

Case Series Drug Analysis Print

Name: FOI 24/307 All Yellow Card reports for COVID-19 Pfizer-BioNTech vaccine (Batch EM4965)

Report Run Date: 23-Apr-2024
Data Lock Date: 22-Apr-2024 18:30:03
Earliest Reaction Date: 01-Feb-2020
MedDRA Version: MedDRA 26.1

FOI 24/307 All Yellow Card reports for COVID-19 Pfizer-BioNTech vaccine (Batch EM4965): FOI 24/307 All UK spontaneous Yellow card reports for COVID-19 Pfizer-BioNTech vaccine (batch EM4965) received up until 15/04/2024

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Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemia deficiencies</i>		
Iron deficiency anaemia	1	0
<i>Anaemias NEC</i>		
Anaemia	4	0
Microcytic anaemia	1	0
<i>Bleeding tendencies</i>		
Haemorrhagic diathesis	1	0
Increased tendency to bruise	4	0
<i>Coagulopathies</i>		
Abnormal clotting factor	1	0
Antiphospholipid syndrome	1	0
Coagulopathy	1	0
<i>Haematological disorders</i>		
Mast cell activation syndrome	2	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	51	0
Lymphadenitis	3	0
Lymphadenopathy	366	0
<i>Neutropenias</i>		
Neutropenia	1	0
<i>Platelet disorders NEC</i>		
Platelet disorder	1	0
<i>Spleen disorders</i>		
Splenomegaly	1	0
<i>Thrombocytopenias</i>		
Acquired amegakaryocytic thrombocytopenia	1	0
Immune thrombocytopenia	1	0
Thrombocytopenia	7	0
Blood disorders SOC TOTAL	448	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac conduction disorders</i>		
Atrioventricular block	4	0
Bundle branch block	1	0
Bundle branch block left	2	0
Bundle branch block right	1	0
<i>Cardiac disorders NEC</i>		
Cardiac disorder	3	0
<i>Cardiac infections and inflammations NEC</i>		
Carditis	2	0
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	86	0
<i>Cardiac valve disorders NEC</i>		
Cardiac valve disease	1	0
<i>Coronary artery disorders NEC</i>		
Coronary artery disease	2	0
<i>Heart failures NEC</i>		
Cardiac failure	3	0
<i>Ischaemic coronary artery disorders</i>		
Angina pectoris	4	0
Myocardial infarction	5	1
<i>Left ventricular failures</i>		
Left ventricular failure	1	0
<i>Mitral valvular disorders</i>		
Mitral valve incompetence	1	0
<i>Myocardial disorders NEC</i>		
Cardiomegaly	2	0
Diastolic dysfunction	1	0
Left ventricular hypertrophy	1	0
Myocardial injury	1	0
<i>Noninfectious myocarditis</i>		
Myocarditis	10	0
<i>Noninfectious pericarditis</i>		
Pericarditis	8	0
Pericarditis constrictive	1	0
<i>Pericardial disorders NEC</i>		
Pericardial effusion	2	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	2	0
Bradycardia	3	0
Cardiac flutter	8	0
Extrasystoles	8	0
Postural orthostatic tachycardia syndrome	1	0
Tachycardia	40	0
<i>Supraventricular arrhythmias</i>		
Arrhythmia supraventricular	1	0
Atrial fibrillation	14	0
Atrial flutter	1	0
Sinus arrhythmia	1	0
Sinus bradycardia	1	0
Supraventricular tachycardia	1	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Ventricular extrasystoles	1	0

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Cardiac disorders Cardiac disorders cont'd		
Cardiac disorders SOC TOTAL	224	1

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Cerebral disorders congenital</i>		
Cerebral palsy	1	0
<i>Neurological disorders congenital NEC</i>		
Tourette's disorder	1	0
Congenital disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear discomfort	3	0
Ear disorder	1	0
Ear pain	24	0
Ear swelling	2	0
<i>Hearing losses</i>		
Deafness	9	0
Deafness bilateral	1	0
Deafness neurosensory	2	0
Deafness unilateral	3	0
Hypoacusis	4	0
Sudden hearing loss	3	0
<i>Hyperacusia</i>		
Hyperacusis	3	0
<i>Inner ear disorders NEC</i>		
Inner ear disorder	1	0
Meniere's disease	1	0
Vestibular disorder	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	66	0
Vertigo	38	0
Vertigo positional	5	0
Ear disorders SOC TOTAL	167	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Thyroiditis	1	0
<i>Adrenal gland disorders NEC</i>		
Adrenal haemorrhage	1	0
<i>Endocrine abnormalities of puberty</i>		
Delayed menarche	1	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	1	0
Ovulation delayed	2	0
<i>Thyroid disorders NEC</i>		
Autoimmune thyroid disorder	1	0
Thyroid disorder	1	0
<i>Thyroid hyperfunction disorders</i>		
Graves' disease	1	0
Hyperthyroidism	2	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	2	0
Endocrine disorders SOC TOTAL	13	0

