

COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 09-Mar-2021
Data Lock Date: 08-Mar-2021 19:00:03

All UK spontaneous reports received between 9/12/20 and 28/02/21 for mRNA Pfizer/BioNTech vaccine analysis print

Case Series Drug Analysis Print

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

Report Run Date: 09-Mar-2021

Data Lock Date: 08-Mar-2021 19:00:03

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemias NEC</i>		
Anaemia	4	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	266	0
Lymphadenitis	42	0
Lymphadenopathy	1931	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	9	0
<i>Platelet disorders NEC</i>		
Platelet anisocytosis	1	0
<i>Spleen disorders</i>		
Splénomegaly	1	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	9	0
Thrombocytopenia	13	1
<i>Thrombocytoses</i>		
Thrombocytosis	2	0
Blood disorders SOC TOTAL	2294	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	536	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	7	0
Angina pectoris	14	0
Arteriospasm coronary	1	0
Myocardial infarction	23	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	6	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	14	0
Cardiac flutter	24	0
Extrasystoles	14	0
Postural orthostatic tachycardia syndrome	2	0
Tachycardia	312	0
<i>Right ventricular failures</i>		
Cor pulmonale	1	0
<i>Supraventricular arrhythmias</i>		
Arrhythmia supraventricular	5	0
Atrial fibrillation	52	0
Atrial flutter	1	0
Atrial tachycardia	2	0
Sinus bradycardia	2	0
Sinus tachycardia	25	0
Supraventricular tachycardia	11	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	39	15
Cardio-respiratory arrest	1	1

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Reaction Name	Total	Fatal
Cardiac disorders Cardiac disorders cont'd		
Pulseless electrical activity	2	0
Ventricular arrhythmia	1	0
Ventricular extrasystoles	4	0
Ventricular fibrillation	4	0
Ventricular tachycardia	1	0
Cardiac disorders SOC TOTAL	1153	26

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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	4	0
Ear discomfort	15	0
Ear disorder	3	0
Ear haemorrhage	1	0
Ear pain	211	0
Ear pruritus	2	0
Ear swelling	6	0
Otorrhoea	1	0
<i>Eustachian tube disorders</i>		
Eustachian tube disorder	1	0
Eustachian tube dysfunction	2	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	20	0
Deafness neurosensory	3	0
Deafness unilateral	3	0
Hypoacusis	29	0
Sudden hearing loss	7	0
<i>Hyperacusia</i>		
Hyperacusis	8	0
<i>Inner ear disorders NEC</i>		
Acute vestibular syndrome	1	0
Inner ear disorder	2	0
Meniere's disease	3	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	16	0
Tinnitus	196	0
Vertigo	258	0
Vertigo labyrinthine	4	0
Vertigo positional	18	0
<i>Middle ear infections and inflammations</i>		
Middle ear inflammation	1	0
Ear disorders SOC TOTAL	819	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>		
Adrenocortical insufficiency acute	3	0
<i>Endocrine abnormalities of puberty</i>		
Premature menarche	1	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	1	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	12	0

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Reaction Name	Total	Fatal
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	12	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	22	0
Excessive eye blinking	1	0
Eyelid ptosis	6	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Autoimmune uveitis	1	0
Iridocyclitis	5	0
Iritis	1	0
Uveitis	8	0
<i>Lacrimation disorders</i>		
Dry eye	29	0
Lacrimation increased	40	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	30	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>		
Eye disorder	10	0
Eye oedema	4	0
Eye pain	245	0
Eye swelling	129	0
Eye ulcer	1	0
Eyelid disorder	2	0
Eyelid pain	3	0
Eyelids pruritus	1	0
Ocular discomfort	7	0
Periorbital oedema	9	0

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Periorbital pain	1	0
Periorbital swelling	31	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye allergy	1	0
Eye discharge	7	0
Eye inflammation	4	0
Eye irritation	27	0
Eye pruritus	83	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	44	0
Eye paraesthesia	1	0
Foreign body sensation in eyes	8	0
Hypoaesthesia eye	4	0
Photophobia	100	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	27	0
Scintillating scotoma	1	0
Vision blurred	225	0
Visual brightness	1	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	15	0
Blindness transient	3	0

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Blindness unilateral	2	0
Central vision loss	1	0
Sudden visual loss	1	0
Visual acuity reduced	1	0
Visual impairment	72	0
Eye disorders SOC TOTAL	1398	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Abdominal findings abnormal</i>		
Gastrointestinal sounds abnormal	3	0
<i>Acute and chronic pancreatitis</i>		
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	5	0
Colitis ulcerative	6	0
Crohn's disease	8	0
<i>Dental disorders NEC</i>		
Teething	1	0
<i>Dental pain and sensation disorders</i>		
Dental discomfort	1	0
Dental paraesthesia	1	0
Hyperaesthesia teeth	7	0
Toothache	20	0
<i>Diaphragmatic hernias</i>		
Hiatus hernia	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	1547	4
Diarrhoea haemorrhagic	4	0
<i>Duodenal and small intestinal stenosis and obstruction</i>		
Small intestinal obstruction	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	83	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	54	0
Aerophagia	2	0
Flatulence	44	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
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Abdominal migraine	1	0
Abdominal pain	306	0
Abdominal pain lower	16	0
Abdominal pain upper	488	0
Abdominal rigidity	2	0
Abdominal tenderness	3	0
Gastrointestinal pain	29	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	46	0
Duodenogastric reflux	2	0
Gastric dilatation	2	0
Gastrooesophageal reflux disease	25	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	1	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	167	0
Acute abdomen	1	0
Anal incontinence	6	0
Breath odour	5	0
Dysphagia	50	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Defaecation urgency	2	0
Frequent bowel movements	9	0
Irritable bowel syndrome	18	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 pain	24	0
Gingival swelling	6	0
Gingivitis ulcerative	1	0
Noninfective gingivitis	1	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	6	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		

