

## Case Series Drug Analysis Print

**Name: Pfizer/BioNTech COVID-19 vaccine spontaneous, suspect reports from Islington, Camden, Haringey, Barnet and Enfield**

Report Run Date: 23-Feb-2022  
Data Lock Date: 22-Feb-2022 18:30:04  
Earliest Reaction Date: 30-Dec-2019  
MedDRA Version: MedDRA 24.1

Pfizer/BioNTech COVID-19 vaccine spontaneous, suspect reports from Islington, Camden, Haringey, Barnet and Enfield: All UK spontaneous, suspect reports associated with the Pfizer/BioNTech COVID-19 vaccine from Islington, Camden, Haringey, Barnet and Enfield Clinical Commissioning Groups up to and including 22/02/2022.

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Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<i><b>Anaemias NEC</b></i>		
Anaemia	4	0
<i><b>Bleeding tendencies</b></i>		
Increased tendency to bruise	2	0
<i><b>Leukopenias NEC</b></i>		
Leukopenia	1	0
<i><b>Lymphatic system disorders NEC</b></i>		
Lymph node pain	40	0
Lymphadenitis	5	0
Lymphadenopathy	201	0
<i><b>Marrow depression and hypoplastic anaemias</b></i>		
Pancytopenia	1	0
<i><b>Neutropenias</b></i>		
Autoimmune neutropenia	1	0
<i><b>Spleen disorders</b></i>		
Splénomegaly	1	0
<i><b>Thrombocytopenias</b></i>		
Immune thrombocytopenia	3	0
Thrombocytopenia	11	0
<b>Blood disorders SOC TOTAL</b>	<b>270</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i><b>Cardiac disorders NEC</b></i>		
Acute cardiac event	1	0
Cardiac disorder	1	0
Cardiovascular disorder	1	0
<i><b>Cardiac infections and inflammations NEC</b></i>		
Carditis	1	0
<i><b>Cardiac signs and symptoms NEC</b></i>		
Cardiac discomfort	2	0
Palpitations	120	0
<i><b>Cardiomyopathies</b></i>		
Congestive cardiomyopathy	1	0
<i><b>Coronary artery disorders NEC</b></i>		
Coronary artery disease	1	1
<i><b>Heart failures NEC</b></i>		
Cardiac failure	2	0
Cardiac failure acute	1	0
<i><b>Ischaemic coronary artery disorders</b></i>		
Acute myocardial infarction	1	0
Angina pectoris	7	0
Arteriospasm coronary	1	0
Myocardial infarction	4	1
<i><b>Myocardial disorders NEC</b></i>		
Cardiomegaly	1	0
Left ventricular dysfunction	1	0
Myocardial fibrosis	1	0
Myocardial injury	2	0
Myocardial oedema	1	0
Myocardial rupture	1	0
<i><b>Noninfectious myocarditis</b></i>		
Myocarditis	18	0
<i><b>Noninfectious pericarditis</b></i>		
Pericarditis	7	0
<i><b>Pericardial disorders NEC</b></i>		
Pericardial haemorrhage	1	1
<i><b>Rate and rhythm disorders NEC</b></i>		
Arrhythmia	5	0
Bradycardia	8	0
Cardiac flutter	13	0
Extrasystoles	3	0
Postural orthostatic tachycardia syndrome	1	0
Tachyarrhythmia	1	0
Tachycardia	52	0
<i><b>Supraventricular arrhythmias</b></i>		
Atrial fibrillation	9	0
Atrial flutter	1	0
Atrial tachycardia	1	0
Sinus tachycardia	4	0
<b>Cardiac disorders SOC TOTAL</b>	<b>275</b>	<b>3</b>

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<b>Ear disorders</b>		
<i><b>Ear disorders NEC</b></i>		
Ear congestion	1	0
Ear discomfort	3	0
Ear pain	20	0
Ear swelling	4	0
<i><b>External ear disorders NEC</b></i>		
External ear pain	1	0
<i><b>Hearing losses</b></i>		
Deafness	5	0
Deafness bilateral	1	0
Deafness neurosensory	1	0
Deafness unilateral	2	0
Hypoacusis	5	0
Sudden hearing loss	2	0
<i><b>Hyperacusia</b></i>		
Hyperacusis	1	0
<i><b>Inner ear disorders NEC</b></i>		
Vestibular disorder	1	0
<i><b>Inner ear signs and symptoms</b></i>		
Tinnitus	42	0
Vertigo	28	0
Vertigo positional	1	0
<b>Ear disorders SOC TOTAL</b>	<b>118</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Endocrine disorders</b>		
<i>Acute and chronic thyroiditis</i>		
Thyroiditis	3	0
<i>Endocrine abnormalities of puberty</i>		
Delayed menarche	1	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	1	0
<i>Thyroid disorders NEC</i>		
Goitre	1	0
<i>Thyroid hyperfunction disorders</i>		
Basedow's disease	1	0
Hyperthyroidism	3	0
<b>Endocrine disorders SOC TOTAL</b>	<b>10</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i><b>Cataract conditions</b></i>		
Cataract	1	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 floaters	2	0
<i><b>Colour blindness (incl acquired)</b></i>		
Dyschromatopsia	1	0
<i><b>Eyelid movement disorders</b></i>		
Blepharospasm	2	0
Eyelid ptosis	1	0
<i><b>Iris and uveal tract infections, irritations and inflammations</b></i>		
Iridocyclitis	2	0
Iritis	1	0
Uveitis	2	0
<i><b>Lacrimation disorders</b></i>		
Dry eye	4	0
Lacrimation increased	6	0
<i><b>Lid, lash and lacrimal infections, irritations and inflammations</b></i>		
Chalazion	1	0
Eyelid oedema	2	0
Eyelid rash	2	0
Swelling of eyelid	2	0
<i><b>Ocular bleeding and vascular disorders NEC</b></i>		
Eye haemorrhage	1	0
<i><b>Ocular disorders NEC</b></i>		
Eye disorder	1	0
Eye pain	30	0
Eye swelling	13	0
Periorbital oedema	1	0
Periorbital swelling	2	0
<i><b>Ocular infections, inflammations and associated manifestations</b></i>		
Eye allergy	4	0
Eye discharge	1	0
Eye inflammation	1	0
Eye irritation	4	0
Eye pruritus	4	0
Ocular hyperaemia	7	0
<i><b>Ocular nerve and muscle disorders</b></i>		
Eye movement disorder	1	0
<i><b>Ocular sensation disorders</b></i>		
Abnormal sensation in eye	1	0
Asthenopia	5	0
Photophobia	7	0
<i><b>Pupil disorders</b></i>		
Pupil fixed	1	0
Pupils unequal	1	0
<i><b>Retinal bleeding and vascular disorders (excl retinopathy)</b></i>		
Retinal artery occlusion	1	0
Retinal haemorrhage	1	0
Retinal vein occlusion	2	0
<i><b>Retinal structural change, deposit and degeneration</b></i>		

