

COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 16-Mar-2021
Data Lock Date: 07-Mar-2021 19:00:03

All UK spontaneous reports received between 9/12/20 and 07/03/21 for mRNA Pfizer/BioNTech vaccine analysis print

Case Series Drug Analysis Print

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

Report Run Date: 16-Mar-2021
Earliest Reaction Date: 03-Apr-1990

Data Lock Date: 07-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemia deficiencies</i>		
Anaemia vitamin B12 deficiency	1	0
<i>Anaemias NEC</i>		
Anaemia	5	0
<i>Anaemias haemolytic immune</i>		
Autoimmune haemolytic anaemia	1	0
<i>Bleeding tendencies</i>		
Increased tendency to bruise	7	0
<i>Coagulopathies</i>		
Coagulopathy	1	0
<i>Leukopenias NEC</i>		
Lymphopenia	1	0
<i>Lymphatic system disorders NEC</i>		
Granulomatous lymphadenitis	1	0
Lymph node pain	301	0
Lymphadenitis	46	0
Lymphadenopathy	2091	0
Lymphatic disorder	1	0
Pseudolymphoma	2	0
<i>Marrow depression and hypoplastic anaemias</i>		
Myelosuppression	1	0
Pancytopenia	1	0
<i>Neutropenias</i>		
Neutropenia	11	0
<i>Platelet disorders NEC</i>		
Platelet anisocytosis	1	0
<i>Spleen disorders</i>		
Spleen atrophy	1	0
Splenomegaly	1	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	11	0
Thrombocytopenia	13	1
<i>Thrombocytoses</i>		
Thrombocytosis	2	0
Blood disorders SOC TOTAL	2500	1

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac conduction disorders</i>		
Bundle branch block right	1	0
<i>Cardiac disorders NEC</i>		
Cardiac disorder	3	0
Cardiovascular disorder	1	0
<i>Cardiac signs and symptoms NEC</i>		
Cardiac discomfort	1	0
Palpitations	574	0
<i>Cardiomyopathies</i>		
Congestive cardiomyopathy	1	0
<i>Coronary artery disorders NEC</i>		
Coronary artery disease	2	1
<i>Heart failures NEC</i>		
Cardiac failure	4	1
Cardiac failure congestive	1	0
Cardiopulmonary failure	1	1
<i>Ischaemic coronary artery disorders</i>		
Acute myocardial infarction	8	0
Angina pectoris	16	0
Arteriospasm coronary	1	0
Myocardial infarction	26	6
<i>Left ventricular failures</i>		
Left ventricular failure	1	0
<i>Myocardial disorders NEC</i>		
Cardiomegaly	1	0
Left ventricular dysfunction	1	0
Myocardial fibrosis	1	0
Myocardial oedema	2	0
Right ventricular enlargement	1	0
<i>Noninfectious myocarditis</i>		
Myocarditis	8	0
<i>Noninfectious pericarditis</i>		
Pericarditis	8	1
<i>Pericardial disorders NEC</i>		
Pericardial effusion	2	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	18	0
Bradycardia	16	0
Cardiac flutter	26	0
Extrasystoles	16	0
Paroxysmal arrhythmia	1	0
Postural orthostatic tachycardia syndrome	2	0
Tachycardia	324	0
<i>Right ventricular failures</i>		
Cor pulmonale	1	0
<i>Supraventricular arrhythmias</i>		
Arrhythmia supraventricular	5	0
Atrial fibrillation	56	0
Atrial flutter	1	0
Atrial tachycardia	2	0
Sinus bradycardia	2	0
Sinus tachycardia	25	0
Supraventricular tachycardia	13	0

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Cardiac disorders Cardiac disorders cont'd		
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	39	15
Cardio-respiratory arrest	1	1
Pulseless electrical activity	2	0
Ventricular arrhythmia	2	1
Ventricular extrasystoles	4	0
Ventricular fibrillation	4	0
Ventricular tachycardia	1	0
Cardiac disorders SOC TOTAL	1226	27

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Cardiac septal defects congenital</i>		
Hypertrophic cardiomyopathy	1	0
<i>Coagulation disorders congenital</i>		
Haemophilia	1	0
<i>Neurological disorders congenital NEC</i>		
Familial hemiplegic migraine	1	0
Familial periodic paralysis	1	0
<i>Retinal disorders congenital</i>		
Retinitis pigmentosa	1	0
Congenital disorders SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear canal erythema	1	0
Ear congestion	5	0
Ear discomfort	15	0
Ear disorder	3	0
Ear haemorrhage	1	0
Ear pain	233	0
Ear pruritus	3	0
Ear swelling	6	0
Otorrhoea	1	0
<i>Eustachian tube disorders</i>		
Eustachian tube disorder	1	0
Eustachian tube dysfunction	3	0
<i>External ear disorders NEC</i>		
Red ear syndrome	2	0
<i>Hearing disorders NEC</i>		
Auditory disorder	1	0
<i>Hearing losses</i>		
Deafness	23	0
Deafness neurosensory	3	0
Deafness unilateral	3	0
Hypoacusis	31	0
Sudden hearing loss	7	0
<i>Hyperacusia</i>		
Hyperacusis	9	0
<i>Inner ear disorders NEC</i>		
Acute vestibular syndrome	1	0
Inner ear disorder	3	0
Meniere's disease	3	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	16	0
Tinnitus	219	0
Vertigo	273	0
Vertigo labyrinthine	4	0
Vertigo positional	22	0
<i>Middle ear infections and inflammations</i>		
Middle ear inflammation	1	0
Ear disorders SOC TOTAL	893	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Thyroiditis subacute	1	0
<i>Adrenal cortical hypofunctions</i>		
Addison's disease	1	0
Adrenocortical insufficiency acute	3	0
<i>Endocrine abnormalities of puberty</i>		
Premature menarche	1	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	2	0
<i>Thyroid disorders NEC</i>		
Goitre	3	0
Thyroid pain	1	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	2	0
Endocrine disorders SOC TOTAL	14	0

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Eye disorders		
<i>Amblyopic vision impairment</i>		
Amblyopia	2	0
<i>Choroid and vitreous haemorrhages and vascular disorders</i>		
Choroidal haemorrhage	1	0
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Vitreous detachment	1	0
Vitreous floaters	13	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	10	0
<i>Conjunctival infections, irritations and inflammations</i>		
Conjunctival hyperaemia	1	0
<i>Corneal infections, oedemas and inflammations</i>		
Keratitis	2	0
Ulcerative keratitis	3	0
<i>Eyelid movement disorders</i>		
Blepharospasm	24	0
Excessive eye blinking	1	0
Eyelid ptosis	7	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Autoimmune uveitis	1	0
Iridocyclitis	5	0
Iritis	2	0
Uveitis	9	0
<i>Lacrimation disorders</i>		
Dry eye	33	0
Lacrimation increased	41	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Blepharitis	2	0
Chalazion	1	0
Eczema eyelids	1	0
Erythema of eyelid	1	0
Eyelid irritation	1	0
Eyelid margin crusting	1	0
Eyelid oedema	1	0
Eyelid rash	4	0
Swelling of eyelid	31	0
<i>Lid, lash and lacrimal structural disorders</i>		
Eyelid exfoliation	1	0
Lagophthalmos	1	0
<i>Ocular bleeding and vascular disorders NEC</i>		
Eye haematoma	1	0
Eye haemorrhage	4	0
<i>Ocular disorders NEC</i>		
Dark circles under eyes	1	0
Eye disorder	10	0
Eye oedema	4	0
Eye pain	265	0
Eye swelling	139	0
Eye ulcer	1	0
Eyelid disorder	2	0
Eyelid pain	3	0
Eyelids pruritus	1	0
Ocular discomfort	9	0

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Eye disorders Eye disorders cont'd		
Periorbital oedema	11	0
Periorbital pain	1	0
Periorbital swelling	35	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye allergy	2	0
Eye discharge	8	0
Eye inflammation	5	0
Eye irritation	30	0
Eye pruritus	86	0
Limbal swelling	1	0
Ocular hyperaemia	55	0
<i>Ocular nerve and muscle disorders</i>		
Binocular eye movement disorder	1	0
Extraocular muscle paresis	1	0
Eye movement disorder	6	0
Ophthalmoplegia	2	0
Strabismus	1	0
<i>Ocular sensation disorders</i>		
Abnormal sensation in eye	5	0
Asthenopia	48	0
Eye paraesthesia	1	0
Foreign body sensation in eyes	8	0
Hypoaesthesia eye	4	0
Photophobia	107	0
<i>Optic disc abnormalities NEC</i>		
Papilloedema	1	0
<i>Pupil disorders</i>		
Miosis	1	0
Mydriasis	5	0
Pupillary disorder	1	0
Pupils unequal	3	0
<i>Retinal bleeding and vascular disorders (excl retinopathy)</i>		
Retinal haemorrhage	1	0
Retinal vein occlusion	2	0
<i>Retinal structural change, deposit and degeneration</i>		
Maculopathy	1	0
Retinal toxicity	1	0
<i>Scleral infections, irritations and inflammations</i>		
Episcleritis	3	0
<i>Visual colour distortions</i>		
Cyanopsia	1	0
Erythropsia	2	0
<i>Visual disorders NEC</i>		
Diplopia	31	0
Halo vision	4	0
Metamorphopsia	3	0
Oscillopsia	1	0
Photopsia	29	0
Scintillating scotoma	1	0
Vision blurred	240	0
Visual brightness	1	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	16	0

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Eye disorders Eye disorders cont'd		
Blindness transient	3	0
Blindness unilateral	2	0
Central vision loss	1	0
Sudden visual loss	1	0
Visual acuity reduced	1	0
Visual impairment	74	0
Eye disorders SOC TOTAL	1489	0

