

# COVID-19 mRNA Pfizer/BioNTech vaccine analysis print

Report Run Date: 22-Feb-2021  
Data Lock Date: 19-Feb-2021 19:00:04

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All UK spontaneous reports received between 9/12/20Á and 14/02/21 for mRNA  
Pfizer/BioNTech vaccineÁ analysis print

## Case Series Drug Analysis Print

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

Report Run Date: 22-Feb-2021  
 Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 19-Feb-2021 19:00:04  
 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<b><i>Anaemias NEC</i></b>		
Anaemia	3	0
<b><i>Anaemias haemolytic immune</i></b>		
Autoimmune haemolytic anaemia	1	0
<b><i>Bleeding tendencies</i></b>		
Increased tendency to bruise	5	0
<b><i>Lymphatic system disorders NEC</i></b>		
Lymph node pain	228	0
Lymphadenitis	34	0
Lymphadenopathy	1536	0
Lymphatic disorder	1	0
Pseudolymphoma	2	0
<b><i>Marrow depression and hypoplastic anaemias</i></b>		
Myelosuppression	1	0
Pancytopenia	1	0
<b><i>Neutropenias</i></b>		
Neutropenia	6	0
<b><i>Platelet disorders NEC</i></b>		
Platelet anisocytosis	1	0
<b><i>Spleen disorders</i></b>		
Splenomegaly	1	0
<b><i>Thrombocytopenias</i></b>		
Immune thrombocytopenia	4	0
Thrombocytopenia	10	0
<b><i>Thrombocytoses</i></b>		
Thrombocytosis	1	0
<b>Blood disorders SOC TOTAL</b>	<b>1835</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i><b>Cardiac conduction disorders</b></i>		
Bundle branch block right	1	0
<i><b>Cardiac disorders NEC</b></i>		
Cardiac disorder	3	0
Cardiovascular disorder	1	0
<i><b>Cardiac signs and symptoms NEC</b></i>		
Palpitations	407	0
<i><b>Coronary artery disorders NEC</b></i>		
Coronary artery disease	1	1
<i><b>Heart failures NEC</b></i>		
Cardiac failure	4	1
Cardiopulmonary failure	1	1
<i><b>Ischaemic coronary artery disorders</b></i>		
Acute myocardial infarction	7	0
Angina pectoris	11	0
Myocardial infarction	21	5
<i><b>Left ventricular failures</b></i>		
Left ventricular failure	1	0
<i><b>Myocardial disorders NEC</b></i>		
Left ventricular dysfunction	1	0
Myocardial oedema	1	0
Right ventricular enlargement	1	0
<i><b>Noninfectious myocarditis</b></i>		
Myocarditis	5	0
<i><b>Noninfectious pericarditis</b></i>		
Pericarditis	4	0
<i><b>Rate and rhythm disorders NEC</b></i>		
Arrhythmia	14	0
Bradycardia	13	0
Cardiac flutter	16	0
Extrasystoles	10	0
Postural orthostatic tachycardia syndrome	1	0
Tachycardia	273	0
<i><b>Supraventricular arrhythmias</b></i>		
Arrhythmia supraventricular	4	0
Atrial fibrillation	39	1
Atrial tachycardia	2	0
Sinus bradycardia	1	0
Sinus tachycardia	24	0
Supraventricular tachycardia	11	0
<i><b>Ventricular arrhythmias and cardiac arrest</b></i>		
Cardiac arrest	31	13
Cardio-respiratory arrest	1	1
Pulseless electrical activity	2	0
Ventricular extrasystoles	2	0
Ventricular fibrillation	4	0
Ventricular tachycardia	1	0
<b>Cardiac disorders SOC TOTAL</b>	<b>919</b>	<b>23</b>

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

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i><b>Ear disorders NEC</b></i>		
Ear canal erythema	1	0
Ear congestion	2	0
Ear discomfort	12	0
Ear disorder	2	0
Ear pain	157	0
Ear pruritus	1	0
Ear swelling	4	0
Otorrhoea	1	0
<i><b>Eustachian tube disorders</b></i>		
Eustachian tube disorder	1	0
<i><b>External ear disorders NEC</b></i>		
Red ear syndrome	1	0
<i><b>Hearing disorders NEC</b></i>		
Auditory disorder	1	0
<i><b>Hearing losses</b></i>		
Deafness	17	0
Deafness neurosensory	2	0
Hypoacusis	19	0
Sudden hearing loss	3	0
<i><b>Hyperacusia</b></i>		
Hyperacusis	8	0
<i><b>Inner ear disorders NEC</b></i>		
Acute vestibular syndrome	1	0
Inner ear disorder	2	0
Meniere's disease	2	0
<i><b>Inner ear signs and symptoms</b></i>		
Motion sickness	13	0
Tinnitus	145	0
Vertigo	204	0
Vertigo labyrinthine	4	0
Vertigo positional	16	0
<i><b>Middle ear infections and inflammations</b></i>		
Middle ear inflammation	1	0
<b>Ear disorders SOC TOTAL</b>	<b>620</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Endocrine disorders</b>		
<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	2	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	1	0
<b>Endocrine disorders SOC TOTAL</b>	<b>6</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i><b>Amblyopic vision impairment</b></i>		
Amblyopia	2	0
<i><b>Choroid and vitreous haemorrhages and vascular disorders</b></i>		
Choroidal haemorrhage	1	0
<i><b>Choroid and vitreous structural change, deposit and degeneration</b></i>		
Vitreous detachment	1	0
Vitreous floaters	9	0
<i><b>Conjunctival and corneal bleeding and vascular disorders</b></i>		
Conjunctival haemorrhage	9	0
<i><b>Corneal infections, oedemas and inflammations</b></i>		
Keratitis	1	0
Ulcerative keratitis	2	0
<i><b>Eyelid movement disorders</b></i>		
Blepharospasm	16	0
Excessive eye blinking	1	0
Eyelid ptosis	4	0
<i><b>Iris and uveal tract infections, irritations and inflammations</b></i>		
Autoimmune uveitis	1	0
Iridocyclitis	5	0
Iritis	1	0
Uveitis	6	0
<i><b>Lacrimation disorders</b></i>		
Dry eye	17	0
Lacrimation increased	29	0
<i><b>Lid, lash and lacrimal infections, irritations and inflammations</b></i>		
Blepharitis	1	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	24	0
<i><b>Lid, lash and lacrimal structural disorders</b></i>		
Eyelid exfoliation	1	0
<i><b>Ocular bleeding and vascular disorders NEC</b></i>		
Eye haematoma	1	0
Eye haemorrhage	2	0
<i><b>Ocular disorders NEC</b></i>		
Eye disorder	10	0
Eye oedema	3	0
Eye pain	199	0
Eye swelling	107	0
Eye ulcer	1	0
Eyelid disorder	1	0
Eyelid pain	3	0
Eyelids pruritus	1	0
Ocular discomfort	6	0
Periorbital oedema	8	0
Periorbital pain	1	0
Periorbital swelling	25	0
<i><b>Ocular infections, inflammations and associated manifestations</b></i>		

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<b>Eye disorders</b> Eye disorders cont'd		
Eye allergy	1	0
Eye discharge	6	0
Eye inflammation	4	0
Eye irritation	21	0
Eye pruritus	62	0
Limbal swelling	1	0
Ocular hyperaemia	48	0
<b>Ocular nerve and muscle disorders</b>		
Binocular eye movement disorder	1	0
Extraocular muscle paresis	1	0
Eye movement disorder	5	0
Ophthalmoplegia	1	0
Strabismus	1	0
<b>Ocular sensation disorders</b>		
Abnormal sensation in eye	5	0
Asthenopia	38	0
Eye paraesthesia	1	0
Foreign body sensation in eyes	6	0
Hypoaesthesia eye	2	0
Photophobia	79	0
<b>Optic disc abnormalities NEC</b>		
Papilloedema	1	0
<b>Pupil disorders</b>		
Miosis	1	0
Mydriasis	4	0
Pupillary disorder	1	0
Pupils unequal	2	0
<b>Retinal bleeding and vascular disorders (excl retinopathy)</b>		
Retinal haemorrhage	1	0
Retinal vein occlusion	2	0
<b>Retinal structural change, deposit and degeneration</b>		
Maculopathy	1	0
Retinal toxicity	1	0
<b>Scleral infections, irritations and inflammations</b>		
Episcleritis	3	0
<b>Visual disorders NEC</b>		
Diplopia	23	0
Halo vision	4	0
Metamorphopsia	2	0
Oscillopsia	1	0
Photopsia	19	0
Vision blurred	169	0
Visual brightness	1	0
<b>Visual impairment and blindness (excl colour blindness)</b>		
Blindness	9	0
Blindness transient	2	0
Blindness unilateral	1	0
Central vision loss	1	0
Sudden visual loss	1	0
Visual acuity reduced	1	0
Visual impairment	55	0
<b>Eye disorders SOC TOTAL</b>	<b>1098</b>	<b>0</b>



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<b>Gastrointestinal disorders</b>		
<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	4	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	16	0
<i>Diaphragmatic hernias</i>		
Hiatus hernia	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	1210	2
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	51	0
Epigastric discomfort	3	0
Eructation	13	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	3	0
Faeces discoloured	8	0
Faeces pale	2	0
Faeces soft	2	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	40	0
Aerophagia	2	0
Flatulence	39	0
<i>Gastric and oesophageal haemorrhages</i>		
Gastric haemorrhage	1	1
<i>Gastritis (excl infective)</i>		
Gastritis	8	0
Reflux gastritis	3	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	252	0
Abdominal pain lower	13	0
Abdominal pain upper	382	0