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Reaction Name	Total	Fatal
<b>Eye disorders</b> Eye disorders cont'd		
Retinal toxicity	1	0
<b>Structural change, deposit and degeneration of eye NEC</b>		
Endocrine ophthalmopathy	1	0
Exophthalmos	1	0
<b>Visual colour distortions</b>		
Chromatopsia	1	0
Cyanopsia	1	0
<b>Visual disorders NEC</b>		
Diplopia	2	0
Metamorphopsia	1	0
Photopsia	2	0
Scintillating scotoma	1	0
Vision blurred	28	0
<b>Visual field disorders</b>		
Visual field defect	2	0
<b>Visual impairment and blindness (excl colour blindness)</b>		
Blindness	3	0
Blindness transient	2	0
Visual impairment	5	0
<b>Eye disorders SOC TOTAL</b>	<b>170</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<b><i>Acute and chronic pancreatitis</i></b>		
Pancreatitis	4	0
Pancreatitis acute	1	0
<b><i>Colitis (excl infective)</i></b>		
Colitis	1	0
Colitis ulcerative	2	0
Crohn's disease	1	0
Inflammatory bowel disease	1	0
<b><i>Dental pain and sensation disorders</i></b>		
Dental paraesthesia	2	0
Hyperaesthesia teeth	1	0
Toothache	3	0
<b><i>Diarrhoea (excl infective)</i></b>		
Diarrhoea	103	0
<b><i>Dyspeptic signs and symptoms</i></b>		
Dyspepsia	8	0
<b><i>Faecal abnormalities NEC</i></b>		
Abnormal faeces	1	0
Faecaloma	1	0
Faeces discoloured	1	0
<b><i>Flatulence, bloating and distension</i></b>		
Abdominal distension	17	0
Aerophagia	1	0
Flatulence	2	0
<b><i>Gastrointestinal and abdominal pains (excl oral and throat)</i></b>		
Abdominal pain	26	0
Abdominal pain lower	3	0
Abdominal pain upper	50	0
Abdominal rigidity	1	0
Gastrointestinal pain	6	0
Oesophageal pain	1	0
<b><i>Gastrointestinal atonic and hypomotility disorders NEC</i></b>		
Constipation	7	0
Gastric dilatation	1	0
Gastrooesophageal reflux disease	1	0
<b><i>Gastrointestinal signs and symptoms NEC</i></b>		
Abdominal discomfort	15	0
Breath odour	2	0
Dysphagia	1	0
<b><i>Gastrointestinal spastic and hypermotility disorders</i></b>		
Defaecation urgency	1	0
Irritable bowel syndrome	3	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 pain	2	0
<b><i>Gingival haemorrhages</i></b>		
Gingival bleeding	2	0
<b><i>Intestinal haemorrhages</i></b>		
Anal haemorrhage	1	0



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<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
Rectal haemorrhage	2	0
<b><i>Nausea and vomiting symptoms</i></b>		
Nausea	297	0
Retching	2	0
Vomiting	91	0
<b><i>Non-site specific gastrointestinal haemorrhages</i></b>		
Gastrointestinal haemorrhage	1	0
Haematemesis	1	0
Upper gastrointestinal haemorrhage	1	0
<b><i>Oral dryness and saliva altered</i></b>		
Dry mouth	16	0
Lip dry	1	0
Salivary hypersecretion	2	0
<b><i>Oral soft tissue disorders NEC</i></b>		
Cheilitis	2	0
<b><i>Oral soft tissue haemorrhages</i></b>		
Mouth haemorrhage	2	0
Oral blood blister	1	0
<b><i>Oral soft tissue signs and symptoms</i></b>		
Hypoaesthesia oral	9	0
Lip pain	3	0
Lip pruritus	1	0
Oral discomfort	5	0
Oral pain	1	0
Paraesthesia oral	12	0
<b><i>Oral soft tissue swelling and oedema</i></b>		
Lip swelling	9	0
Mouth swelling	2	0
Palatal oedema	1	0
<b><i>Peritoneal and retroperitoneal disorders</i></b>		
Ascites	1	0
<b><i>Stomatitis and ulceration</i></b>		
Aphthous ulcer	2	0
Mouth ulceration	6	0
Stomatitis	1	0
<b><i>Tongue disorders</i></b>		
Tongue ulceration	1	0
<b><i>Tongue signs and symptoms</i></b>		
Glossodynia	4	0
Scalloped tongue	2	0
Swollen tongue	7	0
Tongue coated	1	0
Tongue discomfort	3	0
Tongue dry	2	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>767</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>General disorders</b>		
<i>Adverse effect absent</i>		
No adverse event	1	0
<i>Application and instillation site reactions</i>		
Application site acne	1	0
Application site burn	1	0
Application site erythema	1	0
Application site hypoaesthesia	1	0
Application site pain	1	0
<i>Asthenic conditions</i>		
Asthenia	50	0
Chronic fatigue syndrome	1	0
Fatigue	527	0
Malaise	97	1
<i>Body temperature altered</i>		
Hypothermia	1	0
<i>Death and sudden death</i>		
Clinical death	1	1
Death	3	3
<i>Febrile disorders</i>		
Pyrexia	396	0
<i>Feelings and sensations NEC</i>		
Chills	219	0
Feeling abnormal	29	0
Feeling cold	20	0
Feeling drunk	1	0
Feeling hot	19	0
Feeling jittery	1	0
Feeling of body temperature change	1	0
Hangover	2	0
Hunger	2	0
Temperature intolerance	1	0
Thirst	10	0
<i>Gait disturbances</i>		
Gait disturbance	5	0
Gait inability	5	0
<i>General signs and symptoms NEC</i>		
Chronic disease	1	0
Condition aggravated	3	0
Crying	1	0
Effusion	1	0
Exercise tolerance decreased	1	0
Illness	16	0
Influenza like illness	42	0
Local reaction	4	0
Peripheral swelling	62	0
Secretion discharge	1	0
Swelling	58	0
Swelling face	17	0
<i>Implant and catheter site reactions</i>		
Implant site pain	1	0
<i>Inflamations</i>		
Inflammation	14	0