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Gastrointestinal disorders		
<i>Abdominal findings abnormal</i>		
Gastrointestinal sounds abnormal	4	0
<i>Acute and chronic pancreatitis</i>		
Obstructive pancreatitis	1	0
Pancreatitis	2	0
Pancreatitis necrotising	1	0
<i>Anal and rectal disorders NEC</i>		
Anal sphincter atony	1	0
<i>Anal and rectal pains</i>		
Proctalgia	4	0
<i>Anal and rectal signs and symptoms</i>		
Anal spasm	1	0
Anorectal discomfort	3	0
<i>Benign oral cavity neoplasms</i>		
Mouth cyst	2	0
<i>Colitis (excl infective)</i>		
Colitis	6	0
Colitis ulcerative	7	0
Crohn's disease	8	0
<i>Dental disorders NEC</i>		
Teething	2	0
<i>Dental pain and sensation disorders</i>		
Dental discomfort	2	0
Dental paraesthesia	1	0
Hyperaesthesia teeth	8	0
Toothache	24	0
<i>Diaphragmatic hernias</i>		
Hiatus hernia	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	1646	4
Diarrhoea haemorrhagic	5	0
<i>Duodenal and small intestinal stenosis and obstruction</i>		
Small intestinal obstruction	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	86	0
Epigastric discomfort	5	0
Eructation	14	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	3	0
Faeces discoloured	11	0
Faeces pale	2	0
Faeces soft	2	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	59	0
Aerophagia	2	0
Flatulence	46	0
<i>Gastric and oesophageal haemorrhages</i>		
Gastric haemorrhage	2	1
<i>Gastric ulcers and perforation</i>		
Gastric ulcer	1	0
<i>Gastritis (excl infective)</i>		
Gastritis	11	0
Reflux gastritis	3	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal migraine	1	0
Abdominal pain	325	0
Abdominal pain lower	16	0
Abdominal pain upper	520	0
Abdominal rigidity	2	0
Abdominal tenderness	3	0
Gastrointestinal pain	30	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	51	0
Duodenogastric reflux	2	0
Gastric dilatation	2	0
Gastroesophageal reflux disease	28	0
Infrequent bowel movements	1	0
Intestinal pseudo-obstruction	1	0
<i>Gastrointestinal disorders NEC</i>		
Functional gastrointestinal disorder	2	0
Gastric disorder	3	0
Gastrointestinal disorder	2	0
<i>Gastrointestinal dyskinetic disorders</i>		
Change of bowel habit	2	0
Dyschezia	1	0
Gastrointestinal motility disorder	1	0
<i>Gastrointestinal inflammatory disorders NEC</i>		
Enteritis	1	0
<i>Gastrointestinal mucosal dystrophies and secretion disorders</i>		
Hyperchlorhydria	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	180	0
Acute abdomen	1	0
Anal incontinence	7	0
Breath odour	6	0
Dysphagia	53	1
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Defaecation urgency	2	0
Frequent bowel movements	10	0
Irritable bowel syndrome	20	0
Oesophageal spasm	2	0
Pylorospasm	1	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Intestinal obstruction	1	0
<i>Gastrointestinal vascular malformations</i>		
Gastric antral vascular ectasia	1	0
<i>Gastrointestinal vascular occlusion and infarction</i>		
Intestinal ischaemia	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival blister	5	0
Gingival discomfort	2	0
Gingival disorder	2	0
Gingival pain	25	0
Gingival swelling	7	0
Gingivitis ulcerative	1	0
Noninfective gingivitis	1	0

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Gingival haemorrhages</i>		
Gingival bleeding	8	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Gastric varices	1	0
Haemorrhoids	6	0
<i>Intestinal haemorrhages</i>		
Anal haemorrhage	4	0
Rectal haemorrhage	18	0
Small intestinal haemorrhage	3	0
<i>Intestinal ulcers and perforation NEC</i>		
Intestinal perforation	2	2
<i>Malabsorption syndromes</i>		
Coeliac disease	2	0
Steatorrhoea	1	0
<i>Nausea and vomiting symptoms</i>		
Discoloured vomit	4	0
Nausea	4679	1
Regurgitation	1	0
Retching	36	0
Vomiting	1272	2
Vomiting projectile	21	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Gastrointestinal haemorrhage	4	0
Haematemesis	15	2
Haematochezia	11	0
Melaena	5	0
Upper gastrointestinal haemorrhage	2	0
<i>Oesophageal stenosis and obstruction</i>		
Oesophageal stenosis	1	0
<i>Oesophagitis (excl infective)</i>		
Oesophagitis	1	0
<i>Oral dryness and saliva altered</i>		
Aptyalism	1	0
Dry mouth	185	0
Lip dry	13	0
Saliva altered	1	0
Salivary hypersecretion	14	0
<i>Oral soft tissue disorders NEC</i>		
Chapped lips	5	0
Cheilitis	10	0
Enlarged uvula	6	0
Lip blister	8	0
Lip disorder	3	0
Oral disorder	3	0
Oral lichen planus	1	0
Oral papule	1	0
Uvulitis	1	0
<i>Oral soft tissue haemorrhages</i>		
Mouth haemorrhage	2	0
Oral blood blister	6	0
<i>Oral soft tissue signs and symptoms</i>		
Anaesthesia oral	1	0
Hypoaesthesia oral	171	0

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Lip discolouration	1	0
Lip erythema	1	0
Lip exfoliation	3	0
Lip pain	19	0
Lip pruritus	5	0
Lip scab	1	0
Odynophagia	5	0
Oral discomfort	22	0
Oral dysaesthesia	1	0
Oral mucosal blistering	7	0
Oral mucosal eruption	8	0
Oral mucosal erythema	2	0
Oral mucosal exfoliation	2	0
Oral mucosal roughening	1	0
Oral pain	51	0
Oral pruritus	8	0
Paraesthesia oral	438	0
<i>Oral soft tissue swelling and oedema</i>		
Lip oedema	3	0
Lip swelling	253	0
Mouth swelling	28	0
Oedema mouth	1	0
Palatal oedema	2	0
Palatal swelling	1	0
<i>Peritoneal and retroperitoneal disorders</i>		
Ascites	1	0
<i>Peritoneal and retroperitoneal fibrosis and adhesions</i>		
Abdominal adhesions	1	0
<i>Rectal inflammations NEC</i>		
Proctitis	1	0
Proctitis ulcerative	1	0
<i>Salivary gland disorders NEC</i>		
Salivary gland pain	2	0
<i>Salivary gland enlargements</i>		
Parotid gland enlargement	2	0
Salivary gland enlargement	1	0
Submaxillary gland enlargement	4	0
<i>Stomatitis and ulceration</i>		
Aphthous ulcer	12	0
Lip ulceration	2	0
Mouth ulceration	111	0
Oral mucosa erosion	1	0
Palatal ulcer	1	0
Stomatitis	17	0
<i>Tongue disorders</i>		
Glossitis	3	0
Plicated tongue	2	0
Tongue disorder	14	0
Tongue haemorrhage	1	0
Tongue ulceration	8	0
<i>Tongue signs and symptoms</i>		
Glossodynia	68	0
Stiff tongue	1	0

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Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Swollen tongue	188	0
Tongue blistering	6	0
Tongue coated	3	0
Tongue discolouration	5	0
Tongue discomfort	15	0
Tongue dry	5	0
Tongue eruption	6	0
Tongue erythema	1	0
Tongue movement disturbance	2	0
Tongue oedema	11	0
Tongue rough	2	0
Tongue spasm	3	0
Gastrointestinal disorders SOC TOTAL	11193	13

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site bruise	2	0
Administration site erythema	1	0
Administration site extravasation	1	0
Administration site haematoma	1	0
Administration site inflammation	1	0
Administration site joint discomfort	1	0
Administration site joint movement impairment	1	0
Administration site pain	5	0
Administration site warmth	1	0
Puncture site bruise	7	0
Puncture site pain	3	0
Puncture site swelling	1	0
Vessel puncture site bruise	1	0
Vessel puncture site erythema	1	0
Vessel puncture site pain	1	0
<i>Adverse effect absent</i>		
No adverse event	4	0
<i>Application and instillation site reactions</i>		
Application site acne	1	0
Application site bruise	1	0
Application site erythema	2	0
Application site haemorrhage	1	0
Application site joint pain	1	0
Application site mass	1	0
Application site pain	3	0
Application site pruritus	1	0
Application site reaction	1	0
Application site vesicles	1	0
Instillation site warmth	1	0
<i>Asthenic conditions</i>		
Asthenia	466	1
Chronic fatigue syndrome	9	0
Fatigue	6884	1
Malaise	1578	0
Sluggishness	4	0
<i>Body temperature altered</i>		
Hyperthermia	3	0
Hypothermia	14	0
Temperature regulation disorder	4	0
<i>Breast complications associated with device</i>		
Capsular contracture associated with breast implant	1	0
<i>Complications associated with device NEC</i>		
Medical device pain	1	0
Medical device site swelling	1	0
<i>Death and sudden death</i>		
Clinical death	1	1
Death	10	10
Sudden death	15	15
<i>Febrile disorders</i>		
Hyperpyrexia	3	0
Pyrexia	5395	1
<i>Feelings and sensations NEC</i>		

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General disorders General disorders cont'd		
Chills	3545	0
Feeling abnormal	327	0
Feeling cold	390	0
Feeling drunk	19	0
Feeling hot	368	0
Feeling jittery	7	0
Feeling of body temperature change	103	0
Hangover	15	0
Hunger	6	0
Sensation of foreign body	18	0
Temperature intolerance	4	0
Thirst	86	0
Gait disturbances		
Gait disturbance	35	0
Gait inability	20	0
Loss of control of legs	2	0
General signs and symptoms NEC		
Condition aggravated	34	0
Crepitations	1	0
Crying	22	0
Disease recurrence	2	0
Energy increased	3	0
Exercise tolerance decreased	2	0
General physical health deterioration	3	0
Glassy eyes	2	0
Illness	471	1
Induration	2	0
Influenza like illness	824	0
Irritability postvaccinal	1	0
Local reaction	46	0
Multiple organ dysfunction syndrome	1	1
Nonspecific reaction	1	0
Peripheral swelling	846	0
Pre-existing condition improved	3	0
Screaming	2	0
Secretion discharge	5	0
Swelling	628	0
Swelling face	257	0
Implant and catheter site reactions		
Implant site pain	1	0
Implant site rash	1	0
Inflammations		
Inflammation	80	0
Papillitis	1	0
Systemic inflammatory response syndrome	1	0
Infusion site reactions		
Infusion site coldness	1	0
Infusion site joint pain	2	0
Infusion site pain	1	0
Infusion site swelling	1	0
Infusion site urticaria	1	0
Injection site reactions		
Injected limb mobility decreased	10	0

Case Series Drug Analysis Print

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

Report Run Date: 16-Mar-2021

Data Lock Date: 07-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Injection site bruising	17	0
Injection site cyst	1	0
Injection site discolouration	2	0
Injection site discomfort	5	0
Injection site erythema	150	0
Injection site haemorrhage	2	0
Injection site hypoaesthesia	6	0
Injection site indentation	1	0
Injection site induration	2	0
Injection site inflammation	10	0
Injection site joint movement impairment	1	0
Injection site joint pain	8	0
Injection site mass	138	0
Injection site necrosis	2	0
Injection site oedema	9	0
Injection site pain	1171	0
Injection site paraesthesia	5	0
Injection site pruritus	70	0
Injection site rash	43	0
Injection site reaction	12	0
Injection site scab	2	0
Injection site scar	2	0
Injection site swelling	147	0
Injection site urticaria	9	0
Injection site vesicles	3	0
Injection site warmth	57	0
Interactions		
Alcohol interaction	2	0
Drug interaction	3	0
Mass conditions NEC		
Cyst	3	0
Mass	5	0
Nodule	5	0
Mucosal findings abnormal		
Mucosal haemorrhage	1	0
Oedema mucosal	1	0
Necrosis NEC		
Fat necrosis	1	0
Oedema NEC		
Face oedema	12	0
Localised oedema	12	0
Oedema	9	0
Oedema peripheral	16	0
Pain and discomfort NEC		
Axillary pain	346	0
Chest discomfort	411	0
Chest pain	545	0
Discomfort	41	0
Facial discomfort	6	0
Facial pain	63	0
Inflammatory pain	1	0
Non-cardiac chest pain	7	0
Pain	2121	0

