

COVID-19 brand unspecified Vaccine Analysis Print

Report Run Date: 13-Jan-2022
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All UK spontaneous reports received up to and including 12/01/22 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 24.1

Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemia deficiencies</i>		
Iron deficiency anaemia	1	0
<i>Anaemias NEC</i>		
Anaemia	3	0
<i>Coagulopathies</i>		
Disseminated intravascular coagulation	1	0
<i>Eosinophilic disorders</i>		
Eosinophilia	1	0
<i>Haematological disorders</i>		
Blood disorder	1	1
<i>Leukocytoses NEC</i>		
Hyperleukocytosis	1	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	4	0
Lymphadenitis	1	0
Lymphadenopathy	32	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	5	3
Thrombocytopenia	9	0
Blood disorders SOC TOTAL	63	4

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac conduction disorders</i>		
Atrioventricular block	1	0
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	33	0
<i>Heart failures NEC</i>		
Cardiac failure	1	0
<i>Ischaemic coronary artery disorders</i>		
Acute myocardial infarction	1	0
Angina pectoris	6	0
Myocardial infarction	9	3
<i>Myocardial disorders NEC</i>		
Left ventricular dilatation	1	0
Left ventricular dysfunction	1	0
Myocardial injury	1	0
<i>Noninfectious myocarditis</i>		
Immune-mediated myocarditis	1	0
Myocarditis	2	0
<i>Noninfectious pericarditis</i>		
Pericarditis	3	0
<i>Rate and rhythm disorders NEC</i>		
Bradycardia	1	0
Cardiac flutter	3	0
Postural orthostatic tachycardia syndrome	1	0
Tachycardia	8	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	4	0
Atrial tachycardia	1	0
Supraventricular tachycardia	1	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	3	2
Cardiac disorders SOC TOTAL	86	5

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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	9	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	5	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	24	0
Vertigo	14	0
<i>Tympanic membrane disorders (excl infections)</i>		
Tympanic membrane perforation	1	0
Ear disorders SOC TOTAL	68	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Thyroiditis	1	0
<i>Female gonadal function disorders</i>		
Ovulation delayed	1	0
<i>Thyroid hyperfunction disorders</i>		
Thyrotoxic crisis	1	0
Endocrine disorders SOC TOTAL	3	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>Iris and uveal tract infections, irritations and inflammations</i>		
Iridocyclitis	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
Eyelid cyst	1	0
Eyelid margin crusting	1	0
Swelling of eyelid	1	0
<i>Ocular disorders NEC</i>		
Eye disorder	4	0
Eye pain	6	0
Eye swelling	8	0
Ocular discomfort	1	0
Periorbital swelling	3	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye allergy	1	0
Eye pruritus	3	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	5	0
Photopsia	2	0
Vision blurred	12	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	4	0
Blindness transient	1	0
Visual impairment	5	0
Eye disorders SOC TOTAL	81	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	51	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	3	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	2	0
Faeces discoloured	3	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	4	0
Flatulence	1	0
<i>Gastritis (excl infective)</i>		
Gastritis	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	11	0
Abdominal pain lower	3	0
Abdominal pain upper	27	0
Abdominal tenderness	1	0
Gastrointestinal pain	2	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	4	0
Gastroesophageal reflux disease	3	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	15	0
Dysphagia	2	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>Intestinal haemorrhages</i>		
Intestinal haemorrhage	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	137	0
Retching	2	0
Vomiting	57	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>		