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Gastrointestinal disorders		
Gastric varices	1	0
Haemorrhoids	6	0
Intestinal haemorrhages		
Anal haemorrhage	4	0
Rectal haemorrhage	17	0
Small intestinal haemorrhage	3	0
Intestinal ulcers and perforation NEC		
Intestinal perforation	2	2
Malabsorption syndromes		
Coeliac disease	2	0
Steatorrhoea	1	0
Nausea and vomiting symptoms		
Discoloured vomit	4	0
Nausea	4423	1
Regurgitation	1	0
Retching	35	0
Vomiting	1201	2
Vomiting projectile	20	0
Non-site specific gastrointestinal haemorrhages		
Gastrointestinal haemorrhage	3	0
Haematemesis	15	2
Haematochezia	10	0
Melaena	5	0
Upper gastrointestinal haemorrhage	2	0
Oesophageal stenosis and obstruction		
Oesophageal stenosis	1	0
Oesophagitis (excl infective)		
Oesophagitis	1	0
Oral dryness and saliva altered		
Aptyalism	1	0
Dry mouth	171	0
Lip dry	13	0
Saliva altered	1	0
Salivary hypersecretion	13	0
Oral soft tissue disorders NEC		
Chapped lips	5	0
Cheilitis	10	0
Enlarged uvula	6	0
Lip blister	7	0
Lip disorder	2	0
Oral disorder	3	0
Oral lichen planus	1	0
Oral papule	1	0
Uvulitis	1	0
Oral soft tissue haemorrhages		
Mouth haemorrhage	2	0
Oral blood blister	5	0
Oral soft tissue signs and symptoms		
Anaesthesia oral	1	0
Hypoaesthesia oral	158	0
Lip discolouration	1	0
Lip erythema	1	0
Lip exfoliation	3	0

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Lip pain	18	0
Lip pruritus	5	0
Lip scab	1	0
Odynophagia	4	0
Oral discomfort	21	0
Oral dysaesthesia	1	0
Oral mucosal blistering	6	0
Oral mucosal eruption	7	0
Oral mucosal erythema	1	0
Oral mucosal exfoliation	2	0
Oral pain	49	0
Oral pruritus	7	0
Paraesthesia oral	418	0
Oral soft tissue swelling and oedema		
Lip oedema	3	0
Lip swelling	223	0
Mouth swelling	27	0
Oedema mouth	1	0
Palatal oedema	2	0
Palatal swelling	1	0
Peritoneal and retroperitoneal disorders		
Ascites	1	0
Peritoneal and retroperitoneal fibrosis and adhesions		
Abdominal adhesions	1	0
Rectal inflammations NEC		
Proctitis	1	0
Proctitis ulcerative	1	0
Salivary gland disorders NEC		
Salivary gland pain	2	0
Salivary gland enlargements		
Parotid gland enlargement	2	0
Submaxillary gland enlargement	4	0
Stomatitis and ulceration		
Aphthous ulcer	11	0
Lip ulceration	2	0
Mouth ulceration	105	0
Oral mucosa erosion	1	0
Palatal ulcer	1	0
Stomatitis	17	0
Tongue disorders		
Glossitis	3	0
Plicated tongue	2	0
Tongue disorder	13	0
Tongue haemorrhage	1	0
Tongue ulceration	7	0
Tongue signs and symptoms		
Glossodynia	65	0
Stiff tongue	1	0
Swollen tongue	180	0
Tongue blistering	4	0
Tongue coated	3	0
Tongue discolouration	5	0
Tongue discomfort	14	0

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Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Tongue dry	5	0
Tongue eruption	5	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	10534	12

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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 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	437	1
Chronic fatigue syndrome	7	0
Fatigue	6438	1
Malaise	1492	0
Sluggishness	3	0
<i>Body temperature altered</i>		
Hyperthermia	3	0
Hypothermia	13	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	95	95
Sudden death	14	14
<i>Febrile disorders</i>		
Hyperpyrexia	3	0
Pyrexia	5153	0
<i>Feelings and sensations NEC</i>		
Chills	3364	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Feeling abnormal	302	0
Feeling cold	367	0
Feeling drunk	17	0
Feeling hot	355	0
Feeling jittery	7	0
Feeling of body temperature change	101	0
Hangover	14	0
Hunger	6	0
Sensation of foreign body	18	0
Temperature intolerance	4	0
Thirst	81	0
Gait disturbances		
Gait disturbance	34	0
Gait inability	19	0
Loss of control of legs	2	0
General signs and symptoms NEC		
Condition aggravated	31	0
Crepitations	1	0
Crying	21	0
Disease recurrence	2	0
Energy increased	2	0
Exercise tolerance decreased	2	0
General physical health deterioration	3	0
Glassy eyes	2	0
Illness	442	1
Induration	2	0
Influenza like illness	780	0
Irritability postvaccinal	1	0
Local reaction	44	0
Multiple organ dysfunction syndrome	1	1
Nonspecific reaction	1	0
Peripheral swelling	786	0
Pre-existing condition improved	3	0
Screaming	2	0
Secretion discharge	4	0
Swelling	600	0
Swelling face	236	0
Implant and catheter site reactions		
Implant site pain	1	0
Implant site rash	1	0
Inflamations		
Inflammation	74	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
Injection site bruising	16	0

Case Series Drug Analysis Print

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

Report Run Date: 09-Mar-2021
 Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 08-Mar-2021 19:00:03
 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Injection site discolouration	2	0
Injection site discomfort	5	0
Injection site erythema	147	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	131	0
Injection site necrosis	2	0
Injection site oedema	9	0
Injection site pain	1119	0
Injection site paraesthesia	5	0
Injection site pruritus	69	0
Injection site rash	42	0
Injection site reaction	11	0
Injection site scab	2	0
Injection site scar	2	0
Injection site swelling	140	0
Injection site urticaria	7	0
Injection site vesicles	3	0
Injection site warmth	51	0
Interactions		
Alcohol interaction	2	0
Drug interaction	2	0
Mass conditions NEC		
Cyst	2	0
Mass	5	0
Nodule	5	0
Mucosal findings abnormal		
Oedema mucosal	1	0
Necrosis NEC		
Fat necrosis	1	0
Oedema NEC		
Face oedema	11	0
Localised oedema	11	0
Oedema	8	0
Oedema peripheral	14	0
Pain and discomfort NEC		
Axillary pain	316	0
Chest discomfort	386	0
Chest pain	507	0
Discomfort	37	0
Facial discomfort	6	0
Facial pain	59	0
Inflammatory pain	1	0
Non-cardiac chest pain	7	0
Pain	2019	0
Suprapubic pain	1	0
Tenderness	193	0
Therapeutic and nontherapeutic responses		

