FOI 22-817 COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 04-Aug-2022

Data Lock Date: 27-Jul-2022 18:30:04

All suspected spontaneous reports from Isle of Man received up to and including 27/07/2022 for the COVID-19 AstraZeneca vaccine.

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.

Name: FOI 22 817COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 04-Aug-2022 Data Lock Date: 27-Jul-2022 18:30:04
Earliest Reaction Date: 21-Mar-2020 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Blood disorders		
Coagulopathies		
Antiphospholipid syndrome	1	0
Lymphatic system disorders NEC		
Lymph node pain	2	0
Lymphadenopathy	14	0
Polycythaemia (excl rubra vera)		
Stress polycythaemia	1	0
Thrombocytopenias		
Thrombocytopenia	2	0
Blood disorders SOC TOTAL	20	0

Name: FOI 22 817COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 04-Aug-2022 Data Lock Date: 27-Jul-2022 18:30:04
Earliest Reaction Date: 21-Mar-2020 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Cardiac disorders		
Cardiac signs and symptoms NEC		
Palpitations	13	0
Ischaemic coronary artery disorders		
Angina pectoris	3	0
Myocardial infarction	1	0
Noninfectious myocarditis		
Myocarditis	1	0
Rate and rhythm disorders NEC		
Extrasystoles	1	0
Tachycardia	2	0
Supraventricular arrhythmias		
Atrial fibrillation	2	0
Ventricular arrhythmias and cardiac arrest		
Cardiac arrest	1	0
Cardiac disorders SOC TOTAL	24	0

Name: FOI 22 817COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 04-Aug-2022 Data Lock Date: 27-Jul-2022 18:30:04
Earliest Reaction Date: 21-Mar-2020 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Ear disorders		
Ear disorders NEC		
Ear pain	7	0
Hyperacusia		
Hyperacusis	3	0
Inner ear signs and symptoms		
Tinnitus	8	0
Vertigo	10	0
Vertigo positional	1	0
Ear disorders SOC TOTAL	29	0

Name: FOI 22 817COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 04-Aug-2022 Data Lock Date: 27-Jul-2022 18:30:04
Earliest Reaction Date: 21-Mar-2020 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Endocrine disorders		
Adrenal gland disorders NEC		
Haemorrhagic adrenal infarction	1	0
Endocrine disorders SOC TOTAL	1	l o

Name: FOI 22 817COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 04-Aug-2022 Data Lock Date: 27-Jul-2022 18:30:04
Earliest Reaction Date: 21-Mar-2020 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Eye disorders		
Choroid and vitreous structural change, deposit and degeneration		
Vitreous floaters	1	0
Eyelid movement disorders		
Eyelid ptosis	1	0
Iris and uveal tract infections, irritations and inflammations		
Iritis	1	0
Lid, lash and lacrimal structural disorders		
Eyelid skin dryness	1	0
Ocular disorders NEC		
Eye pain	11	0
Ocular infections, inflammations and associated manifestations		
Eye pruritus	2	0
Ocular sensation disorders		
Asthenopia	2	0
Photophobia	3	0
Visual disorders NEC		
Diplopia	1	0
Dysmetropsia	1	0
Photopsia	2	0
Vision blurred	8	0
Visual impairment and blindness (excl colour blindness)		
Blindness	2	0
Visual impairment	3	0
Eve disorders SOC TOTAL	39	0

