

## Case Series Drug Analysis Print

**Name: Meningococcal A,C,W135,Y vaccine spontaneous UK reports**

Report Run Date: 09-Mar-2021

Data Lock Date: 04-Mar-2021 19:00:03

Earliest Reaction Date: 03-Mar-2001

MedDRA Version: MedDRA 23.1

Meningococcal A,C,W135,Y vaccine spontaneous UK reports: All UK spontaneous, suspect reports associated with meningococcal A,C,W135,Y vaccine up to and including 04/03/2021

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Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<i>Anaemias haemolytic NEC</i>		
Haemolytic anaemia	1	0
<i>Anaemias haemolytic mechanical factor</i>		
Haemolytic uraemic syndrome	1	0
<i>Coagulopathies</i>		
Coagulopathy	2	0
<i>Leukocytoses NEC</i>		
Neutrophilia	1	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	2	0
Lymphadenopathy	27	0
<i>Thrombocytopenias</i>		
Thrombocytopenia	1	0
<b>Blood disorders SOC TOTAL</b>	<b>35</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	1	0
<i>Noninfectious myocarditis</i>		
Myocarditis	2	0
<i>Noninfectious pericarditis</i>		
Pericarditis	1	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	2	0
Tachycardia	9	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	2	0
<b>Cardiac disorders SOC TOTAL</b>	<b>17</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Congenital disorders</b>		
<i>Haemoglobinopathies congenital</i>		
Sickle cell trait	1	0
<i>Immune system abnormalities congenital</i>		
Complement deficiency disease	1	0
<i>Neurological disorders congenital NEC</i>		
Tourette's disorder	1	0
<b>Congenital disorders SOC TOTAL</b>	<b>3</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i>Ear disorders NEC</i>		
Ear discomfort	3	0
Ear pain	7	0
Ear swelling	1	0
<i>Hearing losses</i>		
Deafness	1	0
Deafness transitory	1	0
Hypoacusis	7	0
<i>Hyperacusia</i>		
Hyperacusis	2	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	7	0
Vertigo	5	0
<i>Tympanic membrane disorders (excl infections)</i>		
Tympanic membrane perforation	1	0
<b>Ear disorders SOC TOTAL</b>	<b>35</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Endocrine disorders</b>		
<i>Posterior pituitary disorders</i>		
Diabetes insipidus	1	0
<b>Endocrine disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i><b>Eyelid movement disorders</b></i>		
Blepharospasm	2	0
<i><b>Lid, lash and lacrimal infections, irritations and inflammations</b></i>		
Swelling of eyelid	6	0
<i><b>Ocular disorders NEC</b></i>		
Eye disorder	2	0
Eye pain	10	0
Eye swelling	12	0
Periorbital oedema	1	0
<i><b>Ocular infections, inflammations and associated manifestations</b></i>		
Eye irritation	3	0
Eye pruritus	2	0
Ocular hyperaemia	4	0
<i><b>Ocular nerve and muscle disorders</b></i>		
Eye movement disorder	9	0
Gaze palsy	2	0
<i><b>Ocular sensation disorders</b></i>		
Photophobia	32	0
<i><b>Pupil disorders</b></i>		
Mydriasis	3	0
Pupil fixed	1	0
<i><b>Visual colour distortions</b></i>		
Xanthopsia	1	0
<i><b>Visual disorders NEC</b></i>		
Photopsia	3	0
Vision blurred	20	0
<i><b>Visual impairment and blindness (excl colour blindness)</b></i>		
Blindness transient	2	0
Visual impairment	11	0
<b>Eye disorders SOC TOTAL</b>	<b>126</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Colitis (excl infective)</i>		
Colitis ulcerative	2	0
<i>Dental surface disorders</i>		
Tooth discolouration	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	62	0
Diarrhoea haemorrhagic	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	20	0
Abdominal pain lower	3	0
Abdominal pain upper	35	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	1	0
Gastrooesophageal reflux disease	1	0
<i>Gastrointestinal disorders NEC</i>		
Gastric disorder	1	0
Gastrointestinal disorder	1	0
<i>Gastrointestinal dyskinetic disorders</i>		
Gastrointestinal motility disorder	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	11	0
Dysphagia	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival swelling	1	0
<i>Malabsorption syndromes</i>		
Coeliac disease	2	0
<i>Nausea and vomiting symptoms</i>		
Nausea	290	0
Retching	2	0
Vomiting	210	0
Vomiting projectile	1	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematemesis	2	0
<i>Oral dryness and saliva altered</i>		
Salivary hypersecretion	1	0
<i>Oral soft tissue disorders NEC</i>		
Chapped lips	1	0
Oral disorder	1	0
<i>Oral soft tissue signs and symptoms</i>		
Hypoaesthesia oral	2	0
Lip discolouration	1	0
Lip erythema	1	0
Lip pain	1	0
Oral discomfort	1	0
Oral mucosal blistering	2	0
Oral pruritus	1	0
Paraesthesia oral	6	0
<i>Oral soft tissue swelling and oedema</i>		
Lip oedema	1	0
Lip swelling	21	0



