

COVID-19 vaccine brand unspecified analysis print

All UK spontaneous reports received up to and including 15/12/21 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: 16-Dec-2021

Data Lock Date: 15-Dec-2021 18:32:39

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	28	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	59	4

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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	29	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	4	0
<i>Rate and rhythm disorders NEC</i>		
Bradycardia	1	0
Cardiac flutter	3	0
Postural orthostatic tachycardia syndrome	1	0
Tachycardia	6	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	4	0
Supraventricular tachycardia	1	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	2	1
Cardiac disorders SOC TOTAL	77	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	3	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	21	0
Vertigo	13	0
Ear disorders SOC TOTAL	57	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Female gonadal function disorders</i>		
Ovulation delayed	1	0
<i>Thyroid hyperfunction disorders</i>		
Thyrotoxic crisis	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>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
Swelling of eyelid	1	0
<i>Ocular disorders NEC</i>		
Eye disorder	3	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	4	0
Eye disorders SOC TOTAL	78	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	49	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	10	0
Abdominal pain lower	2	0
Abdominal pain upper	25	0
Abdominal tenderness	1	0
Gastrointestinal pain	2	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	3	0
Gastrooesophageal 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	130	0
Retching	2	0
Vomiting	53	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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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Dry mouth	1	0
<i>Oral soft tissue disorders NEC</i>		
Oral papule	1	0
<i>Oral soft tissue signs and symptoms</i>		
Hypoaesthesia oral	1	0
Lip exfoliation	1	0
Oral pain	1	0
Paraesthesia oral	1	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	8	0
Mouth swelling	1	0
<i>Stomatitis and ulceration</i>		
Mouth ulceration	3	0
<i>Tongue disorders</i>		
Glossitis	1	0
<i>Tongue signs and symptoms</i>		
Glossodynia	2	0
Swollen tongue	2	0
Tongue discolouration	1	0
Gastrointestinal disorders SOC TOTAL	355	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	37	0
Chronic fatigue syndrome	1	0
Fatigue	195	0
Malaise	80	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	156	0
<i>Feelings and sensations NEC</i>		
Chills	103	0
Feeling abnormal	22	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	6	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	28	0
Influenza like illness	34	0
Local reaction	1	0
Peripheral swelling	37	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	5	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
Nodule	1	0
Oedema NEC		
Oedema peripheral	1	0
Pain and discomfort NEC		
Axillary pain	10	0
Chest discomfort	7	0
Chest pain	29	0
Discomfort	6	0
Facial discomfort	1	0
Facial pain	3	0
Pain	83	0
Tenderness	1	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	5	0
Drug ineffective	3	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		
Shoulder injury related to vaccine administration	1	0
Vaccination site bruising	1	0
Vaccination site erythema	16	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	10	0
Vaccination site warmth	5	0
General disorders SOC TOTAL	1085	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	1	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	22	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	14	0
Oral herpes	4	0
<i>Infections NEC</i>		
Abscess	1	0
Infection	7	0
Localised infection	1	0
<i>Infectious transmissions</i>		
Vaccine virus shedding	1	0
<i>Influenza viral infections</i>		
Influenza	19	0
<i>Lower respiratory tract and lung infections</i>		
Lower respiratory tract infection	3	1
Pneumonia	9	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>		
Laryngitis	1	0
Nasopharyngitis	9	0
Sinusitis	1	0

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Reaction Name	Total	Fatal
Infections Infections cont'd		
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	125	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>		
Maternal exposure during breast feeding	1	0
Maternal exposure during pregnancy	4	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	10	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	1	0
Inappropriate schedule of product administration	2	0
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	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>		
Contusion	14	0
<i>Underdoses NEC</i>		

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Prescribed underdose	1	0
<i>Vaccination related complications</i>		
Vaccination complication	12	0
Injuries SOC TOTAL	82	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	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	5	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	3	0
Respiratory rate increased	1	0
Weight decreased	5	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
<i>Respiratory and pulmonary function diagnostic procedures</i>		
Peak expiratory flow rate decreased	1	0

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Investigations Investigations cont'd		
<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	84	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	36	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	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	56	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	7	0
Arthropathy	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	5	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	90	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	80	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle disorder	1	0
Muscle fatigue	3	0
Muscle spasms	13	0
Muscle tightness	2	0
Muscle twitching	2	0
<i>Muscle tone abnormalities</i>		
Muscle rigidity	4	0
<i>Muscle weakness conditions</i>		
Muscular weakness	14	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Back disorder	1	0
Mobility decreased	12	0
Musculoskeletal stiffness	13	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	28	0
Limb discomfort	11	0
Musculoskeletal chest pain	1	0
Musculoskeletal discomfort	1	0
Musculoskeletal pain	2	0
Neck pain	14	0
Pain in extremity	110	0
<i>Psoriatic arthropathies</i>		
Psoriatic arthropathy	1	0
<i>Rheumatoid arthropathies</i>		
Rheumatoid arthritis	2	0
<i>Soft tissue disorders NEC</i>		
Axillary mass	1	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Groin pain	1	0
<i>Spondyloarthropathies</i>		
Arthritis reactive	1	0
<i>Tendon disorders</i>		
Tendonitis	1	0
Muscle & tissue disorders SOC TOTAL	450	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

