

Case Series Drug Analysis Print
COVID-19 brand unspecified Vaccine Analysis Print

Report Run Date: 14-Oct-2021
Data Lock Date: 13-Oct-2021 18:30:20

All UK spontaneous reports received up to and including 13/10/21 for COVID-19 vaccines where the brand has not been specified

A report of a suspected ADR to the Yellow Card scheme does not necessarily mean that it was caused by the vaccine, only that the reporter has a suspicion it may have. Underlying or previously undiagnosed illness unrelated to vaccination can also be factors in such reports. The relative number and nature of reports should therefore not be used to compare the safety of the different vaccines. All reports are kept under continual review in order to identify possible new risks.

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemia deficiencies</i>		
Iron deficiency anaemia	1	0
<i>Anaemias NEC</i>		
Anaemia	3	0
<i>Anaemias haemolytic NEC</i>		
Haemolytic anaemia	1	0
<i>Anaemias haemolytic immune</i>		
Autoimmune haemolytic anaemia	1	0
<i>Eosinophilic disorders</i>		
Eosinophilia	1	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	3	0
Lymphadenitis	1	0
Lymphadenopathy	21	0
<i>Marrow depression and hypoplastic anaemias</i>		
Aplastic anaemia	1	0
Myelosuppression	1	0
<i>Neutropenias</i>		
Neutropenia	1	0
<i>Platelet disorders NEC</i>		
Platelet disorder	1	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	3	3
Thrombocytopenia	8	0
Blood disorders SOC TOTAL	47	3

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac conduction disorders</i>		
Bundle branch block	1	0
<i>Cardiac disorders NEC</i>		
Cardiac disorder	1	0
<i>Cardiac signs and symptoms NEC</i>		
Cardiac discomfort	2	0
Palpitations	15	0
<i>Ischaemic coronary artery disorders</i>		
Acute myocardial infarction	1	0
Angina pectoris	2	0
Myocardial infarction	9	3
<i>Myocardial disorders NEC</i>		
Left ventricular dysfunction	1	0
<i>Noninfectious myocarditis</i>		
Immune-mediated myocarditis	1	0
Myocarditis	1	0
<i>Noninfectious pericarditis</i>		
Pericarditis	1	0
<i>Rate and rhythm disorders NEC</i>		
Bradycardia	1	0
Cardiac flutter	1	0
Postural orthostatic tachycardia syndrome	1	0
Tachycardia	2	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	4	0
Supraventricular tachycardia	1	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	1	1
Cardiac disorders SOC TOTAL	46	4

