Name: Hib/MenC

Report Run Date: 15-May-2023

Data Lock Date: 12-May-2023 16:30:03

Earliest Reaction Date: 28-Sep-2006 MedDRA Version: MedDRA 26.0

Hib/MenC: FOI 23/290 - All UK spontaneous reports for Hib/MenC

vaccine up to and including 12/05/2023

Name: Hib/MenC

Report Run Date: 15-May-2023 Data Lock Date: 12-May-2023 16:30:03
Earliest Reaction Date: 28-Sep-2006 MedDRA Version: MedDRA 26.0

Reaction Name	Total	Fatal
Blood disorders		
Anaemias haemolytic immune		
Autoimmune haemolytic anaemia	1	0
Lymphatic system disorders NEC		
Lymphadenopathy	7	'l o
Lymphoid tissue hyperplasia		0
Thrombocytopenias		
Immune thrombocytopenia	1	0
Blood disorders SOC TOTAL	10	

Name: Hib/MenC

Report Run Date: 15-May-2023 Data Lock Date: 12-May-2023 16:30:03
Earliest Reaction Date: 28-Sep-2006 MedDRA Version: MedDRA 26.0

Reaction Name	Total	Fatal
Cardiac disorders		
Cardiac signs and symptoms NEC		
Palpitations	3	8 0
Heart failures NEC		
Cardiac failure	1	0
Ischaemic coronary artery disorders		
Myocardial infarction	1	1
Rate and rhythm disorders NEC		
Bradycardia	2	
Tachycardia	5	5 O
Ventricular arrhythmias and cardiac arrest		
Cardiac arrest	1	1
Cardio-respiratory arrest	1	0
Ventricular tachycardia	1	0
Cardiac disorders SOC TOTAL	15	5 2

Name: Hib/MenC

Report Run Date: 15-May-2023 Data Lock Date: 12-May-2023 16:30:03
Earliest Reaction Date: 28-Sep-2006 MedDRA Version: MedDRA 26.0

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

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Report Run Date: 15-May-2023 Data Lock Date: 12-May-2023 16:30:03
Earliest Reaction Date: 28-Sep-2006 MedDRA Version: MedDRA 26.0

Reaction Name	Total	Fatal
Ear disorders		
Ear disorders NEC		
Ear pain	•	1 0
Ear swelling		2 0
External ear disorders NEC		
Excessive cerumen production	,	1 0
Hearing losses		
Deafness	,	1 0
Ear disorders SOC TOTAL	Į į	5 0

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Report Run Date: 15-May-2023 Data Lock Date: 12-May-2023 16:30:03
Earliest Reaction Date: 28-Sep-2006 MedDRA Version: MedDRA 26.0

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

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Report Run Date: 15-May-2023 Data Lock Date: 12-May-2023 16:30:03
Earliest Reaction Date: 28-Sep-2006 MedDRA Version: MedDRA 26.0

Earliest Reaction Date: 28-Sep-2006 MedDRA Version: MedDRA 2		
Reaction Name	<u> Total</u>	<u>Fatal</u>
Gastrointestinal disorders		
Diarrhoea (excl infective)		
Diarrhoea	63	0
Faecal abnormalities NEC		
Abnormal faeces	1	0
Faecaloma	1	0
Faeces discoloured	1	0
Faeces soft	1	0
Mucous stools	2	0
Flatulence, bloating and distension		
Abdominal distension	4	0
Flatulence	1	0
Gastrointestinal and abdominal pains (excl oral and throat)		
Abdominal pain	4	0
Abdominal pain upper	3	0
Gastrointestinal atonic and hypomotility disorders NEC		
Constipation	2	0
Gastrooesophageal reflux disease	2	0
Gastrointestinal dyskinetic disorders		
Change of bowel habit	1	0
Gastrointestinal motility disorder	1	0
Gastrointestinal signs and symptoms NEC		
Abdominal discomfort	2	0
Gastrointestinal spastic and hypermotility disorders		
Irritable bowel syndrome	1	0
Nausea and vomiting symptoms		
Infantile vomiting	2	0
Nausea	3	0
Vomiting	94	0
Vomiting projectile	8	0
Non-site specific gastrointestinal haemorrhages		
Haematemesis	1	0
Haematochezia	1	0
Oral dryness and saliva altered		
Lip dry	1	0
Oral soft tissue disorders NEC		
Chapped lips	1	0
Lip blister	1	0
Oral soft tissue signs and symptoms		
Oral pain	1	0
Oral soft tissue swelling and oedema		
Lip swelling	3	0
Mouth swelling	1	0
Stomatitis and ulceration		
Mouth ulceration	2	0
Tongue disorders		
Tongue geographic	1	0
Gastrointestinal disorders SOC TOTAL	210	