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Eye disorders		
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Vitreous detachment	1	0
Vitreous floaters	3	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	2	0
<i>Eyelid movement disorders</i>		
Blepharospasm	2	0
Eyelid ptosis	1	0
<i>Glaucomas (excl congenital)</i>		
Angle closure glaucoma	1	0
Glaucoma	1	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Iritis	1	0
<i>Lacrimation disorders</i>		
Dry eye	2	0
Lacrimation increased	3	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Eyelid cyst	1	0
Eyelid rash	2	0
Swelling of eyelid	7	0
<i>Ocular bleeding and vascular disorders NEC</i>		
Eye haemorrhage	1	0
<i>Ocular cysts and polyps</i>		
Conjunctival cyst	1	0
<i>Ocular disorders NEC</i>		
Eye oedema	1	0
Eye pain	29	0
Eye swelling	15	0
Periorbital oedema	1	0
Periorbital swelling	7	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye discharge	1	0
Eye inflammation	3	0
Eye irritation	1	0
Eye pruritus	3	0
Ocular hyperaemia	6	0
<i>Ocular sensation disorders</i>		
Abnormal sensation in eye	2	0
Asthenopia	2	0
Photophobia	10	0
<i>Optic disc abnormalities NEC</i>		
Papilloedema	2	0
<i>Optic nerve bleeding and vascular disorders</i>		
Optic ischaemic neuropathy	1	0
<i>Retinal bleeding and vascular disorders (excl retinopathy)</i>		
Retinal haemorrhage	1	0
Retinal vein occlusion	2	0
<i>Retinal, choroid and vitreous infections and inflammations</i>		
Retinal vasculitis	1	0
<i>Retinopathies NEC</i>		
Acute macular neuroretinopathy	1	0
Retinopathy	2	0

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Eye disorders Eye disorders cont'd		
<i>Visual colour distortions</i>		
Xanthopsia	1	0
<i>Visual disorders NEC</i>		
Diplopia	8	0
Halo vision	1	0
Heteronymous diplopia	1	0
Photopsia	7	0
Scintillating scotoma	1	0
Vision blurred	29	0
<i>Visual field disorders</i>		
Visual field defect	1	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	3	0
Visual impairment	11	0
<i>Visual pathway disorders</i>		
Optic nerve disorder	1	0
Eye disorders SOC TOTAL	184	0

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Gastrointestinal disorders		
<i>Abdominal hernias NEC</i>		
Sciatic hernia	1	0
<i>Acute and chronic pancreatitis</i>		
Pancreatitis	1	0
<i>Colitis (excl infective)</i>		
Colitis	2	0
Colitis ulcerative	3	0
Crohn's disease	1	0
<i>Dental disorders NEC</i>		
Tooth erosion	1	0
<i>Dental pain and sensation disorders</i>		
Dental discomfort	1	0
Hyperaesthesia teeth	2	0
Toothache	11	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	76	0
<i>Diverticula</i>		
Diverticulum	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	18	0
Eructation	1	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	13	0
Flatulence	6	0
<i>Gastric and oesophageal haemorrhages</i>		
Mallory-Weiss syndrome	1	0
<i>Gastritis (excl infective)</i>		
Gastritis	3	0
Reflux gastritis	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	23	0
Abdominal pain lower	1	0
Abdominal pain upper	46	0
Gastrointestinal pain	3	0
Oesophageal pain	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	4	0
Gastrooesophageal reflux disease	3	0
Impaired gastric emptying	1	0
Infrequent bowel movements	1	0
<i>Gastrointestinal disorders NEC</i>		
Gastrointestinal disorder	3	0
Stomach mass	1	0
<i>Gastrointestinal inflammatory disorders NEC</i>		
Intestinal angioedema	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	10	0
Breath odour	1	0
Dysphagia	4	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Irritable bowel syndrome	2	0
<i>Gastrointestinal vascular occlusion and infarction</i>		
Mesenteric vein thrombosis	2	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival pain	2	0
Gingival swelling	2	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	1	0
<i>Intestinal haemorrhages</i>		
Rectal haemorrhage	1	0
<i>Malabsorption syndromes</i>		
Bile acid malabsorption	2	0
<i>Nausea and vomiting symptoms</i>		
Nausea	259	0
Retching	1	0
Vomiting	76	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematemesis	1	0
Haematochezia	3	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	15	0
Lip dry	3	0
Saliva altered	1	0
Salivary hypersecretion	1	0
<i>Oral soft tissue disorders NEC</i>		
Cheilitis	1	0
Enlarged uvula	1	0
Leukoplakia oral	1	0
Oral lichen planus	2	0
<i>Oral soft tissue signs and symptoms</i>		
Hypoaesthesia oral	7	0
Lip pain	1	0
Oral discomfort	3	0
Oral mucosal blistering	1	0
Oral pain	5	0
Paraesthesia oral	23	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	19	0
Mouth swelling	2	0
<i>Peptic ulcers and perforation</i>		
Peptic ulcer haemorrhage	2	0
<i>Salivary gland disorders NEC</i>		
Salivary gland pain	1	0
<i>Stomatitis and ulceration</i>		
Aphthous ulcer	1	0
Mouth ulceration	10	0
Stomatitis	1	0
<i>Tongue disorders</i>		
Tongue disorder	3	0
Tongue ulceration	2	0
<i>Tongue signs and symptoms</i>		
Stiff tongue	1	0

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Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Swollen tongue	7	0
Tongue blistering	1	0
Tongue coated	4	0
Tongue discolouration	1	0
Tongue eruption	1	0
Gastrointestinal disorders SOC TOTAL	720	0