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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
Gastrointestinal disorders cont'd		
Mouth swelling	2	0
<b><i>Stomatitis and ulceration</i></b>		
Mouth ulceration	3	0
<b><i>Tongue disorders</i></b>		
Tongue ulceration	1	0
<b><i>Tongue signs and symptoms</i></b>		
Swollen tongue	6	0
Tongue discolouration	1	0
Tongue eruption	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>704</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>General disorders</b>		
<i>Administration site reactions NEC</i>		
Administration site pain	1	0
Administration site swelling	1	0
<i>Application and instillation site reactions</i>		
Application site erythema	1	0
Application site pain	1	0
Application site pruritus	2	0
<i>Asthenic conditions</i>		
Asthenia	37	0
Chronic fatigue syndrome	1	0
Fatigue	138	0
Malaise	334	0
<i>Febrile disorders</i>		
Hyperpyrexia	1	0
Pyrexia	472	0
<i>Feelings and sensations NEC</i>		
Chills	69	0
Feeling abnormal	16	0
Feeling cold	19	0
Feeling hot	59	0
Feeling of body temperature change	11	0
Hangover	1	0
Thirst	4	0
<i>Gait disturbances</i>		
Gait disturbance	3	0
Loss of control of legs	1	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	2	0
Crepitations	1	0
Crying	19	0
Developmental delay	1	0
Glassy eyes	1	0
Illness	32	0
Induration	12	0
Influenza like illness	65	0
Local reaction	10	0
Multiple organ dysfunction syndrome	1	0
Peripheral swelling	71	0
Screaming	2	0
Swelling	44	0
Swelling face	24	0
<i>Inflammations</i>		
Inflammation	16	0
Systemic inflammatory response syndrome	2	0
<i>Injection site reactions</i>		
Injection site discolouration	1	0
Injection site discomfort	2	0
Injection site erythema	22	0
Injection site hypersensitivity	2	0
Injection site hypoaesthesia	2	0
Injection site induration	2	0
Injection site inflammation	3	0

