

COVID-19 brand unspecified Vaccine Analysis Print

Report Run Date: 18-Nov-2021
Data Lock Date: 17-Nov-2021 18:30:04

All UK spontaneous reports received up to and including 17/11/21 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 brand unspecified Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

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>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>Haematological disorders</i>		
Blood disorder	1	1
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	4	0
Lymphadenitis	1	0
Lymphadenopathy	24	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	4	3
Thrombocytopenia	8	0
Blood disorders SOC TOTAL	53	4

Case Series Drug Analysis Print

Name: COVID-19 brand unspecified Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

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	19	0
<i>Ischaemic coronary artery disorders</i>		
Acute myocardial infarction	1	0
Angina pectoris	3	0
Myocardial infarction	9	3
<i>Myocardial disorders NEC</i>		
Left ventricular dysfunction	1	0
<i>Noninfectious myocarditis</i>		
Immune-mediated myocarditis	1	0
Myocarditis	1	0
<i>Noninfectious pericarditis</i>		
Pericarditis	2	0
<i>Rate and rhythm disorders NEC</i>		
Bradycardia	1	0
Cardiac flutter	1	0
Postural orthostatic tachycardia syndrome	1	0
Tachycardia	4	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	4	0
Supraventricular tachycardia	1	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	1	1
Cardiac disorders SOC TOTAL	54	4

Case Series Drug Analysis Print

Name: COVID-19 brand unspecified Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

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

Case Series Drug Analysis Print

Name: COVID-19 brand unspecified Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

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

Case Series Drug Analysis Print

Name: COVID-19 brand unspecified Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

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

Case Series Drug Analysis Print

Name: COVID-19 brand unspecified Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

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	2	0
Eye pain	5	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	10	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	4	0
Blindness transient	1	0
Visual impairment	3	0
Eye disorders SOC TOTAL	73	0

Case Series Drug Analysis Print

Name: COVID-19 brand unspecified Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

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	43	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
<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	24	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	117	0
Retching	2	0
Vomiting	44	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	1	0

Case Series Drug Analysis Print

Name: COVID-19 brand unspecified Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<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	6	0
<i>Stomatitis and ulceration</i>		
Mouth ulceration	3	0
<i>Tongue disorders</i>		
Glossitis	1	0
<i>Tongue signs and symptoms</i>		
Glossodynia	1	0
Swollen tongue	2	0
Tongue discolouration	1	0
Gastrointestinal disorders SOC TOTAL	321	1

Case Series Drug Analysis Print

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Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

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	35	0
Chronic fatigue syndrome	1	0
Fatigue	178	0
Malaise	75	0
<i>Body temperature altered</i>		
Hyperthermia	1	0
<i>Death and sudden death</i>		
Death	11	11
Sudden death	1	1
<i>Febrile disorders</i>		
Pyrexia	143	0
<i>Feelings and sensations NEC</i>		
Chills	94	0
Feeling abnormal	21	0
Feeling cold	20	0
Feeling hot	13	0
Feeling of body temperature change	8	0
Sensation of foreign body	1	0
Thirst	4	0
<i>Gait disturbances</i>		
Gait disturbance	5	0
Gait inability	2	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	7	0
Crying	1	0
General physical health deterioration	3	0
Illness	26	0
Influenza like illness	31	0
Local reaction	1	0
Peripheral swelling	31	0
Secretion discharge	1	0
Swelling	22	0
Swelling face	11	0
Symptom recurrence	1	0
Unevaluable event	1	0
<i>Inflammations</i>		
Inflammation	5	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	9	0
Injection site pruritus	1	0
Injection site swelling	1	0
<i>Mass conditions NEC</i>		
Cyst	1	0

Case Series Drug Analysis Print

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Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Nodule	1	0
Oedema NEC		
Oedema peripheral	1	0
Pain and discomfort NEC		
Axillary pain	5	0
Chest discomfort	7	0
Chest pain	23	0
Discomfort	6	0
Facial discomfort	1	0
Facial pain	3	0
Pain	72	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	4	0
Drug ineffective	3	0
Drug intolerance	1	0
No reaction on previous exposure to drug	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	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	12	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	9	0
Vaccination site warmth	5	0
General disorders SOC TOTAL	973	12

