

Case Series Drug Analysis Print

Name: Hib/MenC Vaccine Drug Analysis Print

Report Run Date: 08-Nov-2021
Data Lock Date: 17-Oct-2021 22:57:05
Earliest Reaction Date: 28-Sep-2006
MedDRA Version: MedDRA 24.0
Hib/MenC Vaccine Spontaneous UK cases received up to 30/09/2021.
Drug Analysis Print:

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Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemias haemolytic immune</i>		
Autoimmune haemolytic anaemia	1	0
<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	9	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	2	0
<i>Heart failures NEC</i>		
Cardiac failure	1	0
<i>Ischaemic coronary artery disorders</i>		
Myocardial infarction	1	1
<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	14	2

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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	2	0
<i>External ear disorders NEC</i>		
Excessive cerumen production	1	0
<i>Hearing losses</i>		
Deafness	1	0
Ear disorders SOC TOTAL	5	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	9	0
Periorbital swelling	2	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye pruritus	2	0
Ocular hyperaemia	1	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	32	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	61	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	1	0
Faecaloma	1	0
Faeces discoloured	1	0
Faeces soft	1	0
Mucous stools	2	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	4	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 dyskinetic disorders</i>		
Gastrointestinal motility disorder	1	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	88	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	196	0

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Reaction Name	Total	Fatal
General disorders		
<i>Asthenic conditions</i>		
Asthenia	5	0
Decreased activity	1	0
Fatigue	15	0
Malaise	26	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	210	0
<i>Feelings and sensations NEC</i>		
Chills	11	0
Feeling abnormal	4	0
Feeling drunk	1	0
Feeling hot	4	0
Thirst	3	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	4	0
Irritability postvaccinal	1	0
Local reaction	6	0
Peripheral swelling	22	0
Screaming	13	0
Secretion discharge	1	0
Swelling	17	0
Swelling face	10	0
<i>Inflammations</i>		
Inflammation	2	0
<i>Injection site reactions</i>		
Injection site discolouration	2	0
Injection site erythema	17	0
Injection site induration	1	0
Injection site inflammation	6	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	15	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
Inflammatory pain	1	0
Pain	18	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	3	0
Drug ineffective	1	0
Vaccination failure	14	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	6	0
Vaccination site pruritus	1	0
Vaccination site rash	4	0
Vaccination site reaction	1	0
Vaccination site swelling	26	0
Vaccination site vesicles	1	0
Vaccination site warmth	5	0
General disorders SOC TOTAL	642	4

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Immune system disorders		
<i>Allergic conditions NEC</i>		
Allergy to metals	1	0
Hypersensitivity	12	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
Reaction to preservatives	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	7	0
<i>Immunodeficiency disorders NEC</i>		
Immunodeficiency	1	0
Immune system disorders SOC TOTAL	26	0

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Reaction Name	Total	Fatal
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	4	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	4	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	4	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>Urinary tract infections</i>		
Urinary tract infection	1	0
<i>Viral infections NEC</i>		
Viral rash	2	0
Infections SOC TOTAL	102	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>		
Exposure via breast milk	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	24	0
Breath sounds abnormal	1	0
<i>Protein analyses NEC</i>		
C-reactive protein increased	1	0
Investigations SOC TOTAL	42	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	54	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	69	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	5	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	64	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>Acute polyneuropathies</i>		
Guillain-Barre syndrome	1	0
<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
Facial paralysis	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
Myoclonus	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>		

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Nervous system disorders <small>Nervous system disorders cont'd</small>		
Hyperaesthesia	1	0
Paralysis and paresis (excl cranial nerve)		
Paralysis	1	0
Peripheral neuropathies NEC		
Polyneuropathy	1	0
Seizures and seizure disorders NEC		
Epilepsy	2	0
Febrile convulsion	20	0
Partial seizures	2	0
Seizure	10	0
Seizure anoxic	1	0
Status epilepticus	2	0
Sleep disturbances NEC		
Sleep deficit	1	0
Speech and language abnormalities		
Language disorder	1	0
Speech disorder	2	0
Speech disorder developmental	2	0
Tremor (excl congenital)		
Tremor	9	0
Nervous system disorders SOC TOTAL	178	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>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	1	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>		
Anger	1	0
Emotional distress	9	0
Irritability	50	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	8	0
<i>Psychiatric symptoms NEC</i>		
Decreased eye contact	2	0
<i>Sleep disorders NEC</i>		
Sleep disorder	6	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Suicidal and self-injurious behaviour</i>		
Self-injurious ideation	1	0
<i>Tic disorders</i>		
Tic	1	0
Psychiatric disorders SOC TOTAL	146	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Glomerulonephritis and nephrotic syndrome</i>		
Nephrotic syndrome	1	0
<i>Myoneurogenic bladder disorders</i>		
Bladder dysfunction	1	0
Renal & urinary disorders SOC TOTAL	2	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
<i>Testicular and epididymal disorders NEC</i>		
Testicular pain	1	0
Reproductive & breast disorders SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoeic attack	1	0
Dyspnoea	7	0
Grunting	1	0
Hyperventilation	1	0
Hypopnoea	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	13	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>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	1	0
<i>Pulmonary oedemas</i>		
Pulmonary oedema	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Oropharyngeal pain	4	0
Rhinorrhoea	12	0
Throat tightness	1	0
Respiratory disorders SOC TOTAL	64	1

Case Series Drug Analysis Print

Name: Hib/MenC Vaccine Drug Analysis Print

Report Run Date: 08-Nov-2021

Data Lock Date: 17-Oct-2021 22:57:05

Earliest Reaction Date: 28-Sep-2006

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	6	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	3	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	8	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	43	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	10	0
<i>Purpura and related conditions</i>		
Henoch-Schonlein purpura	1	0
Purpura	1	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	114	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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Report Run Date: 08-Nov-2021

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Earliest Reaction Date: 28-Sep-2006

MedDRA Version: MedDRA 24.0

Reaction Name		Total	Fatal
Skin disorders	Skin disorders cont'd		
<i>Urticarias</i>			
	Urticaria	42	0
Skin disorders SOC TOTAL		339	0

Case Series Drug Analysis Print

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Report Run Date: 08-Nov-2021
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MedDRA Version: MedDRA 24.0

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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Report Run Date: 08-Nov-2021

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Earliest Reaction Date: 28-Sep-2006

MedDRA Version: MedDRA 24.0

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	16	0
Vascular disorders SOC TOTAL	30	0
TOTAL REACTIONS FOR DRUG	1995	9
TOTAL REPORTS	662	
TOTAL FATAL OUTCOME REPORTS		9