

COVID-19 vaccine brand unspecified analysis print

All UK spontaneous reports received up to and including 11/08/21 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.

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 12-Aug-2021

Data Lock Date: 11-Aug-2021 18:30:09

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemias NEC</i>		
Anaemia	2	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	2	0
Lymphadenitis	1	0
Lymphadenopathy	22	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	7	0
Blood disorders SOC TOTAL	44	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	11	0
<i>Ischaemic coronary artery disorders</i>		
Acute myocardial infarction	1	0
Angina pectoris	1	0
Myocardial infarction	6	2
<i>Myocardial disorders NEC</i>		
Left ventricular dysfunction	1	0
<i>Noninfectious myocarditis</i>		
Myocarditis	1	0
<i>Noninfectious pericarditis</i>		
Pericarditis	1	0
<i>Rate and rhythm disorders NEC</i>		
Bradycardia	1	0
Cardiac flutter	1	0
Tachycardia	1	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	2	0
Supraventricular tachycardia	1	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	1	1
Cardiac disorders SOC TOTAL	33	3

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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	3	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	15	0
Vertigo	10	0
Ear disorders SOC TOTAL	44	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Vitreous floaters	3	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>		
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	2	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye allergy	1	0
Eye pruritus	1	0
<i>Ocular sensation disorders</i>		
Photophobia	2	0
<i>Pupil disorders</i>		
Pupil fixed	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	3	0
Photopsia	1	0
Vision blurred	8	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	3	0
Blindness transient	1	0
Visual impairment	3	0
Eye disorders SOC TOTAL	52	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	36	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	3	0
<i>Gastritis (excl infective)</i>		
Gastritis	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	8	0
Abdominal pain lower	1	0
Abdominal pain upper	20	0
Gastrointestinal pain	1	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	12	0
Dysphagia	1	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Irritable bowel syndrome	1	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	98	0
Retching	2	0
Vomiting	37	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	5	0
Stomatitis and ulceration		
Mouth ulceration	3	0
Tongue signs and symptoms		
Glossodynia	1	0
Swollen tongue	2	0
Gastrointestinal disorders SOC TOTAL	269	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 burn	1	0
Application site swelling	1	0
<i>Asthenic conditions</i>		
Asthenia	32	0
Fatigue	149	0
Malaise	64	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	119	0
<i>Feelings and sensations NEC</i>		
Chills	83	0
Feeling abnormal	14	0
Feeling cold	18	0
Feeling hot	10	0
Feeling of body temperature change	6	0
Sensation of foreign body	1	0
Thirst	4	0
<i>Gait disturbances</i>		
Gait disturbance	4	0
Gait inability	2	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	5	0
Crying	1	0
General physical health deterioration	3	0
Illness	23	0
Influenza like illness	27	0
Peripheral swelling	25	0
Secretion discharge	1	0
Swelling	18	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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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Oedema peripheral	1	0
<i>Pain and discomfort NEC</i>		
Axillary pain	2	0
Chest discomfort	6	0
Chest pain	16	0
Discomfort	5	0
Facial discomfort	1	0
Facial pain	3	0
Pain	65	0
<i>Therapeutic and nontherapeutic responses</i>		
Adverse drug reaction	5	0
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	12	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	10	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	7	0
Vaccination site warmth	4	0
General disorders SOC TOTAL	823	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	2	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	16	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>Central nervous system and spinal infections</i>		
Encephalitis	1	0
Meningitis aseptic	1	0
<i>Coronavirus infections</i>		
COVID-19	16	0
Suspected COVID-19	1	0
<i>Eye and eyelid infections</i>		
Eye infection	1	0
<i>Fungal infections NEC</i>		
Fungal infection	1	0
<i>Herpes viral infections</i>		
Genital herpes	2	0
Herpes zoster	9	0
Oral herpes	2	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	13	0
<i>Lower respiratory tract and lung infections</i>		
Lower respiratory tract infection	3	1
Pneumonia	5	3
<i>Mumps viral infections</i>		
Mumps	1	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Sepsis	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	1	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
Viral infection	2	0
Infections SOC TOTAL	88	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
<i>Non-site specific injuries NEC</i>		
Fall	8	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>		
Spinal column injury	1	0
<i>Skin injuries NEC</i>		
Contusion	9	0
<i>Underdoses NEC</i>		
Prescribed underdose	1	0
<i>Vaccination related complications</i>		
Vaccination complication	7	0
Injuries SOC TOTAL	57	1