Case Series Drug Analysis Print

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

Report Run Date: 16-Mar-2021
 Earliest Reaction Date: 03-Apr-1990

Data Lock Date: 07-Mar-2021 19:00:03
 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Suprapubic pain	1	0
Tenderness	205	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	31	0
Adverse reaction	1	0
Drug ineffective	87	0
Immediate post-injection reaction	2	0
No reaction on previous exposure to drug	11	0
Therapeutic product effect delayed	1	0
Therapeutic product effect increased	1	0
Therapeutic response unexpected	10	0
Treatment failure	4	0
Ulcers NEC		
Ulcer	4	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	3	0
Shoulder injury related to vaccine administration	1	0
Vaccination site bruising	36	0
Vaccination site cyst	1	0
Vaccination site dermatitis	1	0
Vaccination site discolouration	6	0
Vaccination site discomfort	20	0
Vaccination site eczema	1	0
Vaccination site erythema	250	0
Vaccination site haemorrhage	6	0
Vaccination site hypersensitivity	1	0
Vaccination site hypoaesthesia	3	0
Vaccination site induration	36	0
Vaccination site inflammation	30	0
Vaccination site irritation	4	0
Vaccination site joint discomfort	2	0
Vaccination site joint erythema	4	0
Vaccination site joint movement impairment	12	0
Vaccination site joint pain	20	0
Vaccination site joint swelling	2	0
Vaccination site joint warmth	1	0
Vaccination site lymphadenopathy	1	0
Vaccination site mass	72	0
Vaccination site movement impairment	23	0
Vaccination site oedema	3	0
Vaccination site pain	895	0
Vaccination site paraesthesia	4	0
Vaccination site pruritus	56	0
Vaccination site rash	38	0
Vaccination site reaction	12	0
Vaccination site scab	1	0
Vaccination site scar	1	0
Vaccination site swelling	262	0
Vaccination site ulcer	1	0
Vaccination site urticaria	5	0
Vaccination site vesicles	2	0
Vaccination site warmth	140	0
Withdrawal and rebound effects		

Case Series Drug Analysis Print

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

Report Run Date: 16-Mar-2021

Data Lock Date: 07-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Drug withdrawal syndrome	3	0
Withdrawal syndrome	2	0
General disorders SOC TOTAL	30533	120

Case Series Drug Analysis Print

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

Report Run Date: 16-Mar-2021

Data Lock Date: 07-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	1	0
<i>Cholestasis and jaundice</i>		
Jaundice	4	0
<i>Hepatic and hepatobiliary disorders NEC</i>		
Liver disorder	1	0
<i>Hepatic failure and associated disorders</i>		
Hepatic failure	1	0
<i>Hepatic vascular disorders</i>		
Hepatic artery embolism	1	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	6	0
Liver tenderness	1	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Drug-induced liver injury	1	0
Hepatitis	2	0
Liver injury	3	0
Hepatic disorders SOC TOTAL	21	0

Case Series Drug Analysis Print

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

Report Run Date: 16-Mar-2021
Earliest Reaction Date: 03-Apr-1990

Data Lock Date: 07-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Immune system disorders		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	6	0
<i>Allergic conditions NEC</i>		
Allergic oedema	6	0
Allergy to arthropod bite	1	0
Hypersensitivity	261	0
Multiple allergies	1	0
Serum sickness	2	0
Serum sickness-like reaction	2	0
Type I hypersensitivity	1	0
Type IV hypersensitivity reaction	3	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergic reaction to excipient	3	0
Allergy to chemicals	1	0
Allergy to vaccine	16	0
Contrast media reaction	1	0
Drug hypersensitivity	6	0
Food allergy	2	0
Oral allergy syndrome	1	0
Reaction to colouring	1	0
Reaction to excipient	1	0
Reaction to preservatives	3	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	205	0
Anaphylactic shock	7	0
Anaphylactoid reaction	9	0
Anaphylactoid shock	2	0
<i>Atopic disorders</i>		
Atopy	1	0
Seasonal allergy	2	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	5	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	5	0
Immune system disorder	4	0
Immune-mediated adverse reaction	1	0
Systemic immune activation	1	0
Immune system disorders SOC TOTAL	560	0

Case Series Drug Analysis Print

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

Report Run Date: 16-Mar-2021
Earliest Reaction Date: 03-Apr-1990

Data Lock Date: 07-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Appendicitis	3	0
Diverticulitis	1	0
Dysentery	1	0
Gastroenteritis	8	0
<i>Aspergillus infections</i>		
Bronchopulmonary aspergillosis	1	0
<i>Bacterial infections NEC</i>		
Arthritis bacterial	1	0
Bacterial diarrhoea	1	0
Cellulitis	59	0
Conjunctivitis bacterial	1	0
Ear infection bacterial	1	0
Injection site cellulitis	1	0
Tonsillitis bacterial	1	0
Urinary tract infection bacterial	1	0
Vaccination site cellulitis	11	0
<i>Breast infections</i>		
Breast abscess	1	0
Mastitis	9	0
<i>Candida infections</i>		
Anal candidiasis	1	0
Candida infection	5	0
Oral candidiasis	11	0
Vulvovaginal candidiasis	8	0
<i>Central nervous system and spinal infections</i>		
Encephalitis	3	0
Meningitis	2	0
Meningitis aseptic	1	0
Myelitis	1	0
<i>Clostridia infections</i>		
Clostridium difficile infection	1	0
<i>Coronavirus infections</i>		
Asymptomatic COVID-19	7	0
COVID-19	457	22
COVID-19 pneumonia	12	3
Coronavirus infection	5	0
Suspected COVID-19	30	1
<i>Coxiella infections</i>		
Q fever	6	0
<i>Dental and oral soft tissue infections</i>		
Abscess oral	3	0
Gingivitis	2	0
Parotitis	5	0
Pulpitis dental	1	0
Sialoadenitis	1	0
Tooth abscess	1	0
<i>Ear infections</i>		
Ear infection	13	0
Labyrinthitis	23	0
<i>Epstein-Barr viral infections</i>		
Infectious mononucleosis	3	0
<i>Eye and eyelid infections</i>		

Case Series Drug Analysis Print

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

Report Run Date: 16-Mar-2021
 Earliest Reaction Date: 03-Apr-1990

Data Lock Date: 07-Mar-2021 19:00:03
 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Infections Infections cont'd		
Conjunctivitis	25	0
Eye abscess	1	0
Eye infection	4	0
Hordeolum	5	0
Periorbital infection	1	0
Female reproductive tract infections		
Bartholinitis	1	0
Vulval abscess	1	0
Fungal infections NEC		
Fungal skin infection	1	0
Hepatobiliary and spleen infections		
Biliary sepsis	1	0
Herpes viral infections		
Disseminated varicella zoster virus infection	1	0
Eczema herpeticum	1	0
Genital herpes	7	0
Genital herpes simplex	1	0
Herpes ophthalmic	1	0
Herpes simplex	4	0
Herpes simplex reactivation	1	0
Herpes virus infection	3	0
Herpes zoster	261	0
Herpes zoster oticus	3	0
Nasal herpes	1	0
Ophthalmic herpes zoster	1	0
Oral herpes	89	0
Varicella	1	0
Infections NEC		
Abscess	4	0
Abscess limb	1	0
Abscess soft tissue	1	0
Infection	66	0
Injection site abscess	1	0
Injection site infection	3	0
Localised infection	7	0
Lymph gland infection	3	0
Respiratory tract infection	1	0
Vaccination site abscess	2	0
Vaccination site infection	7	0
Vestibulitis	1	0
Influenza viral infections		
Influenza	442	0
Lower respiratory tract and lung infections		
Bronchitis	4	0
Lower respiratory tract infection	38	5
Pneumonia	20	5
Sputum purulent	1	0
Male reproductive tract infections		
Epididymitis	2	0
Orchitis	2	0
Mumps viral infections		
Mumps	1	0
Muscle and soft tissue infections		

Case Series Drug Analysis Print

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

Report Run Date: 16-Mar-2021
Earliest Reaction Date: 03-Apr-1990

Data Lock Date: 07-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Infections Infections cont'd		
Soft tissue infection	1	0
<i>Neisseria infections</i>		
Gonorrhoea	1	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Sepsis	15	1
Septic shock	1	0
Urosepsis	2	0
<i>Skin structures and soft tissue infections</i>		
Acne pustular	1	0
Folliculitis	3	0
Paronychia	1	0
Pustule	5	0
Rash pustular	4	0
Skin infection	6	0
Subcutaneous abscess	1	0
Vaccination site pustule	1	0
<i>Staphylococcal infections</i>		
Furuncle	10	0
Pneumonia staphylococcal	1	0
Staphylococcal abscess	1	0
Staphylococcal infection	1	0
<i>Streptococcal infections</i>		
Meningitis pneumococcal	1	0
Pharyngitis streptococcal	3	0
<i>Trypanosomal infections</i>		
African trypanosomiasis	1	0
<i>Upper respiratory tract infections</i>		
Laryngitis	2	0
Nasopharyngitis	211	0
Pharyngitis	5	0
Rhinitis	15	0
Sinusitis	23	0
Tonsillitis	22	0
Tracheitis	1	0
<i>Urinary tract infections</i>		
Cystitis	13	0
Kidney infection	5	0
Pyelonephritis	1	0
Urinary tract infection	34	0
<i>Vascular infections</i>		
Haematoma infection	1	0
Lymphangitis	2	0
<i>Viral infections NEC</i>		
Conjunctivitis viral	1	0
Eye infection viral	1	0
Gastroenteritis viral	6	0
Meningitis viral	1	0
Pneumonia viral	1	1
Post viral fatigue syndrome	10	0
Sweating fever	41	0
Vestibular neuronitis	5	0
Viral infection	2	0
Viral labyrinthitis	2	0

