

COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 12-Feb-2021
Data Lock Date: 11-Feb-2021 19:00:03

All UK spontaneous reports received between 09/12/20 and 07/02/21 for mRNA Pfizer/BioNTech vaccine analysis print

Case Series Drug Analysis Print

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

Report Run Date: 12-Feb-2021
 Earliest Reaction Date: 19-Jan-2001

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 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemias NEC</i>		
Anaemia	3	0
<i>Anaemias haemolytic immune</i>		
Autoimmune haemolytic anaemia	1	0
<i>Bleeding tendencies</i>		
Increased tendency to bruise	3	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	208	0
Lymphadenitis	30	0
Lymphadenopathy	1420	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	6	0
<i>Platelet disorders NEC</i>		
Platelet anisocytosis	1	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	4	0
Thrombocytopenia	7	0
<i>Thrombocytoses</i>		
Thrombocytosis	1	0
Blood disorders SOC TOTAL	1689	0

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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>		
Palpitations	365	0
<i>Coronary artery disorders NEC</i>		
Coronary artery disease	1	1
<i>Heart failures NEC</i>		
Cardiac failure	2	0
Cardiopulmonary failure	1	1
<i>Ischaemic coronary artery disorders</i>		
Acute myocardial infarction	6	0
Angina pectoris	10	0
Myocardial infarction	16	3
<i>Left ventricular failures</i>		
Left ventricular failure	1	0
<i>Myocardial disorders NEC</i>		
Left ventricular dysfunction	1	0
Myocardial oedema	1	0
Right ventricular enlargement	1	0
<i>Noninfectious myocarditis</i>		
Myocarditis	5	0
<i>Noninfectious pericarditis</i>		
Pericarditis	4	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	13	0
Bradycardia	13	0
Cardiac flutter	13	0
Extrasystoles	10	0
Postural orthostatic tachycardia syndrome	1	0
Tachycardia	263	0
<i>Supraventricular arrhythmias</i>		
Arrhythmia supraventricular	2	0
Atrial fibrillation	34	1
Atrial tachycardia	2	0
Sinus bradycardia	1	0
Sinus tachycardia	23	0
Supraventricular tachycardia	11	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	27	10
Cardio-respiratory arrest	1	1
Pulseless electrical activity	2	0
Ventricular extrasystoles	2	0
Ventricular fibrillation	4	0
Ventricular tachycardia	1	0
Cardiac disorders SOC TOTAL	842	17

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Neurological disorders congenital NEC</i>		
Familial hemiplegic migraine	1	0
Congenital disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear canal erythema	1	0
Ear congestion	2	0
Ear discomfort	11	0
Ear disorder	2	0
Ear pain	146	0
Ear pruritus	1	0
Ear swelling	4	0
Otorrhoea	1	0
<i>Eustachian tube disorders</i>		
Eustachian tube disorder	1	0
<i>External ear disorders NEC</i>		
Red ear syndrome	1	0
<i>Hearing losses</i>		
Deafness	13	0
Hypoacusis	19	0
Sudden hearing loss	2	0
<i>Hyperacusia</i>		
Hyperacusis	8	0
<i>Inner ear disorders NEC</i>		
Acute vestibular syndrome	1	0
Inner ear disorder	2	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	11	0
Tinnitus	121	0
Vertigo	173	0
Vertigo labyrinthine	2	0
Vertigo positional	14	0
<i>Middle ear infections and inflammations</i>		
Middle ear inflammation	1	0
Ear disorders SOC TOTAL	537	0

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Endocrine disorders		
<i>Adrenal cortical hypofunctions</i>		
Adrenocortical insufficiency acute	1	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	1	0
Endocrine disorders SOC TOTAL	4	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	7	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	8	0
<i>Corneal infections, oedemas and inflammations</i>		
Keratitis	1	0
Ulcerative keratitis	1	0
<i>Eyelid movement disorders</i>		
Blepharospasm	14	0
Excessive eye blinking	1	0
Eyelid ptosis	4	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Autoimmune uveitis	1	0
Iridocyclitis	5	0
Iritis	1	0
Uveitis	6	0
<i>Lacrimation disorders</i>		
Dry eye	16	0
Lacrimation increased	24	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Blepharitis	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	21	0
<i>Lid, lash and lacrimal structural disorders</i>		
Eyelid exfoliation	1	0
<i>Ocular bleeding and vascular disorders NEC</i>		
Eye haemorrhage	1	0
<i>Ocular disorders NEC</i>		
Eye disorder	10	0
Eye oedema	3	0
Eye pain	171	0
Eye swelling	94	0
Eye ulcer	1	0
Eyelid disorder	1	0
Eyelid pain	2	0
Eyelids pruritus	1	0
Ocular discomfort	6	0
Periorbital oedema	7	0
Periorbital pain	1	0
Periorbital swelling	24	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye allergy	1	0
Eye discharge	6	0

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Eye disorders Eye disorders cont'd		
Eye inflammation	3	0
Eye irritation	19	0
Eye pruritus	56	0
Limbal swelling	1	0
Ocular hyperaemia	41	0
Ocular nerve and muscle disorders		
Binocular eye movement disorder	1	0
Extraocular muscle paresis	1	0
Eye movement disorder	5	0
Ophthalmoplegia	1	0
Strabismus	1	0
Ocular sensation disorders		
Abnormal sensation in eye	5	0
Asthenopia	36	0
Eye paraesthesia	1	0
Foreign body sensation in eyes	6	0
Hypoaesthesia eye	1	0
Photophobia	70	0
Optic disc abnormalities NEC		
Papilloedema	1	0
Pupil disorders		
Miosis	1	0
Mydriasis	2	0
Pupillary disorder	1	0
Pupils unequal	2	0
Retinal bleeding and vascular disorders (excl retinopathy)		
Retinal vein occlusion	2	0
Retinal structural change, deposit and degeneration		
Maculopathy	1	0
Scleral infections, irritations and inflammations		
Episcleritis	3	0
Visual disorders NEC		
Diplopia	19	0
Halo vision	4	0
Metamorphopsia	2	0
Oscillopsia	1	0
Photopsia	16	0
Vision blurred	156	0
Visual brightness	1	0
Visual impairment and blindness (excl colour blindness)		
Blindness	9	0
Blindness transient	2	0
Central vision loss	1	0
Visual acuity reduced	1	0
Visual impairment	51	0
Eye disorders SOC TOTAL	978	0

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Gastrointestinal disorders		
<i>Abdominal findings abnormal</i>		
Gastrointestinal sounds abnormal	2	0
<i>Acute and chronic pancreatitis</i>		
Pancreatitis	1	0
Pancreatitis necrotising	1	0
<i>Anal and rectal disorders NEC</i>		
Anal sphincter atony	1	0
<i>Anal and rectal pains</i>		
Proctalgia	2	0
<i>Anal and rectal signs and symptoms</i>		
Anal spasm	1	0
Anorectal discomfort	2	0
<i>Benign oral cavity neoplasms</i>		
Mouth cyst	1	0
<i>Colitis (excl infective)</i>		
Colitis	2	0
Colitis ulcerative	2	0
Crohn's disease	4	0
<i>Dental disorders NEC</i>		
Teething	1	0
<i>Dental pain and sensation disorders</i>		
Dental discomfort	1	0
Hyperaesthesia teeth	5	0
Toothache	11	0
<i>Diaphragmatic hernias</i>		
Hiatus hernia	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	1092	1
Diarrhoea haemorrhagic	3	0
<i>Duodenal and small intestinal stenosis and obstruction</i>		
Small intestinal obstruction	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	50	0
Epigastric discomfort	3	0
Eructation	10	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	3	0
Faeces discoloured	6	0
Faeces pale	2	0
Faeces soft	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	36	0
Aerophagia	2	0
Flatulence	34	0
<i>Gastritis (excl infective)</i>		
Gastritis	8	0
Reflux gastritis	3	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	223	0
Abdominal pain lower	11	0
Abdominal pain upper	339	0
Abdominal rigidity	1	0
Abdominal tenderness	3	0