Name: FOI 22 817COVID-19 AstraZeneca Vaccine Analysis Print

Earliest Reaction Date: 21-Mar-2020 MedDRA Version: MedDRA 25.0		
Reaction Name	Total	Fatal
Gastrointestinal disorders		
Abdominal findings abnormal		
Gastrointestinal sounds abnormal	1	0
Colitis (excl infective)		
Crohn's disease	1	0
Inflammatory bowel disease	1	0
Dental pain and sensation disorders		
Dental discomfort	1	0
Hyperaesthesia teeth	1	0
Toothache	2	0
Diarrhoea (excl infective)		
Diarrhoea	29	0
Dyspeptic signs and symptoms		
Dyspepsia	2	0
Eructation	1	0
Faecal abnormalities NEC		
Faeces hard	1	0
Flatulence, bloating and distension		
Abdominal distension	1	0
Flatulence	2	0
Gastrointestinal and abdominal pains (excl oral and throat)		
Abdominal pain	14	0
Abdominal pain lower	2	0
Abdominal pain upper	12	0
Oesophageal pain	1	0
Gastrointestinal atonic and hypomotility disorders NEC		
Constipation	1	0
Intestinal dilatation	1	0
Gastrointestinal dyskinetic disorders		
Bowel movement irregularity	1	0
Change of bowel habit	1	0
Dyschezia	1	0
Gastrointestinal signs and symptoms NEC		
Abdominal discomfort	2	0
Dysphagia	2	0
Gastrointestinal vascular occlusion and infarction		
Intestinal ischaemia	1	0
Mesenteric arterial occlusion	1	0
Mesenteric artery thrombosis	1	0
Visceral venous thrombosis	1	0
Intestinal haemorrhages		
Rectal haemorrhage	1	0
Nausea and vomiting symptoms		
Nausea	100	
Retching	1	0
Vomiting	33	0
Oral dryness and saliva altered		
Dry mouth	2	0
Lip dry	1	0
Salivary hypersecretion	1	0
Oral soft tissue disorders NEC		
Chapped lips	2	0
Oral soft tissue signs and symptoms		
Hypoaesthesia oral	4	l ol

Name: FOI 22 817COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 04-Aug-2022 Data Lock Date: 27-Jul-2022 18:30:04
Earliest Reaction Date: 21-Mar-2020 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Gastrointestinal disorders cont'd		
Paraesthesia oral	4	0
Oral soft tissue swelling and oedema		
Lip swelling	2	2 0
Stomatitis and ulceration		
Aphthous ulcer	1	0
Mouth ulceration	1	0
Tongue signs and symptoms		
Glossodynia	2	0
Swollen tongue	3	0
Tongue coated	1	0
Tongue discolouration	1	0
Tongue spasm	1	0
Gastrointestinal disorders SOC TOTAL	246	0

Name: FOI 22 817COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 04-Aug-2022 Data Lock Date: 27-Jul-2022 18:30:04
Earliest Reaction Date: 21-Mar-2020 MedDRA Version: MedDRA 25.0

Earliest Reaction Date: 21-Mar-2020	MedDRA Version: MedDRA 25.0		
Reaction Name		<u>Total</u>	<u>Fatal</u>
General disorders			
Asthenic conditions			
Asthenia		18	0
Fatigue		140	0
Malaise		28	0
Complications associated with device NEC			
Medical device site joint pain		1	0
Febrile disorders			
Pyrexia		125	0
Feelings and sensations NEC			
Chills		107	0
Feeling abnormal		7	0
Feeling cold		15	0
Feeling hot		7	0
Feeling of body temperature change		4	0
Hangover			0
Hunger		2	0
Temperature intolerance		1	0
Thirst		5	0
Gait disturbances		٦	U
Gait disturbance		2	0
Loss of control of legs		1	0
General signs and symptoms NEC		1	U
Illness		6	0
Influenza like illness		39	0
Local reaction		1	0
Peripheral swelling		21	0
Swelling		7	0
Swelling face		1	0
Inflammations			U
Inflammation		5	0
Injection site reactions		,	U
Injection site erythema		2	0
Injection site extravasation		1	0
Injection site mass		2	0
Injection site mass Injection site pain		16	0
		10	0
Injection site rash Injection site scab		1	0
Mass conditions NEC		I	U
Mass Conditions NEC		1	0
Oedema NEC		I	U
Oedema peripheral		2	0
Pain and discomfort NEC			U
Axillary pain		1	0
Chest discomfort		2	0
Chest pain		19	0
Discomfort		5	0
Pain		41	
Tenderness		2	0
		2	U
Therapeutic and nontherapeutic responses		2	0
Drug ineffective		2	0
Vaccination site reactions		2	0
Vaccination site erythema		3	0
Vaccination site hypoaesthesia		1	0