Case Series Drug Analysis Print

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

Report Run Date: 16-Mar-2021

Data Lock Date: 07-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Infections Infections cont'd		
Viral pharyngitis	5	0
Viral rash	14	0
Viral tonsillitis	1	0
Infections SOC TOTAL	2210	38

Case Series Drug Analysis Print

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

Report Run Date: 16-Mar-2021
Earliest Reaction Date: 03-Apr-1990

Data Lock Date: 07-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Injuries		
<i>Abdominal and gastrointestinal injuries NEC</i>		
Oral contusion	1	0
Tongue injury	1	0
<i>Accidental exposures to product</i>		
Accidental exposure to product	2	0
<i>Anaesthetic and allied procedural complications</i>		
Delayed recovery from anaesthesia	1	0
<i>Bone and joint injuries NEC</i>		
Joint injury	1	0
<i>Cardiovascular injuries</i>		
Heart injury	1	0
<i>Chest and respiratory tract injuries NEC</i>		
Chest crushing	1	0
<i>Conditions caused by cold</i>		
Chillblains	16	0
<i>Cranial nerve injuries</i>		
Vth nerve injury	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	4	0
Exposure via breast milk	3	0
Foetal exposure during pregnancy	2	0
Maternal exposure before pregnancy	1	0
Maternal exposure during breast feeding	45	0
Maternal exposure during pregnancy	39	0
<i>Eye injuries NEC</i>		
Eye contusion	5	0
Eye injury	2	0
Injury corneal	1	0
Periorbital haematoma	1	0
<i>Gastrointestinal and hepatobiliary procedural complications</i>		
Post procedural constipation	1	0
Postoperative ileus	1	0
Procedural nausea	3	0
<i>Heat injuries (excl thermal burns)</i>		
Heat illness	1	0
Heat oedema	4	0
Heat stroke	1	0
<i>Limb fractures and dislocations</i>		
Atypical femur fracture	1	0
Clavicle fracture	3	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	4	0
Product use issue	5	0
Vaccination error	1	0
Wrong drug	1	0
Wrong technique in product usage process	1	0
<i>Muscle, tendon and ligament injuries</i>		
Epicondylitis	3	0
Ligament sprain	1	0
Muscle injury	2	0
Muscle rupture	1	0
Muscle strain	5	0
Tendon injury	1	0

Case Series Drug Analysis Print

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

Report Run Date: 16-Mar-2021

Data Lock Date: 07-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
<i>Musculoskeletal procedural complications</i>		
Periprosthetic osteolysis	1	0
Post laminectomy syndrome	1	0
<i>Nerve injuries NEC</i>		
Nerve injury	6	0
<i>Neurological and psychiatric procedural complications</i>		
Procedural dizziness	5	0
<i>Non-site specific injuries NEC</i>		
Bite	1	0
Electric shock	4	0
Fall	41	1
Wound	1	0
Wound complication	4	0
Wound secretion	1	0
<i>Non-site specific procedural complications</i>		
Incision site pain	2	0
Infusion related reaction	3	0
Injection related reaction	21	0
Post procedural complication	3	0
<i>Off label uses</i>		
Off label use	7	0
<i>Overdoses NEC</i>		
Overdose	7	0
<i>Peripheral nerve injuries</i>		
Ulnar nerve injury	2	0
<i>Poisoning and toxicity</i>		
Poisoning	2	0
Toxicity to various agents	1	0
<i>Product administration errors and issues</i>		
Accidental overdose	1	0
Contraindicated product administered	1	0
Inappropriate schedule of product administration	10	0
Incomplete course of vaccination	1	0
Product administered at inappropriate site	3	0
Product administered to patient of inappropriate age	1	0
Product administration error	1	0
Product dose omission issue	3	0
<i>Product confusion errors and issues</i>		
Product label confusion	1	0
<i>Product preparation errors and issues</i>		
Product preparation issue	3	0
<i>Radiation injuries</i>		
Sunburn	3	0
<i>Site specific injuries NEC</i>		
Face crushing	1	0
Head injury	2	0
Limb injury	6	0
<i>Skin injuries NEC</i>		
Contusion	137	0
Nail avulsion	1	0
Scar	2	0
Scratch	1	0
Skin abrasion	4	0

Case Series Drug Analysis Print

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

Report Run Date: 16-Mar-2021

Data Lock Date: 07-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Skin injury	1	0
<i>Stoma complications</i>		
Gastrointestinal stoma complication	1	0
Stoma site discharge	1	0
Stoma site extravasation	1	0
Stoma site haemorrhage	1	0
<i>Thermal burns</i>		
Airway burns	1	0
Burn oesophageal	1	0
Burn of internal organs	1	0
Burn oral cavity	1	0
Burns second degree	2	0
Thermal burn	3	0
Thermal burns of eye	3	0
<i>Underdoses NEC</i>		
Underdose	1	0
<i>Vaccination related complications</i>		
Vaccination complication	18	0
Vaccination failure	1	0
Injuries SOC TOTAL	500	1

Case Series Drug Analysis Print

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

Report Run Date: 16-Mar-2021
Earliest Reaction Date: 03-Apr-1990

Data Lock Date: 07-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Investigations		
<i>Adrenal cortex tests</i>		
Cortisol decreased	2	0
<i>Autoimmunity analyses</i>		
Rheumatoid factor	2	0
<i>Blood counts NEC</i>		
Blood count	1	0
<i>Blood gas and acid base analyses</i>		
Blood lactic acid	1	0
Blood lactic acid increased	2	0
Blood pH	1	0
Blood pH increased	3	0
Oxygen consumption decreased	1	0
Oxygen saturation	4	0
Oxygen saturation decreased	28	0
<i>Bone marrow and immune tissue imaging procedures</i>		
Lymph nodes scan abnormal	1	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose	5	0
Blood glucose abnormal	5	0
Blood glucose decreased	8	0
Blood glucose fluctuation	5	0
Blood glucose increased	41	0
Glycosylated haemoglobin increased	1	0
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	2	0
Heart sounds abnormal	1	0
<i>Cardiac function diagnostic procedures</i>		
Central venous pressure	1	0
<i>Central nervous system imaging procedures</i>		
Magnetic resonance imaging brain	6	0
<i>Chemistry analyses NEC</i>		
Inflammatory marker increased	2	0
<i>Coagulation and bleeding analyses</i>		
Bleeding time abnormal	1	0
Coagulation time prolonged	1	0
Fibrin D dimer increased	3	0
International normalised ratio abnormal	1	0
International normalised ratio decreased	7	0
International normalised ratio increased	24	0
<i>ECG investigations</i>		
Electrocardiogram ST segment elevation	2	0
Electrocardiogram abnormal	1	0
<i>Endocrine analyses and imaging NEC</i>		
Hormone level abnormal	1	0
<i>Haematological analyses NEC</i>		
Red blood cell sedimentation rate increased	3	0
<i>Heart rate and pulse investigations</i>		
Heart rate	64	0
Heart rate abnormal	4	0
Heart rate decreased	12	0
Heart rate increased	177	0
Heart rate irregular	22	0
Pulse abnormal	7	0

Case Series Drug Analysis Print

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

Report Run Date: 16-Mar-2021

Data Lock Date: 07-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Radial pulse abnormal	1	0
Immunology analyses NEC		
Antibody test	1	0
Antibody test abnormal	2	0
Immunology test	3	0
Immunology skin tests NEC		
Skin test positive	1	0
Investigations NEC		
Blood test abnormal	2	0
Polymerase chain reaction positive	25	0
Systemic lupus erythematosus disease activity index increased	1	0
Liver function analyses		
Alanine aminotransferase increased	3	0
Aspartate aminotransferase increased	1	0
Gamma-glutamyltransferase increased	1	0
Hepatic enzyme increased	1	0
Liver function test abnormal	3	0
Liver function test increased	6	0
Transaminases increased	1	0
Metabolism tests NEC		
Blood ketone body	2	0
Blood ketone body increased	1	0
Microbiology and serology tests NEC		
Culture negative	1	0
Mineral and electrolyte analyses		
Blood copper increased	1	0
Blood magnesium decreased	1	0
Blood potassium abnormal	1	0
Blood potassium decreased	1	0
Serum ferritin increased	1	0
Musculoskeletal and soft tissue tests NEC		
Swollen joint count increased	1	0
Neurologic diagnostic procedures		
Coma scale abnormal	2	0
Temperature perception test increased	1	0
Ophthalmic function diagnostic procedures		
Intraocular pressure increased	1	0
Physical examination procedures and organ system status		
Body temperature	97	0
Body temperature abnormal	19	0
Body temperature decreased	14	0
Body temperature fluctuation	9	0
Body temperature increased	175	0
Body temperature normal	1	0
Breath sounds abnormal	1	0
Grip strength	2	0
Grip strength decreased	3	0
Lymph node palpable	9	0
Product residue present	1	0
Respiratory rate	2	0
Respiratory rate decreased	2	0
Respiratory rate increased	15	0
Skin temperature	14	0

Case Series Drug Analysis Print

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

Report Run Date: 16-Mar-2021

Data Lock Date: 07-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Temperature difference of extremities	2	0
Weight	1	0
Weight decreased	13	0
Weight increased	3	0
<i>Pituitary analyses anterior</i>		
Blood growth hormone	2	0
Blood thyroid stimulating hormone increased	2	0
<i>Platelet analyses</i>		
Platelet count decreased	5	0
<i>Protein analyses NEC</i>		
C-reactive protein increased	4	0
<i>Red blood cell analyses</i>		
Haematocrit	1	0
Haemoglobin decreased	4	0
<i>Respiratory and pulmonary function diagnostic procedures</i>		
Forced expiratory volume increased	2	0
Peak expiratory flow rate decreased	1	0
Vital capacity	1	0
<i>Respiratory tract and thoracic histopathology procedures</i>		
Sputum abnormal	2	0
<i>Skeletal and cardiac muscle analyses</i>		
Blood creatine phosphokinase increased	1	0
Troponin increased	3	0
<i>Therapeutic drug monitoring analyses</i>		
Analgesic drug level	1	0
Anticoagulation drug level below therapeutic	4	0
Anticoagulation drug level increased	1	0
Drug level decreased	1	0
<i>Thyroid analyses</i>		
Thyroid function test abnormal	1	0
Tri-iodothyronine	1	0
Tri-iodothyronine decreased	2	0
<i>Tissue enzyme analyses NEC</i>		
Blood alkaline phosphatase increased	1	0
<i>Urinalysis NEC</i>		
Blood urine	2	0
Blood urine present	5	0
Glucose urine present	1	0
pH urine	2	0
pH urine increased	1	0
<i>Urinary tract function analyses NEC</i>		
Urine output	5	0
Urine output decreased	3	0
Urine output increased	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure abnormal	3	0
Blood pressure decreased	11	0
Blood pressure increased	76	0
Blood pressure measurement	8	0
Blood pressure systolic decreased	1	0
Blood pressure systolic increased	1	0
<i>Virus identification and serology</i>		
Coronavirus test	1	0