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Gastrointestinal pain	22	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	23	0
Duodenogastric reflux	2	0
Gastroesophageal reflux disease	16	0
<i>Gastrointestinal disorders NEC</i>		
Functional gastrointestinal disorder	2	0
Gastric disorder	2	0
Gastrointestinal disorder	2	0
<i>Gastrointestinal dyskinetic disorders</i>		
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	114	0
Anal incontinence	6	0
Breath odour	5	0
Dysphagia	34	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Defaecation urgency	2	0
Frequent bowel movements	9	0
Irritable bowel syndrome	9	0
Oesophageal spasm	1	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	4	0
Gingival discomfort	2	0
Gingival pain	14	0
Gingival swelling	3	0
Gingivitis ulcerative	1	0
Noninfective gingivitis	1	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	5	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Gastric varices	1	0
Haemorrhoids	3	0
<i>Intestinal haemorrhages</i>		
Anal haemorrhage	3	0
Rectal haemorrhage	11	0
Small intestinal haemorrhage	1	0
<i>Intestinal ulcers and perforation NEC</i>		
Intestinal perforation	2	2
<i>Malabsorption syndromes</i>		
Steatorrhoea	1	0

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Nausea and vomiting symptoms</i>		
Discoloured vomit	3	0
Nausea	3363	1
Regurgitation	1	0
Retching	26	0
Vomiting	894	2
Vomiting projectile	11	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Gastrointestinal haemorrhage	2	0
Haematemesis	14	2
Haematochezia	3	0
Melaena	4	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	126	0
Lip dry	9	0
Salivary hypersecretion	10	0
<i>Oral soft tissue disorders NEC</i>		
Chapped lips	4	0
Cheilitis	8	0
Enlarged uvula	3	0
Lip blister	6	0
Lip disorder	2	0
Oral disorder	3	0
Oral papule	1	0
Uvulitis	1	0
<i>Oral soft tissue haemorrhages</i>		
Mouth haemorrhage	1	0
Oral blood blister	4	0
<i>Oral soft tissue signs and symptoms</i>		
Hypoaesthesia oral	112	0
Lip discolouration	1	0
Lip erythema	1	0
Lip exfoliation	3	0
Lip pain	13	0
Lip pruritus	4	0
Lip scab	1	0
Odynophagia	2	0
Oral discomfort	15	0
Oral mucosal blistering	6	0
Oral mucosal eruption	5	0
Oral mucosal erythema	1	0
Oral mucosal exfoliation	2	0
Oral pain	36	0
Oral pruritus	4	0
Paraesthesia oral	325	0
<i>Oral soft tissue swelling and oedema</i>		
Lip oedema	3	0

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Lip swelling	179	0
Mouth swelling	20	0
Oedema mouth	1	0
Palatal oedema	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	1	0
Submaxillary gland enlargement	4	0
<i>Stomatitis and ulceration</i>		
Aphthous ulcer	7	0
Lip ulceration	2	0
Mouth ulceration	68	0
Oral mucosa erosion	1	0
Palatal ulcer	1	0
Stomatitis	7	0
<i>Tongue disorders</i>		
Glossitis	3	0
Plicated tongue	2	0
Tongue disorder	10	0
Tongue haemorrhage	1	0
Tongue ulceration	7	0
<i>Tongue signs and symptoms</i>		
Glossodynia	47	0
Stiff tongue	1	0
Swollen tongue	126	0
Tongue blistering	2	0
Tongue coated	2	0
Tongue discolouration	4	0
Tongue discomfort	8	0
Tongue dry	4	0
Tongue eruption	4	0
Tongue erythema	1	0
Tongue movement disturbance	1	0
Tongue oedema	9	0
Tongue rough	2	0
Tongue spasm	2	0
Gastrointestinal disorders SOC TOTAL	7749	8

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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 inflammation	1	0
Administration site pain	3	0
Administration site warmth	1	0
Puncture site bruise	5	0
Puncture site pain	3	0
Puncture site swelling	1	0
Vessel puncture site bruise	1	0
<i>Adverse effect absent</i>		
No adverse event	3	0
<i>Application and instillation site reactions</i>		
Application site bruise	1	0
Application site erythema	1	0
Application site haemorrhage	1	0
Application site pain	2	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	327	1
Chronic fatigue syndrome	2	0
Fatigue	4797	1
Malaise	1134	0
Sluggishness	3	0
<i>Body temperature altered</i>		
Hypothermia	10	0
Temperature regulation disorder	4	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	83	83
Sudden death	12	12
<i>Febrile disorders</i>		
Hyperpyrexia	3	0
Pyrexia	4193	0
<i>Feelings and sensations NEC</i>		
Chills	2678	0
Feeling abnormal	214	0
Feeling cold	273	0
Feeling drunk	13	0
Feeling hot	294	0
Feeling jittery	7	0
Feeling of body temperature change	86	0
Hangover	5	0
Hunger	4	0
Sensation of foreign body	14	0
Temperature intolerance	2	0
Thirst	58	0

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General disorders General disorders cont'd		
<i>Gait disturbances</i>		
Gait disturbance	22	0
Gait inability	13	0
Loss of control of legs	1	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	20	0
Crying	9	0
Disease recurrence	1	0
Energy increased	2	0
Exercise tolerance decreased	2	0
General physical health deterioration	2	0
Glassy eyes	2	0
Illness	318	0
Induration	2	0
Influenza like illness	581	0
Local reaction	34	0
Peripheral swelling	564	0
Pre-existing condition improved	2	0
Screaming	2	0
Secretion discharge	3	0
Swelling	458	0
Swelling face	158	0
<i>Inflammations</i>		
Inflammation	59	0
Systemic inflammatory response syndrome	1	0
<i>Infusion site reactions</i>		
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
<i>Injection site reactions</i>		
Injected limb mobility decreased	8	0
Injection site bruising	13	0
Injection site discolouration	2	0
Injection site discomfort	4	0
Injection site erythema	119	0
Injection site haemorrhage	2	0
Injection site hypoaesthesia	5	0
Injection site induration	1	0
Injection site inflammation	10	0
Injection site joint pain	6	0
Injection site mass	109	0
Injection site necrosis	1	0
Injection site oedema	6	0
Injection site pain	886	0
Injection site paraesthesia	4	0
Injection site pruritus	56	0
Injection site rash	23	0
Injection site reaction	10	0
Injection site scab	2	0
Injection site scar	2	0
Injection site swelling	113	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Injection site urticaria	5	0
Injection site vesicles	2	0
Injection site warmth	38	0
Interactions		
Alcohol interaction	2	0
Drug interaction	2	0
Mass conditions NEC		
Cyst	1	0
Mass	4	0
Nodule	3	0
Necrosis NEC		
Fat necrosis	1	0
Oedema NEC		
Face oedema	7	0
Localised oedema	9	0
Oedema	6	0
Oedema peripheral	13	0
Pain and discomfort NEC		
Axillary pain	224	0
Chest discomfort	288	0
Chest pain	362	0
Discomfort	27	0
Facial discomfort	6	0
Facial pain	41	0
Non-cardiac chest pain	6	0
Pain	1619	0
Suprapubic pain	1	0
Tenderness	137	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	55	0
Adverse reaction	1	0
Drug ineffective	77	0
Immediate post-injection reaction	2	0
No reaction on previous exposure to drug	7	0
Therapeutic product effect delayed	1	0
Therapeutic product effect increased	1	0
Therapeutic response unexpected	8	0
Treatment failure	1	0
Ulcers NEC		
Ulcer	2	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	1	0
Shoulder injury related to vaccine administration	1	0
Vaccination site bruising	31	0
Vaccination site dermatitis	1	0
Vaccination site discolouration	5	0
Vaccination site discomfort	17	0
Vaccination site eczema	1	0
Vaccination site erythema	206	0
Vaccination site haemorrhage	4	0
Vaccination site hypoaesthesia	1	0
Vaccination site induration	31	0
Vaccination site inflammation	27	0