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Earliest Reaction Date: 28-Sep-2006 MedDRA Version: MedDRA 26.0

Earliest Reaction Date: 28-Sep-2006	MedDRA Version: MedDRA 26.0		
Reaction Name	<u>To</u>	<u>tal</u>	<u>Fatal</u>
General disorders			
Administration site reactions NEC			
Administration site erythema		1	0
Asthenic conditions			
Asthenia		5	0
Decreased activity		1	0
Fatigue		15	0
Malaise		28	0
Body temperature altered			
Hypothermia		1	0
Death and sudden death			
Death		2	2
Sudden death		1	1
Sudden infant death syndrome		1	1
Febrile disorders			
Pyrexia		221	0
Feelings and sensations NEC			
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
Gait disturbances			
Gait disturbance		9	0
Gait inability		10	0
Loss of control of legs		1	0
General signs and symptoms NEC			
Condition aggravated		2	0
Crepitations		1	0
Crying		45	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		19	0
Swelling face		10	0
Inflammations			
Inflammation		4	0
Injection site reactions			
Injection site bruising		1	0
Injection site discolouration		2	0
Injection site erythema		17	0
Injection site induration		1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd	1000	· atai
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
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
Tenderness	1	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	2	0
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	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
General disorders SOC TOTAL	677	4

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Reaction Name	Total	Fatal
Immune system disorders		
Allergic conditions NEC		
Allergy to metals	1	0
Hypersensitivity	12	0
Allergies to foods, food additives, drugs and other chemicals		
Food allergy	1	0
Milk allergy	2	0
Reaction to excipient	1	0
Reaction to preservatives	1	0
Anaphylactic and anaphylactoid responses		
Anaphylactic reaction	7	0
Immunodeficiency disorders NEC		
Immunodeficiency	1	0
Immune system disorders SOC TOTAL	26	0

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Earliest Reaction Date: 28-Sep-2006 MedDRA Version: MedDRA 26.0

Earliest Reaction Date: 28-Sep-2006 MedDRA Version: MedDRA 26.0		
Reaction Name	<u> Total</u>	<u>Fatal</u>
Infections		
Abdominal and gastrointestinal infections		
Gastroenteritis	1	0
Bacterial infections NEC		
Cellulitis	17	0
Injection site cellulitis	1	0
Periorbital cellulitis	1	0
Skin bacterial infection	2 2	0
Vaccination site cellulitis	2	0
Bone and joint infections		
Intervertebral discitis	1	0
Osteomyelitis	1	0
Central nervous system and spinal infections		
Encephalitis	4	0
Meningitis	2	1
Dental and oral soft tissue infections		
Gingivitis	1	0
Ear infections		
Ear infection	4	0
Otitis media chronic	1	0
Eye and eyelid infections		
Conjunctivitis	3	0
Eye infection	1	0
Haemophilus infections		
Haemophilus infection	4	1
Meningitis haemophilus	1	0
Herpes viral infections		
Oral herpes	1	0
Varicella	1	0
Infections NEC		
Infection	2	0
Localised infection	2 2	0
Vaccination site abscess	2	0
Vaccination site infection	1	0
Lower respiratory tract and lung infections		
Bronchitis	1	0
Lower respiratory tract infection	6	0
Pneumonia	2	0
Neisseria infections		
Meningitis meningococcal	1	0
Meningococcal infection	7	0
Meningococcal sepsis	2	0
Rubeola viral infections		
Measles	1	0
Sepsis, bacteraemia, viraemia and fungaemia NEC		
Sepsis	4	0
Skin structures and soft tissue infections		
Rash pustular	1	0
Skin infection	1	0
Tuberculous infections		
Erythema induratum	1	0
Upper respiratory tract infections		
Croup infectious	1	0
Epiglottitis	3	0

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Earliest Reaction Date: 28-Sep-2006 MedDRA Version: MedDRA 26.0