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Reaction Name	Total	Fatal
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>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
<i>Immunology skin tests NEC</i>		
Skin test positive	1	0
<i>Investigations NEC</i>		
Blood test	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	4	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
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure increased	7	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	1	0
SARS-CoV-2 test positive	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
<i>White blood cell analyses</i>		
Neutrophil count decreased	3	0
Investigations SOC TOTAL	61	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	31	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	3	0
<i>Electrolyte imbalance NEC</i>		
Electrolyte imbalance	1	0
<i>Hyperglycaemic conditions NEC</i>		
Hyperglycaemia	1	0
<i>Sodium imbalance</i>		
Hyponatraemia	1	0
<i>Total fluid volume decreased</i>		
Dehydration	1	0
<i>Water soluble vitamin deficiencies</i>		
Folate deficiency	1	0
Metabolic disorders SOC TOTAL	44	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	3	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	2	0
Periarthritis	2	0
<i>Joint related signs and symptoms</i>		
Arthralgia	69	0
Joint stiffness	1	0
Joint swelling	10	0
<i>Lupus erythematosus (incl subtypes)</i>		
Systemic lupus erythematosus	1	0
<i>Muscle pains</i>		
Fibromyalgia	2	0
Myalgia	55	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle fatigue	3	0
Muscle spasms	10	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	10	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Back disorder	1	0
Mobility decreased	13	0
Musculoskeletal stiffness	12	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	22	0
Limb discomfort	9	0
Musculoskeletal discomfort	1	0
Musculoskeletal pain	1	0
Neck pain	14	0
Pain in extremity	90	0
<i>Psoriatic arthropathies</i>		
Psoriatic arthropathy	1	0
<i>Rheumatoid arthropathies</i>		
Rheumatoid arthritis	2	0
<i>Spondyloarthropathies</i>		
Arthritis reactive	1	0
<i>Tendon disorders</i>		
Tendonitis	1	0
Muscle & tissue disorders SOC TOTAL	356	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>Skin neoplasms benign</i>		
Skin papilloma	1	0
Neoplasms SOC TOTAL	6	0

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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	5	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	8	0
Coordination abnormal	2	0
Dysstasia	2	0
<i>Disturbances in consciousness NEC</i>		
Lethargy	20	0
Loss of consciousness	6	0
Somnolence	14	0
Syncope	9	0
<i>Dyskinesias and movement disorders NEC</i>		
Bradykinesia	1	0
Hypokinesia	1	0
<i>Eye movement disorders</i>		
Vlth nerve paralysis	1	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	1	0
Facial paralysis	4	0
Facial paresis	1	0
<i>Headaches NEC</i>		
Cluster headache	1	0
Headache	219	0
Sinus headache	2	0
Tension headache	5	0
<i>Increased intracranial pressure disorders</i>		
Brain oedema	1	0
<i>Memory loss (excl dementia)</i>		
Amnesia	4	0
Memory impairment	1	0
<i>Meningitis NEC</i>		
Meningitis noninfective	1	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Disturbance in attention	3	0
<i>Migraine headaches</i>		
Migraine	28	0
Retinal migraine	1	0
<i>Mononeuropathies</i>		
Carpal tunnel syndrome	1	0
<i>Multiple sclerosis acute and progressive</i>		
Multiple sclerosis	2	0
<i>Myelitis (incl infective)</i>		
Myelitis transverse	1	0
<i>Narcolepsy and hypersomnia</i>		

