

~~AWW~~ COVID-19 brand unspecified Vaccine Analysis Print

All UK spontaneous reports received up to and including 11/05/2022 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: 12-May-2022

Data Lock Date: 11-May-2022 18:30:05

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemias NEC</i>		
Anaemia	3	0
<i>Coagulopathies</i>		
Disseminated intravascular coagulation	1	0
<i>Eosinophilic disorders</i>		
Eosinophilia	1	0
<i>Haematological disorders</i>		
Blood disorder	1	1
<i>Leukocytoses NEC</i>		
Hyperleukocytosis	1	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	4	0
Lymphadenitis	1	0
Lymphadenopathy	32	0
<i>Marrow depression and hypoplastic anaemias</i>		
Aplastic anaemia	1	0
Myelosuppression	1	0
<i>Neutropenias</i>		
Neutropenia	1	0
<i>Platelet disorders NEC</i>		
Platelet disorder	1	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	5	3
Thrombocytopenia	8	0
Thrombosis with thrombocytopenia syndrome	2	0
<i>White blood cell abnormal findings NEC</i>		
White blood cell disorder	1	0
Blood disorders SOC TOTAL	64	4

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac conduction disorders</i>		
Atrioventricular block	1	0
Bundle branch block	1	0
<i>Cardiac disorders NEC</i>		
Cardiac disorder	1	0
<i>Cardiac signs and symptoms NEC</i>		
Cardiac discomfort	2	0
Palpitations	48	0
<i>Heart failures NEC</i>		
Cardiac failure	1	0
<i>Ischaemic coronary artery disorders</i>		
Acute myocardial infarction	2	0
Angina pectoris	6	0
Myocardial infarction	9	3
Myocardial ischaemia	2	2
<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	5	0
<i>Pericardial disorders NEC</i>		
Pericardial effusion	1	0
<i>Rate and rhythm disorders NEC</i>		
Bradycardia	1	0
Cardiac flutter	3	0
Extrasystoles	1	0
Postural orthostatic tachycardia syndrome	1	0
Tachycardia	13	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	7	0
Atrial tachycardia	1	0
Supraventricular tachycardia	1	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	3	1
Cardiac disorders SOC TOTAL	116	6

