

Case Series Drug Analysis Print

Name: FOI 21/590 - Hepatitis A Vaccine

Report Run Date: 29-Jun-2021

Data Lock Date: 08-Apr-2021 19:00:04

Earliest Reaction Date: 03-Oct-1994

MedDRA Version: MedDRA 23.1

FOI 21/590 - Hepatitis A Vaccine: All UK suspected, spontaneous adverse drug reactions reports associated with the Hepatitis A vaccine until 08/04/2021

Case Series Drug Analysis Print

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Data Lock Date: 08-Apr-2021 19:00:04
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Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemias NEC</i>		
Anaemia	1	0
<i>Bleeding tendencies</i>		
Haemorrhagic disorder	1	0
<i>Leukocytoses NEC</i>		
Leukocytosis	1	0
<i>Lymphatic system disorders NEC</i>		
Lymphadenopathy	4	0
<i>Marrow depression and hypoplastic anaemias</i>		
Aplastic anaemia	1	1
Pancytopenia	1	0
<i>Neutropenias</i>		
Neutropenia	2	0
<i>Spleen disorders</i>		
Splenomegaly	1	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	2	0
Blood disorders SOC TOTAL	14	1

Case Series Drug Analysis Print

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Data Lock Date: 08-Apr-2021 19:00:04
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac disorders NEC</i>		
Cardiac disorder	1	0
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	1	0
<i>Rate and rhythm disorders NEC</i>		
Bradycardia	1	0
Tachycardia	3	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	1	0
Cardiac disorders SOC TOTAL	7	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Congenital disorders		
<i>Cardiac septal defects congenital</i>		
Atrial septal defect	1	0
<i>Congenital disorders NEC</i>		
Congenital anomaly	1	0
<i>Musculoskeletal and connective tissue disorders of limbs congenital</i>		
Syndactyly	1	0
Talipes	1	0
<i>Renal and urinary tract disorders congenital NEC</i>		
Urinary tract malformation	1	0
<i>Renal disorders congenital</i>		
Kidney malformation	1	0
Congenital disorders SOC TOTAL	6	0

Case Series Drug Analysis Print

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Data Lock Date: 08-Apr-2021 19:00:04
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear pain	1	0
<i>Hearing losses</i>		
Deafness neurosensory	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	1	0
Vertigo	4	0
Ear disorders SOC TOTAL	7	0

Case Series Drug Analysis Print

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Data Lock Date: 08-Apr-2021 19:00:04
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Eye disorders		
<i>Ocular infections, inflammations and associated manifestations</i>		
Ocular hyperaemia	1	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	5	0
<i>Pupil disorders</i>		
Mydriasis	1	0
<i>Visual disorders NEC</i>		
Diplopia	1	0
Vision blurred	4	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	1	0
Eye disorders SOC TOTAL	13	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Colitis (excl infective)</i>		
Colitis ulcerative	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	13	0
<i>Dyspeptic signs and symptoms</i>		
Eructation	1	0
<i>Faecal abnormalities NEC</i>		
Faeces pale	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	7	0
Abdominal pain lower	1	0
Abdominal pain upper	4	0
Abdominal rigidity	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Gastric dilatation	1	0
Gastrooesophageal reflux disease	1	0
<i>Gastrointestinal disorders NEC</i>		
Gastric disorder	1	0
Gastrointestinal disorder	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	1	0
Dysphagia	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	28	0
Vomiting	14	0
Vomiting projectile	1	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematochezia	1	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	2	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	2	0
<i>Tongue signs and symptoms</i>		
Swollen tongue	1	0
Gastrointestinal disorders SOC TOTAL	85	0

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site swelling	1	0
<i>Asthenic conditions</i>		
Asthenia	7	0
Chronic fatigue syndrome	3	0
Fatigue	24	0
Malaise	26	0
<i>Febrile disorders</i>		
Pyrexia	35	0
<i>Feelings and sensations NEC</i>		
Chills	9	0
Feeling abnormal	2	0
Feeling cold	1	0
Feeling hot	4	0
Feeling of body temperature change	1	0
<i>Gait disturbances</i>		
Gait disturbance	2	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	2	0
Illness	1	0
Influenza like illness	12	0
Local reaction	3	0
Peripheral swelling	4	0
Swelling	2	0
Swelling face	5	0
<i>Inflammations</i>		
Inflammation	1	0
<i>Injection site reactions</i>		
Injection site bruising	1	0
Injection site erythema	1	0
Injection site inflammation	1	0
Injection site pain	4	0
Injection site pruritus	1	0
Injection site rash	1	0
Injection site reaction	3	0
<i>Mass conditions NEC</i>		
Cyst	1	0
<i>Pain and discomfort NEC</i>		
Chest discomfort	1	0
Chest pain	3	0
Pain	8	0
Tenderness	1	0
<i>Vaccination site reactions</i>		
Vaccination site erythema	2	0
Vaccination site induration	1	0
Vaccination site pain	2	0
Vaccination site swelling	1	0
General disorders SOC TOTAL	177	0