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General disorders General disorders cont'd		
Vaccination site irritation	3	0
Vaccination site joint discomfort	2	0
Vaccination site joint erythema	4	0
Vaccination site joint movement impairment	10	0
Vaccination site joint pain	19	0
Vaccination site joint swelling	2	0
Vaccination site joint warmth	1	0
Vaccination site lymphadenopathy	1	0
Vaccination site mass	52	0
Vaccination site movement impairment	19	0
Vaccination site oedema	3	0
Vaccination site pain	784	0
Vaccination site paraesthesia	4	0
Vaccination site pruritus	51	0
Vaccination site rash	31	0
Vaccination site reaction	10	0
Vaccination site swelling	223	0
Vaccination site ulcer	1	0
Vaccination site urticaria	5	0
Vaccination site vesicles	2	0
Vaccination site warmth	114	0
<i>Withdrawal and rebound effects</i>		
Withdrawal syndrome	1	0
General disorders SOC TOTAL	22521	98

Case Series Drug Analysis Print

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

Report Run Date: 12-Feb-2021

Data Lock Date: 11-Feb-2021 19:00:03

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Hepatic disorders		
<i>Cholestasis and jaundice</i>		
Jaundice	1	0
<i>Hepatic vascular disorders</i>		
Hepatic artery embolism	1	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	5	0
Liver tenderness	1	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Hepatitis	1	0
Liver injury	1	0
Hepatic disorders SOC TOTAL	10	0

Case Series Drug Analysis Print

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

Report Run Date: 12-Feb-2021

Data Lock Date: 11-Feb-2021 19:00:03

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Immune system disorders		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	1	0
<i>Allergic conditions NEC</i>		
Allergic oedema	2	0
Allergy to arthropod bite	1	0
Hypersensitivity	175	0
Serum sickness	2	0
Type I hypersensitivity	1	0
Type IV hypersensitivity reaction	2	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergic reaction to excipient	1	0
Allergy to chemicals	1	0
Allergy to vaccine	14	0
Drug hypersensitivity	3	0
Food allergy	1	0
Reaction to preservatives	3	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	137	0
Anaphylactic shock	4	0
Anaphylactoid reaction	8	0
Anaphylactoid shock	2	0
<i>Atopic disorders</i>		
Seasonal allergy	1	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	2	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	3	0
Immune system disorder	2	0
Immune-mediated adverse reaction	1	0
Immune system disorders SOC TOTAL	367	0

Case Series Drug Analysis Print

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

Report Run Date: 12-Feb-2021

Data Lock Date: 11-Feb-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
Dysentery	1	0
Gastroenteritis	5	0
<i>Aspergillus infections</i>		
Bronchopulmonary aspergillosis	1	0
<i>Bacterial infections NEC</i>		
Arthritis bacterial	1	0
Bacterial diarrhoea	1	0
Cellulitis	49	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	3	0
<i>Candida infections</i>		
Anal candidiasis	1	0
Candida infection	2	0
Oral candidiasis	8	0
Vulvovaginal candidiasis	7	0
<i>Central nervous system and spinal infections</i>		
Encephalitis	3	0
Meningitis	1	0
Myelitis	1	0
<i>Clostridia infections</i>		
Clostridium difficile infection	1	0
<i>Coronavirus infections</i>		
Asymptomatic COVID-19	6	0
COVID-19	331	15
COVID-19 pneumonia	7	2
Coronavirus infection	5	0
Suspected COVID-19	24	0
<i>Coxiella infections</i>		
Q fever	5	0
<i>Dental and oral soft tissue infections</i>		
Abscess oral	2	0
Gingivitis	2	0
Parotitis	4	0
Sialoadenitis	1	0
<i>Ear infections</i>		
Ear infection	8	0
Labyrinthitis	12	0
<i>Epstein-Barr viral infections</i>		
Infectious mononucleosis	1	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	17	0
Eye abscess	1	0
Eye infection	2	0
Hordeolum	3	0
Periorbital infection	1	0

Case Series Drug Analysis Print

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

Report Run Date: 12-Feb-2021
Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 11-Feb-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
<i>Female reproductive tract infections</i>		
Vulval abscess	1	0
<i>Hepatobiliary and spleen infections</i>		
Biliary sepsis	1	0
<i>Herpes viral infections</i>		
Disseminated varicella zoster virus infection	1	0
Genital herpes	2	0
Herpes ophthalmic	1	0
Herpes simplex	1	0
Herpes simplex reactivation	1	0
Herpes virus infection	3	0
Herpes zoster	125	0
Herpes zoster oticus	1	0
Ophthalmic herpes zoster	1	0
Oral herpes	51	0
<i>Infections NEC</i>		
Abscess	2	0
Abscess limb	1	0
Infection	55	0
Injection site abscess	1	0
Injection site infection	2	0
Localised infection	3	0
Lymph gland infection	2	0
Respiratory tract infection	1	0
Vaccination site abscess	2	0
Vaccination site infection	7	0
<i>Influenza viral infections</i>		
Influenza	287	0
<i>Lower respiratory tract and lung infections</i>		
Bronchitis	2	0
Lower respiratory tract infection	23	5
Pneumonia	12	4
Sputum purulent	1	0
<i>Male reproductive tract infections</i>		
Epididymitis	1	0
Orchitis	1	0
<i>Muscle and soft tissue infections</i>		
Soft tissue infection	1	0
<i>Neisseria infections</i>		
Gonorrhoea	1	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Sepsis	8	0
Urosepsis	2	0
<i>Skin structures and soft tissue infections</i>		
Acne pustular	1	0
Folliculitis	2	0
Pustule	3	0
Rash pustular	1	0
Skin infection	4	0
Subcutaneous abscess	1	0
Vaccination site pustule	1	0
<i>Staphylococcal infections</i>		
Furuncle	2	0

Case Series Drug Analysis Print

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

Report Run Date: 12-Feb-2021

Data Lock Date: 11-Feb-2021 19:00:03

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Infections Infections cont'd		
Staphylococcal abscess	1	0
<i>Streptococcal infections</i>		
Pharyngitis streptococcal	2	0
<i>Trypanosomal infections</i>		
African trypanosomiasis	1	0
<i>Upper respiratory tract infections</i>		
Laryngitis	1	0
Nasopharyngitis	140	0
Pharyngitis	4	0
Rhinitis	14	0
Sinusitis	10	0
Tonsillitis	15	0
Tracheitis	1	0
<i>Urinary tract infections</i>		
Cystitis	6	0
Kidney infection	3	0
Pyelonephritis	1	0
Urinary tract infection	19	0
<i>Vascular infections</i>		
Haematoma infection	1	0
<i>Viral infections NEC</i>		
Conjunctivitis viral	1	0
Eye infection viral	1	0
Gastroenteritis viral	4	0
Post viral fatigue syndrome	4	0
Sweating fever	32	0
Vestibular neuronitis	3	0
Viral infection	1	0
Viral labyrinthitis	2	0
Viral pharyngitis	3	0
Viral rash	10	0
Viral tonsillitis	1	0
Infections SOC TOTAL	1436	26