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site irritation	1	0
Administration site pain	1	0
<i>Application and instillation site reactions</i>		
Application site joint erythema	1	0
Application site odour	1	0
Application site pain	1	0
<i>Asthenic conditions</i>		
Asthenia	36	0
Chronic fatigue syndrome	6	0
Fatigue	442	0
Malaise	118	0
<i>Cardiac complications associated with device</i>		
Prosthetic cardiac valve thrombosis	1	0
<i>Death and sudden death</i>		
Sudden death	1	1
<i>Febrile disorders</i>		
Hyperpyrexia	1	0
Pyrexia	228	0
<i>Feelings and sensations NEC</i>		
Chills	198	0
Feeling abnormal	29	0
Feeling cold	22	0
Feeling drunk	2	0
Feeling hot	30	0
Feeling of body temperature change	11	0
Feeling of relaxation	1	0
Hangover	1	0
Sensation of foreign body	1	0
Temperature intolerance	3	0
Thirst	9	0
<i>Gait disturbances</i>		
Gait disturbance	8	0
Gait inability	3	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	12	0
Crying	4	0
Disease recurrence	2	0
Exercise tolerance increased	1	0
Illness	40	0
Influenza like illness	62	0
Local reaction	3	0
Multiple organ dysfunction syndrome	1	0
Peripheral swelling	100	0
Screaming	2	0
Secretion discharge	1	0
Swelling	81	0
Swelling face	24	0
<i>Healing abnormal NEC</i>		
Impaired healing	1	0
<i>Inflammations</i>		
Inflammation	16	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Systemic inflammatory response syndrome	1	0
Injection site reactions		
Injection site bruising	3	0
Injection site coldness	1	0
Injection site eczema	1	0
Injection site erythema	3	0
Injection site inflammation	1	0
Injection site mass	15	0
Injection site pain	54	0
Injection site pruritus	4	0
Injection site rash	3	0
Injection site swelling	5	0
Injection site warmth	3	0
Interactions		
Drug interaction	1	0
Inhibitory drug interaction	1	0
Mass conditions NEC		
Cyst	1	0
Nodule	1	0
Mucosal findings abnormal		
Polyp	1	0
Oedema NEC		
Face oedema	1	0
Oedema	6	0
Oedema peripheral	3	0
Pain and discomfort NEC		
Axillary pain	108	0
Chest discomfort	25	0
Chest pain	94	0
Discomfort	10	0
Facial pain	3	0
Non-cardiac chest pain	1	0
Pain	167	0
Tenderness	23	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	1	0
Drug ineffective	18	0
Inadequate analgesia	1	0
Therapeutic response decreased	1	0
Therapeutic response unexpected	3	0
Vaccination failure	1	0
Trophic disorders		
Hyperplasia	1	0
Vaccination site reactions		
Shoulder injury related to vaccine administration	2	0
Vaccination site erythema	15	0
Vaccination site haemorrhage	1	0
Vaccination site induration	1	0
Vaccination site inflammation	2	0
Vaccination site mass	5	0
Vaccination site movement impairment	1	0
Vaccination site pain	34	0

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General disorders General disorders cont'd		
Vaccination site pruritus	2	0
Vaccination site rash	3	0
Vaccination site reaction	1	0
Vaccination site swelling	18	0
Vaccination site warmth	6	0
<i>Withdrawal and rebound effects</i>		
Withdrawal syndrome	1	0
General disorders SOC TOTAL	2164	1

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	1	0
<i>Cholecystitis and cholelithiasis</i>		
Cholecystitis	1	0
<i>Cholestasis and jaundice</i>		
Jaundice cholestatic	1	0
<i>Hepatic and hepatobiliary disorders NEC</i>		
Liver disorder	1	0
<i>Hepatic vascular disorders</i>		
Portal vein thrombosis	1	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	3	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Hepatitis	1	0
Liver injury	2	0
Hepatic disorders SOC TOTAL	11	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	1	0
<i>Allergic conditions NEC</i>		
Allergic oedema	2	0
Hypersensitivity	20	0
Multiple allergies	2	0
Type IV hypersensitivity reaction	1	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to vaccine	2	0
Drug hypersensitivity	2	0
Food allergy	1	0
Reaction to preservatives	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	6	0
<i>Atopic disorders</i>		
Seasonal allergy	2	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	3	0
<i>Immune and associated conditions NEC</i>		
Cytokine storm	1	0
Immune system disorder	2	0
Immune-mediated adverse reaction	1	0
Immune system disorders SOC TOTAL	47	0

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Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Gastroenteritis	1	0
<i>Bacterial infections NEC</i>		
Arthritis bacterial	1	0
Bacterial infection	1	0
Cellulitis	7	0
<i>Bone and joint infections</i>		
Arthritis infective	1	0
<i>Cardiac infections</i>		
Pericarditis infective	1	0
<i>Central nervous system and spinal infections</i>		
Encephalitis	1	0
<i>Coronavirus infections</i>		
COVID-19	45	2
Post-acute COVID-19 syndrome	1	0
Severe acute respiratory syndrome	1	0
Suspected COVID-19	2	0
<i>Coxiella infections</i>		
Q fever	1	0
<i>Cytomegaloviral infections</i>		
Cytomegalovirus infection	1	0
<i>Dental and oral soft tissue infections</i>		
Tooth infection	3	0
<i>Ear infections</i>		
Ear infection	2	0
Labyrinthitis	2	0
<i>Epstein-Barr viral infections</i>		
Infectious mononucleosis	2	0
<i>Eye and eyelid infections</i>		
Eye infection	1	0
Hordeolum	2	0
<i>Fungal infections NEC</i>		
Fungal infection	2	0
<i>Hepatitis virus infections</i>		
Hepatitis E	1	0
<i>Herpes viral infections</i>		
Genital herpes	2	0
Herpes simplex reactivation	1	0
Herpes zoster	47	0
Herpes zoster oticus	2	0
Nasal herpes	1	0
Oral herpes	9	0
Varicella	2	0
<i>Infections NEC</i>		
Abscess	3	0
Infected cyst	1	0
Infection	6	0
Localised infection	1	0
<i>Influenza viral infections</i>		
Influenza	22	0
<i>Lower respiratory tract and lung infections</i>		
Lower respiratory tract infection	7	0

