

Case Series Drug Analysis Print

Name: FOI 22/671 - Meningitis B Vaccine Drug Analysis Print

Report Run Date: 18-May-2022

Data Lock Date: 17-May-2022 18:30:04

Earliest Reaction Date: 15-Aug-2009

MedDRA Version: MedDRA 25.0

FOI 22/671 - Meningitis B (MenB) Vaccine Drug
Meningitis B Vaccine Analysis Print (DAP). All spontaneous UK suspected
Drug Analysis Print: Adverse Drug Reaction (ADR) reports associated with
the MenB vaccine.

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Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemias NEC</i>		
Anaemia	1	0
<i>Haemolyses NEC</i>		
Haemolysis	2	0
<i>Leukocytoses NEC</i>		
Lymphocytic infiltration	1	0
Neutrophilia	1	0
<i>Lymphatic system disorders NEC</i>		
Lymphadenopathy	7	0
<i>Marrow depression and hypoplastic anaemias</i>		
Myelosuppression	1	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	2	0
Blood disorders SOC TOTAL	15	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	3	0
<i>Coronary artery disorders NEC</i>		
Coronary artery aneurysm	1	0
<i>Rate and rhythm disorders NEC</i>		
Bradycardia	9	0
Bradycardia neonatal	3	0
Tachycardia	27	0
<i>Supraventricular arrhythmias</i>		
Sinus arrhythmia	1	0
Supraventricular tachycardia	1	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	4	2
Cardio-respiratory arrest	4	1
Ventricular fibrillation	1	0
Cardiac disorders SOC TOTAL	54	3

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Congenital disorders NEC</i>		
Young's syndrome	1	0
Congenital disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear discomfort	1	0
Ear pain	1	0
Ear swelling	4	0
<i>Hearing losses</i>		
Deafness	2	0
Hypoacusis	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	2	0
Vertigo	2	0
<i>Tympanic membrane disorders (excl infections)</i>		
Tympanic membrane hyperaemia	1	0
Ear disorders SOC TOTAL	14	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Cataract conditions</i>		
Cataract	1	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	1	0
<i>Eyelid movement disorders</i>		
Excessive eye blinking	1	0
Eyelid function disorder	1	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Iridocyclitis	1	0
<i>Lacrimation disorders</i>		
Lacrimation increased	2	0
Tear discolouration	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>		
Dark circles under eyes	1	0
Eye disorder	1	0
Eye oedema	1	0
Eye pain	2	0
Eye swelling	5	0
Periorbital swelling	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Ocular hyperaemia	1	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	16	0
Gaze palsy	2	0
Strabismus	3	0
<i>Ocular sensation disorders</i>		
Asthenopia	1	0
Photophobia	7	0
<i>Optic disc abnormalities NEC</i>		
Papilloedema	1	0
<i>Pupil disorders</i>		
Anisocoria	1	0
Miosis	1	0
Mydriasis	2	0
Pupillary disorder	1	0
<i>Scleral structural change, deposit and degeneration</i>		
Scleral discolouration	1	0
<i>Visual disorders NEC</i>		
Vision blurred	4	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	1	0
Blindness transient	1	0
Cortical visual impairment	1	0
Visual impairment	4	0
Eye disorders SOC TOTAL	70	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Abdominal findings abnormal</i>		
Gastrointestinal sounds abnormal	3	0
<i>Colitis (excl infective)</i>		
Necrotising colitis	1	1
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	134	0
Diarrhoea haemorrhagic	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	3	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	7	0
Faecaloma	1	0
Faeces discoloured	11	0
Faeces pale	2	0
Faeces soft	1	0
Mucous stools	8	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	7	0
Flatulence	8	0
<i>Gastritis (excl infective)</i>		
Reflux gastritis	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	14	0
Abdominal pain upper	24	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	13	0
Gastrooesophageal reflux disease	9	0
<i>Gastrointestinal disorders NEC</i>		
Gastric disorder	1	0
<i>Gastrointestinal dyskinetic disorders</i>		
Change of bowel habit	1	0
Infant dyschezia	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	13	0
Dysphagia	3	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Frequent bowel movements	3	0
Irritable bowel syndrome	1	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Intussusception	1	0
<i>Malabsorption syndromes</i>		
Coeliac disease	2	0
<i>Nausea and vomiting symptoms</i>		
Infantile vomiting	8	0
Nausea	34	0
Retching	2	0
Vomiting	240	0
Vomiting projectile	27	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematochezia	6	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	1	0
Salivary hypersecretion	1	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Oral soft tissue disorders NEC</i>		
Chapped lips	1	0
Lip disorder	1	0
<i>Oral soft tissue signs and symptoms</i>		
Lip discolouration	1	0
Oral discomfort	1	0
Oral mucosal blistering	1	0
Oral pain	2	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	6	0
<i>Salivary gland enlargements</i>		
Parotid gland enlargement	1	0
Salivary gland enlargement	1	0
<i>Stomatitis and ulceration</i>		
Apthous ulcer	1	0
Mouth ulceration	3	0
<i>Tongue disorders</i>		
Tongue geographic	1	0
Tongue ulceration	1	0
<i>Tongue signs and symptoms</i>		
Protrusion tongue	1	0
Strawberry tongue	1	0
Swollen tongue	4	0
Tongue movement disturbance	1	0
Gastrointestinal disorders SOC TOTAL	621	1