Name: FOI 22 817COVID-19 AstraZeneca Vaccine Analysis Print

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site mass	1	0
Vaccination site movement impairment	2	0
Vaccination site pain	1	0
Vaccination site swelling	1	0
Vaccination site warmth	2	0
General disorders SOC TOTAL	653	0

Name: FOI 22 817COVID-19 AstraZeneca Vaccine Analysis Print

Reaction Name	Total	Fatal
Hepatic disorders		
Hepatic and hepatobiliary disorders NEC		
Liver disorder	1	0
Hepatocellular damage and hepatitis NEC		
Hepatitis acute	1	0
Obstructive bile duct disorders (excl neoplasms)		
Sphincter of Oddi dysfunction	2	0
Hepatic disorders SOC TOTAL	4	0

Name: FOI 22 817COVID-19 AstraZeneca Vaccine Analysis Print

Reaction Name	Total	Fatal
Immune system disorders		
Allergic conditions NEC		
Allergic oedema	1	0
Hypersensitivity	2	0
Anaphylactic and anaphylactoid responses		
Anaphylactic reaction	3	0
Atopic disorders		
Seasonal allergy	1	0
Immune and associated conditions NEC		
Bacille Calmette-Guerin scar reactivation	1	0
Sensitisation	1	0
Immune system disorders SOC TOTAL	9	0

Name: FOI 22 817COVID-19 AstraZeneca Vaccine Analysis Print

Reaction Name	<u>Total</u>	Fatal
Infections		
Bacterial infections NEC		
Bacterial infection	1	0
Candida infections		
Vulvovaginal candidiasis	1	0
Coronavirus infections		
COVID-19	2	0
Suspected COVID-19	1	0
Coxiella infections		
Q fever	1	0
Herpes viral infections		
Herpes zoster	4	· 0
Oral herpes	2	0
Infections NEC		
Infection	5	5 O
Vaccination site infection	1	0
Influenza viral infections		
Influenza	35	0
Lower respiratory tract and lung infections		
Pneumonia	2	2 0
Retroviral infections		
HIV infection	1	0
Sepsis, bacteraemia, viraemia and fungaemia	NEC	
Sepsis	1	0
Upper respiratory tract infections		
Nasopharyngitis	9	
Pharyngitis		0
Sinusitis	1	0
Urinary tract infections		
Urinary tract infection	1	0
Viral infections NEC		
Sweating fever		0
Viral infection	1	0
Infections SOC TOTAL	74	ll o

Name: FOI 22 817COVID-19 AstraZeneca Vaccine Analysis Print

Reaction Name	Total	Fatal
Injuries		
Exposures associated with pregnancy, delivery and lactation		
Maternal exposure during breast feeding	6	0
Medication errors, product use errors and issues NEC		
Inadequate aseptic technique in use of product	1	0
Muscle, tendon and ligament injuries		
Muscle rupture	1	0
Non-site specific procedural complications		
Injection related reaction	4	0
Overdoses NEC		
Intentional overdose	1	0
Product prescribing errors and issues		
Contraindicated product prescribed	1	0
Site specific injuries NEC		
Limb injury	1	0
Skin injuries NEC		
Contusion	4	0
Injuries SOC TOTAL	19	0

Name: FOI 22 817COVID-19 AstraZeneca Vaccine Analysis Print

Reaction Name	Total	Fatal
Investigations		
Central nervous system imaging procedures		
Magnetic resonance imaging head	1	0
Heart rate and pulse investigations		
Heart rate	3	0
Heart rate irregular	1	0
Mineral and electrolyte analyses		
Blood iron decreased	1	0
Blood iron increased	1	0
Physical examination procedures and organ system status		
Body temperature	4	0
Body temperature decreased	2	0
Body temperature fluctuation	1	0
Body temperature increased	7	0
Pituitary analyses anterior		
Blood thyroid stimulating hormone increased	1	0
Urinalysis NEC		
Crystal urine	1	0
Vascular tests NEC (incl blood pressure)		
Blood pressure increased	1	0
White blood cell analyses		
White blood cell count	1	0
Investigations SOC TOTAL	25	0

