0
Self-injurious ideation	2	0
Suicidal ideation	41	0
Suicide attempt	8	0
Suicide threat	1	0
<i>Thinking disturbances</i>		
Bradyphrenia	40	0
Flight of ideas	1	0
Intrusive thoughts	7	0
Morbid thoughts	1	0
Tachyphrenia	7	0
Thinking abnormal	20	0
Thought blocking	1	0
<i>Tic disorders</i>		
Tic	14	0
Psychiatric disorders SOC TOTAL	8654	1

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder discomfort	3	0
Bladder irritation	8	0
Bladder pain	31	0
Dysuria	51	0
Incontinence	35	0
Lower urinary tract symptoms	3	0
Micturition disorder	2	0
Micturition urgency	45	0
Pollakiuria	142	0
Stress urinary incontinence	2	0
Urethral pain	7	0
Urge incontinence	3	0
Urinary hesitation	2	0
Urinary incontinence	64	0
Urinary retention	47	0
Urine flow decreased	18	0
<i>Bladder disorders NEC</i>		
Bladder disorder	9	0
Bladder fibrosis	1	0
Bladder prolapse	1	0
Urinary bladder haemorrhage	3	0
<i>Bladder infections and inflammations</i>		
Cystitis interstitial	6	0
Cystitis noninfective	1	0
<i>Genital and urinary tract disorders NEC</i>		
Genitourinary symptom	2	0
Urinary tract disorder	4	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
Glomerulonephritis minimal lesion	5	0
Glomerulonephritis rapidly progressive	2	0
IgA nephropathy	4	0
Nephrotic syndrome	18	0
<i>Myoneurogenic bladder disorders</i>		
Bladder dysfunction	6	0
Hypertonic bladder	3	0
Hypotonic urinary bladder	1	0
Loss of bladder sensation	3	0
Neurogenic bladder	2	0
<i>Nephritis NEC</i>		
Lupus nephritis	1	0
Nephritis	3	0
Tubulointerstitial nephritis	2	0
<i>Nephropathies and tubular disorders NEC</i>		
Nephropathy	1	0
<i>Renal disorders NEC</i>		
Renal disorder	7	1
Renal haemorrhage	1	0
Renal mass	1	0
<i>Renal failure and impairment</i>		
Acute kidney injury	47	4
Anuria	3	0
Chronic kidney disease	4	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Renal & urinary disorders cont'd</i>		
Oliguria	1	0
Renal failure	23	1
Renal impairment	25	0
Renal injury	2	0
<i>Renal lithiasis</i>		
Nephrolithiasis	10	0
<i>Renal neoplasms</i>		
Renal cyst	1	0
<i>Renal obstructive disorders</i>		
Hydronephrosis	2	0
<i>Renal structural abnormalities and trauma</i>		
Kidney small	2	0
<i>Renal vascular and ischaemic conditions</i>		
Renal aneurysm	1	0
Renal infarct	2	0
Renal tubular necrosis	2	0
Renal vasculitis	1	1
<i>Structural and obstructive urethral disorders (excl congenital)</i>		
Urethral stenosis	1	0
<i>Ureteric disorders NEC</i>		
Ureteric stenosis	1	0
<i>Urinary abnormalities</i>		
Albuminuria	1	0
Chromaturia	60	0
Haematuria	43	0
Ketonuria	1	0
Myoglobinuria	1	0
Proteinuria	12	0
Urine abnormality	11	0
Urine odour abnormal	9	0
<i>Urinary tract lithiasis (excl renal)</i>		
Calculus urinary	1	0
<i>Urinary tract signs and symptoms NEC</i>		
Costovertebral angle tenderness	1	0
Cystitis-like symptom	1	0
Haemorrhage urinary tract	24	1
Nocturia	3	0
Polyuria	9	0
Renal colic	4	0
Renal pain	311	0
Urinary tract discomfort	2	0
Urinary tract pain	6	0
Renal & urinary disorders SOC TOTAL	1178	8

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Benign and malignant breast neoplasms</i>		
Breast cyst	14	0
<i>Breast disorders NEC</i>		
Breast disorder	2	0
Breast enlargement	26	0
Breast mass	125	0
Gynaecomastia	4	0
Mastoptosis	1	0
Nipple disorder	1	0
<i>Breast infections and inflammations</i>		
Breast inflammation	5	0
Nipple inflammation	2	0
<i>Breast signs and symptoms</i>		
Breast discharge	4	0
Breast discomfort	11	0
Breast engorgement	11	0
Breast haematoma	1	0
Breast oedema	5	0
Breast pain	705	0
Breast swelling	151	0
Breast tenderness	85	0
Nipple pain	39	1
Nipple swelling	4	0
<i>Cervix disorders NEC</i>		
Cervical dysplasia	2	0
Cervix disorder	1	0
Cervix haemorrhage uterine	5	0
Ectropion of cervix	4	0
<i>Cervix infections and inflammations</i>		
Cervix inflammation	1	0
<i>Cervix neoplasms</i>		
Cervical polyp	1	0
<i>Erection and ejaculation conditions and disorders</i>		
Ejaculation disorder	2	0
Ejaculation failure	3	0
Erectile dysfunction	68	0
Erection increased	3	0
Organic erectile dysfunction	16	0
Painful ejaculation	1	0