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site bruise	2	0
Administration site erythema	3	0
Administration site inflammation	1	0
Administration site swelling	1	0
<i>Application and instillation site reactions</i>		
Application site erythema	1	0
Application site rash	1	0
Application site swelling	2	0
<i>Asthenic conditions</i>		
Asthenia	13	0
Decreased activity	1	0
Fatigue	38	0
Malaise	116	0
<i>Body temperature altered</i>		
Hyperthermia	1	0
Hypothermia	4	0
<i>Death and sudden death</i>		
Death	7	7
Sudden death	5	5
Sudden infant death syndrome	6	5
<i>Febrile disorders</i>		
Fever neonatal	1	0
Hyperpyrexia	10	0
Pyrexia	892	0
<i>Feelings and sensations NEC</i>		
Chills	33	0
Feeling abnormal	17	0
Feeling cold	8	0
Feeling drunk	1	0
Feeling hot	33	0
Feeling jittery	1	0
Feeling of body temperature change	1	0
Thirst	2	0
Thirst decreased	3	0
<i>Gait disturbances</i>		
Gait disturbance	26	0
Gait inability	17	0
Loss of control of legs	1	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	6	0
Crying	177	0
Developmental delay	4	0
Developmental regression	3	0
Foaming at mouth	1	0
General physical health deterioration	2	0
General symptom	1	0
Glassy eyes	4	0
High-pitched crying	20	0
Illness	22	0
Induration	18	0
Influenza like illness	6	0
Irritability postvaccinal	4	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Local reaction	12	0
Moaning	4	0
Multiple organ dysfunction syndrome	1	0
Peripheral swelling	85	0
Screaming	57	0
Secretion discharge	4	0
Swelling	66	0
Swelling face	15	0
Inflamations		
Inflammation	20	0
Systemic inflammatory response syndrome	1	0
Injection site reactions		
Injected limb mobility decreased	2	0
Injection site bruising	6	0
Injection site discolouration	4	0
Injection site discomfort	2	0
Injection site erythema	31	0
Injection site extravasation	1	0
Injection site haemorrhage	1	0
Injection site indentation	1	0
Injection site induration	6	0
Injection site inflammation	8	0
Injection site joint erythema	1	0
Injection site joint inflammation	1	0
Injection site mass	73	0
Injection site nodule	4	0
Injection site oedema	1	0
Injection site pain	32	0
Injection site pruritus	10	0
Injection site rash	4	0
Injection site reaction	4	0
Injection site scar	1	0
Injection site swelling	24	0
Injection site urticaria	1	0
Injection site vesicles	6	0
Injection site warmth	9	0
Mass conditions NEC		
Mass	25	0
Oedema NEC		
Oedema	2	0
Oedema peripheral	2	0
Pain and discomfort NEC		
Chest discomfort	1	0
Chest pain	3	0
Discomfort	18	0
Pain	82	0
Tenderness	12	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	1	0
Drug ineffective	1	0
Immediate post-injection reaction	1	0
Vaccination failure	5	0
Ulcers NEC		