Case Series Drug Analysis Print

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

Report Run Date: 09-Mar-2021
 Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 08-Mar-2021 19:00:03
 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Adverse drug reaction	15	0
Drug ineffective	84	0
Immediate post-injection reaction	2	0
No reaction on previous exposure to drug	10	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	2	0
Shoulder injury related to vaccine administration	1	0
Vaccination site bruising	34	0
Vaccination site cyst	1	0
Vaccination site dermatitis	1	0
Vaccination site discolouration	5	0
Vaccination site discomfort	19	0
Vaccination site eczema	1	0
Vaccination site erythema	248	0
Vaccination site haemorrhage	6	0
Vaccination site hypersensitivity	1	0
Vaccination site hypoaesthesia	2	0
Vaccination site induration	34	0
Vaccination site inflammation	29	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	70	0
Vaccination site movement impairment	23	0
Vaccination site oedema	3	0
Vaccination site pain	885	0
Vaccination site paraesthesia	4	0
Vaccination site pruritus	54	0
Vaccination site rash	38	0
Vaccination site reaction	12	0
Vaccination site scab	1	0
Vaccination site swelling	261	0
Vaccination site ulcer	1	0
Vaccination site urticaria	5	0
Vaccination site vesicles	2	0
Vaccination site warmth	139	0
Withdrawal and rebound effects		
Drug withdrawal syndrome	3	0
Withdrawal syndrome	1	0
General disorders SOC TOTAL	28915	114

Case Series Drug Analysis Print

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

Report Run Date: 09-Mar-2021

Data Lock Date: 08-Mar-2021 19:00:03

Earliest Reaction Date: 19-Jan-2001

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	3	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>		
Hepatitis	2	0
Liver injury	2	0
Hepatic disorders SOC TOTAL	18	0

Case Series Drug Analysis Print

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

Report Run Date: 09-Mar-2021
Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 08-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Immune system disorders		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	5	0
<i>Allergic conditions NEC</i>		
Allergic oedema	4	0
Allergy to arthropod bite	1	0
Hypersensitivity	246	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	15	0
Contrast media reaction	1	0
Drug hypersensitivity	6	0
Food allergy	2	0
Reaction to excipient	1	0
Reaction to preservatives	3	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	197	0
Anaphylactic shock	7	0
Anaphylactoid reaction	8	0
Anaphylactoid shock	2	0
<i>Atopic disorders</i>		
Seasonal allergy	2	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	4	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	528	0

Case Series Drug Analysis Print

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

Report Run Date: 09-Mar-2021

Data Lock Date: 08-Mar-2021 19:00:03

Earliest Reaction Date: 19-Jan-2001

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	57	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	7	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	437	22
COVID-19 pneumonia	10	3
Coronavirus infection	4	0
Suspected COVID-19	29	0
<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	22	0
<i>Epstein-Barr viral infections</i>		
Infectious mononucleosis	1	0
<i>Eye and eyelid infections</i>		

Case Series Drug Analysis Print

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

Report Run Date: 09-Mar-2021

Data Lock Date: 08-Mar-2021 19:00:03

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Infections Infections cont'd		
Conjunctivitis	24	0
Eye abscess	1	0
Eye infection	4	0
Hordeolum	4	0
Periorbital infection	1	0
Female reproductive tract infections		
Bartholinitis	1	0
Vulval abscess	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	6	0
Herpes ophthalmic	1	0
Herpes simplex	3	0
Herpes simplex reactivation	1	0
Herpes virus infection	3	0
Herpes zoster	231	0
Herpes zoster oticus	3	0
Ophthalmic herpes zoster	1	0
Oral herpes	82	0
Infections NEC		
Abscess	3	0
Abscess limb	1	0
Abscess soft tissue	1	0
Infection	65	0
Injection site abscess	1	0
Injection site infection	3	0
Localised infection	7	0
Lymph gland infection	2	0
Respiratory tract infection	1	0
Vaccination site abscess	2	0
Vaccination site infection	7	0
Vestibulitis	1	0
Influenza viral infections		
Influenza	415	0
Lower respiratory tract and lung infections		
Bronchitis	4	0
Lower respiratory tract infection	36	5
Pneumonia	19	6
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		
Soft tissue infection	1	0
Neisseria infections		
Gonorrhoea	1	0
Sepsis, bacteraemia, viraemia and fungaemia NEC		
Sepsis	13	1

Case Series Drug Analysis Print

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

Report Run Date: 09-Mar-2021
Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 08-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Infections Infections cont'd		
Urosepsis	2	0
<i>Skin structures and soft tissue infections</i>		
Acne pustular	1	0
Folliculitis	3	0
Paronychia	1	0
Pustule	4	0
Rash pustular	3	0
Skin infection	5	0
Subcutaneous abscess	1	0
Vaccination site pustule	1	0
<i>Staphylococcal infections</i>		
Furuncle	7	0
Pneumonia staphylococcal	1	0
Staphylococcal abscess	1	0
<i>Streptococcal infections</i>		
Pharyngitis streptococcal	3	0
<i>Trypanosomal infections</i>		
African trypanosomiasis	1	0
<i>Upper respiratory tract infections</i>		
Laryngitis	2	0
Nasopharyngitis	194	0
Pharyngitis	5	0
Rhinitis	15	0
Sinusitis	23	0
Tonsillitis	20	0
Tracheitis	1	0
<i>Urinary tract infections</i>		
Cystitis	12	0
Kidney infection	5	0
Pyelonephritis	1	0
Urinary tract infection	32	0
<i>Vascular infections</i>		
Haematoma infection	1	0
Lymphangitis	1	0
<i>Viral infections NEC</i>		
Conjunctivitis viral	1	0
Eye infection viral	1	0
Gastroenteritis viral	5	0
Meningitis viral	1	0
Pneumonia viral	1	1
Post viral fatigue syndrome	8	0
Sweating fever	38	0
Vestibular neuronitis	5	0
Viral infection	1	0
Viral labyrinthitis	2	0
Viral pharyngitis	4	0
Viral rash	14	0
Viral tonsillitis	1	0
Infections SOC TOTAL	2059	38