Spontaneous ejaculation	1	0
Spontaneous penile erection	2	0
<i>Fallopian tube and ovary infections and inflammations</i>		
Noninfective oophoritis	5	0
<i>Lactation disorders</i>		
Breast milk discolouration	3	0
Breast milk odour abnormal	2	0
Galactorrhoea	5	0
Galactostasis	1	0
Lactation disorder	9	0
Lactation puerperal increased	5	0
Suppressed lactation	46	0
<i>Menopausal effects NEC</i>		
Artificial menopause	1	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Menopausal disorder	1	0
Menopausal symptoms	32	0
Menopause delayed	1	0
Premature menopause	18	0
<i>Menopausal effects on the genitourinary tract</i>		
Atrophic vulvovaginitis	2	0
Postmenopausal haemorrhage	99	0
<i>Menstruation and uterine bleeding NEC</i>		
Abnormal uterine bleeding	6	0
Abnormal withdrawal bleeding	1	0
Bleeding anovulatory	1	0
Dysmenorrhoea	2816	0
Intermenstrual bleeding	1105	0
Menstrual discomfort	29	0
Menstrual disorder	1859	0
Menstruation irregular	3287	0
Premenstrual dysphoric disorder	11	0
Premenstrual headache	11	0
Premenstrual pain	123	0
Premenstrual syndrome	108	0
Retrograde menstruation	1	0
Withdrawal bleed	15	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	594	0
Hypomenorrhoea	650	0
Menstruation delayed	4842	0
Oligomenorrhoea	163	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	5349	0
Menometrorrhagia	17	0
Polymenorrhoea	846	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>		
Haemorrhagic ovarian cyst	1	0
Ovarian cyst	27	0
Ovarian cyst ruptured	1	0
Polycystic ovaries	47	0
<i>Ovarian and fallopian tube disorders NEC</i>		
Adnexal torsion	1	0
Hydrosalpinx	2	0
Ovarian enlargement	1	0
Ovarian haemorrhage	6	0
Ovulation disorder	2	0
Ovulation pain	66	0
Premature ovulation	4	0
<i>Pelvic prolapse conditions</i>		
Vaginal prolapse	1	0
<i>Pelvis and broad ligament disorders NEC</i>		
Adnexa uteri mass	1	0
Adnexa uteri pain	50	0
Pelvic congestion	1	0
Pelvic floor muscle weakness	1	0
Pelvic haemorrhage	20	0
<i>Penile and scrotal infections and inflammations</i>		

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Balanoposthitis	3	0
<i>Penile disorders NEC (excl erection and ejaculation)</i>		
Penile blister	1	0
Penile discharge	1	0
Penile discomfort	1	0
Penile erythema	1	0
Penile haemorrhage	3	0
Penile oedema	1	0
Penile pain	1	0
Penile size reduced	1	0
Penile swelling	5	0
Penis disorder	10	0
<i>Prostate and seminal vesicles infections and inflammations</i>		
Prostatitis	4	0
<i>Prostatic neoplasms and hypertrophy</i>		
Benign prostatic hyperplasia	2	0
<i>Prostatic signs, symptoms and disorders NEC</i>		
Prostatic pain	1	0
Prostatomegaly	3	0
<i>Reproductive tract disorders NEC (excl neoplasms)</i>		
Genital erosion	1	0
Genital haemorrhage	24	0
Genital hypoaesthesia	1	0
Genital lesion	2	0
Genital paraesthesia	1	0
Genital ulceration	6	0
Perineal ulceration	1	0
<i>Reproductive tract infections and inflammations NEC</i>		
Genital tract inflammation	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Genital burning sensation	2	0
Genital erythema	1	0
Genital pain	6	0
Genital rash	4	0
Genital swelling	3	0
Pelvic discomfort	6	0
Pelvic pain	107	0
Perineal pain	2	0
Perineal rash	1	0
Pruritus genital	4	0
<i>Scrotal disorders NEC</i>		
Acquired hydrocele	1	0
Scrotal angiokeratoma	1	0
Scrotal discomfort	1	0
Scrotal erythema	2	0
Scrotal exfoliation	2	0
Scrotal pain	22	0
Scrotal swelling	4	0
Scrotum erosion	1	0
Varicocele	2	0
<i>Sexual function and fertility disorders NEC</i>		
Dyspareunia	6	0
Infertility	12	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Infertility female	4	0
Sexual dysfunction	8	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	4	0
Testicular oedema	1	0
Testicular pain	60	0
Testicular swelling	10	0
Testicular torsion	1	0
Testis discomfort	3	0
<i>Testicular and epididymal neoplasms</i>		
Testicular cyst	1	0
<i>Uterine disorders NEC</i>		
Adenomyosis	7	0
Endometrial thickening	4	0
Endometriosis	87	0
Uterine haemorrhage	39	0
Uterine pain	14	0
<i>Uterine infections and inflammations (excl cervix)</i>		
Uterine inflammation	1	0