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<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
Abdominal rigidity	1	0
Abdominal tenderness	3	0
Gastrointestinal pain	25	0
<b><i>Gastrointestinal atonic and hypomotility disorders NEC</i></b>		
Constipation	30	0
Duodenogastric reflux	2	0
Gastroesophageal reflux disease	18	0
Intestinal pseudo-obstruction	1	0
<b><i>Gastrointestinal disorders NEC</i></b>		
Functional gastrointestinal disorder	2	0
Gastric disorder	3	0
Gastrointestinal disorder	2	0
<b><i>Gastrointestinal dyskinetic disorders</i></b>		
Dyschezia	1	0
Gastrointestinal motility disorder	1	0
<b><i>Gastrointestinal inflammatory disorders NEC</i></b>		
Enteritis	1	0
<b><i>Gastrointestinal mucosal dystrophies and secretion disorders</i></b>		
Hyperchlorhydria	1	0
<b><i>Gastrointestinal signs and symptoms NEC</i></b>		
Abdominal discomfort	130	0
Anal incontinence	6	0
Breath odour	5	0
Dysphagia	38	0
<b><i>Gastrointestinal spastic and hypermotility disorders</i></b>		
Defaecation urgency	2	0
Frequent bowel movements	9	0
Irritable bowel syndrome	11	0
Oesophageal spasm	1	0
Pylorospasm	1	0
<b><i>Gastrointestinal stenosis and obstruction NEC</i></b>		
Intestinal obstruction	1	0
<b><i>Gastrointestinal vascular malformations</i></b>		
Gastric antral vascular ectasia	1	0
<b><i>Gastrointestinal vascular occlusion and infarction</i></b>		
Intestinal ischaemia	1	0
<b><i>Gingival disorders, signs and symptoms NEC</i></b>		
Gingival blister	5	0
Gingival discomfort	2	0
Gingival pain	19	0
Gingival swelling	3	0
Gingivitis ulcerative	1	0
Noninfective gingivitis	1	0
<b><i>Gingival haemorrhages</i></b>		
Gingival bleeding	5	0
<b><i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i></b>		
Gastric varices	1	0
Haemorrhoids	4	0
<b><i>Intestinal haemorrhages</i></b>		
Anal haemorrhage	4	0
Rectal haemorrhage	12	0
Small intestinal haemorrhage	1	0
<b><i>Intestinal ulcers and perforation NEC</i></b>		

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<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
Intestinal perforation	2	2
<b>Malabsorption syndromes</b>		
Steatorrhoea	1	0
<b>Nausea and vomiting symptoms</b>		
Discoloured vomit	3	0
Nausea	3652	1
Regurgitation	1	0
Retching	29	0
Vomiting	974	2
Vomiting projectile	16	0
<b>Non-site specific gastrointestinal haemorrhages</b>		
Gastrointestinal haemorrhage	2	0
Haematemesis	15	2
Haematochezia	3	0
Melaena	4	0
Upper gastrointestinal haemorrhage	2	0
<b>Oesophageal stenosis and obstruction</b>		
Oesophageal stenosis	1	0
<b>Oesophagitis (excl infective)</b>		
Oesophagitis	1	0
<b>Oral dryness and saliva altered</b>		
Aptyalism	1	0
Dry mouth	134	0
Lip dry	9	0
Salivary hypersecretion	11	0
<b>Oral soft tissue disorders NEC</b>		
Chapped lips	4	0
Cheilitis	8	0
Enlarged uvula	4	0
Lip blister	6	0
Lip disorder	2	0
Oral disorder	3	0
Oral lichen planus	1	0
Oral papule	1	0
Uvulitis	1	0
<b>Oral soft tissue haemorrhages</b>		
Mouth haemorrhage	1	0
Oral blood blister	4	0
<b>Oral soft tissue signs and symptoms</b>		
Hypoaesthesia oral	123	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	17	0
Oral mucosal blistering	6	0
Oral mucosal eruption	6	0
Oral mucosal erythema	1	0
Oral mucosal exfoliation	2	0
Oral pain	43	0

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<b>Gastrointestinal disorders</b>		
Oral pruritus	4	0
Paraesthesia oral	349	0
<b>Oral soft tissue swelling and oedema</b>		
Lip oedema	3	0
Lip swelling	192	0
Mouth swelling	21	0
Oedema mouth	1	0
Palatal oedema	1	0
Palatal swelling	1	0
<b>Peritoneal and retroperitoneal disorders</b>		
Ascites	1	0
<b>Peritoneal and retroperitoneal fibrosis and adhesions</b>		
Abdominal adhesions	1	0
<b>Rectal inflammations NEC</b>		
Proctitis	1	0
Proctitis ulcerative	1	0
<b>Salivary gland disorders NEC</b>		
Salivary gland pain	2	0
<b>Salivary gland enlargements</b>		
Parotid gland enlargement	1	0
Submaxillary gland enlargement	4	0
<b>Stomatitis and ulceration</b>		
Aphthous ulcer	7	0
Lip ulceration	2	0
Mouth ulceration	81	0
Oral mucosa erosion	1	0
Palatal ulcer	1	0
Stomatitis	8	0
<b>Tongue disorders</b>		
Glossitis	3	0
Plicated tongue	2	0
Tongue disorder	11	0
Tongue haemorrhage	1	0
Tongue ulceration	7	0
<b>Tongue signs and symptoms</b>		
Glossodynia	52	0
Stiff tongue	1	0
Swollen tongue	143	0
Tongue blistering	3	0
Tongue coated	3	0
Tongue discolouration	5	0
Tongue discomfort	11	0
Tongue dry	4	0
Tongue eruption	4	0
Tongue erythema	1	0
Tongue movement disturbance	2	0
Tongue oedema	10	0
Tongue rough	2	0
Tongue spasm	3	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>8506</b>	<b>10</b>

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<b>General disorders</b>		
<b><i>Administration site reactions NEC</i></b>		
Administration site bruise	2	0
Administration site erythema	1	0
Administration site inflammation	1	0
Administration site pain	4	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
<b><i>Adverse effect absent</i></b>		
No adverse event	3	0
<b><i>Application and instillation site reactions</i></b>		
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
<b><i>Asthenic conditions</i></b>		
Asthenia	363	1
Chronic fatigue syndrome	3	0
Fatigue	5220	1
Malaise	1241	0
Sluggishness	3	0
<b><i>Body temperature altered</i></b>		
Hypothermia	11	0
Temperature regulation disorder	4	0
<b><i>Complications associated with device NEC</i></b>		
Medical device pain	1	0
Medical device site swelling	1	0
<b><i>Death and sudden death</i></b>		
Clinical death	1	1
Death	90	90
Death neonatal	1	1
Sudden death	12	12
<b><i>Febrile disorders</i></b>		
Hyperpyrexia	3	0
Pyrexia	4477	0
<b><i>Feelings and sensations NEC</i></b>		
Chills	2883	0
Feeling abnormal	229	0
Feeling cold	293	0
Feeling drunk	13	0
Feeling hot	310	0
Feeling jittery	7	0
Feeling of body temperature change	89	0
Hangover	7	0
Hunger	5	0
Sensation of foreign body	15	0
Temperature intolerance	2	0

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<b>General disorders</b> General disorders cont'd		
Thirst	64	0
<b>Gait disturbances</b>		
Gait disturbance	27	0
Gait inability	17	0
Loss of control of legs	1	0
<b>General signs and symptoms NEC</b>		
Condition aggravated	24	0
Crying	13	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	351	0
Induration	2	0
Influenza like illness	630	0
Irritability postvaccinal	1	0
Local reaction	35	0
Multiple organ dysfunction syndrome	1	1
Peripheral swelling	644	0
Pre-existing condition improved	2	0
Screaming	2	0
Secretion discharge	4	0
Swelling	496	0
Swelling face	182	0
<b>Inflammations</b>		
Inflammation	65	0
Papillitis	1	0
Systemic inflammatory response syndrome	1	0
<b>Infusion site reactions</b>		
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
<b>Injection site reactions</b>		
Injected limb mobility decreased	9	0
Injection site bruising	14	0
Injection site discolouration	2	0
Injection site discomfort	4	0
Injection site erythema	129	0
Injection site haemorrhage	2	0
Injection site hypoaesthesia	5	0
Injection site indentation	1	0
Injection site induration	1	0
Injection site inflammation	10	0
Injection site joint pain	8	0
Injection site mass	115	0
Injection site necrosis	1	0
Injection site oedema	7	0
Injection site pain	954	0
Injection site paraesthesia	4	0
Injection site pruritus	60	0

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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Injection site rash	26	0
Injection site reaction	11	0
Injection site scab	2	0
Injection site scar	2	0
Injection site swelling	119	0
Injection site urticaria	6	0
Injection site vesicles	2	0
Injection site warmth	39	0
<b>Interactions</b>		
Alcohol interaction	2	0
Drug interaction	2	0
<b>Mass conditions NEC</b>		
Cyst	2	0
Mass	4	0
Nodule	4	0
<b>Necrosis NEC</b>		
Fat necrosis	1	0
<b>Oedema NEC</b>		
Face oedema	9	0
Localised oedema	9	0
Oedema	6	0
Oedema peripheral	13	0
<b>Pain and discomfort NEC</b>		
Axillary pain	240	0
Chest discomfort	312	0
Chest pain	405	0
Discomfort	31	0
Facial discomfort	6	0
Facial pain	43	0
Non-cardiac chest pain	6	0
Pain	1737	0
Suprapubic pain	1	0
Tenderness	149	0
<b>Therapeutic and nontherapeutic responses</b>		
Adverse drug reaction	27	0
Adverse event	1	0
Adverse reaction	1	0
Drug ineffective	84	0
Immediate post-injection reaction	2	0
No reaction on previous exposure to drug	9	0
Therapeutic product effect delayed	1	0
Therapeutic product effect increased	1	0
Therapeutic response unexpected	9	0
Treatment failure	2	0
<b>Ulcers NEC</b>		
Ulcer	2	0
<b>Vaccination site reactions</b>		
Extensive swelling of vaccinated limb	2	0
Shoulder injury related to vaccine administration	1	0
Vaccination site bruising	33	0
Vaccination site dermatitis	1	0
Vaccination site discolouration	5	0
Vaccination site discomfort	17	0