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Dry mouth	1	0
Oral soft tissue disorders NEC		
Oral papule	1	0
Oral soft tissue signs and symptoms		
Hypoaesthesia oral	1	0
Lip exfoliation	1	0
Oral pain	1	0
Paraesthesia oral	1	0
Oral soft tissue swelling and oedema		
Lip swelling	8	0
Mouth swelling	1	0
Stomatitis and ulceration		
Aphthous ulcer	1	0
Mouth ulceration	3	0
Tongue disorders		
Glossitis	1	0
Tongue signs and symptoms		
Glossodynia	2	0
Swollen tongue	2	0
Tongue discolouration	1	0
Gastrointestinal disorders SOC TOTAL	374	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	43	0
Chronic fatigue syndrome	1	0
Fatigue	202	0
Malaise	84	0
<i>Body temperature altered</i>		
Hyperthermia	1	0
Hypothermia	1	0
<i>Death and sudden death</i>		
Death	12	12
Sudden death	1	1
<i>Febrile disorders</i>		
Pyrexia	162	0
<i>Feelings and sensations NEC</i>		
Chills	105	0
Feeling abnormal	24	0
Feeling cold	22	0
Feeling hot	13	0
Feeling of body temperature change	10	0
Sensation of foreign body	1	0
Thirst	5	0
<i>Gait disturbances</i>		
Gait disturbance	8	0
Gait inability	2	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	8	0
Crying	1	0
General physical health deterioration	3	0
Illness	29	0
Influenza like illness	36	0
Local reaction	1	0
Peripheral swelling	38	0
Secretion discharge	1	0
Swelling	27	0
Swelling face	13	0
Symptom recurrence	1	0
Unevaluable event	1	0
<i>Inflammations</i>		
Inflammation	6	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	6	0
Injection site pain	11	0
Injection site pruritus	1	0
Injection site reaction	1	0
Injection site swelling	3	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Injection site warmth	1	0
Interactions		
Drug interaction	1	0
Mass conditions NEC		
Cyst	2	0
Mass	1	0
Nodule	1	0
Oedema NEC		
Oedema peripheral	1	0
Pain and discomfort NEC		
Axillary pain	10	0
Chest discomfort	7	0
Chest pain	34	0
Discomfort	6	0
Facial discomfort	1	0
Facial pain	4	0
Pain	89	0
Tenderness	1	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	5	0
Adverse reaction	1	0
Drug ineffective	4	0
Drug intolerance	1	0
No reaction on previous exposure to drug	1	0
Surgical failure	1	0
Therapeutic product effect decreased	1	0
Therapeutic product ineffective	1	0
Therapeutic response decreased	1	0
Therapeutic response unexpected	1	0
Vaccination site reactions		
Vaccination site bruising	2	0
Vaccination site erythema	17	0
Vaccination site hypoaesthesia	1	0
Vaccination site induration	2	0
Vaccination site inflammation	2	0
Vaccination site mass	4	0
Vaccination site movement impairment	1	0
Vaccination site pain	14	0
Vaccination site papule	1	0
Vaccination site pruritus	3	0
Vaccination site rash	2	0
Vaccination site reaction	1	0
Vaccination site scab	1	0
Vaccination site swelling	11	0
Vaccination site warmth	6	0
General disorders SOC TOTAL	1137	13

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Cholecystitis and cholelithiasis</i>		
Cholecystitis acute	1	0
<i>Cholestasis and jaundice</i>		
Jaundice	1	0
<i>Hepatic vascular disorders</i>		
Portal vein thrombosis	3	0
Hepatic disorders SOC TOTAL	5	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	6	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	2	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	19	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
Cellulitis	2	0
<i>Breast infections</i>		
Mastitis	1	0
<i>Caliciviral infections</i>		
Norovirus infection	1	0
<i>Candida infections</i>		
Candida infection	1	0
<i>Central nervous system and spinal infections</i>		
Encephalitis	1	0
Meningitis aseptic	1	0
<i>Clostridia infections</i>		
Clostridium difficile infection	1	0
<i>Coronavirus infections</i>		
COVID-19	27	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>		
Disseminated varicella zoster vaccine virus infection	1	0
Genital herpes	2	0
Herpes zoster	13	0
Herpes zoster oticus	1	0
Oral herpes	4	0
<i>Infections NEC</i>		
Abscess	1	0
Infection	9	0
Localised infection	1	0
<i>Infectious transmissions</i>		
Vaccine virus shedding	1	0
<i>Influenza viral infections</i>		
Influenza	21	0
<i>Lower respiratory tract and lung infections</i>		
Lower respiratory tract infection	3	1
Pneumonia	11	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	2	0
<i>Trypanosomal infections</i>		
African trypanosomiasis	1	0
<i>Upper respiratory tract infections</i>		
Laryngitis	1	0

