

Case Series Drug Analysis Print

Name: MENITORIX FOI 21/1063

Report Run Date: 07-Oct-2021
Data Lock Date: 30-Sep-2021 18:30:04
Earliest Reaction Date: 28-Sep-2006
MedDRA Version: MedDRA 24.0

MENITORIX FOI
21/1063:

All UK spontaneous reports received up until 30-Sep-2021 for the MENITORIX Vaccine analysis print. 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.

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Reaction Name	Total	Fatal
Blood disorders		
<i>Lymphatic system disorders NEC</i>		
Lymphadenopathy	6	0
Lymphoid tissue hyperplasia	1	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	1	0
Blood disorders SOC TOTAL	8	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	1	0
<i>Heart failures NEC</i>		
Cardiac failure	1	0
<i>Rate and rhythm disorders NEC</i>		
Bradycardia	2	0
Tachycardia	5	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	1	1
Cardio-respiratory arrest	1	0
Ventricular tachycardia	1	0
Cardiac disorders SOC TOTAL	12	1

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Musculoskeletal and connective tissue disorders of limbs congenital</i>		
Polydactyly	1	0
Syndactyly	1	0
Congenital disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear pain	1	0
Ear swelling	1	0
<i>External ear disorders NEC</i>		
Excessive cerumen production	1	0
<i>Hearing losses</i>		
Deafness	1	0
Ear disorders SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Eyelid movement disorders</i>		
Excessive eye blinking	2	0
Eyelid function disorder	1	0
Eyelid ptosis	1	0
<i>Lacrimation disorders</i>		
Lacrimation increased	1	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Erythema of eyelid	1	0
Swelling of eyelid	2	0
<i>Ocular disorders NEC</i>		
Eye disorder	1	0
Eye oedema	1	0
Eye swelling	8	0
Periorbital swelling	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye pruritus	2	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	3	0
Strabismus	1	0
<i>Pupil disorders</i>		
Mydriasis	2	0
Pupil fixed	1	0
Pupils unequal	1	0
Eye disorders SOC TOTAL	29	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	58	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	1	0
Faecaloma	1	0
Faeces discoloured	1	0
Mucous stools	2	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 upper	3	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	2	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Irritable bowel syndrome	1	0
<i>Nausea and vomiting symptoms</i>		
Infantile vomiting	2	0
Nausea	2	0
Vomiting	86	0
Vomiting projectile	8	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematemesis	1	0
Haematochezia	1	0
<i>Oral soft tissue disorders NEC</i>		
Chapped lips	1	0
<i>Oral soft tissue signs and symptoms</i>		
Oral pain	1	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	3	0
Mouth swelling	1	0
<i>Stomatitis and ulceration</i>		
Mouth ulceration	1	0
<i>Tongue disorders</i>		
Tongue geographic	1	0
Gastrointestinal disorders SOC TOTAL	188	0

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General disorders		
<i>Asthenic conditions</i>		
Asthenia	5	0
Decreased activity	1	0
Fatigue	14	0
Malaise	25	0
<i>Body temperature altered</i>		
Hypothermia	1	0
<i>Death and sudden death</i>		
Death	2	2
Sudden death	1	1
Sudden infant death syndrome	1	1
<i>Febrile disorders</i>		
Pyrexia	206	0
<i>Feelings and sensations NEC</i>		
Chills	11	0
Feeling abnormal	4	0
Feeling drunk	1	0
Feeling hot	4	0
Thirst	2	0
Thirst decreased	2	0
<i>Gait disturbances</i>		
Gait disturbance	9	0
Gait inability	9	0
Loss of control of legs	1	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	2	0
Crepitations	1	0
Crying	41	0
Developmental delay	2	0
Developmental regression	1	0
Foaming at mouth	1	0
Glassy eyes	1	0
High-pitched crying	3	0
Illness	9	0
Induration	1	0
Influenza like illness	3	0
Irritability postvaccinal	1	0
Local reaction	6	0
Peripheral swelling	22	0
Screaming	13	0
Secretion discharge	1	0
Swelling	16	0
Swelling face	10	0
<i>Inflammations</i>		
Inflammation	2	0
<i>Injection site reactions</i>		
Injection site discolouration	2	0
Injection site erythema	16	0
Injection site induration	1	0
Injection site inflammation	5	0
Injection site mass	2	0
Injection site oedema	1	0
Injection site pain	3	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Injection site rash	3	0
Injection site reaction	5	0
Injection site swelling	13	0
Injection site urticaria	3	0
Injection site warmth	3	0
Mass conditions NEC		
Mass	1	0
Oedema NEC		
Oedema peripheral	2	0
Pain and discomfort NEC		
Chest discomfort	1	0
Discomfort	2	0
Pain	18	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	2	0
Drug ineffective	1	0
Vaccination failure	13	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	1	0
Vaccination site bruising	3	0
Vaccination site discolouration	1	0
Vaccination site discomfort	1	0
Vaccination site erythema	24	0
Vaccination site induration	4	0
Vaccination site inflammation	4	0
Vaccination site mass	12	0
Vaccination site pain	5	0
Vaccination site pruritus	1	0
Vaccination site rash	4	0
Vaccination site reaction	1	0
Vaccination site swelling	25	0
Vaccination site vesicles	1	0
Vaccination site warmth	5	0
General disorders SOC TOTAL	624	4