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Infections Infections cont'd		
Pneumonia	6	0
Sepsis, bacteraemia, viraemia and fungaemia NEC		
Sepsis	2	1
Skin structures and soft tissue infections		
Pustule	1	0
Rash pustular	1	0
Skin infection	2	0
Subcutaneous abscess	1	0
Staphylococcal infections		
Furuncle	2	0
Upper respiratory tract infections		
Chronic sinusitis	1	0
Epiglottitis	1	0
Laryngitis	3	0
Nasopharyngitis	18	0
Sinusitis	4	0
Tonsillitis	2	0
Urinary tract infections		
Cystitis	4	0
Kidney infection	1	0
Urinary tract infection	2	0
Viral infections NEC		
Gastroenteritis viral	2	0
Sweating fever	3	0
Viral diarrhoea	1	0
Viral rash	2	0
Infections SOC TOTAL	242	3

Case Series Drug Analysis Print

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Earliest Reaction Date: 01-Feb-2020

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Reaction Name	Total	Fatal
Injuries		
<i>Abdominal and gastrointestinal injuries NEC</i>		
Oral contusion	1	0
Tooth fracture	1	0
<i>Anaesthetic and allied procedural complications</i>		
Sedation complication	1	0
<i>Cardiovascular injuries</i>		
Aortic injury	1	0
<i>Conditions caused by cold</i>		
Chillblains	2	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Maternal exposure during breast feeding	20	0
Maternal exposure during pregnancy	14	0
<i>Eye injuries NEC</i>		
Eye injury	1	0
<i>Fractures and dislocations NEC</i>		
Joint dislocation	1	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	4	0
<i>Muscle, tendon and ligament injuries</i>		
Ligament sprain	1	0
Muscle injury	2	0
Muscle strain	1	0
Tendon rupture	3	0
<i>Nerve injuries NEC</i>		
Nerve injury	4	0
<i>Neurological and psychiatric procedural complications</i>		
Post procedural stroke	1	0
<i>Non-site specific injuries NEC</i>		
Arthropod bite	2	0
Electric shock	1	0
Fall	3	0
Foreign body	1	0
Injury	1	0
Wound complication	1	0
<i>Non-site specific procedural complications</i>		
Seroma	1	0
<i>Off label uses</i>		
Off label use	5	0
<i>Poisoning and toxicity</i>		
Alcohol poisoning	1	0
<i>Product administration errors and issues</i>		
Inappropriate schedule of product administration	60	0
Wrong product administered	1	0
<i>Radiation injuries</i>		
Sunburn	1	0
<i>Site specific injuries NEC</i>		
Limb injury	2	0
<i>Skin injuries NEC</i>		
Contusion	36	0
<i>Underdoses NEC</i>		
Underdose	1	0
<i>Vaccination related complications</i>		

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Immunisation reaction	1	0
Injuries SOC TOTAL	176	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Investigations		
<i>Adrenal cortex tests</i>		
Cortisol decreased	1	0
<i>Auditory and vestibular diagnostic procedures</i>		
Acoustic stimulation tests	1	0
<i>Blood counts NEC</i>		
Full blood count	1	0
<i>Blood gas and acid base analyses</i>		
Blood lactic acid	1	0
Blood pH	1	0
Oxygen consumption decreased	1	0
Oxygen saturation decreased	1	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose decreased	1	0
Blood glucose increased	3	0
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	1	0
<i>Central nervous system imaging procedures</i>		
Computerised tomogram head	1	0
<i>Chemistry analyses NEC</i>		
Histamine level	1	0
<i>Cholesterol analyses</i>		
Remnant-like lipoprotein particles	1	0
<i>Coagulation and bleeding analyses</i>		
International normalised ratio abnormal	1	0
<i>ECG investigations</i>		
Electrocardiogram	1	0
Electrocardiogram abnormal	1	0
<i>Endocrine analyses and imaging NEC</i>		
Hormone level abnormal	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate	6	0
Heart rate abnormal	1	0
Heart rate decreased	3	0
Heart rate increased	16	0
Heart rate irregular	8	0
<i>Hepatobiliary function diagnostic procedures</i>		
Liver function test	1	0
Liver function test abnormal	1	0
<i>Investigations NEC</i>		
Blood test abnormal	1	0
<i>Mineral and electrolyte analyses</i>		
Serum ferritin decreased	1	0
<i>Musculoskeletal and soft tissue imaging procedures</i>		
Skull X-ray	2	0
<i>Neurologic diagnostic procedures</i>		
Coma scale abnormal	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature	6	0
Body temperature abnormal	2	0
Body temperature decreased	2	0
Body temperature fluctuation	2	0
Body temperature increased	9	0