Case Series Drug Analysis Print

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Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

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

Case Series Drug Analysis Print

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Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Immune system disorders		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	1	0
<i>Allergic conditions NEC</i>		
Hypersensitivity	5	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	18	0

Case Series Drug Analysis Print

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Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

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Infections		
<i>Abdominal and gastrointestinal infections</i>		
Appendicitis	1	0
<i>Bacterial infections NEC</i>		
Arthritis bacterial	1	0
<i>Breast infections</i>		
Mastitis	1	0
<i>Caliciviral infections</i>		
Norovirus infection	1	0
<i>Central nervous system and spinal infections</i>		
Encephalitis	1	0
Meningitis aseptic	1	0
<i>Coronavirus infections</i>		
COVID-19	20	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	12	0
Oral herpes	3	0
<i>Infections NEC</i>		
Infection	6	0
Localised infection	1	0
<i>Infectious transmissions</i>		
Vaccine virus shedding	1	0
<i>Influenza viral infections</i>		
Influenza	17	0
<i>Lower respiratory tract and lung infections</i>		
Lower respiratory tract infection	3	1
Pneumonia	8	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	8	0
Sinusitis	1	0
Tonsillitis	2	0
<i>Urinary tract infections</i>		
Kidney infection	2	0
Urinary tract infection	3	0
<i>Viral infections NEC</i>		
Gastroenteritis viral	1	0

Case Series Drug Analysis Print

Name: COVID-19 brand unspecified Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Infections Infections cont'd		
Sweating fever	1	0
Viral infection	2	0
Infections SOC TOTAL	110	4

Case Series Drug Analysis Print

Name: COVID-19 brand unspecified Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

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	3	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	1	0
Prescription drug used without a prescription	1	0
Vaccination error	1	0
Wrong technique in product usage process	2	0
<i>Muscle, tendon and ligament injuries</i>		
Muscle strain	1	0
Tendon rupture	1	0
<i>Non-site specific injuries NEC</i>		
Fall	9	0
<i>Non-site specific procedural complications</i>		
Incision site pain	1	0
Injection related reaction	2	0
<i>Overdoses NEC</i>		
Overdose	1	0
<i>Product administration errors and issues</i>		
Incorrect route of product administration	1	0
Product administered at inappropriate site	1	0
Product dose omission in error	1	0
Product dose omission issue	2	0
Wrong product administered	1	0
<i>Product dispensing errors and issues</i>		
Product dispensing error	1	0
<i>Site specific injuries NEC</i>		
Limb injury	1	0
Spinal column injury	1	0
<i>Skin injuries NEC</i>		
Contusion	13	0
<i>Thermal burns</i>		
Burns third degree	1	0
<i>Underdoses NEC</i>		
Prescribed underdose	1	0
<i>Vaccination related complications</i>		
Vaccination complication	10	0
Injuries SOC TOTAL	70	1

Case Series Drug Analysis Print

Name: COVID-19 brand unspecified Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

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	2	0
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	2	0
<i>Cerebrospinal fluid tests (excl microbiology)</i>		
CSF glucose decreased	1	0
CSF protein increased	1	0
<i>Cholesterol analyses</i>		
Blood cholesterol increased	1	0
<i>Coagulation and bleeding analyses</i>		
Fibrin D dimer increased	2	0
International normalised ratio increased	3	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>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
Weight decreased	5	0
Weight increased	1	0
<i>Platelet analyses</i>		
Platelet count decreased	1	0
<i>Red blood cell analyses</i>		
Haemoglobin E	1	0
Haemoglobin decreased	1	0
<i>Respiratory and pulmonary function diagnostic procedures</i>		
Peak expiratory flow rate decreased	1	0
<i>Skeletal and cardiac muscle analyses</i>		
Blood creatine phosphokinase increased	1	0
<i>Therapeutic drug monitoring analyses</i>		
Anticoagulation drug level below therapeutic	1	0
<i>Triglyceride analyses</i>		
Blood triglycerides	1	0
Blood triglycerides increased	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure decreased	1	0