## Case Series Drug Analysis Print

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

Report Run Date: 22-Feb-2021

Data Lock Date: 19-Feb-2021 19:00:04

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Vaccination site eczema	1	0
Vaccination site erythema	221	0
Vaccination site haemorrhage	5	0
Vaccination site hypoaesthesia	1	0
Vaccination site induration	32	0
Vaccination site inflammation	27	0
Vaccination site irritation	4	0
Vaccination site joint discomfort	2	0
Vaccination site joint erythema	4	0
Vaccination site joint movement impairment	11	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	59	0
Vaccination site movement impairment	20	0
Vaccination site oedema	3	0
Vaccination site pain	817	0
Vaccination site paraesthesia	4	0
Vaccination site pruritus	52	0
Vaccination site rash	32	0
Vaccination site reaction	11	0
Vaccination site swelling	241	0
Vaccination site ulcer	1	0
Vaccination site urticaria	5	0
Vaccination site vesicles	2	0
Vaccination site warmth	123	0
<b><i>Withdrawal and rebound effects</i></b>		
Drug withdrawal syndrome	1	0
Withdrawal syndrome	1	0
<b>General disorders SOC TOTAL</b>	<b>24313</b>	<b>107</b>



## Case Series Drug Analysis Print

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

Report Run Date: 22-Feb-2021

Data Lock Date: 19-Feb-2021 19:00:04

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Hepatic disorders</b>		
<i><b>Cholestasis and jaundice</b></i>		
Jaundice	2	0
<i><b>Hepatic vascular disorders</b></i>		
Hepatic artery embolism	1	0
<i><b>Hepatobiliary signs and symptoms</b></i>		
Hepatic pain	5	0
Liver tenderness	1	0
<i><b>Hepatocellular damage and hepatitis NEC</b></i>		
Hepatitis	2	0
Liver injury	2	0
<b>Hepatic disorders SOC TOTAL</b>	<b>13</b>	<b>0</b>

## Case Series Drug Analysis Print

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

Report Run Date: 22-Feb-2021  
 Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 19-Feb-2021 19:00:04  
 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	2	0
<i>Allergic conditions NEC</i>		
Allergic oedema	3	0
Allergy to arthropod bite	1	0
Hypersensitivity	195	0
Serum sickness	2	0
Serum sickness-like reaction	1	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	1	0
Allergy to chemicals	1	0
Allergy to vaccine	15	0
Contrast media reaction	1	0
Drug hypersensitivity	4	0
Food allergy	1	0
Reaction to preservatives	3	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	152	0
Anaphylactic shock	6	0
Anaphylactoid reaction	8	0
Anaphylactoid shock	2	0
<i>Atopic disorders</i>		
Seasonal allergy	1	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	4	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
<b>Immune system disorders SOC TOTAL</b>	<b>413</b>	<b>0</b>

## Case Series Drug Analysis Print

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

Report Run Date: 22-Feb-2021

Data Lock Date: 19-Feb-2021 19:00:04

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Infections</b>		
<b><i>Abdominal and gastrointestinal infections</i></b>		
Appendicitis	3	0
Dysentery	1	0
Gastroenteritis	6	0
<b><i>Aspergillus infections</i></b>		
Bronchopulmonary aspergillosis	1	0
<b><i>Bacterial infections NEC</i></b>		
Arthritis bacterial	1	0
Bacterial diarrhoea	1	0
Cellulitis	52	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
<b><i>Breast infections</i></b>		
Breast abscess	1	0
Mastitis	4	0
<b><i>Candida infections</i></b>		
Anal candidiasis	1	0
Candida infection	2	0
Oral candidiasis	9	0
Vulvovaginal candidiasis	8	0
<b><i>Central nervous system and spinal infections</i></b>		
Encephalitis	3	0
Meningitis	2	0
Myelitis	1	0
<b><i>Clostridia infections</i></b>		
Clostridium difficile infection	1	0
<b><i>Coronavirus infections</i></b>		
Asymptomatic COVID-19	6	0
COVID-19	374	16
COVID-19 pneumonia	8	2
Coronavirus infection	5	0
Suspected COVID-19	26	0
<b><i>Coxiella infections</i></b>		
Q fever	5	0
<b><i>Dental and oral soft tissue infections</i></b>		
Abscess oral	3	0
Gingivitis	2	0
Parotitis	5	0
Sialoadenitis	1	0
<b><i>Ear infections</i></b>		
Ear infection	9	0
Labyrinthitis	15	0
<b><i>Epstein-Barr viral infections</i></b>		
Infectious mononucleosis	1	0
<b><i>Eye and eyelid infections</i></b>		
Conjunctivitis	19	0
Eye abscess	1	0
Eye infection	2	0
Hordeolum	3	0

## Case Series Drug Analysis Print

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

Report Run Date: 22-Feb-2021  
Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 19-Feb-2021 19:00:04  
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Infections</b> Infections cont'd		
Periorbital infection	1	0
<b>Female reproductive tract infections</b>		
Vulval abscess	1	0
<b>Hepatobiliary and spleen infections</b>		
Biliary sepsis	1	0
<b>Herpes viral infections</b>		
Disseminated varicella zoster virus infection	1	0
Genital herpes	4	0
Herpes ophthalmic	1	0
Herpes simplex	2	0
Herpes simplex reactivation	1	0
Herpes virus infection	3	0
Herpes zoster	154	0
Herpes zoster oticus	1	0
Ophthalmic herpes zoster	1	0
Oral herpes	64	0
<b>Infections NEC</b>		
Abscess	2	0
Abscess limb	1	0
Infection	60	0
Injection site abscess	1	0
Injection site infection	2	0
Localised infection	4	0
Lymph gland infection	2	0
Respiratory tract infection	1	0
Vaccination site abscess	2	0
Vaccination site infection	7	0
Vestibulitis	1	0
<b>Influenza viral infections</b>		
Influenza	337	0
<b>Lower respiratory tract and lung infections</b>		
Bronchitis	3	0
Lower respiratory tract infection	27	5
Pneumonia	15	4
Sputum purulent	1	0
<b>Male reproductive tract infections</b>		
Epididymitis	1	0
Orchitis	2	0
<b>Muscle and soft tissue infections</b>		
Soft tissue infection	1	0
<b>Neisseria infections</b>		
Gonorrhoea	1	0
<b>Sepsis, bacteraemia, viraemia and fungaemia NEC</b>		
Sepsis	10	0
Urosepsis	2	0
<b>Skin structures and soft tissue infections</b>		
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

## Case Series Drug Analysis Print

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

Report Run Date: 22-Feb-2021

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Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Infections</b>		
Infections cont'd		
<b><i>Staphylococcal infections</i></b>		
Furuncle	4	0
Pneumonia staphylococcal	1	0
Staphylococcal abscess	1	0
<b><i>Streptococcal infections</i></b>		
Pharyngitis streptococcal	2	0
<b><i>Trypanosomal infections</i></b>		
African trypanosomiasis	1	0
<b><i>Upper respiratory tract infections</i></b>		
Laryngitis	1	0
Nasopharyngitis	163	0
Pharyngitis	5	0
Rhinitis	14	0
Sinusitis	12	0
Tonsillitis	17	0
Tracheitis	1	0
<b><i>Urinary tract infections</i></b>		
Cystitis	9	0
Kidney infection	3	0
Pyelonephritis	1	0
Urinary tract infection	26	0
<b><i>Vascular infections</i></b>		
Haematoma infection	1	0
Lymphangitis	1	0
<b><i>Viral infections NEC</i></b>		
Conjunctivitis viral	1	0
Eye infection viral	1	0
Gastroenteritis viral	5	0
Pneumonia viral	1	1
Post viral fatigue syndrome	4	0
Sweating fever	32	0
Vestibular neuronitis	3	0
Viral infection	1	0
Viral labyrinthitis	2	0
Viral pharyngitis	4	0
Viral rash	12	0
Viral tonsillitis	1	0
<b>Infections SOC TOTAL</b>	<b>1659</b>	<b>28</b>

## Case Series Drug Analysis Print

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

Report Run Date: 22-Feb-2021  
Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 19-Feb-2021 19:00:04  
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Injuries</b>		
<b><i>Abdominal and gastrointestinal injuries NEC</i></b>		
Oral contusion	1	0
Tongue injury	1	0
<b><i>Anaesthetic and allied procedural complications</i></b>		
Delayed recovery from anaesthesia	1	0
<b><i>Bone and joint injuries NEC</i></b>		
Joint injury	1	0
<b><i>Chest and respiratory tract injuries NEC</i></b>		
Chest crushing	1	0
<b><i>Conditions caused by cold</i></b>		
Chillblains	10	0
<b><i>Exposures associated with pregnancy, delivery and lactation</i></b>		
Exposure during pregnancy	4	0
Foetal exposure during pregnancy	2	0
Maternal exposure during breast feeding	9	0
Maternal exposure during pregnancy	26	0
<b><i>Eye injuries NEC</i></b>		
Eye contusion	4	0
Eye injury	2	0
Injury corneal	1	0
Periorbital haematoma	1	0
<b><i>Gastrointestinal and hepatobiliary procedural complications</i></b>		
Post procedural constipation	1	0
Postoperative ileus	1	0
Procedural nausea	3	0
<b><i>Heat injuries (excl thermal burns)</i></b>		
Heat illness	1	0
Heat oedema	3	0
Heat stroke	1	0
<b><i>Limb fractures and dislocations</i></b>		
Atypical femur fracture	1	0
Clavicle fracture	1	0
<b><i>Medication errors, product use errors and issues NEC</i></b>		
Medication error	1	0
Product use issue	3	0
Vaccination error	1	0
Wrong technique in product usage process	1	0
<b><i>Muscle, tendon and ligament injuries</i></b>		
Epicondylitis	2	0
Muscle injury	1	0
Muscle strain	3	0
Tendon injury	1	0
<b><i>Musculoskeletal procedural complications</i></b>		
Post laminectomy syndrome	1	0
<b><i>Nerve injuries NEC</i></b>		
Nerve injury	4	0
<b><i>Neurological and psychiatric procedural complications</i></b>		
Procedural dizziness	4	0
<b><i>Non-site specific injuries NEC</i></b>		
Bite	1	0
Electric shock	3	0
Fall	33	1
Wound	1	0