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Grip strength decreased	2	0
Lymph node palpable	2	0
Menstruation normal	1	0
Skin temperature	2	0
Weight decreased	3	0
Platelet analyses		
Mean platelet volume increased	1	0
Platelet count decreased	3	0
Protein analyses NEC		
C-reactive protein increased	1	0
Respiratory tract and thoracic imaging procedures		
Computerised tomogram thorax	1	0
Skeletal and cardiac muscle analyses		
Troponin increased	1	0
Urinalysis NEC		
Blood urine	1	0
Blood urine present	2	0
Urinary tract function analyses NEC		
Urine output increased	1	0
Vascular tests NEC (incl blood pressure)		
Blood pressure abnormal	1	0
Blood pressure decreased	2	0
Blood pressure increased	12	0
Virus identification and serology		
SARS-CoV-2 test positive	1	0
Investigations SOC TOTAL	118	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	20	0
<i>Calcium metabolism disorders</i>		
Tetany	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	2	0
Type 2 diabetes mellitus	1	0
<i>Diabetic complications NEC</i>		
Diabetic ketosis	1	0
<i>Disorders of purine metabolism</i>		
Gout	4	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Alcohol intolerance	1	0
Food intolerance	1	0
Histamine intolerance	2	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	1	0
Feeding disorder	1	0
Food aversion	1	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	1	0
<i>Sodium imbalance</i>		
Hyponatraemia	1	0
<i>Sugar intolerance (excl glucose intolerance)</i>		
Lactose intolerance	1	0
<i>Total fluid volume decreased</i>		
Dehydration	4	0
<i>Total fluid volume increased</i>		
Fluid retention	1	0
Metabolic disorders SOC TOTAL	44	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	13	0
Arthropathy	2	0
Autoimmune arthritis	1	0
Polyarthritits	1	0
Seronegative arthritis	1	0
<i>Bone disorders NEC</i>		
Medial tibial stress syndrome	1	0
Osteitis	2	0
<i>Bone related signs and symptoms</i>		
Bone pain	4	0
Pain in jaw	9	0
Spinal pain	6	0
<i>Bursal disorders</i>		
Bursitis	2	0
<i>Cartilage disorders</i>		
Costochondritis	1	0
<i>Connective tissue disorders NEC</i>		
Polymyalgia rheumatica	2	0
<i>Extremity deformities</i>		
Finger deformity	2	0
Foot deformity	1	0
<i>Joint related disorders NEC</i>		
Joint laxity	1	0
Joint lock	1	0
Periarthritis	12	0
Rotator cuff syndrome	4	0
Temporomandibular joint syndrome	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	222	0
Jaw clicking	1	0
Joint noise	1	0
Joint range of motion decreased	3	0
Joint stiffness	12	0
Joint swelling	20	0
<i>Muscle infections and inflammations</i>		
Myositis	2	0
Polymyositis	2	0
<i>Muscle pains</i>		
Fibromyalgia	4	0
Myalgia	193	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle atrophy	4	0
Muscle disorder	1	0
Muscle fatigue	7	0
Muscle oedema	1	0
Muscle spasms	21	0
Muscle swelling	1	0
Muscle tightness	2	0
Muscle twitching	8	0
<i>Muscle tone abnormalities</i>		
Muscle rigidity	1	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Muscle & tissue disorders cont'd		
Trismus	1	0
Muscle weakness conditions		
Muscular weakness	32	0
Musculoskeletal and connective tissue conditions NEC		
Limb mass	1	0
Mobility decreased	4	0
Musculoskeletal stiffness	35	0
Musculoskeletal and connective tissue pain and discomfort		
Back pain	46	0
Flank pain	2	0
Limb discomfort	21	0
Musculoskeletal chest pain	7	0
Musculoskeletal discomfort	1	0
Neck pain	44	0
Pain in extremity	232	0
Osteoarthropathies		
Osteoarthritis	3	0
Psoriatic arthropathies		
Psoriatic arthropathy	1	0
Rheumatoid arthropathies		
Rheumatoid arthritis	7	0
Soft tissue disorders NEC		
Axillary mass	16	0
Fluctuance	1	0
Groin pain	2	0
Neck mass	1	0
Soft tissue disorder	1	0
Spondyloarthropathies		
Ankylosing spondylitis	1	0
Tendon disorders		
Tendon pain	2	0
Tendonitis	1	0
Trigger finger	1	0
Muscle & tissue disorders SOC TOTAL	1036	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>Bladder neoplasms malignant</i>		
Bladder cancer	1	0
<i>Breast and nipple neoplasms benign</i>		
Fibroadenoma of breast	1	0
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	2	0
<i>Colorectal neoplasms malignant</i>		
Rectal cancer	1	0
<i>Islet cell neoplasms and APUDoma NEC</i>		
Pancreatic neuroendocrine tumour	1	0
<i>Lymphomas unspecified NEC</i>		
Lymphoma	3	0
<i>Metastases to specified sites</i>		
Metastases to bone	1	0
Metastases to central nervous system	1	0
Metastases to spine	1	0
<i>Nervous system neoplasms unspecified malignancy NEC</i>		
Brain neoplasm	1	0
<i>Prostatic neoplasms malignant</i>		
Prostate cancer	1	0
<i>Renal neoplasms malignant</i>		
Renal cancer	1	0
Renal cell carcinoma	1	0
<i>Reproductive neoplasms female benign NEC</i>		
Benign hydatidiform mole	1	0
<i>Soft tissue neoplasms benign NEC</i>		
Lipoma	2	0
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	1	0
Neoplasms SOC TOTAL	20	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	1	0
<i>Autonomic nervous system disorders</i>		
Autonomic nervous system imbalance	1	0
Horner's syndrome	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebral haemorrhage	3	0
Cerebral infarction	1	0
Cerebrovascular accident	9	0
Ischaemic stroke	1	0
Subarachnoid haemorrhage	1	0
<i>Cerebrovascular venous and sinus thrombosis</i>		
Cerebral venous sinus thrombosis	1	0
<i>Coordination and balance disturbances</i>		
Balance disorder	14	0
Coordination abnormal	5	0
Dysstasia	2	0
Nystagmus	2	0
<i>Cortical dysfunction NEC</i>		
Aphasia	1	0
Dyslexia	1	0
Dyspraxia	1	0
<i>Disturbances in consciousness NEC</i>		
Altered state of consciousness	1	0
Depressed level of consciousness	1	0
Lethargy	53	0
Loss of consciousness	5	0
Somnolence	18	0
Syncope	41	0
<i>Dyskinesias and movement disorders NEC</i>		
Dyskinesia	1	0
Hyperkinesia	1	0
Hypokinesia	5	0
Movement disorder	1	0
Psychomotor hyperactivity	1	0
<i>Dystonias</i>		
Dystonia	1	0
<i>Eye movement disorders</i>		
Vlth nerve paralysis	2	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	11	0
Facial nerve disorder	1	0
Facial paralysis	7	0
Facial paresis	4	0
Facial spasm	2	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	3	0
<i>Headaches NEC</i>		
Cluster headache	9	0
Cold-stimulus headache	2	0
Headache	522	0
Occipital neuralgia	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Sinus headache	2	0
Tension headache	12	0
Increased intracranial pressure disorders		
Idiopathic intracranial hypertension	1	0
Intracranial pressure increased	1	0
Lumbar spinal cord and nerve root disorders		
Sciatica	2	0
Memory loss (excl dementia)		
Amnesia	3	0
Memory impairment	8	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	2	0
Disturbance in attention	11	0
Mental impairment	2	0
Migraine headaches		
Hemiplegic migraine	1	0
Migraine	61	0
Migraine with aura	4	0
Migraine without aura	3	0
Retinal migraine	1	0
Typical aura without headache	1	0
Mononeuropathies		
Carpal tunnel syndrome	1	0
Nerve compression	1	0
Motor neurone diseases		
Motor neurone disease	1	0
Multiple sclerosis acute and progressive		
Multiple sclerosis	1	0
Muscle tone abnormal		
Hypotonia	1	0
Narcolepsy and hypersomnia		
Hypersomnia	3	0
Nervous system disorders NEC		
Nervous system disorder	1	0
Neurological signs and symptoms NEC		
Brain fog	13	0
Dizziness	180	0
Dizziness exertional	1	0
Dizziness postural	22	0
Drooling	1	0
Fontanelle bulging	1	0
Head discomfort	7	0
Neurological symptom	1	0
Persistent postural-perceptual dizziness	2	0
Presyncope	10	0
Tongue biting	1	0
Neuromuscular disorders NEC		
Muscle contractions involuntary	1	0
Muscle spasticity	1	0
Neuromuscular junction dysfunction		
Myasthenia gravis crisis	1	0
Olfactory nerve disorders		

