

## Case Series Drug Analysis Print

### Name: FOI 24/181 Hib/MenC Vaccine Analysis Print

Report Run Date: 07-Mar-2024  
Data Lock Date: 06-Mar-2024 18:30:04  
Earliest Reaction Date: 28-Sep-2006  
MedDRA Version: MedDRA 26.1

FOI 24/181 Hib/MenC Vaccine Analysis Print: FOI 24/181 - All UK spontaneous suspected Adverse Drug Reaction (ADR) reports associated with the Hib/MenC vaccine up to and including 06/03/2024

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Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<i>Anaemias haemolytic immune</i>		
Autoimmune haemolytic anaemia	1	0
<i>Lymphatic system disorders NEC</i>		
Lymphadenopathy	7	0
Lymphoid tissue hyperplasia	1	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	1	0
<b>Blood disorders SOC TOTAL</b>	<b>10</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	3	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
<b>Cardiac disorders SOC TOTAL</b>	<b>15</b>	<b>2</b>

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Reaction Name	Total	Fatal
<b>Congenital disorders</b>		
<i>Connective tissue disorders congenital</i>		
Hypermobility syndrome	1	0
<i>Musculoskeletal and connective tissue disorders of limbs congenital</i>		
Polydactyly	1	0
Syndactyly	1	0
<b>Congenital disorders SOC TOTAL</b>	<b>3</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<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
<b>Ear disorders SOC TOTAL</b>	<b>5</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i><b>Eyelid movement disorders</b></i>		
Excessive eye blinking	2	0
Eyelid function disorder	1	0
Eyelid ptosis	1	0
<i><b>Lacrimation disorders</b></i>		
Lacrimation increased	1	0
<i><b>Lid, lash and lacrimal infections, irritations and inflammations</b></i>		
Erythema of eyelid	1	0
Swelling of eyelid	2	0
<i><b>Ocular disorders NEC</b></i>		
Eye disorder	1	0
Eye oedema	1	0
Eye swelling	9	0
Periorbital swelling	3	0
<i><b>Ocular infections, inflammations and associated manifestations</b></i>		
Eye pruritus	2	0
Ocular hyperaemia	1	0
<i><b>Ocular nerve and muscle disorders</b></i>		
Eye movement disorder	3	0
Strabismus	1	0
<i><b>Ocular sensation disorders</b></i>		
Asthenopia	1	0
<i><b>Pupil disorders</b></i>		
Anisocoria	1	0
Mydriasis	2	0
Pupil fixed	1	0
<b>Eye disorders SOC TOTAL</b>	<b>34</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	65	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	2	0
Gastrooesophageal reflux disease	2	0
<i>Gastrointestinal dyskinetic disorders</i>		
Change of bowel habit	1	0
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	3	0
Vomiting	94	0
Vomiting projectile	8	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematemesis	1	0
Haematochezia	1	0
<i>Oral dryness and saliva altered</i>		
Lip dry	1	0
<i>Oral soft tissue disorders NEC</i>		
Chapped lips	1	0
Lip blister	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	2	0
<i>Tongue disorders</i>		
Tongue geographic	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>212</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>General disorders</b>		
<i>Administration site reactions NEC</i>		
Administration site erythema	1	0
<i>Asthenic conditions</i>		
Asthenia	6	0
Decreased activity	1	0
Fatigue	16	0
Malaise	28	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	223	0
<i>Feelings and sensations NEC</i>		
Chills	12	0
Feeling abnormal	4	0
Feeling drunk	1	0
Feeling hot	5	0
Feeling of body temperature change	1	0
Thirst	3	0
Thirst decreased	2	0
<i>Gait disturbances</i>		
Gait disturbance	9	0
Gait inability	10	0
Loss of control of legs	1	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	2	0
Crepitations	1	0
Crying	46	0
Developmental delay	3	0
Developmental regression	1	0
Foaming at mouth	1	0
Glassy eyes	1	0
High-pitched crying	3	0
Illness	10	0
Induration	2	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	19	0
Swelling face	10	0
<i>Inflammations</i>		
Inflammation	4	0
<i>Injection site reactions</i>		
Injection site bruising	1	0
Injection site discolouration	2	0
Injection site erythema	17	0
Injection site induration	1	0