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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	3	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 neurosensory	1	0
Deafness unilateral	1	0
Hypoacusis	6	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	28	0
Vertigo	16	0
<i>Tympanic membrane disorders (excl infections)</i>		
Tympanic membrane perforation	1	0
Ear disorders SOC TOTAL	78	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Thyroiditis	1	0
<i>Adrenal cortical hypofunctions</i>		
Adrenal insufficiency	1	0
<i>Adrenal gland disorders NEC</i>		
Adrenal haemorrhage	2	0
<i>Female gonadal function disorders</i>		
Ovulation delayed	1	0
<i>Thyroid hyperfunction disorders</i>		
Thyrotoxic crisis	1	0
Endocrine disorders SOC TOTAL	6	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>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	9	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
Ocular hyperaemia	1	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	1	0
<i>Ocular sensation disorders</i>		
Photophobia	4	0
<i>Pupil disorders</i>		
Anisocoria	1	0
Pupil fixed	1	0
<i>Retinal bleeding and vascular disorders (excl retinopathy)</i>		
Retinal haemorrhage	1	0
Retinal vein occlusion	3	0
<i>Retinal structural change, deposit and degeneration</i>		
Macular degeneration	1	0
Retinal toxicity	1	0
<i>Structural change, deposit and degeneration of eye NEC</i>		
Exophthalmos	1	0
<i>Visual disorders NEC</i>		
Diplopia	5	0
Photopsia	2	0
Vision blurred	15	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	4	0
Blindness transient	1	0
Visual impairment	7	0
Eye disorders SOC TOTAL	93	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	3	0
Colitis ulcerative	2	0
Crohn's disease	2	0
<i>Dental pain and sensation disorders</i>		
Toothache	3	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	56	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	4	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	2	0
Faeces discoloured	4	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	14	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	16	0
Anal incontinence	1	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	146	0
Retching	4	0
Vomiting	65	0
Vomiting projectile	2	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Gastrointestinal haemorrhage	1	1
Haematemesis	3	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders Gastrointestinal disorders cont'd		
<i>Oral dryness and saliva altered</i>		
Dry mouth	1	0
<i>Oral soft tissue disorders NEC</i>		
Enlarged uvula	1	0
Oral papule	1	0
<i>Oral soft tissue haemorrhages</i>		
Oral blood blister	1	0
<i>Oral soft tissue signs and symptoms</i>		
Hypoaesthesia oral	2	0
Lip erythema	1	0
Lip exfoliation	1	0
Oral mucosal eruption	1	0
Oral pain	1	0
Paraesthesia oral	2	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	7	0
Mouth swelling	2	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	415	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	49	0
Chronic fatigue syndrome	1	0
Fatigue	226	0
Malaise	89	0
<i>Body temperature altered</i>		
Hyperthermia	1	0
Hypothermia	1	0
<i>Death and sudden death</i>		
Death	14	14
Sudden death	1	1
<i>Febrile disorders</i>		
Pyrexia	180	0
<i>Feelings and sensations NEC</i>		
Chills	111	0
Feeling abnormal	27	0
Feeling cold	25	0
Feeling hot	14	0
Feeling of body temperature change	11	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	13	0
Crying	2	0
General physical health deterioration	3	0
Ill-defined disorder	1	0
Illness	32	0
Induration	1	0
Influenza like illness	36	0
Local reaction	1	0
Peripheral swelling	40	0
Secretion discharge	1	0
Swelling	30	0
Swelling face	15	0
Symptom recurrence	1	0
Unevaluable event	2	0
<i>Inflammations</i>		
Inflammation	8	1
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 paraesthesia	1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Injection site pruritus	1	0
Injection site reaction	1	0
Injection site swelling	3	0
Injection site warmth	1	0
Interactions		
Device interaction	2	0
Drug interaction	1	0
Drug-device interaction	2	0
Mass conditions NEC		
Cyst	2	0
Mass	1	0
Nodule	1	0
Oedema NEC		
Oedema	2	0
Oedema peripheral	1	0
Pain and discomfort NEC		
Axillary pain	11	0
Chest discomfort	9	0
Chest pain	44	0
Discomfort	6	0
Facial discomfort	1	0
Facial pain	4	0
Pain	100	0
Tenderness	1	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	1	0
Drug ineffective	17	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	3	0
Vaccination site bruising	2	0
Vaccination site erythema	18	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	3	0
Vaccination site pain	18	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	15	0
Vaccination site warmth	7	0
General disorders SOC TOTAL	1282	16

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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>		
Hepatic infarction	1	0
Hepatic vein thrombosis	1	0
Portal vein thrombosis	5	1
Hepatic disorders SOC TOTAL	9	1

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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	8	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
Anaphylactic shock	1	0
<i>Atopic disorders</i>		
Seasonal allergy	1	0
<i>Immune and associated conditions NEC</i>		
Immune system disorder	1	0
Immunisation reaction	12	0
<i>Immunodeficiency disorders NEC</i>		
Immunodeficiency	1	0
<i>Transplant rejections</i>		
Corneal graft rejection	1	0
Immune system disorders SOC TOTAL	36	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	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	51	1
Post-acute COVID-19 syndrome	2	0
Suspected COVID-19	3	0
<i>Ear infections</i>		
Ear infection	2	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	2	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	19	0
Herpes zoster oticus	1	0
Oral herpes	3	0
Varicella	1	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>		

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Furuncle	2	0
<i>Trypanosomal infections</i>		
African trypanosomiasis	1	0
<i>Upper respiratory tract infections</i>		
Laryngitis	1	0
Nasopharyngitis	11	0
Sinusitis	1	0
Tonsillitis	2	0
Upper respiratory tract infection	1	0
<i>Urinary tract infections</i>		
Kidney infection	2	0
Urinary tract infection	5	0
<i>Viral infections NEC</i>		
Gastroenteritis viral	1	0
Sweating fever	1	0
Viral infection	3	0
Infections SOC TOTAL	184	5