Case Series Drug Analysis Print

Name: FOI 21/590 - Hepatitis A Vaccine

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 Earliest Reaction Date: 03-Oct-1994

Data Lock Date: 08-Apr-2021 19:00:04
 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Hepatic disorders		
<i>Cholecystitis and cholelithiasis</i>		
Cholelithiasis	1	0
<i>Cholestasis and jaundice</i>		
Hepatitis cholestatic	1	0
Jaundice	7	0
<i>Hepatic enzymes and function abnormalities</i>		
Hepatic function abnormal	1	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Autoimmune hepatitis	2	0
Hepatitis	2	0
Hepatitis acute	1	0
Hepatic disorders SOC TOTAL	15	0

Case Series Drug Analysis Print

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Data Lock Date: 08-Apr-2021 19:00:04
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Hypersensitivity	3	0
Serum sickness	1	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Milk allergy	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	5	0
Immune system disorders SOC TOTAL	10	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Gastroenteritis	1	0
<i>Arenaviral infections</i>		
Choriomeningitis lymphocytic	1	0
<i>Bacterial infections NEC</i>		
Cellulitis	1	0
<i>Central nervous system and spinal infections</i>		
Encephalitis	1	0
Meningitis aseptic	1	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	2	0
<i>Hepatitis viral infections</i>		
Gianotti-Crosti syndrome	1	0
Hepatitis A	5	0
<i>Herpes viral infections</i>		
Herpes zoster	1	0
<i>Male reproductive tract infections</i>		
Orchitis	1	0
<i>Salmonella infections</i>		
Typhoid fever	1	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Neutropenic sepsis	1	0
<i>Staphylococcal infections</i>		
Furuncle	1	0
<i>Upper respiratory tract infections</i>		
Nasopharyngitis	1	0
Tonsillitis	1	0
Upper respiratory tract infection	1	0
<i>Viral infections NEC</i>		
Encephalitis viral	1	0
Post viral fatigue syndrome	1	0
Viral infection	1	0
Infections SOC TOTAL	24	0

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Reaction Name	Total	Fatal
Injuries		
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	1	0
Maternal exposure before pregnancy	1	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	1	0
<i>Non-site specific injuries NEC</i>		
Fall	2	0
Foreign body	1	0
Wound haemorrhage	1	0
Wound secretion	1	0
<i>Overdoses NEC</i>		
Overdose	1	0
<i>Product administration errors and issues</i>		
Expired product administered	1	0
Inappropriate schedule of product administration	1	0
Incomplete course of vaccination	2	0
<i>Site specific injuries NEC</i>		
Head injury	1	0
<i>Skin injuries NEC</i>		
Skin laceration	1	0
<i>Vaccination related complications</i>		
Post vaccination syndrome	1	0
Vaccination failure	3	0
Injuries SOC TOTAL	19	0