Reaction Name	Total	Fatal
Infections Infections cont'd		
Nasopharyngitis	3	3 0
Rhinitis		3 0
Tonsillitis		6 0
Tracheitis		ı 0
Upper respiratory tract infection	2	2 0
Urinary tract infections		
Urinary tract infection		I 0
Viral infections NEC		
Viral rash	2	2 0
Infections SOC TOTAL	105	5 2

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

Name: Hib/MenC

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Reaction Name	Total	Fatal
Investigations		
Bacteria identification and serology (excl mycobacteria)		
Neisseria test positive	1	0
Chemistry analyses NEC		
Inflammatory marker increased	1	0
Coagulation and bleeding analyses		
Bleeding time prolonged	1	0
Heart rate and pulse investigations		
Heart rate abnormal	2	0
Heart rate increased	6	0
Immunoglobulin analyses		
Blood immunoglobulin G increased	1	0
Physical examination procedures and organ system status		
Body temperature abnormal	1	0
Body temperature decreased	2	0
Body temperature fluctuation	1	0
Body temperature increased	27	0
Breath sounds abnormal	1	0
Protein analyses NEC		
C-reactive protein increased	1	0
Investigations SOC TOTAL	45	0

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

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Earliest Reaction Date: 28-Sep-2006 MedDRA Version: MedDRA 26.0

Reaction Name	Total	Fatal
Muscle & tissue disorders		
Extremity deformities		
Foot deformity	1	0
Joint related signs and symptoms		
Arthralgia	3	0
Joint stiffness	1	0
Joint swelling	1	0
Muscle pains		
Myalgia	4	0
Muscle related signs and symptoms NEC		
Muscle tightness	1	0
Muscle twitching	1	0
Muscle tone abnormalities		
Floppy infant	3	0
Muscle weakness conditions		
Muscular weakness	6	0
Musculoskeletal and connective tissue conditions NEC		
Limb mass	1	0
Musculoskeletal stiffness	4	0
Weight bearing difficulty	7	0
Musculoskeletal and connective tissue pain and discomfort		
Back pain	1	0
Limb discomfort	4	0
Musculoskeletal pain	1	0
Neck pain	1	0
Pain in extremity	27	0
Muscle & tissue disorders SOC TOTAL	67	0

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Reaction Name	Total	Fatal
Neoplasms		
Skin neoplasms malignant and unspecified (excl melanoma)		
Neoplasm skin	1	0
Neoplasms SOC TOTAL	1	l o

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Earliest Reaction Date: 28-Sep-2006 MedDRA Version: MedDRA 26.0

Earliest Reaction Date: 28-Sep-2006 MedDRA Version: MedDRA 26.0		
Reaction Name	<u>Total</u>	<u>Fatal</u>
Nervous system disorders		
Abnormal reflexes		
Areflexia	1	0
Absence seizures		
Petit mal epilepsy	1	0
Acute polyneuropathies		
Guillain-Barre syndrome	1	0
Central nervous system vascular disorders NEC		
Brain hypoxia	1	0
Coordination and balance disturbances		
Balance disorder	4	0
Coordination abnormal	1	0
Dysstasia	2	0
Hand-eye coordination impaired	1	0
Cortical dysfunction NEC		
Aphasia	3	0
Dyspraxia	1	0
Sensory processing disorder	1	0
Disturbances in consciousness NEC		
Lethargy	23	0
Loss of consciousness	3	0
Somnolence	19	0
Syncope	2	0
Dyskinesias and movement disorders NEC		
Dyskinesia	4	0
Fine motor delay	1	0
Hypokinesia	4	0
Movement disorder	1	0
Psychomotor hyperactivity	2	0
Facial cranial nerve disorders		
Bell's palsy	1	0
Facial paralysis	1	0
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	1	0
Headaches NEC		
Headache	8	0
Increased intracranial pressure disorders		
Brain oedema	1	0
Migraine headaches		
Migraine	1	0
Muscle tone abnormal		
Hypotonia	10	0
Narcolepsy and hypersomnia		
Hypersomnia	3	0
Nervous system disorders NEC		
Nervous system disorder	1	0
Neurological signs and symptoms NEC		
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
Nervous system disorders us system disorders cont'd		
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

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

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Earliest Reaction Date: 28-Sep-2006 MedDRA Version: MedDRA 26.0

