

Case Series Drug Analysis Print

Name: FOI 22/679 Hib/MenC Vaccine Analysis Print (VAP)

Report Run Date: 07-Jun-2022
Data Lock Date: 31-May-2022 18:30:04
Earliest Reaction Date: 28-Sep-2006
MedDRA Version: MedDRA 25.0

FOI 22/679 Hib/MenC Vaccine Analysis Print (VAP): All UK spontaneous suspected Adverse Drug Reaction (ADR) reports associated with the Hib/MenC vaccine up to and including 31/05/2022

Case Series Drug Analysis Print

Name: FOI 22/679 Hib/MenC Vaccine Analysis Print (VAP)

Report Run Date: 07-Jun-2022

Data Lock Date: 31-May-2022 18:30:04

Earliest Reaction Date: 28-Sep-2006

MedDRA Version: MedDRA 25.0

| Reaction Name | Total | Fatal |
|---------------------------------------|-----------|----------|
| Blood disorders | | |
| <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 |
| Blood disorders SOC TOTAL | 10 | 0 |

Case Series Drug Analysis Print

Name: FOI 22/679 Hib/MenC Vaccine Analysis Print (VAP)

Report Run Date: 07-Jun-2022
 Earliest Reaction Date: 28-Sep-2006

Data Lock Date: 31-May-2022 18:30:04
 MedDRA Version: MedDRA 25.0

| 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 |

Case Series Drug Analysis Print

Name: FOI 22/679 Hib/MenC Vaccine Analysis Print (VAP)

Report Run Date: 07-Jun-2022

Data Lock Date: 31-May-2022 18:30:04

Earliest Reaction Date: 28-Sep-2006

MedDRA Version: MedDRA 25.0

| 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 |

Case Series Drug Analysis Print

Name: FOI 22/679 Hib/MenC Vaccine Analysis Print (VAP)

Report Run Date: 07-Jun-2022

Data Lock Date: 31-May-2022 18:30:04

Earliest Reaction Date: 28-Sep-2006

MedDRA Version: MedDRA 25.0

| 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 |

Case Series Drug Analysis Print

Name: FOI 22/679 Hib/MenC Vaccine Analysis Print (VAP)

Report Run Date: 07-Jun-2022
 Earliest Reaction Date: 28-Sep-2006

Data Lock Date: 31-May-2022 18:30:04
 MedDRA Version: MedDRA 25.0

| 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>Ocular sensation disorders</i> | | |
| Asthenopia | 1 | 0 |
| <i>Pupil disorders</i> | | |
| Anisocoria | 1 | 0 |
| Mydriasis | 2 | 0 |
| Pupil fixed | 1 | 0 |
| Eye disorders SOC TOTAL | 33 | 0 |

Case Series Drug Analysis Print

Name: FOI 22/679 Hib/MenC Vaccine Analysis Print (VAP)

Report Run Date: 07-Jun-2022
Earliest Reaction Date: 28-Sep-2006

Data Lock Date: 31-May-2022 18:30:04
MedDRA Version: MedDRA 25.0

| 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 | 3 | 0 |
| Vomiting | 89 | 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 | 198 | 0 |

Case Series Drug Analysis Print

Name: FOI 22/679 Hib/MenC Vaccine Analysis Print (VAP)

Report Run Date: 07-Jun-2022

Data Lock Date: 31-May-2022 18:30:04

Earliest Reaction Date: 28-Sep-2006

MedDRA Version: MedDRA 25.0

| Reaction Name | Total | Fatal |
|--|-------|-------|
| General disorders | | |
| <i>Administration site reactions NEC</i> | | |
| Administration site erythema | 1 | 0 |
| <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 | 213 | 0 |
| <i>Feelings and sensations NEC</i> | | |
| Chills | 12 | 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 | 10 | 0 |
| Loss of control of legs | 1 | 0 |
| <i>General signs and symptoms NEC</i> | | |
| Condition aggravated | 2 | 0 |
| Crepitations | 1 | 0 |
| Crying | 44 | 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 | 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 | 18 | 0 |
| Swelling face | 10 | 0 |
| <i>Inflammations</i> | | |
| Inflammation | 3 | 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 |
| Injection site inflammation | 6 | 0 |

Case Series Drug Analysis Print

Name: FOI 22/679 Hib/MenC Vaccine Analysis Print (VAP)

Report Run Date: 07-Jun-2022

Data Lock Date: 31-May-2022 18:30:04

Earliest Reaction Date: 28-Sep-2006

MedDRA Version: MedDRA 25.0

| Reaction Name | Total | Fatal |
|---|------------|----------|
| General disorders General disorders cont'd | | |
| Injection site mass | 2 | 0 |
| Injection site oedema | 1 | 0 |
| Injection site pain | 3 | 0 |
| 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 | | |
| Drug ineffective | 1 | 0 |
| Vaccination failure | 14 | 0 |
| Vaccination site reactions | | |
| 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 | 12 | 0 |
| Vaccination site pain | 7 | 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 | 654 | 4 |

Case Series Drug Analysis Print

Name: FOI 22/679 Hib/MenC Vaccine Analysis Print (VAP)