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Cardiac disorders congenital NEC</i>		
Heart disease congenital	1	0
Congenital disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear discomfort	2	0
Ear disorder	1	0
Ear pain	5	0
Ear swelling	1	0
<i>Eustachian tube disorders</i>		
Eustachian tube disorder	1	0
Eustachian tube dysfunction	1	0
<i>External ear disorders NEC</i>		
Excessive cerumen production	2	0
<i>Hearing losses</i>		
Deafness	2	0
Deafness unilateral	1	0
Hypoacusis	4	0
<i>Hyperacusia</i>		
Hyperacusis	1	0
<i>Inner ear disorders NEC</i>		
Vestibular disorder	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	16	0
Vertigo	10	0
Ear disorders SOC TOTAL	48	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Female gonadal function disorders</i>		
Ovulation delayed	1	0
<i>Thyroid disorders NEC</i>		
Thyroid disorder	1	0
Endocrine disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Vitreous floaters	5	0
<i>Corneal infections, oedemas and inflammations</i>		
Keratitis	1	0
<i>Lacrimation disorders</i>		
Dry eye	2	0
Lacrimation increased	2	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Chalazion	1	0
Swelling of eyelid	1	0
<i>Ocular disorders NEC</i>		
Eye disorder	1	0
Eye pain	3	0
Eye swelling	7	0
Ocular discomfort	1	0
Periorbital swelling	3	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye allergy	1	0
Eye pruritus	1	0
<i>Ocular sensation disorders</i>		
Photophobia	4	0
<i>Pupil disorders</i>		
Pupil fixed	1	0
Pupils unequal	1	0
<i>Retinal bleeding and vascular disorders (excl retinopathy)</i>		
Retinal haemorrhage	1	0
Retinal vein occlusion	2	0
<i>Retinal structural change, deposit and degeneration</i>		
Macular degeneration	1	0
Retinal toxicity	1	0
<i>Visual disorders NEC</i>		
Diplopia	4	0
Photopsia	1	0
Vision blurred	10	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	4	0
Blindness transient	1	0
Visual impairment	3	0
Eye disorders SOC TOTAL	63	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Anal and rectal pains</i>		
Proctalgia	1	0
<i>Colitis (excl infective)</i>		
Colitis	2	0
Colitis ulcerative	1	0
Crohn's disease	1	0
<i>Dental pain and sensation disorders</i>		
Toothache	3	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	39	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	3	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	2	0
Faeces discoloured	2	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	4	0
<i>Gastritis (excl infective)</i>		
Gastritis	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	10	0
Abdominal pain lower	1	0
Abdominal pain upper	22	0
Gastrointestinal pain	2	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	3	0
Gastrooesophageal reflux disease	2	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	14	0
Dysphagia	1	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Irritable bowel syndrome	2	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Ileus	1	0
<i>Gastrointestinal vascular occlusion and infarction</i>		
Mesenteric vein thrombosis	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival pain	2	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Haemorrhoids	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	106	0
Retching	2	0
Vomiting	41	0
Vomiting projectile	2	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Gastrointestinal haemorrhage	1	1
Haematemesis	1	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	2	0
<i>Oral soft tissue disorders NEC</i>		
Oral papule	1	0
<i>Oral soft tissue signs and symptoms</i>		

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Hypoaesthesia oral	1	0
Lip exfoliation	1	0
Lip pain	1	0
Oral pain	1	0
Paraesthesia oral	1	0
Oral soft tissue swelling and oedema		
Lip swelling	6	0
Stomatitis and ulceration		
Mouth ulceration	3	0
Tongue disorders		
Glossitis	1	0
Tongue signs and symptoms		
Glossodynia	1	0
Swollen tongue	2	0
Tongue discolouration	1	0
Gastrointestinal disorders SOC TOTAL	296	1

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site erythema	1	0
<i>Application and instillation site reactions</i>		
Application site swelling	1	0
<i>Asthenic conditions</i>		
Asthenia	33	0
Chronic fatigue syndrome	1	0
Fatigue	160	0
Malaise	69	0
<i>Body temperature altered</i>		
Hyperthermia	1	0
<i>Death and sudden death</i>		
Death	10	10
Sudden death	1	1
<i>Febrile disorders</i>		
Pyrexia	129	0
<i>Feelings and sensations NEC</i>		
Chills	88	0
Feeling abnormal	18	0
Feeling cold	19	0
Feeling hot	11	0
Feeling of body temperature change	6	0
Sensation of foreign body	1	0
Thirst	4	0
<i>Gait disturbances</i>		
Gait disturbance	5	0
Gait inability	2	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	6	0
Crying	1	0
General physical health deterioration	3	0
Illness	23	0
Influenza like illness	28	0
Peripheral swelling	26	0
Secretion discharge	1	0
Swelling	17	0
Swelling face	10	0
Unevaluable event	1	0
<i>Inflammations</i>		
Inflammation	4	0
Systemic inflammatory response syndrome	1	0
<i>Injection site reactions</i>		
Injection site discomfort	1	0
Injection site erythema	3	0
Injection site inflammation	2	0
Injection site mass	5	0
Injection site pain	7	0
Injection site pruritus	1	0
Injection site swelling	1	0
<i>Mass conditions NEC</i>		
Cyst	1	0
Nodule	1	0
<i>Oedema NEC</i>		