Name: FOI 22 817COVID-19 AstraZeneca Vaccine Analysis Print

Reaction Name	Total	Fatal
Metabolic disorders		
Appetite disorders		
Decreased appetite	13	0
Total fluid volume decreased		
Dehydration	4	0
Total fluid volume increased		
Fluid retention	1	0
Metabolic disorders SOC TOTAL	18	0

Name: FOI 22 817COVID-19 AstraZeneca Vaccine Analysis Print

Poostion Name	Total	Fatal
Reaction Name	Tolai	ralai
Muscle & tissue disorders		
Arthropathies NEC	2	0
Arthritis Remarking AVEC	2	0
Bone disorders NEC	ا	0
Medial tibial stress syndrome	1	0
Bone related signs and symptoms		0
Bone pain	4	0
Cartilage disorders		0
Costochondritis	1	0
Joint related disorders NEC		0
Periarthritis	1	0
Temporomandibular joint syndrome	1	0
Joint related signs and symptoms	0.5	
Arthralgia	65	0
Joint stiffness	2	0
Joint swelling	6	0
Muscle pains		
Fibromyalgia	1	0
Myalgia	62	0
Muscle related signs and symptoms NEC	_	_
Muscle fatigue	5	0
Muscle spasms	11	0
Muscle tightness	1	0
Muscle twitching	1	0
Muscle weakness conditions		
Muscular weakness	6	0
Musculoskeletal and connective tissue conditions NEC	_	
Mobility decreased	2	0
Musculoskeletal stiffness	10	0
Musculoskeletal and connective tissue pain and discomfort		
Back pain	12	0
Limb discomfort	10	0
Musculoskeletal chest pain	1	0
Musculoskeletal discomfort	1	0
Neck pain	11	0
Pain in extremity	70	0
Rheumatoid arthropathies		
Rheumatoid arthritis	1	0
Tendon disorders		
Tendon pain	1	0
Tendonitis	2	0
Tenosynovitis	1	0
Muscle & tissue disorders SOC TOTAL	292	0

Name: FOI 22 817COVID-19 AstraZeneca Vaccine Analysis Print

Reaction Name	Total	Fatal
Neoplasms		
Breast and nipple neoplasms malignant		
Breast cancer	1	0
Neoplasms SOC TOTAL	1	0

Name: FOI 22 817COVID-19 AstraZeneca Vaccine Analysis Print

Earliest Reaction Date: 21-Mar-2020 MedDRA Version: MedDRA 25.0		
Reaction Name	Total	<u>Fatal</u>
Nervous system disorders		
Abnormal reflexes		
Areflexia	1	0
Acute polyneuropathies		
Guillain-Barre syndrome	1	0
Central nervous system haemorrhages and cerebrovascular accidents		
Cerebrovascular accident	4	1
Coordination and balance disturbances		
Balance disorder	1	0
Dysstasia	1	0
Cortical dysfunction NEC		
Aphasia	1	0
Disturbances in consciousness NEC		
Lethargy	11	0
Loss of consciousness	4	0
Somnolence	4	0
Syncope	8	0
Dyskinesias and movement disorders NEC		
Movement disorder	1	0
Facial cranial nerve disorders		
Bell's palsy	3	0
Headaches NEC		
Cluster headache	1	0
Headache	235	0
Sinus headache	2	0
Tension headache	7	0
Thunderclap headache	1	0
Memory loss (excl dementia)		
Memory impairment	2	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	1	0
Disturbance in attention	3	0
Migraine headaches		
Migraine	23	0
Migraine without aura	1	0
Multiple sclerosis acute and progressive		
Multiple sclerosis	1	0
Neurological signs and symptoms NEC		
Dizziness	64	0
Dizziness postural	4	0
Head discomfort	1	0
Neurological symptom	2 2	0
Presyncope	2	0
Paraesthesias and dysaesthesias		
Burning sensation	4	0
Hypoaesthesia	17	0
Paraesthesia	27	0
Parkinson's disease and parkinsonism		
Freezing phenomenon	1	0
Seizures and seizure disorders NEC		
Epilepsy	2	0
Sensory abnormalities NEC		
Ageusia	1	0
Dysgeusia	5	0