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<b>General disorders</b> General disorders cont'd		
Injection site inflammation	6	0
Injection site mass	3	0
Injection site oedema	1	0
Injection site pain	3	0
Injection site rash	4	0
Injection site reaction	5	0
Injection site swelling	15	0
Injection site urticaria	3	0
Injection site vesicles	1	0
Injection site warmth	3	0
<b>Mass conditions NEC</b>		
Mass	1	0
<b>Oedema NEC</b>		
Oedema peripheral	2	0
<b>Pain and discomfort NEC</b>		
Chest discomfort	1	0
Discomfort	2	0
Inflammatory pain	1	0
Pain	18	0
Tenderness	1	0
<b>Therapeutic and nontherapeutic responses</b>		
Adverse drug reaction	2	0
Drug ineffective	1	0
Vaccination failure	14	0
<b>Vaccination site reactions</b>		
Extensive swelling of vaccinated limb	2	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	13	0
Vaccination site pain	7	0
Vaccination site pruritus	1	0
Vaccination site rash	5	0
Vaccination site reaction	1	0
Vaccination site swelling	26	0
Vaccination site vesicles	1	0
Vaccination site warmth	5	0
<b>General disorders SOC TOTAL</b>	<b>684</b>	<b>4</b>

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Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<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	8	0
<i>Immunodeficiency disorders NEC</i>		
Immunodeficiency	1	0
<b>Immune system disorders SOC TOTAL</b>	<b>27</b>	<b>0</b>

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

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<b>Infections</b>		
Infections cont'd		
Epiglottitis	3	0
Nasopharyngitis	3	0
Rhinitis	3	0
Tonsillitis	6	0
Tracheitis	1	0
Upper respiratory tract infection	2	0
<b>Urinary tract infections</b>		
Urinary tract infection	1	0
<b>Viral infections NEC</b>		
Bronchiolitis	1	0
Viral rash	2	0
<b>Infections SOC TOTAL</b>	<b>107</b>	<b>2</b>

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Reaction Name	Total	Fatal
<b>Injuries</b>		
<i><b>Cerebral injuries NEC</b></i>		
Craniocerebral injury	1	0
<i><b>Exposures associated with pregnancy, delivery and lactation</b></i>		
Exposure via breast milk	1	0
<i><b>Medication errors, product use errors and issues NEC</b></i>		
Vaccination error	1	0
Wrong technique in product usage process	1	0
<i><b>Non-site specific injuries NEC</b></i>		
Fall	1	0
Injury	1	0
<i><b>Overdoses NEC</b></i>		
Overdose	1	0
<i><b>Product administration errors and issues</b></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><b>Product prescribing errors and issues</b></i>		
Product prescribing error	1	0
<i><b>Skin injuries NEC</b></i>		
Contusion	1	0
Scar	1	0
Skin laceration	1	0
<b>Injuries SOC TOTAL</b>	<b>25</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Investigations</b>		
<i><b>Bacteria identification and serology (excl mycobacteria)</b></i>		
Neisseria test positive	1	0
<i><b>Chemistry analyses NEC</b></i>		
Inflammatory marker increased	1	0
<i><b>Coagulation and bleeding analyses</b></i>		
Bleeding time prolonged	1	0
<i><b>Heart rate and pulse investigations</b></i>		
Heart rate abnormal	2	0
Heart rate increased	6	0
<i><b>Immunoglobulin analyses</b></i>		
Blood immunoglobulin G increased	1	0
<i><b>Physical examination procedures and organ system status</b></i>		
Body temperature abnormal	1	0
Body temperature decreased	2	0
Body temperature fluctuation	1	0
Body temperature increased	28	0
Breath sounds abnormal	1	0
<i><b>Protein analyses NEC</b></i>		
C-reactive protein increased	1	0
<b>Investigations SOC TOTAL</b>	<b>46</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i><b>Appetite disorders</b></i>		
Decreased appetite	59	0
Food refusal	1	0
Hypophagia	2	0
<i><b>Fluid intake decreased</b></i>		
Fluid intake reduced	1	0
<i><b>Food malabsorption and intolerance syndromes (excl sugar intolerance)</b></i>		
Dairy intolerance	1	0
Food intolerance	2	0
<i><b>General nutritional disorders NEC</b></i>		
Abnormal loss of weight	1	0
Food aversion	1	0
Poor feeding infant	2	0
Weight gain poor	1	0
<i><b>Metabolic acidoses (excl diabetic acidoses)</b></i>		
Metabolic acidosis	1	0
<i><b>Total fluid volume decreased</b></i>		
Dehydration	2	0
<b>Metabolic disorders SOC TOTAL</b>	<b>74</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i>Extremity deformities</i>		
Foot deformity	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	4	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	6	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
Neck pain	1	0
Pain in extremity	27	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>67</b>	<b>0</b>