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Allergy to metals	1	0
Hypersensitivity	11	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Food allergy	1	0
Milk allergy	2	0
Reaction to excipient	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	6	0
<i>Immunodeficiency disorders NEC</i>		
Immunodeficiency	1	0
Immune system disorders SOC TOTAL	23	0

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Infections		
<i>Abdominal and gastrointestinal infections</i>		
Gastroenteritis	1	0
<i>Bacterial infections NEC</i>		
Cellulitis	17	0
Injection site cellulitis	1	0
Periorbital cellulitis	1	0
Skin bacterial infection	2	0
Vaccination site cellulitis	2	0
<i>Bone and joint infections</i>		
Intervertebral discitis	1	0
Osteomyelitis	1	0
<i>Central nervous system and spinal infections</i>		
Encephalitis	2	0
Meningitis	2	1
<i>Dental and oral soft tissue infections</i>		
Gingivitis	1	0
<i>Ear infections</i>		
Ear infection	4	0
Otitis media	1	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	3	0
Eye infection	1	0
<i>Haemophilus infections</i>		
Haemophilus infection	3	1
Meningitis haemophilus	1	0
<i>Herpes viral infections</i>		
Oral herpes	1	0
Varicella	1	0
<i>Infections NEC</i>		
Infection	2	0
Localised infection	2	0
Vaccination site abscess	2	0
Vaccination site infection	1	0
<i>Lower respiratory tract and lung infections</i>		
Bronchitis	1	0
Lower respiratory tract infection	6	0
Pneumonia	2	0
<i>Neisseria infections</i>		
Meningitis meningococcal	1	0
Meningococcal infection	7	0
Meningococcal sepsis	2	0
<i>Rubeola viral infections</i>		
Measles	1	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Sepsis	3	0
<i>Tuberculous infections</i>		
Erythema induratum	1	0
<i>Upper respiratory tract infections</i>		
Croup infectious	1	0
Epiglottitis	3	0
Nasopharyngitis	3	0
Rhinitis	3	0
Tonsillitis	5	0

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Tracheitis	1	0
Upper respiratory tract infection	2	0
<i>Viral infections NEC</i>		
Viral rash	2	0
Infections SOC TOTAL	97	2

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Reaction Name	Total	Fatal
Injuries		
<i>Cerebral injuries NEC</i>		
Craniocerebral injury	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Maternal exposure during breast feeding	1	0
<i>Medication errors, product use errors and issues NEC</i>		
Vaccination error	1	0
Wrong technique in product usage process	1	0
<i>Non-site specific injuries NEC</i>		
Fall	1	0
Injury	1	0
<i>Overdoses NEC</i>		
Overdose	1	0
<i>Product administration errors and issues</i>		
Accidental overdose	2	0
Expired product administered	1	0
Extra dose administered	1	0
Inappropriate schedule of product administration	3	0
Incorrect dose administered	1	0
Product administered at inappropriate site	1	0
Product administered to patient of inappropriate age	1	0
Wrong product administered	4	0
<i>Product prescribing errors and issues</i>		
Product prescribing error	1	0
<i>Skin injuries NEC</i>		
Contusion	1	0
Scar	1	0
Skin laceration	1	0
Injuries SOC TOTAL	25	0