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Ulcer	1	0
<i>Vaccination site reactions</i>		
Extensive swelling of vaccinated limb	7	0
Vaccination site bruising	27	0
Vaccination site cyst	3	0
Vaccination site discharge	4	0
Vaccination site discolouration	12	0
Vaccination site discomfort	7	0
Vaccination site eczema	1	0
Vaccination site erythema	211	0
Vaccination site granuloma	2	0
Vaccination site haematoma	4	0
Vaccination site haemorrhage	3	0
Vaccination site hypersensitivity	2	0
Vaccination site induration	80	0
Vaccination site inflammation	32	0
Vaccination site injury	1	0
Vaccination site irritation	3	0
Vaccination site joint erythema	2	0
Vaccination site joint movement impairment	2	0
Vaccination site joint pain	1	0
Vaccination site macule	1	0
Vaccination site mass	139	0
Vaccination site movement impairment	9	0
Vaccination site nodule	12	0
Vaccination site oedema	3	0
Vaccination site pain	140	0
Vaccination site pallor	1	0
Vaccination site papule	2	0
Vaccination site pruritus	7	0
Vaccination site rash	29	0
Vaccination site reaction	10	0
Vaccination site scar	7	0
Vaccination site swelling	183	0
Vaccination site urticaria	1	0
Vaccination site vesicles	3	0
Vaccination site warmth	52	0
General disorders SOC TOTAL	3171	17

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Cholestasis and jaundice</i>		
Jaundice	1	0
Jaundice cholestatic	1	0
<i>Hepatic enzymes and function abnormalities</i>		
Hepatic function abnormal	1	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Hepatitis	1	0
Hepatic disorders SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Allergy to metals	1	0
Hypersensitivity	31	0
Multiple allergies	3	0
Type I hypersensitivity	1	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to vaccine	3	0
Food allergy	3	0
Milk allergy	4	0
Reaction to excipient	1	0
Reaction to preservatives	2	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	22	0
Anaphylactic shock	1	0
<i>Atopic disorders</i>		
Atopy	1	0
<i>Immune and associated conditions NEC</i>		
Haemophagocytic lymphohistiocytosis	1	1
Immune system disorder	1	0
Immunisation reaction	4	0
<i>Immunodeficiency disorders NEC</i>		
Immunodeficiency	1	0
Immune system disorders SOC TOTAL	80	1

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Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Gastroenteritis	2	0
<i>Adenoviral infections</i>		
Adenoviral meningitis	1	0
<i>Bacterial infections NEC</i>		
Arthritis bacterial	2	0
Bacterial infection	2	0
Bacterial sepsis	1	0
Cellulitis	38	0
Injection site cellulitis	1	0
Meningitis bacterial	1	0
Periorbital cellulitis	1	0
Skin bacterial infection	3	0
Urinary tract infection bacterial	1	0
Vaccination site cellulitis	21	0
<i>Bone and joint infections</i>		
Osteomyelitis	1	0
<i>Bordetella infections</i>		
Pertussis	1	0
<i>Central nervous system and spinal infections</i>		
Encephalitis	3	0
Meningitis	8	0
Meningitis aseptic	9	0
<i>Ear infections</i>		
Ear infection	4	0
Otitis externa	1	0
<i>Enteroviral infections NEC</i>		
Meningitis enteroviral	1	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	3	0
Eye infection	1	0
<i>Herpes viral infections</i>		
Varicella	1	0
<i>Infections NEC</i>		
Abscess	3	0
Abscess limb	1	0
Infection	4	0
Injection site infection	2	0
Localised infection	3	0
Lymph gland infection	1	0
Respiratory tract infection	1	0
Vaccination site abscess	4	0
Vaccination site infection	11	0
<i>Influenza viral infections</i>		
Influenza	1	0
<i>Lower respiratory tract and lung infections</i>		
Lower respiratory tract infection	3	0
Pneumonia	4	0
Pneumonia aspiration	1	0
<i>Neisseria infections</i>		
Meningitis meningococcal	2	0
Meningococcal carditis	1	0
Meningococcal infection	1	0