Psychiatric disorders Abnormal behaviour NEC	Earliest Reaction Date: 28-Sep-2006 MedDRA Version: MedDRA 26.0		
Abnormal behaviour NEC	Reaction Name	<u>Total</u>	<u>Fatal</u>
Abnormal behaviour Breath holding 3 0 0 0 0 0 0 0 0 0			
Breath holding Staring Affect alterations NEC Affect lability 1	Abnormal behaviour NEC		
Staring	Abnormal behaviour		-
Affect alterations NEC Affect lability 1 0 Anxiety symptoms 4 0 0 Apitation 4 0 0 Attention deficit and disruptive behaviour disorders 4 0 Attention deficit hyperactivity disorder 1 0 Behaviour and socialisation disturbances 3 0 Aggression 5 0 Disturbance in social behaviour 1 0 Personality change 3 3 0 Social avoidant behaviour 1 0 0 Cognitive and attention disorders and disturbances NEC 1 0 Daydread attention disorders and disturbances NEC 1 0 Daydread attention disorders and disturbances NEC 1 0 Catatonia 1 0 0 Decreased physical activity levels 1 0 Catatonia 1 0 0 Dyssomnias 1 1 0 Dyssomnias 2 0 0 P	Breath holding	3	0
Affect lability Anxiety symptoms Agitation Anxiety Attention deficit and disruptive behaviour disorders Attention deficit hyperactivity disorder Behaviour and socialisation disturbances Aggression Disturbance in social behaviour Personality change Social avoidant behaviour Personality change Social avoidant behaviour Cognitive and attention disorders and disturbances NEC Daydreaming Confusion and disorientation Disorientation Disorientation Decreased physical activity levels Catatonia Delirium	Staring	2	0
Anxiety symptoms	Affect alterations NEC		
Agitation Anxiety Attention deficit and disruptive behaviour disorders Attention deficit hyperactivity disorder Behaviour and socialisation disturbances Aggression Disturbance in social behaviour Personality change Social avoidant behaviour Personality change Social avoidant behaviour Cognitive and attention disorders and disturbances NEC Daydreaming Confusion and disorientation Disorientation Disorientation Disorientation Decreased physical activity levels Catatonia Delirium Disturbances in initiating and maintaining sleep Initial insomnia Insom	Affect lability	1	0
Arixiety Attention deficit and disruptive behaviour disorders Attention deficit hyperactivity disorder Behaviour and socialisation disturbances Aggression Disturbance in social behaviour Personality change Social avoidant behaviour Ocognitive and attention disorders and disturbances NEC Daydreaming Confusion and disorientation Disorientation Disorientation Disorientation Disturbances in initiating and maintaining sleep Initial insomnia Insomnia Middle insomnia Disorientation Disorientation Disturbances in initiating and maintaining sleep Initial insomnia	Anxiety symptoms		
Attention deficit and disruptive behaviour disorders Attention deficit hyperactivity disorder Behaviour and socialisation disturbances Aggression Disturbance in social behaviour Personality change Social avoidant behaviour Cognitive and attention disorders and disturbances NEC Daydreaming Confusion and disorientation Disorientation Disorientation Disorientation Delirium Delirium Disturbances in initiating and maintaining sleep Initial insomnia Insomnia Insomnia Dyssomnias Poor quality sleep Eating disorders NEC Eating disorder NEC Eating disorder Emotional disturbances NEC Anger Emotional disturbances NEC Anger Emotional distress Irritability Mood altered Fluctuating mood symptoms Mood swings Increased physical activity levels Restlessness Mood atterations with depressive symptoms Depressed mood Tearfulness Mood disorders NEC Listless Mood Sessive-compulsive disorders and symptoms Obsessive-compulsive disorders and symptoms Sleep terror 1 0 1 0 2 0 3 0 0 0 0 0 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0	Agitation	4	0
