

Case Series Drug Analysis Print

Name: FOI 24/307 All Yellow Card reports for COVID-19 Pfizer-BioNTech vaccine (Batch FH0114)

Report Run Date: 23-Apr-2024
Data Lock Date: 22-Apr-2024 18:30:03
Earliest Reaction Date: 22-Jan-2021
MedDRA Version: MedDRA 26.1

FOI 24/307 All Yellow Card reports for COVID-19 Pfizer-BioNTech vaccine (Batch FH0114): FOI 24/307 All UK spontaneous Yellow card reports for COVID-19 Pfizer-BioNTech vaccine (batch FH0114) received up until 15/04/2024

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Reaction Name	Total	Fatal
Blood disorders		
<i>Bleeding tendencies</i>		
Increased tendency to bruise	1	0
<i>Leukocytoses NEC</i>		
Neutrophilia	1	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	5	0
Lymphadenopathy	19	0
<i>Polycythaemia (excl rubra vera)</i>		
Polycythaemia	1	0
<i>Thrombocytopenias</i>		
Thrombocytopenia	1	0
Blood disorders SOC TOTAL	28	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac conduction disorders</i>		
Bundle branch block left	1	0
<i>Cardiac disorders NEC</i>		
Cardiac disorder	2	0
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	23	0
<i>Heart failures NEC</i>		
Cardiac failure congestive	1	1
<i>Ischaemic coronary artery disorders</i>		
Angina pectoris	1	0
Myocardial infarction	2	0
<i>Myocardial disorders NEC</i>		
Cardiomegaly	1	0
Left ventricular dysfunction	1	0
<i>Noninfectious myocarditis</i>		
Myocarditis	2	0
Myopericarditis	1	0
<i>Noninfectious pericarditis</i>		
Pericarditis	4	0
<i>Pericardial disorders NEC</i>		
Pericardial effusion	3	1
<i>Rate and rhythm disorders NEC</i>		
Bradycardia	1	0
Tachycardia	15	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	5	0
Atrial flutter	1	0
Supraventricular extrasystoles	1	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	2	1
Ventricular extrasystoles	1	0
Ventricular tachycardia	1	0
Cardiac disorders SOC TOTAL	69	3

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear pain	2	0
<i>Hearing losses</i>		
Deafness	1	0
Deafness bilateral	1	0
Deafness transitory	1	0
Hypoacusis	1	0
<i>Hyperacusia</i>		
Hyperacusis	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	12	0
Vertigo	4	0
Ear disorders SOC TOTAL	23	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	2	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Iritis	1	0
Uveitis	1	0
<i>Ocular disorders NEC</i>		
Eye swelling	3	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye allergy	1	0
Eye inflammation	1	0
Eye pruritus	1	0
Ocular hyperaemia	1	0
<i>Ocular sensation disorders</i>		
Asthenopia	1	0
Photophobia	3	0
<i>Refractive and accommodative disorders</i>		
Hypermetropia	1	0
<i>Retinal bleeding and vascular disorders (excl retinopathy)</i>		
Retinal vein occlusion	1	0
<i>Visual disorders NEC</i>		
Diplopia	1	0
Vision blurred	3	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	1	0
Visual impairment	3	0
Eye disorders SOC TOTAL	25	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Abdominal findings abnormal</i>		
Gastrointestinal sounds abnormal	1	0
<i>Colitis (excl infective)</i>		
Colitis	1	0
Colitis ulcerative	1	0
<i>Dental pain and sensation disorders</i>		
Toothache	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	13	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	3	0
Flatulence	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	4	0
Abdominal pain lower	2	0
Abdominal pain upper	8	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	2	0
<i>Nausea and vomiting symptoms</i>		
Nausea	35	0
Retching	1	0
Vomiting	15	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	4	0
<i>Oral soft tissue haemorrhages</i>		
Oral blood blister	1	0
<i>Oral soft tissue signs and symptoms</i>		
Hypoaesthesia oral	1	0
Lip pain	1	0
Paraesthesia oral	1	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	4	0
<i>Peptic ulcers and perforation</i>		
Peptic ulcer haemorrhage	1	0
<i>Tongue signs and symptoms</i>		
Glossodynia	4	0
Swollen tongue	3	0
Gastrointestinal disorders SOC TOTAL	109	0