## Case Series Drug Analysis Print

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

Report Run Date: 22-Feb-2021  
Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 19-Feb-2021 19:00:04  
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Injuries</b> Injuries cont'd		
Wound complication	3	0
Wound secretion	1	0
<b>Non-site specific procedural complications</b>		
Incision site pain	1	0
Infusion related reaction	3	0
Injection related reaction	14	0
Post procedural complication	2	0
<b>Off label uses</b>		
Off label use	3	0
<b>Overdoses NEC</b>		
Overdose	7	0
<b>Peripheral nerve injuries</b>		
Ulnar nerve injury	2	0
<b>Poisoning and toxicity</b>		
Poisoning	1	0
<b>Product administration errors and issues</b>		
Accidental overdose	1	0
Contraindicated product administered	1	0
Inappropriate schedule of product administration	7	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
<b>Product preparation errors and issues</b>		
Product preparation issue	3	0
<b>Radiation injuries</b>		
Sunburn	2	0
<b>Site specific injuries NEC</b>		
Face crushing	1	0
Head injury	1	0
Limb injury	4	0
<b>Skin injuries NEC</b>		
Contusion	102	0
Scar	1	0
Skin abrasion	3	0
<b>Stoma complications</b>		
Gastrointestinal stoma complication	1	0
Stoma site discharge	1	0
Stoma site extravasation	1	0
Stoma site haemorrhage	1	0
<b>Thermal burns</b>		
Airway burns	1	0
Burn oesophageal	1	0
Burn of internal organs	1	0
Burns second degree	2	0
Thermal burn	2	0
Thermal burns of eye	1	0
<b>Underdoses NEC</b>		
Underdose	1	0
<b>Vaccination related complications</b>		
Vaccination complication	13	0
<b>Injuries SOC TOTAL</b>	<b>334</b>	<b>1</b>

## Case Series Drug Analysis Print

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

Report Run Date: 22-Feb-2021

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Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Investigations</b>		
<i><b>Adrenal cortex tests</b></i>		
Cortisol decreased	1	0
<i><b>Blood gas and acid base analyses</b></i>		
Blood lactic acid	1	0
Blood lactic acid increased	2	0
Blood pH	1	0
Blood pH increased	2	0
Oxygen consumption decreased	1	0
Oxygen saturation	4	0
Oxygen saturation decreased	20	0
<i><b>Carbohydrate tolerance analyses (incl diabetes)</b></i>		
Blood glucose	2	0
Blood glucose decreased	5	0
Blood glucose fluctuation	2	0
Blood glucose increased	26	0
Glycosylated haemoglobin increased	1	0
<i><b>Cardiac auscultatory investigations</b></i>		
Cardiac murmur	1	0
<i><b>Cardiac function diagnostic procedures</b></i>		
Central venous pressure	1	0
<i><b>Central nervous system imaging procedures</b></i>		
Magnetic resonance imaging brain	4	0
<i><b>Chemistry analyses NEC</b></i>		
Inflammatory marker increased	1	0
<i><b>Coagulation and bleeding analyses</b></i>		
Bleeding time abnormal	1	0
Coagulation time prolonged	1	0
Fibrin D dimer increased	2	0
International normalised ratio abnormal	1	0
International normalised ratio decreased	5	0
International normalised ratio increased	19	0
<i><b>ECG investigations</b></i>		
Electrocardiogram ST segment elevation	1	0
<i><b>Endocrine analyses and imaging NEC</b></i>		
Hormone level abnormal	1	0
<i><b>Haematological analyses NEC</b></i>		
Red blood cell sedimentation rate increased	2	0
<i><b>Heart rate and pulse investigations</b></i>		
Heart rate	45	0
Heart rate abnormal	3	0
Heart rate decreased	9	0
Heart rate increased	141	0
Heart rate irregular	17	0
Pulse abnormal	6	0
Radial pulse abnormal	1	0
<i><b>Immunology analyses NEC</b></i>		
Antibody test	1	0
Antibody test abnormal	1	0
Immunology test	3	0
<i><b>Investigations NEC</b></i>		
Blood test abnormal	2	0
Polymerase chain reaction positive	14	0
Systemic lupus erythematosus disease activity index increased	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
<b>Investigations</b> Investigations cont'd		
<b><i>Liver function analyses</i></b>		
Alanine aminotransferase increased	3	0
Gamma-glutamyltransferase increased	1	0
Hepatic enzyme increased	1	0
Liver function test abnormal	2	0
Liver function test increased	3	0
Transaminases increased	1	0
<b><i>Metabolism tests NEC</i></b>		
Blood ketone body	1	0
Blood ketone body increased	1	0
<b><i>Microbiology and serology tests NEC</i></b>		
Culture negative	1	0
<b><i>Mineral and electrolyte analyses</i></b>		
Blood magnesium decreased	1	0
Blood potassium abnormal	1	0
Blood potassium decreased	1	0
Serum ferritin increased	1	0
<b><i>Musculoskeletal and soft tissue tests NEC</i></b>		
Swollen joint count increased	1	0
<b><i>Neurologic diagnostic procedures</i></b>		
Coma scale abnormal	2	0
<b><i>Ophthalmic function diagnostic procedures</i></b>		
Intraocular pressure increased	1	0
<b><i>Physical examination procedures and organ system status</i></b>		
Body temperature	72	0
Body temperature abnormal	18	0
Body temperature decreased	11	0
Body temperature fluctuation	7	0
Body temperature increased	150	0
Body temperature normal	1	0
Breath sounds abnormal	1	0
Grip strength	2	0
Grip strength decreased	2	0
Lymph node palpable	8	0
Product residue present	1	0
Respiratory rate	2	0
Respiratory rate decreased	2	0
Respiratory rate increased	14	0
Skin temperature	9	0
Temperature difference of extremities	1	0
Weight	1	0
Weight decreased	8	0
Weight increased	1	0
<b><i>Pituitary analyses anterior</i></b>		
Blood growth hormone	2	0
<b><i>Platelet analyses</i></b>		
Platelet count decreased	3	0
<b><i>Protein analyses NEC</i></b>		
C-reactive protein increased	4	0
<b><i>Red blood cell analyses</i></b>		
Haematocrit	1	0
Haemoglobin decreased	3	0
<b><i>Respiratory and pulmonary function diagnostic procedures</i></b>		

## Case Series Drug Analysis Print

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Report Run Date: 22-Feb-2021

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Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
Forced expiratory volume increased	1	0
Peak expiratory flow rate decreased	1	0
Vital capacity	1	0
<b>Respiratory tract and thoracic histopathology procedures</b>		
Sputum abnormal	1	0
<b>Skeletal and cardiac muscle analyses</b>		
Blood creatine phosphokinase increased	1	0
Troponin increased	3	0
<b>Therapeutic drug monitoring analyses</b>		
Anticoagulation drug level below therapeutic	4	0
Anticoagulation drug level increased	1	0
<b>Thyroid analyses</b>		
Tri-iodothyronine	1	0
Tri-iodothyronine decreased	1	0
<b>Tissue enzyme analyses NEC</b>		
Blood alkaline phosphatase increased	1	0
<b>Urinalysis NEC</b>		
Blood urine present	5	0
pH urine	2	0
pH urine increased	1	0
<b>Urinary tract function analyses NEC</b>		
Urine output	3	0
Urine output decreased	3	0
Urine output increased	1	0
<b>Vascular tests NEC (incl blood pressure)</b>		
Blood pressure abnormal	2	0
Blood pressure decreased	9	0
Blood pressure increased	62	0
Blood pressure measurement	7	0
Blood pressure systolic decreased	1	0
Blood pressure systolic increased	2	0
<b>Virus identification and serology</b>		
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	12	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	30	0
Viral test	1	0
<b>White blood cell analyses</b>		
White blood cell count decreased	1	0
White blood cell count increased	1	0
<b>Investigations SOC TOTAL</b>	<b>874</b>	<b>0</b>

## Case Series Drug Analysis Print

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Report Run Date: 22-Feb-2021  
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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<b><i>Appetite disorders</i></b>		
Appetite disorder	1	0
Decreased appetite	322	0
Eating disorder symptom	1	0
Food craving	2	0
Food refusal	3	0
Hypophagia	3	0
Increased appetite	3	0
Salt craving	1	0
<b><i>Diabetes mellitus (incl subtypes)</i></b>		
Diabetes mellitus inadequate control	3	1
Type 1 diabetes mellitus	3	0
<b><i>Diabetic complications NEC</i></b>		
Diabetic complication	1	0
Diabetic ketoacidosis	3	0
<b><i>Disorders of purine metabolism</i></b>		
Gout	15	0
<b><i>Electrolyte imbalance NEC</i></b>		
Fluid imbalance	1	0
<b><i>Fluid intake increased</i></b>		
Polydipsia	1	0
<b><i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i></b>		
Gluten sensitivity	1	0
Histamine intolerance	1	0
<b><i>General nutritional disorders NEC</i></b>		
Abnormal weight gain	3	0
Feeding disorder	9	0
Food aversion	2	0
Poor feeding infant	1	0
<b><i>Hyperglycaemic conditions NEC</i></b>		
Hyperglycaemia	15	0
<b><i>Hypoglycaemic conditions NEC</i></b>		
Hypoglycaemia	25	0
Postprandial hypoglycaemia	1	0
<b><i>Lipid metabolism and deposit disorders NEC</i></b>		
Body fat disorder	1	0
<b><i>Metabolic acidoses (excl diabetic acidoses)</i></b>		
Ketoacidosis	3	0
Metabolic acidosis	1	0
<b><i>Mixed acid-base disorders</i></b>		
Acidosis	2	0
<b><i>Potassium imbalance</i></b>		
Hyperkalaemia	1	0
Hypokalaemic syndrome	1	0
<b><i>Sodium imbalance</i></b>		
Hyponatraemia	2	0
<b><i>Total fluid volume decreased</i></b>		
Dehydration	33	0
<b><i>Total fluid volume increased</i></b>		
Fluid retention	3	0
<b>Metabolic disorders SOC TOTAL</b>	<b>468</b>	<b>1</b>