Report Run Date: 07-Jun-2022
 Earliest Reaction Date: 28-Sep-2006

Data Lock Date: 31-May-2022 18:30:04
 MedDRA Version: MedDRA 25.0

| Reaction Name | Total | Fatal |
|---|-----------|----------|
| 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 |

Case Series Drug Analysis Print

Name: FOI 22/679 Hib/MenC Vaccine Analysis Print (VAP)

Report Run Date: 07-Jun-2022
Earliest Reaction Date: 28-Sep-2006

Data Lock Date: 31-May-2022 18:30:04
MedDRA Version: MedDRA 25.0

| 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 chronic | 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 |

Case Series Drug Analysis Print

Name: FOI 22/679 Hib/MenC Vaccine Analysis Print (VAP)

Report Run Date: 07-Jun-2022

Data Lock Date: 31-May-2022 18:30:04

Earliest Reaction Date: 28-Sep-2006

MedDRA Version: MedDRA 25.0

| 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 |

Case Series Drug Analysis Print

Name: FOI 22/679 Hib/MenC Vaccine Analysis Print (VAP)

Report Run Date: 07-Jun-2022

Data Lock Date: 31-May-2022 18:30:04

Earliest Reaction Date: 28-Sep-2006

MedDRA Version: MedDRA 25.0

| 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 |

Case Series Drug Analysis Print

Name: FOI 22/679 Hib/MenC Vaccine Analysis Print (VAP)

Report Run Date: 07-Jun-2022

Data Lock Date: 31-May-2022 18:30:04

Earliest Reaction Date: 28-Sep-2006

MedDRA Version: MedDRA 25.0

| 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 | 26 | 0 |
| Breath sounds abnormal | 1 | 0 |
| <i>Protein analyses NEC</i> | | |
| C-reactive protein increased | 1 | 0 |
| Investigations SOC TOTAL | 44 | 0 |

Case Series Drug Analysis Print

Name: FOI 22/679 Hib/MenC Vaccine Analysis Print (VAP)

Report Run Date: 07-Jun-2022

Data Lock Date: 31-May-2022 18:30:04

Earliest Reaction Date: 28-Sep-2006

MedDRA Version: MedDRA 25.0

| Reaction Name | Total | Fatal |
|---|-----------|----------|
| Metabolic disorders | | |
| <i>Appetite disorders</i> | | |
| Decreased appetite | 55 | 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 | 70 | 0 |

Case Series Drug Analysis Print

Name: FOI 22/679 Hib/MenC Vaccine Analysis Print (VAP)

Report Run Date: 07-Jun-2022

Data Lock Date: 31-May-2022 18:30:04

Earliest Reaction Date: 28-Sep-2006

MedDRA Version: MedDRA 25.0

| Reaction Name | Total | Fatal |
|--|-----------|----------|
| Muscle & tissue disorders | | |
| <i>Extremity deformities</i> | | |
| Foot deformity | 1 | 0 |
| <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 | 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 |
| Musculoskeletal pain | 1 | 0 |
| Neck pain | 1 | 0 |
| Pain in extremity | 26 | 0 |
| Muscle & tissue disorders SOC TOTAL | 67 | 0 |

Case Series Drug Analysis Print

Name: FOI 22/679 Hib/MenC Vaccine Analysis Print (VAP)

Report Run Date: 07-Jun-2022

Data Lock Date: 31-May-2022 18:30:04

Earliest Reaction Date: 28-Sep-2006

MedDRA Version: MedDRA 25.0

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

Case Series Drug Analysis Print

Name: FOI 22/679 Hib/MenC Vaccine Analysis Print (VAP)

Report Run Date: 07-Jun-2022

Data Lock Date: 31-May-2022 18:30:04

Earliest Reaction Date: 28-Sep-2006

MedDRA Version: MedDRA 25.0

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Nervous system disorders | | |
| <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 | 4 | 0 |
| Fine motor delay | 1 | 0 |
| Hypokinesia | 4 | 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 |

Case Series Drug Analysis Print

Name: FOI 22/679 Hib/MenC Vaccine Analysis Print (VAP)

Report Run Date: 07-Jun-2022

Data Lock Date: 31-May-2022 18:30:04

Earliest Reaction Date: 28-Sep-2006

MedDRA Version: MedDRA 25.0

| Reaction Name | Total | Fatal |
|--|------------|----------|
| Nervous system disorders <small>Nervous system disorders cont'd</small> | | |
| Myoclonus | 1 | 0 |
| Presyncope | 3 | 0 |
| Unresponsive to stimuli | 10 | 0 |
| Neuromuscular disorders NEC | | |
| Hypotonic-hyporesponsive episode | 1 | 0 |
| Paraesthesias and dysaesthesias | | |
| Hyperaesthesia | 1 | 0 |
| Paralysis and paresis (excl cranial nerve) | | |
| Monoplegia | 1 | 0 |
| Paralysis | 2 | 0 |
| Peripheral neuropathies NEC | | |
| Polyneuropathy | 1 | 0 |
| Seizures and seizure disorders NEC | | |
| Epilepsy | 2 | 0 |
| Febrile convulsion | 20 | 0 |
| Partial seizures | 2 | 0 |
| Seizure | 11 | 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 | 11 | 0 |
| Nervous system disorders SOC TOTAL | 190 | 0 |