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Meningococcal sepsis	2	0
Rotaviral infections		
Rotavirus infection	1	0
Rubeola viral infections		
Measles	1	0
Sepsis, bacteraemia, viraemia and fungaemia NEC		
Sepsis	18	0
Sepsis neonatal	1	0
Skin structures and soft tissue infections		
Eczema infected	1	0
Skin infection	4	0
Subcutaneous abscess	1	0
Vaccination site pustule	1	0
Staphylococcal infections		
Furuncle	1	0
Streptococcal infections		
Cellulitis streptococcal	1	0
Scarlet fever	1	0
Tuberculous infections		
Erythema induratum	3	0
Upper respiratory tract infections		
Croup infectious	3	0
Nasopharyngitis	9	0
Pharyngitis	1	0
Tonsillitis	3	0
Upper respiratory tract infection	1	0
Urinary tract infections		
Kidney infection	1	0
Urinary tract infection	3	0
Viral infections NEC		
Bronchiolitis	4	0
Gastroenteritis viral	2	0
Meningitis viral	2	0
Viral infection	1	0
Viral rash	4	0
Viral upper respiratory tract infection	1	0
Infections SOC TOTAL	221	0

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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
Maternal exposure during breast feeding	1	0
<i>Fractures and dislocations NEC</i>		
Joint dislocation	1	0
<i>Gastrointestinal and hepatobiliary procedural complications</i>		
Procedural vomiting	3	0
<i>Medication errors, product use errors and issues NEC</i>		
Inadequate aseptic technique in use of product	1	0
Medication error	4	0
Vaccination error	1	0
Wrong technique in product usage process	2	0
<i>Muscle, tendon and ligament injuries</i>		
Muscle injury	1	0
<i>Non-site specific injuries NEC</i>		
Fall	3	0
Wound secretion	1	0
<i>Non-site specific procedural complications</i>		
Post procedural swelling	1	0
<i>Occupational exposures</i>		
Occupational exposure to product	1	0
<i>Product administration errors and issues</i>		
Accidental underdose	1	0
Expired product administered	1	0
Extra dose administered	1	0
Inappropriate schedule of product administration	3	0
Incomplete course of vaccination	3	0
Incorrect dose administered	2	0
Incorrect route of product administration	1	0
Lack of vaccination site rotation	1	0
Product administered at inappropriate site	5	0
Product administered to patient of inappropriate age	5	0
Product administration error	2	0
<i>Product monitoring errors and issues</i>		
Drug monitoring procedure not performed	1	0
<i>Product prescribing errors and issues</i>		
Product prescribing error	1	0
<i>Product storage errors and issues in the product use system</i>		
Product storage error	4	0
<i>Skin injuries NEC</i>		
Contusion	15	0
Scar	2	0
Skin injury	1	0
Skin laceration	1	0
Injuries SOC TOTAL	72	0