<i>Uterine neoplasms</i>		
Uterine polyp	4	0
<i>Uterine tone disorders</i>		
Uterine spasm	30	0
<i>Vulvovaginal cysts and neoplasms</i>		
Bartholin's cyst	1	0
Vaginal cyst	7	0
Vaginal polyp	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	1534	0
Vaginal mucosal blistering	1	0
Vaginal ulceration	2	0
Vulval disorder	1	0
Vulval haemorrhage	32	0
Vulval ulceration	7	0
Vulvovaginal ulceration	4	0
<i>Vulvovaginal signs and symptoms</i>		
Clitoral engorgement	1	0
Coital bleeding	6	0
Labia enlarged	1	0
Vaginal discharge	78	0
Vaginal lesion	1	0
Vaginal odour	3	0
Vulval oedema	2	0
Vulvovaginal burning sensation	6	0
Vulvovaginal discomfort	1	0
Vulvovaginal dryness	5	0
Vulvovaginal erythema	2	0
Vulvovaginal pain	27	0
Vulvovaginal pruritus	10	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
Reproductive & breast disorders cont'd		
Vulvovaginal rash	2	0
Vulvovaginal swelling	4	0
Reproductive & breast disorders SOC TOTAL	25892	1

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	6	0
Apnoeic attack	1	0
Dyspnoea	5306	5
Dyspnoea at rest	11	0
Dyspnoea exertional	36	1
Grunting	1	0
Hyperventilation	52	0
Hypopnoea	114	0
Hypoventilation	1	0
Irregular breathing	22	0
Mouth breathing	7	0
Nocturnal dyspnoea	2	0
Orthopnoea	3	0
Respiration abnormal	60	0
Respiratory arrest	17	0
Respiratory depression	1	0
Respiratory distress	19	0
Sleep apnoea syndrome	13	0
Tachypnoea	29	0
<i>Bronchial conditions NEC</i>		
Bronchial secretion retention	4	0
Bronchiectasis	15	0
<i>Bronchospasm and obstruction</i>		
Asthma	364	0
Asthma late onset	3	0
Bronchospasm	17	0
Chronic obstructive pulmonary disease	22	1
Cough variant asthma	6	0
Obstructive airways disorder	9	0
Reversible airways obstruction	1	0
Wheezing	414	0
<i>Conditions associated with abnormal gas exchange</i>		
Asphyxia	2	0
Cyanosis central	1	0
Hyperoxia	1	0
Hypoxia	30	2
Respiratory acidosis	2	0
<i>Coughing and associated symptoms</i>		
Allergic cough	7	0
Cough	2593	2
Cough decreased	2	0
Haemoptysis	64	0
Productive cough	180	0
Sputum discoloured	10	0
Sputum increased	3	0
<i>Diaphragmatic disorders</i>		
Acquired diaphragmatic eventration	1	0
Diaphragm muscle weakness	1	0
<i>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</i>		
Laryngeal disorder	1	0
Reflux laryngitis	2	0

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Vocal cord disorder	1	0
Vocal cord dysfunction	2	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Epiglottic oedema	1	0
Laryngeal obstruction	1	0
Laryngeal oedema	4	0
Laryngospasm	1	0
Stridor	24	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Alveolitis	1	0
Autoimmune lung disease	1	0
Hypersensitivity pneumonitis	1	0
Lower respiratory tract inflammation	1	0
Pneumonitis	30	1
Pulmonary sarcoidosis	2	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	33	0
Increased bronchial secretion	3	0
Increased viscosity of bronchial secretion	1	0
Lung hyperinflation	2	0
Lung opacity	3	0
Pleuritic pain	20	0
Pulmonary haemorrhage	1	0
Pulmonary pain	102	0
Rales	5	0
Respiratory fremitus	1	0
<i>Mediastinal disorders</i>		
Mediastinal mass	1	0
Pulmonary hilum mass	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	294	0
Nasal inflammation	4	0
Rhinitis allergic	20	0
<i>Nasal disorders NEC</i>		
Epistaxis	952	0
Intranasal hypoaesthesia	2	0
Intranasal paraesthesia	1	0
Nasal crusting	2	0
Nasal disorder	3	0
Nasal dryness	36	0
Nasal mucosal discolouration	1	0
Nasal odour	6	0
Nasal oedema	8	0
Nasal polyps	1	0
Nasal pruritus	12	0
Nasal ulcer	1	0
<i>Neonatal hypoxic conditions</i>		
Dry lung syndrome	1	0
Gasping syndrome	1	0
Infantile apnoea	2	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Allergic sinusitis	1	0
Paranasal sinus inflammation	4	0

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Sinonasal obstruction	11	0
Sinus congestion	65	0
Sinus disorder	6	0
<i>Parenchymal lung disorders NEC</i>		
Atelectasis	3	0
Combined pulmonary fibrosis and emphysema	1	0
Emphysema	3	0
Interstitial lung disease	11	0
Lung consolidation	5	0
Lung infiltration	2	1
Organising pneumonia	1	0