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Anosmia	3	0
Parosmia	4	0
<i>Optic nerve disorders NEC</i>		
Optic neuritis	2	0
<i>Paraesthesias and dysaesthesias</i>		
Burning sensation	13	0
Formication	1	0
Hyperaesthesia	5	0
Hypoaesthesia	58	0
Paraesthesia	84	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Hemiparesis	4	0
Hemiplegia	1	0
Monoparesis	3	0
Paralysis	2	0
<i>Partial complex seizures</i>		
Focal dyscognitive seizures	1	0
<i>Peripheral neuropathies NEC</i>		
Neuropathy peripheral	3	0
<i>Seizures and seizure disorders NEC</i>		
Clonic convulsion	1	0
Epilepsy	9	0
Febrile convulsion	1	0
Partial seizures with secondary generalisation	1	0
Seizure	12	0
<i>Sensory abnormalities NEC</i>		
Ageusia	5	0
Dysgeusia	25	0
Electric shock sensation	4	0
Neuralgia	12	0
Restless legs syndrome	5	0
Sensory disturbance	2	0
Sensory loss	2	0
Taste disorder	7	0
<i>Speech and language abnormalities</i>		
Dysarthria	7	0
Incoherent	1	0
Language disorder	1	0
Slow speech	1	0
Speech disorder	3	0
<i>Spinal cord and nerve root disorders NEC</i>		
Radiculitis brachial	1	0
<i>Transient cerebrovascular events</i>		
Transient ischaemic attack	11	0
<i>Tremor (excl congenital)</i>		
Tremor	30	0
Nervous system disorders SOC TOTAL	1429	0

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	7	0
<i>Maternal complications of labour NEC</i>		
Uterine hypertonus	1	0
Pregnancy conditions SOC TOTAL	8	0