Case Series Drug Analysis Print

Name: FOI 22/679 Hib/MenC Vaccine Analysis Print (VAP)

Report Run Date: 07-Jun-2022

Data Lock Date: 31-May-2022 18:30:04

Earliest Reaction Date: 28-Sep-2006

MedDRA Version: MedDRA 25.0

| 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 |

Case Series Drug Analysis Print

Name: FOI 22/679 Hib/MenC Vaccine Analysis Print (VAP)

Report Run Date: 07-Jun-2022

Data Lock Date: 31-May-2022 18:30:04

Earliest Reaction Date: 28-Sep-2006

MedDRA Version: MedDRA 25.0

| 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 | 4 | 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>Cognitive and attention disorders and disturbances NEC</i> | | |
| Daydreaming | 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 | 10 | 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 |

Case Series Drug Analysis Print

Name: FOI 22/679 Hib/MenC Vaccine Analysis Print (VAP)

Report Run Date: 07-Jun-2022

Data Lock Date: 31-May-2022 18:30:04

Earliest Reaction Date: 28-Sep-2006

MedDRA Version: MedDRA 25.0

| Reaction Name | Total | Fatal |
|--|------------|----------|
| Psychiatric disorders <small>Psychiatric disorders cont'd</small> | | |
| <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> | | |
| Tic | 1 | 0 |
| Psychiatric disorders SOC TOTAL | 149 | 0 |

Case Series Drug Analysis Print

Name: FOI 22/679 Hib/MenC Vaccine Analysis Print (VAP)

Report Run Date: 07-Jun-2022

Data Lock Date: 31-May-2022 18:30:04

Earliest Reaction Date: 28-Sep-2006

MedDRA Version: MedDRA 25.0

| 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 |

Case Series Drug Analysis Print

Name: FOI 22/679 Hib/MenC Vaccine Analysis Print (VAP)

Report Run Date: 07-Jun-2022

Data Lock Date: 31-May-2022 18:30:04

Earliest Reaction Date: 28-Sep-2006

MedDRA Version: MedDRA 25.0

| 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 |

Case Series Drug Analysis Print

Name: FOI 22/679 Hib/MenC Vaccine Analysis Print (VAP)

Report Run Date: 07-Jun-2022
 Earliest Reaction Date: 28-Sep-2006

Data Lock Date: 31-May-2022 18:30:04
 MedDRA Version: MedDRA 25.0

| 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: FOI 22/679 Hib/MenC Vaccine Analysis Print (VAP)

Report Run Date: 07-Jun-2022

Data Lock Date: 31-May-2022 18:30:04

Earliest Reaction Date: 28-Sep-2006

MedDRA Version: MedDRA 25.0

| 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 |
| Miliaria | 1 | 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 |
| 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 | 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 | 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 | 10 | 0 |
| <i>Purpura and related conditions</i> | | |
| Henoch-Schonlein purpura | 1 | 0 |
| Purpura | 1 | 0 |
| <i>Rashes, eruptions and exanthems NEC</i> | | |
| Rash | 120 | 0 |
| Rash erythematous | 14 | 0 |
| Rash macular | 12 | 0 |
| Rash maculo-papular | 8 | 0 |
| Rash morbilliform | 13 | 0 |
| Rash papular | 8 | 0 |
| Rash pruritic | 4 | 0 |
| Rash rubelliform | 2 | 0 |
| Rash vesicular | 1 | 0 |

Case Series Drug Analysis Print

Name: FOI 22/679 Hib/MenC Vaccine Analysis Print (VAP)

Report Run Date: 07-Jun-2022

Data Lock Date: 31-May-2022 18:30:04

Earliest Reaction Date: 28-Sep-2006

MedDRA Version: MedDRA 25.0

| Reaction Name | Total | Fatal |
|---|------------|----------|
| Skin disorders Skin disorders cont'd | | |
| Systemic lupus erythematosus rash | 1 | 0 |
| Skin vasomotor conditions | | |
| Livedo reticularis | 1 | 0 |
| Urticarias | | |
| Urticaria | 42 | 0 |
| Skin disorders SOC TOTAL | 354 | 0 |

Case Series Drug Analysis Print

Name: FOI 22/679 Hib/MenC Vaccine Analysis Print (VAP)

Report Run Date: 07-Jun-2022

Data Lock Date: 31-May-2022 18:30:04

Earliest Reaction Date: 28-Sep-2006

MedDRA Version: MedDRA 25.0

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

Case Series Drug Analysis Print

Name: FOI 22/679 Hib/MenC Vaccine Analysis Print (VAP)

Report Run Date: 07-Jun-2022
 Earliest Reaction Date: 28-Sep-2006

Data Lock Date: 31-May-2022 18:30:04
 MedDRA Version: MedDRA 25.0

| 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 | 2047 | 9 |
| TOTAL REPORTS | 678 | |
| TOTAL FATAL OUTCOME REPORTS | | 9 |