Pulmonary alveolar haemorrhage	1	0
Pulmonary cavitation	1	0
Pulmonary fibrosis	8	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Hyperactive pharyngeal reflex	1	0
Pharyngeal enanthema	1	0
Pharyngeal erythema	7	0
Pharyngeal haemorrhage	2	0
Pharyngeal hypoaesthesia	37	0
Pharyngeal inflammation	4	0
Pharyngeal lesion	1	0
Pharyngeal mass	1	0
Pharyngeal oedema	14	0
Pharyngeal paraesthesia	55	0
Pharyngeal swelling	260	0
Pharyngeal ulceration	14	0
Tonsillar erythema	11	0
Tonsillar haemorrhage	1	0
Tonsillar hypertrophy	87	0
Tonsillar inflammation	3	0
Tonsillar ulcer	1	0
Tonsillolith	1	0
<i>Pleural infections and inflammations</i>		
Pleurisy	35	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	35	0
Pneumothorax	9	0
Pneumothorax spontaneous	3	0
<i>Pulmonary hypertension</i>		
Pulmonary hypertension	3	0
<i>Pulmonary oedemas</i>		
Acute respiratory distress syndrome	2	1
Pulmonary congestion	18	0
Pulmonary oedema	21	2
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary artery thrombosis	2	0
Pulmonary embolism	459	34
Pulmonary infarction	6	0
Pulmonary thrombosis	8	1
<i>Respiratory failures (excl neonatal)</i>		
Acute respiratory failure	3	1
Respiratory failure	12	2

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
<i>Respiratory signs and symptoms NEC</i>		
Allergic respiratory symptom	6	0
Diaphragmalgia	7	0
Nasal flaring	1	0
Painful respiration	14	1
Pleural rub	1	0
Respiratory symptom	19	0
Suffocation feeling	2	0
Use of accessory respiratory muscles	1	0
<i>Respiratory tract disorders NEC</i>		
Aspiration	3	0
Lung disorder	7	1
Pulmonary mass	5	0
Respiratory disorder	15	1
Respiratory tract congestion	4	0
Respiratory tract haemorrhage	1	0
Respiratory tract inflammation	2	0
Respiratory tract irritation	9	0
Respiratory tract oedema	4	0
<i>Thoracic musculoskeletal disorders</i>		
Respiratory muscle weakness	2	0
<i>Tracheal disorders (excl infections and neoplasms)</i>		
Tracheal disorder	1	0
Tracheal pain	2	0
<i>Upper respiratory tract neoplasms</i>		
Tonsillar cyst	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	126	0
Catarrh	29	0
Choking	17	0
Choking sensation	5	0
Dry throat	174	0
Dysphonia	161	0
Increased upper airway secretion	6	0
Increased viscosity of upper respiratory secretion	32	0
Laryngeal pain	1	0
Nasal discharge discolouration	3	0
Nasal discomfort	49	0
Nasal obstruction	2	0
Oropharyngeal blistering	11	0
Oropharyngeal discomfort	69	0
Oropharyngeal pain	2918	0
Oropharyngeal plaque	2	0
Paranasal sinus discomfort	46	0
Rhinalgia	12	0
Rhinorrhoea	934	0
Sinus pain	222	0
Sneezing	396	0
Snoring	7	0
Throat clearing	8	0
Throat irritation	235	0
Throat tightness	267	0
Upper airway obstruction	2	0

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Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Upper respiratory tract congestion	2	0
Upper respiratory tract irritation	1	0
Upper-airway cough syndrome	12	0
Yawning	28	0
<i>Vascular pulmonary disorders NEC</i>		
Acute chest syndrome	1	0
Respiratory disorders SOC TOTAL	18171	57

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	197	0
Acne cystic	24	0
Dermatitis acneiform	13	0
<i>Alopecias</i>		
Alopecia	315	0
Alopecia areata	49	0
Alopecia totalis	3	0
Androgenetic alopecia	2	0
Diffuse alopecia	3	0
Hypotrichosis	1	0
Lichen planopilaris	1	0
Madarosis	6	0
<i>Angioedemas</i>		
Angioedema	231	0
Circumoral swelling	1	0
<i>Apocrine and eccrine gland disorders</i>		
Anhidrosis	1	0
Bromhidrosis	1	0
Cold sweat	793	0
Hidradenitis	4	0
Hyperhidrosis	2365	0
Hypohidrosis	2	0
Milia	2	0
Miliaria	104	0
Night sweats	713	0
Sweat discolouration	1	0
<i>Bullous conditions</i>		
Blister	471	0
Blister rupture	1	0
Blood blister	33	0
Dermatitis bullous	12	0
Erythema multiforme	38	0
Fracture blisters	1	0
Herpes gestationis	1	0
Pemphigoid	27	0
Pemphigus	9	0
Stevens-Johnson syndrome	6	0
Toxic epidermal necrolysis	2	1
<i>Connective tissue disorders</i>		
Cutaneous lupus erythematosus	2	0
Dermatomyositis	8	0
Subacute cutaneous lupus erythematosus	1	0
<i>Dermal and epidermal conditions NEC</i>		