Case Series Drug Analysis Print

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

Report Run Date: 12-Feb-2021
Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 11-Feb-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
<i>Anaesthetic and allied procedural complications</i>		
Delayed recovery from anaesthesia	1	0
<i>Chest and respiratory tract injuries NEC</i>		
Chest crushing	1	0
<i>Conditions caused by cold</i>		
Chillblains	8	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	4	0
Foetal exposure during pregnancy	1	0
Maternal exposure during breast feeding	9	0
Maternal exposure during pregnancy	18	0
<i>Eye injuries NEC</i>		
Eye contusion	3	0
Eye injury	2	0
Injury corneal	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>Medication errors, product use errors and issues NEC</i>		
Medication error	1	0
Product use issue	2	0
Vaccination error	1	0
Wrong technique in product usage process	1	0
<i>Muscle, tendon and ligament injuries</i>		
Epicondylitis	1	0
Muscle injury	1	0
Muscle strain	3	0
<i>Musculoskeletal procedural complications</i>		
Post laminectomy syndrome	1	0
<i>Nerve injuries NEC</i>		
Nerve injury	3	0
<i>Neurological and psychiatric procedural complications</i>		
Procedural dizziness	4	0
<i>Non-site specific injuries NEC</i>		
Bite	1	0
Electric shock	3	0
Fall	33	1
Wound	1	0
Wound complication	3	0
<i>Non-site specific procedural complications</i>		
Incision site pain	1	0
Infusion related reaction	2	0
Injection related reaction	9	0
Post procedural complication	2	0
<i>Off label uses</i>		
Off label use	2	0

Case Series Drug Analysis Print

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

Report Run Date: 12-Feb-2021
 Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 11-Feb-2021 19:00:03
 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
<i>Overdoses NEC</i>		
Overdose	7	0
<i>Peripheral nerve injuries</i>		
Ulnar nerve injury	1	0
<i>Poisoning and toxicity</i>		
Poisoning	1	0
<i>Product administration errors and issues</i>		
Accidental overdose	1	0
Contraindicated product administered	1	0
Inappropriate schedule of product administration	5	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 preparation errors and issues</i>		
Product preparation issue	3	0
<i>Radiation injuries</i>		
Sunburn	1	0
<i>Site specific injuries NEC</i>		
Face crushing	1	0
Head injury	1	0
Limb injury	2	0
<i>Skin injuries NEC</i>		
Contusion	87	0
Scar	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
<i>Thermal burns</i>		
Burn oesophageal	1	0
Burn of internal organs	1	0
Burns second degree	2	0
Thermal burn	2	0
<i>Underdoses NEC</i>		
Underdose	1	0
<i>Vaccination related complications</i>		
Vaccination complication	12	0
Injuries SOC TOTAL	281	1

Case Series Drug Analysis Print

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

Report Run Date: 12-Feb-2021
Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 11-Feb-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Investigations		
<i>Adrenal cortex tests</i>		
Cortisol decreased	1	0
<i>Blood gas and acid base analyses</i>		
Blood lactic acid	1	0
Blood lactic acid increased	2	0
Blood pH increased	1	0
Oxygen consumption decreased	1	0
Oxygen saturation	4	0
Oxygen saturation decreased	18	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose	1	0
Blood glucose decreased	4	0
Blood glucose fluctuation	1	0
Blood glucose increased	19	0
Glycosylated haemoglobin increased	1	0
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	1	0
<i>Cardiac function diagnostic procedures</i>		
Central venous pressure	1	0
<i>Central nervous system imaging procedures</i>		
Magnetic resonance imaging brain	4	0
<i>Chemistry analyses NEC</i>		
Inflammatory marker increased	1	0
<i>Coagulation and bleeding analyses</i>		
Fibrin D dimer increased	1	0
International normalised ratio abnormal	1	0
International normalised ratio decreased	4	0
International normalised ratio increased	16	0
<i>ECG investigations</i>		
Electrocardiogram ST segment elevation	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	37	0
Heart rate abnormal	3	0
Heart rate decreased	9	0
Heart rate increased	127	0
Heart rate irregular	13	0
Pulse abnormal	6	0
Radial pulse abnormal	1	0
<i>Immunology analyses NEC</i>		
Antibody test	1	0
Immunology test	3	0
<i>Investigations NEC</i>		
Blood test abnormal	2	0
Polymerase chain reaction positive	6	0
Systemic lupus erythematosus disease activity index increased	1	0
<i>Liver function analyses</i>		
Alanine aminotransferase increased	2	0
Gamma-glutamyltransferase increased	1	0
Hepatic enzyme increased	1	0

Case Series Drug Analysis Print

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

Report Run Date: 12-Feb-2021
 Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 11-Feb-2021 19:00:03
 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Liver function test abnormal	1	0
Liver function test increased	2	0
Transaminases increased	1	0
Metabolism tests NEC		
Blood ketone body increased	1	0
Microbiology and serology tests NEC		
Culture negative	1	0
Mineral and electrolyte analyses		
Blood potassium abnormal	1	0
Blood potassium decreased	1	0
Serum ferritin 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	72	0
Body temperature abnormal	17	0
Body temperature decreased	8	0
Body temperature fluctuation	5	0
Body temperature increased	144	0
Body temperature normal	1	0
Breath sounds abnormal	1	0
Grip strength	2	0
Grip strength decreased	2	0
Lymph node palpable	7	0
Respiratory rate	2	0
Respiratory rate decreased	2	0
Respiratory rate increased	12	0
Skin temperature	8	0
Temperature difference of extremities	1	0
Weight	1	0
Weight decreased	7	0
Weight increased	1	0
Pituitary analyses anterior		
Blood growth hormone	2	0
Platelet analyses		
Platelet count decreased	2	0
Protein analyses NEC		
C-reactive protein increased	4	0
Red blood cell analyses		
Haemoglobin decreased	3	0
Respiratory and pulmonary function diagnostic procedures		
Forced expiratory volume increased	1	0
Peak expiratory flow rate decreased	1	0
Vital capacity	1	0
Respiratory tract and thoracic histopathology procedures		
Sputum abnormal	1	0
Skeletal and cardiac muscle analyses		
Blood creatine phosphokinase increased	1	0
Troponin increased	3	0
Therapeutic drug monitoring analyses		
Anticoagulation drug level below therapeutic	3	0

Case Series Drug Analysis Print

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Report Run Date: 12-Feb-2021
 Earliest Reaction Date: 19-Jan-2001

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 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Anticoagulation drug level increased	1	0
Thyroid analyses		
Tri-iodothyronine	1	0
Tri-iodothyronine decreased	1	0
Tissue enzyme analyses NEC		
Blood alkaline phosphatase increased	1	0
Urinalysis NEC		
Blood urine present	5	0
pH urine	1	0
pH urine increased	1	0
Urinary tract function analyses NEC		
Urine output	2	0
Urine output decreased	3	0
Urine output increased	1	0
Vascular tests NEC (incl blood pressure)		
Blood pressure abnormal	2	0
Blood pressure decreased	9	0
Blood pressure increased	56	0
Blood pressure measurement	6	0
Blood pressure systolic decreased	1	0
Blood pressure systolic increased	2	0
Virus identification and serology		
Coronavirus test positive	2	0
SARS-CoV-1 test positive	1	0
SARS-CoV-2 antibody test	1	0
SARS-CoV-2 antibody test negative	9	0
SARS-CoV-2 test	10	0
SARS-CoV-2 test false positive	1	0
SARS-CoV-2 test negative	1	0
SARS-CoV-2 test positive	23	0
Viral test	1	0
White blood cell analyses		
White blood cell count decreased	1	0
White blood cell count increased	1	0
Investigations SOC TOTAL	771	0