## Case Series Drug Analysis Print

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

Report Run Date: 22-Feb-2021  
Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 19-Feb-2021 19:00:04  
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<b><i>Arthropathies NEC</i></b>		
Arthritis	40	0
Arthropathy	4	0
Sacroiliitis	1	0
<b><i>Bone disorders NEC</i></b>		
Medial tibial stress syndrome	2	0
Spinal disorder	1	0
<b><i>Bone related signs and symptoms</i></b>		
Bone pain	68	0
Bone swelling	1	0
Coccydynia	1	0
Pain in jaw	65	0
Spinal pain	7	0
<b><i>Bursal disorders</i></b>		
Bursitis	5	0
<b><i>Cartilage disorders</i></b>		
Costochondritis	8	0
<b><i>Connective tissue disorders NEC</i></b>		
Polymyalgia rheumatica	3	0
Sjogren's syndrome	1	0
<b><i>Crystal arthropathic disorders</i></b>		
Crystal arthropathy	1	0
<b><i>Epiphyseal disorders</i></b>		
Epiphyses premature fusion	1	0
<b><i>Extremity deformities</i></b>		
Foot deformity	1	0
<b><i>Joint related disorders NEC</i></b>		
Joint lock	1	0
Periarthritis	7	0
Temporomandibular joint syndrome	1	0
<b><i>Joint related signs and symptoms</i></b>		
Arthralgia	2176	0
Jaw clicking	2	0
Joint effusion	4	0
Joint noise	3	0
Joint range of motion decreased	2	0
Joint stiffness	40	0
Joint swelling	59	0
Joint warmth	3	0
<b><i>Lupus erythematosus (incl subtypes)</i></b>		
Systemic lupus erythematosus	2	0
<b><i>Muscle infections and inflammations</i></b>		
Antisynthetase syndrome	1	0
Myositis	3	0
Polymyositis	1	0
<b><i>Muscle pains</i></b>		
Fibromyalgia	13	0
Myalgia	3288	0
Myofascial pain syndrome	4	0
<b><i>Muscle related signs and symptoms NEC</i></b>		
Muscle discomfort	1	0
Muscle disorder	2	0
Muscle fatigue	86	0

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i>Muscle &amp; tissue disorders cont'd</i>		
Muscle spasms	139	0
Muscle swelling	7	0
Muscle tightness	11	0
Muscle twitching	57	0
<b><i>Muscle tone abnormalities</i></b>		
Muscle rigidity	7	0
Nuchal rigidity	3	0
Torticollis	1	0
Trismus	6	0
<b><i>Muscle weakness conditions</i></b>		
Muscular weakness	165	0
<b><i>Musculoskeletal and connective tissue conditions NEC</i></b>		
Limb mass	2	0
Mastication disorder	1	0
Mobility decreased	14	0
Musculoskeletal disorder	3	0
Musculoskeletal stiffness	244	0
Posture abnormal	1	0
<b><i>Musculoskeletal and connective tissue infections and inflammations NEC</i></b>		
Fasciitis	1	0
Plantar fasciitis	1	0
<b><i>Musculoskeletal and connective tissue pain and discomfort</i></b>		
Back pain	467	0
Flank pain	7	0
Limb discomfort	341	0
Musculoskeletal chest pain	28	0
Musculoskeletal discomfort	18	0
Musculoskeletal pain	15	0
Neck pain	393	0
Pain in extremity	2513	0
Rheumatic disorder	1	0
<b><i>Myopathies</i></b>		
Rhabdomyolysis	3	0
<b><i>Osteoarthropathies</i></b>		
Osteoarthritis	5	0
<b><i>Psoriatic arthropathies</i></b>		
Psoriatic arthropathy	2	0
<b><i>Rheumatoid arthropathies</i></b>		
Rheumatoid arthritis	9	0
<b><i>Soft tissue disorders NEC</i></b>		
Axillary mass	34	0
Groin pain	22	0
Neck mass	6	0
<b><i>Spondyloarthropathies</i></b>		
Ankylosing spondylitis	2	0
Arthritis reactive	6	0
<b><i>Synovial disorders</i></b>		
Synovial cyst	3	0
Synovitis	2	0
<b><i>Tendon disorders</i></b>		
Tendon pain	2	0
Tendonitis	2	0
<b><i>Trunk deformities</i></b>		

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
Muscle & tissue disorders cont'd		
Drooping shoulder syndrome	1	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>10454</b>	<b>0</b>

## Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<b>Neoplasms</b>		
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	1	0
<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>Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified</i>		
Tonsil cancer	1	0
<i>Plasma cell myelomas</i>		
Plasma cell myeloma	1	0
<i>Skin neoplasms benign</i>		
Acrochordon	1	0
Melanocytic naevus	1	0
<i>Soft tissue sarcomas histology unspecified</i>		
Sarcoma	1	0
<b>Neoplasms SOC TOTAL</b>	<b>14</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i><b>Abnormal reflexes</b></i>		
Extensor plantar response	1	0
Hyperreflexia	1	0
Hyporeflexia	3	0
<i><b>Abnormal sleep-related events</b></i>		
Sleep paralysis	2	0
<i><b>Absence seizures</b></i>		
Petit mal epilepsy	5	0
<i><b>Acute polyneuropathies</b></i>		
Guillain-Barre syndrome	1	0
<i><b>Autonomic nervous system disorders</b></i>		
Anticholinergic syndrome	1	0
Autonomic nervous system imbalance	1	0
<i><b>Central nervous system aneurysms and dissections</b></i>		
Vertebral artery dissection	1	0
<i><b>Central nervous system haemorrhages and cerebrovascular accidents</b></i>		
Brain stem infarction	1	1
Cerebellar infarction	2	0
Cerebellar stroke	1	0
Cerebral artery occlusion	1	0
Cerebral haemorrhage	8	3
Cerebral infarction	6	0
Cerebrovascular accident	45	4
Haemorrhage intracranial	2	0
Haemorrhagic stroke	1	1
Ischaemic cerebral infarction	1	0
Ischaemic stroke	9	1
Lacunar infarction	2	0
Lacunar stroke	1	0
Subarachnoid haemorrhage	2	1
<i><b>Central nervous system inflammatory disorders NEC</b></i>		
Gliosis	1	0
<i><b>Cerebrovascular venous and sinus thrombosis</b></i>		
Cerebral venous sinus thrombosis	1	0
<i><b>Cervical spinal cord and nerve root disorders</b></i>		
Cervicobrachial syndrome	1	0
<i><b>Choreiform movements</b></i>		
Chorea	1	0
<i><b>Coordination and balance disturbances</b></i>		
Ataxia	1	0
Balance disorder	65	0
Coordination abnormal	10	0
Dysstasia	13	0
<i><b>Cortical dysfunction NEC</b></i>		
Aphasia	10	0
Neurologic neglect syndrome	1	0
<i><b>Cranial nerve disorders NEC</b></i>		
Cranial nerve disorder	1	0
<i><b>Dementia (excl Alzheimer's type)</b></i>		
Dementia	4	0
Dementia with Lewy bodies	1	0
<i><b>Disturbances in consciousness NEC</b></i>		
Altered state of consciousness	4	0



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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Consciousness fluctuating	2	0
Depressed level of consciousness	6	0
Lethargy	628	0
Loss of consciousness	64	0
Sedation	3	0
Somnolence	179	0
Stupor	1	0
Syncope	257	0
<b><i>Dyskinesias and movement disorders NEC</i></b>		
Bradykinesia	3	0
Dyskinesia	5	0
Extrapyramidal disorder	1	0
Fine motor skill dysfunction	2	0
Hypokinesia	3	0
Motor dysfunction	1	0
Movement disorder	6	0
Psychomotor hyperactivity	4	0
<b><i>Dystonias</i></b>		
Dystonia	5	0
Writer's cramp	1	0
<b><i>Encephalopathies NEC</i></b>		
Posterior reversible encephalopathy syndrome	1	0
<b><i>Eye movement disorders</i></b>		
IIIrd nerve paralysis	1	0
VIth nerve paralysis	3	0
<b><i>Facial cranial nerve disorders</i></b>		
Facial nerve disorder	1	0
Facial paralysis	115	0
Facial paresis	19	0
Facial spasm	10	0
<b><i>Generalised tonic-clonic seizures</i></b>		
Generalised tonic-clonic seizure	4	0
<b><i>Headaches NEC</i></b>		
Cervicogenic headache	1	0
Cluster headache	44	0
Cold-stimulus headache	1	0
Exertional headache	4	0
Headache	7093	0
Medication overuse headache	2	0
New daily persistent headache	2	0
Occipital neuralgia	1	0
Ophthalmoplegic migraine	1	0
Primary cough headache	2	0
Primary headache associated with sexual activity	1	0
Sinus headache	87	0
Tension headache	116	0
Thunderclap headache	1	0
Vascular headache	2	0
<b><i>Lumbar spinal cord and nerve root disorders</i></b>		
Sciatica	8	0
<b><i>Memory loss (excl dementia)</i></b>		
Amnesia	11	0
Memory impairment	24	0