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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Injection site mass	8	0
Injection site pain	19	0
Injection site pruritus	8	0
Injection site rash	2	0
Injection site reaction	4	0
Injection site swelling	20	0
Injection site vesicles	1	0
Injection site warmth	5	0
<b>Mass conditions NEC</b>		
Mass	2	0
<b>Oedema NEC</b>		
Face oedema	1	0
Oedema	1	0
Oedema peripheral	1	0
<b>Pain and discomfort NEC</b>		
Axillary pain	13	0
Chest discomfort	11	0
Chest pain	13	0
Discomfort	4	0
Pain	90	0
Tenderness	9	0
<b>Therapeutic and nontherapeutic responses</b>		
Adverse event	1	0
Drug ineffective	3	0
Treatment noncompliance	1	0
<b>Ulcers NEC</b>		
Ulcer	1	0
<b>Vaccination site reactions</b>		
Extensive swelling of vaccinated limb	1	0
Vaccination site bruising	3	0
Vaccination site discharge	1	0
Vaccination site discomfort	6	0
Vaccination site erythema	85	0
Vaccination site induration	14	0
Vaccination site inflammation	15	0
Vaccination site irritation	1	0
Vaccination site joint pain	2	0
Vaccination site mass	5	0
Vaccination site movement impairment	3	0
Vaccination site nodule	1	0
Vaccination site oedema	1	0
Vaccination site pain	67	0
Vaccination site papule	1	0
Vaccination site paraesthesia	1	0
Vaccination site pruritus	7	0
Vaccination site rash	7	0
Vaccination site reaction	5	0
Vaccination site swelling	90	0
Vaccination site vesicles	1	0
Vaccination site warmth	41	0
<b>General disorders SOC TOTAL</b>	<b>2085</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Hepatic disorders</b>		
<i>Bile duct infections and inflammations</i>		
Cholangitis sclerosing	1	0
<i>Cholestasis and jaundice</i>		
Jaundice	5	0
<i>Hepatic enzymes and function abnormalities</i>		
Hepatic function abnormal	1	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatomegaly	1	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Hepatitis acute	1	0
<b>Hepatic disorders SOC TOTAL</b>	<b>9</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i>Allergic conditions NEC</i>		
Hypersensitivity	28	0
Serum sickness	1	0
Type III immune complex mediated reaction	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	32	0
Anaphylactic shock	1	0
Anaphylactoid reaction	1	0
<i>Immune and associated conditions NEC</i>		
Multisystem inflammatory syndrome in children	1	0
<b>Immune system disorders SOC TOTAL</b>	<b>65</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Infections</b>		
<b><i>Abdominal and gastrointestinal infections</i></b>		
Appendicitis	1	0
<b><i>Bacterial infections NEC</i></b>		
Cellulitis	30	0
Injection site cellulitis	1	0
Meningitis bacterial	1	0
Skin bacterial infection	1	0
Vaccination site cellulitis	3	0
<b><i>Central nervous system and spinal infections</i></b>		
Encephalitis	3	0
Meningitis	3	0
<b><i>Ear infections</i></b>		
Ear infection	2	0
Otitis externa	1	0
Otitis media	3	0
<b><i>Epstein-Barr viral infections</i></b>		
Infectious mononucleosis	2	0
<b><i>Herpes viral infections</i></b>		
Herpes zoster	1	0
<b><i>Infections NEC</i></b>		
Abscess	1	0
Infection	4	0
Injection site infection	2	0
Localised infection	1	0
Vaccination site abscess	1	0
Vaccination site infection	5	0
<b><i>Influenza viral infections</i></b>		
Influenza	5	0
<b><i>Lower respiratory tract and lung infections</i></b>		
Lower respiratory tract infection	1	0
<b><i>Neisseria infections</i></b>		
Meningitis meningococcal	2	0
Meningococcal infection	6	0
<b><i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i></b>		
Sepsis	5	1
<b><i>Skin structures and soft tissue infections</i></b>		
Pustule	2	0
Skin infection	1	0
Vaccination site pustule	1	0
<b><i>Staphylococcal infections</i></b>		
Bullous impetigo	1	0
<b><i>Tuberculous infections</i></b>		
Erythema induratum	1	0
<b><i>Upper respiratory tract infections</i></b>		
Croup infectious	1	0
Nasopharyngitis	17	0
Peritonsillar abscess	1	0
Pharyngitis	2	0
Rhinitis	1	0
Sinusitis	1	0
Tonsillitis	5	0
Upper respiratory tract infection	1	0