Case Series Drug Analysis Print

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Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Blood pressure increased	8	0
<i>Virus identification and serology</i>		
SARS-CoV-2 test	1	0
SARS-CoV-2 test false negative	1	0
SARS-CoV-2 test negative	2	0
SARS-CoV-2 test positive	2	0
<i>White blood cell analyses</i>		
Neutrophil count decreased	3	0
Investigations SOC TOTAL	74	0

Case Series Drug Analysis Print

Name: COVID-19 brand unspecified Vaccine Analysis Print

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Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	34	0
Hypophagia	2	0
Increased appetite	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	1	0
Diabetes mellitus inadequate control	1	0
<i>Disorders of purine metabolism</i>		
Gout	4	0
<i>Electrolyte imbalance NEC</i>		
Electrolyte imbalance	1	0
<i>Hyperglycaemic conditions NEC</i>		
Hyperglycaemia	2	0
<i>Phosphorus metabolism disorders</i>		
Hypophosphataemia	1	0
<i>Sodium imbalance</i>		
Hyponatraemia	1	0
<i>Total fluid volume decreased</i>		
Dehydration	3	0
<i>Water soluble vitamin deficiencies</i>		
Folate deficiency	1	0
Metabolic disorders SOC TOTAL	52	0

Case Series Drug Analysis Print

Name: COVID-19 brand unspecified Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	6	0
Arthropathy	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	4	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	3	0
<i>Joint related disorders NEC</i>		
Hypermobility syndrome	1	0
Joint lock	1	0
Periarthritis	3	0
<i>Joint related signs and symptoms</i>		
Arthralgia	79	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	70	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle disorder	1	0
Muscle fatigue	3	0
Muscle spasms	12	0
Muscle tightness	2	0
Muscle twitching	1	0
<i>Muscle tone abnormalities</i>		
Muscle rigidity	4	0
<i>Muscle weakness conditions</i>		
Muscular weakness	13	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	25	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	106	0
<i>Psoriatic arthropathies</i>		
Psoriatic arthropathy	1	0
<i>Rheumatoid arthropathies</i>		
Rheumatoid arthritis	2	0
<i>Soft tissue disorders NEC</i>		
Groin pain	1	0

Case Series Drug Analysis Print

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Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

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Muscle & tissue disorders		
Muscle & tissue disorders cont'd		
<i>Spondyloarthropathies</i>		
Arthritis reactive	1	0
<i>Tendon disorders</i>		
Tendonitis	1	0
Muscle & tissue disorders SOC TOTAL	416	0

Case Series Drug Analysis Print

Name: COVID-19 brand unspecified Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

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 chronic lymphocytic</i>		
Chronic lymphocytic leukaemia	1	0
<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	0

Case Series Drug Analysis Print

Name: COVID-19 brand unspecified Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	5	0
<i>Autonomic nervous system disorders</i>		
Orthostatic intolerance	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Basilar artery thrombosis	1	1
Carotid artery occlusion	1	0
Cerebrovascular accident	7	0
Haemorrhage intracranial	1	0
<i>Cerebrovascular venous and sinus thrombosis</i>		
Cerebral venous sinus thrombosis	1	1
<i>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	26	0
Loss of consciousness	7	0
Somnolence	14	0
Syncope	15	0
<i>Dyskinesias and movement disorders NEC</i>		
Bradykinesia	1	0
Hypokinesia	1	0
<i>Encephalopathies NEC</i>		
Autoimmune encephalopathy	1	0
<i>Eye movement disorders</i>		
VIth nerve paralysis	1	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	2	0
Facial paralysis	5	0
Facial paresis	1	0
<i>Headaches NEC</i>		
Cluster headache	1	0
Headache	251	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
Disturbance in attention	3	0
Mental impairment	1	0
<i>Migraine headaches</i>		
Migraine	32	0