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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
<i><b>Injection site reactions</b></i>		
Injected limb mobility decreased	2	0
Injection site bruising	3	0
Injection site erythema	10	0
Injection site hypoaesthesia	2	0
Injection site mass	7	0
Injection site pain	82	0
Injection site pruritus	5	0
Injection site rash	5	0
Injection site swelling	11	0
Injection site warmth	3	0
<i><b>Interactions</b></i>		
Alcohol interaction	1	0
Drug interaction	1	0
<i><b>Mass conditions NEC</b></i>		
Cyst	1	0
Mass	1	0
Nodule	1	0
<i><b>Oedema NEC</b></i>		
Oedema	4	0
Oedema peripheral	3	0
<i><b>Pain and discomfort NEC</b></i>		
Axillary pain	64	0
Chest discomfort	40	0
Chest pain	124	0
Discomfort	12	0
Facial discomfort	2	0
Facial pain	5	0
Pain	204	0
Suprapubic pain	1	0
Tenderness	16	0
<i><b>Therapeutic and nontherapeutic responses</b></i>		
No reaction on previous exposure to drug	2	0
Vaccination failure	1	0
<i><b>Ulcers NEC</b></i>		
Ulcer	1	0
<i><b>Vaccination site reactions</b></i>		
Shoulder injury related to vaccine administration	1	0
Vaccination site discolouration	1	0
Vaccination site erythema	9	0
Vaccination site induration	1	0
Vaccination site joint pain	1	0
Vaccination site mass	4	0
Vaccination site pain	43	0
Vaccination site pruritus	3	0
Vaccination site rash	2	0
Vaccination site swelling	13	0
Vaccination site warmth	2	0
<i><b>Withdrawal and rebound effects</b></i>		
Drug withdrawal syndrome	1	0
Withdrawal syndrome	1	0
<b>General disorders SOC TOTAL</b>	<b>2315</b>	<b>5</b>

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Reaction Name	Total	Fatal
<b>Hepatic disorders</b>		
<i>Cholecystitis and cholelithiasis</i>		
Cholelithiasis	1	0
<i>Cholestasis and jaundice</i>		
Jaundice	1	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	2	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Hepatitis	1	0
Liver injury	2	0
<b>Hepatic disorders SOC TOTAL</b>	<b>7</b>	<b>0</b>

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<b>Immune system disorders</b>		
<i>Allergic conditions NEC</i>		
Hypersensitivity	20	0
Type III immune complex mediated reaction	1	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to vaccine	2	0
Contrast media reaction	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	3	0
Anaphylactoid reaction	1	0
<i>Atopic disorders</i>		
Seasonal allergy	1	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	2	0
Immune system disorder	2	0
Multisystem inflammatory syndrome in children	2	0
Systemic immune activation	1	0
<i>Transplant rejections</i>		
Corneal graft rejection	2	0
<b>Immune system disorders SOC TOTAL</b>	<b>38</b>	<b>0</b>

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<b>Infections</b>		
<b><i>Abdominal and gastrointestinal infections</i></b>		
Appendicitis	3	0
Gastroenteritis	1	0
<b><i>Bacterial infections NEC</i></b>		
Bacterial infection	1	0
Cellulitis	2	0
Gangrene	1	0
<b><i>Candida infections</i></b>		
Vulvovaginal candidiasis	1	0
<b><i>Central nervous system and spinal infections</i></b>		
Encephalitis	1	0
Meningitis	1	0
<b><i>Coronavirus infections</i></b>		
COVID-19	43	0
COVID-19 pneumonia	1	0
Suspected COVID-19	3	0
<b><i>Coxiella infections</i></b>		
Q fever	1	0
<b><i>Ear infections</i></b>		
Ear infection	2	0
Labyrinthitis	1	0
<b><i>Epstein-Barr viral infections</i></b>		
Epstein-Barr virus infection reactivation	1	0
Infectious mononucleosis	1	0
<b><i>Escherichia infections</i></b>		
Escherichia bacteraemia	1	0
<b><i>Eye and eyelid infections</i></b>		
Conjunctivitis	1	0
Eye infection	1	0
Hordeolum	4	0
Keratouveitis	1	0
Periorbital infection	1	0
<b><i>Female reproductive tract infections</i></b>		
Bartholinitis	1	0
Vulvitis	1	0
<b><i>Fungal infections NEC</i></b>		
Onychomycosis	2	0
<b><i>Herpes viral infections</i></b>		
Genital herpes	4	0
Genital herpes simplex	1	0
Herpes simplex	2	0
Herpes simplex reactivation	1	0
Herpes virus infection	1	0
Herpes zoster	29	0
Herpes zoster oticus	1	0
Oral herpes	6	0
<b><i>Infections NEC</i></b>		
Abscess	1	0
Infection	4	0
Injection site infection	1	0
Localised infection	1	0
<b><i>Influenza viral infections</i></b>		