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General disorders General disorders cont'd		
Oedema peripheral	1	0
<i>Pain and discomfort NEC</i>		
Axillary pain	3	0
Chest discomfort	7	0
Chest pain	18	0
Discomfort	6	0
Facial discomfort	1	0
Facial pain	3	0
Pain	68	0
<i>Therapeutic and nontherapeutic responses</i>		
Drug ineffective	2	0
Drug intolerance	1	0
No reaction on previous exposure to drug	1	0
Therapeutic product ineffective	1	0
Therapeutic response decreased	1	0
Therapeutic response unexpected	1	0
<i>Vaccination site reactions</i>		
Vaccination site bruising	1	0
Vaccination site erythema	13	0
Vaccination site hypoaesthesia	1	0
Vaccination site induration	1	0
Vaccination site inflammation	2	0
Vaccination site mass	4	0
Vaccination site movement impairment	1	0
Vaccination site pain	11	0
Vaccination site papule	1	0
Vaccination site pruritus	2	0
Vaccination site rash	2	0
Vaccination site reaction	1	0
Vaccination site scab	1	0
Vaccination site swelling	8	0
Vaccination site warmth	4	0
General disorders SOC TOTAL	870	11

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Cholestasis and jaundice</i>		
Jaundice	1	0
<i>Hepatic vascular disorders</i>		
Portal vein thrombosis	3	0
Hepatic disorders SOC TOTAL	4	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>		
Hypersensitivity	4	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to vaccine	3	0
Drug hypersensitivity	3	0
Food allergy	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	1	0
<i>Atopic disorders</i>		
Seasonal allergy	1	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	1	0
<i>Immunodeficiency disorders NEC</i>		
Immunodeficiency	1	0
<i>Transplant rejections</i>		
Corneal graft rejection	1	0
Immune system disorders SOC TOTAL	17	0

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Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Appendicitis	1	0
<i>Bacterial infections NEC</i>		
Arthritis bacterial	1	0
<i>Breast infections</i>		
Mastitis	1	0
<i>Caliciviral infections</i>		
Norovirus infection	1	0
<i>Central nervous system and spinal infections</i>		
Encephalitis	1	0
Meningitis aseptic	1	0
<i>Coronavirus infections</i>		
COVID-19	18	0
Suspected COVID-19	1	0
<i>Eye and eyelid infections</i>		
Eye infection	1	0
Hordeolum	1	0
<i>Fungal infections NEC</i>		
Fungal infection	1	0
<i>Herpes viral infections</i>		
Genital herpes	2	0
Herpes zoster	11	0
Oral herpes	3	0
<i>Infections NEC</i>		
Infection	5	0
Localised infection	1	0
<i>Infectious transmissions</i>		
Vaccine virus shedding	1	0
<i>Influenza viral infections</i>		
Influenza	14	0
<i>Lower respiratory tract and lung infections</i>		
Lower respiratory tract infection	3	1
Pneumonia	6	3
<i>Mumps viral infections</i>		
Mumps	1	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Sepsis	2	0
<i>Skin structures and soft tissue infections</i>		
Rash pustular	1	0
<i>Staphylococcal infections</i>		
Furuncle	1	0
<i>Trypanosomal infections</i>		
African trypanosomiasis	1	0
<i>Upper respiratory tract infections</i>		
Nasopharyngitis	8	0
Sinusitis	1	0
Tonsillitis	2	0
<i>Urinary tract infections</i>		
Kidney infection	2	0
Urinary tract infection	3	0
<i>Viral infections NEC</i>		
Gastroenteritis viral	1	0
Sweating fever	1	0

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Viral infection	2	0
Infections SOC TOTAL	100	4