Case Series Drug Analysis Print

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

Report Run Date: 09-Mar-2021
Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 08-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>Chest and respiratory tract injuries NEC</i>		
Chest crushing	1	0
<i>Conditions caused by cold</i>		
Chillblains	15	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	24	0
Maternal exposure during pregnancy	41	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	3	0
Heat stroke	1	0
<i>Limb fractures and dislocations</i>		
Atypical femur fracture	1	0
Clavicle fracture	2	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
<i>Musculoskeletal procedural complications</i>		
Post laminectomy syndrome	1	0
<i>Nerve injuries NEC</i>		
Nerve injury	6	0

Case Series Drug Analysis Print

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

Report Run Date: 09-Mar-2021

Data Lock Date: 08-Mar-2021 19:00:03

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
<i>Neurological and psychiatric procedural complications</i>		
Procedural dizziness	5	0
<i>Non-site specific injuries NEC</i>		
Bite	1	0
Electric shock	3	0
Fall	40	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	20	0
Post procedural complication	2	0
<i>Off label uses</i>		
Off label use	6	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	9	0
Incomplete course of vaccination	1	0
Product administered at inappropriate site	4	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	129	0
Nail avulsion	1	0
Scar	2	0
Scratch	1	0
Skin abrasion	3	0
<i>Stoma complications</i>		
Gastrointestinal stoma complication	1	0
Stoma site discharge	1	0
Stoma site extravasation	1	0
Stoma site haemorrhage	1	0

Case Series Drug Analysis Print

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Report Run Date: 09-Mar-2021

Data Lock Date: 08-Mar-2021 19:00:03

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
<i>Thermal burns</i>		
Airway burns	1	0
Burn oesophageal	1	0
Burn of internal organs	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	17	0
Vaccination failure	1	0
Injuries SOC TOTAL	458	1

Case Series Drug Analysis Print

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Report Run Date: 09-Mar-2021
Earliest Reaction Date: 19-Jan-2001

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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	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	24	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose	3	0
Blood glucose abnormal	4	0
Blood glucose decreased	7	0
Blood glucose fluctuation	3	0
Blood glucose increased	39	0
Glycosylated haemoglobin increased	1	0
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	1	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	5	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	6	0
International normalised ratio increased	22	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	2	0
<i>Heart rate and pulse investigations</i>		
Heart rate	61	0
Heart rate abnormal	4	0
Heart rate decreased	11	0
Heart rate increased	168	0
Heart rate irregular	22	0
Pulse abnormal	7	0
Radial pulse abnormal	1	0
<i>Immunology analyses NEC</i>		
Antibody test	1	0
Antibody test abnormal	2	0

Case Series Drug Analysis Print

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

Report Run Date: 09-Mar-2021
Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 08-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Immunology test	3	0
Immunology skin tests NEC		
Skin test positive	1	0
Investigations NEC		
Blood test abnormal	2	0
Polymerase chain reaction positive	16	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	2	0
Liver function test increased	6	0
Transaminases increased	1	0
Metabolism tests NEC		
Blood ketone body	1	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
Ophthalmic function diagnostic procedures		
Intraocular pressure increased	1	0
Physical examination procedures and organ system status		
Body temperature	92	0
Body temperature abnormal	19	0
Body temperature decreased	14	0
Body temperature fluctuation	9	0
Body temperature increased	169	0
Body temperature normal	1	0
Breath sounds abnormal	1	0
Grip strength	2	0
Grip strength decreased	2	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	13	0
Temperature difference of extremities	2	0
Weight	1	0
Weight decreased	12	0
Weight increased	2	0
Pituitary analyses anterior		

Case Series Drug Analysis Print

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Earliest Reaction Date: 19-Jan-2001

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Blood growth hormone	2	0
Blood thyroid stimulating hormone increased	2	0
Platelet analyses		
Platelet count decreased	5	0
Protein analyses NEC		
C-reactive protein increased	4	0
Red blood cell analyses		
Haematocrit	1	0
Haemoglobin decreased	4	0
Respiratory and pulmonary function diagnostic procedures		
Forced expiratory volume increased	2	0
Peak expiratory flow rate decreased	1	0
Vital capacity	1	0
Respiratory tract and thoracic histopathology procedures		
Sputum abnormal	2	0
Skeletal and cardiac muscle analyses		
Blood creatine phosphokinase increased	1	0
Troponin increased	3	0
Therapeutic drug monitoring analyses		
Analgesic drug level	1	0
Anticoagulation drug level below therapeutic	4	0
Anticoagulation drug level increased	1	0
Drug level decreased	1	0
Thyroid analyses		
Thyroid function test abnormal	1	0
Tri-iodothyronine	1	0
Tri-iodothyronine decreased	2	0
Tissue enzyme analyses NEC		
Blood alkaline phosphatase increased	1	0
Urinalysis NEC		
Blood urine	2	0
Blood urine present	5	0
Glucose urine present	1	0
pH urine	2	0
pH urine increased	1	0
Urinary tract function analyses NEC		
Urine output	4	0
Urine output decreased	3	0
Urine output increased	1	0
Vascular tests NEC (incl blood pressure)		
Blood pressure abnormal	3	0
Blood pressure decreased	11	0
Blood pressure increased	74	0
Blood pressure measurement	8	0
Blood pressure systolic decreased	1	0
Blood pressure systolic increased	1	0
Virus identification and serology		
Coronavirus test	1	0
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	1	0

Case Series Drug Analysis Print

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Report Run Date: 09-Mar-2021

Data Lock Date: 08-Mar-2021 19:00:03

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
SARS-CoV-2 test	11	0
SARS-CoV-2 test false positive	1	0
SARS-CoV-2 test negative	2	0
SARS-CoV-2 test positive	36	0
Viral test	1	0
<i>Vitamin analyses</i>		
Blood folate decreased	1	0
<i>White blood cell analyses</i>		
White blood cell count decreased	2	0
White blood cell count increased	1	0
Investigations SOC TOTAL	1073	0