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Reaction Name	Total	Fatal
<b>Infections</b> Infections cont'd		
Influenza	36	0
<b>Lower respiratory tract and lung infections</b>		
Lower respiratory tract infection	5	0
Pneumonia	1	0
<b>Male reproductive tract infections</b>		
Prostate infection	1	0
<b>Sepsis, bacteraemia, viraemia and fungaemia NEC</b>		
Sepsis	2	0
Urosepsis	1	0
<b>Skin structures and soft tissue infections</b>		
Pustule	1	0
Rash pustular	1	0
Skin infection	1	0
<b>Staphylococcal infections</b>		
Furuncle	2	0
<b>Tinea infections</b>		
Tinea infection	1	0
<b>Upper respiratory tract infections</b>		
Chronic sinusitis	1	0
Laryngitis	1	0
Nasopharyngitis	21	0
Rhinitis	2	0
Sinusitis	3	0
Tracheitis	1	0
<b>Urinary tract infections</b>		
Cystitis	7	0
Kidney infection	1	0
Urinary tract infection	3	0
<b>Vascular infections</b>		
Lymphangitis	2	0
<b>Viral infections NEC</b>		
Conjunctivitis viral	1	0
Post viral fatigue syndrome	2	0
Sweating fever	5	0
Vestibular neuronitis	1	0
<b>Infections SOC TOTAL</b>	<b>232</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Injuries</b>		
<b><i>Abdominal and gastrointestinal injuries NEC</i></b>		
Splenic rupture	1	0
<b><i>Accidental exposures to product</i></b>		
Accidental exposure to product	1	0
<b><i>Cardiac and vascular procedural complications</i></b>		
Ischaemic contracture of the left ventricle	1	0
<b><i>Chest and respiratory tract injuries NEC</i></b>		
Chest crushing	2	0
<b><i>Conditions caused by cold</i></b>		
Chillblains	1	0
<b><i>Exposures associated with pregnancy, delivery and lactation</i></b>		
Exposure via breast milk	2	0
Maternal exposure during breast feeding	42	0
Maternal exposure during pregnancy	20	0
<b><i>Eye injuries NEC</i></b>		
Foreign body in eye	1	0
<b><i>Gastrointestinal and hepatobiliary procedural complications</i></b>		
Procedural nausea	1	0
<b><i>Medication errors, product use errors and issues NEC</i></b>		
Vaccination error	1	0
<b><i>Muscle, tendon and ligament injuries</i></b>		
Mallet finger	1	0
Muscle injury	3	0
Muscle strain	1	0
Tendon rupture	1	0
<b><i>Nerve injuries NEC</i></b>		
Nerve injury	1	0
<b><i>Non-site specific injuries NEC</i></b>		
Fall	2	0
Foreign body	2	0
Injury	1	0
<b><i>Non-site specific procedural complications</i></b>		
Infusion related reaction	1	0
Injection related reaction	2	0
<b><i>Product administration errors and issues</i></b>		
Product administration error	1	0
<b><i>Site specific injuries NEC</i></b>		
Limb injury	1	0
<b><i>Skin injuries NEC</i></b>		
Contusion	33	0
Scratch	1	0
Skin laceration	1	0
<b><i>Vaccination related complications</i></b>		
Vaccination complication	1	0
<b>Injuries SOC TOTAL</b>	<b>126</b>	<b>0</b>



## Case Series Drug Analysis Print

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Report Run Date: 23-Feb-2022

Data Lock Date: 22-Feb-2022 18:30:04

Earliest Reaction Date: 30-Dec-2019

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Investigations</b>		
<b><i>Autoimmunity analyses</i></b>		
Antinuclear antibody	1	0
<b><i>Blood gas and acid base analyses</i></b>		
Blood pH	1	0
Oxygen saturation decreased	4	0
<b><i>Carbohydrate tolerance analyses (incl diabetes)</i></b>		
Blood glucose	1	0
Blood glucose abnormal	1	0
Blood glucose decreased	1	0
Blood glucose increased	3	0
<b><i>Cardiac auscultatory investigations</i></b>		
Cardiac murmur	2	0
Heart sounds	1	0
<b><i>Cardiac function diagnostic procedures</i></b>		
Ejection fraction decreased	1	0
<b><i>Central nervous system imaging procedures</i></b>		
Computerised tomogram head	1	0
<b><i>Coagulation and bleeding analyses</i></b>		
Clot retraction	1	1
Coagulation time prolonged	1	0
Coagulation time shortened	1	0
Fibrin D dimer increased	1	0
International normalised ratio decreased	1	0
<b><i>ECG investigations</i></b>		
Electrocardiogram	1	0
Electrocardiogram ST segment elevation	1	0
Electrocardiogram abnormal	2	0
<b><i>Endocrine analyses and imaging NEC</i></b>		
Hormone level abnormal	3	0
<b><i>Foetal and neonatal diagnostic procedures</i></b>		
Foetal non-stress test	1	0
<b><i>Heart rate and pulse investigations</i></b>		
Heart rate	15	0
Heart rate abnormal	2	0
Heart rate decreased	1	0
Heart rate increased	23	0
Heart rate irregular	12	0
Pulse abnormal	1	0
Sinus rhythm	1	0
<b><i>Immunology analyses NEC</i></b>		
Antibody test	1	0
Immunology test	1	0
<b><i>Investigations NEC</i></b>		
Blood test	1	0
<b><i>Liver function analyses</i></b>		
Alanine aminotransferase increased	1	0
Blood bilirubin increased	1	0
Liver function test abnormal	2	0
Liver function test increased	2	0
Transaminases increased	1	0
<b><i>Mineral and electrolyte analyses</i></b>		
Blood magnesium decreased	1	0

## Case Series Drug Analysis Print

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Earliest Reaction Date: 30-Dec-2019

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Investigations</b>		
Investigations cont'd		
Blood sodium decreased	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	4	0
Body temperature increased	12	0
Grip strength	1	0
Lymph node palpable	2	0
Product residue present	1	0
Respiratory rate increased	1	0
Weight decreased	1	0
Weight increased	1	0
<b><i>Pituitary analyses anterior</i></b>		
Blood thyroid stimulating hormone increased	2	0
<b><i>Protein analyses NEC</i></b>		
C-reactive protein increased	2	0
<b><i>Renal function analyses</i></b>		
Blood creatinine increased	2	0
<b><i>Reproductive organ and breast histopathology procedures</i></b>		
Biopsy breast	1	0
<b><i>Respiratory and pulmonary function diagnostic procedures</i></b>		
Total lung capacity decreased	1	0
<b><i>Respiratory tract and thoracic imaging procedures</i></b>		
Chest X-ray	1	0
Computerised tomogram thorax	1	0
<b><i>Tissue enzyme analyses NEC</i></b>		
Blood alkaline phosphatase increased	1	0
<b><i>Urinalysis NEC</i></b>		
Blood urine present	1	0
pH urine	1	0
<b><i>Vascular tests NEC (incl blood pressure)</i></b>		
Blood pressure decreased	4	0
Blood pressure increased	4	0
Blood pressure measurement	2	0
Blood pressure systolic decreased	1	0
<b><i>Virus identification and serology</i></b>		
Coronavirus test	1	0
SARS-CoV-2 antibody test	1	0
SARS-CoV-2 test positive	1	0
Viral test	1	0
<b>Investigations SOC TOTAL</b>	<b>150</b>	<b>1</b>