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

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Abnormal reflexes</i>		
Areflexia	1	0
<i>Absence seizures</i>		
Petit mal epilepsy	1	0
<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	3	0
Somnolence	19	0
Syncope	2	0
<i>Dyskinesias and movement disorders NEC</i>		
Dyskinesia	5	0
Fine motor delay	1	0
Hypokinesia	5	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	8	0
<i>Increased intracranial pressure disorders</i>		
Brain oedema	1	0
<i>Migraine headaches</i>		
Migraine	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	4	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

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b> <small>Nervous system disorders cont'd</small>		
Myoclonus	1	0
Presyncope	3	0
Unresponsive to stimuli	10	0
<b>Neuromuscular disorders NEC</b>		
Hypotonic-hyporesponsive episode	1	0
<b>Paraesthesias and dysaesthesias</b>		
Hyperaesthesia	1	0
<b>Paralysis and paresis (excl cranial nerve)</b>		
Monoplegia	1	0
Paralysis	2	0
<b>Peripheral neuropathies NEC</b>		
Polyneuropathy	1	0
<b>Seizures and seizure disorders NEC</b>		
Epilepsy	2	0
Febrile convulsion	21	0
Partial seizures	2	0
Seizure	11	0
Seizure anoxic	1	0
Status epilepticus	2	0
<b>Sleep disturbances NEC</b>		
Sleep deficit	1	0
<b>Speech and language abnormalities</b>		
Language disorder	1	0
Speech disorder	2	0
Speech disorder developmental	3	0
<b>Tremor (excl congenital)</b>		
Tremor	11	0
<b>Nervous system disorders SOC TOTAL</b>	<b>194</b>	<b>0</b>

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

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<b><i>Abnormal behaviour NEC</i></b>		
Abnormal behaviour	9	0
Breath holding	3	0
Staring	2	0
<b><i>Affect alterations NEC</i></b>		
Affect lability	1	0
<b><i>Anxiety symptoms</i></b>		
Agitation	4	0
Anxiety	2	0
<b><i>Attention deficit and disruptive behaviour disorders</i></b>		
Attention deficit hyperactivity disorder	2	0
<b><i>Behaviour and socialisation disturbances</i></b>		
Aggression	5	0
Disturbance in social behaviour	1	0
Personality change	3	0
Social avoidant behaviour	1	0
<b><i>Cognitive and attention disorders and disturbances NEC</i></b>		
Daydreaming	1	0
<b><i>Confusion and disorientation</i></b>		
Disorientation	1	0
<b><i>Decreased physical activity levels</i></b>		
Catatonia	1	0
<b><i>Deliria</i></b>		
Delirium	1	0
<b><i>Disturbances in initiating and maintaining sleep</i></b>		
Initial insomnia	1	0
Insomnia	12	0
Middle insomnia	2	0
<b><i>Dyssomnias</i></b>		
Poor quality sleep	4	0
<b><i>Eating disorders NEC</i></b>		
Eating disorder	1	0
<b><i>Emotional and mood disturbances NEC</i></b>		
Anger	1	0
Emotional distress	9	0
Irritability	52	0
Mood altered	1	0
<b><i>Fluctuating mood symptoms</i></b>		
Mood swings	1	0
<b><i>Increased physical activity levels</i></b>		
Restlessness	10	0
<b><i>Mental disorders NEC</i></b>		
Mental disorder	2	0
<b><i>Mood alterations with depressive symptoms</i></b>		
Depressed mood	2	0
Tearfulness	1	0
<b><i>Mood disorders NEC</i></b>		
Listless	4	0
<b><i>Obsessive-compulsive disorders and symptoms</i></b>		
Obsessive-compulsive symptom	1	0
<b><i>Parasomnias</i></b>		
Sleep terror	1	0
<b><i>Pervasive developmental disorders NEC</i></b>		