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Reaction Name	Total	Fatal
Investigations		
<i>Blood gas and acid base analyses</i>		
Oxygen saturation decreased	12	0
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	1	0
<i>Cerebrospinal fluid tests (excl microbiology)</i>		
CSF white blood cell count increased	1	0
<i>Chemistry analyses NEC</i>		
Inflammatory marker increased	2	0
<i>Heart rate and pulse investigations</i>		
Heart rate abnormal	3	0
Heart rate decreased	1	0
Heart rate increased	22	0
Pulse abnormal	1	0
<i>Hepatobiliary function diagnostic procedures</i>		
Blood bilirubin increased	1	0
<i>Mineral and electrolyte analyses</i>		
Blood magnesium decreased	1	0
<i>Neurologic diagnostic procedures</i>		
Coma scale abnormal	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature	1	0
Body temperature abnormal	7	0
Body temperature decreased	5	0
Body temperature fluctuation	3	0
Body temperature increased	93	0
Breath sounds abnormal	1	0
Respiratory rate decreased	1	0
Respiratory rate increased	14	0
<i>Platelet analyses</i>		
Platelet count increased	1	0
<i>Protein analyses NEC</i>		
C-reactive protein increased	18	0
<i>Red blood cell analyses</i>		
Haemoglobin decreased	2	0
<i>Respiratory and pulmonary function diagnostic procedures</i>		
Apnoea test abnormal	1	0
<i>Respiratory tract and thoracic imaging procedures</i>		
Chest X-ray abnormal	1	0
<i>Tissue enzyme analyses NEC</i>		
Enzyme level increased	1	0
<i>Urinary tract function analyses NEC</i>		
Urine output decreased	4	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure decreased	1	0
Capillary nail refill test abnormal	1	0
<i>Virus identification and serology</i>		
Enterovirus test positive	1	0
<i>White blood cell analyses</i>		
Lymphocyte count increased	1	0
Neutrophil count decreased	1	0
White blood cell count increased	6	0
Investigations SOC TOTAL	210	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	1	0
Decreased appetite	93	0
Food refusal	3	0
Hypophagia	8	0
<i>Fluid intake decreased</i>		
Fluid intake reduced	5	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>		
Feeding disorder	1	0
Food aversion	3	0
Poor feeding infant	78	0
Weight gain poor	1	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	2	0
<i>Metabolic acidoses (excl diabetic acidoses)</i>		
Lactic acidosis	1	0
Metabolic acidosis	2	0
<i>Potassium imbalance</i>		
Hyperkalaemia	1	0
<i>Sodium imbalance</i>		
Hyponatraemia	1	0
<i>Sugar intolerance (excl glucose intolerance)</i>		
Lactose intolerance	1	0
<i>Total fluid volume decreased</i>		
Dehydration	4	0
Metabolic disorders SOC TOTAL	208	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	1	0
Arthropathy	1	0
<i>Extremity deformities</i>		
Foot deformity	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	19	0
Joint effusion	1	0
Joint stiffness	1	0
Joint swelling	4	0
<i>Muscle infections and inflammations</i>		
Myositis	3	0
<i>Muscle pains</i>		
Myalgia	16	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle spasms	4	0
Muscle tightness	1	0
Muscle twitching	8	0
<i>Muscle tone abnormalities</i>		
Floppy infant	40	0
Muscle rigidity	5	0
<i>Muscle weakness conditions</i>		
Muscular weakness	8	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Infantile back arching	2	0