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i><b>Appetite disorders</b></i>		
Appetite disorder	1	0
Decreased appetite	30	0
Food craving	1	0
Hyperphagia	1	0
Increased appetite	2	0
<i><b>Diabetes mellitus (incl subtypes)</b></i>		
Diabetes mellitus	1	0
<i><b>Disorders of purine metabolism</b></i>		
Gout	2	0
<i><b>Fluid intake increased</b></i>		
Polydipsia	1	0
<i><b>Food malabsorption and intolerance syndromes (excl sugar intolerance)</b></i>		
Gluten sensitivity	1	0
Histamine intolerance	1	0
<i><b>General nutritional disorders NEC</b></i>		
Abnormal weight gain	1	0
Feeding disorder	1	0
Food aversion	1	0
<i><b>Hyperglycaemic conditions NEC</b></i>		
Hyperglycaemia	1	0
<i><b>Hypoglycaemic conditions NEC</b></i>		
Hypoglycaemia	4	0
Postprandial hypoglycaemia	1	0
<i><b>Iron deficiencies</b></i>		
Iron deficiency	1	0
<i><b>Sodium imbalance</b></i>		
Hyponatraemia	1	0
<i><b>Total fluid volume decreased</b></i>		
Dehydration	3	0
<i><b>Total fluid volume increased</b></i>		
Fluid retention	1	0
<i><b>Vitamin deficiencies NEC</b></i>		
Hypovitaminosis	1	0
<i><b>Water soluble vitamin deficiencies</b></i>		
Folate deficiency	1	0
<b>Metabolic disorders SOC TOTAL</b>	<b>58</b>	<b>0</b>

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Earliest Reaction Date: 30-Dec-2019

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<b><i>Arthropathies NEC</i></b>		
Arthritis	4	0
Arthropathy	1	0
<b><i>Bone related signs and symptoms</i></b>		
Bone pain	5	0
Bone swelling	1	0
Pain in jaw	10	0
Spinal pain	1	0
<b><i>Cartilage disorders</i></b>		
Costochondritis	4	0
<b><i>Connective tissue disorders NEC</i></b>		
Connective tissue disorder	1	0
<b><i>Extremity deformities</i></b>		
Finger deformity	1	0
<b><i>Joint related disorders NEC</i></b>		
Periarthritis	5	0
<b><i>Joint related signs and symptoms</i></b>		
Arthralgia	181	0
Joint effusion	1	0
Joint stiffness	4	0
Joint swelling	10	0
<b><i>Muscle infections and inflammations</i></b>		
Immune-mediated myositis	1	0
Myositis	3	0
<b><i>Muscle pains</i></b>		
Fibromyalgia	4	0
Myalgia	259	0
<b><i>Muscle related signs and symptoms NEC</i></b>		
Muscle fatigue	8	0
Muscle spasms	54	0
Muscle tightness	4	0
Muscle twitching	12	0
<b><i>Muscle tone abnormalities</i></b>		
Muscle rigidity	1	0
Trismus	2	0
<b><i>Muscle weakness conditions</i></b>		
Muscular weakness	22	0
<b><i>Musculoskeletal and connective tissue conditions NEC</i></b>		
Mandibular mass	1	0
Mastication disorder	1	0
Mobility decreased	1	0
Musculoskeletal stiffness	30	0
<b><i>Musculoskeletal and connective tissue pain and discomfort</i></b>		
Back pain	68	0
Flank pain	2	0
Limb discomfort	21	0
Musculoskeletal chest pain	4	0
Musculoskeletal discomfort	3	0
Musculoskeletal pain	4	0
Neck pain	40	0
Pain in extremity	270	0
Rheumatic disorder	1	0

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i>Muscle &amp; tissue disorders cont'd</i>		
<b><i>Osteoarthropathies</i></b>		
Nodal osteoarthritis	1	0
<b><i>Soft tissue disorders NEC</i></b>		
Axillary mass	7	0
Groin pain	2	0
Neck mass	1	0
<b><i>Spondyloarthropathies</i></b>		
Arthritis reactive	1	0
<b><i>Synovial disorders</i></b>		
Synovial cyst	1	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>1058</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Neoplasms</b>		
<i>Cervix neoplasms malignant</i>		
Cervix carcinoma	1	0
<b>Neoplasms SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Earliest Reaction Date: 30-Dec-2019

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<b><i>Absence seizures</i></b>		
Petit mal epilepsy	1	0
<b><i>Central nervous system haemorrhages and cerebrovascular accidents</i></b>		
Cerebellar stroke	2	0
Cerebral artery occlusion	1	0
Cerebral haemorrhage	2	0
Cerebral infarction	1	0
Cerebrovascular accident	13	0
Embolic stroke	1	0
Ischaemic stroke	1	0
Vertebrobasilar stroke	1	0
<b><i>Cerebrovascular venous and sinus thrombosis</i></b>		
Cerebral venous sinus thrombosis	2	0
<b><i>Coordination and balance disturbances</i></b>		
Balance disorder	3	0
Dysstasia	1	0
<b><i>Cortical dysfunction NEC</i></b>		
Aphasia	4	0
Visuospatial deficit	1	0
<b><i>Disturbances in consciousness NEC</i></b>		
Altered state of consciousness	2	0
Depressed level of consciousness	3	0
Lethargy	28	0
Loss of consciousness	18	0
Somnolence	18	0
Syncope	53	0
<b><i>Dyskinesias and movement disorders NEC</i></b>		
Dyskinesia	1	0
Hypokinesia	1	0
Psychomotor hyperactivity	1	0
<b><i>Dystonias</i></b>		
Dystonia	1	0
<b><i>Encephalitis NEC</i></b>		
Noninfective encephalitis	1	0
<b><i>Facial cranial nerve disorders</i></b>		
Bell's palsy	7	0
Facial nerve disorder	1	0
Facial paralysis	7	0
Facial paresis	3	0
Facial spasm	1	0
<b><i>Generalised tonic-clonic seizures</i></b>		
Generalised tonic-clonic seizure	1	0
<b><i>Headaches NEC</i></b>		
Cluster headache	7	0
Headache	548	0
New daily persistent headache	1	0
Sinus headache	5	0
Tension headache	8	0
Vascular headache	2	0
<b><i>Lumbar spinal cord and nerve root disorders</i></b>		
Sciatica	4	0
<b><i>Memory loss (excl dementia)</i></b>		