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Reaction Name	Total	Fatal
Injuries		
<i>Bone and joint injuries NEC</i>		
Joint injury	1	0
<i>Cerebral injuries NEC</i>		
Subdural haematoma	1	1
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Maternal exposure during breast feeding	1	0
Maternal exposure during pregnancy	2	0
<i>Exposures to agents or circumstances NEC</i>		
Exposure to vaccinated person	2	0
<i>Eye injuries NEC</i>		
Eye contusion	1	0
Eye injury	3	0
<i>Intentional product misuses</i>		
Intentional product misuse	1	0
<i>Intentional product use issues</i>		
Intentional dose omission	2	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	1	0
Prescription drug used without a prescription	1	0
Vaccination error	1	0
Wrong technique in product usage process	2	0
<i>Muscle, tendon and ligament injuries</i>		
Muscle strain	1	0
Tendon rupture	1	0
<i>Non-site specific injuries NEC</i>		
Fall	9	0
<i>Non-site specific procedural complications</i>		
Incision site pain	1	0
Injection related reaction	2	0
<i>Overdoses NEC</i>		
Overdose	1	0
<i>Product administration errors and issues</i>		
Incorrect route of product administration	1	0
Product administered at inappropriate site	1	0
Product dose omission in error	1	0
Product dose omission issue	2	0
Wrong product administered	1	0
<i>Product dispensing errors and issues</i>		
Product dispensing error	1	0
<i>Site specific injuries NEC</i>		
Limb injury	1	0
Spinal column injury	1	0
<i>Skin injuries NEC</i>		
Contusion	13	0
<i>Underdoses NEC</i>		
Prescribed underdose	1	0
<i>Vaccination related complications</i>		
Vaccination complication	9	0
Injuries SOC TOTAL	66	1

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Investigations		
<i>Blood gas and acid base analyses</i>		
Oxygen saturation decreased	1	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose increased	1	0
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	2	0
<i>Cerebrospinal fluid tests (excl microbiology)</i>		
CSF glucose decreased	1	0
CSF protein increased	1	0
<i>Cholesterol analyses</i>		
Blood cholesterol increased	1	0
<i>Coagulation and bleeding analyses</i>		
Fibrin D dimer increased	2	0
International normalised ratio increased	2	0
<i>Heart rate and pulse investigations</i>		
Heart rate	6	0
Heart rate decreased	1	0
Heart rate increased	5	0
Heart rate irregular	1	0
<i>Immunology skin tests NEC</i>		
Skin test positive	1	0
<i>Investigations NEC</i>		
Blood test	1	0
Quality of life decreased	1	0
<i>Liver function analyses</i>		
Liver function test	1	0
<i>Mineral and electrolyte analyses</i>		
Blood iron decreased	1	0
Blood potassium decreased	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature	2	0
Body temperature abnormal	1	0
Body temperature decreased	2	0
Body temperature fluctuation	1	0
Body temperature increased	2	0
Weight decreased	5	0
Weight increased	1	0
<i>Platelet analyses</i>		
Platelet count decreased	1	0
<i>Red blood cell analyses</i>		
Haemoglobin E	1	0
Haemoglobin decreased	1	0
<i>Respiratory and pulmonary function diagnostic procedures</i>		
Peak expiratory flow rate decreased	1	0
<i>Skeletal and cardiac muscle analyses</i>		
Blood creatine phosphokinase increased	1	0
<i>Therapeutic drug monitoring analyses</i>		
Anticoagulation drug level below therapeutic	1	0
<i>Triglyceride analyses</i>		
Blood triglycerides	1	0
Blood triglycerides increased	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure decreased	1	0

