

# Case Series Drug Analysis Print

**Name: Men C Hib**

Report Run Date: 20-Feb-2014  
Data Lock Date: 13-Feb-2014 23:37:16  
Earliest Reaction Date: 28-Sep-2006  
MedDRA Version: MedDRA 16.1  
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Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<i>Lymphatic system disorders NEC</i>		
Lymphadenopathy	3	0
Lymphoid tissue hyperplasia	1	0
<b>Blood disorders SOC TOTAL</b>	<b>4</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i>Cardiac signs and symptoms NEC</i>		
Cyanosis	3	0
Palpitations	1	0
<i>Rate and rhythm disorders NEC</i>		
Bradycardia	2	0
Tachycardia	1	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	1	1
<b>Cardiac disorders SOC TOTAL</b>	<b>8</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i>Ocular disorders NEC</i>		
Eye oedema	1	0
Eye swelling	2	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	2	0
<i>Pupil disorders</i>		
Mydriasis	1	0
<b>Eye disorders SOC TOTAL</b>	<b>6</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	28	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	3	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	1	0
Vomiting	32	0
<i>Oral soft tissue swelling and oedema</i>		
Oedema mouth	1	0
<i>Stomatitis and ulceration</i>		
Mouth ulceration	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>68</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>General disorders</b>		
<i><b>Asthenic conditions</b></i>		
Asthenia	1	0
Fatigue	3	0
Malaise	10	0
<i><b>Body temperature altered</b></i>		
Hypothermia	1	0
<i><b>Death and sudden death</b></i>		
Death	1	1
<i><b>Febrile disorders</b></i>		
Pyrexia	52	0
<i><b>Feelings and sensations NEC</b></i>		
Chills	4	0
Thirst	1	0
<i><b>General signs and symptoms NEC</b></i>		
Condition aggravated	1	0
Crying	12	0
Foaming at mouth	1	0
Influenza like illness	1	0
Irritability	15	0
Local reaction	5	0
Local swelling	10	0
Swelling	4	0
<i><b>Inflammations</b></i>		
Inflammation	1	0
<i><b>Injection site reactions</b></i>		
Injection site discolouration	1	0
Injection site erythema	8	0
Injection site induration	1	0
Injection site inflammation	5	0
Injection site oedema	1	0
Injection site pain	2	0
Injection site rash	2	0
Injection site reaction	4	0
Injection site swelling	11	0
Injection site urticaria	2	0
Injection site warmth	2	0
<i><b>Oedema NEC</b></i>		
Oedema peripheral	2	0
<i><b>Pain and discomfort NEC</b></i>		
Chest discomfort	1	0
Inflammatory pain	1	0
Pain	2	0
<i><b>Product quality issues NEC</b></i>		
Product quality issue	1	0
<b>General disorders SOC TOTAL</b>	<b>169</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i>Allergic conditions NEC</i>		
Hypersensitivity	2	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Food allergy	1	0
Reaction to preservatives	1	0
<i>Anaphylactic responses</i>		
Anaphylactic reaction	4	0
<b>Immune system disorders SOC TOTAL</b>	<b>8</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Infections</b>		
<i><b>Bacterial infections NEC</b></i>		
Cellulitis	3	0
Injection site cellulitis	1	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>		
Meningitis	1	1
<i><b>Haemophilus infections</b></i>		
Haemophilus infection	2	1
<i><b>Infections NEC</b></i>		
Infection	1	0
<i><b>Lower respiratory tract and lung infections</b></i>		
Bronchitis	1	0
Bronchopneumonia	1	0
Lower respiratory tract infection	3	0
Pneumonia	1	0
<i><b>Neisseria infections</b></i>		
Meningococcal infection	7	0
Meningococcal sepsis	4	0
<i><b>Sepsis, bacteraemia, viraemia and fungaemia NEC</b></i>		
Sepsis	2	0
<i><b>Tuberculous infections</b></i>		
Erythema induratum	1	0
<i><b>Upper respiratory tract infections</b></i>		
Acute tonsillitis	1	0
Epiglottitis	3	0
Rhinitis	1	0
Tracheitis	1	0
<i><b>Viral infections NEC</b></i>		
Viral rash	1	0
<b>Infections SOC TOTAL</b>	<b>37</b>	<b>2</b>