Case Series Drug Analysis Print

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Report Run Date: 12-Feb-2021
Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 11-Feb-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	1	0
Decreased appetite	288	0
Eating disorder symptom	1	0
Food craving	1	0
Food refusal	3	0
Hypophagia	3	0
Increased appetite	3	0
Salt craving	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus inadequate control	2	1
Type 1 diabetes mellitus	2	0
<i>Diabetic complications NEC</i>		
Diabetic complication	1	0
Diabetic ketoacidosis	3	0
<i>Disorders of purine metabolism</i>		
Gout	12	0
<i>Electrolyte imbalance NEC</i>		
Fluid imbalance	1	0
<i>Fluid intake increased</i>		
Polydipsia	1	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 weight gain	3	0
Feeding disorder	8	0
Food aversion	2	0
Poor feeding infant	1	0
<i>Hyperglycaemic conditions NEC</i>		
Hyperglycaemia	14	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	21	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	3	0
<i>Mixed acid-base disorders</i>		
Acidosis	2	0
<i>Potassium imbalance</i>		
Hypokalaemic syndrome	1	0
<i>Sodium imbalance</i>		
Hyponatraemia	2	0
<i>Total fluid volume decreased</i>		
Dehydration	31	0
<i>Total fluid volume increased</i>		
Fluid retention	3	0
Metabolic disorders SOC TOTAL	418	1

Case Series Drug Analysis Print

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

Report Run Date: 12-Feb-2021
Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 11-Feb-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	35	0
Arthropathy	4	0
Sacroiliitis	1	0
<i>Bone disorders NEC</i>		
Medial tibial stress syndrome	1	0
Spinal disorder	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	60	0
Bone swelling	1	0
Coccydynia	1	0
Pain in jaw	56	0
Spinal pain	7	0
<i>Bursal disorders</i>		
Bursitis	2	0
<i>Cartilage disorders</i>		
Costochondritis	6	0
<i>Connective tissue disorders NEC</i>		
Polymyalgia rheumatica	3	0
<i>Epiphyseal disorders</i>		
Epiphyses premature fusion	1	0
<i>Extremity deformities</i>		
Foot deformity	1	0
<i>Joint related disorders NEC</i>		
Joint lock	1	0
Periarthritis	6	0
Temporomandibular joint syndrome	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	2010	0
Jaw clicking	2	0
Joint effusion	4	0
Joint noise	2	0
Joint range of motion decreased	2	0
Joint stiffness	39	0
Joint swelling	53	0
Joint warmth	3	0
<i>Lupus erythematosus (incl subtypes)</i>		
Systemic lupus erythematosus	1	0
<i>Muscle infections and inflammations</i>		
Antisynthetase syndrome	1	0
Myositis	2	0
Polymyositis	1	0
<i>Muscle pains</i>		
Fibromyalgia	12	0
Myalgia	3059	0
Myofascial pain syndrome	3	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle discomfort	1	0
Muscle disorder	2	0
Muscle fatigue	75	0
Muscle spasms	121	0
Muscle swelling	6	0
Muscle tightness	8	0

Case Series Drug Analysis Print

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

Report Run Date: 12-Feb-2021
 Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 11-Feb-2021 19:00:03
 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Muscle & tissue disorders		
Muscle & tissue disorders cont'd		
Muscle twitching	51	0
Muscle tone abnormalities		
Muscle rigidity	7	0
Nuchal rigidity	3	0
Torticollis	1	0
Trismus	6	0
Muscle weakness conditions		
Muscular weakness	144	0
Musculoskeletal and connective tissue conditions NEC		
Limb mass	2	0
Mastication disorder	1	0
Mobility decreased	13	0
Musculoskeletal disorder	3	0
Musculoskeletal stiffness	228	0
Posture abnormal	1	0
Musculoskeletal and connective tissue infections and inflammations NEC		
Fasciitis	1	0
Plantar fasciitis	1	0
Musculoskeletal and connective tissue pain and discomfort		
Back pain	433	0
Flank pain	7	0
Limb discomfort	313	0
Musculoskeletal chest pain	21	0
Musculoskeletal discomfort	17	0
Musculoskeletal pain	15	0
Neck pain	360	0
Pain in extremity	2258	0
Rheumatic disorder	1	0
Myopathies		
Rhabdomyolysis	3	0
Osteoarthropathies		
Osteoarthritis	4	0
Psoriatic arthropathies		
Psoriatic arthropathy	1	0
Rheumatoid arthropathies		
Rheumatoid arthritis	8	0
Soft tissue disorders NEC		
Axillary mass	29	0
Groin pain	21	0
Neck mass	6	0
Spondyloarthropathies		
Ankylosing spondylitis	2	0
Arthritis reactive	5	0
Synovial disorders		
Synovial cyst	1	0
Synovitis	2	0
Tendon disorders		
Tendon pain	1	0
Tendonitis	2	0
Trunk deformities		
Drooping shoulder syndrome	1	0
Muscle & tissue disorders SOC TOTAL	9568	0

Case Series Drug Analysis Print

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Report Run Date: 12-Feb-2021

Data Lock Date: 11-Feb-2021 19:00:03

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Neoplasms		
<i>Lymphomas unspecified NEC</i>		
Lymphoma	4	0
<i>Metastases to specified sites</i>		
Metastases to lymph nodes	2	0
<i>Neoplasms malignant site unspecified NEC</i>		
Neoplasm malignant	1	0
Second primary malignancy	1	0
<i>Plasma cell myelomas</i>		
Plasma cell myeloma	1	0
<i>Skin neoplasms benign</i>		
Melanocytic naevus	1	0
<i>Soft tissue sarcomas histology unspecified</i>		
Sarcoma	1	0
Neoplasms SOC TOTAL	11	0

Case Series Drug Analysis Print

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Report Run Date: 12-Feb-2021
Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 11-Feb-2021 19:00:03
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	3	0
<i>Abnormal sleep-related events</i>		
Sleep paralysis	2	0
<i>Absence seizures</i>		
Petit mal epilepsy	4	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	1	0
<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	1	0
Cerebral artery occlusion	1	0
Cerebral haemorrhage	6	2
Cerebral infarction	6	0
Cerebrovascular accident	37	3
Haemorrhage intracranial	2	0
Haemorrhagic stroke	1	1
Ischaemic cerebral infarction	1	0
Ischaemic stroke	8	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>Cerebrovascular venous and sinus thrombosis</i>		
Cerebral venous sinus thrombosis	1	0
<i>Cervical spinal cord and nerve root disorders</i>		
Cervicobrachial syndrome	1	0
<i>Coordination and balance disturbances</i>		
Ataxia	1	0
Balance disorder	59	0
Coordination abnormal	9	0
Dysstasia	11	0
<i>Cortical dysfunction NEC</i>		
Aphasia	10	0
<i>Cranial nerve disorders NEC</i>		
Cranial nerve disorder	1	0
<i>Dementia (excl Alzheimer's type)</i>		
Dementia	3	0
Dementia with Lewy bodies	1	0
<i>Disturbances in consciousness NEC</i>		
Altered state of consciousness	4	0
Consciousness fluctuating	2	0
Depressed level of consciousness	5	0
Lethargy	574	0

Case Series Drug Analysis Print

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

Report Run Date: 12-Feb-2021

Data Lock Date: 11-Feb-2021 19:00:03

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>		
Loss of consciousness	59	0
Sedation	3	0
Somnolence	157	0
Stupor	1	0
Syncope	226	0
<i>Dyskinesias and movement disorders NEC</i>		
Bradykinesia	3	0
Dyskinesia	1	0
Extrapyramidal disorder	1	0
Fine motor skill dysfunction	1	0
Hypokinesia	3	0
Motor dysfunction	1	0
Movement disorder	5	0
Psychomotor hyperactivity	4	0
<i>Dystonias</i>		
Dystonia	5	0
Writer's cramp	1	0
<i>Encephalopathies NEC</i>		
Posterior reversible encephalopathy syndrome	1	0
<i>Eye movement disorders</i>		
IIIrd nerve paralysis	1	0
VIth nerve paralysis	2	0
<i>Facial cranial nerve disorders</i>		
Facial nerve disorder	1	0
Facial paralysis	98	0
Facial paresis	17	0
Facial spasm	8	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	4	0
<i>Headaches NEC</i>		
Cervicogenic headache	1	0
Cluster headache	39	0
Cold-stimulus headache	1	0
Exertional headache	3	0
Headache	6492	0
Medication overuse headache	2	0
New daily persistent headache	2	0
Occipital neuralgia	1	0
Ophthalmoplegic migraine	1	0
Primary cough headache	1	0
Primary headache associated with sexual activity	1	0
Sinus headache	84	0
Tension headache	109	0
Thunderclap headache	1	0
Vascular headache	1	0
<i>Lumbar spinal cord and nerve root disorders</i>		
Sciatica	8	0
<i>Memory loss (excl dementia)</i>		
Amnesia	10	0
Memory impairment	22	0
Transient global amnesia	1	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	9	0