Acute febrile neutrophilic dermatosis	1	0
Dermatosis	1	0
Dry skin	245	0
Koebner phenomenon	1	0
Macule	5	0
Neutrophilic dermatosis	1	0
Pain of skin	287	0
Papule	110	0
Pathergy reaction	1	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Scab	22	0
Scar pain	15	0
Sensitive skin	186	0
Shagreen skin	1	0
Skin burning sensation	230	0
Skin degenerative disorder	1	0
Skin discolouration	138	0
Skin discomfort	4	0
Skin disorder	32	0
Skin fissures	8	0
Skin indentation	2	0
Skin induration	5	0
Skin lesion	45	0
Skin lesion inflammation	1	0
Skin necrosis	2	0
Skin odour abnormal	21	0
Skin plaque	3	0
Skin reaction	148	0
Skin sensitisation	41	0
Skin swelling	98	0
Skin texture abnormal	2	0
Skin tightness	26	0
Skin warm	312	0
Skin weeping	11	0
Sticky skin	3	0
Target skin lesion	3	0
Transient acantholytic dermatosis	1	0
Yellow skin	26	0
<i>Dermatitis and eczema</i>		
Dermatitis	141	0
Dermatitis allergic	258	0
Dermatitis atopic	42	0
Dermatitis contact	22	0
Dermatitis diaper	4	0
Dyshidrotic eczema	28	0
Eczema	340	0
Eczema asteatotic	11	0
Eczema infantile	1	0
Eczema nummular	5	0
Eczema weeping	3	0
Hand dermatitis	2	0
Intertrigo	1	0
Neurodermatitis	3	0
Perioral dermatitis	2	0
Seborrhoeic dermatitis	6	0
Skin irritation	126	0
Stasis dermatitis	1	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	34	0
Drug reaction with eosinophilia and systemic symptoms	1	0
Fixed eruption	2	0
Palmar-plantar erythrodysesthesia syndrome	1	0
Toxic skin eruption	2	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
<i>Erythemas</i>		
Erythema	2235	0
Palmar erythema	4	0
Red man syndrome	2	0
<i>Exfoliative conditions</i>		
Dermatitis exfoliative	2	0
Dermatitis exfoliative generalised	5	0
Exfoliative rash	20	0
Keratolysis exfoliativa acquired	2	0
Skin exfoliation	121	0
<i>Granulomatous and deep cutaneous inflammatory conditions</i>		
Cutaneous sarcoidosis	1	0
Granuloma annulare	5	0
Necrobiosis lipoidica diabetorum	1	0
<i>Hyperkeratoses</i>		
Hyperkeratosis	1	0
Keratosis pilaris	3	0
Lichenoid keratosis	3	0
<i>Hyperpigmentation disorders</i>		
Argyria	1	0
Chloasma	1	0
Ephelides	1	0
Skin hyperpigmentation	6	0
Solar lentigo	3	0
<i>Hypertrichoses</i>		
Hirsutism	2	0
Hypertrichosis	1	0
<i>Hypopigmentation disorders</i>		
Skin depigmentation	4	0
Skin hypopigmentation	1	0
Vitiligo	19	0
<i>Lipodystrophies</i>		
Lipoatrophy	4	0
Lipodystrophy acquired	1	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
Nail discolouration	11	0
Nail disorder	4	0
Nail pigmentation	2	0
Nail ridging	3	0
Onychalgia	8	0
Onychoclasia	5	0
Onychomadesis	2	0
Splinter haemorrhages	3	0
<i>Panniculitides</i>		
Erythema nodosum	27	0
Panniculitis	1	0
<i>Papulosquamous conditions</i>		
Erythema annulare	2	0
Lichen planus	22	0
Lichen sclerosus	9	0
Parapsoriasis	4	0
Pityriasis rosea	122	0
Pityriasis rubra pilaris	1	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	65	0
Polymorphic light eruption	3	0
Solar dermatitis	2	0
<i>Pigmentation changes NEC</i>		
Haemosiderin stain	1	0
Pigmentation disorder	15	0
<i>Pilar disorders NEC</i>		
Hair colour changes	11	0
Hair disorder	1	0
Hair growth abnormal	5	0
Hair texture abnormal	6	0
Piloerection	27	0
Pseudofolliculitis	3	0
Trichorrhexis	3	0
<i>Pruritus NEC</i>		
Itching scar	8	0
Pruritus	5581	0
<i>Psoriatic conditions</i>		
Dermatitis psoriasiform	5	0
Guttate psoriasis	19	0
Nail psoriasis	2	0
Palmoplantar pustulosis	2	0
Psoriasis	201	0
Pustular psoriasis	3	0
Rebound psoriasis	1	0
<i>Purpura and related conditions</i>		
Ecchymosis	1	0
Henoch-Schonlein purpura	11	0
Petechiae	143	0
Purpura	58	0
<i>Pustular conditions</i>		
Acute generalised exanthematous pustulosis	2	0
<i>Rashes, eruptions and exanthems NEC</i>		
Butterfly rash	6	0
Rash	5865	1
Rash erythematous	1224	0
Rash macular	511	0
Rash maculo-papular	64	0
Rash morbilliform	45	0
Rash papular	354	0
Rash pruritic	1233	0
Rash vesicular	78	0
Systemic lupus erythematosus rash	7	0
<i>Rosaceas</i>		
Rosacea	33	0
<i>Scaly conditions</i>		
Dandruff	5	0
Pityriasis	26	0
<i>Sebaceous gland disorders</i>		
Seborrhoea	10	0