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	1	0
<i>Respiratory tract and pleural neoplasms malignant cell type unspecified NEC</i>		
Throat cancer	1	0
<i>Skin neoplasms benign</i>		
Skin papilloma	1	0
Neoplasms SOC TOTAL	8	1

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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	7	0
Haemorrhage intracranial	2	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	9	0
Coordination abnormal	2	0
Dysstasia	2	0
<i>Cortical dysfunction NEC</i>		
Aphasia	2	0
<i>Disturbances in consciousness NEC</i>		
Lethargy	29	0
Loss of consciousness	10	0
Somnolence	15	0
Syncope	17	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	6	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	267	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	6	0
Memory impairment	3	0
<i>Meningitis NEC</i>		
Meningitis noninfective	1	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Disturbance in attention	3	0
Mental impairment	1	0
Migraine headaches		
Migraine	34	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	1	0
Nervous system disorders NEC		
Nervous system disorder	2	0
Neurological signs and symptoms NEC		
Dizziness	96	0
Dizziness postural	7	0
Meningism	1	0
Myoclonus	1	0
Neurological symptom	1	0
Presyncope	3	0
Unresponsive to stimuli	3	0
Olfactory nerve disorders		
Anosmia	2	0
Parosmia	2	0
Paraesthesias and dysaesthesias		
Burning sensation	11	0
Hypoaesthesia	33	0
Paraesthesia	41	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	2	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
Psychogenic seizure	1	0
Seizure	9	0
Seizure like phenomena	1	0
Sensory abnormalities NEC		
Ageusia	6	0
Dysgeusia	7	0
Neuralgia	8	0
Restless legs syndrome	2	0
Sensory disturbance	3	0
Sensory loss	1	0
Taste disorder	1	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
<i>Speech and language abnormalities</i>		
Dysarthria	5	0
<i>Transient cerebrovascular events</i>		
Transient ischaemic attack	3	0
<i>Tremor (excl congenital)</i>		
Tremor	49	0
<i>Trigeminal disorders</i>		
Trigeminal neuralgia	1	0
Nervous system disorders SOC TOTAL	769	2

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	3	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	5	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	9	0
Nervousness	2	0
Stress	3	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	4	0
<i>Dissociative states</i>		
Dissociative amnesia	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	13	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	4	0
Negative thoughts	1	0
<i>Panic attacks and disorders</i>		
Panic attack	3	0
<i>Parasomnias</i>		
Abnormal dreams	1	0
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	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

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Suicide attempt	1	0
<i>Thinking disturbances</i>		
Bradyphrenia	3	0
Psychiatric disorders SOC TOTAL	96	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
Urinary retention	1	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	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	29	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	16	0
Intermenstrual bleeding	11	0
Menstrual disorder	16	0
Menstruation irregular	17	0
Premenstrual syndrome	2	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	5	0
Hypomenorrhoea	4	0
Menstruation delayed	22	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	36	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	9	0
Vulvovaginal disorder	1	0
<i>Vulvovaginal signs and symptoms</i>		
Vaginal discharge	1	0
Reproductive & breast disorders SOC TOTAL	166	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	63	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	3	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	1	0
<i>Coughing and associated symptoms</i>		
Cough	22	0
Haemoptysis	1	0
Productive cough	5	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	1	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	14	0
Paranasal sinus discomfort	1	0
Rhinorrhoea	6	0
Sneezing	4	0
Throat irritation	2	0
Yawning	2	0
Respiratory disorders SOC TOTAL	171	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
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	3	0
Seborrhoeic dermatitis	1	0
Skin irritation	2	0
<i>Erythemas</i>		
Erythema	30	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	37	0
<i>Psoriatic conditions</i>		
Psoriasis	1	0
<i>Purpura and related conditions</i>		
Petechiae	2	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	64	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Rash erythematous	8	0
Rash macular	3	0
Rash morbilliform	1	0
Rash papular	2	0
Rash pruritic	16	0
Rash vesicular	1	0
Scaly conditions		
Pityriasis	1	0
Skin haemorrhages		
Haemorrhage subcutaneous	1	0
Skin haemorrhage	1	0
Urticarias		
Cold urticaria	2	0
Urticaria	16	0
Skin disorders SOC TOTAL	292	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>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>Therapeutic procedures NEC</i>		
Bed rest	1	0
Hospitalisation	1	0
Interchange of vaccine products	1	0
Surgical & medical procedures SOC TOTAL	10	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	21	0
<i>Non-site specific embolism and thrombosis</i>		
Thrombosis	10	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	12	0
<i>Vascular hypotensive disorders</i>		
Hypotension	2	0
Vascular disorders SOC TOTAL	93	0
TOTAL REACTIONS FOR DRUG	4179	36
TOTAL REPORTS	1362	
TOTAL FATAL OUTCOME REPORTS		36