Case Series Drug Analysis Print

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

Report Run Date: 16-Mar-2021

Data Lock Date: 07-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Coronavirus test positive	2	0
SARS-CoV-1 test positive	1	0
SARS-CoV-2 antibody test	2	0
SARS-CoV-2 antibody test negative	13	0
SARS-CoV-2 antibody test positive	2	0
SARS-CoV-2 test	12	0
SARS-CoV-2 test false positive	1	0
SARS-CoV-2 test negative	2	0
SARS-CoV-2 test positive	39	0
Viral test	1	0
Vitamin analyses		
Blood folate decreased	1	0
White blood cell analyses		
White blood cell count decreased	2	0
White blood cell count increased	1	0
Investigations SOC TOTAL	1142	0

Case Series Drug Analysis Print

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

Report Run Date: 16-Mar-2021
Earliest Reaction Date: 03-Apr-1990

Data Lock Date: 07-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	2	0
Decreased appetite	403	0
Eating disorder symptom	1	0
Food craving	2	0
Food refusal	4	0
Hypophagia	5	0
Increased appetite	3	0
Salt craving	2	0
<i>Calcium metabolism disorders</i>		
Hypocalcaemia	1	0
Tetany	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	5	0
Diabetes mellitus inadequate control	3	1
Increased insulin requirement	1	0
Type 1 diabetes mellitus	6	0
<i>Diabetic complications NEC</i>		
Diabetic complication	1	0
Diabetic ketoacidosis	4	0
<i>Disorders of purine metabolism</i>		
Gout	20	0
<i>Electrolyte imbalance NEC</i>		
Fluid imbalance	1	0
<i>Fluid intake increased</i>		
Polydipsia	3	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Gluten sensitivity	1	0
Histamine intolerance	2	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	1	0
Abnormal weight gain	4	0
Feeding disorder	12	0
Food aversion	2	0
Overweight	1	0
Poor feeding infant	1	0
<i>Hyperglycaemic conditions NEC</i>		
Hyperglycaemia	27	0
Insulin resistance	2	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	35	0
Postprandial hypoglycaemia	1	0
<i>Iron deficiencies</i>		
Iron deficiency	1	0
<i>Lipid metabolism and deposit disorders NEC</i>		
Body fat disorder	1	0
<i>Metabolic acidoses (excl diabetic acidoses)</i>		
Ketoacidosis	4	0
Metabolic acidosis	2	0
<i>Mixed acid-base disorders</i>		
Acidosis	2	0
<i>Potassium imbalance</i>		
Hyperkalaemia	1	0

Case Series Drug Analysis Print

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Report Run Date: 16-Mar-2021

Data Lock Date: 07-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
Hypokalaemia	1	0
Hypokalaemic syndrome	1	0
Sodium imbalance		
Hyponatraemia	4	0
Hyponatraemic syndrome	1	0
Total fluid volume decreased		
Dehydration	48	0
Total fluid volume increased		
Fluid retention	4	0
Hypervolaemia	1	0
Vitamin deficiencies NEC		
Hypovitaminosis	1	0
Metabolic disorders SOC TOTAL	629	1

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	60	0
Arthropathy	6	0
Polyarthritis	3	0
Sacroiliitis	1	0
<i>Bone disorders NEC</i>		
Medial tibial stress syndrome	2	0
Spinal disorder	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	101	0
Bone swelling	3	0
Coccydynia	1	0
Pain in jaw	92	0
Spinal pain	13	0
<i>Bursal disorders</i>		
Bursitis	10	0
<i>Cartilage disorders</i>		
Costochondritis	12	0
<i>Connective tissue disorders NEC</i>		
Polymyalgia rheumatica	6	0
Sjogren's syndrome	1	0
<i>Crystal arthropathic disorders</i>		
Crystal arthropathy	1	0
<i>Epiphyseal disorders</i>		
Epiphyses premature fusion	1	0
<i>Extremity deformities</i>		
Foot deformity	1	0
Musculoskeletal deformity	1	0
<i>Joint related disorders NEC</i>		
Joint destruction	1	0
Joint laxity	1	0
Joint lock	2	0
Periarthritis	17	0
Temporomandibular joint syndrome	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	2832	0
Jaw clicking	2	0
Joint effusion	8	0
Joint noise	4	0
Joint range of motion decreased	2	0
Joint stiffness	63	0
Joint swelling	91	0
Joint vibration	1	0
Joint warmth	4	0
<i>Lupus erythematosus (incl subtypes)</i>		
Lupus-like syndrome	1	0
Systemic lupus erythematosus	3	0
<i>Muscle infections and inflammations</i>		
Antisynthetase syndrome	1	0
Myositis	4	0
Polymyositis	1	0
<i>Muscle pains</i>		
Fibromyalgia	18	0

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Earliest Reaction Date: 03-Apr-1990

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Myalgia	4085	0
Myofascial pain syndrome	5	0
Muscle related signs and symptoms NEC		
Muscle atrophy	2	0
Muscle discomfort	1	0
Muscle disorder	2	0
Muscle fatigue	114	0
Muscle spasms	187	0
Muscle swelling	9	0
Muscle tightness	21	0
Muscle twitching	90	0
Muscle tone abnormalities		
Muscle rigidity	7	0
Nuchal rigidity	4	0
Torticollis	2	0
Trismus	9	0
Muscle weakness conditions		
Muscular weakness	220	0
Musculoskeletal and connective tissue conditions NEC		
Limb mass	2	0
Mandibular mass	2	0
Mastication disorder	1	0
Mobility decreased	17	0
Musculoskeletal disorder	4	0
Musculoskeletal stiffness	326	0
Posture abnormal	1	0
Musculoskeletal and connective tissue infections and inflammations NEC		
Fasciitis	1	0
Plantar fasciitis	3	0
Musculoskeletal and connective tissue pain and discomfort		
Back pain	609	0
Flank pain	10	0
Limb discomfort	435	0
Musculoskeletal chest pain	40	0
Musculoskeletal discomfort	23	0
Musculoskeletal pain	19	0
Neck pain	502	0
Pain in extremity	3344	1
Rheumatic disorder	1	0
Myopathies		
Rhabdomyolysis	3	0
Osteoarthropathies		
Osteoarthritis	6	0
Psoriatic arthropathies		
Psoriatic arthropathy	2	0
Rheumatoid arthropathies		
Rheumatoid arthritis	23	0
Soft tissue disorders NEC		
Axillary mass	47	0
Groin pain	29	0
Neck mass	10	0
Spondyloarthropathies		
Ankylosing spondylitis	3	0

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 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Muscle & tissue disorders		
Muscle & tissue disorders cont'd		
Arthritis reactive	9	0
Synovial disorders		
Synovial cyst	5	0
Synovitis	3	0
Tendon disorders		
Enthesopathy	1	0
Tendon pain	3	0
Tendonitis	5	0
Tenosynovitis	1	0
Tenosynovitis stenosans	1	0
Trigger finger	1	0
Trunk deformities		
Drooping shoulder syndrome	1	0
Muscle & tissue disorders SOC TOTAL	13624	1

Case Series Drug Analysis Print

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Report Run Date: 16-Mar-2021

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Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Neoplasms		
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	3	0
<i>Lymphomas unspecified NEC</i>		
Lymphoma	5	0
<i>Metastases to specified sites</i>		
Metastases to liver	1	0
Metastases to lymph nodes	3	0
<i>Myeloproliferative disorders (excl leukaemias)</i>		
Essential thrombocythaemia	1	0
<i>Neoplasms malignant site unspecified NEC</i>		
Neoplasm malignant	1	0
Second primary malignancy	1	0
<i>Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified</i>		
Tonsil cancer	1	0
<i>Pancreatic neoplasms malignant (excl islet cell and carcinoid)</i>		
Pancreatic carcinoma	1	0
<i>Plasma cell myelomas</i>		
Plasma cell myeloma	1	0
<i>Skin neoplasms benign</i>		
Acrochordon	1	0
Anogenital warts	1	0
Melanocytic naevus	2	0
Skin papilloma	1	0
<i>Skin neoplasms malignant and unspecified (excl melanoma)</i>		
Neoplasm skin	1	0
<i>Soft tissue neoplasms benign NEC</i>		
Lipoma	1	0
Lymphangioma	1	0
<i>Soft tissue sarcomas histology unspecified</i>		
Sarcoma	1	0
Neoplasms SOC TOTAL	27	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Extensor plantar response	1	0
Hyperreflexia	1	0
Hyporeflexia	4	0
<i>Abnormal sleep-related events</i>		
Sleep paralysis	3	0
<i>Absence seizures</i>		
Petit mal epilepsy	7	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	8	1
<i>Autonomic nervous system disorders</i>		
Anticholinergic syndrome	1	0
Autonomic nervous system imbalance	1	0
<i>Central nervous system aneurysms and dissections</i>		
Vertebral artery dissection	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Brain stem infarction	1	1
Cerebellar infarction	2	0
Cerebellar stroke	2	0
Cerebral artery occlusion	1	0
Cerebral haemorrhage	10	3
Cerebral infarction	7	0
Cerebrovascular accident	60	3
Embolic stroke	1	0
Haemorrhage intracranial	3	0
Haemorrhagic stroke	1	1
Ischaemic cerebral infarction	1	0
Ischaemic stroke	11	1
Lacunar infarction	2	0
Lacunar stroke	1	0
Subarachnoid haemorrhage	2	1
<i>Central nervous system inflammatory disorders NEC</i>		
Gliosis	1	0
<i>Central nervous system vascular disorders NEC</i>		
Reversible cerebral vasoconstriction syndrome	1	0
<i>Cerebrovascular venous and sinus thrombosis</i>		
Cerebral venous sinus thrombosis	1	0
<i>Cervical spinal cord and nerve root disorders</i>		
Cervicobrachial syndrome	2	0
<i>Choreiform movements</i>		
Chorea	2	0
<i>Coma states</i>		
Coma	1	0
Hypoglycaemic coma	1	0
<i>Coordination and balance disturbances</i>		
Ataxia	1	0
Balance disorder	96	0
Coordination abnormal	12	0
Dysstasia	15	0
Nystagmus	1	0
<i>Cortical dysfunction NEC</i>		
Aphasia	16	0
Neurologic neglect syndrome	1	0

Case Series Drug Analysis Print

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Report Run Date: 16-Mar-2021
Earliest Reaction Date: 03-Apr-1990