Limb mass	5	0
Mobility decreased	4	0
Musculoskeletal stiffness	37	0
Posture abnormal	2	0
Toe walking	1	0
Weight bearing difficulty	20	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	2	0
Limb discomfort	12	0
Musculoskeletal discomfort	2	0
Neck pain	5	0
Pain in extremity	262	0
<i>Spondyloarthropathies</i>		
Arthritis reactive	2	0
<i>Synovial disorders</i>		
Synovitis	2	0
Muscle & tissue disorders SOC TOTAL	471	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Areflexia	1	0
Kernig's sign	1	0
<i>Absence seizures</i>		
Petit mal epilepsy	11	0
<i>Central nervous system vascular disorders NEC</i>		
Brain hypoxia	1	0
<i>Coordination and balance disturbances</i>		
Ataxia	1	0
Balance disorder	5	0
Coordination abnormal	2	0
Dysstasia	7	0
Nystagmus	1	0
<i>Cortical dysfunction NEC</i>		
Aphasia	2	0
<i>Disturbances in consciousness NEC</i>		
Consciousness fluctuating	2	0
Depressed level of consciousness	3	0
Lethargy	70	0
Loss of consciousness	15	0
Postictal state	1	0
Somnolence	87	0
Syncope	59	0
<i>Dyskinesias and movement disorders NEC</i>		
Dyskinesia	12	0
Hypokinesia	5	0
Movement disorder	4	0
<i>Dystonias</i>		
Opisthotonus	2	0
<i>Eye movement disorders</i>		
VIth nerve paralysis	1	0
<i>Facial cranial nerve disorders</i>		
Facial spasm	1	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	16	0
<i>Headaches NEC</i>		
Headache	64	0
Tension headache	1	0
<i>Intellectual disabilities</i>		
Intellectual disability	1	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Disturbance in attention	2	0
Mental impairment	1	0
<i>Migraine headaches</i>		
Migraine	3	0
Migraine with aura	1	0
<i>Muscle tone abnormal</i>		
Hypertonia	2	0
Hypotonia	43	0
<i>Narcolepsy and hypersomnia</i>		
Hypersomnia	8	0
<i>Nervous system disorders NEC</i>		
Meningeal disorder	1	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Meningocele acquired	1	0
Nervous system disorder	1	0
Neurological signs and symptoms NEC		
Agitation neonatal	1	0
Decerebrate posture	1	0
Dizziness	32	0
Drooling	2	0
Exaggerated startle response	2	0
Fontanelle bulging	6	0
Hyporesponsive to stimuli	4	0
Inability to crawl	1	0
Infant irritability	3	0
Meningism	3	0
Myoclonus	2	0
Neurological decompensation	1	0
Pleocytosis	6	0
Presyncope	11	0
Slow response to stimuli	1	0
Unresponsive to stimuli	69	0
Neuromuscular disorders NEC		
Hypotonic-hyporesponsive episode	11	0
Muscle spasticity	1	0
Paraesthesias and dysaesthesias		
Hyperaesthesia	2	0
Hypoaesthesia	3	0
Paraesthesia	2	0
Paralysis and paresis (excl cranial nerve)		
Monoplegia	4	0
Paralysis	3	0
Seizures and seizure disorders NEC		
Epilepsy	4	0
Epileptic encephalopathy	1	0
Febrile convulsion	50	0
Infantile spasms	2	0
Partial seizures	8	0
Seizure	54	0
Seizure anoxic	2	0
Seizure like phenomena	2	0
Status epilepticus	2	0
Tonic clonic movements	1	0
Tonic convulsion	1	0
Sensory abnormalities NEC		
Aura	2	0
Sensory disturbance	2	0
Taste disorder	1	0
Sleep disturbances NEC		
Sudden onset of sleep	1	0
Speech and language abnormalities		
Dysarthria	1	0
Speech disorder	3	0
Speech disorder developmental	1	0
Tremor (excl congenital)		
Tremor	26	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Nervous system disorders SOC TOTAL	774	0