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Reaction Name	Total	Fatal
<b>Infections</b> Infections cont'd		
<i>Viral infections NEC</i>		
Meningitis viral	2	0
Viral infection	2	0
Viral rash	1	0
<b>Infections SOC TOTAL</b>	<b>125</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Injuries</b>		
<i>Accidental exposures to product</i>		
Accidental exposure to product	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Drug exposure before pregnancy	1	0
Maternal exposure during pregnancy	1	0
<i>Neurological and psychiatric procedural complications</i>		
Post lumbar puncture syndrome	1	0
<i>Non-site specific injuries NEC</i>		
Fall	1	0
<i>Non-site specific procedural complications</i>		
Shunt malfunction	1	0
<i>Off label uses</i>		
Off label use	1	0
<i>Pathways and sources of exposure</i>		
Exposure via skin contact	1	0
<i>Poisoning and toxicity</i>		
Toxicity to various agents	1	0
<i>Product administration errors and issues</i>		
Inappropriate schedule of product administration	4	0
Incorrect product administration duration	1	0
Incorrect route of product administration	1	0
Product administered at inappropriate site	1	0
Wrong product administered	4	0
<i>Skin injuries NEC</i>		
Contusion	8	0
Skin abrasion	1	0
<i>Vaccination related complications</i>		
Post vaccination syndrome	1	0
Vaccination complication	7	0
Vaccination failure	4	0
<b>Injuries SOC TOTAL</b>	<b>41</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Investigations</b>		
<i><b>Carbohydrate tolerance analyses (incl diabetes)</b></i>		
Blood glucose decreased	3	0
<i><b>Coagulation and bleeding analyses</b></i>		
International normalised ratio increased	1	0
<i><b>ECG investigations</b></i>		
Electrocardiogram abnormal	1	0
<i><b>Heart rate and pulse investigations</b></i>		
Heart rate increased	10	0
Heart rate irregular	3	0
Pulse abnormal	7	0
<i><b>Liver function analyses</b></i>		
Blood bilirubin increased	2	0
Liver function test abnormal	2	0
<i><b>Mineral and electrolyte analyses</b></i>		
Blood iron decreased	1	0
<i><b>Physical examination procedures and organ system status</b></i>		
Body temperature	1	0
Body temperature abnormal	3	0
Body temperature fluctuation	3	0
Body temperature increased	77	0
Respiratory rate increased	7	0
Weight decreased	1	0
<i><b>Platelet analyses</b></i>		
Platelet count decreased	1	0
<i><b>Red blood cell analyses</b></i>		
Haemoglobin decreased	1	0
<i><b>Skeletal and cardiac muscle analyses</b></i>		
Troponin increased	1	0
<i><b>Urinalysis NEC</b></i>		
Blood urine present	2	0
<i><b>Vascular tests NEC (incl blood pressure)</b></i>		
Blood pressure decreased	2	0
<i><b>Vitamin analyses</b></i>		
Vitamin D decreased	1	0
<i><b>White blood cell analyses</b></i>		
White blood cell count increased	1	0
<b>Investigations SOC TOTAL</b>	<b>131</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i><b>Appetite disorders</b></i>		
Appetite disorder	1	0
Decreased appetite	70	0
Diet refusal	2	0
<i><b>Diabetes mellitus (incl subtypes)</b></i>		
Type 1 diabetes mellitus	2	0
<i><b>General nutritional disorders NEC</b></i>		
Abnormal loss of weight	1	0
Poor feeding infant	1	0
Weight gain poor	1	0
<i><b>Hypoglycaemic conditions NEC</b></i>		
Hypoglycaemia	1	0
<i><b>Total fluid volume decreased</b></i>		
Dehydration	1	0
<b>Metabolic disorders SOC TOTAL</b>	<b>80</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i><b>Bone related signs and symptoms</b></i>		
Bone pain	2	0
Coccydynia	1	0
Spinal pain	3	0
<i><b>Joint related signs and symptoms</b></i>		
Arthralgia	44	0