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Nasopharyngitis	9	0
Sinusitis	1	0
Tonsillitis	2	0
Urinary tract infections		
Kidney infection	2	0
Urinary tract infection	4	0
Viral infections NEC		
Gastroenteritis viral	1	0
Sweating fever	1	0
Viral infection	2	0
Infections SOC TOTAL	139	4

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Reaction Name	Total	Fatal
Injuries		
<i>Abdominal and gastrointestinal injuries NEC</i>		
Gallbladder injury	1	0
<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>		
Exposure via breast milk	1	0
Maternal exposure during breast feeding	1	0
Maternal exposure during pregnancy	6	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	2	0
<i>Intentional product use issues</i>		
Intentional dose omission	2	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	2	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>Nerve injuries NEC</i>		
Nerve injury	1	0
<i>Non-site specific injuries NEC</i>		
Fall	11	0
<i>Non-site specific procedural complications</i>		
Incision site pain	1	0
Injection related reaction	2	0
<i>Off label uses</i>		
Off label use	1	0
<i>Overdoses NEC</i>		
Overdose	1	0
<i>Product administration errors and issues</i>		
Expired product administered	2	0
Inappropriate schedule of product administration	2	0
Incorrect route of product administration	1	0
Product administered at inappropriate site	1	0
Product administration error	1	0
Product dose omission in error	1	0
Product dose omission issue	3	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>		

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Contusion	14	0
Underdoses NEC		
Prescribed underdose	1	0
Vaccination related complications		
Vaccination complication	12	0
Injuries SOC TOTAL	88	1

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Investigations		
<i>Autoimmunity analyses</i>		
Anti-HLA antibody test positive	1	0
<i>Blood gas and acid base analyses</i>		
Oxygen saturation decreased	1	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose increased	2	0
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	2	0
<i>Cardiac function diagnostic procedures</i>		
Myocardial strain imaging	1	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	3	0
<i>ECG investigations</i>		
Electrocardiogram abnormal	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate	7	0
Heart rate decreased	1	0
Heart rate increased	7	0
Heart rate irregular	1	0
<i>Hepatobiliary imaging procedures</i>		
Liver scan	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	4	0
Respiratory rate increased	1	0
Weight decreased	6	0
Weight increased	2	0
<i>Platelet analyses</i>		
Platelet count decreased	1	0
Platelet count increased	1	0
<i>Red blood cell analyses</i>		
Haemoglobin E	1	0
Haemoglobin decreased	1	0
Red cell distribution width increased	1	0

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Investigations		
Investigations cont'd		
<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
Troponin 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
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
Neutrophil count increased	1	0
White blood cell count increased	1	0
Investigations SOC TOTAL	89	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	38	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>General nutritional disorders NEC</i>		
Feeding disorder	1	0
<i>Hyperglycaemic conditions NEC</i>		
Hyperglycaemia	3	0
<i>Phosphorus metabolism disorders</i>		
Hypophosphataemia	1	0
<i>Sodium imbalance</i>		
Hyponatraemia	1	0
<i>Total fluid volume decreased</i>		
Dehydration	4	0
<i>Water soluble vitamin deficiencies</i>		
Folate deficiency	1	0
Metabolic disorders SOC TOTAL	59	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	8	0
Arthropathy	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	5	0
Pain in jaw	1	0
Spinal pain	1	0
<i>Bursal disorders</i>		
Bursitis	1	0
<i>Cartilage disorders</i>		
Costochondritis	3	0
<i>Connective tissue disorders NEC</i>		
Polymyalgia rheumatica	4	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	95	0
Joint stiffness	3	0
Joint swelling	10	0
<i>Lupus erythematosus (incl subtypes)</i>		
Systemic lupus erythematosus	2	0
<i>Muscle pains</i>		
Fibromyalgia	2	0
Myalgia	85	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle disorder	1	0
Muscle fatigue	3	0
Muscle spasms	16	0
Muscle tightness	2	0
Muscle twitching	3	0
<i>Muscle tone abnormalities</i>		
Muscle rigidity	4	0
<i>Muscle weakness conditions</i>		
Muscular weakness	17	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Back disorder	1	0
Mobility decreased	12	0
Musculoskeletal stiffness	15	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	33	0
Limb discomfort	13	0
Musculoskeletal chest pain	2	0
Musculoskeletal discomfort	1	0
Musculoskeletal pain	2	0
Neck pain	15	0
Pain in extremity	117	0
<i>Psoriatic arthropathies</i>		
Psoriatic arthropathy	1	0
<i>Rheumatoid arthropathies</i>		
Rheumatoid arthritis	2	0
<i>Soft tissue disorders NEC</i>		