Case Series Drug Analysis Print

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Earliest Reaction Date: 19-Jan-2001

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	2	0
Decreased appetite	381	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
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	4	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	19	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	1	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	22	0
Insulin resistance	1	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	32	0
Postprandial hypoglycaemia	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
Hypokalaemia	1	0
Hypokalaemic syndrome	1	0
<i>Sodium imbalance</i>		

Case Series Drug Analysis Print

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

Report Run Date: 09-Mar-2021

Data Lock Date: 08-Mar-2021 19:00:03

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
Hyponatraemia	4	0
<i>Total fluid volume decreased</i>		
Dehydration	44	0
<i>Total fluid volume increased</i>		
Fluid retention	4	0
Hypervolaemia	1	0
Metabolic disorders SOC TOTAL	587	1

Case Series Drug Analysis Print

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

Report Run Date: 09-Mar-2021
Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 08-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	56	0
Arthropathy	5	0
Polyarthrits	2	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	92	0
Bone swelling	2	0
Coccydynia	1	0
Pain in jaw	86	0
Spinal pain	12	0
<i>Bursal disorders</i>		
Bursitis	9	0
<i>Cartilage disorders</i>		
Costochondritis	11	0
<i>Connective tissue disorders NEC</i>		
Polymyalgia rheumatica	5	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	1	0
Periarthritis	13	0
Temporomandibular joint syndrome	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	2647	0
Jaw clicking	2	0
Joint effusion	5	0
Joint noise	4	0
Joint range of motion decreased	2	0
Joint stiffness	58	0
Joint swelling	80	0
Joint vibration	1	0
Joint warmth	3	0
<i>Lupus erythematosus (incl subtypes)</i>		
Systemic lupus erythematosus	3	0
<i>Muscle infections and inflammations</i>		
Antisynthetase syndrome	1	0
Myositis	3	0
Polymyositis	1	0
<i>Muscle pains</i>		
Fibromyalgia	17	0
Myalgia	3888	0

Case Series Drug Analysis Print

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Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Muscle & tissue disorders		
Myofascial pain syndrome	5	0
Muscle related signs and symptoms NEC		
Muscle atrophy	1	0
Muscle discomfort	1	0
Muscle disorder	2	0
Muscle fatigue	110	0
Muscle spasms	180	0
Muscle swelling	8	0
Muscle tightness	19	0
Muscle twitching	85	0
Muscle tone abnormalities		
Muscle rigidity	7	0
Nuchal rigidity	4	0
Torticollis	2	0
Trismus	9	0
Muscle weakness conditions		
Muscular weakness	204	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	306	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	568	0
Flank pain	8	0
Limb discomfort	408	0
Musculoskeletal chest pain	38	0
Musculoskeletal discomfort	22	0
Musculoskeletal pain	18	0
Neck pain	474	0
Pain in extremity	3152	0
Rheumatic disorder	1	0
Myopathies		
Rhabdomyolysis	3	0
Osteoarthropathies		
Osteoarthritis	6	0
Psoriatic arthropathies		
Psoriatic arthropathy	2	0
Rheumatoid arthropathies		
Rheumatoid arthritis	22	0
Soft tissue disorders NEC		
Axillary mass	41	0
Groin pain	28	0
Neck mass	8	0
Spondyloarthropathies		
Ankylosing spondylitis	3	0
Arthritis reactive	7	0

Case Series Drug Analysis Print

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Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
<i>Synovial disorders</i>		
Synovial cyst	5	0
Synovitis	3	0
<i>Tendon disorders</i>		
Enthesopathy	1	0
Tendon pain	2	0
Tendonitis	4	0
Tenosynovitis	1	0
Tenosynovitis stenosaurs	1	0
<i>Trunk deformities</i>		
Drooping shoulder syndrome	1	0
Muscle & tissue disorders SOC TOTAL	12823	0

Case Series Drug Analysis Print

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Report Run Date: 09-Mar-2021

Data Lock Date: 08-Mar-2021 19:00:03

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Neoplasms		
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	2	0
<i>Lymphomas unspecified NEC</i>		
Lymphoma	5	0
<i>Metastases to specified sites</i>		
Metastases to lymph nodes	2	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	24	0

Case Series Drug Analysis Print

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Earliest Reaction Date: 19-Jan-2001

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MedDRA Version: MedDRA 23.1

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	2	0
<i>Absence seizures</i>		
Petit mal epilepsy	5	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	7	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	55	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	1	0
<i>Coordination and balance disturbances</i>		
Ataxia	1	0
Balance disorder	92	0
Coordination abnormal	11	0
Dysstasia	14	0
Nystagmus	1	0
<i>Cortical dysfunction NEC</i>		
Aphasia	16	0
Neurologic neglect syndrome	1	0
<i>Cranial nerve disorders NEC</i>		
Cranial nerve disorder	2	0
<i>Dementia (excl Alzheimer's type)</i>		

Case Series Drug Analysis Print

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

Report Run Date: 09-Mar-2021
 Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 08-Mar-2021 19:00:03
 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Dementia	4	0
Dementia with Lewy bodies	1	0
Demyelinating disorders NEC		
Demyelination	1	0
Disturbances in consciousness NEC		
Altered state of consciousness	4	0
Consciousness fluctuating	2	0
Depressed level of consciousness	8	0
Lethargy	732	0
Loss of consciousness	91	0
Sedation	3	0
Somnolence	237	0
Stupor	1	0
Syncope	316	0
Dyskinesias and movement disorders NEC		
Akathisia	1	0
Bradykinesia	4	0
Dyskinesia	6	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
Dystonias		
Dystonia	5	0
Writer's cramp	1	0
Encephalopathies NEC		
Encephalopathy	1	0
Posterior reversible encephalopathy syndrome	1	0
Eye movement disorders		
IIIrd nerve paralysis	2	0
VIth nerve paralysis	3	0
Facial cranial nerve disorders		
Facial nerve disorder	1	0
Facial paralysis	168	0
Facial paresis	25	0
Facial spasm	12	0
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	9	0
Headaches NEC		
Cervicogenic headache	2	0
Cluster headache	56	0
Cold-stimulus headache	2	0
Drug withdrawal headache	1	0
Exertional headache	3	0
Headache	8571	0
Medication overuse headache	2	0
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