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Hypersomnia	1	0
<i>Nervous system disorders NEC</i>		
Nervous system disorder	1	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	76	0
Dizziness postural	6	0
Meningism	1	0
Myoclonus	1	0
Neurological symptom	1	0
Presyncope	2	0
Unresponsive to stimuli	2	0
<i>Olfactory nerve disorders</i>		
Anosmia	1	0
Parosmia	2	0
<i>Paraesthesias and dysaesthesias</i>		
Burning sensation	7	0
Hypoaesthesia	20	0
Paraesthesia	28	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Hemiparesis	2	0
Monoplegia	1	0
Paralysis	2	0
<i>Parkinson's disease and parkinsonism</i>		
Freezing phenomenon	1	0
Parkinson's disease	1	0
<i>Peripheral neuropathies NEC</i>		
Neuropathy peripheral	1	0
<i>Seizures and seizure disorders NEC</i>		
Convulsions local	1	0
Epilepsy	2	0
Seizure	5	0
Seizure like phenomena	1	0
<i>Sensory abnormalities NEC</i>		
Ageusia	4	0
Dysgeusia	6	0
Neuralgia	5	0
Restless legs syndrome	2	0
Sensory disturbance	3	0
Sensory loss	1	0
Taste disorder	1	0
<i>Speech and language abnormalities</i>		
Dysarthria	4	0
<i>Transient cerebrovascular events</i>		
Transient ischaemic attack	3	0
<i>Tremor (excl congenital)</i>		
Tremor	37	0
<i>Trigeminal disorders</i>		
Trigeminal neuralgia	1	0
Nervous system disorders SOC TOTAL	588	2

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

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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

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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	14	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	9	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	4	0
<i>Increased physical activity levels</i>		
Restlessness	1	0
<i>Mental disorders NEC</i>		
Mental disorder	1	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	4	0
Negative thoughts	1	0
<i>Panic attacks and disorders</i>		
Panic attack	1	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	73	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	1	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	23	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	12	0
Intermenstrual bleeding	8	0
Menstrual disorder	9	0
Menstruation irregular	11	0
Premenstrual syndrome	2	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	4	0
Hypomenorrhoea	2	0
Menstruation delayed	14	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	26	0
Polymenorrhoea	3	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	4	0
<i>Vulvovaginal signs and symptoms</i>		
Vaginal discharge	1	0
Reproductive & breast disorders SOC TOTAL	112	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	38	1
Hypopnoea	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	12	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	8	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	9	1
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	109	3

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	1	0
<i>Alopecias</i>		
Alopecia	5	0
<i>Angioedemas</i>		
Angioedema	3	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	6	0
Hyperhidrosis	28	0
Night sweats	3	0
<i>Bullous conditions</i>		
Blister	1	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	3	0
Pain of skin	1	0
Papule	1	0
Scar pain	1	0
Sensitive skin	2	0
Skin burning sensation	1	0
Skin discolouration	2	0
Skin disorder	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
Skin irritation	2	0
<i>Erythemas</i>		
Erythema	20	0
<i>Exfoliative conditions</i>		
Skin exfoliation	2	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	1	0
<i>Pigmentation changes NEC</i>		
Pigmentation disorder	1	0
<i>Pruritus NEC</i>		
Pruritus	26	0
<i>Purpura and related conditions</i>		
Petechiae	1	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	49	0
Rash erythematous	5	0
Rash macular	1	0
Rash papular	1	0
Rash pruritic	13	0
Rash vesicular	1	0
<i>Scaly conditions</i>		
Pityriasis	1	0
<i>Skin haemorrhages</i>		
Haemorrhage subcutaneous	1	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
<i>Urticarias</i>		
Cold urticaria	1	0
Urticaria	12	0
Skin disorders SOC TOTAL	208	0

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Reaction Name	Total	Fatal
Social circumstances		
<i>Age related issues</i>		
Menopause	2	0
Postmenopause	1	0
Social circumstances SOC TOTAL	3	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
Surgical & medical procedures SOC TOTAL	6	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	1	0
Shock	2	0
<i>Haemorrhages NEC</i>		
Haematoma	1	0
Haemorrhage	11	0
<i>Non-site specific embolism and thrombosis</i>		
Thrombosis	8	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	9	0
Jugular vein thrombosis	1	0
Thrombophlebitis	1	0
<i>Peripheral vascular disorders NEC</i>		
Erythromelalgia	1	0
Flushing	1	0
Hot flush	6	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	2	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	10	0
<i>Vascular hypotensive disorders</i>		
Hypotension	2	0
Vascular disorders SOC TOTAL	70	0
TOTAL REACTIONS FOR DRUG	3093	28
TOTAL REPORTS	1022	
TOTAL FATAL OUTCOME REPORTS		28