

COVID-19 vaccine brand unspecified analysis print

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All UK spontaneous reports received up to and including FÍ BEG21 for COVID-19 vaccines where the brand has not been specified.

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Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 18-Feb-2022

Data Lock Date: 16-Feb-2022 18:30:05

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	31	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	10	0
Blood disorders SOC TOTAL	63	4

Case Series Drug Analysis Print

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Data Lock Date: 16-Feb-2022 18:30:05

MedDRA Version: MedDRA 24.1

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	38	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	4	0
<i>Rate and rhythm disorders NEC</i>		
Bradycardia	1	0
Cardiac flutter	3	0
Postural orthostatic tachycardia syndrome	1	0
Tachycardia	11	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	1
Cardiac disorders SOC TOTAL	95	4

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 18-Feb-2022

Data Lock Date: 16-Feb-2022 18:30:05

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 vaccine brand unspecified analysis print

Report Run Date: 18-Feb-2022

Data Lock Date: 16-Feb-2022 18:30:05

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	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	15	0
<i>Tympanic membrane disorders (excl infections)</i>		
Tympanic membrane perforation	1	0
Ear disorders SOC TOTAL	69	0

Case Series Drug Analysis Print

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Report Run Date: 18-Feb-2022

Data Lock Date: 16-Feb-2022 18:30:05

MedDRA Version: MedDRA 24.1

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

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 18-Feb-2022

Data Lock Date: 16-Feb-2022 18:30:05

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>Eyelid movement disorders</i>		
Blepharospasm	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 discharge	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	13	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	84	0

Case Series Drug Analysis Print

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Report Run Date: 18-Feb-2022

Data Lock Date: 16-Feb-2022 18:30:05

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	52	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
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	139	0
Retching	3	0
Vomiting	56	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>		

Case Series Drug Analysis Print

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Report Run Date: 18-Feb-2022

Data Lock Date: 16-Feb-2022 18:30:05

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
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	376	1

Case Series Drug Analysis Print

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Data Lock Date: 16-Feb-2022 18:30:05

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	45	0
Chronic fatigue syndrome	1	0
Fatigue	211	0
Malaise	86	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	165	0
<i>Feelings and sensations NEC</i>		
Chills	107	0
Feeling abnormal	24	0
Feeling cold	23	0
Feeling hot	14	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	9	0
Crying	1	0
General physical health deterioration	3	0
Illness	30	0
Influenza like illness	36	0
Local reaction	1	0
Peripheral swelling	40	0
Secretion discharge	1	0
Swelling	28	0
Swelling face	14	0
Symptom recurrence	1	0
Unevaluable event	1	0
<i>Inflammations</i>		
Inflammation	7	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	12	0
Injection site pruritus	1	0
Injection site reaction	1	0
Injection site swelling	3	0

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Injection site warmth	1	0
Interactions		
Drug interaction	2	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	11	0
Chest discomfort	7	0
Chest pain	36	0
Discomfort	6	0
Facial discomfort	1	0
Facial pain	4	0
Pain	93	0
Tenderness	1	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	2	0
Adverse reaction	1	0
Drug ineffective	6	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	2	0
Vaccination site pain	15	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	13	0
Vaccination site warmth	6	0
General disorders SOC TOTAL	1176	13

Case Series Drug Analysis Print

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Data Lock Date: 16-Feb-2022 18:30:05

MedDRA Version: MedDRA 24.1

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

Case Series Drug Analysis Print

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Report Run Date: 18-Feb-2022

Data Lock Date: 16-Feb-2022 18:30:05

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	6	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to vaccine	4	0
Drug hypersensitivity	3	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>		
Immune system disorder	1	0
<i>Immunodeficiency disorders NEC</i>		
Immunodeficiency	1	0
<i>Transplant rejections</i>		
Corneal graft rejection	1	0
Immune system disorders SOC TOTAL	21	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Appendicitis	1	0
<i>Bacterial infections NEC</i>		
Arthritis bacterial	1	0
Cellulitis	3	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	34	0
Suspected COVID-19	2	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	1	0
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	15	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	22	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>		

Case Series Drug Analysis Print

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Report Run Date: 18-Feb-2022

Data Lock Date: 16-Feb-2022 18:30:05

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Laryngitis	1	0
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	152	4

Case Series Drug Analysis Print

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Data Lock Date: 16-Feb-2022 18:30:05

MedDRA Version: MedDRA 24.1

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	2	0
Maternal exposure during breast feeding	3	0
Maternal exposure during pregnancy	8	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
Retinal injury	1	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	3	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	2	0
Product administered at inappropriate site	2	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	2	0
Spinal column injury	1	0

Case Series Drug Analysis Print

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Data Lock Date: 16-Feb-2022 18:30:05

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
<i>Skin injuries NEC</i>		
Contusion	15	0
<i>Underdoses NEC</i>		
Prescribed underdose	1	0
<i>Vaccination related complications</i>		
Vaccination complication	13	0
Injuries SOC TOTAL	100	1