<i>Skin and subcutaneous conditions NEC</i>		
Cellulite	2	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Cutaneous symptom	5	0
Reactive perforating collagenosis	1	0
Skin mass	23	0
<i>Skin and subcutaneous tissue ulcerations</i>		
Ischaemic skin ulcer	1	0
Mucocutaneous ulceration	1	0
Pyoderma gangrenosum	1	0
Scleroderma associated digital ulcer	1	0
Skin erosion	24	0
Skin ulcer	21	0
<i>Skin cysts and polyps</i>		
Dermal cyst	13	0
<i>Skin dystrophies</i>		
Keloid scar	3	0
Skin wrinkling	2	0
<i>Skin haemorrhages</i>		
Haemorrhage subcutaneous	15	0
Skin haemorrhage	19	0
<i>Skin hyperplasias and hypertrophies</i>		
Skin hypertrophy	2	0
<i>Skin hypoplasias and atrophies</i>		
Skin atrophy	3	0
Skin striae	7	0
<i>Skin injuries and mechanical dermatoses</i>		
Decubitus ulcer	2	0
Needle track marks	5	0
<i>Skin preneoplastic conditions NEC</i>		
Actinic keratosis	1	0
<i>Skin vascular conditions NEC</i>		
Angiodermatitis	1	0
Skin oedema	4	0
<i>Skin vasculitides</i>		
Capillaritis	2	0
Cutaneous vasculitis	14	0
Hypersensitivity vasculitis	1	0
Vasculitic rash	22	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	23	0
<i>Telangiectasia and related conditions</i>		
Spider naevus	1	0
Telangiectasia	1	0
<i>Urticarias</i>		
Chronic spontaneous urticaria	12	0
Cold urticaria	7	0
Idiopathic urticaria	1	0
Mechanical urticaria	10	0
Solar urticaria	2	0
Urticaria	1944	0
Urticaria cholinergic	2	0
Urticaria chronic	26	0
Urticaria contact	1	0
Urticaria papular	5	0
Urticaria thermal	7	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Urticarial vasculitis	5	0
Skin disorders SOC TOTAL	29077	2

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Reaction Name	Total	Fatal
Social circumstances		
<i>Age related issues</i>		
Infant	2	0
Menarche	3	0
Menopause	40	0
Postmenopause	3	0
<i>Criminal activity</i>		
Verbal abuse	1	0
<i>Dependents</i>		
Sick relative	6	0
<i>Dietary and nutritional issues</i>		
Feeding tube user	1	0
<i>Disability issues</i>		
Bedridden	26	0
Breast prosthesis user	3	0
Disability	2	0
Hearing disability	2	0
Housebound	1	0
Immobile	13	0
Impaired driving ability	4	0
Impaired work ability	16	0
Loss of personal independence in daily activities	40	0
Physical disability	5	0
Sight disability	11	0
Sitting disability	4	0
Walking disability	1	0
Wheelchair user	1	0
<i>Economic circumstances</i>		
High income	1	0
Low income	1	0
<i>Educational issues</i>		
Educational problem	1	0
Illiteracy	1	0
<i>Employment issues</i>		
Job dissatisfaction	1	0
Retirement	5	0
Sick leave	1	0
Stress at work	3	0
<i>Family and partner issues</i>		
Bed sharing	1	0
<i>Non-occupational and unspecified environmental problems</i>		
Flooding	1	0
Water pollution	2	0
<i>Pregnancy related circumstances</i>		
Breast feeding	16	0
Multigravida	1	0
Parity	1	0
<i>Social issues NEC</i>		
Exercise adequate	2	0
Hair dye user	2	0
Impaired quality of life	3	0
<i>Tobacco use</i>		
Ex-tobacco user	1	0
Non-tobacco user	4	0

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Reaction Name	Total	Fatal
Social circumstances Social circumstances cont'd		
Tobacco user	1	0
Social circumstances SOC TOTAL	234	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Anaesthesia and allied procedures</i>		
Local anaesthesia	2	0
Nerve block	5	0
<i>Analgesia supportive care</i>		
Analgesic therapy	1	0
<i>Antiinfective therapies</i>		
COVID-19 prophylaxis	2	0
COVID-19 treatment	4	0
<i>Arterial therapeutic procedures (excl aortic)</i>		
Splenic artery embolisation	1	0
<i>Blood and blood product treatment</i>		
Transfusion	2	0
<i>Breast therapeutic procedures NEC</i>		
Axillary lymphadenectomy	3	0
Mammoplasty	1	0
<i>Bronchial and pulmonary therapeutic procedures</i>		
Airway secretion clearance therapy	1	0
<i>Cardiac device therapeutic procedures</i>		
Cardiac pacemaker insertion	1	0
<i>Cardiac therapeutic procedures NEC</i>		
Cardiac operation	1	0
<i>Contraceptive methods female</i>		
Contraception	1	0
Contraceptive implant	3	0
Oral contraception	1	0
<i>Contraceptive methods male</i>		
Condom	1	0
<i>Dental and gingival therapeutic procedures</i>		