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General disorders		
<i>Asthenic conditions</i>		
Asthenia	9	0
Chronic fatigue syndrome	1	0
Fatigue	81	0
Malaise	17	0
<i>Death and sudden death</i>		
Death	1	1
<i>Febrile disorders</i>		
Pyrexia	47	0
<i>Feelings and sensations NEC</i>		
Chills	24	0
Feeling abnormal	4	0
Feeling cold	4	0
Feeling drunk	1	0
Feeling hot	3	0
Feeling of body temperature change	2	0
Temperature intolerance	1	0
Thirst	2	0
<i>Gait disturbances</i>		
Gait inability	1	0
Loss of control of legs	1	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	2	0
Illness	11	0
Influenza like illness	9	0
Organ failure	1	0
Peripheral swelling	10	0
Swelling	15	0
Swelling face	4	0
<i>Inflammations</i>		
Inflammation	1	0
<i>Injection site reactions</i>		
Injection site mass	1	0
Injection site necrosis	1	0
Injection site pain	5	0
Injection site swelling	1	0
<i>Oedema NEC</i>		
Oedema	1	0
Oedema peripheral	1	0
<i>Pain and discomfort NEC</i>		
Axillary pain	6	0
Chest discomfort	7	0
Chest pain	33	0
Discomfort	3	0
Facial pain	1	0
Non-cardiac chest pain	1	0
Pain	37	0
Tenderness	4	0
<i>Therapeutic and nontherapeutic responses</i>		
Adverse drug reaction	1	0
Drug ineffective	3	0
Therapeutic response unexpected	1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
<i>Vaccination site reactions</i>		
Shoulder injury related to vaccine administration	1	0
Vaccination site bruising	1	0
Vaccination site discomfort	1	0
Vaccination site erythema	4	0
Vaccination site mass	1	0
Vaccination site pain	2	0
Vaccination site rash	1	0
Vaccination site swelling	3	0
Vaccination site warmth	1	0
<i>Withdrawal and rebound effects</i>		
Withdrawal syndrome	1	0
General disorders SOC TOTAL	375	1

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	1	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Liver injury	1	0
Hepatic disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Hypersensitivity	3	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to vaccine	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	1	0
Immune system disorders SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Appendicitis	1	0
Diverticulitis	1	0
<i>Coronavirus infections</i>		
COVID-19	21	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	1	0
<i>Herpes viral infections</i>		
Herpes zoster	9	0
Varicella zoster virus infection	1	0
<i>Influenza viral infections</i>		
Influenza	3	0
<i>Lower respiratory tract and lung infections</i>		
Lower respiratory tract infection	3	0
<i>Skin structures and soft tissue infections</i>		
Pustule	1	0
Subcutaneous abscess	1	0
<i>Upper respiratory tract infections</i>		
Nasopharyngitis	3	0
Rhinitis	1	0
<i>Urinary tract infections</i>		
Cystitis	1	0
Urinary tract infection	1	0
<i>Viral infections NEC</i>		
Sweating fever	1	0
Viral infection	1	0
Infections SOC TOTAL	50	0

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Reaction Name	Total	Fatal
Injuries		
<i>Cardiovascular injuries</i>		
Vascular injury	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Maternal exposure during breast feeding	3	0
Maternal exposure during pregnancy	2	0
<i>Medication errors, product use errors and issues NEC</i>		
Product use issue	1	0
<i>Muscle, tendon and ligament injuries</i>		
Muscle injury	1	0
<i>Non-site specific injuries NEC</i>		
Fall	1	0
<i>Off label uses</i>		
Off label use	5	0
<i>Product administration errors and issues</i>		
Product administered at inappropriate site	1	0
<i>Skin injuries NEC</i>		
Contusion	5	0
<i>Vaccination related complications</i>		
Immunisation reaction	1	0
Injuries SOC TOTAL	21	0