Attention deficit hyperactivity disorder Behaviour and socialisation disturbances Aggression Disturbance in social behaviour Personality change Social avoidant behaviour Cognitive and attention disorders and disturbances NEC Daydreaming Confusion and disorientation Disorientation Disorientation Disorientation Decreased physical activity levels Catatonia Deliria Deliria Deliria Delirium Disturbances in initiating and maintaining sleep Initial insomnia Insomnia Insomnia Middle insomnia Dyssomnias Poor quality sleep Eating disorders NEC Eating disorder NEC Eating disorder I Emotional and mood disturbances NEC Anger Emotional distress Irritability Mood altered Fluctuating mood symptoms Mood avings Increased physical activity levels Restlessness Mond alterations with depressive symptoms Depressed mood Tearfulness Mood disorders NEC Listless Obsessive-compulsive disorders and symptoms Obsessive-compulsive disorders and symptoms Obsessive-compulsive disorders and symptoms Sleep terror 1 0 Parasomnias Sleep terror 1 0 Parasomnias Sleep terror 1 0 Parasomnias Sleep terror 1 0 Parasomnias Sleep terror	Anxiety	2	0
Behaviour and socialisation disturbances	Attention deficit and disruptive behaviour disorders		
Aggression Disturbance in social behaviour Personality change Social avoidant behaviour Cognitive and attention disorders and disturbances NEC Daydreaming Confusion and disorientation Disorientation Disorientation Decreased physical activity levels Catatonia Deliriu Delirium Disturbances in initiating and maintaining sleep Initial insomnia Insomnia Insomnia Insomnia Insomnia Poor quality sleep Eating disorder NEC Eating disorder Emotional distress Irritability Mood altered Fluctuating mood symptoms Mood awings Increased physical activity levels Restlessness Mental disorder NEC Mental disorder NEC Mental disorder Indicating the side of	Attention deficit hyperactivity disorder	1	0
Disturbance in social behaviour	Behaviour and socialisation disturbances		
Personality change Social avoidant behaviour Cognitive and attention disorders and disturbances NEC Daydreaming Confusion and disorientation Disorientation Disorientation Decreased physical activity levels Catatonia Deliria Deliria Delirium Disturbances in initiating and maintaining sleep Initial insomnia	Aggression	5	0
Social avoidant behaviour Cognitive and attention disorders and disturbances NEC Daydreaming 1	Disturbance in social behaviour	1	0
Cognitive and attention disorders and disturbances NEC Daydreaming Confusion and disorientation Disorientation Disorientation Decreased physical activity levels Catatonia Deliria Deliria Delirium Disturbances in initiating and maintaining sleep Initial insomnia Insomnias Insomnia	Personality change	3	0
Daydreaming Confusion and disorientation Disorientation Disorientation Decreased physical activity levels Catatonia Deliria Deliria Delirium Disturbances in initiating and maintaining sleep Initial insomnia Insomnias I	Social avoidant behaviour	1	0
Daydreaming Confusion and disorientation Disorientation Disorientation Decreased physical activity levels Catatonia Deliria Deliria Delirium Disturbances in initiating and maintaining sleep Initial insomnia Insomnias I	Cognitive and attention disorders and disturbances NEC		
Discrientation		1	0
Decreased physical activity levels	Confusion and disorientation		