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Neonatal metabolic and endocrine disorders</i>		
Hypothermia neonatal	1	0
Pregnancy conditions SOC TOTAL	1	0

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Reaction Name	Total	Fatal
<i>Device issues NEC</i>		
Device issue	1	0
<i>Device physical property and chemical issues</i>		
Syringe issue	1	0
<i>Product label issues</i>		
Product lot number issue	2	0
<i>Product quality issues NEC</i>		
Product complaint	1	0
Product quality issue	4	0
null SOC TOTAL	9	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	19	0
Behaviour disorder	2	0
Breath holding	8	0
Regressive behaviour	1	0
Staring	7	0
<i>Affect alterations NEC</i>		
Flat affect	1	0
<i>Anxiety disorders NEC</i>		
Separation anxiety disorder	1	0
<i>Anxiety symptoms</i>		
Agitation	14	0
Anxiety	2	0
Stress	1	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	1	0
Personality change	5	0
Social avoidant behaviour	6	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Daydreaming	1	0
<i>Communications disorders</i>		
Communication disorder	1	0
Mutism	1	0
<i>Confusion and disorientation</i>		
Confusional state	4	0
<i>Decreased physical activity levels</i>		
Catatonia	1	0
<i>Deliria</i>		
Delirium	3	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	23	0
Middle insomnia	2	0
<i>Dyssomnias</i>		
Poor quality sleep	8	0
<i>Eating disorders NEC</i>		
Eating disorder	2	0
<i>Emotional and mood disturbances NEC</i>		
Anger	2	0
Emotional disorder	3	0
Emotional distress	22	0
Irritability	186	0
Mood altered	5	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Phonophobia	1	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	3	0
Hallucination, visual	1	0
Hallucinations, mixed	1	0
<i>Increased physical activity levels</i>		
Restlessness	36	0
<i>Mental disorders NEC</i>		
Mental disorder	1	0
<i>Mood alterations with depressive symptoms</i>		

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Decreased interest	2	0
Depressed mood	4	0
Tearfulness	4	0
Mood disorders NEC		
Listless	10	0
Panic attacks and disorders		
Panic reaction	2	0
Parasomnias		
Abnormal dreams	2	0
Nightmare	4	0
Sleep terror	7	0
Pervasive developmental disorders NEC		
Autism spectrum disorder	3	0
Psychiatric symptoms NEC		
Decreased eye contact	1	0
Sleep disorders NEC		
Sleep disorder	15	0
Somatic symptom disorders		
Conversion disorder	1	0
Stereotypies and automatisms		
Bruxism	1	0
Tic disorders		
Tic	2	0
Psychiatric disorders SOC TOTAL	433	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Dysuria	1	0
Pollakiuria	1	0
Urinary incontinence	2	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
Nephrotic syndrome	1	0
<i>Renal failure and impairment</i>		
Acute kidney injury	1	0
Anuria	1	0
<i>Renal structural abnormalities and trauma</i>		
Kidney enlargement	1	0
<i>Urinary abnormalities</i>		
Chromaturia	1	0
Urine odour abnormal	1	0
Renal & urinary disorders SOC TOTAL	10	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive tract disorders NEC (excl neoplasms)</i>		
Genital blister	1	0
<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
Reproductive & breast disorders SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	30	0
Apnoeic attack	2	0
Dyspnoea	47	0
Grunting	3	0
Hyperventilation	1	0
Hypopnoea	10	0
Hypoventilation	1	0
Irregular breathing	2	0
Respiration abnormal	2	0
Respiratory arrest	14	1
Respiratory depression	1	0
Respiratory distress	3	0
Tachypnoea	10	0
<i>Bronchospasm and obstruction</i>		
Wheezing	11	0
<i>Conditions associated with abnormal gas exchange</i>		
Cyanosis central	1	0
Respiratory acidosis	2	0
<i>Coughing and associated symptoms</i>		
Cough	22	0
Haemoptysis	1	0
Productive cough	1	0
Sputum discoloured	1	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Stridor	2	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	1	0
Rales	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	4	0
<i>Nasal disorders NEC</i>		
Epistaxis	7	0
<i>Neonatal hypoxic conditions</i>		
Brief resolved unexplained event	1	0
Infantile apnoea	7	0
Neonatal hypoxia	6	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal erythema	2	0
Pharyngeal swelling	1	0
Tonsillar hypertrophy	1	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	1	0
<i>Respiratory failures (excl neonatal)</i>		
Acute respiratory failure	1	0
<i>Respiratory signs and symptoms NEC</i>		
Use of accessory respiratory muscles	1	0
<i>Respiratory tract disorders NEC</i>		
Respiratory disorder	4	0
<i>Upper respiratory tract signs and symptoms</i>		
Choking	3	0
Dysphonia	2	0
Increased viscosity of upper respiratory secretion	1	0

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Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Nasal obstruction	1	0
Oropharyngeal blistering	1	0
Oropharyngeal pain	11	0
Rhinorrhoea	11	0
Sneezing	1	0
Throat tightness	1	0
Respiratory disorders SOC TOTAL	237	1