Case Series Drug Analysis Print

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

Report Run Date: 12-Feb-2021
 Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 11-Feb-2021 19:00:03
 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Disturbance in attention	46	0
Mental impairment	6	0
Migraine headaches		
Hemiplegic migraine	2	0
Migraine	432	0
Migraine with aura	27	0
Retinal migraine	4	0
Typical aura without headache	1	0
Vestibular migraine	1	0
Mononeuropathies		
Carpal tunnel syndrome	2	0
Mononeuropathy	1	0
Nerve compression	2	0
Peroneal nerve palsy	2	0
Multiple sclerosis acute and progressive		
Multiple sclerosis	1	0
Multiple sclerosis relapse	5	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	3	0
Narcolepsy and hypersomnia		
Hypersomnia	18	0
Narcolepsy	1	0
Nervous system disorders NEC		
Nervous system disorder	1	0
Neurologic visual problems NEC		
Tunnel vision	4	0
Visual field defect	3	0
Neurological signs and symptoms NEC		
Dizziness	1832	0
Dizziness exertional	6	0
Dizziness postural	145	0
Drooling	2	0
Head discomfort	43	0
Hyporesponsive to stimuli	1	0
Inability to crawl	1	0
Myoclonus	2	0
Neurological symptom	3	0
Persistent postural-perceptual dizziness	2	0
Presyncope	122	0
Slow response to stimuli	2	0
Unresponsive to stimuli	14	0
Neuromuscular disorders NEC		
Muscle contractions involuntary	4	0
Muscle spasticity	1	0
Neuromuscular pain	1	0
Neuromuscular junction dysfunction		
Myasthenia gravis	2	0
Olfactory nerve disorders		

Case Series Drug Analysis Print

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Data Lock Date: 11-Feb-2021 19:00:03

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>		
Anosmia	49	0
Hyposmia	5	0
Parosmia	34	0
Optic nerve disorders NEC		
Optic neuritis	3	0
Paraesthesias and dysaesthesias		
Burning sensation	73	0
Dysaesthesia	3	0
Formication	6	0
Hemiparaesthesia	1	0
Hyperaesthesia	18	0
Hypoaesthesia	398	0
Paraesthesia	604	0
Paralysis and paresis (excl cranial nerve)		
Hemiparesis	11	0
Hemiplegia	3	0
Locked-in syndrome	1	0
Monoparesis	11	0
Monoplegia	6	0
Paralysis	14	0
Paraparesis	1	0
Parkinson's disease and parkinsonism		
Freezing phenomenon	1	0
Parkinsonian gait	1	0
Parkinsonism	2	0
Partial complex seizures		
Dreamy state	1	0
Temporal lobe epilepsy	1	0
Peripheral neuropathies NEC		
Neuropathy peripheral	13	0
Peripheral sensory neuropathy	2	0
Seizures and seizure disorders NEC		
Clonic convulsion	1	0
Epilepsy	10	0
Febrile convulsion	2	0
Partial seizures	1	0
Psychogenic seizure	3	0
Seizure	54	0
Status epilepticus	3	0
Tonic convulsion	3	0
Sensory abnormalities NEC		
Ageusia	105	0
Allodynia	3	0
Aura	7	0
Dysgeusia	277	0
Hypergeusia	1	0
Neuralgia	54	0
Restless legs syndrome	19	0
Sensory disturbance	10	0
Sensory loss	7	0
Taste disorder	53	0
Sleep disturbances NEC		
Poor quality sleep	33	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 <small>Nervous system disorders cont'd</small>		
<i>Speech and language abnormalities</i>		
Dysarthria	24	0
Repetitive speech	1	0
Speech disorder	6	0
<i>Spinal cord and nerve root disorders NEC</i>		
Radiculitis brachial	1	0
Radiculopathy	1	0
<i>Structural brain disorders NEC</i>		
Brain injury	2	2
<i>Transient cerebrovascular events</i>		
Transient ischaemic attack	15	0
<i>Tremor (excl congenital)</i>		
Essential tremor	1	0
Resting tremor	1	0
Tremor	328	0
<i>Trigeminal disorders</i>		
Facial neuralgia	5	0
Trigeminal nerve disorder	1	0
Trigeminal neuralgia	6	0
Nervous system disorders SOC TOTAL	13213	11

Case Series Drug Analysis Print

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Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	5	0
<i>Maternal complications of pregnancy NEC</i>		
Morning sickness	1	0
<i>Normal pregnancy, labour and delivery</i>		
Pregnancy	2	0
<i>Unintended pregnancies</i>		
Pregnancy with implant contraceptive	1	0
Pregnancy conditions SOC TOTAL	9	0

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Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<i>Device malfunction events NEC</i>		
Device stimulation issue	1	0
Oversensing	5	0
<i>Product contamination and sterility issues</i>		
Product contamination physical	1	0
<i>Product physical issues</i>		
Product taste abnormal	1	0
<i>Product quality issues NEC</i>		
Product origin unknown	1	0
null SOC TOTAL	9	0

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Affect alterations NEC</i>		
Flat affect	1	0
<i>Anxiety symptoms</i>		
Agitation	20	0
Anxiety	87	0
Nervousness	45	0
Tension	11	0
<i>Behaviour and socialisation disturbances</i>		
Indifference	2	0
Paranoia	4	0
Social avoidant behaviour	2	0
Soliloquy	1	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Daydreaming	1	0
Mental fatigue	32	0
<i>Communications disorders</i>		
Communication disorder	1	0
<i>Confusion and disorientation</i>		
Confusional state	136	0
Disorientation	43	0
<i>Decreased physical activity levels</i>		
Catatonia	1	0
<i>Deliria</i>		
Delirium	28	0
<i>Depressive disorders</i>		
Depression	14	0
<i>Dissociative states</i>		
Depersonalisation/derealisation disorder	2	0
Dissociation	3	0
Dissociative amnesia	1	0
Dissociative disorder	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Initial insomnia	3	0
Insomnia	191	0
Middle insomnia	3	0
Terminal insomnia	1	0
<i>Dyssomnias</i>		
Dyssomnia	1	0
<i>Eating disorders NEC</i>		
Eating disorder	1	0
<i>Emotional and mood disturbances NEC</i>		
Anger	3	0
Dysphoria	1	0
Emotional disorder	5	0
Emotional distress	3	0
Euphoric mood	3	0
Irritability	29	0
Mood altered	4	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Fear of falling	1	0
Phonophobia	1	0
Social fear	1	0
<i>Fluctuating mood symptoms</i>		