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Blood pressure increased	8	0
<i>Virus identification and serology</i>		
SARS-CoV-2 test	1	0
SARS-CoV-2 test false negative	1	0
SARS-CoV-2 test negative	2	0
SARS-CoV-2 test positive	2	0
<i>White blood cell analyses</i>		
Neutrophil count decreased	3	0
Investigations SOC TOTAL	70	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	33	0
Hypophagia	2	0
Increased appetite	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	1	0
Diabetes mellitus inadequate control	1	0
<i>Disorders of purine metabolism</i>		
Gout	4	0
<i>Electrolyte imbalance NEC</i>		
Electrolyte imbalance	1	0
<i>Hyperglycaemic conditions NEC</i>		
Hyperglycaemia	2	0
<i>Sodium imbalance</i>		
Hyponatraemia	1	0
<i>Total fluid volume decreased</i>		
Dehydration	3	0
<i>Water soluble vitamin deficiencies</i>		
Folate deficiency	1	0
Metabolic disorders SOC TOTAL	50	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	4	0
Arthropathy	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	4	0
Spinal pain	1	0
<i>Cartilage disorders</i>		
Costochondritis	3	0
<i>Connective tissue disorders NEC</i>		
Polymyalgia rheumatica	3	0
<i>Joint related disorders NEC</i>		
Hypermobility syndrome	1	0
Joint lock	1	0
Periarthritis	2	0
<i>Joint related signs and symptoms</i>		
Arthralgia	75	0
Joint stiffness	2	0
Joint swelling	10	0
<i>Lupus erythematosus (incl subtypes)</i>		
Systemic lupus erythematosus	1	0
<i>Muscle pains</i>		
Fibromyalgia	2	0
Myalgia	64	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle fatigue	3	0
Muscle spasms	12	0
Muscle tightness	2	0
Muscle twitching	1	0
<i>Muscle tone abnormalities</i>		
Muscle rigidity	4	0
<i>Muscle weakness conditions</i>		
Muscular weakness	11	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Back disorder	1	0
Mobility decreased	12	0
Musculoskeletal stiffness	12	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	25	0
Limb discomfort	9	0
Musculoskeletal chest pain	1	0
Musculoskeletal discomfort	1	0
Musculoskeletal pain	1	0
Neck pain	14	0
Pain in extremity	100	0
<i>Psoriatic arthropathies</i>		
Psoriatic arthropathy	1	0
<i>Rheumatoid arthropathies</i>		
Rheumatoid arthritis	2	0
<i>Soft tissue disorders NEC</i>		
Groin pain	1	0
<i>Spondyloarthropathies</i>		
Arthritis reactive	1	0
<i>Tendon disorders</i>		

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Muscle & tissue disorders cont'd		
Tendonitis	1	0
Muscle & tissue disorders SOC TOTAL	389	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	1	0
Breast cancer female	1	0
<i>Haematologic neoplasms NEC</i>		
Benign lymph node neoplasm	1	0
<i>Leukaemias chronic lymphocytic</i>		
Chronic lymphocytic leukaemia	1	0
<i>Neoplasms malignant site unspecified NEC</i>		
Malignant neoplasm progression	1	0
<i>Respiratory tract and pleural neoplasms malignant cell type unspecified NEC</i>		
Lung neoplasm malignant	1	1
<i>Skin neoplasms benign</i>		
Skin papilloma	1	0
Neoplasms SOC TOTAL	7	1