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Reaction Name	Total	Fatal
Skin disorders		
Angioedemas		
Angioedema	1	0
Apocrine and eccrine gland disorders		
Cold sweat	14	0
Hyperhidrosis	20	0
Hypohidrosis	1	0
Miliaria	2	0
Bullous conditions		
Blister	16	0
Dermatitis bullous	1	0
Erythema multiforme	2	0
Pemphigoid	1	0
Dermal and epidermal conditions NEC		
Dry skin	5	0
Macule	1	0
Pain of skin	4	0
Papule	11	0
Scab	1	0
Skin burning sensation	1	0
Skin discolouration	50	0
Skin disorder	1	0
Skin indentation	1	0
Skin induration	12	0
Skin lesion	2	0
Skin odour abnormal	1	0
Skin plaque	2	0
Skin reaction	10	0
Skin tightness	2	0
Skin warm	40	0
Skin weeping	1	0
Dermatitis and eczema		
Dermatitis	1	0
Dermatitis allergic	16	0
Dermatitis atopic	2	0
Dermatitis diaper	4	0
Eczema	14	0
Eczema infantile	1	0
Dermatitis ascribed to specific agent		
Drug eruption	1	0
Palmar-plantar erythrodysesthesia syndrome	1	0
Erythemas		
Erythema	185	0
Exfoliative conditions		
Skin exfoliation	4	0
Hypertrichoses		
Hypertrichosis	1	0
Pilar disorders NEC		
Hair growth abnormal	1	0
Pruritus NEC		
Pruritus	21	0
Purpura and related conditions		
Henoch-Schonlein purpura	3	0
Petechiae	33	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Purpura	11	0
<i>Pustular conditions</i>		
Acute generalised exanthematous pustulosis	1	0
Rash follicular	1	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	205	0
Rash erythematous	24	0
Rash macular	48	0
Rash maculo-papular	5	0
Rash morbilliform	12	0
Rash papular	18	0
Rash pruritic	5	0
Rash vesicular	3	0
<i>Skin and subcutaneous conditions NEC</i>		
Skin mass	8	0
<i>Skin and subcutaneous tissue ulcerations</i>		
Skin erosion	1	0
<i>Skin cysts and polyps</i>		
Dermal cyst	1	0
<i>Skin dystrophies</i>		
Skin wrinkling	4	0
<i>Skin injuries and mechanical dermatoses</i>		
Needle track marks	1	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	29	0
<i>Urticarias</i>		
Urticaria	57	0
Urticaria pressure	1	0
Skin disorders SOC TOTAL	926	0

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Reaction Name	Total	Fatal
Social circumstances		
<i>Disability issues</i>		
Bedridden	1	0
Immobile	1	0
Social circumstances SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Gastrointestinal therapeutic procedures NEC</i>		
Antidiarrhoeal supportive care	1	0
Surgical & medical procedures SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Arterial infections and inflammations</i>		
Kawasaki's disease	6	1
<i>Circulatory collapse and shock</i>		
Circulatory collapse	8	0
Hypoperfusion	1	0
Neurogenic shock	1	0
Peripheral circulatory failure	1	0
Shock	4	0
<i>Haemorrhages NEC</i>		
Haematoma	1	0
<i>Lymphoedemas</i>		
Lymphoedema	1	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Fibromuscular dysplasia	1	1
<i>Peripheral embolism and thrombosis</i>		
Deep vein thrombosis	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	26	0
Flushing	8	0
Hot flush	2	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	13	0
Poor peripheral circulation	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	145	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	1	0
Orthostatic hypertension	1	0
<i>Vascular hypotensive disorders</i>		
Hypotension	2	0
Vascular disorders SOC TOTAL	224	2
TOTAL REACTIONS FOR DRUG	7833	25
TOTAL REPORTS	2935	
TOTAL FATAL OUTCOME REPORTS		25