Case Series Drug Analysis Print

Name: COVID-19 brand unspecified Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Retinal migraine	1	0
Mononeuropathies		
Carpal tunnel syndrome	1	0
Multiple sclerosis acute and progressive		
Multiple sclerosis	2	0
Narcolepsy and hypersomnia		
Hypersomnia	1	0
Nervous system disorders NEC		
Nervous system disorder	2	0
Neurological signs and symptoms NEC		
Dizziness	90	0
Dizziness postural	7	0
Meningism	1	0
Myoclonus	1	0
Neurological symptom	1	0
Presyncope	3	0
Unresponsive to stimuli	2	0
Olfactory nerve disorders		
Anosmia	1	0
Parosmia	2	0
Paraesthesias and dysaesthesias		
Burning sensation	9	0
Hypoaesthesia	26	0
Paraesthesia	34	0
Paralysis and paresis (excl cranial nerve)		
Hemiparesis	2	0
Hemiplegia	1	0
Monoplegia	1	0
Paralysis	2	0
Parkinson's disease and parkinsonism		
Freezing phenomenon	1	0
Parkinson's disease	1	0
Peripheral neuropathies NEC		
Neuropathy peripheral	1	0
Seizures and seizure disorders NEC		
Convulsions local	1	0
Epilepsy	3	0
Seizure	8	0
Seizure like phenomena	1	0
Sensory abnormalities NEC		
Ageusia	4	0
Dysgeusia	7	0
Neuralgia	7	0
Restless legs syndrome	2	0
Sensory disturbance	3	0
Sensory loss	1	0
Taste disorder	1	0
Speech and language abnormalities		
Dysarthria	5	0
Transient cerebrovascular events		
Transient ischaemic attack	3	0
Tremor (excl congenital)		
Tremor	45	0

Case Series Drug Analysis Print

Name: COVID-19 brand unspecified Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
<i>Trigeminal disorders</i>		
Trigeminal neuralgia	1	0
Nervous system disorders SOC TOTAL	699	2

Case Series Drug Analysis Print

Name: COVID-19 brand unspecified Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

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

Case Series Drug Analysis Print

Name: COVID-19 brand unspecified Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

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

Case Series Drug Analysis Print

Name: COVID-19 brand unspecified Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	1	0
<i>Anxiety symptoms</i>		
Anxiety	8	0
Nervousness	2	0
Stress	2	0
<i>Behaviour and socialisation disturbances</i>		
Personality change	1	0
<i>Confusion and disorientation</i>		
Confusional state	15	0
Disorientation	5	0
<i>Deliria</i>		
Delirium	1	0
<i>Depressive disorders</i>		
Depression	2	0
<i>Dissociative states</i>		
Dissociative amnesia	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	12	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	2	0
<i>Mental disorders NEC</i>		
Mental disorder	2	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	4	0
Negative thoughts	1	0
<i>Panic attacks and disorders</i>		
Panic attack	2	0
<i>Parasomnias</i>		
Nightmare	1	0
<i>Perception disturbances NEC</i>		
Autoscopy	1	0
<i>Psychotic disorder NEC</i>		
Acute psychosis	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	4	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

Case Series Drug Analysis Print

Name: COVID-19 brand unspecified Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Psychiatric disorders ^{Psychiatric disorders cont'd}		
Psychiatric disorders SOC TOTAL	87	0

Case Series Drug Analysis Print

Name: COVID-19 brand unspecified Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Dysuria	1	0
Urinary incontinence	3	0
Urine flow decreased	1	0
<i>Bladder disorders NEC</i>		
Bladder disorder	1	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
Nephrotic syndrome	2	0
<i>Nephritis NEC</i>		
Nephritis	1	0
<i>Renal failure and impairment</i>		
Acute kidney injury	2	0
Renal impairment	1	0
<i>Renal lithiasis</i>		
Nephrolithiasis	2	0
<i>Renal neoplasms</i>		
Renal cyst	1	0
<i>Renal vascular and ischaemic conditions</i>		
Renal infarct	1	0
Renal vein thrombosis	1	0
<i>Urinary abnormalities</i>		
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	25	0