Case Series Drug Analysis Print

Name: COVID-19 brand unspecified Vaccine Analysis Print

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	5	0
<i>Autonomic nervous system disorders</i>		
Orthostatic intolerance	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Basilar artery thrombosis	1	1
Carotid artery occlusion	1	0
Cerebrovascular accident	7	0
Haemorrhage intracranial	1	0
<i>Cerebrovascular venous and sinus thrombosis</i>		
Cerebral venous sinus thrombosis	1	1
<i>Coordination and balance disturbances</i>		
Balance disorder	9	0
Coordination abnormal	2	0
Dysstasia	2	0
<i>Cortical dysfunction NEC</i>		
Aphasia	2	0
<i>Disturbances in consciousness NEC</i>		
Lethargy	22	0
Loss of consciousness	6	0
Somnolence	14	0
Syncope	11	0
<i>Dyskinesias and movement disorders NEC</i>		
Bradykinesia	1	0
Hypokinesia	1	0
<i>Encephalopathies NEC</i>		
Autoimmune encephalopathy	1	0
<i>Eye movement disorders</i>		
Vlth nerve paralysis	1	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	2	0
Facial paralysis	5	0
Facial paresis	1	0
<i>Headaches NEC</i>		
Cluster headache	1	0
Headache	235	0
Sinus headache	2	0
Tension headache	4	0
<i>Increased intracranial pressure disorders</i>		
Brain oedema	1	0
<i>Memory loss (excl dementia)</i>		
Amnesia	6	0
Memory impairment	1	0
<i>Meningitis NEC</i>		
Meningitis noninfective	1	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	1	0
Disturbance in attention	3	0
Mental impairment	1	0
<i>Migraine headaches</i>		
Migraine	29	0
Retinal migraine	1	0
<i>Mononeuropathies</i>		

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Carpal tunnel syndrome	1	0
Multiple sclerosis acute and progressive		
Multiple sclerosis	2	0
Narcolepsy and hypersomnia		
Hypersomnia	1	0
Nervous system disorders NEC		
Nervous system disorder	1	0
Neurological signs and symptoms NEC		
Dizziness	86	0
Dizziness postural	7	0
Meningism	1	0
Myoclonus	1	0
Neurological symptom	1	0
Presyncope	2	0
Unresponsive to stimuli	2	0
Olfactory nerve disorders		
Anosmia	1	0
Parosmia	2	0
Paraesthesias and dysaesthesias		
Burning sensation	7	0
Hypoaesthesia	23	0
Paraesthesia	33	0
Paralysis and paresis (excl cranial nerve)		
Hemiparesis	2	0
Hemiplegia	1	0
Monoplegia	1	0
Paralysis	2	0
Parkinson's disease and parkinsonism		
Freezing phenomenon	1	0
Parkinson's disease	1	0
Peripheral neuropathies NEC		
Neuropathy peripheral	1	0
Seizures and seizure disorders NEC		
Convulsions local	1	0
Epilepsy	3	0
Seizure	7	0
Seizure like phenomena	1	0
Sensory abnormalities NEC		
Ageusia	4	0
Dysgeusia	6	0
Neuralgia	6	0
Restless legs syndrome	2	0
Sensory disturbance	3	0
Sensory loss	1	0
Taste disorder	1	0
Speech and language abnormalities		
Dysarthria	4	0
Transient cerebrovascular events		
Transient ischaemic attack	3	0
Tremor (excl congenital)		
Tremor	39	0
Trigeminal disorders		
Trigeminal neuralgia	1	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Nervous system disorders SOC TOTAL	645	2