Data Lock Date: 07-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
<i>Cranial nerve disorders NEC</i>		
Cranial nerve disorder	2	0
<i>Dementia (excl Alzheimer's type)</i>		
Dementia	4	0
Dementia with Lewy bodies	1	0
Senile dementia	1	0
<i>Demyelinating disorders NEC</i>		
Demyelination	1	0
<i>Disturbances in consciousness NEC</i>		
Altered state of consciousness	4	0
Consciousness fluctuating	2	0
Depressed level of consciousness	7	0
Lethargy	764	0
Loss of consciousness	100	0
Sedation	3	0
Somnolence	258	0
Stupor	1	0
Syncope	332	0
<i>Dyskinesias and movement disorders NEC</i>		
Akathisia	1	0
Bradykinesia	4	0
Dyskinesia	7	0
Extrapyramidal disorder	1	0
Fine motor skill dysfunction	3	0
Hypokinesia	8	1
Motor dysfunction	1	0
Movement disorder	10	0
Psychomotor hyperactivity	4	0
<i>Dystonias</i>		
Dystonia	6	0
Writer's cramp	1	0
<i>Encephalopathies NEC</i>		
Encephalopathy	1	0
Posterior reversible encephalopathy syndrome	1	0
<i>Eye movement disorders</i>		
IIIrd nerve paralysis	2	0
IVth nerve paralysis	1	0
VIth nerve paralysis	3	0
<i>Facial cranial nerve disorders</i>		
Facial nerve disorder	1	0
Facial paralysis	184	0
Facial paresis	27	0
Facial spasm	12	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	9	0
<i>Headaches NEC</i>		
Cervicogenic headache	2	0
Cluster headache	60	0
Cold-stimulus headache	3	0
Drug withdrawal headache	1	0
Exertional headache	3	0
Headache	9053	0
Medication overuse headache	2	0

Case Series Drug Analysis Print

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Report Run Date: 16-Mar-2021
Earliest Reaction Date: 03-Apr-1990

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
New daily persistent headache	2	0
Occipital neuralgia	2	0
Ophthalmoplegic migraine	1	0
Primary cough headache	2	0
Primary headache associated with sexual activity	1	0
Sinus headache	116	0
Tension headache	150	0
Thunderclap headache	1	0
Vascular headache	5	0
Lumbar spinal cord and nerve root disorders		
Sciatica	13	0
Memory loss (excl dementia)		
Amnesia	19	0
Memory impairment	31	0
Transient global amnesia	2	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	16	0
Disturbance in attention	69	0
Mental impairment	10	0
Migraine headaches		
Hemiplegic migraine	3	0
Migraine	659	0
Migraine with aura	37	0
Migraine without aura	1	0
Retinal migraine	10	0
Typical aura without headache	1	0
Vestibular migraine	3	0
Mononeuropathies		
Carpal tunnel syndrome	4	0
Mononeuropathy	1	0
Nerve compression	3	0
Peroneal nerve palsy	2	0
Sciatic nerve neuropathy	1	0
Multiple sclerosis acute and progressive		
Multiple sclerosis	6	0
Multiple sclerosis relapse	7	0
Muscle tone abnormal		
Hypotonia	4	0
Muscle tone disorder	1	0
Serotonin syndrome	1	0
Stiff leg syndrome	1	0
Myelitis (incl infective)		
Myelitis transverse	10	0
Narcolepsy and hypersomnia		
Hypersomnia	21	0
Narcolepsy	2	0
Nervous system disorders NEC		
Nervous system disorder	1	0
Neurologic visual problems NEC		
Hemianopia	1	0
Tunnel vision	4	0
Visual field defect	3	0
Neurological signs and symptoms NEC		

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Dizziness	2670	0
Dizziness exertional	14	0
Dizziness postural	233	0
Drooling	3	0
Head discomfort	63	0
Hyporesponsive to stimuli	1	0
Inability to crawl	1	0
Myoclonus	5	0
Neurological symptom	9	0
Persistent postural-perceptual dizziness	4	0
Presyncope	170	0
Slow response to stimuli	2	0
Tongue biting	1	0
Unresponsive to stimuli	17	1
Neuromuscular disorders NEC		
Muscle contractions involuntary	5	0
Muscle spasticity	4	0
Neuromuscular pain	1	0
Neuromuscular junction dysfunction		
Myasthenia gravis	2	0
Myasthenia gravis crisis	1	0
Olfactory nerve disorders		
Anosmia	70	0
Hyposmia	6	0
Parosmia	58	0
Optic nerve disorders NEC		
Optic neuritis	5	0
Paraesthesias and dysaesthesias		
Burning feet syndrome	1	0
Burning sensation	112	0
Dysaesthesia	3	0
Formication	11	0
Hemiparaesthesia	1	0
Hyperaesthesia	25	0
Hypoaesthesia	616	0
Paraesthesia	890	0
Synaesthesia	1	0
Paralysis and paresis (excl cranial nerve)		
Diplegia	2	1
Hemiparesis	12	0
Hemiplegia	6	0
Locked-in syndrome	1	0
Monoparesis	18	0
Monoplegia	15	0
Paralysis	22	0
Paraparesis	1	0
Paresis	1	0
Parkinson's disease and parkinsonism		
Freezing phenomenon	3	0
Parkinsonian gait	1	0
Parkinsonism	4	0
Partial complex seizures		
Dreamy state	2	0

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Temporal lobe epilepsy	1	0
Peripheral neuropathies NEC		
Neuritis	2	0
Neuropathy peripheral	22	0
Peripheral sensory neuropathy	3	0
Seizures and seizure disorders NEC		
Atonic seizures	3	0
Clonic convulsion	1	0
Epilepsy	36	0
Febrile convulsion	1	0
Partial seizures	5	0
Post stroke seizure	1	0
Psychogenic seizure	4	0
Seizure	117	1
Seizure cluster	3	0
Seizure like phenomena	1	0
Status epilepticus	2	0
Tonic clonic movements	1	0
Tonic convulsion	6	0
Sensory abnormalities NEC		
Ageusia	154	0
Allodynia	4	0
Aura	7	0
Dysgeusia	408	0
Hypergeusia	1	0
Loss of proprioception	1	0
Neuralgia	93	0
Phantom limb syndrome	2	0
Post herpetic neuralgia	3	0
Restless legs syndrome	26	0
Sensory disturbance	16	0
Sensory loss	10	0
Taste disorder	77	0
Sleep disturbances NEC		
Poor quality sleep	51	0
Sleep deficit	2	0
Speech and language abnormalities		
Dysarthria	39	0
Incoherent	1	0
Repetitive speech	1	0
Speech disorder	7	0
Spinal cord and nerve root disorders NEC		
Radiculitis brachial	1	0
Radiculopathy	1	0
Structural brain disorders NEC		
Brain injury	2	2
Transient cerebrovascular events		
Transient ischaemic attack	21	0
Tremor (excl congenital)		
Essential tremor	1	0
Resting tremor	1	0
Tremor	484	0
Trigeminal disorders		

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Facial neuralgia	10	0
Numb chin syndrome	1	0
Trigeminal nerve disorder	2	0
Trigeminal neuralgia	12	0
Nervous system disorders SOC TOTAL	19142	17

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	23	0
<i>Gestational age and weight conditions</i>		
Premature baby	1	1
<i>Labour onset and length abnormalities</i>		
Premature delivery	1	0
Premature labour	1	0
<i>Maternal complications of pregnancy NEC</i>		
Morning sickness	7	0
Preterm premature rupture of membranes	1	0
<i>Normal pregnancy, labour and delivery</i>		
Pregnancy	5	0
Pregnancy conditions SOC TOTAL	39	1

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Reaction Name	Total	Fatal
<i>Device issues NEC</i>		
Device issue	1	0
<i>Device malfunction events NEC</i>		
Device infusion issue	1	0
Device stimulation issue	1	0
Oversensing	5	0
<i>Device physical property and chemical issues</i>		
Needle issue	1	0
<i>Product physical issues</i>		
Product odour abnormal	1	0
Product taste abnormal	4	0
<i>Product quality issues NEC</i>		
Product origin unknown	1	0
null SOC TOTAL	15	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Affect alterations NEC</i>		
Affect lability	1	0
Constricted affect	1	0
Flat affect	2	0
Inappropriate affect	2	0
<i>Anxiety symptoms</i>		
Agitation	29	0
Anxiety	133	0
Immunisation anxiety related reaction	1	0
Nervousness	57	0
Stress	3	0
Tension	12	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	1	0
Indifference	2	0
Paranoia	6	0
Social avoidant behaviour	2	0
Soliloquy	1	0
<i>Bipolar disorders</i>		
Bipolar disorder	1	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Daydreaming	1	0
Mental fatigue	54	0
<i>Communications disorders</i>		
Communication disorder	2	0
<i>Confusion and disorientation</i>		
Confusional state	201	0
Disorientation	68	0
<i>Decreased physical activity levels</i>		
Catatonia	1	0
<i>Deliria</i>		
Delirium	37	0
<i>Delusional symptoms</i>		
Delusion	1	0
<i>Depressive disorders</i>		
Depression	44	0
<i>Dissociative states</i>		
Depersonalisation/derealisation disorder	2	0
Dissociation	5	0
Dissociative amnesia	1	0
Dissociative disorder	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Initial insomnia	4	0
Insomnia	270	0
Middle insomnia	6	0
Terminal insomnia	1	0
<i>Dyssomnias</i>		
Dyssomnia	1	0
<i>Eating disorders NEC</i>		
Eating disorder	2	0
Selective eating disorder	1	0
<i>Emotional and mood disturbances NEC</i>		
Anger	3	0

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Earliest Reaction Date: 03-Apr-1990

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Dysphoria	1	0
Emotional disorder	6	0
Emotional distress	6	0
Euphoric mood	7	0
Irritability	46	0
Mood altered	10	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Fear of falling	1	0
Osmophobia	1	0
Phonophobia	1	0
Social fear	1	0
<i>Fluctuating mood symptoms</i>		
Mood swings	8	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	57	0
Hallucination, auditory	3	0
Hallucination, olfactory	2	0
Hallucination, tactile	1	0
Hallucination, visual	6	0
Hallucinations, mixed	1	0
<i>Increased physical activity levels</i>		
Restlessness	27	0
<i>Mental disorders NEC</i>		
Mental disorder	2	0
<i>Mental disorders due to a general medical condition NEC</i>		
Neuropsychiatric symptoms	1	0
<i>Mood alterations with depressive symptoms</i>		
Decreased interest	3	0
Depressed mood	64	0
Feeling of despair	1	0
Feelings of worthlessness	1	0
Negative thoughts	1	0
Sense of a foreshortened future	2	0
Tearfulness	6	0
<i>Mood alterations with manic symptoms</i>		
Hypomania	1	0
Mania	1	0
<i>Mood disorders NEC</i>		
Apathy	7	0
Laziness	1	0
Listless	4	0
<i>Narcolepsy and associated conditions</i>		
Hypnagogic hallucination	2	0
Sleep attacks	2	0
<i>Obsessive-compulsive disorders and symptoms</i>		
Obsessive-compulsive symptom	1	0
<i>Orgasmic disorders and disturbances</i>		
Anorgasmia	1	0
<i>Panic attacks and disorders</i>		
Panic attack	26	0
Panic disorder	3	0
Panic reaction	6	0
<i>Parasomnias</i>		