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Reaction Name	Total	Fatal
Investigations		
<i>Cardiac function diagnostic procedures</i>		
Ejection fraction decreased	1	0
<i>Central nervous system imaging procedures</i>		
Computerised tomogram head	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate	3	0
Heart rate abnormal	1	0
Heart rate increased	7	0
Heart rate irregular	4	0
<i>Hepatobiliary function diagnostic procedures</i>		
Liver function test abnormal	1	0
Liver function test increased	1	0
<i>Microbiology and serology tests NEC</i>		
Nasopharyngeal swab	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature	1	0
Body temperature increased	1	0
Grip strength decreased	1	0
Temperature difference of extremities	1	0
Weight increased	1	0
<i>Renal function analyses</i>		
Glomerular filtration rate decreased	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure abnormal	1	0
Blood pressure increased	2	0
<i>Virus identification and serology</i>		
SARS-CoV-2 test	1	0
Investigations SOC TOTAL	30	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	7	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	1	0
<i>Elevated cholesterol</i>		
Hypercholesterolaemia	1	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	1	0
<i>Metabolic disorders NEC</i>		
Hypercatabolism	1	0
Metabolic disorders SOC TOTAL	11	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	7	0
<i>Bone related signs and symptoms</i>		
Bone pain	1	0
Pain in jaw	1	0
Spinal pain	1	0
<i>Connective tissue disorders NEC</i>		
Polymyalgia rheumatica	1	0
<i>Joint related disorders NEC</i>		
Periarthritis	3	0
<i>Joint related signs and symptoms</i>		
Arthralgia	37	0
Joint stiffness	2	0
Joint swelling	2	0
<i>Muscle pains</i>		
Fibromyalgia	1	0
Myalgia	22	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle fatigue	2	0
Muscle spasms	1	0
Muscle twitching	1	0
<i>Muscle weakness conditions</i>		
Muscular weakness	2	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Mobility decreased	1	0
Musculoskeletal stiffness	6	0
<i>Musculoskeletal and connective tissue infections and inflammations NEC</i>		
Plantar fasciitis	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	2	0
Limb discomfort	3	0
Neck pain	3	0
Pain in extremity	50	0
<i>Rheumatoid arthropathies</i>		
Rheumatoid arthritis	1	0
<i>Soft tissue disorders NEC</i>		
Axillary mass	1	0
Groin pain	1	0
Neck mass	1	0
<i>Tendon disorders</i>		
Tendon pain	1	0
Muscle & tissue disorders SOC TOTAL	155	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>Renal neoplasms malignant</i>		
Clear cell renal cell carcinoma	1	0
Neoplasms SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Central nervous system aneurysms and dissections</i>		
Carotid artery dissection	1	0
Vertebrobasilar artery dissection	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebrovascular accident	1	0
Ischaemic stroke	1	0
Middle cerebral artery stroke	1	0
<i>Coordination and balance disturbances</i>		
Balance disorder	2	0
<i>Disturbances in consciousness NEC</i>		
Lethargy	3	0
Loss of consciousness	4	0
Somnolence	4	0
Syncope	16	0
<i>Dyskinesias and movement disorders NEC</i>		
Psychomotor hyperactivity	1	0
<i>Headaches NEC</i>		
Cluster headache	1	0
Cold-stimulus headache	1	0
Headache	75	0
Sinus headache	1	0
Tension headache	1	0
<i>Lumbar spinal cord and nerve root disorders</i>		
Sciatica	1	0
<i>Memory loss (excl dementia)</i>		
Amnesia	2	0
Memory impairment	1	0
<i>Migraine headaches</i>		
Migraine	11	0
Typical aura without headache	1	0
<i>Mononeuropathies</i>		
Carpal tunnel syndrome	1	0
Nerve compression	1	0
<i>Neurological signs and symptoms NEC</i>		
Brain fog	2	0
Dizziness	27	0
Dizziness postural	4	0
Neurological symptom	1	0
Presyncope	3	0
<i>Olfactory nerve disorders</i>		
Anosmia	3	0
Parosmia	3	0
<i>Paraesthesias and dysaesthesias</i>		
Burning sensation	5	0
Hyperaesthesia	1	0
Hypoaesthesia	7	0
Paraesthesia	13	0
<i>Seizures and seizure disorders NEC</i>		
Partial seizures	1	0
Seizure	4	0
<i>Sensory abnormalities NEC</i>		
Ageusia	5	0

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Nervous system disorders		
Nervous system disorders cont'd		
Dysgeusia	5	0
Neuralgia	3	0
<i>Speech and language abnormalities</i>		
Dysarthria	2	0
<i>Tremor (excl congenital)</i>		
Tremor	9	0
Nervous system disorders SOC TOTAL	230	0

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	1	0
Pregnancy conditions SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Affect alterations NEC</i>		
Constricted affect	1	0
<i>Anxiety symptoms</i>		
Anxiety	5	0
Nervousness	1	0
Stress	1	0
Tension	1	0
<i>Confusion and disorientation</i>		
Disorientation	3	0
<i>Depressive disorders</i>		
Depression	1	0
Major depression	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	11	0
Middle insomnia	3	0
<i>Dyssomnias</i>		
Poor quality sleep	1	0
<i>Mood disorders NEC</i>		
Listless	1	0
<i>Parasomnias</i>		
Nightmare	1	0
Psychiatric disorders SOC TOTAL	31	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Pollakiuria	1	0
Urinary incontinence	1	0
Renal & urinary disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Breast signs and symptoms</i>		
Breast pain	1	0
Breast tenderness	1	0
<i>Erection and ejaculation conditions and disorders</i>		
Organic erectile dysfunction	1	0
<i>Menstruation and uterine bleeding NEC</i>		
Dysmenorrhoea	4	0
Menstrual discomfort	1	0
Menstrual disorder	4	0
Menstruation irregular	5	0
Premenstrual syndrome	1	0
<i>Menstruation with decreased bleeding</i>		
Hypomenorrhoea	1	0
Menstruation delayed	6	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	10	0
Polymenorrhoea	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Genital rash	1	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular swelling	1	0
<i>Uterine tone disorders</i>		
Uterine spasm	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	2	0
Reproductive & breast disorders SOC TOTAL	41	0