Tooth extraction	1	0
<i>Dietary and nutritional therapies</i>		
Medical diet	8	0
Nothing by mouth order	12	0
Wheat-free diet	1	0
<i>External ear therapeutic procedures</i>		
Ear irrigation	1	0
<i>Fertility and fertilisation interventions female</i>		
Endometrial scratching	1	0
<i>Gastrointestinal therapeutic procedures NEC</i>		
Intestinal anastomosis	1	0
Prophylaxis of nausea and vomiting	15	0
<i>Gynaecological therapeutic procedures NEC</i>		
Menstrual cycle management	13	0
<i>Haematological therapeutic procedures NEC</i>		
Anticoagulant therapy	1	0
<i>Head, neck and oral cavity therapeutic procedures NEC</i>		
Neck lift	1	0
<i>Hernia repairs</i>		
Hernia repair	1	0
<i>Hormonal therapeutic procedures NEC</i>		
Hormone replacement therapy	1	0
Hormone therapy	8	0
<i>Immunisations</i>		
COVID-19 immunisation	104	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Surgical & medical procedures cont'd</i>		
Immunisation	369	1
<i>Induced abortions</i>		
Abortion induced	2	0
<i>Joint therapeutic procedures</i>		
Joint injection	4	0
Joint surgery	1	0
Knee arthroplasty	1	0
<i>Large intestine therapeutic procedures</i>		
Appendectomy	3	0
<i>Limb therapeutic procedures</i>		
Arm amputation	1	0
Limb immobilisation	12	0
Limb operation	9	0
<i>Lymphoid tissue therapeutic procedures</i>		
Lymphadenectomy	3	0
Splenectomy	1	0
<i>Mastectomies</i>		
Breast conserving surgery	4	0
<i>Nail therapeutic procedures</i>		
Nail operation	3	0
<i>Nervous system therapeutic procedures NEC</i>		
Multiple sclerosis relapse prophylaxis	2	0
<i>Obstetric therapeutic procedures</i>		
Caesarean section	1	0
Labour stimulation	1	0
<i>Orbit and globe therapeutic procedures</i>		
Strabismus correction	1	0
<i>Ovarian therapeutic procedures</i>		
Ovarian operation	1	0
<i>Peripheral nerve therapeutic procedures</i>		
Neurolysis	1	0
Peripheral nerve neurostimulation	1	0
<i>Phototherapies</i>		
UV light therapy	1	0
<i>Prophylactic procedures NEC</i>		
Anaphylaxis prophylaxis	2	0
Immune tolerance induction	1	0
Prophylaxis against transplant rejection	1	0
Reproductive system disorder prophylaxis	1	0
<i>Psychiatric therapies</i>		
Electroconvulsive therapy	1	0
<i>Renal therapeutic procedures</i>		
Dialysis	1	0
<i>Respiratory tract therapeutic procedures NEC</i>		
Asthma prophylaxis	3	0
<i>Retinal therapeutic procedures</i>		
Retinopexy	1	0
<i>Skin and subcutaneous tissue therapeutic procedures NEC</i>		
Dermal filler injection	4	0
Therapeutic skin care topical	1	0
<i>Skull and brain therapeutic procedures</i>		
Cerebrovascular operation	1	0
Posterior fossa decompression	1	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Surgical & medical procedures cont'd</i>		
<i>Small intestine therapeutic procedures</i>		
Ileostomy	1	0
<i>Therapeutic bladder catheterisation</i>		
Bladder catheterisation	2	0
<i>Therapeutic procedures NEC</i>		
Abscess drainage	1	0
Anaphylaxis treatment	7	0
Bed rest	5	0
Emergency care	1	0
Fatigue management	1	0
Hospitalisation	14	0
Injection	63	0
Interchange of vaccine products	120	0
Localised alternating hot and cold therapy	2	0
Magnetic therapy	1	0
Mass excision	3	0
Medical procedure	1	0
Medication dilution	2	0
Physical fitness training	1	0
Product used for unknown indication	3	0
Promotion of wound healing	1	0
Specialist consultation	1	0
Stoma care	1	0
Therapeutic procedure	1	0
Therapy change	1	0
Vehicle solution use	1	0
<i>Tracheal therapeutic procedures</i>		
Tracheostomy	1	0
<i>Uterine therapeutic procedures</i>		
Endometrial ablation	2	0
<i>Vascular therapeutic procedures NEC</i>		
Thrombolysis	1	0
Vasodilation procedure	1	0
Surgical & medical procedures SOC TOTAL	878	1

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Accelerated and malignant hypertension</i>		
Hypertensive crisis	12	0
Hypertensive urgency	2	0
Malignant hypertension	4	0
<i>Aneurysms and dissections non-site specific</i>		
Aneurysm	3	0
Artery dissection	2	0
<i>Aortic aneurysms and dissections</i>		
Acute aortic syndrome	1	0
Aortic aneurysm rupture	1	1