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Axillary mass	1	0
Groin pain	1	0
Neck mass	2	0
<i>Spondyloarthropathies</i>		
Arthritis reactive	1	0
<i>Tendon disorders</i>		
Tendonitis	1	0
Trigger finger	1	0
Muscle & tissue disorders SOC TOTAL	492	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 acute myeloid</i>		
Acute myeloid leukaemia	1	1
<i>Neoplasms malignant site unspecified NEC</i>		
Malignant neoplasm progression	1	0
Neoplasm malignant	3	0
<i>Respiratory tract and pleural neoplasms malignant cell type unspecified NEC</i>		
Lung neoplasm malignant	1	1
Throat cancer	1	0
<i>Skin neoplasms benign</i>		
Skin papilloma	1	0
Neoplasms SOC TOTAL	11	2

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	6	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	8	0
Haemorrhage intracranial	2	0
Ischaemic stroke	1	0
<i>Cerebrovascular venous and sinus thrombosis</i>		
Cerebral venous sinus thrombosis	1	1
<i>Coma states</i>		
Coma	1	0
<i>Coordination and balance disturbances</i>		
Balance disorder	10	0
Coordination abnormal	2	0
Dysstasia	2	0
<i>Cortical dysfunction NEC</i>		
Aphasia	3	0
<i>Disturbances in consciousness NEC</i>		
Lethargy	30	0
Loss of consciousness	10	0
Somnolence	15	0
Syncope	18	0
<i>Dyskinesias and movement disorders NEC</i>		
Bradykinesia	1	0
Hypokinesia	1	0
Movement disorder	2	0
<i>Encephalopathies NEC</i>		
Autoimmune encephalopathy	1	0
<i>Eye movement disorders</i>		
VIth nerve paralysis	1	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	3	0
Facial paralysis	7	0
Facial paresis	1	0
Facial spasm	1	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	1	0
<i>Headaches NEC</i>		
Cluster headache	1	0
Headache	280	0
Sinus headache	2	0
Tension headache	6	0
<i>Increased intracranial pressure disorders</i>		
Brain oedema	1	0
<i>Memory loss (excl dementia)</i>		
Amnesia	7	0
Memory impairment	3	0
<i>Meningitis NEC</i>		
Meningitis noninfective	1	0
<i>Mental impairment (excl dementia and memory loss)</i>		

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Cognitive disorder	1	0
Disturbance in attention	3	0
Mental impairment	1	0
Migraine headaches		
Migraine	36	0
Retinal migraine	1	0
Mononeuropathies		
Carpal tunnel syndrome	1	0
Peroneal nerve palsy	1	0
Multiple sclerosis acute and progressive		
Multiple sclerosis	2	0
Narcolepsy and hypersomnia		
Hypersomnia	2	0
Nervous system disorders NEC		
Nervous system disorder	2	0
Neurological signs and symptoms NEC		
Dizziness	101	0
Dizziness exertional	1	0
Dizziness postural	7	0
Head discomfort	2	0
Meningism	1	0
Myoclonus	1	0
Neurological symptom	1	0
Presyncope	3	0
Unresponsive to stimuli	3	0
Olfactory nerve disorders		
Anosmia	3	0
Parosmia	4	0
Paraesthesias and dysaesthesias		
Burning sensation	12	0
Hypoaesthesia	35	0
Paraesthesia	46	0
Paralysis and paresis (excl cranial nerve)		
Hemiparesis	2	0
Hemiplegia	1	0
Monoparesis	1	0
Monoplegia	1	0
Paralysis	2	0
Parkinson's disease and parkinsonism		
Freezing phenomenon	2	0
Parkinson's disease	1	0
Peripheral neuropathies NEC		
Neuropathy peripheral	1	0
Seizures and seizure disorders NEC		
Convulsions local	1	0
Epilepsy	4	0
Psychogenic seizure	1	0
Seizure	10	0
Seizure like phenomena	1	0
Sensory abnormalities NEC		
Ageusia	6	0
Dysgeusia	7	0
Neuralgia	8	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Restless legs syndrome	2	0
Sensory disturbance	3	0
Sensory loss	1	0
Taste disorder	2	0
Speech and language abnormalities		
Dysarthria	5	0
Transient cerebrovascular events		
Transient ischaemic attack	4	0
Tremor (excl congenital)		
Tremor	50	0
Trigeminal disorders		
Trigeminal neuralgia	1	0
Nervous system disorders SOC TOTAL	819	2