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Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	34	0
Hypopnoea	1	0
<i>Bronchospasm and obstruction</i>		
Asthma	2	0
Wheezing	1	0
<i>Coughing and associated symptoms</i>		
Cough	6	0
Productive cough	1	0
<i>Nasal disorders NEC</i>		
Epistaxis	4	0
Nasal dryness	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal swelling	3	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	1	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	4	0
<i>Respiratory signs and symptoms NEC</i>		
Painful respiration	1	0
<i>Tracheal disorders (excl infections and neoplasms)</i>		
Tracheal pain	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Catarrh	1	0
Choking	2	0
Oropharyngeal discomfort	1	0
Oropharyngeal pain	7	0
Sneezing	2	0
Throat irritation	1	0
Throat tightness	1	0
Respiratory disorders SOC TOTAL	75	0

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	3	0
Acne cystic	1	0
<i>Alopecias</i>		
Alopecia	4	0
Madarosis	1	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	3	0
Hyperhidrosis	7	0
Night sweats	7	0
<i>Bullous conditions</i>		
Blood blister	1	0
Erythema multiforme	1	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	3	0
Skin discolouration	2	0
Skin reaction	1	0
Skin warm	1	0
Target skin lesion	1	0
<i>Dermatitis and eczema</i>		
Dermatitis allergic	2	0
Eczema	4	0
Skin irritation	2	0
<i>Erythemas</i>		
Erythema	8	0
<i>Pruritus NEC</i>		
Pruritus	20	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	27	0
Rash erythematous	3	0
Rash macular	1	0
Rash papular	1	0
Rash pruritic	6	0
Rash vesicular	1	0
<i>Skin haemorrhages</i>		
Haemorrhage subcutaneous	1	0
<i>Skin injuries and mechanical dermatoses</i>		
Needle track marks	1	0
<i>Urticarias</i>		
Urticaria	9	0
Skin disorders SOC TOTAL	122	0

Case Series Drug Analysis Print

Name: FOI 24/307 All Yellow Card reports for COVID-19 Pfizer-BioNTech vaccine (Batch FH0114)

Report Run Date: 23-Apr-2024

Data Lock Date: 22-Apr-2024 18:30:03

Earliest Reaction Date: 22-Jan-2021

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Gastrointestinal therapeutic procedures NEC</i>		
Prophylaxis of nausea and vomiting	1	0
<i>Immunisations</i>		
Immunisation	6	0
<i>Limb therapeutic procedures</i>		
Limb immobilisation	1	0
<i>Therapeutic procedures NEC</i>		
Interchange of vaccine products	3	0
Surgical & medical procedures SOC TOTAL	11	0

Case Series Drug Analysis Print

Name: FOI 24/307 All Yellow Card reports for COVID-19 Pfizer-BioNTech vaccine (Batch FH0114)

Report Run Date: 23-Apr-2024
Earliest Reaction Date: 22-Jan-2021

Data Lock Date: 22-Apr-2024 18:30:03
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Vascular disorders		
<i>Arterial infections and inflammations</i>		
Giant cell arteritis	2	0
<i>Haemorrhages NEC</i>		
Haematoma	1	0
Haemorrhage	2	0
<i>Lymphoedemas</i>		
Lymphoedema	2	0
<i>Non-site specific embolism and thrombosis</i>		
Thrombosis	2	0
<i>Non-site specific vascular disorders NEC</i>		
Vascular pain	1	0
Vasodilatation	1	0
<i>Peripheral embolism and thrombosis</i>		
Deep vein thrombosis	1	0
Superficial vein thrombosis	1	0
Thrombophlebitis	1	0
<i>Peripheral vascular disorders NEC</i>		
Hot flush	2	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	1	0
Poor peripheral circulation	1	0
Raynaud's phenomenon	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	1	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	3	0
<i>Vascular hypotensive disorders</i>		
Hypotension	2	0
Vascular disorders SOC TOTAL	25	0
TOTAL REACTIONS FOR DRUG	1442	4
TOTAL REPORTS	488	
TOTAL FATAL OUTCOME REPORTS		4