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Reaction Name	Total	Fatal
<i>Device malfunction events NEC</i>		
Thrombosis in device	1	0
null SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Affect alterations NEC</i>		
Flat affect	1	0
Inappropriate affect	2	0
<i>Anxiety symptoms</i>		
Agitation	1	0
Anxiety	20	0
Nervousness	5	0
Stress	2	0
Tension	2	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	1	0
<i>Behaviour and socialisation disturbances</i>		
Social avoidant behaviour	1	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Executive dysfunction	1	0
Mental fatigue	3	0
<i>Confusion and disorientation</i>		
Confusional state	25	0
Disorientation	3	0
<i>Deliria</i>		
Delirium	2	0
<i>Depressive disorders</i>		
Depression	8	0
Depression suicidal	1	0
Major depression	2	0
<i>Dissociative states</i>		
Dissociation	4	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	27	0
<i>Dyssomnias</i>		
Poor quality sleep	4	0
<i>Eating disorders NEC</i>		
Eating disorder	1	0
<i>Emotional and mood disturbances NEC</i>		
Anger	2	0
Emotional disorder	1	0
Emotional distress	3	0
Irritability	3	0
Mood altered	1	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Fear	3	0
Social anxiety disorder	1	0
<i>Fluctuating mood symptoms</i>		
Mood swings	8	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	5	0
Hallucination, auditory	2	0
Hallucination, visual	2	0
<i>Increased physical activity levels</i>		
Restlessness	1	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	7	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Tearfulness	3	0
<i>Narcolepsy and associated conditions</i>		
Hypnopompic hallucination	1	0
<i>Panic attacks and disorders</i>		
Panic attack	9	0
<i>Parasomnias</i>		
Nightmare	3	0
Sleep terror	1	0
<i>Perception disturbances NEC</i>		
Autoscopy	1	0
<i>Pervasive developmental disorders NEC</i>		
Autism spectrum disorder	1	0
<i>Sexual desire disorders</i>		
Libido disorder	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	4	0
<i>Somatic symptom disorders</i>		
Habit cough	1	0
<i>Speech articulation and rhythm disturbances</i>		
Dysphemia	3	0
<i>Stereotypies and automatisms</i>		
Bruxism	1	0
<i>Stress disorders</i>		
Burnout syndrome	1	0
Post-traumatic stress disorder	1	0
<i>Suicidal and self-injurious behaviour</i>		
Suicidal ideation	1	0
<i>Tic disorders</i>		
Tic	1	0
Psychiatric disorders SOC TOTAL	188	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder discomfort	2	0
Micturition urgency	1	0
Pollakiuria	6	0
Urinary hesitation	1	0
<i>Bladder disorders NEC</i>		
Bladder disorder	1	0
<i>Genital and urinary tract disorders NEC</i>		
Urinary tract disorder	1	0
<i>Renal disorders NEC</i>		
Renal disorder	2	0
<i>Renal failure and impairment</i>		
Acute kidney injury	1	0
Chronic kidney disease	1	0
Renal failure	1	0
<i>Renal obstructive disorders</i>		
Hydronephrosis	1	0
<i>Urinary abnormalities</i>		
Chromaturia	2	0
Haematuria	1	0
<i>Urinary tract signs and symptoms NEC</i>		
Renal pain	8	0
Renal & urinary disorders SOC TOTAL	29	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Breast disorders NEC</i>		
Breast mass	2	0
<i>Breast signs and symptoms</i>		
Breast discomfort	1	0
Breast pain	16	0
Breast swelling	3	0
Breast tenderness	4	0
<i>Erection and ejaculation conditions and disorders</i>		
Erectile dysfunction	4	0
<i>Lactation disorders</i>		
Galactorrhoea	1	0
<i>Menopausal effects NEC</i>		
Menopausal symptoms	2	0
<i>Menopausal effects on the genitourinary tract</i>		
Postmenopausal haemorrhage	7	0
<i>Menstruation and uterine bleeding NEC</i>		
Abnormal uterine bleeding	1	0
Dysmenorrhoea	29	0
Intermenstrual bleeding	16	0
Menstrual disorder	41	0
Menstruation irregular	53	0
Ovulation pain	1	0
Premenstrual dysphoric disorder	1	0
Premenstrual pain	2	0
Premenstrual syndrome	2	0
Withdrawal bleed	1	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	13	0
Hypomenorrhoea	14	0
Menstruation delayed	48	0
Oligomenorrhoea	5	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	92	0
Polymenorrhoea	14	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>		
Polycystic ovaries	1	0
<i>Reproductive tract disorders NEC (excl neoplasms)</i>		
Genital haemorrhage	2	0
Genital ulceration	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Pelvic pain	5	0
<i>Scrotal disorders NEC</i>		
Scrotal pain	1	0
<i>Sexual function and fertility disorders NEC</i>		
Dyspareunia	1	0
Infertility female	2	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular pain	1	0
Testis discomfort	1	0
<i>Uterine disorders NEC</i>		
Adenomyosis	1	0
Endometriosis	4	0

Case Series Drug Analysis Print

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Report Run Date: 23-Apr-2024

Data Lock Date: 22-Apr-2024 18:30:03

Earliest Reaction Date: 01-Feb-2020

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	28	0
<i>Vulvovaginal signs and symptoms</i>		
Coital bleeding	1	0
Vaginal discharge	1	0
Vulval oedema	1	0
Vulvovaginal discomfort	1	0
Vulvovaginal dryness	1	0
Reproductive & breast disorders SOC TOTAL	426	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	105	0
Dyspnoea at rest	1	0
Dyspnoea exertional	2	0
Hyperventilation	2	0
Hypopnoea	4	0
Respiration abnormal	1	0
Respiratory arrest	1	0
Sleep apnoea syndrome	2	0
Tachypnoea	1	0
<i>Bronchial conditions NEC</i>		
Bronchiectasis	2	0
<i>Bronchospasm and obstruction</i>		
Asthma	6	0
Bronchospasm	1	0
Cough variant asthma	1	0
Wheezing	11	0
<i>Coughing and associated symptoms</i>		
Cough	37	0
Haemoptysis	1	0
Productive cough	2	0
<i>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</i>		
Vocal cord disorder	1	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	1	0
Pleuritic pain	1	0
Pulmonary pain	5	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	9	0
Rhinitis allergic	1	0
<i>Nasal disorders NEC</i>		
Epistaxis	20	0
Nasal oedema	1	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Sinonasal obstruction	1	0
<i>Parenchymal lung disorders NEC</i>		
Lung consolidation	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal hypoaesthesia	2	0
Pharyngeal paraesthesia	2	0
Pharyngeal swelling	5	0
Tonsillar hypertrophy	1	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	3	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	12	1
<i>Respiratory failures (excl neonatal)</i>		
Respiratory failure	1	0
<i>Respiratory tract disorders NEC</i>		
Respiratory disorder	1	0
Respiratory tract congestion	1	0