Catatonia 1 0 Deliria 1 0 Delirium 1 0 Disturbances in initiating and maintaining sleep 1 0 Initial insomnia 12 0 Insomnia 12 0 Middle insomnia 2 0 Poor quality sleep 4 0 Poor quality sleep 4 0 Eating disorders NEC 1 0 Eating disorders NEC 1 0 Anger 1 0 Emotional and mood disturbances NEC 1 0 Anger 1 0 Emotional distress 9 0 Irritability 52 0 Mood altered 1 0 Fluctuating mood symptoms 1 0 Mondswings 1 0 Increased physical activity levels 1 0 Restlessness 10 0 Mental disorders NEC 1 0 Mental disorders NEC 2 0 Mod disorders NEC	Disorientation	1	0
Catatonia 1 0 Deliria 1 0 Delirium 1 0 Disturbances in initiating and maintaining sleep 1 0 Initial insomnia 12 0 Insomnia 12 0 Middle insomnia 2 0 Poor quality sleep 4 0 Poor quality sleep 4 0 Eating disorders NEC 1 0 Eating disorders NEC 1 0 Anger 1 0 Emotional and mood disturbances NEC 1 0 Anger 1 0 Emotional distress 9 0 Irritability 52 0 Mood altered 1 0 Fluctuating mood symptoms 1 0 Mondswings 1 0 Increased physical activity levels 1 0 Restlessness 10 0 Mental disorders NEC 1 0 Mental disorders NEC 2 0 Mod disorders NEC	Decreased physical activity levels		
Delirium		1	0
Disturbances in initiating and maintaining sleep Initial insomnia	Deliria		
Initial insomnia	Delirium	1	0
Initial insomnia	Disturbances in initiating and maintaining sleep		
Middle insomnia 2 0 Dyssomnias 4 0 Poor quality sleep 4 0 Eating disorders NEC 1 0 Emotional and mood disturbances NEC 2 0 Anger 1 0 Emotional distress 9 0 Irritability 52 0 Mood altered 1 0 Fluctuating mood symptoms 1 0 Mood swings 1 0 Increased physical activity levels 1 0 Restlessness 10 0 Mental disorders NEC 10 0 Mental disorders NEC 2 0 Mental disorders with depressive symptoms 2 0 Depressed mood 2 0 Tearfulness 1 0 Mood disorders NEC 1 0 Listless 4 0 Obsessive-compulsive disorders and symptoms 0 0 Obsessive-compulsive symptom 1 0 Parasomnias 1 0	· · · · · · · · · · · · · · · · · · ·	1	0
Dyssomnias 4 0 Eating disorders NEC 1 0 Eating disorder 1 0 Emotional and mood disturbances NEC 1 0 Anger 1 0 Emotional distress 9 0 Irritability 52 0 Mood altered 1 0 Fluctuating mood symptoms 1 0 Mood swings 1 0 Increased physical activity levels 1 0 Restlessness 10 0 Mental disorder NEC 2 0 Mental disorder NEC 2 0 Mood alterations with depressive symptoms 2 0 Depressed mood 2 0 Tearfulness 1 0 Mood disorders NEC 1 0 Listless 4 0 Obsessive-compulsive disorders and symptoms 1 0 Obsessive-compulsive symptom 1 0 Parasomnias 1	Insomnia	12	0
Poor quality sleep	Middle insomnia	2	0
Poor quality sleep	Dyssomnias		
Eating disorder SNEC 1 0 Emotional and mood disturbances NEC 1 0 Anger Emotional distress 9 0 0 Emotional distress 9 0 0 Irritability 52 0 0 Mood altered 10 1 0 Fluctuating mood symptoms Mood swings 10 1 0 Mood swings 11 0 0 Increased physical activity levels 12 0 0 Restlessness 11 0 0 Mental disorders NEC 15 2 0 Mental disorder Mec 2 0 Mood alterations with depressive symptoms 1 0 0 Depressed mood 2 0 0 0 Tearfulness 11 0 0 0 Mood disorders NEC 15 0 0 0 Listless 15 4 0 Obsessive-compulsive disorders and symptoms 1 0 0 Obsessive-compulsive symptom 1 0 0 Parasomnias 15 1 0 0 Sleep terror 15 1 0 0	•	4	0
Eating disorder 1 0 Emotional and mood disturbances NEC 1 0 Anger 1 0 Emotional distress 9 0 Irritability 52 0 Mood altered 1 0 Fluctuating mood symptoms 1 0 Mood swings 1 0 Increased physical activity levels 1 0 Restlessness 10 0 Mental disorders NEC 2 0 Mood alterations with depressive symptoms 2 0 Depressed mood 2 0 Tearfulness 1 0 Mood disorders NEC 1 0 Listless 4 0 Obsessive-compulsive disorders and symptoms 0 0 Obsessive-compulsive symptom 1 0 Parasomnias 1 0 Sleep terror 1 0			