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Abnormal dreams	55	0
Confusional arousal	1	0
Nightmare	44	0
Parasomnia	1	0
Sleep terror	2	0
Perception disturbances NEC		
Autoscopy	2	0
Derealisation	4	0
Flashback	1	0
Illusion	1	0
Psychiatric elimination disorders		
Enuresis	4	0
Psychiatric symptoms NEC		
Hypervigilance	2	0
Trance	1	0
Psychotic disorder NEC		
Psychotic behaviour	1	0
Psychotic disorder	6	0
Sexual desire disorders		
Libido decreased	1	0
Libido increased	1	0
Loss of libido	2	0
Sleep disorders NEC		
Sleep disorder	47	0
Somatic symptom disorders		
Habit cough	5	0
Somatic symptom disorder	1	0
Vomiting psychogenic	1	0
Speech and language usage disturbances		
Disorganised speech	2	0
Logorrhoea	2	0
Speech articulation and rhythm disturbances		
Dysphemia	2	0
Lack of spontaneous speech	1	0
Pressure of speech	1	0
Stereotypies and automatisms		
Bruxism	3	0
Head banging	2	0
Stereotypy	1	0
Substance related and addictive disorders		
Alcoholic hangover	1	0
Suicidal and self-injurious behaviour		
Intentional self-injury	2	0
Suicidal ideation	1	0
Suicide attempt	1	0
Thinking disturbances		
Bradyphrenia	12	0
Tachyphrenia	1	0
Thinking abnormal	3	0
Psychiatric disorders SOC TOTAL	1499	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder discomfort	1	0
Bladder pain	2	0
Dysuria	11	0
Incontinence	10	0
Micturition disorder	1	0
Micturition urgency	6	0
Pollakiuria	18	0
Urethral pain	1	0
Urinary incontinence	18	0
Urinary retention	17	0
Urine flow decreased	1	0
<i>Bladder disorders NEC</i>		
Bladder disorder	3	0
<i>Genital and urinary tract disorders NEC</i>		
Urinary tract disorder	2	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
Glomerulonephritis minimal lesion	1	0
Nephrotic syndrome	3	0
<i>Myoneurogenic bladder disorders</i>		
Bladder dysfunction	1	0
Hypertonic bladder	1	0
Loss of bladder sensation	1	0
Neurogenic bladder	1	0
<i>Nephritis NEC</i>		
Nephritis	1	0
Tubulointerstitial nephritis	1	0
<i>Renal failure and impairment</i>		
Acute kidney injury	11	0
Anuria	1	0
Chronic kidney disease	2	0
Renal failure	4	0
Renal impairment	2	0
<i>Urinary abnormalities</i>		
Chromaturia	13	0
Haematuria	8	0
Proteinuria	3	0
Urine abnormality	5	0
Urine odour abnormal	3	0
<i>Urinary tract signs and symptoms NEC</i>		
Costovertebral angle tenderness	1	0
Cystitis-like symptom	1	0
Haemorrhage urinary tract	5	0
Nocturia	1	0
Polyuria	2	0
Renal pain	63	0
Urinary tract pain	1	0
Renal & urinary disorders SOC TOTAL	227	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Benign and malignant breast neoplasms</i>		
Breast cyst	2	0
<i>Breast disorders NEC</i>		
Breast mass	10	0
Gynaecomastia	1	0
<i>Breast signs and symptoms</i>		
Breast discomfort	2	0
Breast haematoma	1	0
Breast oedema	1	0
Breast pain	60	0
Breast swelling	13	0
Breast tenderness	8	0
Nipple pain	5	0
Nipple swelling	2	0
<i>Erection and ejaculation conditions and disorders</i>		
Erectile dysfunction	8	0
<i>Menopausal effects NEC</i>		
Menopausal symptoms	2	0
<i>Menopausal effects on the genitourinary tract</i>		
Postmenopausal haemorrhage	3	0
<i>Menstruation and uterine bleeding NEC</i>		
Dysfunctional uterine bleeding	1	0
Dysmenorrhoea	23	0
Menstrual disorder	26	0
Menstruation irregular	21	0
Metrorrhagia	11	0
Premenstrual pain	2	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	10	0
Hypomenorrhoea	15	0
Menstruation delayed	44	0
Oligomenorrhoea	1	0
<i>Menstruation with increased bleeding</i>		
Menorrhagia	52	0
Polymenorrhoea	8	0
<i>Ovarian and fallopian tube disorders NEC</i>		
Ovulation pain	3	0
<i>Pelvis and broad ligament disorders NEC</i>		
Adnexa uteri pain	3	0
Pelvic haemorrhage	3	0
<i>Penile disorders NEC (excl erection and ejaculation)</i>		
Penile swelling	3	0
Penis disorder	1	0
<i>Prostatic signs, symptoms and disorders NEC</i>		
Prostatomegaly	2	0
<i>Reproductive tract disorders NEC (excl neoplasms)</i>		
Genital haemorrhage	1	0
Genital ulceration	2	0
<i>Reproductive tract infections and inflammations NEC</i>		
Genital tract inflammation	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Genital pain	2	0
Pelvic discomfort	2	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Pelvic pain	10	0
Perineal pain	1	0
Scrotal disorders NEC		
Scrotal erythema	1	0
Scrotal exfoliation	1	0
Scrotal pain	3	0
Scrotal swelling	3	0
Sexual function and fertility disorders NEC		
Infertility	1	0
Spermatogenesis and semen disorders		
Haemospermia	1	0
Testicular and epididymal disorders NEC		
Testicular pain	7	0
Testicular swelling	3	0
Uterine disorders NEC		
Endometriosis	3	0
Uterine pain	1	0
Uterine tone disorders		
Uterine spasm	1	0
Vulvovaginal disorders NEC		
Vaginal haemorrhage	40	0
Vulval haemorrhage	1	0
Vulval ulceration	2	0
Vulvovaginal ulceration	1	0
Vulvovaginal signs and symptoms		
Vaginal discharge	2	0
Vulval oedema	1	0
Vulvovaginal burning sensation	1	0
Vulvovaginal pain	2	0
Vulvovaginal pruritus	1	0
Reproductive & breast disorders SOC TOTAL	442	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	1	0
Dyspnoea	969	2
Dyspnoea at rest	1	0
Dyspnoea exertional	9	1
Hyperventilation	14	0
Hypopnoea	19	0
Irregular breathing	6	0
Mouth breathing	3	0
Orthopnoea	3	0
Respiration abnormal	18	0
Respiratory arrest	5	0
Respiratory depression	1	0
Respiratory distress	5	0
Sleep apnoea syndrome	1	0
Tachypnoea	17	0
<i>Bronchial conditions NEC</i>		
Bronchial secretion retention	1	0
Bronchiectasis	4	0
<i>Bronchospasm and obstruction</i>		
Asthma	98	0
Asthma late onset	2	0
Bronchospasm	6	0
Chronic obstructive pulmonary disease	7	0
Obstructive airways disorder	1	0
Reversible airways obstruction	1	0
Wheezing	132	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	10	1
Respiratory acidosis	1	0
<i>Coughing and associated symptoms</i>		
Allergic cough	2	0
Cough	702	1
Cough decreased	2	0
Haemoptysis	7	0
Productive cough	41	0
Sputum discoloured	1	0
<i>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</i>		
Laryngeal disorder	1	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Epiglottic oedema	1	0
Laryngeal obstruction	1	0
Laryngospasm	1	0
Stridor	8	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Hypersensitivity pneumonitis	1	0
Pneumonia aspiration	5	3
Pneumonitis	9	3
Pulmonary sarcoidosis	1	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	3	0
Increased bronchial secretion	1	0

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Pleuritic pain	6	0
Pulmonary pain	30	0
Rales	2	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	65	0
Nasal inflammation	1	0
Rhinitis allergic	4	0
<i>Nasal disorders NEC</i>		
Epistaxis	171	0
Intranasal hyposaesthesia	1	0
Intranasal paraesthesia	1	0
Nasal disorder	1	0
Nasal dryness	6	0
Nasal odour	4	0
Nasal oedema	1	0
Nasal pruritus	4	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Allergic sinusitis	1	0
Paranasal sinus inflammation	1	0
Sinonasal obstruction	3	0
Sinus congestion	14	0
Sinus disorder	2	0
<i>Parenchymal lung disorders NEC</i>		
Atelectasis	1	0
Emphysema	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal erythema	3	0
Pharyngeal haemorrhage	1	0
Pharyngeal hyposaesthesia	12	0
Pharyngeal inflammation	3	0
Pharyngeal oedema	5	0
Pharyngeal paraesthesia	26	0
Pharyngeal swelling	84	0
Pharyngeal ulceration	6	0
Tonsillar erythema	1	0
Tonsillar haemorrhage	1	0
Tonsillar hypertrophy	25	0
Tonsillar inflammation	3	0
<i>Pleural infections and inflammations</i>		
Pleurisy	5	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	1	0
Pneumothorax	1	0
<i>Pulmonary hypertensions</i>		
Pulmonary hypertension	1	0
<i>Pulmonary oedemas</i>		
Pulmonary congestion	3	0
Pulmonary oedema	3	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	20	1
Pulmonary infarction	1	0
Pulmonary thrombosis	1	0
<i>Respiratory failures (excl neonatal)</i>		