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	2	0
<i>Normal pregnancy, labour and delivery</i>		
Pregnancy	1	0
Pregnancy conditions SOC TOTAL	3	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<i>Product supply and availability issues</i>		
Product availability issue	1	0
null SOC TOTAL	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	1	0
<i>Anxiety symptoms</i>		
Anxiety	7	0
Nervousness	2	0
Stress	2	0
<i>Behaviour and socialisation disturbances</i>		
Personality change	1	0
<i>Confusion and disorientation</i>		
Confusional state	15	0
Disorientation	5	0
<i>Deliria</i>		
Delirium	1	0
<i>Depressive disorders</i>		
Depression	2	0
<i>Dissociative states</i>		
Dissociative amnesia	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	11	0
<i>Dyssomnias</i>		
Poor quality sleep	1	0
<i>Emotional and mood disturbances NEC</i>		
Emotional disorder	1	0
Irritability	1	0
Mood altered	1	0
<i>Fluctuating mood symptoms</i>		
Mood swings	1	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	5	0
<i>Increased physical activity levels</i>		
Restlessness	2	0
<i>Mental disorders NEC</i>		
Mental disorder	2	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	4	0
Negative thoughts	1	0
<i>Panic attacks and disorders</i>		
Panic attack	2	0
<i>Parasomnias</i>		
Nightmare	1	0
<i>Perception disturbances NEC</i>		
Autoscopy	1	0
<i>Psychotic disorder NEC</i>		
Acute psychosis	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	3	0
<i>Suicidal and self-injurious behaviour</i>		
Intentional self-injury	1	0
Suicidal ideation	1	0
Suicide attempt	1	0
<i>Thinking disturbances</i>		
Bradyphrenia	2	0
Psychiatric disorders SOC TOTAL	80	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Dysuria	1	0
Urinary incontinence	3	0
Urine flow decreased	1	0
<i>Bladder disorders NEC</i>		
Bladder disorder	1	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
Nephrotic syndrome	2	0
<i>Nephritis NEC</i>		
Nephritis	1	0
<i>Renal failure and impairment</i>		
Acute kidney injury	2	0
Renal impairment	1	0
<i>Renal lithiasis</i>		
Nephrolithiasis	2	0
<i>Renal neoplasms</i>		
Renal cyst	1	0
<i>Renal vascular and ischaemic conditions</i>		
Renal infarct	1	0
Renal vein thrombosis	1	0
<i>Urinary abnormalities</i>		
Haematuria	2	0
Urine odour abnormal	1	0
<i>Urinary tract signs and symptoms NEC</i>		
Nocturia	1	0
Renal pain	3	0
Renal & urinary disorders SOC TOTAL	24	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Breast signs and symptoms</i>		
Breast pain	2	0
Breast swelling	1	0
<i>Fallopian tube and ovary infections and inflammations</i>		
Noninfective oophoritis	1	0
<i>Menopausal effects NEC</i>		
Menopausal symptoms	1	0
Premature menopause	3	0
<i>Menopausal effects on the genitourinary tract</i>		
Postmenopausal haemorrhage	1	0
<i>Menstruation and uterine bleeding NEC</i>		
Dysmenorrhoea	13	0
Intermenstrual bleeding	10	0
Menstrual disorder	15	0
Menstruation irregular	16	0
Premenstrual syndrome	2	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	5	0
Hypomenorrhoea	4	0
Menstruation delayed	23	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	34	0
Polymenorrhoea	5	0
<i>Ovarian and fallopian tube disorders NEC</i>		
Ovulation disorder	1	0
Ovulation pain	1	0
<i>Pelvis and broad ligament disorders NEC</i>		
Adnexa uteri pain	1	0
Pelvic haemorrhage	1	0
<i>Prostatic signs, symptoms and disorders NEC</i>		
Prostatic pain	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Genital swelling	1	0
Pelvic pain	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	8	0
<i>Vulvovaginal signs and symptoms</i>		
Vaginal discharge	1	0
Reproductive & breast disorders SOC TOTAL	152	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	45	1
Hypopnoea	1	0
Respiratory arrest	1	0
Tachypnoea	1	0
<i>Bronchospasm and obstruction</i>		
Asthma	2	0
Chronic obstructive pulmonary disease	1	0
Wheezing	2	0
<i>Coughing and associated symptoms</i>		
Cough	14	0
Haemoptysis	2	0
Productive cough	2	0
<i>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</i>		
Reflux laryngitis	1	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Pneumonitis	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	2	0
<i>Nasal disorders NEC</i>		
Epistaxis	9	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Sinus congestion	1	0
<i>Parenchymal lung disorders NEC</i>		
Interstitial lung disease	1	0
Pulmonary fibrosis	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal swelling	1	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	10	2
Pulmonary thrombosis	1	1
<i>Respiratory tract disorders NEC</i>		
Lung disorder	1	0
Pulmonary mass	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Nasal discomfort	1	0
Oropharyngeal pain	10	0
Paranasal sinus discomfort	1	0
Rhinorrhoea	4	0
Sneezing	2	0
Throat irritation	2	0
Yawning	2	0
Respiratory disorders SOC TOTAL	123	4