Aortic dissection	1	0
<i>Aortic embolism and thrombosis</i>		
Aortic embolus	5	0
Aortic thrombosis	4	0
<i>Aortic infections and inflammations</i>		
Aortitis	1	0
<i>Aortic necrosis and vascular insufficiency</i>		
Aortic occlusion	1	0
<i>Arterial infections and inflammations</i>		
Arteritis	2	0
Giant cell arteritis	15	0
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	13	0
Labile blood pressure	3	0
<i>Bruising, ecchymosis and purpura</i>		
Achenbach syndrome	4	0
<i>Circulatory collapse and shock</i>		
CT hypotension complex	2	0
Circulatory collapse	77	0
Hypoperfusion	2	0
Hypovolaemic shock	1	1
Neurogenic shock	23	0
Peripheral circulatory failure	6	0
Shock	21	0
Shock symptom	1	0
<i>Haemorrhages NEC</i>		
Arterial haemorrhage	1	0
Bloody discharge	24	0
Haematoma	50	0
Haemorrhage	1222	2
Internal haemorrhage	10	0
Venous haemorrhage	2	0
<i>Lymphangiopathies</i>		
Lymphangiopathy	1	0
Lymphocele	6	0
Lymphorrhoea	1	0
Lymphostasis	1	0
<i>Lymphoedemas</i>		
Lymphoedema	219	0
<i>Non-site specific embolism and thrombosis</i>		
Arterial thrombosis	4	0
Embolism	62	0
Embolism arterial	1	0

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Reaction Name	Total	Fatal
Vascular disorders <small>Vascular disorders cont'd</small>		
Embolism venous	7	0
Microembolism	1	0
Thrombosis	439	8
Venous thrombosis	7	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Arterial occlusive disease	2	0
Arterial spasm	1	0
Arteriosclerosis	3	0
Haemorrhagic infarction	1	0
Infarction	3	0
Ischaemia	11	0
Peripheral venous disease	1	0
Vascular occlusion	1	0
Vasospasm	1	0
<i>Non-site specific vascular disorders NEC</i>		
Capillary disorder	1	0
Capillary fragility	4	0
Superficial vein prominence	2	0
Vascular pain	34	0
Vascular wall hypertrophy	1	0
Vasodilatation	36	0
Vein discolouration	5	0
Vein disorder	7	0
Vein rupture	6	0
<i>Peripheral aneurysms and dissections</i>		
Peripheral artery aneurysm	1	0
<i>Peripheral embolism and thrombosis</i>		
Axillary vein thrombosis	1	0
Blue toe syndrome	30	0
Deep vein thrombosis	304	1
Femoral artery embolism	1	0
Jugular vein thrombosis	3	0
Pelvic venous thrombosis	4	0
Peripheral artery thrombosis	2	0
Peripheral embolism	2	0
Subclavian vein thrombosis	3	0
Superficial vein thrombosis	24	0
Thrombophlebitis	25	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	47	0
Erythromelalgia	2	0
Flushing	434	0
Hot flush	1150	0
Peripheral vascular disorder	1	0
Vein wall hypertrophy	1	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Claudication of jaw muscles	1	0
Extremity necrosis	3	0
Iliac artery occlusion	1	0
Intermittent claudication	3	0
Ischaemic limb pain	2	0
Jugular vein occlusion	2	0
Peripheral arterial occlusive disease	2	0

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Reaction Name	Total	Fatal
Vascular disorders <small>Vascular disorders cont'd</small>		
Peripheral artery occlusion	1	0
Peripheral coldness	345	0
Peripheral ischaemia	12	0
Poor peripheral circulation	17	0
Raynaud's phenomenon	57	0
Subclavian vein occlusion	1	0
Vasoconstriction	2	0
Phlebitis NEC		
Phlebitis	34	0
Phlebitis superficial	8	0
Site specific vascular disorders NEC		
Aortic disorder	1	0
Inferior vena cava dilatation	1	0
Pallor	397	0
Varicose veins NEC		
Spider vein	6	0
Varicophlebitis	4	0
Varicose vein	32	0
Vascular hypertensive disorders NEC		
Diastolic hypertension	5	0
Essential hypertension	3	0
Hypertension	636	0
Labile hypertension	1	0
Orthostatic hypertension	1	0
Secondary hypertension	1	0
Systolic hypertension	7	0
White coat hypertension	1	0
Vascular hypotensive disorders		
Capillary leak syndrome	1	0
Diastolic hypotension	1	0
Hypotension	408	1
Orthostatic hypotension	32	0
Vasculitides NEC		
Behcet's syndrome	5	0
Diffuse vasculitis	1	0
Granulomatosis with polyangiitis	2	0
MAGIC syndrome	1	0
Thromboangiitis obliterans	1	0
Vasculitis	51	0
Vena caval embolism and thrombosis		
Vena cava embolism	1	0
Vena cava thrombosis	1	0
Vascular disorders SOC TOTAL	6512	14
TOTAL REACTIONS FOR DRUG	416479	666
TOTAL REPORTS	145446	
TOTAL FATAL OUTCOME REPORTS		666