Emotional and mood disturbances NEC Anger 1 0 Emotional distress 9 0 Irritability 52 0 Mood altered 1 0 Fluctuating mood symptoms 1 0 Mood swings 1 0 Increased physical activity levels 1 0 Restlessness 10 0 Mental disorders NEC 2 0 Mood alterations with depressive symptoms 2 0 Depressed mood 2 0 Tearfulness 1 0 Mood disorders NEC 1 0 Listless 4 0 Obsessive-compulsive disorders and symptoms 0 0 Obsessive-compulsive symptom 1 0 Parasomnias 1 0 Sleep terror 1 0		1	0
Emotional distress 9 0			
Emotional distress 9 0	Anger	1	0
Irritability		9	0
Mood altered Fluctuating mood symptoms Mood swings Increased physical activity levels Restlessness Restlessness Mental disorders NEC Mental disorder Mood alterations with depressive symptoms Depressed mood Tearfulness Mood disorders NEC Listless Obsessive-compulsive disorders and symptoms Obsessive-compulsive symptom Parasomnias Sleep terror 1 0		52	0
Mood swings10Increased physical activity levels100Restlessness100Mental disorders NEC20Mental disorder20Mood alterations with depressive symptoms20Depressed mood20Tearfulness10Mood disorders NEC10Listless40Obsessive-compulsive disorders and symptoms10Obsessive-compulsive symptom10Parasomnias10Sleep terror10	1 · · · · · · · · · · · · · · · · · · ·	1	0
Mood swings10Increased physical activity levels100Restlessness100Mental disorders NEC20Mental disorder20Mood alterations with depressive symptoms20Depressed mood20Tearfulness10Mood disorders NEC10Listless40Obsessive-compulsive disorders and symptoms10Obsessive-compulsive symptom10Parasomnias10Sleep terror10	Fluctuating mood symptoms		
Increased physical activity levels Restlessness 10 0 Mental disorders NEC Mental disorder 2 0 Mood alterations with depressive symptoms Depressed mood 2 0 Tearfulness 1 0 Mood disorders NEC Listless 4 0 Obsessive-compulsive disorders and symptoms Obsessive-compulsive symptom 1 0 Parasomnias Sleep terror 1 0		1	0
Restlessness 10 0 Mental disorders NEC 2 0 Mental disorder 2 0 Mood alterations with depressive symptoms 2 0 Depressed mood 2 0 Tearfulness 1 0 Mood disorders NEC 2 0 Listless 4 0 Obsessive-compulsive disorders and symptoms 1 0 Obsessive-compulsive symptom 1 0 Parasomnias 3 1 0 Sleep terror 1 0 </td <td></td> <td></td> <td></td>			
Mental disorder 2 0 Mood alterations with depressive symptoms 2 0 Depressed mood 2 0 Tearfulness 1 0 Mood disorders NEC 2 0 Listless 4 0 Obsessive-compulsive disorders and symptoms 0 Obsessive-compulsive symptom 1 0 Parasomnias 1 0 Sleep terror 1 0		10	0
Mood alterations with depressive symptomsDepressed mood20Tearfulness10Mood disorders NEC20Listless40Obsessive-compulsive disorders and symptoms0Obsessive-compulsive symptom10Parasomnias10Sleep terror10	Mental disorders NEC		
Depressed mood 2 0 Tearfulness 1 0 Mood disorders NEC 2 0 Listless 4 0 Obsessive-compulsive disorders and symptoms 0 Obsessive-compulsive symptom 1 0 Parasomnias 1 0 Sleep terror 1 0	Mental disorder	2	0
Depressed mood 2 0 Tearfulness 1 0 Mood disorders NEC 2 0 Listless 4 0 Obsessive-compulsive disorders and symptoms 0 Obsessive-compulsive symptom 1 0 Parasomnias 1 0 Sleep terror 1 0	Mood alterations with depressive symptoms		
Tearfulness 1 0 Mood disorders NEC Listless 4 0 Obsessive-compulsive disorders and symptoms Obsessive-compulsive symptom 1 0 Parasomnias Sleep terror 1 0		2	0
Listless Obsessive-compulsive disorders and symptoms Obsessive-compulsive symptom 1 0 Parasomnias Sleep terror 1 0		1	0
Listless Obsessive-compulsive disorders and symptoms Obsessive-compulsive symptom 1 0 Parasomnias Sleep terror 1 0			
Obsessive-compulsive disorders and symptoms10Obsessive-compulsive symptom10Parasomnias10Sleep terror10		4	0
Obsessive-compulsive symptom 1 0 Parasomnias Sleep terror 1 0			
Parasomnias Sleep terror 1 0		1	0
Sleep terror 1 0			
· ·		1	0
	Pervasive developmental disorders NEC		