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Reaction Name	Total	Fatal
<b>Injuries</b>		
<i><b>Maladministrations</b></i>		
Expired drug administered	1	0
Inappropriate schedule of drug administration	2	0
Incorrect dose administered	1	0
Wrong drug administered	3	0
<i><b>Medication errors NEC</b></i>		
Drug prescribing error	1	0
Vaccination error	1	0
<i><b>Overdoses</b></i>		
Accidental overdose	2	0
Overdose	1	0
<i><b>Skin injuries NEC</b></i>		
Laceration	1	0
<i><b>Vaccination related complications</b></i>		
Vaccination failure	13	0
<b>Injuries SOC TOTAL</b>	<b>26</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Investigations</b>		
<i><b>Bacteria identification and serology (excl mycobacteria)</b></i>		
Neisseria test positive	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 increased	3	0
<i><b>Physical examination procedures and organ system status</b></i>		
Body temperature fluctuation	1	0
Body temperature increased	11	0
<i><b>Protein analyses NEC</b></i>		
C-reactive protein increased	1	0
<b>Investigations SOC TOTAL</b>	<b>18</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i>Appetite disorders</i>		
Decreased appetite	12	0
<i>General nutritional disorders NEC</i>		
Weight gain poor	1	0
<i>Metabolic acidoses (excl diabetic acidoses)</i>		
Metabolic acidosis	1	0
<b>Metabolic disorders SOC TOTAL</b>	<b>14</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	1	0
Limb discomfort	1	0
Pain in extremity	2	0
<i>Musculoskeletal and connective tissue signs and symptoms NEC</i>		
Musculoskeletal stiffness	1	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>5</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Coordination and balance disturbances</i>		
Balance disorder	2	0
<i>Cortical dysfunction NEC</i>		
Aphasia	1	0
<i>Developmental disorders cognitive</i>		
Autism	1	0
<i>Disturbances in consciousness NEC</i>		
Lethargy	5	0
Somnolence	7	0
Syncope	1	0
<i>Dyskinesias and movement disorders NEC</i>		
Dyskinesia	2	0
Psychomotor hyperactivity	1	0
<i>Encephalitis NEC</i>		
Encephalitis	1	0
<i>Facial cranial nerve disorders</i>		
VIIth nerve paralysis	2	0
<i>Headaches NEC</i>		
Headache	1	0
<i>Increased intracranial pressure disorders</i>		
Brain oedema	1	0
<i>Muscle tone abnormal</i>		
Hypotonia	7	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	2	0
Meningism	1	0
Presyncope	3	0
Unresponsive to stimuli	2	0
<i>Paraesthesias and dysaesthesias</i>		
Hyperaesthesia	1	0
<i>Seizures and seizure disorders NEC</i>		
Convulsion	3	0
Epilepsy	1	0
Febrile convulsion	11	0
Status epilepticus	1	0
<i>Speech and language abnormalities</i>		
Speech disorder developmental	1	0
<i>Tremor (excl congenital)</i>		
Tremor	1	0
<b>Nervous system disorders SOC TOTAL</b>	<b>59</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	1	0
Breath holding	1	0
Staring	1	0
<b><i>Anxiety symptoms</i></b>		
Agitation	2	0
<b><i>Behaviour and socialisation disturbances</i></b>		
Aggression	1	0
Personality change	1	0
Social avoidant behaviour	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	3	0
<b><i>Emotional and mood disturbances NEC</i></b>		
Emotional distress	3	0
<b><i>Fluctuating mood symptoms</i></b>		
Mood swings	1	0
<b><i>Increased physical activity levels</i></b>		
Restlessness	2	0
<b><i>Mood disorders NEC</i></b>		
Listless	2	0
<b><i>Pervasive developmental disorders NEC</i></b>		
Autism spectrum disorder	1	0
Childhood disintegrative disorder	1	0
<b><i>Sleep disorders NEC</i></b>		
Sleep disorder	1	0
<b><i>Speech articulation and rhythm disturbances</i></b>		
Screaming	6	0
<b><i>Tic disorders</i></b>		
Tic	1	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>32</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i>Testicular and epididymal disorders NEC</i>		
Testicular pain	1	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>1</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	1	0
Grunting	1	0
Tachypnoea	1	0
<i><b>Bronchospasm and obstruction</b></i>		
Wheezing	2	0
<i><b>Coughing and associated symptoms</b></i>		
Cough	5	0
<i><b>Parenchymal lung disorders NEC</b></i>		
Lung consolidation	1	0
<i><b>Pulmonary oedemas</b></i>		
Pulmonary oedema	1	0
<i><b>Upper respiratory tract signs and symptoms</b></i>		
Oropharyngeal pain	1	0
Rhinorrhoea	5	0
Throat tightness	1	0
<b>Respiratory disorders SOC TOTAL</b>	<b>20</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<i>Angioedemas</i>		
Angioedema	1	0
Swelling face	1	0
<i>Apocrine and eccrine gland disorders</i>		
Hyperhidrosis	3	0
<i>Bullous conditions</i>		
Blister	6	0
Blood blister	1	0
Erythema multiforme	3	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	2	0
Skin disorder	1	0
Skin reaction	1	0
Skin tightness	1	0
<i>Dermatitis and eczema</i>		
Dermatitis	1	0
Dermatitis allergic	2	0
Eczema	2	0
Eczema weeping	1	0
<i>Erythemas</i>		
Erythema	17	0
Generalised erythema	1	0
Rash erythematous	3	0
<i>Papulosquamous conditions</i>		
Rash papular	3	0
<i>Pigmentation changes NEC</i>		
Pigmentation disorder	1	0
<i>Pruritus NEC</i>		
Pruritus	5	0
Rash pruritic	2	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	30	0
Rash generalised	13	0
Rash macular	9	0
Rash maculo-papular	5	0
Rash morbilliform	1	0
Rash vesicular	1	0
Systemic lupus erythematosus rash	1	0
<i>Urticarias</i>		
Urticaria	27	0
<b>Skin disorders SOC TOTAL</b>	<b>145</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>		
Flushing	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	7	0
<b>Vascular disorders SOC TOTAL</b>	<b>11</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>631</b>	<b>4</b>
<b>TOTAL REPORTS</b>	<b>244</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>4</b>