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Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Respiratory tract irritation	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	4	0
Dry throat	2	0
Dysphonia	8	0
Increased upper airway secretion	1	0
Nasal discomfort	1	0
Oropharyngeal pain	51	0
Paranasal sinus discomfort	1	0
Rhinalgia	2	0
Rhinorrhoea	18	0
Sinus pain	3	0
Sneezing	4	0
Throat irritation	3	0
Throat tightness	2	0
Yawning	1	0
Respiratory disorders SOC TOTAL	351	1

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	1	0
<i>Alopecias</i>		
Alopecia	11	0
Alopecia areata	1	0
Lichen planopilaris	1	0
<i>Angioedemas</i>		
Angioedema	6	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	12	0
Hyperhidrosis	44	0
Miliaria	1	0
Night sweats	13	0
<i>Bullous conditions</i>		
Blister	12	0
Erythema multiforme	2	0
Herpes gestationis	1	0
Pemphigoid	2	0
Stevens-Johnson syndrome	1	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	9	0
Pain of skin	9	0
Sensitive skin	2	0
Skin burning sensation	7	0
Skin discolouration	6	0
Skin fragility	1	0
Skin lesion	1	0
Skin odour abnormal	1	0
Skin reaction	3	0
Skin swelling	3	0
Skin tightness	1	0
Skin warm	6	0
Skin weeping	1	0
<i>Dermatitis and eczema</i>		
Dermatitis	6	0
Dermatitis allergic	4	0
Dermatitis atopic	1	0
Dyshidrotic eczema	1	0
Eczema	10	0
Skin irritation	1	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	1	0
<i>Erythemas</i>		
Erythema	49	0
<i>Exfoliative conditions</i>		
Skin exfoliation	3	0
<i>Granulomatous and deep cutaneous inflammatory conditions</i>		
Granuloma annulare	1	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
Nail disorder	2	0
<i>Panniculitides</i>		
Erythema nodosum	1	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
<i>Papulosquamous conditions</i>		
Lichen planus	2	0
Pityriasis rosea	2	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	3	0
<i>Pigmentation changes NEC</i>		
Pigmentation disorder	1	0
<i>Pilar disorders NEC</i>		
Piloerection	2	0
<i>Pruritus NEC</i>		
Pruritus	125	0
<i>Psoriatic conditions</i>		
Guttate psoriasis	1	0
Nail psoriasis	1	0
Psoriasis	10	0
<i>Purpura and related conditions</i>		
Petechiae	7	0
Purpura	1	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	133	0
Rash erythematous	28	0
Rash macular	14	0
Rash morbilliform	3	0
Rash papular	6	0
Rash pruritic	25	0
Rash vesicular	2	0
<i>Rosaceas</i>		
Rosacea	2	0
<i>Skin and subcutaneous conditions NEC</i>		
Skin mass	1	0
<i>Skin and subcutaneous tissue ulcerations</i>		
Skin erosion	1	0
Skin ulcer	1	0
<i>Skin vasculitides</i>		
Capillaritis	1	0
<i>Urticarias</i>		
Chronic spontaneous urticaria	1	0
Mechanical urticaria	1	0
Urticaria	32	0
Urticarial vasculitis	2	0
Skin disorders SOC TOTAL	646	0

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Reaction Name	Total	Fatal
Social circumstances		
<i>Age related issues</i>		
Menopause	2	0
Postmenopause	1	0
<i>Disability issues</i>		
Hearing disability	1	0
Impaired work ability	2	0
Loss of personal independence in daily activities	3	0
Social circumstances SOC TOTAL	9	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Anaesthesia and allied procedures</i>		
Nerve block	1	0
<i>Contraceptive methods female</i>		
Oral contraception	1	0
<i>Dietary and nutritional therapies</i>		
Medical diet	2	0
<i>Hormonal therapeutic procedures NEC</i>		
Hormone replacement therapy	1	0
<i>Immunisations</i>		
COVID-19 immunisation	3	0
Immunisation	1	0
<i>Therapeutic procedures NEC</i>		
Hospitalisation	1	0
Interchange of vaccine products	1	0
Surgical & medical procedures SOC TOTAL	11	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Accelerated and malignant hypertension</i>		
Hypertensive crisis	2	0
<i>Arterial infections and inflammations</i>		
Giant cell arteritis	1	0
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	1	0
<i>Circulatory collapse and shock</i>		
Shock	1	0
<i>Haemorrhages NEC</i>		
Haematoma	2	0
Haemorrhage	29	0
Internal haemorrhage	1	0
<i>Lymphoedemas</i>		
Lymphoedema	8	0
<i>Non-site specific embolism and thrombosis</i>		
Embolism	4	0
Embolism venous	1	0
Thrombosis	10	0
<i>Non-site specific vascular disorders NEC</i>		
Vein rupture	1	0
<i>Peripheral embolism and thrombosis</i>		
Blue toe syndrome	1	0
Deep vein thrombosis	9	0
Peripheral embolism	1	0
Superficial vein thrombosis	1	0
Thrombophlebitis	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	1	0
Flushing	15	0
Hot flush	20	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	6	0
Peripheral ischaemia	1	0
Poor peripheral circulation	2	0
<i>Phlebitis NEC</i>		
Phlebitis	2	0
<i>Site specific vascular disorders NEC</i>		
Pallor	5	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	20	0
<i>Vascular hypotensive disorders</i>		
Hypotension	11	0
Orthostatic hypotension	2	0
<i>Vasculitides NEC</i>		
Vasculitis	5	0
Vascular disorders SOC TOTAL	164	0
TOTAL REACTIONS FOR DRUG	8878	6
TOTAL REPORTS	2851	
TOTAL FATAL OUTCOME REPORTS		6