

COVID-19 vaccine brand unspecified analysis print

Report Run Date: 29-Apr-2021
Data Lock Date: 28-Apr-2021 18:30:09

All UK spontaneous reports received up to and including 28/04/21 for COVID-19 vaccines where the brand has not been specified

Case Series Drug Analysis Print

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Earliest Reaction Date: 06-Feb-2020

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Blood disorders		
<i>Coagulopathies</i>		
Coagulopathy	1	0
<i>Lymphatic system disorders NEC</i>		
Lymphadenopathy	10	0
<i>Marrow depression and hypoplastic anaemias</i>		
Aplastic anaemia	1	0
Myelosuppression	1	0
<i>Neutropenias</i>		
Neutropenia	2	0
<i>Thrombocytopenias</i>		
Heparin-induced thrombocytopenia	1	0
Immune thrombocytopenia	4	3
Thrombocytopenia	4	0
Blood disorders SOC TOTAL	24	3

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	7	0
<i>Ischaemic coronary artery disorders</i>		
Acute myocardial infarction	1	0
Myocardial infarction	3	2
<i>Myocardial disorders NEC</i>		
Left ventricular dysfunction	1	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	2	0
Supraventricular tachycardia	1	0
Cardiac disorders SOC TOTAL	15	2

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear discomfort	2	0
Ear pain	3	0
Ear swelling	1	0
<i>External ear disorders NEC</i>		
Excessive cerumen production	1	0
<i>Hearing losses</i>		
Hypoacusis	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	7	0
Vertigo	7	0
Ear disorders SOC TOTAL	22	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Vitreous floaters	3	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	1	0
<i>Lacrimation disorders</i>		
Lacrimation increased	2	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Swelling of eyelid	1	0
<i>Ocular disorders NEC</i>		
Eye pain	2	0
Eye swelling	3	0
Ocular discomfort	2	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye allergy	1	0
Eye pruritus	1	0
<i>Ocular sensation disorders</i>		
Photophobia	2	0
<i>Retinal bleeding and vascular disorders (excl retinopathy)</i>		
Retinal haemorrhage	1	0
<i>Retinal structural change, deposit and degeneration</i>		
Retinal toxicity	1	0
<i>Visual disorders NEC</i>		
Diplopia	2	0
Photopsia	1	0
Vision blurred	4	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	1	0
Blindness transient	1	0
Visual impairment	3	0
Eye disorders SOC TOTAL	32	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Anal and rectal pains</i>		
Proctalgia	1	0
<i>Dental pain and sensation disorders</i>		
Toothache	2	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	24	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	2	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	2	0
Faecaloma	1	0
Faeces discoloured	2	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	1	0
<i>Gastritis (excl infective)</i>		
Gastritis	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	2	0
Abdominal pain upper	11	0
Gastrointestinal pain	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	1	0
Gastrooesophageal reflux disease	2	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	10	0
Anal incontinence	1	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Irritable bowel syndrome	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	67	0
Vomiting	29	0
Vomiting projectile	1	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	2	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 pain	1	0
Oral pain	2	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	3	0
Mouth swelling	1	0
<i>Stomatitis and ulceration</i>		
Mouth ulceration	4	0
<i>Tongue signs and symptoms</i>		
Swollen tongue	1	0
Gastrointestinal disorders SOC TOTAL	178	0

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Reaction Name	Total	Fatal
General disorders		
<i>Application and instillation site reactions</i>		
Application site burn	1	0
Application site swelling	1	0
<i>Asthenic conditions</i>		
Asthenia	17	0
Fatigue	105	0
Malaise	38	0
<i>Death and sudden death</i>		
Death	6	6
<i>Febrile disorders</i>		
Pyrexia	89	0
<i>Feelings and sensations NEC</i>		
Chills	72	0
Feeling abnormal	5	0
Feeling cold	17	0
Feeling hot	9	0
Feeling of body temperature change	5	0
Thirst	3	0
<i>Gait disturbances</i>		
Gait disturbance	4	0
Gait inability	1	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	3	0
Crying	1	0
Illness	13	0
Influenza like illness	16	0
Peripheral swelling	17	0
Swelling	13	0
Swelling face	7	0
Unevaluable event	1	0
<i>Inflammations</i>		
Inflammation	1	0
Systemic inflammatory response syndrome	1	0
<i>Injection site reactions</i>		
Injection site erythema	2	0
Injection site inflammation	1	0
Injection site mass	4	0
Injection site pain	3	0
Injection site pruritus	1	0
<i>Mass conditions NEC</i>		
Mass	1	0
<i>Pain and discomfort NEC</i>		
Axillary pain	1	0
Chest discomfort	6	0
Chest pain	9	0
Discomfort	2	0
Facial discomfort	1	0
Facial pain	1	0
Pain	47	0
<i>Therapeutic and nontherapeutic responses</i>		
Adverse drug reaction	6	0
No reaction on previous exposure to drug	1	0
<i>Vaccination site reactions</i>		