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
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	2	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	2	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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Reaction Name	Total	Fatal
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	91	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

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 18-Feb-2022

Data Lock Date: 16-Feb-2022 18:30:05

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	11	0
Arthropathy	1	0
Palindromic rheumatism	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	2	0
<i>Cartilage disorders</i>		
Costochondritis	3	0
<i>Connective tissue disorders NEC</i>		
Polymyalgia rheumatica	5	0
<i>Joint related disorders NEC</i>		
Hypermobility syndrome	1	0
Joint lock	2	0
Periarthritis	3	0
Rotator cuff syndrome	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	102	0
Joint stiffness	3	0
Joint swelling	11	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	17	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	18	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Back disorder	1	0
Mobility decreased	12	0
Musculoskeletal disorder	1	0
Musculoskeletal stiffness	16	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	36	0
Limb discomfort	14	0
Musculoskeletal chest pain	2	0
Musculoskeletal discomfort	1	0
Musculoskeletal pain	2	0
Neck pain	15	0
Pain in extremity	125	0
<i>Osteoarthropathies</i>		
Osteoarthritis	1	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 18-Feb-2022

Data Lock Date: 16-Feb-2022 18:30:05

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
<i>Psoriatic arthropathies</i>		
Psoriatic arthropathy	1	0
<i>Rheumatoid arthropathies</i>		
Rheumatoid arthritis	4	0
<i>Soft tissue disorders NEC</i>		
Axillary mass	1	0
Groin pain	2	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	529	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 18-Feb-2022

Data Lock Date: 16-Feb-2022 18:30:05

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>Lymphomas unspecified NEC</i>		
Lymphoma	1	0
<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>Respiratory tract small cell carcinomas</i>		
Small cell lung cancer metastatic	1	1
<i>Skin neoplasms benign</i>		
Skin papilloma	1	0
Neoplasms SOC TOTAL	13	3

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 18-Feb-2022

Data Lock Date: 16-Feb-2022 18:30:05

MedDRA Version: MedDRA 24.1

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
Cerebral haemorrhage	1	0
Cerebrovascular accident	9	1
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	11	0
Somnolence	15	0
Syncope	19	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	285	0
Sinus headache	2	0
Tension headache	6	0
<i>Increased intracranial pressure disorders</i>		
Brain oedema	1	0
<i>Lumbar spinal cord and nerve root disorders</i>		
Sciatica	1	0
<i>Memory loss (excl dementia)</i>		
Amnesia	7	0
Memory impairment	3	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 18-Feb-2022

Data Lock Date: 16-Feb-2022 18:30:05

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
<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	36	0
Retinal migraine	1	0
<i>Mononeuropathies</i>		
Carpal tunnel syndrome	1	0
Peroneal nerve palsy	1	0
<i>Multiple sclerosis acute and progressive</i>		
Multiple sclerosis	2	0
<i>Muscle tone abnormal</i>		
Hypotonia	1	0
<i>Narcolepsy and hypersomnia</i>		
Hypersomnia	2	0
<i>Nervous system disorders NEC</i>		
Nervous system disorder	2	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	102	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
<i>Olfactory nerve disorders</i>		
Anosmia	3	0
Parosmia	4	0
<i>Paraesthesias and dysaesthesias</i>		
Burning sensation	14	0
Hypoaesthesia	35	0
Paraesthesia	48	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Hemiparesis	2	0
Hemiplegia	1	0
Monoparesis	1	0
Monoplegia	1	0
Paralysis	3	0
<i>Parkinson's disease and parkinsonism</i>		
Freezing phenomenon	2	0
Parkinson's disease	1	0
<i>Peripheral neuropathies NEC</i>		
Neuropathy peripheral	1	0
<i>Seizures and seizure disorders NEC</i>		
Convulsions local	1	0
Epilepsy	4	0
Psychogenic seizure	1	0
Seizure	11	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 18-Feb-2022

Data Lock Date: 16-Feb-2022 18:30:05

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Seizure like phenomena	1	0
<i>Sensory abnormalities NEC</i>		
Ageusia	6	0
Dysgeusia	8	0
Neuralgia	8	0
Restless legs syndrome	2	0
Sensory disturbance	3	0
Sensory loss	1	0
Taste disorder	2	0
<i>Speech and language abnormalities</i>		
Dysarthria	6	0
<i>Transient cerebrovascular events</i>		
Transient ischaemic attack	6	0
<i>Tremor (excl congenital)</i>		
Tremor	50	0
<i>Trigeminal disorders</i>		
Trigeminal neuralgia	1	0
Nervous system disorders SOC TOTAL	840	3

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 18-Feb-2022

Data Lock Date: 16-Feb-2022 18:30:05

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	6	0
<i>Maternal complications of pregnancy NEC</i>		
Biochemical pregnancy	1	0
Preterm premature rupture of membranes	1	0
<i>Normal pregnancy, labour and delivery</i>		
Pregnancy	1	0
Pregnancy conditions SOC TOTAL	9	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 18-Feb-2022