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Reaction Name	Total	Fatal
Investigations		
<i>Heart rate and pulse investigations</i>		
Heart rate decreased	1	0
Pulse abnormal	1	0
<i>Liver function analyses</i>		
Aspartate aminotransferase increased	1	0
Blood bilirubin increased	1	0
Gamma-glutamyltransferase increased	1	0
Liver function test abnormal	3	0
Liver function test increased	2	0
Transaminases increased	1	0
<i>Neurologic diagnostic procedures</i>		
Electroencephalogram abnormal	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature fluctuation	1	0
Body temperature increased	2	0
Weight decreased	1	0
<i>Platelet analyses</i>		
Platelet count decreased	1	0
<i>Tissue enzyme analyses NEC</i>		
Blood alkaline phosphatase increased	1	0
<i>Toxicology laboratory analyses</i>		
Blood aluminium increased	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure decreased	3	0
<i>White blood cell analyses</i>		
Neutrophil count decreased	1	0
White blood cell count decreased	1	0
Investigations SOC TOTAL	24	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	13	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	1	0
<i>Hyperlipidaemias NEC</i>		
Hyperlipidaemia	1	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	1	0
Hypoglycaemia neonatal	1	0
<i>Total fluid volume decreased</i>		
Dehydration	1	0
Metabolic disorders SOC TOTAL	18	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	1	0
Arthropathy	2	0
Polyarthritis	2	0
<i>Connective tissue disorders NEC</i>		
Myofascitis	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	19	0
Joint swelling	2	0
<i>Muscle infections and inflammations</i>		
Myositis	1	0
<i>Muscle pains</i>		
Fibromyalgia	1	0
Myalgia	12	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle disorder	1	0
Muscle spasms	1	0
<i>Muscle tone abnormalities</i>		
Floppy infant	1	0
Muscle rigidity	1	0
Trismus	1	0
<i>Muscle weakness conditions</i>		
Muscular weakness	5	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Musculoskeletal stiffness	6	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	3	0
Limb discomfort	3	0
Musculoskeletal chest pain	1	0
Neck pain	1	0
Pain in extremity	8	0
<i>Rheumatoid arthropathies</i>		
Rheumatoid arthritis	1	0
Muscle & tissue disorders SOC TOTAL	74	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Neoplasms		
<i>Leukaemias myeloid NEC</i>		
Myeloid leukaemia	1	0
<i>Reproductive neoplasms female benign NEC</i>		
Benign hydatidiform mole	1	0
<i>Skin melanomas (excl ocular)</i>		
Malignant melanoma	1	0
<i>Skin neoplasms malignant and unspecified (excl melanoma)</i>		
Basal cell carcinoma	1	0
Neoplasms SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebrovascular accident	1	0
<i>Coordination and balance disturbances</i>		
Balance disorder	4	0
<i>Demyelinating disorders NEC</i>		
Acute disseminated encephalomyelitis	1	0
<i>Disturbances in consciousness NEC</i>		
Lethargy	10	0
Loss of consciousness	4	0
Somnolence	1	0
Syncope	12	0
<i>Dyskinesias and movement disorders NEC</i>		
Clumsiness	1	0
Dyskinesia	2	0
<i>Facial cranial nerve disorders</i>		
Facial paralysis	4	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	1	0
<i>Headaches NEC</i>		
Headache	30	0
<i>Memory loss (excl dementia)</i>		
Memory impairment	1	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	2	0
Mental impairment	1	0
<i>Migraine headaches</i>		
Hemiplegic migraine	1	0
<i>Mixed cranial nerve disorders</i>		
Bulbar palsy	1	0
<i>Mononeuropathies</i>		
Peroneal nerve palsy	1	0
<i>Motor neurone diseases</i>		
Motor neurone disease	1	0
<i>Myelitis (incl infective)</i>		
Myelitis transverse	3	0
<i>Narcolepsy and hypersomnia</i>		
Hypersomnia	1	0
<i>Nervous system disorders NEC</i>		
Nervous system disorder	1	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	20	0
Myoclonus	1	0
Presyncope	5	0
Unresponsive to stimuli	3	0
<i>Neuromuscular disorders NEC</i>		
Muscle contractions involuntary	1	0
<i>Paraesthesias and dysaesthesias</i>		
Burning sensation	1	0
Hyperaesthesia	1	0
Hypoaesthesia	6	0
Paraesthesia	11	0

Case Series Drug Analysis Print

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 Earliest Reaction Date: 03-Oct-1994

Data Lock Date: 08-Apr-2021 19:00:04
 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
<i>Paralysis and paresis (excl cranial nerve)</i>		
Hemiparesis	1	0
Paralysis	2	0
<i>Peripheral neuropathies NEC</i>		
Neuropathy peripheral	1	0
Peripheral motor neuropathy	1	0
Peripheral sensorimotor neuropathy	1	0
Polyneuropathy	1	0
<i>Seizures and seizure disorders NEC</i>		
Epilepsy	1	0
Febrile convulsion	1	0
Seizure	8	0
<i>Sensory abnormalities NEC</i>		
Sensory disturbance	1	0
Sensory loss	1	0
<i>Speech and language abnormalities</i>		
Speech disorder	2	0
<i>Spinal cord and nerve root disorders NEC</i>		
Radiculopathy	2	0
<i>Tremor (excl congenital)</i>		
Tremor	5	0
Nervous system disorders SOC TOTAL	162	0