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	1	0
<i>Alopecias</i>		
Alopecia	6	0
<i>Angioedemas</i>		
Angioedema	3	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	6	0
Hyperhidrosis	34	0
Night sweats	3	0
<i>Bullous conditions</i>		
Blister	1	0
Erythema multiforme	1	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	2	0
Pain of skin	1	0
Papule	1	0
Scar pain	1	0
Sensitive skin	2	0
Skin burning sensation	2	0
Skin discolouration	2	0
Skin disorder	1	0
Skin fissures	1	0
Skin indentation	1	0
Skin reaction	1	0
Skin swelling	1	0
Skin warm	1	0
Yellow skin	1	0
<i>Dermatitis and eczema</i>		
Dermatitis allergic	4	0
Eczema	2	0
Seborrhoeic dermatitis	1	0
Skin irritation	2	0
<i>Erythemas</i>		
Erythema	21	0
<i>Exfoliative conditions</i>		
Skin exfoliation	2	0
<i>Hyperkeratoses</i>		
Lichenoid keratosis	1	0
<i>Papulosquamous conditions</i>		
Lichen planus	1	0
<i>Photosensitivity and photodermatitis conditions</i>		
Photosensitivity reaction	1	0
<i>Pigmentation changes NEC</i>		
Pigmentation disorder	1	0
<i>Pruritus NEC</i>		
Pruritus	31	0
<i>Purpura and related conditions</i>		
Petechiae	1	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	57	0
Rash erythematous	6	0
Rash macular	3	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Rash morbilliform	1	0
Rash papular	1	0
Rash pruritic	14	0
Rash vesicular	1	0
Scaly conditions		
Pityriasis	1	0
Skin haemorrhages		
Haemorrhage subcutaneous	1	0
Skin haemorrhage	1	0
Urticarias		
Cold urticaria	1	0
Urticaria	13	0
Skin disorders SOC TOTAL	241	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>		
Bedridden	1	0
Social circumstances SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Contraceptive methods female</i>		
Contraception	1	0
<i>Immunisations</i>		
COVID-19 immunisation	1	0
Immunisation	1	0
<i>Joint therapeutic procedures</i>		
Knee operation	1	0
<i>Nail therapeutic procedures</i>		
Nail operation	1	0
<i>Therapeutic procedures NEC</i>		
Bed rest	1	0
Hospitalisation	1	0
Surgical & medical procedures SOC TOTAL	7	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Aneurysms and dissections non-site specific</i>		
Aneurysm	1	0
<i>Aortic embolism and thrombosis</i>		
Aortic embolus	2	0
Aortic thrombosis	1	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	2	0
Shock	3	0
<i>Haemorrhages NEC</i>		
Haematoma	1	0
Haemorrhage	17	0
<i>Non-site specific embolism and thrombosis</i>		
Thrombosis	9	0
<i>Non-site specific vascular disorders NEC</i>		
Vascular pain	2	0
Vascular rupture	1	0
Vein discolouration	1	0
<i>Peripheral embolism and thrombosis</i>		
Deep vein thrombosis	10	0
Jugular vein thrombosis	1	0
Thrombophlebitis	1	0
<i>Peripheral vascular disorders NEC</i>		
Erythromelalgia	1	0
Flushing	2	0
Hot flush	6	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	2	0
Raynaud's phenomenon	1	0
<i>Phlebitis NEC</i>		
Phlebitis	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	3	0
<i>Varicose veins NEC</i>		
Spider vein	1	0
Varicose vein	1	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	11	0
<i>Vascular hypotensive disorders</i>		
Hypotension	2	0
Vascular disorders SOC TOTAL	83	0
TOTAL REACTIONS FOR DRUG	3439	31
TOTAL REPORTS	1148	
TOTAL FATAL OUTCOME REPORTS		31