Case Series Drug Analysis Print

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Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Sinus headache	111	0
Tension headache	139	0
Thunderclap headache	1	0
Vascular headache	5	0
<i>Lumbar spinal cord and nerve root disorders</i>		
Sciatica	11	0
<i>Memory loss (excl dementia)</i>		
Amnesia	15	0
Memory impairment	30	0
Transient global amnesia	2	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	13	0
Disturbance in attention	66	0
Mental impairment	10	0
<i>Migraine headaches</i>		
Hemiplegic migraine	3	0
Migraine	612	0
Migraine with aura	35	0
Migraine without aura	1	0
Retinal migraine	10	0
Typical aura without headache	1	0
Vestibular migraine	2	0
<i>Mononeuropathies</i>		
Carpal tunnel syndrome	4	0
Mononeuropathy	1	0
Nerve compression	3	0
Peroneal nerve palsy	2	0
Sciatic nerve neuropathy	1	0
<i>Multiple sclerosis acute and progressive</i>		
Multiple sclerosis	6	0
Multiple sclerosis relapse	7	0
<i>Muscle tone abnormal</i>		
Hypotonia	4	0
Muscle tone disorder	1	0
Serotonin syndrome	1	0
Stiff leg syndrome	1	0
<i>Myelitis (incl infective)</i>		
Myelitis transverse	8	0
<i>Narcolepsy and hypersomnia</i>		
Hypersomnia	21	0
Narcolepsy	2	0
<i>Nervous system disorders NEC</i>		
Nervous system disorder	1	0
<i>Neurologic visual problems NEC</i>		
Hemianopia	1	0
Tunnel vision	4	0
Visual field defect	3	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	2534	0
Dizziness exertional	12	0
Dizziness postural	222	0
Drooling	3	0
Head discomfort	60	0

Case Series Drug Analysis Print

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Report Run Date: 09-Mar-2021
Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 08-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Hyporesponsive to stimuli	1	0
Inability to crawl	1	0
Myoclonus	4	0
Neurological symptom	8	0
Persistent postural-perceptual dizziness	4	0
Presyncope	160	0
Slow response to stimuli	2	0
Unresponsive to stimuli	16	1
Neuromuscular disorders NEC		
Muscle contractions involuntary	5	0
Muscle spasticity	4	0
Neuromuscular pain	1	0
Neuromuscular junction dysfunction		
Myasthenia gravis	2	0
Olfactory nerve disorders		
Anosmia	65	0
Hyposmia	6	0
Parosmia	53	0
Optic nerve disorders NEC		
Optic neuritis	5	0
Paraesthesias and dysaesthesias		
Burning feet syndrome	1	0
Burning sensation	106	0
Dysaesthesia	3	0
Formication	10	0
Hemiparaesthesia	1	0
Hyperaesthesia	22	0
Hypoaesthesia	572	0
Paraesthesia	840	0
Synaesthesia	1	0
Paralysis and paresis (excl cranial nerve)		
Diplegia	1	1
Hemiparesis	12	0
Hemiplegia	5	0
Locked-in syndrome	1	0
Monoparesis	18	0
Monoplegia	14	0
Paralysis	19	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
Temporal lobe epilepsy	1	0
Peripheral neuropathies NEC		
Neuritis	2	0
Neuropathy peripheral	21	0
Peripheral sensory neuropathy	3	0
Seizures and seizure disorders NEC		
Atonic seizures	2	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Clonic convulsion	1	0
Epilepsy	29	0
Febrile convulsion	1	0
Partial seizures	4	0
Psychogenic seizure	3	0
Seizure	108	1
Seizure cluster	1	0
Seizure like phenomena	1	0
Status epilepticus	1	0
Tonic clonic movements	1	0
Tonic convulsion	6	0
Sensory abnormalities NEC		
Ageusia	139	0
Allodynia	4	0
Aura	7	0
Dysgeusia	384	0
Hypergeusia	1	0
Neuralgia	88	0
Phantom limb syndrome	1	0
Post herpetic neuralgia	3	0
Restless legs syndrome	25	0
Sensory disturbance	15	0
Sensory loss	10	0
Taste disorder	76	0
Sleep disturbances NEC		
Poor quality sleep	49	0
Sleep deficit	2	0
Speech and language abnormalities		
Dysarthria	35	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	20	0
Tremor (excl congenital)		
Essential tremor	1	0
Resting tremor	1	0
Tremor	455	0
Trigeminal disorders		
Facial neuralgia	9	0
Numb chin syndrome	1	0
Trigeminal nerve disorder	1	0
Trigeminal neuralgia	12	0
Nervous system disorders SOC TOTAL	18059	17

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	18	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	34	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	3	0
<i>Product quality issues NEC</i>		
Product origin unknown	1	0
null SOC TOTAL	14	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Affect alterations NEC</i>		
Affect lability	1	0
Flat affect	2	0
Inappropriate affect	1	0
<i>Anxiety symptoms</i>		
Agitation	27	0
Anxiety	125	0
Immunisation anxiety related reaction	1	0
Nervousness	55	0
Stress	2	0
Tension	11	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	49	0
<i>Communications disorders</i>		
Communication disorder	2	0
<i>Confusion and disorientation</i>		
Confusional state	192	0
Disorientation	64	0
<i>Decreased physical activity levels</i>		
Catatonia	1	0
<i>Deliria</i>		
Delirium	35	0
<i>Delusional symptoms</i>		
Delusion	1	0
<i>Depressive disorders</i>		
Depression	36	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	254	0
Middle insomnia	6	0
Terminal insomnia	1	0
<i>Dyssomnias</i>		
Dyssomnia	1	0
<i>Eating disorders NEC</i>		
Eating disorder	2	0
<i>Emotional and mood disturbances NEC</i>		
Anger	3	0
Dysphoria	1	0
Emotional disorder	6	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Emotional distress	6	0
Euphoric mood	7	0
Irritability	45	0
Mood altered	9	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	7	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	56	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	26	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	58	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	1	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	25	0
Panic disorder	2	0
Panic reaction	6	0
<i>Parasomnias</i>		
Abnormal dreams	52	0
Confusional arousal	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Nightmare	41	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	5	0
Sexual desire disorders		
Libido decreased	1	0
Libido increased	1	0
Loss of libido	1	0
Sleep disorders NEC		
Sleep disorder	42	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	1	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
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	1409	0