Name: FOI 22 817COVID-19 AstraZeneca Vaccine Analysis Print

Reaction Name	Total	Fatal
Nervous system disorders us system disorders cont'd		
Neuralgia	1	0
Taste disorder	5	0
Speech and language abnormalities		
Dysarthria	1	0
Transient cerebrovascular events		
Transient ischaemic attack	5	0
Tremor (excl congenital)		
Tremor	34	0
Trigeminal disorders		
Trigeminal neuralgia	1	0
Nervous system disorders SOC TOTAL	494	1

Name: FOI 22 817COVID-19 AstraZeneca Vaccine Analysis Print

Reaction Name	<u>Total</u>	Fatal
Device malfunction events NEC		
Thrombosis in device	2	<u>2</u> 0
null SOC TOTAL	2	2l ol

Name: FOI 22 817COVID-19 AstraZeneca Vaccine Analysis Print

Reaction Name	Total	Fatal
Psychiatric disorders	l	, atai
Anxiety symptoms		
Agitation	1	0
Anxiety	6	0
Stress	2	0
Cognitive and attention disorders and disturbances NEC		
Mental fatigue	2	0
Confusion and disorientation		
Confusional state	3	0
Disorientation	1	0
Deliria		
Delirium	2	0
Depressive disorders		
Depression	3	0
Disturbances in initiating and maintaining sleep		
Insomnia	8	0
Dyssomnias		
Poor quality sleep	4	0
Emotional and mood disturbances NEC		
Anger	1	0
Irritability	2	0
Fear symptoms and phobic disorders (incl social phobia)		
Fear	1	0
Hallucinations (excl sleep-related)		
Hallucination, visual	1	0
Increased physical activity levels		
Restlessness	1	0
Mood alterations with depressive symptoms		
Depressed mood	1	0
Tearfulness	1	0
Mood disorders NEC		
Listless	1	0
Parasomnias		
Abnormal dreams	2	0
Nightmare	3	0
Somatic symptom disorders		
Habit cough	1	0
Stress disorders		
Catastrophic reaction	1	0
Psychiatric disorders SOC TOTAL	48	0

Name: FOI 22 817COVID-19 AstraZeneca Vaccine Analysis Print

Reaction Name	Total	Fatal
Renal & urinary disorders		
Bladder and urethral symptoms		
Dysuria	1	0
Pollakiuria	2	0
Urinary incontinence	1	0
Bladder neoplasms		
Bladder cyst	1	0
Renal failure and impairment		
Acute kidney injury	1	0
Renal & urinary disorders SOC TOTAL	6	0

Name: FOI 22 817COVID-19 AstraZeneca Vaccine Analysis Print

Reaction Name	Total	Fatal
Reproductive & breast disorders		
Breast signs and symptoms		
Breast pain	3	0
Breast tenderness	1	0
Erection and ejaculation conditions and disorders		
Erectile dysfunction	1	0
Organic erectile dysfunction	1	0
Menopausal effects NEC		
Menopausal symptoms	1	0
Menstruation and uterine bleeding NEC		
Dysmenorrhoea	1	0
Intermenstrual bleeding	1	0
Menstrual disorder	3	0
Menstruation irregular	5	0
Menstruation with decreased bleeding		
Amenorrhoea	2	0
Hypomenorrhoea	1	0
Menstruation delayed	5	0
Menstruation with increased bleeding		
Heavy menstrual bleeding	10	0
Menometrorrhagia	1	0
Polymenorrhoea	1	0
Ovarian and fallopian tube cysts and neoplasms		
Polycystic ovaries	1	0
Ovarian and fallopian tube disorders NEC		
Ovulation pain	1	0
Pelvis and broad ligament disorders NEC		
Adnexa uteri pain	1	0
Scrotal disorders NEC		
Scrotal pain	1	0
Vulvovaginal disorders NEC		
Vaginal haemorrhage	1	0
Vulvovaginal signs and symptoms		
Vulvovaginal burning sensation	1	0
Reproductive & breast disorders SOC TOTAL	43	0