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	4	0
<i>Maternal complications of pregnancy NEC</i>		
Preterm premature rupture of membranes	1	0
<i>Normal pregnancy, labour and delivery</i>		
Pregnancy	1	0
Pregnancy conditions SOC TOTAL	6	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>		
Agitation	1	0
Anxiety	9	0
Nervousness	2	0
Stress	3	0
<i>Behaviour and socialisation disturbances</i>		
Personality change	1	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Mental fatigue	1	0
<i>Confusion and disorientation</i>		
Confusional state	16	0
Disorientation	5	0
<i>Deliria</i>		
Delirium	1	0
<i>Depressive disorders</i>		
Depression	4	0
<i>Dissociative states</i>		
Dissociative amnesia	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	15	0
<i>Dyssomnias</i>		
Poor quality sleep	2	0
<i>Emotional and mood disturbances NEC</i>		
Anger	1	0
Emotional disorder	1	0
Irritability	1	0
Mood altered	1	0
<i>Fluctuating mood symptoms</i>		
Mood swings	2	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	5	0
<i>Increased physical activity levels</i>		
Restlessness	3	0
<i>Mental disorders NEC</i>		
Mental disorder	2	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	5	0
Negative thoughts	1	0
<i>Mood disorders NEC</i>		
Apathy	1	0
<i>Panic attacks and disorders</i>		
Panic attack	4	0
<i>Parasomnias</i>		
Abnormal dreams	1	0
Nightmare	1	0
Somnambulism	1	0
<i>Perception disturbances NEC</i>		
Autoscopy	1	0
<i>Psychotic disorder NEC</i>		
Acute psychosis	1	0
<i>Sleep disorders NEC</i>		

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Sleep disorder	4	0
<i>Stress disorders</i>		
Post-traumatic stress disorder	1	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	3	0
Psychiatric disorders SOC TOTAL	105	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Dysuria	1	0
Pollakiuria	1	0
Urinary incontinence	3	0
Urinary retention	2	0
Urine flow decreased	1	0
<i>Bladder disorders NEC</i>		
Bladder disorder	1	0
Urinary bladder haemorrhage	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
Oliguria	1	0
Renal failure	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>		
Chromaturia	1	0
Haematuria	3	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	32	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Breast disorders NEC</i>		
Breast mass	1	0
<i>Breast signs and symptoms</i>		
Breast pain	4	0
Breast swelling	1	0
Breast tenderness	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	2	0
<i>Menstruation and uterine bleeding NEC</i>		
Dysmenorrhoea	18	0
Intermenstrual bleeding	11	0
Menstrual disorder	18	0
Menstruation irregular	21	0
Premenstrual syndrome	2	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	6	0
Hypomenorrhoea	4	0
Menstruation delayed	26	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	40	0
Polymenorrhoea	7	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	9	0
Vulvovaginal disorder	1	0
<i>Vulvovaginal signs and symptoms</i>		
Vaginal discharge	1	0
Reproductive & breast disorders SOC TOTAL	185	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	67	1
Dyspnoea exertional	1	0
Hypopnoea	1	0
Respiratory arrest	1	0
Tachypnoea	1	0
<i>Bronchospasm and obstruction</i>		
Asthma	2	0
Chronic obstructive pulmonary disease	2	1
Wheezing	4	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	1	0
<i>Coughing and associated symptoms</i>		
Cough	25	0
Haemoptysis	1	0
Productive cough	6	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>Lower respiratory tract signs and symptoms</i>		
Pulmonary pain	2	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	3	0
<i>Nasal disorders NEC</i>		
Epistaxis	11	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Sinus congestion	1	0
<i>Parenchymal lung disorders NEC</i>		
Pulmonary fibrosis	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal swelling	1	0
<i>Pulmonary oedemas</i>		
Pulmonary congestion	1	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	13	3
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>		
Dysphonia	1	0
Nasal discomfort	1	0
Oropharyngeal pain	16	0
Paranasal sinus discomfort	1	0
Rhinorrhoea	8	0
Sneezing	4	0
Throat irritation	3	0
Yawning	2	0
Respiratory disorders SOC TOTAL	186	6