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b> <small>Nervous system disorders cont'd</small>		
Amnesia	4	0
Memory impairment	9	0
Transient global amnesia	1	0
<b>Mental impairment (excl dementia and memory loss)</b>		
Cognitive disorder	2	0
Disturbance in attention	6	0
Mental impairment	1	0
<b>Migraine headaches</b>		
Hemiplegic migraine	2	0
Migraine	56	0
Migraine with aura	4	0
Ophthalmic migraine	1	0
<b>Mononeuropathies</b>		
Carpal tunnel syndrome	1	0
Cubital tunnel syndrome	1	0
Peripheral nerve lesion	1	0
<b>Multiple sclerosis acute and progressive</b>		
Multiple sclerosis relapse	5	0
<b>Muscle tone abnormal</b>		
Hypotonia	1	0
<b>Narcolepsy and hypersomnia</b>		
Narcolepsy	1	0
<b>Nervous system disorders NEC</b>		
Nervous system disorder	1	0
<b>Neurological signs and symptoms NEC</b>		
Clonus	1	0
Dizziness	205	0
Dizziness exertional	1	0
Dizziness postural	10	0
Head discomfort	12	0
Inability to crawl	1	0
Neurological symptom	3	0
Patient elopement	1	0
Persistent postural-perceptual dizziness	1	0
Presyncope	10	0
Sensory overload	1	0
<b>Neuromuscular disorders NEC</b>		
Muscle contractions involuntary	1	0
<b>Olfactory nerve disorders</b>		
Anosmia	6	0
Parosmia	9	0
<b>Optic nerve disorders NEC</b>		
Optic neuritis	2	0
<b>Paraesthesias and dysaesthesias</b>		
Burning sensation	16	0
Formication	1	0
Hyperaesthesia	6	0
Hypoaesthesia	64	0
Paraesthesia	86	0
<b>Paralysis and paresis (excl cranial nerve)</b>		
Hemiparesis	4	0
Hemiplegia	1	0



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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Monoparesis	3	0
Monoplegia	1	0
Paralysis	3	0
Paresis	1	0
<b><i>Parkinson's disease and parkinsonism</i></b>		
Reduced facial expression	1	0
<b><i>Peripheral neuropathies NEC</i></b>		
Neuropathy peripheral	5	0
Peripheral sensory neuropathy	1	0
Thoracic outlet syndrome	1	0
<b><i>Seizures and seizure disorders NEC</i></b>		
Atonic seizures	1	0
Epilepsy	3	0
Seizure	4	0
Status epilepticus	1	0
Tonic clonic movements	1	0
<b><i>Sensory abnormalities NEC</i></b>		
Ageusia	13	0
Allodynia	1	0
Aura	1	0
Dysgeusia	25	0
Electric shock sensation	1	0
Neuralgia	11	0
Restless legs syndrome	2	0
Sensory disturbance	3	0
Taste disorder	4	0
<b><i>Speech and language abnormalities</i></b>		
Dysarthria	3	0
Slow speech	1	0
<b><i>Transient cerebrovascular events</i></b>		
Transient ischaemic attack	4	0
<b><i>Tremor (excl congenital)</i></b>		
Tremor	31	0
<b>Nervous system disorders SOC TOTAL</b>	<b>1421</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Pregnancy conditions</b>		
<i>Abortions spontaneous</i>		
Abortion spontaneous	8	0
<i>Foetal complications NEC</i>		
Foetal hypokinesia	1	0
<i>Haemorrhagic complications of pregnancy</i>		
Premature separation of placenta	1	0
<i>Normal pregnancy, labour and delivery</i>		
Live birth	1	0
Pregnancy	1	0
<i>Postpartum complications NEC</i>		
Postpartum haemorrhage	1	0
<i>Unintended pregnancies</i>		
Unintended pregnancy	1	0
<b>Pregnancy conditions SOC TOTAL</b>	<b>14</b>	<b>0</b>

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Reaction Name	Total	Fatal
<i>Product physical issues</i>		
Liquid product physical issue	1	0
<b>null SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<b><i>Abnormal behaviour NEC</i></b>		
Breath holding	1	0
<b><i>Affect alterations NEC</i></b>		
Affect lability	1	0
<b><i>Anxiety symptoms</i></b>		
Agitation	1	0
Anxiety	23	0
Immunisation anxiety related reaction	1	0
Nervousness	1	0
Stress	2	0
Tension	1	0
<b><i>Cognitive and attention disorders and disturbances NEC</i></b>		
Mental fatigue	9	0
<b><i>Confusion and disorientation</i></b>		
Confusional state	21	0
Disorientation	9	0
<b><i>Deliria</i></b>		
Delirium	7	0
<b><i>Depressive disorders</i></b>		
Depression	9	0
Major depression	1	0
<b><i>Dissociative states</i></b>		
Dissociation	2	0
<b><i>Disturbances in initiating and maintaining sleep</i></b>		
Insomnia	36	0
Terminal insomnia	1	0
<b><i>Dyssomnias</i></b>		
Poor quality sleep	9	0
<b><i>Emotional and mood disturbances NEC</i></b>		
Emotional distress	1	0
Euphoric mood	2	0
Irritability	6	0
Mood altered	2	0
<b><i>Fear symptoms and phobic disorders (incl social phobia)</i></b>		
Fear of eating	1	0
Phobia	1	0
<b><i>Fluctuating mood symptoms</i></b>		
Mood swings	7	0
<b><i>Hallucinations (excl sleep-related)</i></b>		
Hallucination	6	0
<b><i>Increased physical activity levels</i></b>		
Restlessness	2	0
<b><i>Mood alterations with depressive symptoms</i></b>		
Depressed mood	8	0
Tearfulness	2	0
<b><i>Narcolepsy and associated conditions</i></b>		
Hypnopompic hallucination	1	0
Sleep attacks	1	0
<b><i>Panic attacks and disorders</i></b>		
Panic attack	9	0
<b><i>Parasomnias</i></b>		
Abnormal dreams	4	0