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Transient global amnesia	1	0
<b><i>Mental impairment (excl dementia and memory loss)</i></b>		
Cognitive disorder	9	0
Disturbance in attention	48	0
Mental impairment	6	0
<b><i>Migraine headaches</i></b>		
Hemiplegic migraine	2	0
Migraine	478	0
Migraine with aura	30	0
Retinal migraine	7	0
Typical aura without headache	1	0
Vestibular migraine	1	0
<b><i>Mononeuropathies</i></b>		
Carpal tunnel syndrome	2	0
Mononeuropathy	1	0
Nerve compression	3	0
Peroneal nerve palsy	2	0
<b><i>Multiple sclerosis acute and progressive</i></b>		
Multiple sclerosis	3	0
Multiple sclerosis relapse	5	0
<b><i>Muscle tone abnormal</i></b>		
Hypotonia	4	0
Muscle tone disorder	1	0
Serotonin syndrome	1	0
Stiff leg syndrome	1	0
<b><i>Myelitis (incl infective)</i></b>		
Myelitis transverse	4	0
<b><i>Narcolepsy and hypersomnia</i></b>		
Hypersomnia	19	0
Narcolepsy	1	0
<b><i>Nervous system disorders NEC</i></b>		
Nervous system disorder	1	0
<b><i>Neurologic visual problems NEC</i></b>		
Tunnel vision	4	0
Visual field defect	3	0
<b><i>Neurological signs and symptoms NEC</i></b>		
Dizziness	2018	0
Dizziness exertional	7	0
Dizziness postural	167	0
Drooling	2	0
Head discomfort	48	0
Hyporesponsive to stimuli	1	0
Inability to crawl	1	0
Myoclonus	3	0
Neurological symptom	4	0
Persistent postural-perceptual dizziness	2	0
Presyncope	133	0
Slow response to stimuli	2	0
Unresponsive to stimuli	15	0
<b><i>Neuromuscular disorders NEC</i></b>		
Muscle contractions involuntary	4	0
Muscle spasticity	1	0
Neuromuscular pain	1	0

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
<b><i>Neuromuscular junction dysfunction</i></b>		
Myasthenia gravis	2	0
<b><i>Olfactory nerve disorders</i></b>		
Anosmia	56	0
Hyposmia	5	0
Parosmia	42	0
<b><i>Optic nerve disorders NEC</i></b>		
Optic neuritis	4	0
<b><i>Paraesthesias and dysaesthesias</i></b>		
Burning sensation	83	0
Dysaesthesia	3	0
Formication	8	0
Hemiparaesthesia	1	0
Hyperaesthesia	21	0
Hypoaesthesia	438	0
Paraesthesia	658	0
Synaesthesia	1	0
<b><i>Paralysis and paresis (excl cranial nerve)</i></b>		
Hemiparesis	11	0
Hemiplegia	3	0
Locked-in syndrome	1	0
Monoparesis	13	0
Monoplegia	9	0
Paralysis	16	0
Paraparesis	1	0
Paresis	1	0
<b><i>Parkinson's disease and parkinsonism</i></b>		
Freezing phenomenon	1	0
Parkinsonian gait	1	0
Parkinsonism	2	0
<b><i>Partial complex seizures</i></b>		
Dreamy state	1	0
Temporal lobe epilepsy	1	0
<b><i>Peripheral neuropathies NEC</i></b>		
Neuropathy peripheral	13	0
Peripheral sensory neuropathy	3	0
<b><i>Seizures and seizure disorders NEC</i></b>		
Clonic convulsion	1	0
Epilepsy	13	0
Febrile convulsion	2	0
Partial seizures	1	0
Psychogenic seizure	3	0
Seizure	67	1
Seizure cluster	1	0
Status epilepticus	5	0
Tonic convulsion	5	0
<b><i>Sensory abnormalities NEC</i></b>		
Ageusia	117	0
Allodynia	3	0
Aura	7	0
Dysgeusia	306	0
Hypergeusia	1	0
Neuralgia	64	0

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
Nervous system disorders cont'd		
Phantom limb syndrome	1	0
Post herpetic neuralgia	1	0
Restless legs syndrome	20	0
Sensory disturbance	10	0
Sensory loss	7	0
Taste disorder	56	0
<b>Sleep disturbances NEC</b>		
Poor quality sleep	41	0
<b>Speech and language abnormalities</b>		
Dysarthria	27	0
Incoherent	1	0
Repetitive speech	1	0
Speech disorder	6	0
<b>Spinal cord and nerve root disorders NEC</b>		
Radiculitis brachial	1	0
Radiculopathy	1	0
<b>Structural brain disorders NEC</b>		
Brain injury	2	2
<b>Transient cerebrovascular events</b>		
Transient ischaemic attack	16	0
<b>Tremor (excl congenital)</b>		
Essential tremor	1	0
Resting tremor	1	0
Tremor	371	0
<b>Trigeminal disorders</b>		
Facial neuralgia	6	0
Numb chin syndrome	1	0
Trigeminal nerve disorder	1	0
Trigeminal neuralgia	7	0
<b>Nervous system disorders SOC TOTAL</b>	<b>14559</b>	<b>14</b>

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Reaction Name	Total	Fatal
<b>Pregnancy conditions</b>		
<i>Abortions spontaneous</i>		
Abortion spontaneous	8	0
<i>Labour onset and length abnormalities</i>		
Premature labour	1	0
<i>Maternal complications of pregnancy NEC</i>		
Morning sickness	3	0
<i>Normal pregnancy, labour and delivery</i>		
Pregnancy	5	0
<i>Unintended pregnancies</i>		
Pregnancy with implant contraceptive	1	0
<b>Pregnancy conditions SOC TOTAL</b>	<b>18</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b><i>Device issues NEC</i></b>		
Device issue	1	0
<b><i>Device malfunction events NEC</i></b>		
Device stimulation issue	1	0
Oversensing	5	0
<b><i>Product contamination and sterility issues</i></b>		
Product contamination physical	1	0
<b><i>Product physical issues</i></b>		
Product taste abnormal	2	0
<b><i>Product quality issues NEC</i></b>		
Product origin unknown	1	0
<b>null SOC TOTAL</b>	<b>11</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<i><b>Affect alterations NEC</b></i>		
Flat affect	1	0
<i><b>Anxiety symptoms</b></i>		
Agitation	22	0
Anxiety	93	0
Nervousness	47	0
Stress	1	0
Tension	11	0
<i><b>Behaviour and socialisation disturbances</b></i>		
Indifference	2	0
Paranoia	4	0
Social avoidant behaviour	2	0
Soliloquy	1	0
<i><b>Cognitive and attention disorders and disturbances NEC</b></i>		
Daydreaming	1	0
Mental fatigue	34	0
<i><b>Communications disorders</b></i>		
Communication disorder	1	0
<i><b>Confusion and disorientation</b></i>		
Confusional state	149	0
Disorientation	46	0
<i><b>Decreased physical activity levels</b></i>		
Catatonia	1	0
<i><b>Deliria</b></i>		
Delirium	33	0
<i><b>Delusional symptoms</b></i>		
Delusion	1	0
<i><b>Depressive disorders</b></i>		
Depression	18	0
<i><b>Dissociative states</b></i>		
Depersonalisation/derealisation disorder	2	0
Dissociation	4	0
Dissociative amnesia	1	0
Dissociative disorder	1	0
<i><b>Disturbances in initiating and maintaining sleep</b></i>		
Initial insomnia	3	0
Insomnia	208	0
Middle insomnia	4	0
Terminal insomnia	1	0
<i><b>Dyssomnias</b></i>		
Dyssomnia	1	0
<i><b>Eating disorders NEC</b></i>		
Eating disorder	1	0
<i><b>Emotional and mood disturbances NEC</b></i>		
Anger	3	0
Dysphoria	1	0
Emotional disorder	5	0
Emotional distress	6	0
Euphoric mood	4	0
Irritability	31	0
Mood altered	4	0
<i><b>Fear symptoms and phobic disorders (incl social phobia)</b></i>		
Fear of falling	1	0

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Phonophobia	1	0
Social fear	1	0
<b>Fluctuating mood symptoms</b>		
Mood swings	5	0
<b>Hallucinations (excl sleep-related)</b>		
Hallucination	47	0
Hallucination, auditory	2	0
Hallucination, olfactory	1	0
Hallucination, tactile	1	0
Hallucination, visual	5	0
Hallucinations, mixed	1	0
<b>Increased physical activity levels</b>		
Restlessness	24	0
<b>Mental disorders NEC</b>		
Mental disorder	1	0
<b>Mental disorders due to a general medical condition NEC</b>		
Neuropsychiatric symptoms	1	0
<b>Mood alterations with depressive symptoms</b>		
Decreased interest	3	0
Depressed mood	42	0
Feeling of despair	1	0
Negative thoughts	1	0
Sense of a foreshortened future	2	0
Tearfulness	3	0
<b>Mood disorders NEC</b>		
Apathy	3	0
Laziness	1	0
Listless	3	0
<b>Narcolepsy and associated conditions</b>		
Sleep attacks	2	0
<b>Obsessive-compulsive disorders and symptoms</b>		
Obsessive-compulsive symptom	1	0
<b>Orgasmic disorders and disturbances</b>		
Anorgasmia	1	0
<b>Panic attacks and disorders</b>		
Panic attack	20	0
Panic disorder	1	0
Panic reaction	5	0
<b>Parasomnias</b>		
Abnormal dreams	39	0
Nightmare	32	0
Sleep terror	2	0
<b>Perception disturbances NEC</b>		
Autoscopy	2	0
Derealisation	2	0
Flashback	1	0
Illusion	1	0
<b>Psychiatric elimination disorders</b>		
Enuresis	4	0
<b>Psychiatric symptoms NEC</b>		
Hypervigilance	1	0
Trance	1	0
<b>Psychotic disorder NEC</b>		