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Reaction Name	Total	Fatal
Investigations		
<i>Bacteria identification and serology (excl mycobacteria)</i>		
Neisseria test positive	1	0
<i>Chemistry analyses NEC</i>		
Inflammatory marker increased	1	0
<i>Coagulation and bleeding analyses</i>		
Bleeding time prolonged	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate abnormal	2	0
Heart rate increased	6	0
<i>Immunoglobulin analyses</i>		
Blood immunoglobulin G increased	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	22	0
Breath sounds abnormal	1	0
<i>Protein analyses NEC</i>		
C-reactive protein increased	1	0
Investigations SOC TOTAL	40	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	53	0
Food refusal	1	0
Hypophagia	2	0
<i>Fluid intake decreased</i>		
Fluid intake reduced	1	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Dairy intolerance	1	0
Food intolerance	2	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	1	0
Food aversion	1	0
Poor feeding infant	2	0
Weight gain poor	1	0
<i>Metabolic acidoses (excl diabetic acidoses)</i>		
Metabolic acidosis	1	0
<i>Total fluid volume decreased</i>		
Dehydration	2	0
Metabolic disorders SOC TOTAL	68	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Joint related disorders NEC</i>		
Hypermobility syndrome	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	3	0
Joint stiffness	1	0
Joint swelling	1	0
<i>Muscle pains</i>		
Myalgia	4	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle tightness	1	0
Muscle twitching	1	0
<i>Muscle tone abnormalities</i>		
Floppy infant	3	0
<i>Muscle weakness conditions</i>		
Muscular weakness	4	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Limb mass	1	0
Musculoskeletal stiffness	4	0
Weight bearing difficulty	7	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	1	0
Limb discomfort	4	0
Musculoskeletal pain	1	0
Pain in extremity	26	0
Muscle & tissue disorders SOC TOTAL	63	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>Skin neoplasms malignant and unspecified (excl melanoma)</i>		
Neoplasm skin	1	0
Neoplasms SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Central nervous system vascular disorders NEC</i>		
Brain hypoxia	1	0
<i>Coordination and balance disturbances</i>		
Balance disorder	4	0
Coordination abnormal	1	0
Dysstasia	2	0
Hand-eye coordination impaired	1	0
<i>Cortical dysfunction NEC</i>		
Aphasia	3	0
Dyspraxia	1	0
Sensory processing disorder	1	0
<i>Disturbances in consciousness NEC</i>		
Lethargy	23	0
Loss of consciousness	2	0
Somnolence	19	0
Syncope	2	0
<i>Dyskinesias and movement disorders NEC</i>		
Dyskinesia	4	0
Fine motor delay	1	0
Hypokinesia	3	0
Movement disorder	1	0
Psychomotor hyperactivity	2	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	1	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	1	0
<i>Headaches NEC</i>		
Headache	7	0
<i>Increased intracranial pressure disorders</i>		
Brain oedema	1	0
<i>Muscle tone abnormal</i>		
Hypotonia	10	0
<i>Narcolepsy and hypersomnia</i>		
Hypersomnia	3	0
<i>Nervous system disorders NEC</i>		
Nervous system disorder	1	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	3	0
Dizziness postural	1	0
Drooling	1	0
Exaggerated startle response	1	0
Inability to crawl	1	0
Infant irritability	3	0
Meningism	1	0
Presyncope	3	0
Unresponsive to stimuli	10	0
<i>Neuromuscular disorders NEC</i>		
Hypotonic-hyporesponsive episode	1	0
<i>Paraesthesias and dysaesthesias</i>		
Hyperaesthesia	1	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Paralysis	1	0
<i>Seizures and seizure disorders NEC</i>		

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Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Epilepsy	1	0
Febrile convulsion	17	0
Partial seizures	2	0
Seizure	10	0
Seizure anoxic	1	0
Status epilepticus	1	0
<i>Sleep disturbances NEC</i>		
Sleep deficit	1	0
<i>Speech and language abnormalities</i>		
Language disorder	1	0
Speech disorder	2	0
Speech disorder developmental	2	0
<i>Tremor (excl congenital)</i>		
Tremor	7	0
Nervous system disorders SOC TOTAL	167	0

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Reaction Name	Total	Fatal
<i>Product label issues</i>		
Product lot number issue	1	0
<i>Product quality issues NEC</i>		
Product complaint	1	0
null SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	7	0
Breath holding	3	0
Staring	2	0
<i>Anxiety symptoms</i>		
Agitation	3	0
Anxiety	2	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	4	0
Disturbance in social behaviour	1	0
Personality change	3	0
Social avoidant behaviour	1	0
<i>Confusion and disorientation</i>		
Disorientation	1	0
<i>Decreased physical activity levels</i>		
Catatonia	1	0
<i>Deliria</i>		
Delirium	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Initial insomnia	1	0
Insomnia	11	0
Middle insomnia	2	0
<i>Dyssomnias</i>		
Poor quality sleep	2	0
<i>Eating disorders NEC</i>		
Eating disorder	1	0
<i>Emotional and mood disturbances NEC</i>		
Emotional distress	9	0
Irritability	48	0
<i>Fluctuating mood symptoms</i>		
Mood swings	1	0
<i>Increased physical activity levels</i>		
Restlessness	9	0
<i>Mental disorders NEC</i>		
Mental disorder	2	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	2	0
Tearfulness	1	0
<i>Mood disorders NEC</i>		
Listless	4	0
<i>Obsessive-compulsive disorders and symptoms</i>		
Obsessive-compulsive symptom	1	0
<i>Parasomnias</i>		
Sleep terror	1	0
<i>Pervasive developmental disorders NEC</i>		
Autism spectrum disorder	7	0
<i>Psychiatric symptoms NEC</i>		
Decreased eye contact	2	0
<i>Sleep disorders NEC</i>		
Sleep disorder	6	0
<i>Suicidal and self-injurious behaviour</i>		
Self-injurious ideation	1	0
<i>Tic disorders</i>		