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Nightmare	5	0
Sleep talking	1	0
Somnambulism	1	0
<b><i>Perception disturbances NEC</i></b>		
Autoscopy	1	0
Flashback	1	0
<b><i>Psychiatric symptoms NEC</i></b>		
Psychiatric symptom	1	0
<b><i>Sexual arousal disorders</i></b>		
Disturbance in sexual arousal	1	0
<b><i>Sexual desire disorders</i></b>		
Libido increased	1	0
<b><i>Sleep disorders NEC</i></b>		
Sleep disorder	3	0
<b><i>Stress disorders</i></b>		
Burnout syndrome	1	0
<b><i>Thinking disturbances</i></b>		
Bradyphrenia	2	0
Thinking abnormal	1	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>207</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>		
Micturition urgency	1	0
Pollakiuria	4	0
Urinary retention	1	0
Urine flow decreased	1	0
<i><b>Glomerulonephritis and nephrotic syndrome</b></i>		
Nephrotic syndrome	1	0
<i><b>Renal failure and impairment</b></i>		
Acute kidney injury	1	0
Renal impairment	1	0
<i><b>Renal structural abnormalities and trauma</b></i>		
Kidney small	1	0
<i><b>Urinary abnormalities</b></i>		
Chromaturia	5	0
Haematuria	4	0
Urine abnormality	1	0
Urine odour abnormal	1	0
<i><b>Urinary tract signs and symptoms NEC</b></i>		
Nocturia	1	0
Renal pain	7	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>30</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i><b>Benign and malignant breast neoplasms</b></i>		
Breast cyst	1	0
<i><b>Breast disorders NEC</b></i>		
Breast mass	5	0
<i><b>Breast signs and symptoms</b></i>		
Breast discomfort	1	0
Breast engorgement	1	0
Breast pain	6	0
Breast swelling	5	0
Breast tenderness	4	0
Nipple pain	1	0
<i><b>Cervix disorders NEC</b></i>		
Ectropion of cervix	1	0
<i><b>Erection and ejaculation conditions and disorders</b></i>		
Erectile dysfunction	3	0
<i><b>Lactation disorders</b></i>		
Lactation disorder	1	0
<i><b>Menopausal effects NEC</b></i>		
Menopausal symptoms	1	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	68	0
Intermenstrual bleeding	23	0
Menstrual discomfort	1	0
Menstrual disorder	41	0
Menstruation irregular	91	0
Premenstrual pain	3	0
Premenstrual syndrome	3	0
Withdrawal bleed	1	0
<i><b>Menstruation with decreased bleeding</b></i>		
Amenorrhoea	26	0
Hypomenorrhoea	21	0
Menstruation delayed	124	0
Oligomenorrhoea	5	0
<i><b>Menstruation with increased bleeding</b></i>		
Heavy menstrual bleeding	139	0
Menometrorrhagia	1	0
Polymenorrhoea	21	0
<i><b>Ovarian and fallopian tube cysts and neoplasms</b></i>		
Ovarian cyst	1	0
Polycystic ovaries	1	0
<i><b>Ovarian and fallopian tube disorders NEC</b></i>		
Hydrosalpinx	1	0
Ovarian necrosis	1	0
Ovulation pain	3	0
<i><b>Pelvis and broad ligament disorders NEC</b></i>		
Pelvic haemorrhage	1	0
<i><b>Reproductive tract disorders NEC (excl neoplasms)</b></i>		
Genital haemorrhage	1	0
<i><b>Reproductive tract signs and symptoms NEC</b></i>		
Pelvic pain	1	0

## Case Series Drug Analysis Print

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Report Run Date: 23-Feb-2022  
Earliest Reaction Date: 30-Dec-2019

Data Lock Date: 22-Feb-2022 18:30:04  
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i>Reproductive &amp; breast disorders cont'd</i>		
<b>Scrotal disorders NEC</b>		
Scrotal pain	2	0
<b>Sexual function and fertility disorders NEC</b>		
Infertility female	1	0
<b>Spermatogenesis and semen disorders</b>		
Haematospermia	1	0
<b>Testicular and epididymal disorders NEC</b>		
Testicular pain	1	0
Testicular swelling	1	0
<b>Uterine disorders NEC</b>		
Endometrial thickening	1	0
Endometriosis	1	0
<b>Uterine neoplasms</b>		
Uterine polyp	1	0
<b>Vulvovaginal disorders NEC</b>		
Vaginal haemorrhage	34	0
Vulval haemorrhage	1	0
Vulvovaginal ulceration	1	0
<b>Vulvovaginal signs and symptoms</b>		
Labia enlarged	1	0
Vaginal discharge	3	0
Vulvovaginal burning sensation	1	0
Vulvovaginal dryness	1	0
Vulvovaginal pain	1	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>661</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Dyspnoea	136	0
Dyspnoea exertional	1	0
Hyperventilation	2	0
Hypopnoea	4	0
Irregular breathing	2	0
Respiration abnormal	1	0
Respiratory arrest	1	0
Tachypnoea	2	0
<i><b>Bronchospasm and obstruction</b></i>		
Asthma	6	0
Cough variant asthma	1	0
Obstructive airways disorder	1	0
Wheezing	1	0
<i><b>Coughing and associated symptoms</b></i>		
Cough	44	0
Haemoptysis	2	0
Productive cough	4	0
<i><b>Diaphragmatic disorders</b></i>		
Diaphragmatic disorder	1	0
<i><b>Lower respiratory tract signs and symptoms</b></i>		
Hiccups	2	0
Pulmonary pain	3	0
<i><b>Nasal congestion and inflammations</b></i>		
Nasal congestion	11	0
Rhinitis allergic	1	0
<i><b>Nasal disorders NEC</b></i>		
Epistaxis	21	0
<i><b>Paranasal sinus disorders (excl infections and neoplasms)</b></i>		
Sinus congestion	3	0
<i><b>Pharyngeal disorders (excl infections and neoplasms)</b></i>		
Pharyngeal paraesthesia	1	0
Pharyngeal swelling	5	0
Tonsillar hypertrophy	1	0
<i><b>Pneumothorax and pleural effusions NEC</b></i>		
Pleural effusion	3	0
Pneumothorax	1	0
<i><b>Pulmonary oedemas</b></i>		
Pulmonary congestion	1	0
<i><b>Pulmonary thrombotic and embolic conditions</b></i>		
Pulmonary embolism	11	0
<i><b>Respiratory signs and symptoms NEC</b></i>		
Allergic respiratory symptom	1	0
Painful respiration	1	0
<i><b>Upper respiratory tract signs and symptoms</b></i>		
Aphonia	1	0
Catarrh	1	0
Choking	1	0
Dry throat	4	0
Increased viscosity of upper respiratory secretion	1	0
Nasal discomfort	1	0
Oropharyngeal discomfort	1	0