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site bruising	2	0
Vaccination site erythema	9	0
Vaccination site induration	1	0
Vaccination site inflammation	2	0
Vaccination site mass	3	0
Vaccination site pain	11	0
Vaccination site papule	1	0
Vaccination site pruritus	2	0
Vaccination site rash	3	0
Vaccination site reaction	1	0
Vaccination site swelling	6	0
Vaccination site vesicles	1	0
Vaccination site warmth	3	0
General disorders SOC TOTAL	577	6

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Cholestasis and jaundice</i>		
Jaundice	1	0
<i>Hepatic vascular disorders</i>		
Portal vein thrombosis	2	0
Hepatic disorders SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	1	0
<i>Allergic conditions NEC</i>		
Hypersensitivity	3	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to vaccine	2	0
Drug hypersensitivity	1	0
<i>Transplant rejections</i>		
Corneal graft rejection	1	0
Immune system disorders SOC TOTAL	8	0

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Reaction Name	Total	Fatal
Infections		
<i>Bacterial infections NEC</i>		
Vaccination site cellulitis	1	0
<i>Central nervous system and spinal infections</i>		
Encephalitis	1	0
Meningitis aseptic	1	0
<i>Coronavirus infections</i>		
COVID-19	6	0
Suspected COVID-19	1	0
<i>Herpes viral infections</i>		
Herpes zoster	6	0
Oral herpes	2	0
<i>Infections NEC</i>		
Infection	2	0
<i>Infectious transmissions</i>		
Vaccine virus shedding	1	0
<i>Influenza viral infections</i>		
Influenza	9	0
<i>Lower respiratory tract and lung infections</i>		
Lower respiratory tract infection	1	0
Pneumonia	2	1
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Sepsis	1	0
<i>Staphylococcal infections</i>		
Furuncle	1	0
<i>Upper respiratory tract infections</i>		
Nasopharyngitis	2	0
<i>Urinary tract infections</i>		
Cystitis	1	0
<i>Viral infections NEC</i>		
Gastroenteritis viral	1	0
Sweating fever	1	0
Infections SOC TOTAL	40	1

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Reaction Name	Total	Fatal
Injuries		
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Maternal exposure during breast feeding	1	0
<i>Eye injuries NEC</i>		
Eye contusion	1	0
Eye injury	2	0
<i>Intentional product use issues</i>		
Intentional dose omission	1	0
Intentional product use issue	1	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	1	0
Vaccination error	1	0
Wrong technique in product usage process	1	0
<i>Non-site specific injuries NEC</i>		
Fall	3	0
<i>Non-site specific procedural complications</i>		
Incision site pain	1	0
Injection related reaction	2	0
<i>Product administration errors and issues</i>		
Incorrect route of product administration	1	0
<i>Skin injuries NEC</i>		
Contusion	3	0
<i>Vaccination related complications</i>		
Vaccination complication	3	0
Injuries SOC TOTAL	22	0