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Reaction Name	Total	Fatal
Injuries		
<i>Abdominal and gastrointestinal injuries NEC</i>		
Gallbladder injury	1	0
<i>Bone and joint injuries NEC</i>		
Joint injury	1	0
<i>Cerebral injuries NEC</i>		
Subdural haematoma	1	1
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure via breast milk	2	0
Maternal exposure during breast feeding	1	0
Maternal exposure during pregnancy	9	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	12	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	4	0
Incorrect route of product administration	1	0
Product administered at inappropriate site	5	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

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
<i>Skin injuries NEC</i>		
Contusion	16	0
<i>Skin procedural complications</i>		
Dermal filler reaction	2	0
<i>Underdoses NEC</i>		
Prescribed underdose	1	0
<i>Vaccination related complications</i>		
Vaccination complication	1	0
Injuries SOC TOTAL	95	1

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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	3	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>Chemistry analyses NEC</i>		
Inflammatory marker 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	8	0
Heart rate decreased	2	0
Heart rate increased	11	0
Heart rate irregular	3	0
<i>Hepatobiliary function diagnostic procedures</i>		
Liver function test	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
Blood test abnormal	1	0
Quality of life decreased	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
Breath sounds abnormal	1	0
Respiratory rate decreased	1	0
Respiratory rate increased	1	0
Weight decreased	7	0
Weight increased	2	0
<i>Platelet analyses</i>		
Platelet count decreased	1	0

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Platelet count increased	1	0
Red blood cell analyses		
Haemoglobin E	1	0
Haemoglobin decreased	1	0
Red cell distribution width increased	1	0
Respiratory and pulmonary function diagnostic procedures		
Peak expiratory flow rate decreased	1	0
Respiratory tract and thoracic histopathology procedures		
Aspiration pleural cavity	1	0
Skeletal and cardiac muscle analyses		
Blood creatine phosphokinase increased	1	0
Therapeutic drug monitoring analyses		
Anticoagulation drug level below therapeutic	1	0
Triglyceride analyses		
Blood triglycerides	1	0
Blood triglycerides increased	1	0
Vascular tests NEC (incl blood pressure)		
Blood pressure abnormal	1	0
Blood pressure decreased	1	0
Blood pressure increased	10	0
Virus identification and serology		
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
White blood cell analyses		
Neutrophil count decreased	3	0
Neutrophil count increased	1	0
White blood cell count increased	1	0
Investigations SOC TOTAL	107	0

Case Series Drug Analysis Print

Name: COVID-19 brand unspecified Vaccine Analysis Print

Report Run Date: 12-May-2022

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MedDRA Version: MedDRA 25.0

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	2	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>		
Abnormal weight gain	1	0
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	5	0
<i>Water soluble vitamin deficiencies</i>		
Folate deficiency	1	0
Metabolic disorders SOC TOTAL	62	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	13	0
Arthropathy	1	0
Polyarthritis	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	4	0
<i>Cartilage disorders</i>		
Costochondritis	4	0
<i>Connective tissue disorders NEC</i>		
Polymyalgia rheumatica	6	0
<i>Joint related disorders NEC</i>		
Hypermobility syndrome	1	0
Joint lock	2	0
Periarthritis	4	0
Rotator cuff syndrome	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	108	0
Joint stiffness	4	0
Joint swelling	11	0
<i>Lupus erythematosus (incl subtypes)</i>		
Systemic lupus erythematosus	2	0
<i>Muscle pains</i>		
Fibromyalgia	3	0
Myalgia	90	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle disorder	1	0
Muscle fatigue	3	0
Muscle spasms	18	0
Muscle tightness	2	0
Muscle twitching	5	0
<i>Muscle tone abnormalities</i>		
Muscle rigidity	5	0
<i>Muscle weakness conditions</i>		
Muscular weakness	19	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Back disorder	1	0
Mobility decreased	14	0
Musculoskeletal disorder	1	0
Musculoskeletal stiffness	17	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	38	0
Limb discomfort	15	0
Musculoskeletal chest pain	2	0
Musculoskeletal discomfort	1	0
Musculoskeletal pain	2	0
Neck pain	17	0
Pain in extremity	139	0
<i>Osteoarthropathies</i>		
Osteoarthritis	1	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders Muscle & tissue disorders cont'd		
<i>Psoriatic arthropathies</i>		
Psoriatic arthropathy	1	0
<i>Rheumatoid arthropathies</i>		
Rheumatoid arthritis	5	0
<i>Soft tissue disorders NEC</i>		
Axillary mass	2	0
Groin pain	2	0
Neck mass	2	0
<i>Spondyloarthropathies</i>		
Arthritis reactive	1	0
Spondyloarthropathy	1	0
<i>Tendon disorders</i>		
Tendon pain	1	0
Tendonitis	1	0
Trigger finger	1	0
Muscle & tissue disorders SOC TOTAL	580	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	1	0
Breast cancer female	1	0
<i>Haematologic neoplasms NEC</i>		
Benign lymph node neoplasm	1	0
<i>Leukaemias acute myeloid</i>		
Acute myeloid leukaemia	1	1
<i>Lymphomas unspecified NEC</i>		
Lymphoma	1	0
<i>Neoplasms malignant site unspecified NEC</i>		
Malignant neoplasm progression	1	0
Neoplasm malignant	3	0
<i>Nervous system neoplasms unspecified malignancy NEC</i>		
Brain neoplasm	1	0
<i>Respiratory tract and pleural neoplasms malignant cell type unspecified NEC</i>		
Lung neoplasm malignant	1	1
Throat cancer	1	0
<i>Skin neoplasms benign</i>		
Acrochordon	1	0
Skin papilloma	1	0
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	1	0
Neoplasms SOC TOTAL	15	2