Name: Hib/MenC

Report Run Date: 15-May-2023 Data Lock Date: 12-May-2023 16:30:03
Earliest Reaction Date: 28-Sep-2006 MedDRA Version: MedDRA 26.0

Reaction Name	Total	Fatal
Psychiatric disorders ^{Psychiatric} disorders cont'd		
Autism spectrum disorder	3	3 0
Psychiatric symptoms NEC		
Decreased eye contact	2	0
Sleep disorders NEC		
Sleep disorder	6	6 0
Suicidal and self-injurious behaviour		
Self-injurious ideation	1	0
Tic disorders		
Tic	1	0
Psychiatric disorders SOC TOTAL	159	el o

Name: Hib/MenC

Report Run Date: 15-May-2023 Data Lock Date: 12-May-2023 16:30:03
Earliest Reaction Date: 28-Sep-2006 MedDRA Version: MedDRA 26.0

Reaction Name	Total	Fatal
Renal & urinary disorders		
Glomerulonephritis and nephrotic syndrome		
Nephrotic syndrome	1	0
Myoneurogenic bladder disorders		
Bladder dysfunction	1	0
Renal & urinary disorders SOC TOTAL	2	0

Name: Hib/MenC

Report Run Date: 15-May-2023 Data Lock Date: 12-May-2023 16:30:03
Earliest Reaction Date: 28-Sep-2006 MedDRA Version: MedDRA 26.0

Reaction Name	Total	Fatal
Reproductive & breast disorders		
Reproductive tract signs and symptoms NEC		
Genital rash	1	0
Genital swelling		0
Scrotal disorders NEC		
Scrotal swelling		0
Testicular and epididymal disorders NEC		
Testicular pain		0
Testicular swelling	1	0
Vulvovaginal disorders NEC		
Vaginal haemorrhage	1	0
Reproductive & breast disorders SOC TOTAL	6	l o

Name: Hib/MenC

Report Run Date: 15-May-2023 Data Lock Date: 12-May-2023 16:30:03
Earliest Reaction Date: 28-Sep-2006 MedDRA Version: MedDRA 26.0

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

Name: Hib/MenC

Report Run Date: 15-May-2023 Data Lock Date: 12-May-2023 16:30:03
Earliest Reaction Date: 28-Sep-2006 MedDRA Version: MedDRA 26.0

Earliest Reaction Date: 28-Sep-2006 MedDRA Version: MedDRA 26		
Reaction Name	Total	<u>Fatal</u>
Skin disorders		
Angioedemas		
Angioedema	2	0
Apocrine and eccrine gland disorders		
Cold sweat	2	0
Hyperhidrosis	6	0
Miliaria	1	0
Bullous conditions		
Blister	8	0
Blood blister	1	0
Erythema multiforme	4	0
Dermal and epidermal conditions NEC		
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
Dermatitis and eczema		
Dermatitis	1	0
Dermatitis allergic	8	0
Dermatitis atopic	1	0
Dermatitis diaper	2	0
Eczema	8	0
Eczema weeping	1	0
Dermatitis ascribed to specific agent		
Drug eruption	1	0
Erythemas		
Erythema	45	0
Pigmentation changes NEC		
Pigmentation disorder	1	0
Pilar disorders NEC		
Hair growth abnormal	1	0
Pruritus NEC		
Pruritus	10	0
Purpura and related conditions		
Henoch-Schonlein purpura	1	0
Purpura	1	0
Rashes, eruptions and exanthems NEC		
Rash	127	0
Rash erythematous	15	0
Rash macular	12	0
Rash maculo-papular	8	
Rash morbilliform	14	
Rash papular	8	0
Rash pruritic	4	
Rash rubelliform	2	0
Rash vesicular	1	0

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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	365	0

Name: Hib/MenC

Report Run Date: 15-May-2023 Data Lock Date: 12-May-2023 16:30:03
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Reaction Name	Total	Fatal
Social circumstances		
Disability issues		
Immobile	1	0
Social circumstances SOC TOTAL	1	l o

Name: Hib/MenC

Report Run Date: 15-May-2023 Data Lock Date: 12-May-2023 16:30:03
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Reaction Name	Total	Fatal
Vascular disorders		
Haemorrhages NEC		
Haematoma	2	0
Haemorrhage	1	0
Peripheral vascular disorders NEC		
Cyanosis	6	0
Flushing	2	0
Hot flush	1	0
Peripheral vasoconstriction, necrosis and vascular insufficiency		
Peripheral coldness	2	0
Site specific vascular disorders NEC		
Pallor	16	0
Vascular disorders SOC TOTAL	30	0
TOTAL REACTIONS FOR DRUG	2120	9
TOTAL REPORTS	704	
TOTAL FATAL OUTCOME REPORTS		9