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Reaction Name	Total	Fatal
Psychiatric disorders ^P Psychiatric disorders cont'd		
Tic	1	0
Psychiatric disorders SOC TOTAL	141	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Glomerulonephritis and nephrotic syndrome</i>		
Nephrotic syndrome	1	0
Renal & urinary disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive tract signs and symptoms NEC</i>		
Genital rash	1	0
Genital swelling	1	0
<i>Scrotal disorders NEC</i>		
Scrotal swelling	1	0
Reproductive & breast disorders SOC TOTAL	3	0

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Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoeic attack	1	0
Dyspnoea	5	0
Grunting	1	0
Hyperventilation	1	0
Respiratory arrest	2	1
Tachypnoea	1	0
<i>Bronchospasm and obstruction</i>		
Wheezing	8	0
<i>Conditions associated with abnormal gas exchange</i>		
Asphyxia	1	0
<i>Coughing and associated symptoms</i>		
Cough	11	0
Productive cough	2	0
<i>Lower respiratory tract signs and symptoms</i>		
Rales	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	3	0
<i>Parenchymal lung disorders NEC</i>		
Lung consolidation	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal erythema	1	0
Pharyngeal swelling	1	0
<i>Pulmonary oedemas</i>		
Pulmonary oedema	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Oropharyngeal pain	4	0
Rhinorrhoea	9	0
Throat tightness	1	0
Respiratory disorders SOC TOTAL	55	1

Case Series Drug Analysis Print

Name: MENITORIX FOI 21/1063

Report Run Date: 07-Oct-2021
 Earliest Reaction Date: 28-Sep-2006

Data Lock Date: 30-Sep-2021 18:30:04
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Skin disorders		
<i>Angioedemas</i>		
Angioedema	2	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	2	0
Hyperhidrosis	5	0
<i>Bullous conditions</i>		
Blister	7	0
Blood blister	1	0
Erythema multiforme	4	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	2	0
Pain of skin	1	0
Papule	4	0
Skin burning sensation	1	0
Skin disorder	2	0
Skin induration	1	0
Skin lesion	1	0
Skin reaction	1	0
Skin tightness	1	0
Skin warm	7	0
<i>Dermatitis and eczema</i>		
Dermatitis	1	0
Dermatitis allergic	7	0
Dermatitis atopic	1	0
Dermatitis diaper	2	0
Eczema	8	0
Eczema weeping	1	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	1	0
<i>Erythemas</i>		
Erythema	42	0
<i>Pigmentation changes NEC</i>		
Pigmentation disorder	1	0
<i>Pilar disorders NEC</i>		
Hair growth abnormal	1	0
<i>Pruritus NEC</i>		
Pruritus	9	0
<i>Purpura and related conditions</i>		
Henoch-Schonlein purpura	1	0
Purpura	1	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	109	0
Rash erythematous	12	0
Rash macular	12	0
Rash maculo-papular	8	0
Rash morbilliform	13	0
Rash papular	7	0
Rash pruritic	3	0
Rash rubelliform	2	0
Rash vesicular	1	0
Systemic lupus erythematosus rash	1	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	1	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
<i>Urticarias</i>		
Urticaria	39	0
Skin disorders SOC TOTAL	326	0

Case Series Drug Analysis Print

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

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Haemorrhages NEC</i>		
Haematoma	2	0
Haemorrhage	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	6	0
Flushing	2	0
Hot flush	1	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	2	0
<i>Site specific vascular disorders NEC</i>		
Pallor	15	0
Vascular disorders SOC TOTAL	29	0
TOTAL REACTIONS FOR DRUG	1909	8
TOTAL REPORTS	633	
TOTAL FATAL OUTCOME REPORTS		8