Case Series Drug Analysis Print

Name: COVID-19 brand unspecified Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Breast disorders NEC</i>		
Breast mass	1	0
<i>Breast signs and symptoms</i>		
Breast pain	3	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	1	0
<i>Menstruation and uterine bleeding NEC</i>		
Dysmenorrhoea	15	0
Intermenstrual bleeding	11	0
Menstrual disorder	16	0
Menstruation irregular	16	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	34	0
Polymenorrhoea	5	0
<i>Ovarian and fallopian tube disorders NEC</i>		
Ovulation disorder	1	0
Ovulation pain	1	0
<i>Pelvis and broad ligament disorders NEC</i>		
Adnexa uteri pain	1	0
Pelvic haemorrhage	1	0
<i>Prostatic signs, symptoms and disorders NEC</i>		
Prostatic pain	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Genital swelling	1	0
Pelvic pain	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	8	0
Vulvovaginal disorder	1	0
<i>Vulvovaginal signs and symptoms</i>		
Vaginal discharge	1	0
Reproductive & breast disorders SOC TOTAL	159	0

Case Series Drug Analysis Print

Name: COVID-19 brand unspecified Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	51	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	1	0
Wheezing	3	0
<i>Coughing and associated symptoms</i>		
Cough	19	0
Haemoptysis	1	0
Productive cough	4	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	3	0
<i>Nasal disorders NEC</i>		
Epistaxis	10	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	12	2
Pulmonary thrombosis	1	1
<i>Respiratory tract disorders NEC</i>		
Lung disorder	1	0
Pulmonary mass	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Nasal discomfort	1	0
Oropharyngeal pain	13	0
Paranasal sinus discomfort	1	0
Rhinorrhoea	5	0
Sneezing	3	0
Throat irritation	2	0
Yawning	2	0
Respiratory disorders SOC TOTAL	146	4

Case Series Drug Analysis Print

Name: COVID-19 brand unspecified Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	1	0
<i>Alopecias</i>		
Alopecia	6	0
<i>Angioedemas</i>		
Angioedema	4	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	7	0
Hyperhidrosis	37	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	28	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	36	0
<i>Purpura and related conditions</i>		
Petechiae	1	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	63	0
Rash erythematous	7	0
Rash macular	3	0

Case Series Drug Analysis Print

Name: COVID-19 brand unspecified Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Rash morbilliform	1	0
Rash papular	2	0
Rash pruritic	15	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	15	0
Skin disorders SOC TOTAL	273	0

Case Series Drug Analysis Print

Name: COVID-19 brand unspecified Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

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

Case Series Drug Analysis Print

Name: COVID-19 brand unspecified Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

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

Case Series Drug Analysis Print

Name: COVID-19 brand unspecified Vaccine Analysis Print

Report Run Date: 18-Nov-2021

Data Lock Date: 17-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

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	19	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	10	0
Jugular vein thrombosis	1	0
Thrombophlebitis	1	0
<i>Peripheral vascular disorders NEC</i>		
Erythromelalgia	1	0
Flushing	2	0
Hot flush	6	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	2	0
Raynaud's phenomenon	1	0
<i>Phlebitis NEC</i>		
Phlebitis	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	3	0
<i>Varicose veins NEC</i>		
Spider vein	1	0
Varicose vein	1	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	11	0
<i>Vascular hypotensive disorders</i>		
Hypotension	2	0
Vascular disorders SOC TOTAL	86	0
TOTAL REACTIONS FOR DRUG	3768	32
TOTAL REPORTS	1254	
TOTAL FATAL OUTCOME REPORTS		32