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Acute respiratory failure	2	1
Respiratory failure	4	0
<i>Respiratory signs and symptoms NEC</i>		
Diaphragmalgia	1	0
Painful respiration	3	0
Respiratory symptom	4	0
<i>Respiratory tract disorders NEC</i>		
Aspiration	2	1
Respiratory disorder	3	0
Respiratory tract irritation	1	0
Respiratory tract oedema	1	0
<i>Thoracic musculoskeletal disorders</i>		
Respiratory muscle weakness	1	0
<i>Tracheal disorders (excl infections and neoplasms)</i>		
Tracheal pain	1	0
<i>Upper respiratory tract neoplasms</i>		
Tonsillar cyst	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	23	0
Catarrh	8	0
Choking	4	1
Dry throat	57	0
Dysphonia	46	0
Increased upper airway secretion	3	0
Increased viscosity of upper respiratory secretion	3	0
Nasal discharge discolouration	1	0
Nasal discomfort	14	0
Nasal obstruction	2	0
Oropharyngeal blistering	6	0
Oropharyngeal discomfort	21	0
Oropharyngeal pain	843	0
Paranasal sinus discomfort	10	0
Rhinalgia	6	0
Rhinorrhoea	216	0
Sinus pain	54	0
Sneezing	101	0
Snoring	2	0
Throat clearing	3	0
Throat irritation	77	0
Throat tightness	97	0
Upper airway obstruction	2	0
Upper-airway cough syndrome	2	0
Yawning	3	0
Respiratory disorders SOC TOTAL	4276	15

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	9	0
Acne cystic	1	0
Dermatitis acneiform	2	0
<i>Alopecias</i>		
Alopecia	14	0
Madarosis	1	0
<i>Angioedemas</i>		
Angioedema	70	0
Circumoral swelling	1	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	210	0
Hidradenitis	1	0
Hyperhidrosis	568	0
Miliaria	23	0
Night sweats	202	0
<i>Bullous conditions</i>		
Blister	83	0
Blood blister	4	0
Dermatitis bullous	4	0
Erythema multiforme	12	0
Fracture blisters	1	0
Pemphigoid	4	0
Pemphigus	2	0
Stevens-Johnson syndrome	2	0
Toxic epidermal necrolysis	2	1
<i>Connective tissue disorders</i>		
Dermatomyositis	2	0
<i>Dermal and epidermal conditions NEC</i>		
Acute febrile neutrophilic dermatosis	1	0
Dermatosis	1	0
Dry skin	50	0
Macule	2	0
Pain of skin	86	0
Papule	19	0
Pathergy reaction	1	0
Peau d'orange	2	0
Scab	2	0
Scar pain	4	0
Sensitive skin	51	0
Skin burning sensation	65	0
Skin discolouration	29	0
Skin discomfort	1	0
Skin disorder	1	0
Skin fissures	2	0
Skin indentation	2	0
Skin induration	2	0
Skin lesion	11	0
Skin necrosis	1	0
Skin odour abnormal	3	0
Skin reaction	37	0
Skin sensitisation	6	0
Skin swelling	29	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Skin tightness	13	0
Skin warm	99	0
Skin weeping	2	0
Sticky skin	1	0
Yellow skin	5	0
<i>Dermatitis and eczema</i>		
Dermatitis	35	0
Dermatitis allergic	66	0
Dermatitis atopic	8	0
Dermatitis diaper	1	0
Dyshidrotic eczema	3	0
Eczema	39	0
Eczema asteatotic	1	0
Eczema nummular	2	0
Eczema weeping	1	0
Perioral dermatitis	1	0
Skin irritation	32	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	12	0
Fixed eruption	1	0
Toxic skin eruption	1	0
<i>Erythemas</i>		
Erythema	760	0
Red man syndrome	1	0
<i>Exfoliative conditions</i>		
Dermatitis exfoliative	1	0
Exfoliative rash	4	0
Skin exfoliation	22	0
<i>Hyperkeratoses</i>		
Lichenoid keratosis	1	0
<i>Hyperpigmentation disorders</i>		
Ephelides	1	0
Skin hyperpigmentation	1	0
<i>Hypopigmentation disorders</i>		
Skin depigmentation	1	0
Skin hypopigmentation	1	0
<i>Lipodystrophies</i>		
Lipoatrophy	1	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
Nail discolouration	4	0
Nail disorder	1	0
Onychalgia	4	0
Splinter haemorrhages	1	0
<i>Panniculitides</i>		
Erythema nodosum	5	0
<i>Papulosquamous conditions</i>		
Erythema annulare	1	0
Lichen planus	1	0
Parapsoriasis	1	0
Pityriasis rosea	21	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	11	0
<i>Pigmentation changes NEC</i>		

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Haemosiderin stain	1	0
Pigmentation disorder	2	0
Pilar disorders NEC		
Piloerection	4	0
Pseudofolliculitis	1	0
Pruritus NEC		
Itching scar	4	0
Pruritus	1463	0
Psoriatic conditions		
Guttate psoriasis	1	0
Psoriasis	23	0
Pustular psoriasis	1	0
Purpura and related conditions		
Petechiae	24	0
Purpura	10	0
Rashes, eruptions and exanthems NEC		
Butterfly rash	1	0
Rash	1467	0
Rash erythematous	344	0
Rash macular	143	0
Rash maculo-papular	25	0
Rash morbilliform	8	0
Rash papular	85	0
Rash pruritic	323	0
Rash vesicular	14	0
Systemic lupus erythematosus rash	3	0
Rosaceas		
Rosacea	3	0
Scaly conditions		
Pityriasis	6	0
Skin and subcutaneous conditions NEC		
Cutaneous symptom	1	0
Skin mass	3	0
Skin and subcutaneous tissue ulcerations		
Scleroderma associated digital ulcer	1	0
Skin erosion	9	0
Skin ulcer	1	0
Skin cysts and polyps		
Dermal cyst	1	0
Skin haemorrhages		
Haemorrhage subcutaneous	2	0
Skin haemorrhage	2	0
Skin hyperplasias and hypertrophies		
Skin hypertrophy	1	0
Skin injuries and mechanical dermatoses		
Decubitus ulcer	1	0
Skin vasculitides		
Cutaneous vasculitis	1	0
Vasculitic rash	4	0
Skin vasomotor conditions		
Livedo reticularis	14	0
Urticarias		
Chronic spontaneous urticaria	1	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Cold urticaria	1	0
Idiopathic urticaria	1	0
Mechanical urticaria	1	0
Urticaria	509	0
Urticaria chronic	1	0
Urticaria papular	2	0
Urticaria thermal	2	0
Skin disorders SOC TOTAL	7308	1

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Reaction Name	Total	Fatal
Social circumstances		
<i>Criminal activity</i>		
Verbal abuse	1	0
<i>Disability issues</i>		
Bedridden	8	0
Breast prosthesis user	1	0
Immobile	4	0
Impaired driving ability	1	0
Loss of personal independence in daily activities	1	0
Sight disability	1	0
Sitting disability	1	0
<i>Economic circumstances</i>		
High income	1	0
Low income	1	0
<i>Educational issues</i>		
Illiteracy	1	0
<i>Pregnancy related circumstances</i>		
Breast feeding	1	0
<i>Tobacco use</i>		
Non-tobacco user	2	0
Social circumstances SOC TOTAL	24	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Bronchial and pulmonary therapeutic procedures</i>		
Airway secretion clearance therapy	1	0
<i>Contraceptive methods male</i>		
Condom	1	0
<i>Dietary and nutritional therapies</i>		
Diabetic diet	1	0
Medical diet	1	0
Nothing by mouth order	1	0
<i>Fertility and fertilisation interventions female</i>		
Endometrial scratching	1	0
<i>Gastrointestinal therapeutic procedures NEC</i>		
Prophylaxis of nausea and vomiting	7	0
<i>Haematological therapeutic procedures NEC</i>		
Anticoagulant therapy	1	0
<i>Immunisations</i>		
COVID-19 immunisation	20	0
Immunisation	7	0
<i>Joint therapeutic procedures</i>		
Joint surgery	1	0
<i>Limb therapeutic procedures</i>		
Limb immobilisation	2	0
Limb operation	1	0
<i>Mastectomies</i>		
Breast conserving surgery	1	0
<i>Prophylactic procedures NEC</i>		
Anaphylaxis 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	2	0
<i>Therapeutic procedures NEC</i>		
Abscess drainage	1	0
Anaphylaxis treatment	1	0
Bed rest	2	0
Fatigue management	1	0
Hospitalisation	2	0
Injection	6	0
Medication dilution	1	0
Product used for unknown indication	1	0
Therapy change	1	0
Surgical & medical procedures SOC TOTAL	67	0

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Earliest Reaction Date: 03-Apr-1990

Data Lock Date: 07-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Vascular disorders		
<i>Accelerated and malignant hypertension</i>		
Hypertensive crisis	1	0
<i>Aortic necrosis and vascular insufficiency</i>		
Aortic stenosis	1	0
<i>Arterial infections and inflammations</i>		
Arteritis	1	0
Giant cell arteritis	2	0
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	3	0
Labile blood pressure	2	0
<i>Bruising, ecchymosis and purpura</i>		
Achenbach syndrome	1	0
<i>Circulatory collapse and shock</i>		
CT hypotension complex	2	0
Circulatory collapse	27	0
Neurogenic shock	14	0
Peripheral circulatory failure	2	0
Shock	4	0
<i>Haemorrhages NEC</i>		
Haematoma	10	0
Haemorrhage	25	1
Venous haemorrhage	1	0
<i>Lymphangiopathies</i>		
Lymphocele	1	0
<i>Lymphoedemas</i>		
Lymphoedema	46	0
<i>Non-site specific embolism and thrombosis</i>		
Thrombosis	12	0
Venous thrombosis	1	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Haemorrhagic infarction	1	0
Vasospasm	1	0
<i>Non-site specific vascular disorders NEC</i>		
Superficial vein prominence	1	0
Vascular pain	3	0
Vasodilatation	5	0
Vein discolouration	1	0
Vein disorder	2	0
Vein rupture	2	0
<i>Peripheral embolism and thrombosis</i>		
Blue toe syndrome	4	0
Deep vein thrombosis	9	0
Pelvic venous thrombosis	1	0
Thrombophlebitis	5	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	16	0
Flushing	198	0
Hot flush	324	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	83	0
Peripheral ischaemia	3	0
Poor peripheral circulation	1	0
Raynaud's phenomenon	15	0

Case Series Drug Analysis Print

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

Report Run Date: 16-Mar-2021

Data Lock Date: 07-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
Vasoconstriction	1	0
Phlebitis NEC		
Phlebitis	4	0
Site specific vascular disorders NEC		
Pallor	80	0
Vascular hypertensive disorders NEC		
Diastolic hypertension	1	0
Essential hypertension	1	0
Hypertension	156	0
Systolic hypertension	1	0
Vascular hypotensive disorders		
Hypotension	108	0
Orthostatic hypotension	8	0
Vasculitides NEC		
Behcet's syndrome	2	0
MAGIC syndrome	1	0
Vasculitis	9	0
Vena caval embolism and thrombosis		
Vena cava embolism	1	0
Vena cava thrombosis	1	0
Vascular disorders SOC TOTAL	1205	1
TOTAL REACTIONS FOR DRUG	1008	237
TOTAL REPORTS	35325	
TOTAL FATAL OUTCOME REPORTS		237