Case Series Drug Analysis Print

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

Report Run Date: 09-Mar-2021
Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 08-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder discomfort	1	0
Bladder pain	1	0
Dysuria	11	0
Incontinence	10	0
Micturition disorder	1	0
Micturition urgency	6	0
Pollakiuria	16	0
Urethral pain	1	0
Urinary incontinence	16	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	2	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	10	0
Anuria	2	0
Chronic kidney disease	1	0
Renal failure	4	0
Renal impairment	1	0
<i>Urinary abnormalities</i>		
Chromaturia	12	0
Haematuria	7	0
Proteinuria	2	0
Urine abnormality	5	0
Urine odour abnormal	3	0
<i>Urinary tract signs and symptoms NEC</i>		
Costovertebral angle tenderness	1	0
Haemorrhage urinary tract	4	0
Nocturia	1	0
Polyuria	2	0
Renal pain	61	0
Urinary tract pain	1	0
Renal & urinary disorders SOC TOTAL	212	0

Case Series Drug Analysis Print

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

Report Run Date: 09-Mar-2021

Data Lock Date: 08-Mar-2021 19:00:03

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

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	9	0
Gynaecomastia	1	0
<i>Breast signs and symptoms</i>		
Breast discomfort	2	0
Breast haematoma	1	0
Breast oedema	1	0
Breast pain	52	0
Breast swelling	11	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	2	0
<i>Menstruation and uterine bleeding NEC</i>		
Dysmenorrhoea	20	0
Menstrual disorder	20	0
Menstruation irregular	19	0
Metrorrhagia	11	0
Premenstrual pain	2	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	8	0
Hypomenorrhoea	12	0
Menstruation delayed	38	0
Oligomenorrhoea	1	0
<i>Menstruation with increased bleeding</i>		
Menorrhagia	45	0
Polymenorrhoea	6	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	2	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
Pelvic pain	8	0

Case Series Drug Analysis Print

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

Report Run Date: 09-Mar-2021

Data Lock Date: 08-Mar-2021 19:00:03

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
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	6	0
Testicular swelling	3	0
Uterine disorders NEC		
Endometriosis	2	0
Uterine pain	1	0
Uterine tone disorders		
Uterine spasm	1	0
Vulvovaginal disorders NEC		
Vaginal haemorrhage	39	0
Vulval ulceration	2	0
Vulvovaginal signs and symptoms		
Vaginal discharge	2	0
Vulval oedema	1	0
Vulvovaginal burning sensation	1	0
Vulvovaginal pain	1	0
Vulvovaginal pruritus	1	0
Reproductive & breast disorders SOC TOTAL	389	0

Case Series Drug Analysis Print

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

Report Run Date: 09-Mar-2021
Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 08-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	1	0
Dyspnoea	917	2
Dyspnoea at rest	1	0
Dyspnoea exertional	8	1
Hyperventilation	12	0
Hypopnoea	16	0
Irregular breathing	6	0
Mouth breathing	3	0
Orthopnoea	3	0
Respiration abnormal	17	0
Respiratory arrest	5	0
Respiratory depression	1	0
Respiratory distress	4	0
Sleep apnoea syndrome	1	0
Tachypnoea	15	0
<i>Bronchial conditions NEC</i>		
Bronchial secretion retention	1	0
Bronchiectasis	4	0
<i>Bronchospasm and obstruction</i>		
Asthma	87	0
Asthma late onset	1	0
Bronchospasm	6	0
Chronic obstructive pulmonary disease	6	0
Obstructive airways disorder	1	0
Reversible airways obstruction	1	0
Wheezing	120	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	10	1
<i>Coughing and associated symptoms</i>		
Allergic cough	1	0
Cough	662	1
Cough decreased	1	0
Haemoptysis	7	0
Productive cough	38	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	4	2
Pneumonitis	9	3
Pulmonary sarcoidosis	1	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	3	0
Increased bronchial secretion	1	0
Pleuritic pain	6	0

Case Series Drug Analysis Print

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Report Run Date: 09-Mar-2021

Data Lock Date: 08-Mar-2021 19:00:03

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Pulmonary pain	28	0
Rales	2	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	61	0
Nasal inflammation	1	0
Rhinitis allergic	4	0
<i>Nasal disorders NEC</i>		
Epistaxis	159	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	3	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	77	0
Pharyngeal ulceration	6	0
Tonsillar erythema	1	0
Tonsillar haemorrhage	1	0
Tonsillar hypertrophy	24	0
Tonsillar inflammation	3	0
<i>Pleural infections and inflammations</i>		
Pleurisy	4	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	1	0
Pneumothorax	1	0
<i>Pulmonary oedemas</i>		
Pulmonary congestion	3	0
Pulmonary oedema	3	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	15	1
Pulmonary infarction	1	0
Pulmonary thrombosis	1	0
<i>Respiratory failures (excl neonatal)</i>		
Acute respiratory failure	2	1
Respiratory failure	2	0
<i>Respiratory signs and symptoms NEC</i>		

Case Series Drug Analysis Print

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

Report Run Date: 09-Mar-2021
 Earliest Reaction Date: 19-Jan-2001

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 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Diaphragmalgia	1	0
Painful respiration	3	0
Respiratory symptom	4	0
<i>Respiratory tract disorders NEC</i>		
Aspiration	2	1
Respiratory disorder	2	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	21	0
Catarrh	8	0
Choking	4	1
Dry throat	52	0
Dysphonia	42	0
Increased upper airway secretion	3	0
Increased viscosity of upper respiratory secretion	3	0
Nasal discharge discolouration	1	0
Nasal discomfort	13	0
Nasal obstruction	2	0
Oropharyngeal blistering	6	0
Oropharyngeal discomfort	21	0
Oropharyngeal pain	781	0
Paranasal sinus discomfort	10	0
Rhinalgia	6	0
Rhinorrhoea	194	0
Sinus pain	51	0
Sneezing	94	0
Snoring	2	0
Throat clearing	3	0
Throat irritation	72	0
Throat tightness	89	0
Upper airway obstruction	2	0
Upper-airway cough syndrome	2	0
Yawning	3	0
Respiratory disorders SOC TOTAL	3986	14