## Case Series Drug Analysis Print

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Report Run Date: 07-Mar-2024  
 Earliest Reaction Date: 28-Sep-2006

Data Lock Date: 06-Mar-2024 18:30:04  
 MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Autism spectrum disorder	9	0
<b>Psychiatric symptoms NEC</b>		
Decreased eye contact	2	0
<b>Sleep disorders NEC</b>		
Sleep disorder	6	0
<b>Suicidal and self-injurious behaviour</b>		
Self-injurious ideation	1	0
<b>Tic disorders</b>		
Tic	1	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>161</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i>Glomerulonephritis and nephrotic syndrome</i>		
Nephrotic syndrome	1	0
<i>Myoneurogenic bladder disorders</i>		
Bladder dysfunction	1	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>2</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<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
Testicular swelling	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	1	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>6</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Apnoeic attack	1	0
Dyspnoea	9	0
Grunting	1	0
Hyperventilation	1	0
Hypopnoea	1	0
Respiratory arrest	2	1
Tachypnoea	1	0
<i><b>Bronchospasm and obstruction</b></i>		
Wheezing	8	0
<i><b>Conditions associated with abnormal gas exchange</b></i>		
Asphyxia	1	0
<i><b>Coughing and associated symptoms</b></i>		
Cough	13	0
Productive cough	2	0
<i><b>Lower respiratory tract signs and symptoms</b></i>		
Rales	1	0
<i><b>Nasal congestion and inflammations</b></i>		
Nasal congestion	3	0
<i><b>Parenchymal lung disorders NEC</b></i>		
Lung consolidation	1	0
<i><b>Pharyngeal disorders (excl infections and neoplasms)</b></i>		
Pharyngeal erythema	1	0
Pharyngeal swelling	1	0
<i><b>Pneumothorax and pleural effusions NEC</b></i>		
Pleural effusion	1	0
<i><b>Pulmonary oedemas</b></i>		
Pulmonary oedema	1	0
<i><b>Upper respiratory tract signs and symptoms</b></i>		
Oropharyngeal pain	5	0
Rhinorrhoea	13	0
Throat tightness	1	0
<b>Respiratory disorders SOC TOTAL</b>	<b>68</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<i>Angioedemas</i>		
Angioedema	2	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	2	0
Hyperhidrosis	6	0
Miliaria	1	0
<i>Bullous conditions</i>		
Blister	8	0
Blood blister	1	0
Erythema multiforme	4	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	3	0
Macule	1	0
Pain of skin	1	0
Papule	4	0
Scab	1	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	8	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	45	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	11	0
<i>Purpura and related conditions</i>		
Henoch-Schonlein purpura	1	0
Purpura	1	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	130	0
Rash erythematous	15	0
Rash macular	12	0
Rash maculo-papular	8	0
Rash morbilliform	14	0
Rash papular	8	0
Rash pruritic	4	0
Rash rubelliform	2	0
Rash vesicular	1	0

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Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Systemic lupus erythematosus rash	1	0
<b>Skin vasomotor conditions</b>		
Livedo reticularis	1	0
<b>Urticarias</b>		
Urticaria	42	0
<b>Skin disorders SOC TOTAL</b>	<b>369</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Social circumstances</b>		
<i>Disability issues</i>		
Immobile	2	0
<b>Social circumstances SOC TOTAL</b>	<b>2</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<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
<b>Vascular disorders SOC TOTAL</b>	<b>30</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>2144</b>	<b>9</b>
<b>TOTAL REPORTS</b>	<b>718</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>9</b>