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	7	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 infarction	1	0
Cerebral thrombosis	1	0
Cerebrovascular accident	11	1
Haemorrhage intracranial	2	0
Ischaemic stroke	1	0
<i>Cerebrovascular venous and sinus thrombosis</i>		
Cerebral venous sinus thrombosis	2	1
<i>Coma states</i>		
Coma	1	0
<i>Coordination and balance disturbances</i>		
Balance disorder	12	0
Coordination abnormal	2	0
Dysstasia	2	0
<i>Cortical dysfunction NEC</i>		
Aphasia	4	0
<i>Dementia (excl Alzheimer's type)</i>		
Dementia	1	0
<i>Disturbances in consciousness NEC</i>		
Depressed level of consciousness	2	0
Lethargy	31	0
Loss of consciousness	13	0
Somnolence	16	0
Syncope	19	0
<i>Dyskinesias and movement disorders NEC</i>		
Bradykinesia	1	0
Hypokinesia	2	0
Movement disorder	2	0
<i>Encephalopathies NEC</i>		
Autoimmune encephalopathy	1	0
<i>Eye movement disorders</i>		
Vlth 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	305	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>		

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Reaction Name	Total	Fatal
Nervous system disorders Nervous system disorders cont'd		
Sciatica	1	0
Memory loss (excl dementia)		
Amnesia	8	0
Memory impairment	3	0
Meningitis NEC		
Meningitis noninfective	1	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	2	0
Disturbance in attention	5	0
Mental impairment	1	0
Migraine headaches		
Migraine	37	0
Retinal migraine	1	0
Mononeuropathies		
Carpal tunnel syndrome	1	0
Peroneal nerve palsy	1	0
Motor neurone diseases		
Motor neurone disease	1	0
Multiple sclerosis acute and progressive		
Multiple sclerosis	2	0
Muscle tone abnormal		
Hypotonia	1	0
Narcolepsy and hypersomnia		
Hypersomnia	2	0
Nervous system disorders NEC		
Nervous system disorder	2	0
Neurological signs and symptoms NEC		
Dizziness	112	0
Dizziness exertional	1	0
Dizziness postural	7	0
Head discomfort	2	0
Meningism	1	0
Myoclonus	1	0
Neurological symptom	2	0
Presyncope	4	0
Unresponsive to stimuli	3	0
Olfactory nerve disorders		
Anosmia	3	0
Parosmia	4	0
Paraesthesias and dysaesthesias		
Burning sensation	14	0
Formication	1	0
Hypoaesthesia	37	0
Paraesthesia	53	0
Paralysis and paresis (excl cranial nerve)		
Hemiparesis	2	0
Hemiplegia	2	0
Monoparesis	1	0
Monoplegia	2	0
Paralysis	3	0
Paraparesis	1	0
Parkinson's disease and parkinsonism		
Freezing phenomenon	2	0