Data Lock Date: 16-Feb-2022 18:30:05

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 vaccine brand unspecified analysis print

Report Run Date: 18-Feb-2022

Data Lock Date: 16-Feb-2022 18:30:05

MedDRA Version: MedDRA 24.1

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	4	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>		

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 18-Feb-2022

Data Lock Date: 16-Feb-2022 18:30:05

MedDRA Version: MedDRA 24.1

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	107	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 18-Feb-2022

Data Lock Date: 16-Feb-2022 18:30:05

MedDRA Version: MedDRA 24.1

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

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 18-Feb-2022

Data Lock Date: 16-Feb-2022 18:30:05

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Breast disorders NEC</i>		
Breast mass	2	0
<i>Breast infections and inflammations</i>		
Plasma cell mastitis	1	0
<i>Breast signs and symptoms</i>		
Breast pain	5	0
Breast swelling	1	0
Breast tenderness	1	0
<i>Fallopian tube and ovary infections and inflammations</i>		
Noninfective oophoritis	1	0
<i>Lactation disorders</i>		
Suppressed lactation	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	20	0
Intermenstrual bleeding	11	0
Menstrual disorder	19	0
Menstruation irregular	25	0
Premenstrual syndrome	2	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	8	0
Hypomenorrhoea	4	0
Menstruation delayed	28	0
Oligomenorrhoea	2	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	43	0
Polymenorrhoea	8	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	2	0
<i>Uterine disorders NEC</i>		
Uterine pain	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	10	0
Vulvovaginal disorder	1	0
<i>Vulvovaginal signs and symptoms</i>		
Vaginal discharge	1	0
Reproductive & breast disorders SOC TOTAL	209	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 18-Feb-2022

Data Lock Date: 16-Feb-2022 18:30:05

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	73	1
Dyspnoea exertional	1	0
Hypopnoea	1	0
Respiratory arrest	1	0
Tachypnoea	1	0
<i>Bronchospasm and obstruction</i>		
Asthma	3	0
Chronic obstructive pulmonary disease	2	1
Wheezing	5	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	1	0
<i>Coughing and associated symptoms</i>		
Cough	26	0
Haemoptysis	3	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>		
Emphysema	1	0
Pulmonary fibrosis	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal swelling	1	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	2	0
<i>Pulmonary oedemas</i>		
Pulmonary congestion	1	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	14	3
Pulmonary thrombosis	1	1
<i>Respiratory tract disorders NEC</i>		
Lung disorder	1	0
Pulmonary mass	1	0
Respiratory tract irritation	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

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 18-Feb-2022

Data Lock Date: 16-Feb-2022 18:30:05

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Yawning	2	0
Respiratory disorders SOC TOTAL	202	6

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 18-Feb-2022

Data Lock Date: 16-Feb-2022 18:30:05

MedDRA Version: MedDRA 24.1

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	4	0
Blister rupture	1	0
Erythema multiforme	2	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	2	0
Pain of skin	2	0
Papule	3	0
Scar pain	1	0
Sensitive skin	2	0
Skin burning sensation	2	0
Skin discolouration	4	0
Skin disorder	2	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	35	0
<i>Exfoliative conditions</i>		
Skin exfoliation	2	0
<i>Hyperkeratoses</i>		
Lichenoid keratosis	1	0
<i>Papulosquamous conditions</i>		
Lichen planus	1	0
Lichen sclerosus	1	0
Parapsoriasis	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	43	0
<i>Psoriatic conditions</i>		
Guttate psoriasis	2	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 18-Feb-2022

Data Lock Date: 16-Feb-2022 18:30:05

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Psoriasis	2	0
<i>Purpura and related conditions</i>		
Petechiae	2	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	68	0
Rash erythematous	9	0
Rash macular	4	0
Rash morbilliform	1	0
Rash papular	2	0
Rash pruritic	19	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	332	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 18-Feb-2022

Data Lock Date: 16-Feb-2022 18:30:05

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	2	0
Housebound	1	0
Social circumstances SOC TOTAL	6	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 18-Feb-2022

Data Lock Date: 16-Feb-2022 18:30:05

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	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>Therapeutic procedures NEC</i>		
Bed rest	1	0
Hospitalisation	1	0
Interchange of vaccine products	1	0
Surgical & medical procedures SOC TOTAL	11	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 18-Feb-2022

Data Lock Date: 16-Feb-2022 18:30:05

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	3	0
Shock	3	0
<i>Haemorrhages NEC</i>		
Haematoma	1	0
Haemorrhage	22	0
<i>Non-site specific embolism and thrombosis</i>		
Thrombosis	12	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	17	0
<i>Vascular hypotensive disorders</i>		
Hypotension	2	0
<i>Vasculitides NEC</i>		
Vasculitis	1	0
Vascular disorders SOC TOTAL	103	0
TOTAL REACTIONS FOR DRUG	4689	39
TOTAL REPORTS	1538	
TOTAL FATAL OUTCOME REPORTS		39