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Reaction Name	Total	Fatal
Investigations		
<i>Blood gas and acid base analyses</i>		
Oxygen saturation decreased	1	0
<i>Coagulation and bleeding analyses</i>		
Fibrin D dimer increased	1	0
International normalised ratio increased	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate	3	0
Heart rate decreased	1	0
Heart rate increased	1	0
<i>Immunology skin tests NEC</i>		
Skin test positive	1	0
<i>Investigations NEC</i>		
Blood test	1	0
<i>Mineral and electrolyte analyses</i>		
Blood potassium decreased	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature abnormal	1	0
Body temperature decreased	2	0
Body temperature fluctuation	1	0
Body temperature increased	1	0
Weight decreased	1	0
<i>Platelet analyses</i>		
Platelet count decreased	1	0
<i>Red blood cell analyses</i>		
Haemoglobin decreased	1	0
<i>Respiratory and pulmonary function diagnostic procedures</i>		
Peak expiratory flow rate decreased	1	0
<i>Therapeutic drug monitoring analyses</i>		
Anticoagulation drug level below therapeutic	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure increased	5	0
<i>White blood cell analyses</i>		
Neutrophil count decreased	3	0
Investigations SOC TOTAL	29	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	34	0
Hypophagia	2	0
<i>Hyperglycaemic conditions NEC</i>		
Hyperglycaemia	1	0
<i>Sodium imbalance</i>		
Hyponatraemia	1	0
<i>Water soluble vitamin deficiencies</i>		
Folate deficiency	1	0
Metabolic disorders SOC TOTAL	39	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	1	0
Spinal pain	1	0
<i>Cartilage disorders</i>		
Costochondritis	1	0
<i>Joint related disorders NEC</i>		
Joint lock	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	44	0
Joint stiffness	1	0
Joint swelling	2	0
<i>Muscle pains</i>		
Myalgia	41	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle fatigue	2	0
Muscle spasms	4	0
Muscle tightness	2	0
Muscle twitching	1	0
<i>Muscle tone abnormalities</i>		
Muscle rigidity	2	0
<i>Muscle weakness conditions</i>		
Muscular weakness	10	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Mobility decreased	1	0
Musculoskeletal stiffness	7	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	9	0
Limb discomfort	5	0
Musculoskeletal chest pain	1	0
Musculoskeletal pain	1	0
Neck pain	8	0
Pain in extremity	52	0
<i>Psoriatic arthropathies</i>		
Psoriatic arthropathy	1	0
Muscle & tissue disorders SOC TOTAL	199	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	2	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebrovascular accident	3	0
Haemorrhage intracranial	1	0
<i>Coordination and balance disturbances</i>		
Balance disorder	6	0
Dysstasia	2	0
<i>Disturbances in consciousness NEC</i>		
Lethargy	13	0
Loss of consciousness	3	0
Somnolence	11	0
Syncope	4	0
<i>Dyskinesias and movement disorders NEC</i>		
Bradykinesia	1	0
Hypokinesia	1	0
<i>Eye movement disorders</i>		
VIth nerve paralysis	1	0
<i>Facial cranial nerve disorders</i>		
Facial paralysis	2	0
Facial paresis	1	0
<i>Headaches NEC</i>		
Headache	158	0
Sinus headache	1	0
Tension headache	1	0
<i>Memory loss (excl dementia)</i>		
Amnesia	3	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Disturbance in attention	3	0
<i>Migraine headaches</i>		
Migraine	13	0
Retinal migraine	1	0
<i>Mononeuropathies</i>		
Carpal tunnel syndrome	1	0
<i>Narcolepsy and hypersomnia</i>		
Hypersomnia	1	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	47	0
Dizziness postural	4	0
Neurological symptom	1	0
Presyncope	1	0
<i>Olfactory nerve disorders</i>		
Anosmia	1	0
Parosmia	1	0
<i>Paraesthesias and dysaesthesias</i>		
Burning sensation	3	0
Hypoaesthesia	6	0
Paraesthesia	11	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Hemiparesis	1	0
Monoplegia	1	0
Paralysis	1	0
<i>Parkinson's disease and parkinsonism</i>		

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Nervous system disorders <small>Nervous system disorders cont'd</small>		
Freezing phenomenon	1	0
Seizures and seizure disorders NEC		
Convulsions local	1	0
Epilepsy	1	0
Seizure	3	0
Sensory abnormalities NEC		
Ageusia	2	0
Dysgeusia	3	0
Neuralgia	1	0
Sensory disturbance	1	0
Sleep disturbances NEC		
Poor quality sleep	1	0
Speech and language abnormalities		
Dysarthria	2	0
Transient cerebrovascular events		
Transient ischaemic attack	2	0
Tremor (excl congenital)		
Tremor	32	0
Nervous system disorders SOC TOTAL	361	0