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	1	0
<i>Alopecias</i>		
Alopecia	7	0
<i>Angioedemas</i>		
Angioedema	4	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	8	0
Hyperhidrosis	45	0
Night sweats	3	0
<i>Bullous conditions</i>		
Blister	3	0
Blister rupture	1	0
Erythema multiforme	1	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	2	0
Pain of skin	1	0
Papule	2	0
Scar pain	1	0
Sensitive skin	3	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	5	0
Dermatitis atopic	1	0
Eczema	4	0
Seborrhoeic dermatitis	1	0
Skin irritation	2	0
<i>Erythemas</i>		
Erythema	33	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 photodermatosis conditions</i>		
Photosensitivity reaction	1	0
<i>Pigmentation changes NEC</i>		
Pigmentation disorder	1	0
<i>Pruritus NEC</i>		
Pruritus	41	0
<i>Psoriatic conditions</i>		
Psoriasis	2	0
<i>Purpura and related conditions</i>		
Petechiae	2	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
<i>Rashes, eruptions and exantheams NEC</i>		
Rash	67	0
Rash erythematous	8	0
Rash macular	3	0
Rash morbilliform	1	0
Rash papular	2	0
Rash pruritic	17	0
Rash vesicular	1	0
<i>Scaly conditions</i>		
Pityriasis	1	0
<i>Skin and subcutaneous conditions NEC</i>		
Skin mass	1	0
<i>Skin haemorrhages</i>		
Haemorrhage subcutaneous	1	0
Skin haemorrhage	1	0
<i>Urticarias</i>		
Cold urticaria	2	0
Urticaria	18	0
Skin disorders SOC TOTAL	313	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	2	0
Social circumstances SOC TOTAL	5	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	2	0
<i>Joint therapeutic procedures</i>		
Knee operation	1	0
<i>Limb therapeutic procedures</i>		
Foot operation	1	0
<i>Nail therapeutic procedures</i>		
Nail operation	1	0
<i>Obstetric therapeutic procedures</i>		
Caesarean section	1	0
<i>Respiratory tract therapeutic procedures NEC</i>		
Asthma prophylaxis	1	0
<i>Therapeutic procedures NEC</i>		
Bed rest	1	0
Hospitalisation	1	0
Interchange of vaccine products	1	0
Surgical & medical procedures SOC TOTAL	12	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	22	0
<i>Non-site specific embolism and thrombosis</i>		
Thrombosis	11	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	12	0
Jugular vein thrombosis	1	0
Thrombophlebitis	1	0
<i>Peripheral vascular disorders NEC</i>		
Erythromelalgia	1	0
Flushing	2	0
Hot flush	7	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	4	0
<i>Varicose veins NEC</i>		
Spider vein	1	0
Varicose vein	1	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	15	0
<i>Vascular hypotensive disorders</i>		
Hypotension	2	0
Vascular disorders SOC TOTAL	98	0
TOTAL REACTIONS FOR DRUG	4477	38
TOTAL REPORTS	1462	
TOTAL FATAL OUTCOME REPORTS		38