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Mood swings	3	0
Hallucinations (excl sleep-related)		
Hallucination	41	0
Hallucination, auditory	2	0
Hallucination, olfactory	1	0
Hallucination, tactile	1	0
Hallucination, visual	5	0
Hallucinations, mixed	1	0
Increased physical activity levels		
Restlessness	23	0
Mental disorders NEC		
Mental disorder	1	0
Mood alterations with depressive symptoms		
Decreased interest	3	0
Depressed mood	38	0
Feeling of despair	1	0
Negative thoughts	1	0
Sense of a foreshortened future	1	0
Tearfulness	2	0
Mood disorders NEC		
Apathy	3	0
Laziness	1	0
Listless	3	0
Narcolepsy and associated conditions		
Sleep attacks	2	0
Obsessive-compulsive disorders and symptoms		
Obsessive-compulsive symptom	1	0
Orgasmic disorders and disturbances		
Anorgasmia	1	0
Panic attacks and disorders		
Panic attack	19	0
Panic disorder	1	0
Panic reaction	5	0
Parasomnias		
Abnormal dreams	36	0
Nightmare	31	0
Sleep terror	2	0
Perception disturbances NEC		
Autoscopy	1	0
Derealisation	2	0
Flashback	1	0
Illusion	1	0
Psychiatric elimination disorders		
Enuresis	4	0
Psychiatric symptoms NEC		
Hypervigilance	1	0
Trance	1	0
Psychotic disorder NEC		
Psychotic behaviour	1	0
Psychotic disorder	4	0
Sleep disorders NEC		
Sleep disorder	31	0
Somatic symptom disorders		

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
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Habit cough	3	0
Vomiting psychogenic	1	0
<i>Speech and language usage disturbances</i>		
Disorganised speech	2	0
Logorrhoea	1	0
<i>Speech articulation and rhythm disturbances</i>		
Dysphemia	1	0
<i>Stereotypies and automatisms</i>		
Bruxism	2	0
Head banging	2	0
Stereotypy	1	0
<i>Suicidal and self-injurious behaviour</i>		
Intentional self-injury	1	0
Suicidal ideation	1	0
<i>Thinking disturbances</i>		
Bradyphrenia	9	0
Thinking abnormal	3	0
Psychiatric disorders SOC TOTAL	990	0

Case Series Drug Analysis Print

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Data Lock Date: 11-Feb-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
Dysuria	8	0
Incontinence	6	0
Micturition disorder	1	0
Micturition urgency	4	0
Pollakiuria	12	0
Urinary incontinence	14	0
Urinary retention	10	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>Myoneurogenic bladder disorders</i>		
Hypertonic bladder	1	0
Loss of bladder sensation	1	0
<i>Nephritis NEC</i>		
Nephritis	1	0
<i>Renal failure and impairment</i>		
Acute kidney injury	5	0
Anuria	1	0
Renal failure	2	0
<i>Urinary abnormalities</i>		
Chromaturia	11	0
Haematuria	6	0
Proteinuria	2	0
Urine abnormality	4	0
Urine odour abnormal	2	0
<i>Urinary tract signs and symptoms NEC</i>		
Costovertebral angle tenderness	1	0
Haemorrhage urinary tract	3	0
Nocturia	1	0
Polyuria	1	0
Renal pain	43	0
Urinary tract pain	1	0
Renal & urinary disorders SOC TOTAL	148	0

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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	5	0
<i>Breast signs and symptoms</i>		
Breast discomfort	2	0
Breast pain	34	0
Breast swelling	9	0
Breast tenderness	4	0
Nipple pain	5	0
Nipple swelling	2	0
<i>Erection and ejaculation conditions and disorders</i>		
Erectile dysfunction	6	0
<i>Menopausal effects NEC</i>		
Menopausal symptoms	2	0
<i>Menopausal effects on the genitourinary tract</i>		
Postmenopausal haemorrhage	1	0
<i>Menstruation and uterine bleeding NEC</i>		
Dysmenorrhoea	15	0
Menstrual disorder	11	0
Menstruation irregular	9	0
Metrorrhagia	7	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	2	0
Hypomenorrhoea	7	0
Menstruation delayed	13	0
Oligomenorrhoea	1	0
<i>Menstruation with increased bleeding</i>		
Menorrhagia	26	0
Polymenorrhoea	4	0
<i>Ovarian and fallopian tube disorders NEC</i>		
Ovulation pain	2	0
<i>Pelvis and broad ligament disorders NEC</i>		
Adnexa uteri pain	3	0
<i>Penile disorders NEC (excl erection and ejaculation)</i>		
Penile swelling	1	0
<i>Prostatic signs, symptoms and disorders NEC</i>		
Prostatomegaly	1	0
<i>Reproductive tract disorders NEC (excl neoplasms)</i>		
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	1	0
Pelvic discomfort	2	0
Pelvic pain	5	0
Perineal pain	1	0
<i>Scrotal disorders NEC</i>		
Scrotal erythema	1	0
Scrotal exfoliation	1	0
Scrotal pain	3	0
Scrotal swelling	1	0
<i>Spermatogenesis and semen disorders</i>		

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Haematospermia	1	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular pain	4	0
Testicular swelling	2	0
<i>Uterine disorders NEC</i>		
Uterine pain	1	0
<i>Uterine tone disorders</i>		
Uterine spasm	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	23	0
Vulval ulceration	2	0
<i>Vulvovaginal signs and symptoms</i>		
Vulvovaginal pruritus	1	0
Reproductive & breast disorders SOC TOTAL	227	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	645	0
Dyspnoea at rest	1	0
Dyspnoea exertional	6	1
Hyperventilation	5	0
Hypopnoea	14	0
Irregular breathing	6	0
Mouth breathing	2	0
Orthopnoea	2	0
Respiration abnormal	12	0
Respiratory arrest	4	0
Respiratory distress	3	0
Sleep apnoea syndrome	1	0
Tachypnoea	12	0
<i>Bronchial conditions NEC</i>		
Bronchial secretion retention	1	0
Bronchiectasis	2	0
<i>Bronchospasm and obstruction</i>		
Asthma	56	0
Bronchospasm	6	0
Chronic obstructive pulmonary disease	3	0
Obstructive airways disorder	1	0
Reversible airways obstruction	1	0
Wheezing	85	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	8	1
<i>Coughing and associated symptoms</i>		
Allergic cough	1	0
Cough	498	0
Haemoptysis	8	0
Productive cough	29	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
Stridor	5	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Hypersensitivity pneumonitis	1	0
Pneumonia aspiration	3	2
Pneumonitis	8	3
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	2	0
Pleuritic pain	4	0
Pulmonary pain	19	0
Rales	2	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	39	0
Rhinitis allergic	3	0
<i>Nasal disorders NEC</i>		
Epistaxis	116	0
Intranasal hypoesthesia	1	0

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Intranasal paraesthesia	1	0
Nasal disorder	1	0
Nasal dryness	3	0
Nasal odour	3	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	2	0
Sinus congestion	11	0
Sinus disorder	1	0
<i>Parenchymal lung disorders NEC</i>		
Atelectasis	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal erythema	3	0
Pharyngeal haemorrhage	1	0
Pharyngeal hypoaesthesia	10	0
Pharyngeal inflammation	3	0
Pharyngeal oedema	3	0
Pharyngeal paraesthesia	21	0
Pharyngeal swelling	62	0
Pharyngeal ulceration	5	0
Tonsillar erythema	1	0
Tonsillar hypertrophy	18	0
Tonsillar inflammation	3	0
<i>Pleural infections and inflammations</i>		
Pleurisy	3	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	1	0
<i>Pulmonary oedemas</i>		
Pulmonary congestion	3	0
Pulmonary oedema	2	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	8	1
Pulmonary infarction	1	0
<i>Respiratory failures (excl neonatal)</i>		
Acute respiratory failure	2	1
<i>Respiratory signs and symptoms NEC</i>		
Painful respiration	2	0
Respiratory symptom	1	0
<i>Respiratory tract disorders NEC</i>		
Aspiration	1	0
Respiratory disorder	1	0
Respiratory tract irritation	1	0
Respiratory tract oedema	1	0
<i>Upper respiratory tract neoplasms</i>		
Tonsillar cyst	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	14	0
Catarrh	4	0
Choking	3	0
Dry throat	41	0