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Reaction Name	Total	Fatal
Nervous system disorders Nervous system disorders cont'd		
Parkinson's disease	1	0
Peripheral neuropathies NEC		
Neuropathy peripheral	1	0
Seizures and seizure disorders NEC		
Convulsions local	1	0
Epilepsy	6	0
Psychogenic seizure	1	0
Seizure	13	0
Seizure like phenomena	1	0
Sensory abnormalities NEC		
Ageusia	6	0
Dysgeusia	9	0
Neuralgia	8	0
Restless legs syndrome	2	0
Sensory disturbance	4	0
Sensory loss	1	0
Taste disorder	3	0
Speech and language abnormalities		
Dysarthria	5	0
Transient cerebrovascular events		
Transient ischaemic attack	7	0
Tremor (excl congenital)		
Tremor	52	0
Trigeminal disorders		
Trigeminal neuralgia	1	0
Nervous system disorders SOC TOTAL	914	3

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	7	1
<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	10	1

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Reaction Name	Total	Fatal
<i>Product quality issues NEC</i>		
Product complaint	3	0
<i>Product supply and availability issues</i>		
Product availability issue	1	0
null SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	1	0
<i>Anxiety symptoms</i>		
Agitation	1	0
Anxiety	11	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	2	0
<i>Confusion and disorientation</i>		
Confusional state	20	0
Disorientation	7	0
<i>Deliria</i>		
Delirium	2	0
<i>Depressive disorders</i>		
Depression	5	0
<i>Dissociative states</i>		
Dissociative amnesia	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	15	0
Middle insomnia	1	0
<i>Dyssomnias</i>		
Poor quality sleep	3	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	4	0
<i>Mental disorders NEC</i>		
Mental disorder	2	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	6	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

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Reaction Name	Total	Fatal
Psychiatric disorders Psychiatric disorders cont'd		
<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	2	0
Suicide attempt	2	0
<i>Thinking disturbances</i>		
Bradyphrenia	3	0
Psychiatric disorders SOC TOTAL	124	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Dysuria	1	0
Incontinence	1	0
Pollakiuria	2	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>		
Lupus nephritis	1	0
Nephritis	1	0
<i>Renal failure and impairment</i>		
Acute kidney injury	2	0
Oliguria	1	0
Renal failure	1	0
Renal impairment	2	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	2	0
Renal vein thrombosis	1	0
<i>Urinary abnormalities</i>		
Chromaturia	2	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	38	0

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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>Menopausal effects NEC</i>		
Menopausal symptoms	2	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	25	0
Intermenstrual bleeding	12	0
Menstrual discomfort	1	0
Menstrual disorder	21	0
Menstruation irregular	30	0
Premenstrual syndrome	3	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	9	0
Hypomenorrhoea	4	0
Menstruation delayed	32	0
Oligomenorrhoea	1	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	48	0
Polymenorrhoea	9	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>		
Ovarian cyst ruptured	1	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>Testicular and epididymal disorders NEC</i>		
Testicular pain	1	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	236	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	81	1
Dyspnoea exertional	1	0
Hyperventilation	1	0
Hypopnoea	1	0
Respiration abnormal	1	0
Respiratory arrest	1	0
Tachypnoea	1	0
<i>Bronchospasm and obstruction</i>		
Asthma	5	0
Chronic obstructive pulmonary disease	2	1
Wheezing	5	0
<i>Conditions associated with abnormal gas exchange</i>		
Asphyxia	1	1
Hypoxia	1	0
<i>Coughing and associated symptoms</i>		
Cough	30	0
Haemoptysis	2	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	12	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	1	0
<i>Pulmonary oedemas</i>		
Pulmonary congestion	1	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	17	3
Pulmonary thrombosis	1	1
<i>Respiratory tract disorders NEC</i>		
Lung disorder	2	0
Pulmonary mass	1	0
Respiratory tract irritation	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	1	0
Catarrh	1	0
Dysphonia	2	0
Nasal discomfort	1	0