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
Respiratory disorders cont'd		
Oropharyngeal pain	67	0
Paranasal sinus discomfort	1	0
Rhinorrhoea	22	0
Sinus pain	3	0
Sneezing	8	0
Throat irritation	4	0
Throat tightness	3	0
<b>Respiratory disorders SOC TOTAL</b>	<b>393</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<i><b>Acnes</b></i>		
Acne	6	0
Acne cystic	1	0
<i><b>Alopecias</b></i>		
Alopecia	12	0
Alopecia areata	1	0
<i><b>Angioedemas</b></i>		
Angioedema	8	0
<i><b>Apocrine and eccrine gland disorders</b></i>		
Cold sweat	13	0
Hyperhidrosis	51	0
Miliaria	1	0
Night sweats	17	0
<i><b>Bullous conditions</b></i>		
Blister	9	0
Pemphigoid	1	0
<i><b>Dermal and epidermal conditions NEC</b></i>		
Dry skin	7	0
Pain of skin	9	0
Papule	3	0
Scab	2	0
Sensitive skin	2	0
Skin burning sensation	5	0
Skin discolouration	3	0
Skin lesion	1	0
Skin odour abnormal	1	0
Skin reaction	1	0
Skin sensitisation	2	0
Skin swelling	2	0
Skin warm	8	0
<i><b>Dermatitis and eczema</b></i>		
Dermatitis	4	0
Dermatitis allergic	10	0
Dermatitis atopic	2	0
Eczema	6	0
Skin irritation	3	0
<i><b>Dermatitis ascribed to specific agent</b></i>		
Drug eruption	1	0
<i><b>Erythemas</b></i>		
Erythema	37	0
<i><b>Exfoliative conditions</b></i>		
Exfoliative rash	2	0
Skin exfoliation	3	0
<i><b>Hyperpigmentation disorders</b></i>		
Skin hyperpigmentation	1	0
<i><b>Hypopigmentation disorders</b></i>		
Skin hypopigmentation	1	0
<i><b>Nail and nail bed conditions (excl infections and infestations)</b></i>		
Onychomadesis	1	0
<i><b>Panniculitides</b></i>		
Erythema nodosum	1	0
<i><b>Papulosquamous conditions</b></i>		

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Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Lichen sclerosus	2	0
Pityriasis rosea	1	0
<b>Photosensitivity and photodermatosis conditions</b>		
Photosensitivity reaction	1	0
<b>Pigmentation changes NEC</b>		
Pigmentation disorder	1	0
<b>Pruritus NEC</b>		
Pruritus	120	0
<b>Psoriatic conditions</b>		
Guttate psoriasis	1	0
Nail psoriasis	1	0
Psoriasis	4	0
<b>Purpura and related conditions</b>		
Henoch-Schonlein purpura	1	0
Petechiae	3	0
Purpura	4	0
<b>Rashes, eruptions and exanthems NEC</b>		
Rash	130	0
Rash erythematous	22	0
Rash macular	8	0
Rash maculo-papular	2	0
Rash morbilliform	1	0
Rash papular	9	0
Rash pruritic	39	0
Rash vesicular	2	0
<b>Rosaceas</b>		
Rosacea	2	0
<b>Skin and subcutaneous tissue ulcerations</b>		
Skin erosion	1	0
Skin ulcer	1	0
<b>Skin cysts and polyps</b>		
Dermal cyst	1	0
<b>Skin vasculitides</b>		
Cutaneous vasculitis	2	0
<b>Urticarias</b>		
Urticaria	41	0
Urticaria chronic	1	0
<b>Skin disorders SOC TOTAL</b>	<b>639</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Social circumstances</b>		
<i>Age related issues</i>		
Menopause	1	0
<i>Disability issues</i>		
Housebound	1	0
<b>Social circumstances SOC TOTAL</b>	<b>2</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
<i>Contraceptive methods male</i>		
Condom	1	0
<i>Dietary and nutritional therapies</i>		
Nothing by mouth order	1	0
<i>Gynaecological therapeutic procedures NEC</i>		
Menstrual cycle management	1	0
<i>Immunisations</i>		
COVID-19 immunisation	3	0
<i>Large intestine therapeutic procedures</i>		
Appendectomy	1	0
<i>Limb therapeutic procedures</i>		
Limb immobilisation	1	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>8</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<i><b>Arterial infections and inflammations</b></i>		
Giant cell arteritis	2	0
<i><b>Circulatory collapse and shock</b></i>		
Circulatory collapse	2	0
<i><b>Haemorrhages NEC</b></i>		
Haematoma	2	0
Haemorrhage	25	0
<i><b>Lymphoedemas</b></i>		
Lymphoedema	5	0
<i><b>Non-site specific embolism and thrombosis</b></i>		
Embolism	4	0
Thrombosis	12	0
Venous thrombosis	1	0
<i><b>Non-site specific necrosis and vascular insufficiency NEC</b></i>		
Arterial spasm	1	0
Ischaemia	1	0
<i><b>Non-site specific vascular disorders NEC</b></i>		
Vascular pain	2	0
Vasodilatation	1	0
<i><b>Peripheral embolism and thrombosis</b></i>		
Deep vein thrombosis	7	0
Pelvic venous thrombosis	1	0
<i><b>Peripheral vascular disorders NEC</b></i>		
Flushing	1	0
Hot flush	18	0
Vein wall hypertrophy	1	0
<i><b>Peripheral vasoconstriction, necrosis and vascular insufficiency</b></i>		
Jugular vein occlusion	1	0
Peripheral coldness	8	0
Poor peripheral circulation	1	0
Raynaud's phenomenon	5	0
<i><b>Site specific vascular disorders NEC</b></i>		
Pallor	4	0
<i><b>Varicose veins NEC</b></i>		
Spider vein	1	0
Varicose vein	1	0
<i><b>Vascular hypertensive disorders NEC</b></i>		
Hypertension	16	0
<i><b>Vascular hypotensive disorders</b></i>		
Hypotension	12	0
<i><b>Vasculitides NEC</b></i>		
Behcet's syndrome	1	0
Vasculitis	2	0
<b>Vascular disorders SOC TOTAL</b>	<b>138</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>9109</b>	<b>9</b>
<b>TOTAL REPORTS</b>	<b>3203</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>9</b>