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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Psychotic behaviour	1	0
Psychotic disorder	4	0
<b><i>Sleep disorders NEC</i></b>		
Sleep disorder	35	0
<b><i>Somatic symptom disorders</i></b>		
Habit cough	3	0
Vomiting psychogenic	1	0
<b><i>Speech and language usage disturbances</i></b>		
Disorganised speech	2	0
Logorrhoea	1	0
<b><i>Speech articulation and rhythm disturbances</i></b>		
Dysphemia	1	0
<b><i>Stereotypies and automatisms</i></b>		
Bruxism	2	0
Head banging	2	0
Stereotypy	1	0
<b><i>Suicidal and self-injurious behaviour</i></b>		
Intentional self-injury	1	0
Suicidal ideation	1	0
<b><i>Thinking disturbances</i></b>		
Bradyphrenia	9	0
Thinking abnormal	3	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>1080</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i><b>Bladder and urethral symptoms</b></i>		
Bladder discomfort	1	0
Dysuria	8	0
Incontinence	7	0
Micturition disorder	1	0
Micturition urgency	5	0
Pollakiuria	14	0
Urethral pain	1	0
Urinary incontinence	14	0
Urinary retention	12	0
Urine flow decreased	1	0
<i><b>Bladder disorders NEC</b></i>		
Bladder disorder	3	0
<i><b>Genital and urinary tract disorders NEC</b></i>		
Urinary tract disorder	2	0
<i><b>Myoneurogenic bladder disorders</b></i>		
Hypertonic bladder	1	0
Loss of bladder sensation	1	0
Neurogenic bladder	1	0
<i><b>Nephritis NEC</b></i>		
Nephritis	1	0
<i><b>Renal failure and impairment</b></i>		
Acute kidney injury	7	0
Anuria	1	0
Renal failure	3	0
<i><b>Urinary abnormalities</b></i>		
Chromaturia	11	0
Haematuria	6	0
Proteinuria	2	0
Urine abnormality	4	0
Urine odour abnormal	2	0
<i><b>Urinary tract signs and symptoms NEC</b></i>		
Costovertebral angle tenderness	1	0
Haemorrhage urinary tract	4	0
Nocturia	1	0
Polyuria	1	0
Renal pain	48	0
Urinary tract pain	1	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>165</b>	<b>0</b>

## Case Series Drug Analysis Print

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

Report Run Date: 22-Feb-2021

Data Lock Date: 19-Feb-2021 19:00:04

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i><b>Benign and malignant breast neoplasms</b></i>		
Breast cyst	2	0
<i><b>Breast disorders NEC</b></i>		
Breast mass	6	0
Gynaecomastia	1	0
<i><b>Breast signs and symptoms</b></i>		
Breast discomfort	2	0
Breast pain	37	0
Breast swelling	9	0
Breast tenderness	6	0
Nipple pain	5	0
Nipple swelling	2	0
<i><b>Erection and ejaculation conditions and disorders</b></i>		
Erectile dysfunction	6	0
<i><b>Menopausal effects NEC</b></i>		
Menopausal symptoms	2	0
<i><b>Menopausal effects on the genitourinary tract</b></i>		
Postmenopausal haemorrhage	1	0
<i><b>Menstruation and uterine bleeding NEC</b></i>		
Dysmenorrhoea	16	0
Menstrual disorder	16	0
Menstruation irregular	14	0
Metrorrhagia	8	0
Premenstrual pain	1	0
<i><b>Menstruation with decreased bleeding</b></i>		
Amenorrhoea	5	0
Hypomenorrhoea	9	0
Menstruation delayed	26	0
Oligomenorrhoea	1	0
<i><b>Menstruation with increased bleeding</b></i>		
Menorrhagia	31	0
Polymenorrhoea	5	0
<i><b>Ovarian and fallopian tube disorders NEC</b></i>		
Ovulation pain	3	0
<i><b>Pelvis and broad ligament disorders NEC</b></i>		
Adnexa uteri pain	3	0
<i><b>Penile disorders NEC (excl erection and ejaculation)</b></i>		
Penile swelling	2	0
<i><b>Prostatic signs, symptoms and disorders NEC</b></i>		
Prostatomegaly	1	0
<i><b>Reproductive tract disorders NEC (excl neoplasms)</b></i>		
Genital ulceration	2	0
<i><b>Reproductive tract infections and inflammations NEC</b></i>		
Genital tract inflammation	1	0
<i><b>Reproductive tract signs and symptoms NEC</b></i>		
Genital pain	2	0
Pelvic discomfort	2	0
Pelvic pain	5	0
Perineal pain	1	0
<i><b>Scrotal disorders NEC</b></i>		
Scrotal erythema	1	0
Scrotal exfoliation	1	0
Scrotal pain	3	0

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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i>Reproductive &amp; breast disorders cont'd</i>		
Scrotal swelling	1	0
<b><i>Sexual function and fertility disorders NEC</i></b>		
Infertility	1	0
<b><i>Spermatogenesis and semen disorders</i></b>		
Haemospermia	1	0
<b><i>Testicular and epididymal disorders NEC</i></b>		
Testicular pain	4	0
Testicular swelling	2	0
<b><i>Uterine disorders NEC</i></b>		
Endometriosis	2	0
Uterine pain	1	0
<b><i>Uterine tone disorders</i></b>		
Uterine spasm	1	0
<b><i>Vulvovaginal disorders NEC</i></b>		
Vaginal haemorrhage	29	0
Vulval ulceration	2	0
<b><i>Vulvovaginal signs and symptoms</i></b>		
Vulvovaginal pruritus	1	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>283</b>	<b>0</b>

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 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Apnoea	1	0
Dyspnoea	728	2
Dyspnoea at rest	1	0
Dyspnoea exertional	6	1
Hyperventilation	6	0
Hypopnoea	14	0
Irregular breathing	6	0
Mouth breathing	2	0
Orthopnoea	2	0
Respiration abnormal	15	0
Respiratory arrest	4	0
Respiratory distress	3	0
Sleep apnoea syndrome	1	0
Tachypnoea	13	0
<i><b>Bronchial conditions NEC</b></i>		
Bronchial secretion retention	1	0
Bronchiectasis	3	0
<i><b>Bronchospasm and obstruction</b></i>		
Asthma	68	0
Bronchospasm	6	0
Chronic obstructive pulmonary disease	4	0
Obstructive airways disorder	1	0
Reversible airways obstruction	1	0
Wheezing	92	0
<i><b>Conditions associated with abnormal gas exchange</b></i>		
Hypoxia	9	1
<i><b>Coughing and associated symptoms</b></i>		
Allergic cough	1	0
Cough	543	0
Haemoptysis	8	0
Productive cough	32	0
Sputum discoloured	1	0
<i><b>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</b></i>		
Laryngeal disorder	1	0
<i><b>Laryngeal spasm, oedema and obstruction</b></i>		
Epiglottic oedema	1	0
Stridor	6	0
<i><b>Lower respiratory tract inflammatory and immunologic conditions</b></i>		
Hypersensitivity pneumonitis	1	0
Pneumonia aspiration	3	2
Pneumonitis	8	3
<i><b>Lower respiratory tract signs and symptoms</b></i>		
Hiccups	2	0
Increased bronchial secretion	1	0
Pleuritic pain	4	0
Pulmonary pain	23	0
Rales	2	0
<i><b>Nasal congestion and inflammations</b></i>		
Nasal congestion	47	0
Nasal inflammation	1	0
Rhinitis allergic	3	0

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b> <small>Respiratory disorders cont'd</small>		
<b><i>Nasal disorders NEC</i></b>		
Epistaxis	135	0
Intranasal hypoaesthesia	1	0
Intranasal paraesthesia	1	0
Nasal disorder	1	0
Nasal dryness	4	0
Nasal odour	3	0
Nasal oedema	1	0
Nasal pruritus	3	0
<b><i>Paranasal sinus disorders (excl infections and neoplasms)</i></b>		
Allergic sinusitis	1	0
Paranasal sinus inflammation	1	0
Sinonasal obstruction	2	0
Sinus congestion	12	0
Sinus disorder	1	0
<b><i>Parenchymal lung disorders NEC</i></b>		
Atelectasis	1	0
<b><i>Pharyngeal disorders (excl infections and neoplasms)</i></b>		
Pharyngeal erythema	3	0
Pharyngeal haemorrhage	1	0
Pharyngeal hypoaesthesia	10	0
Pharyngeal inflammation	3	0
Pharyngeal oedema	3	0
Pharyngeal paraesthesia	22	0
Pharyngeal swelling	65	0
Pharyngeal ulceration	5	0
Tonsillar erythema	1	0
Tonsillar hypertrophy	18	0
Tonsillar inflammation	3	0
<b><i>Pleural infections and inflammations</i></b>		
Pleurisy	3	0
<b><i>Pneumothorax and pleural effusions NEC</i></b>		
Pleural effusion	1	0
<b><i>Pulmonary oedemas</i></b>		
Pulmonary congestion	3	0
Pulmonary oedema	2	0
<b><i>Pulmonary thrombotic and embolic conditions</i></b>		
Pulmonary embolism	10	1
Pulmonary infarction	1	0
Pulmonary thrombosis	1	0
<b><i>Respiratory failures (excl neonatal)</i></b>		
Acute respiratory failure	2	1
<b><i>Respiratory signs and symptoms NEC</i></b>		
Painful respiration	2	0
Respiratory symptom	2	0
<b><i>Respiratory tract disorders NEC</i></b>		
Aspiration	1	0
Respiratory disorder	2	0
Respiratory tract irritation	1	0
Respiratory tract oedema	1	0
<b><i>Tracheal disorders (excl infections and neoplasms)</i></b>		
Tracheal pain	1	0
<b><i>Upper respiratory tract neoplasms</i></b>		