Case Series Drug Analysis Print

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Data Lock Date: 08-Apr-2021 19:00:04
 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	7	0
Abortion threatened	1	0
<i>Foetal complications NEC</i>		
Foetal distress syndrome	1	0
<i>Gestational age and weight conditions</i>		
Premature baby	2	0
<i>Hypertension associated disorders of pregnancy</i>		
Pre-eclampsia	1	0
<i>Maternal complications of delivery NEC</i>		
Retained placenta or membranes	1	0
<i>Maternal complications of pregnancy NEC</i>		
Ectopic pregnancy	2	0
<i>Neonatal hepatobiliary disorders</i>		
Jaundice neonatal	1	0
<i>Normal pregnancy, labour and delivery</i>		
Live birth	1	0
<i>Postpartum complications NEC</i>		
Postpartum haemorrhage	1	0
Pregnancy conditions SOC TOTAL	18	0

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Data Lock Date: 08-Apr-2021 19:00:04
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Reaction Name	Total	Fatal
<i>Manufacturing laboratory controls issues</i>		
Out of specification test results	1	0
<i>Product quality issues NEC</i>		
Product quality issue	1	0
null SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Anxiety symptoms</i>		
Agitation	1	0
Anxiety	2	0
Nervousness	1	0
<i>Confusion and disorientation</i>		
Disorientation	2	0
<i>Decreased physical activity levels</i>		
Catatonia	1	0
<i>Deliria</i>		
Delirium	1	0
<i>Depressive disorders</i>		
Depression	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	1	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	1	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	1	0
Tearfulness	2	0
<i>Mood disorders NEC</i>		
Listless	1	0
<i>Panic attacks and disorders</i>		
Panic attack	2	0
<i>Psychotic disorder NEC</i>		
Acute psychosis	1	0
Psychotic behaviour	1	0
Psychiatric disorders SOC TOTAL	19	0

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Data Lock Date: 08-Apr-2021 19:00:04
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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder disorders NEC</i>		
Bladder disorder	1	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
IgA nephropathy	1	0
<i>Urinary abnormalities</i>		
Haematuria	1	0
Proteinuria	1	0
Renal & urinary disorders SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	5	0
Hypopnoea	1	0
Respiration abnormal	1	0
Respiratory arrest	1	0
Sleep apnoea syndrome	2	0
<i>Bronchospasm and obstruction</i>		
Wheezing	1	0
<i>Coughing and associated symptoms</i>		
Cough	2	0
Haemoptysis	1	0
<i>Lower respiratory tract signs and symptoms</i>		
Pleuritic pain	1	0
<i>Parenchymal lung disorders NEC</i>		
Interstitial lung disease	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal swelling	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Oropharyngeal pain	6	0
Rhinorrhoea	1	0
Sneezing	1	0
Yawning	1	0
Respiratory disorders SOC TOTAL	26	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Skin disorders		
<i>Angioedemas</i>		
Angioedema	3	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	3	0
Hyperhidrosis	4	0
Miliaria	1	0
<i>Dermal and epidermal conditions NEC</i>		
Skin discolouration	2	0
Skin plaque	1	0
Skin reaction	1	0
<i>Dermatitis and eczema</i>		
Dermatitis allergic	1	0
<i>Erythemas</i>		
Erythema	7	0
<i>Panniculitides</i>		
Erythema nodosum	1	0
<i>Papulosquamous conditions</i>		
Lichen planus	1	0
<i>Pruritus NEC</i>		
Pruritus	6	0
<i>Rashes, eruptions and exanths NEC</i>		
Rash	20	0
Rash erythematous	2	0
Rash macular	3	0
Rash maculo-papular	1	0
Rash papular	1	0
Rash pruritic	6	0
Rash rubelliform	1	0
<i>Skin and subcutaneous conditions NEC</i>		
Skin mass	1	0
<i>Skin vasculitides</i>		
Vasculitic rash	1	0
<i>Telangiectasia and related conditions</i>		
Spider naevus	1	0
<i>Urticarias</i>		
Urticaria	26	0
Skin disorders SOC TOTAL	94	0

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Report Run Date: 29-Jun-2021

Data Lock Date: 08-Apr-2021 19:00:04

Earliest Reaction Date: 03-Oct-1994

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Social circumstances		
<i>Disability issues</i>		
Loss of personal independence in daily activities	1	0
Social circumstances SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Circulatory collapse and shock</i>		
Circulatory collapse	5	0
<i>Peripheral embolism and thrombosis</i>		
Thrombophlebitis	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	2	0
Flushing	1	0
Hot flush	2	0
<i>Site specific vascular disorders NEC</i>		
Pallor	6	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	1	0
<i>Vascular hypotensive disorders</i>		
Hypotension	6	0
<i>Vasculitides NEC</i>		
Vasculitis	1	0
Vascular disorders SOC TOTAL	25	0
TOTAL REACTIONS FOR DRUG	848	1
TOTAL REPORTS	296	
TOTAL FATAL OUTCOME REPORTS		1