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

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Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	1	0
<i>Anxiety symptoms</i>		
Anxiety	2	0
Nervousness	2	0
Stress	1	0
<i>Confusion and disorientation</i>		
Confusional state	9	0
Disorientation	5	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	4	0
<i>Emotional and mood disturbances NEC</i>		
Emotional disorder	1	0
Irritability	1	0
Mood altered	1	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	4	0
<i>Increased physical activity levels</i>		
Restlessness	1	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	1	0
<i>Panic attacks and disorders</i>		
Panic attack	1	0
<i>Perception disturbances NEC</i>		
Autoscopy	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	2	0
<i>Suicidal and self-injurious behaviour</i>		
Suicidal ideation	1	0
<i>Thinking disturbances</i>		
Bradyphrenia	1	0
Psychiatric disorders SOC TOTAL	39	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Dysuria	1	0
Urinary incontinence	2	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
Nephrotic syndrome	1	0
<i>Renal lithiasis</i>		
Nephrolithiasis	1	0
<i>Renal neoplasms</i>		
Renal cyst	1	0
<i>Urinary abnormalities</i>		
Haematuria	2	0
Urine odour abnormal	1	0
<i>Urinary tract signs and symptoms NEC</i>		
Renal pain	2	0
Renal & urinary disorders SOC TOTAL	11	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Breast signs and symptoms</i>		
Breast pain	1	0
<i>Menopausal effects NEC</i>		
Premature menopause	1	0
<i>Menopausal effects on the genitourinary tract</i>		
Postmenopausal haemorrhage	1	0
<i>Menstruation and uterine bleeding NEC</i>		
Menstruation irregular	1	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	1	0
<i>Menstruation with increased bleeding</i>		
Polymenorrhoea	1	0
Reproductive & breast disorders SOC TOTAL	6	0

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Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	24	1
Hypopnoea	1	0
<i>Bronchospasm and obstruction</i>		
Asthma	1	0
Chronic obstructive pulmonary disease	1	0
Wheezing	2	0
<i>Coughing and associated symptoms</i>		
Cough	7	0
Haemoptysis	1	0
Productive cough	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	1	0
<i>Nasal disorders NEC</i>		
Epistaxis	2	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	4	1
<i>Respiratory tract disorders NEC</i>		
Lung disorder	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Oropharyngeal pain	5	0
Rhinorrhoea	4	0
Yawning	1	0
Respiratory disorders SOC TOTAL	56	2

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Reaction Name	Total	Fatal
Skin disorders		
<i>Alopecias</i>		
Alopecia	2	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	5	0
Hyperhidrosis	16	0
Night sweats	2	0
<i>Bullous conditions</i>		
Blister	1	0
Blood blister	1	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	1	0
Scar pain	1	0
Sensitive skin	1	0
Skin burning sensation	1	0
Skin discolouration	1	0
Skin indentation	1	0
Skin reaction	1	0
Skin swelling	1	0
<i>Dermatitis and eczema</i>		
Dermatitis allergic	1	0
<i>Erythemas</i>		
Erythema	12	0
<i>Exfoliative conditions</i>		
Skin exfoliation	1	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	1	0
<i>Pruritus NEC</i>		
Pruritus	18	0
<i>Purpura and related conditions</i>		
Petechiae	1	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	25	0
Rash erythematous	3	0
Rash macular	1	0
Rash papular	1	0
Rash pruritic	8	0
Rash vesicular	1	0
<i>Urticarias</i>		
Urticaria	7	0
Skin disorders SOC TOTAL	115	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 29-Apr-2021

Data Lock Date: 28-Apr-2021 18:30:09

Earliest Reaction Date: 06-Feb-2020

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Social circumstances		
<i>Disability issues</i>		
Bedridden	1	0
Social circumstances SOC TOTAL	1	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 29-Apr-2021

Data Lock Date: 28-Apr-2021 18:30:09

Earliest Reaction Date: 06-Feb-2020

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Immunisations</i>		
COVID-19 immunisation	1	0
<i>Joint therapeutic procedures</i>		
Knee operation	1	0
Surgical & medical procedures SOC TOTAL	2	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine brand unspecified analysis print

Report Run Date: 29-Apr-2021

Data Lock Date: 28-Apr-2021 18:30:09

Earliest Reaction Date: 06-Feb-2020

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Vascular disorders		
<i>Aneurysms and dissections non-site specific</i>		
Aneurysm	1	0
<i>Aortic embolism and thrombosis</i>		
Aortic thrombosis	1	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	1	0
Shock	1	0
<i>Haemorrhages NEC</i>		
Haematoma	1	0
<i>Non-site specific embolism and thrombosis</i>		
Thrombosis	3	0
<i>Non-site specific vascular disorders NEC</i>		
Vascular pain	1	0
Vascular rupture	1	0
Vein discolouration	1	0
<i>Peripheral embolism and thrombosis</i>		
Deep vein thrombosis	5	0
Jugular vein thrombosis	1	0
<i>Peripheral vascular disorders NEC</i>		
Flushing	1	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	1	0
<i>Phlebitis NEC</i>		
Phlebitis	1	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	7	0
Vascular disorders SOC TOTAL	27	0
TOTAL REACTIONS FOR DRUG	1807	14
TOTAL REPORTS	574	
TOTAL FATAL OUTCOME REPORTS		14