Name: FOI 22 817COVID-19 AstraZeneca Vaccine Analysis Print

Reaction Name	Total	Fatal
Respiratory disorders		
Breathing abnormalities		
Dyspnoea	22	0
Hypopnoea	1	0
Bronchospasm and obstruction		
Bronchospasm	1	0
Wheezing	2	0
Coughing and associated symptoms		
Cough	8	0
Nasal disorders NEC		
Epistaxis	7	0
Parenchymal lung disorders NEC		
Atelectasis	1	0
Pharyngeal disorders (excl infections and neoplasms)		
Tonsillar hypertrophy	1	0
Pneumothorax and pleural effusions NEC		
Pleural effusion	1	0
Pulmonary thrombotic and embolic conditions		
Pulmonary embolism	5	0
Upper respiratory tract signs and symptoms		
Catarrh	1	0
Dry throat	1	0
Dysphonia	1	0
Oropharyngeal pain	9	0
Rhinorrhoea	2	0
Sinus pain	2	0
Sneezing	1	0
Throat irritation	2	0
Respiratory disorders SOC TOTAL	68	0

Name: FOI 22 817COVID-19 AstraZeneca Vaccine Analysis Print

Reaction Name	MedDRA Version: MedDRA 25.0 Tot		Fatal
Skin disorders			Гацаі
Angioedemas			
Angioedema		1	0
Angioedema Apocrine and eccrine gland disorders		- '	U
Cold sweat		3	0
Hyperhidrosis		27	0
Miliaria		1	0
Night sweats		4	0
Bullous conditions		- 4	U
Blister		3	0
Erythema multiforme		1	0
Dermal and epidermal conditions NEC		- '	U
Pain of skin		2	0
Papule		1	0
Skin burning sensation		2	0
Skin odour abnormal		1	0
Skin reaction		1	0
Skin warm		3	0
Dermatitis and eczema		Ĭ	
Dermatitis allergic		3	0
Eczema		1	0
Erythemas			
Erythema		9	0
Exfoliative conditions		Ĭ	J
Skin exfoliation		1	0
Pruritus NEC			Ū
Pruritus		26	0
Purpura and related conditions			
Purpura		1	0
Rashes, eruptions and exanthems NEC			
Rash		27	0
Rash erythematous		3	0
Rash macular		4	0
Rash pruritic		2	0
Rash vesicular		1	0
Rosaceas			
Rosacea		1	0
Skin haemorrhages			
Haemorrhage subcutaneous		1	0
Skin vasomotor conditions			
Livedo reticularis		1	0
Urticarias			
Urticaria		6	0
Skin disorders SOC TOTAL		137	0

Name: FOI 22 817COVID-19 AstraZeneca Vaccine Analysis Print

Reaction Name	Total	Fatal
Surgical & medical procedures		
Immunisations		
COVID-19 immunisation	1	0
Immunisation	3	0
Therapeutic procedures NEC		
Catheter management	1	0
Vascular therapeutic procedures NEC		
Clamping of blood vessel	1	0
Surgical & medical procedures SOC TOTAL	6	0

Name: FOI 22 817COVID-19 AstraZeneca Vaccine Analysis Print

Reaction Name	Total	Fatal
Vascular disorders		
Aortic infections and inflammations		
Aortitis	1	0
Arterial infections and inflammations		
Arteritis	1	0
Circulatory collapse and shock		
Circulatory collapse	2	0
Haemorrhages NEC		
Haematoma	1	0
Haemorrhage	4	0
Non-site specific embolism and thrombosis		
Thrombosis	5	0
Non-site specific vascular disorders NEC		
Vascular pain	1	0
Peripheral embolism and thrombosis		
Blue toe syndrome	1	0
Deep vein thrombosis	4	0
Peripheral vascular disorders NEC		
Cyanosis	1	0
Flushing	1	0
Hot flush	14	0
Peripheral vasoconstriction, necrosis and vascular insufficiency		
Peripheral coldness	7	0
Raynaud's phenomenon	1	0
Vasculitides NEC		
Vasculitis	2	0
Vascular disorders SOC TOTAL	46	
TOTAL REACTIONS FOR DRUG	2304	1
TOTAL REPORTS	627	
TOTAL FATAL OUTCOME REPORTS		1