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Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Oropharyngeal pain	17	0
Paranasal sinus discomfort	1	0
Rhinorrhoea	9	0
Sneezing	5	0
Throat irritation	3	0
Throat tightness	1	0
Yawning	2	0
Respiratory disorders SOC TOTAL	229	7

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	1	0
<i>Alopecias</i>		
Alopecia	8	0
<i>Angioedemas</i>		
Angioedema	4	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	12	0
Hyperhidrosis	46	0
Night sweats	3	0
<i>Bullous conditions</i>		
Blister	5	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 induration	2	0
Skin reaction	1	0
Skin swelling	3	0
Skin warm	2	0
Yellow skin	1	0
<i>Dermatitis and eczema</i>		
Dermatitis allergic	5	0
Dermatitis atopic	1	0
Eczema	6	0
Eczema weeping	1	0
Seborrhoeic dermatitis	1	0
Skin irritation	2	0
<i>Erythemas</i>		
Erythema	36	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>Pilar disorders NEC</i>		
Hair growth abnormal	1	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
<i>Pruritus NEC</i>		
Pruritus	48	0
<i>Psoriatic conditions</i>		
Guttate psoriasis	2	0
Psoriasis	3	0
<i>Purpura and related conditions</i>		
Petechiae	2	0
Purpura	1	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	72	0
Rash erythematous	10	0
Rash macular	4	0
Rash morbilliform	1	0
Rash papular	2	0
Rash pruritic	20	0
Rash vesicular	1	0
<i>Scaly conditions</i>		
Pityriasis	1	0
<i>Skin and subcutaneous conditions NEC</i>		
Skin mass	3	0
<i>Skin haemorrhages</i>		
Haemorrhage subcutaneous	1	0
Skin haemorrhage	1	0
<i>Skin vasculitides</i>		
Capillaritis	1	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	1	0
<i>Urticarias</i>		
Cold urticaria	2	0
Urticaria	23	0
Skin disorders SOC TOTAL	371	0

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Reaction Name	Total	Fatal
Social circumstances		
<i>Age related issues</i>		
Menopause	2	0
Postmenopause	1	0
<i>Disability issues</i>		
Bedridden	2	0
<i>Social issues NEC</i>		
Impaired quality of life	1	0
Social circumstances SOC TOTAL	6	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Contraceptive methods female</i>		
Contraception	1	0
<i>Immunisations</i>		
COVID-19 immunisation	1	0
Immunisation	2	0
<i>Joint therapeutic procedures</i>		
Knee operation	1	0
<i>Limb therapeutic procedures</i>		
Foot operation	1	0
<i>Nail therapeutic procedures</i>		
Nail operation	1	0
<i>Obstetric therapeutic procedures</i>		
Caesarean section	1	0
<i>Therapeutic procedures NEC</i>		
Bed rest	1	0
Hospitalisation	1	0
Interchange of vaccine products	2	0
Surgical & medical procedures SOC TOTAL	12	0

Case Series Drug Analysis Print

Name: COVID-19 brand unspecified Vaccine Analysis Print

Report Run Date: 12-May-2022

Data Lock Date: 11-May-2022 18:30:05

MedDRA Version: MedDRA 25.0

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	1	0
Aortic thrombosis	1	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	2	0
Shock	3	0
<i>Haemorrhages NEC</i>		
Haematoma	1	0
Haemorrhage	22	0
<i>Non-site specific embolism and thrombosis</i>		
Thrombosis	13	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	11	0
Jugular vein thrombosis	1	0
Thrombophlebitis	1	0
<i>Peripheral vascular disorders NEC</i>		
Erythromelalgia	1	0
Flushing	3	0
Hot flush	7	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	2	0
Peripheral ischaemia	1	0
Raynaud's phenomenon	1	0
<i>Phlebitis NEC</i>		
Phlebitis	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	5	0
<i>Varicose veins NEC</i>		
Spider vein	1	0
Varicose vein	1	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	20	0
<i>Vascular hypotensive disorders</i>		
Hypotension	2	0
<i>Vasculitides NEC</i>		
Vasculitis	1	0
Vascular disorders SOC TOTAL	107	0
TOTAL REACTIONS FOR DRUG	5194	47
TOTAL REPORTS	1695	
TOTAL FATAL OUTCOME REPORTS		47