Case Series Drug Analysis Print

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Data Lock Date: 08-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	8	0
Acne cystic	1	0
Dermatitis acneiform	1	0
<i>Alopecias</i>		
Alopecia	13	0
Madarosis	1	0
<i>Angioedemas</i>		
Angioedema	62	0
Circumoral swelling	1	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	188	0
Hyperhidrosis	537	0
Miliaria	20	0
Night sweats	189	0
<i>Bullous conditions</i>		
Blister	76	0
Blood blister	3	0
Dermatitis bullous	4	0
Erythema multiforme	10	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	1	0
<i>Dermal and epidermal conditions NEC</i>		
Acute febrile neutrophilic dermatosis	1	0
Dermatosis	1	0
Dry skin	46	0
Macule	2	0
Pain of skin	86	0
Papule	19	0
Pathergy reaction	1	0
Peau d'orange	2	0
Scar pain	4	0
Sensitive skin	50	0
Skin burning sensation	61	0
Skin discolouration	27	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	33	0
Skin sensitisation	5	0
Skin swelling	25	0
Skin tightness	13	0
Skin warm	92	0

Case Series Drug Analysis Print

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Report Run Date: 09-Mar-2021
Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 08-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Skin weeping	2	0
Sticky skin	1	0
Yellow skin	5	0
<i>Dermatitis and eczema</i>		
Dermatitis	32	0
Dermatitis allergic	58	0
Dermatitis atopic	7	0
Dermatitis diaper	1	0
Dyshidrotic eczema	3	0
Eczema	34	0
Eczema asteatotic	1	0
Eczema nummular	2	0
Eczema weeping	1	0
Perioral dermatitis	1	0
Skin irritation	31	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	723	0
Red man syndrome	1	0
<i>Exfoliative conditions</i>		
Dermatitis exfoliative	1	0
Exfoliative rash	4	0
Skin exfoliation	21	0
<i>Hyperkeratoses</i>		
Lichenoid keratosis	1	0
<i>Hyperpigmentation disorders</i>		
Ephelides	1	0
Skin hyperpigmentation	1	0
<i>Hypopigmentation disorders</i>		
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	19	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	11	0
<i>Pigmentation changes NEC</i>		
Haemosiderin stain	1	0
Pigmentation disorder	2	0
<i>Pilar disorders NEC</i>		

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Piloerection	4	0
Pseudofolliculitis	1	0
Pruritus NEC		
Itching scar	4	0
Pruritus	1360	0
Psoriatic conditions		
Psoriasis	21	0
Pustular psoriasis	1	0
Purpura and related conditions		
Petechiae	24	0
Purpura	9	0
Rashes, eruptions and exanthems NEC		
Butterfly rash	1	0
Rash	1367	0
Rash erythematous	315	0
Rash macular	132	0
Rash maculo-papular	22	0
Rash morbilliform	8	0
Rash papular	79	0
Rash pruritic	300	0
Rash vesicular	13	0
Systemic lupus erythematosus rash	3	0
Rosaceas		
Rosacea	3	0
Scaly conditions		
Pityriasis	5	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	2	0
Skin vasomotor conditions		
Livedo reticularis	13	0
Urticarias		
Chronic spontaneous urticaria	1	0
Cold urticaria	1	0
Idiopathic urticaria	1	0
Mechanical urticaria	1	0
Urticaria	474	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Urticaria chronic	1	0
Urticaria papular	2	0
Urticaria thermal	2	0
Skin disorders SOC TOTAL	6809	1

Case Series Drug Analysis Print

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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
Sight disability	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	20	0

Case Series Drug Analysis Print

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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	6	0
<i>Immunisations</i>		
COVID-19 immunisation	17	0
Immunisation	5	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	4	0
Medication dilution	1	0
Product used for unknown indication	1	0
Therapy change	1	0
Surgical & medical procedures SOC TOTAL	58	0

Case Series Drug Analysis Print

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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>Circulatory collapse and shock</i>		
CT hypotension complex	2	0
Circulatory collapse	27	0
Neurogenic shock	13	0
Peripheral circulatory failure	2	0
Shock	3	0
<i>Haemorrhages NEC</i>		
Haematoma	10	0
Haemorrhage	22	1
Venous haemorrhage	1	0
<i>Lymphangiopathies</i>		
Lymphocele	1	0
<i>Lymphoedemas</i>		
Lymphoedema	40	0
<i>Non-site specific embolism and thrombosis</i>		
Thrombosis	10	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	2	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	8	0
Thrombophlebitis	4	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	14	0
Flushing	190	0
Hot flush	305	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	77	0
Peripheral ischaemia	3	0
Poor peripheral circulation	1	0
Raynaud's phenomenon	12	0
Vasoconstriction	1	0
<i>Phlebitis NEC</i>		
Phlebitis	4	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Vascular disorders <i>Vascular disorders cont'd</i>		
<i>Site specific vascular disorders NEC</i>		
Pallor	69	0
<i>Vascular hypertensive disorders NEC</i>		
Diastolic hypertension	1	0
Essential hypertension	1	0
Hypertension	150	0
Systolic hypertension	1	0
<i>Vascular hypotensive disorders</i>		
Hypotension	99	0
Orthostatic hypotension	7	0
<i>Vasculitides NEC</i>		
Behcet's syndrome	1	0
Vasculitis	8	0
<i>Vena caval embolism and thrombosis</i>		
Vena cava embolism	1	0
Vena cava thrombosis	1	0
Vascular disorders SOC TOTAL	1119	1
TOTAL REACTIONS FOR DRUG	94809	227
TOTAL REPORTS	33207	
TOTAL FATAL OUTCOME REPORTS		227