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b> <small>Respiratory disorders cont'd</small>		
Tonsillar cyst	1	0
<b><i>Upper respiratory tract signs and symptoms</i></b>		
Aphonia	15	0
Catarrh	5	0
Choking	3	0
Dry throat	46	0
Dysphonia	32	0
Increased upper airway secretion	3	0
Increased viscosity of upper respiratory secretion	3	0
Nasal discharge discolouration	1	0
Nasal discomfort	11	0
Nasal obstruction	2	0
Oropharyngeal blistering	6	0
Oropharyngeal discomfort	18	0
Oropharyngeal pain	638	0
Paranasal sinus discomfort	8	0
Rhinalgia	6	0
Rhinorrhoea	159	0
Sinus pain	42	0
Sneezing	80	0
Snoring	2	0
Throat clearing	3	0
Throat irritation	60	0
Throat tightness	76	0
Upper airway obstruction	1	0
Upper-airway cough syndrome	2	0
Yawning	1	0
<b>Respiratory disorders SOC TOTAL</b>	<b>3233</b>	<b>11</b>

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Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<b><i>Acnes</i></b>		
Acne	6	0
<b><i>Alopecias</i></b>		
Alopecia	10	0
<b><i>Angioedemas</i></b>		
Angioedema	47	0
Circumoral swelling	1	0
<b><i>Apocrine and eccrine gland disorders</i></b>		
Cold sweat	154	0
Hyperhidrosis	406	0
Miliaria	14	0
Night sweats	161	0
<b><i>Bullous conditions</i></b>		
Blister	54	0
Blood blister	1	0
Dermatitis bullous	3	0
Erythema multiforme	6	0
Fracture blisters	1	0
Pemphigoid	3	0
Pemphigus	2	0
Stevens-Johnson syndrome	2	0
Toxic epidermal necrolysis	2	1
<b><i>Dermal and epidermal conditions NEC</i></b>		
Acute febrile neutrophilic dermatosis	1	0
Dermatosis	1	0
Dry skin	34	0
Macule	1	0
Pain of skin	75	0
Papule	14	0
Pathergy reaction	1	0
Peau d'orange	2	0
Scar pain	4	0
Sensitive skin	43	0
Skin burning sensation	45	0
Skin discolouration	23	0
Skin discomfort	1	0
Skin disorder	1	0
Skin indentation	1	0
Skin induration	2	0
Skin lesion	7	0
Skin necrosis	1	0
Skin odour abnormal	2	0
Skin reaction	28	0
Skin sensitisation	5	0
Skin swelling	18	0
Skin tightness	12	0
Skin warm	76	0
Sticky skin	1	0
Yellow skin	4	0
<b><i>Dermatitis and eczema</i></b>		
Dermatitis	25	0
Dermatitis allergic	46	0
Dermatitis atopic	1	0



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Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Dyshidrotic eczema	2	0
Eczema	26	0
Eczema asteatotic	1	0
Eczema nummular	2	0
Eczema weeping	1	0
Perioral dermatitis	1	0
Skin irritation	25	0
<b><i>Dermatitis ascribed to specific agent</i></b>		
Drug eruption	7	0
Fixed eruption	1	0
Toxic skin eruption	1	0
<b><i>Erythemas</i></b>		
Erythema	604	0
Red man syndrome	1	0
<b><i>Exfoliative conditions</i></b>		
Dermatitis exfoliative	1	0
Exfoliative rash	1	0
Skin exfoliation	18	0
<b><i>Hyperpigmentation disorders</i></b>		
Ephelides	1	0
Skin hyperpigmentation	1	0
<b><i>Hypopigmentation disorders</i></b>		
Skin hypopigmentation	1	0
<b><i>Lipodystrophies</i></b>		
Lipoatrophy	1	0
<b><i>Nail and nail bed conditions (excl infections and infestations)</i></b>		
Nail discolouration	3	0
Nail disorder	1	0
Onychalgia	3	0
<b><i>Panniculitides</i></b>		
Erythema nodosum	4	0
<b><i>Papulosquamous conditions</i></b>		
Erythema annulare	1	0
Lichen planus	1	0
Pityriasis rosea	13	0
<b><i>Photosensitivity and photodermatitis conditions</i></b>		
Photosensitivity reaction	7	0
<b><i>Pigmentation changes NEC</i></b>		
Haemosiderin stain	1	0
Pigmentation disorder	2	0
<b><i>Pilar disorders NEC</i></b>		
Piloerection	3	0
<b><i>Pruritus NEC</i></b>		
Itching scar	3	0
Pruritus	1068	0
<b><i>Psoriatic conditions</i></b>		
Psoriasis	12	0
Pustular psoriasis	1	0
<b><i>Purpura and related conditions</i></b>		
Petechiae	20	0
Purpura	7	0
<b><i>Rashes, eruptions and exanthems NEC</i></b>		
Rash	1097	0

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Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Rash erythematous	233	0
Rash macular	112	0
Rash maculo-papular	16	0
Rash morbilliform	7	0
Rash papular	59	0
Rash pruritic	220	0
Rash vesicular	9	0
Systemic lupus erythematosus rash	1	0
<b>Rosaceas</b>		
Rosacea	2	0
<b>Scaly conditions</b>		
Pityriasis	4	0
<b>Skin and subcutaneous conditions NEC</b>		
Cutaneous symptom	1	0
Skin mass	3	0
<b>Skin and subcutaneous tissue ulcerations</b>		
Scleroderma associated digital ulcer	1	0
Skin erosion	8	0
Skin ulcer	1	0
<b>Skin cysts and polyps</b>		
Dermal cyst	1	0
<b>Skin haemorrhages</b>		
Haemorrhage subcutaneous	2	0
Skin haemorrhage	2	0
<b>Skin hyperplasias and hypertrophies</b>		
Skin hypertrophy	1	0
<b>Skin vasculitides</b>		
Cutaneous vasculitis	1	0
Vasculitic rash	1	0
<b>Skin vasomotor conditions</b>		
Livedo reticularis	12	0
<b>Urticarias</b>		
Chronic spontaneous urticaria	1	0
Cold urticaria	1	0
Idiopathic urticaria	1	0
Mechanical urticaria	1	0
Urticaria	389	0
Urticaria chronic	1	0
Urticaria papular	1	0
Urticaria thermal	2	0
<b>Skin disorders SOC TOTAL</b>	<b>5385</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Social circumstances</b>		
<i><b>Criminal activity</b></i>		
Verbal abuse	1	0
<i><b>Disability issues</b></i>		
Bedridden	8	0
Breast prosthesis user	1	0
Immobile	2	0
<i><b>Pregnancy related circumstances</b></i>		
Breast feeding	1	0
<i><b>Tobacco use</b></i>		
Non-tobacco user	1	0
<b>Social circumstances SOC TOTAL</b>	<b>14</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
<i>Dietary and nutritional therapies</i>		
Diabetic diet	1	0
<i>Gastrointestinal therapeutic procedures NEC</i>		
Prophylaxis of nausea and vomiting	5	0
<i>Immunisations</i>		
COVID-19 immunisation	7	0
Immunisation	4	0
<i>Limb therapeutic procedures</i>		
Limb immobilisation	2	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	2	0
Fatigue management	1	0
Hospitalisation	1	0
Injection	1	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>30</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<i><b>Accelerated and malignant hypertension</b></i>		
Hypertensive crisis	1	0
<i><b>Aortic necrosis and vascular insufficiency</b></i>		
Aortic stenosis	1	0
<i><b>Arterial infections and inflammations</b></i>		
Arteritis	1	0
Giant cell arteritis	2	0
<i><b>Blood pressure disorders NEC</b></i>		
Blood pressure fluctuation	2	0
Labile blood pressure	1	0
<i><b>Circulatory collapse and shock</b></i>		
CT hypotension complex	1	0
Circulatory collapse	24	0
Neurogenic shock	11	0
Peripheral circulatory failure	2	0
Shock	2	0
<i><b>Haemorrhages NEC</b></i>		
Haematoma	10	0
Haemorrhage	17	1
Venous haemorrhage	1	0
<i><b>Lymphangiopathies</b></i>		
Lymphocele	1	0
<i><b>Lymphoedemas</b></i>		
Lymphoedema	27	0
<i><b>Non-site specific embolism and thrombosis</b></i>		
Thrombosis	8	0
<i><b>Non-site specific necrosis and vascular insufficiency NEC</b></i>		
Haemorrhagic infarction	1	0
<i><b>Non-site specific vascular disorders NEC</b></i>		
Superficial vein prominence	1	0
Vascular pain	1	0
Vasodilatation	5	0
Vein discolouration	1	0
Vein disorder	2	0
Vein rupture	1	0
<i><b>Peripheral embolism and thrombosis</b></i>		
Blue toe syndrome	3	0
Deep vein thrombosis	6	0
Thrombophlebitis	2	0
<i><b>Peripheral vascular disorders NEC</b></i>		
Cyanosis	11	0
Flushing	160	0
Hot flush	243	0
<i><b>Peripheral vasoconstriction, necrosis and vascular insufficiency</b></i>		
Peripheral coldness	65	0
Peripheral ischaemia	1	0
Poor peripheral circulation	1	0
Raynaud's phenomenon	7	0
Vasoconstriction	1	0
<i><b>Phlebitis NEC</b></i>		
Phlebitis	1	0
<i><b>Site specific vascular disorders NEC</b></i>		
Pallor	52	0

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Reaction Name	Total	Fatal
<b>Vascular disorders</b> <i>Vascular disorders cont'd</i>		
<i><b>Vascular hypertensive disorders NEC</b></i>		
Hypertension	123	0
Systolic hypertension	1	0
<i><b>Vascular hypotensive disorders</b></i>		
Hypotension	86	0
Orthostatic hypotension	5	0
<i><b>Vasculitides NEC</b></i>		
Behcet's syndrome	1	0
Vasculitis	7	0
<i><b>Vena caval embolism and thrombosis</b></i>		
Vena cava embolism	1	0
Vena cava thrombosis	1	0
<b>Vascular disorders SOC TOTAL</b>	<b>902</b>	<b>1</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>77207</b>	<b>197</b>
<b>TOTAL REPORTS</b>	<b>26823</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>197</b>