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Dysphonia	29	0
Increased upper airway secretion	3	0
Increased viscosity of upper respiratory secretion	2	0
Nasal discharge discolouration	1	0
Nasal discomfort	8	0
Nasal obstruction	2	0
Oropharyngeal blistering	6	0
Oropharyngeal discomfort	18	0
Oropharyngeal pain	583	0
Paranasal sinus discomfort	7	0
Rhinalgia	5	0
Rhinorrhoea	129	0
Sinus pain	38	0
Sneezing	69	0
Snoring	2	0
Throat clearing	3	0
Throat irritation	54	0
Throat tightness	74	0
Upper airway obstruction	1	0
Upper-airway cough syndrome	1	0
Yawning	1	0
Respiratory disorders SOC TOTAL	2903	9

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	5	0
<i>Alopecias</i>		
Alopecia	8	0
<i>Angioedemas</i>		
Angioedema	43	0
Circumoral swelling	1	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	146	0
Hyperhidrosis	365	0
Miliaria	13	0
Night sweats	148	0
<i>Bullous conditions</i>		
Blister	42	0
Blood blister	1	0
Dermatitis bullous	3	0
Erythema multiforme	5	0
Pemphigoid	3	0
Stevens-Johnson syndrome	1	0
Toxic epidermal necrolysis	1	1
<i>Dermal and epidermal conditions NEC</i>		
Acute febrile neutrophilic dermatosis	1	0
Dermatosis	1	0
Dry skin	28	0
Macule	1	0
Pain of skin	68	0
Papule	15	0
Pathergy reaction	1	0
Peau d'orange	2	0
Scar pain	4	0
Sensitive skin	42	0
Skin burning sensation	40	0
Skin discolouration	23	0
Skin discomfort	1	0
Skin disorder	1	0
Skin induration	1	0
Skin lesion	5	0
Skin necrosis	1	0
Skin odour abnormal	2	0
Skin reaction	23	0
Skin sensitisation	4	0
Skin swelling	15	0
Skin tightness	11	0
Skin warm	64	0
Sticky skin	1	0
Yellow skin	4	0
<i>Dermatitis and eczema</i>		
Dermatitis	20	0
Dermatitis allergic	40	0
Dermatitis atopic	1	0
Dyshidrotic eczema	2	0
Eczema	19	0
Eczema asteatotic	1	0

Case Series Drug Analysis Print

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 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Eczema nummular	2	0
Eczema weeping	1	0
Perioral dermatitis	1	0
Skin irritation	22	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	6	0
Fixed eruption	1	0
Toxic skin eruption	1	0
<i>Erythemas</i>		
Erythema	544	0
Red man syndrome	1	0
<i>Exfoliative conditions</i>		
Exfoliative rash	1	0
Skin exfoliation	15	0
<i>Hyperpigmentation disorders</i>		
Ephelides	1	0
<i>Hypopigmentation disorders</i>		
Skin hypopigmentation	1	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
Nail discolouration	3	0
Nail disorder	1	0
Onychalgia	3	0
<i>Panniculitides</i>		
Erythema nodosum	3	0
<i>Papulosquamous conditions</i>		
Erythema annulare	1	0
Lichen planus	1	0
Pityriasis rosea	11	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	6	0
<i>Pigmentation changes NEC</i>		
Pigmentation disorder	2	0
<i>Pilar disorders NEC</i>		
Piloerection	3	0
<i>Pruritus NEC</i>		
Itching scar	3	0
Pruritus	958	0
<i>Psoriatic conditions</i>		
Psoriasis	7	0
<i>Purpura and related conditions</i>		
Petechiae	18	0
Purpura	7	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	975	0
Rash erythematous	199	0
Rash macular	102	0
Rash maculo-papular	16	0
Rash morbilliform	6	0
Rash papular	56	0
Rash pruritic	187	0
Rash vesicular	5	0
<i>Rosaceas</i>		
Rosacea	2	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
<i>Scaly conditions</i>		
Pityriasis	3	0
<i>Skin and subcutaneous conditions NEC</i>		
Cutaneous symptom	1	0
Skin mass	3	0
<i>Skin and subcutaneous tissue ulcerations</i>		
Scleroderma associated digital ulcer	1	0
Skin erosion	6	0
Skin ulcer	1	0
<i>Skin cysts and polyps</i>		
Dermal cyst	1	0
<i>Skin haemorrhages</i>		
Haemorrhage subcutaneous	2	0
Skin haemorrhage	2	0
<i>Skin hyperplasias and hypertrophies</i>		
Skin hypertrophy	1	0
<i>Skin vasculitides</i>		
Cutaneous vasculitis	1	0
Vasculitic rash	1	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	11	0
<i>Urticarias</i>		
Chronic spontaneous urticaria	1	0
Cold urticaria	1	0
Idiopathic urticaria	1	0
Mechanical urticaria	1	0
Urticaria	352	0
Urticaria papular	1	0
Urticaria thermal	2	0
Skin disorders SOC TOTAL	4792	1

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Reaction Name	Total	Fatal
Social circumstances		
<i>Criminal activity</i>		
Verbal abuse	1	0
<i>Disability issues</i>		
Bedridden	7	0
Breast prosthesis user	1	0
Immobile	2	0
<i>Tobacco use</i>		
Non-tobacco user	1	0
Social circumstances SOC TOTAL	12	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Gastrointestinal therapeutic procedures NEC</i>		
Prophylaxis of nausea and vomiting	5	0
<i>Immunisations</i>		
COVID-19 immunisation	5	0
Immunisation	4	0
<i>Limb therapeutic procedures</i>		
Limb immobilisation	1	0
Limb operation	1	0
<i>Mastectomies</i>		
Breast conserving surgery	1	0
<i>Psychiatric therapies</i>		
Electroconvulsive therapy	1	0
<i>Respiratory tract therapeutic procedures NEC</i>		
Asthma prophylaxis	2	0
<i>Therapeutic procedures NEC</i>		
Anaphylaxis treatment	1	0
Bed rest	1	0
Fatigue management	1	0
Hospitalisation	1	0
Injection	1	0
Surgical & medical procedures SOC TOTAL	25	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Accelerated and malignant hypertension</i>		
Hypertensive crisis	1	0
<i>Arterial infections and inflammations</i>		
Arteritis	1	0
Giant cell arteritis	1	0
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	2	0
Labile blood pressure	1	0
<i>Circulatory collapse and shock</i>		
CT hypotension complex	1	0
Circulatory collapse	23	0
Neurogenic shock	10	0
Peripheral circulatory failure	2	0
Shock	1	0
<i>Haemorrhages NEC</i>		
Haematoma	8	0
Haemorrhage	10	1
<i>Lymphangiopathies</i>		
Lymphocele	1	0
<i>Lymphoedemas</i>		
Lymphoedema	21	0
<i>Non-site specific embolism and thrombosis</i>		
Thrombosis	7	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Haemorrhagic infarction	1	0
<i>Non-site specific vascular disorders NEC</i>		
Superficial vein prominence	1	0
Vascular pain	1	0
Vasodilatation	4	0
Vein discolouration	1	0
Vein disorder	2	0
Vein rupture	1	0
<i>Peripheral embolism and thrombosis</i>		
Blue toe syndrome	3	0
Deep vein thrombosis	5	0
Thrombophlebitis	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	10	0
Flushing	149	0
Hot flush	215	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	61	0
Peripheral ischaemia	1	0
Poor peripheral circulation	1	0
Raynaud's phenomenon	7	0
Vasoconstriction	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	43	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	108	0
Systolic hypertension	1	0
<i>Vascular hypotensive disorders</i>		
Hypotension	83	0

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Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
Orthostatic hypotension	4	0
<i>Vasculitides NEC</i>		
Vasculitis	7	0
<i>Vena caval embolism and thrombosis</i>		
Vena cava embolism	1	0
Vena cava thrombosis	1	0
Vascular disorders SOC TOTAL	803	1
TOTAL REACTIONS FOR DRUG	70314	173
TOTAL REPORTS	24207	
TOTAL FATAL OUTCOME REPORTS		173