Joint stiffness	2	0
Joint swelling	9	0
<i><b>Muscle pains</b></i>		
Myalgia	90	0
<i><b>Muscle related signs and symptoms NEC</b></i>		
Muscle spasms	7	0
Muscle swelling	3	0
Muscle tightness	1	0
Muscle twitching	7	0
<i><b>Muscle tone abnormalities</b></i>		
Muscle rigidity	9	0
<i><b>Muscle weakness conditions</b></i>		
Muscular weakness	19	0
<i><b>Musculoskeletal and connective tissue conditions NEC</b></i>		
Growth retardation	1	0
Limb mass	1	0
Musculoskeletal stiffness	39	0
<i><b>Musculoskeletal and connective tissue pain and discomfort</b></i>		
Back pain	43	0
Limb discomfort	23	0
Musculoskeletal chest pain	2	0
Musculoskeletal discomfort	2	0
Musculoskeletal pain	1	0
Neck pain	31	0
Pain in extremity	185	0
<i><b>Soft tissue disorders NEC</b></i>		
Axillary mass	4	0
Groin pain	1	0
Neck mass	2	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>532</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Neoplasms</b>		
<i>Leukaemias NEC</i>		
Leukaemia	1	0
<i>Skin neoplasms benign</i>		
Acrochordon	1	0
<b>Neoplasms SOC TOTAL</b>	<b>2</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Absence seizures</i>		
Petit mal epilepsy	1	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	3	0
<i>Coordination and balance disturbances</i>		
Ataxia	2	0
Balance disorder	5	0
Cerebellar ataxia	1	0
Coordination abnormal	1	0
Dysstasia	1	0
<i>Cortical dysfunction NEC</i>		
Aphasia	1	0
<i>Disturbances in consciousness NEC</i>		
Altered state of consciousness	3	0
Consciousness fluctuating	1	0
Depressed level of consciousness	1	0
Lethargy	56	0
Loss of consciousness	16	0
Somnolence	50	0
Syncope	132	0
<i>Dyskinesias and movement disorders NEC</i>		
Dyskinesia	11	0
Psychomotor hyperactivity	2	0
<i>Encephalitis NEC</i>		
Encephalitis autoimmune	1	0
<i>Facial cranial nerve disorders</i>		
Facial paralysis	3	0
Facial paresis	2	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	6	0
<i>Headaches NEC</i>		
Headache	498	0
Medication overuse headache	1	0
Tension headache	4	0
<i>Increased intracranial pressure disorders</i>		
Idiopathic intracranial hypertension	1	0
<i>Lumbar spinal cord and nerve root disorders</i>		
Sciatica	1	0
<i>Memory loss (excl dementia)</i>		
Amnesia	1	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Disturbance in attention	4	0
<i>Migraine headaches</i>		
Migraine	10	0
Migraine with aura	1	0
<i>Multiple sclerosis acute and progressive</i>		
Multiple sclerosis	1	0
<i>Muscle tone abnormal</i>		
Hypotonia	5	0
<i>Myelitis (incl infective)</i>		
Myelitis transverse	1	0
<i>Narcolepsy and hypersomnia</i>		

## Case Series Drug Analysis Print

### Name: Meningococcal A,C,W135,Y vaccine spontaneous UK reports

Report Run Date: 09-Mar-2021  
Earliest Reaction Date: 03-Mar-2001

Data Lock Date: 04-Mar-2021 19:00:03  
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Hypersomnia	3	0
<b><i>Nervous system disorders NEC</i></b>		
Central nervous system lesion	1	0
<b><i>Neurologic visual problems NEC</i></b>		
Visual field defect	1	0
<b><i>Neurological signs and symptoms NEC</i></b>		
Dizziness	298	0
Dizziness postural	7	0
Head discomfort	4	0
Hyporesponsive to stimuli	1	0
Meningism	2	0
Myoclonus	2	0
Neurological symptom	2	0
Presyncope	14	0
Unresponsive to stimuli	10	0
<b><i>Neuromuscular disorders NEC</i></b>		
Hypotonic-hyporesponsive episode	1	0
<b><i>Paraesthesias and dysaesthesias</i></b>		
Burning sensation	2	0
Hyperaesthesia	4	0
Hypoaesthesia	25	0
Paraesthesia	40	0
<b><i>Paralysis and paresis (excl cranial nerve)</i></b>		
Paralysis	3	0
<b><i>Seizures and seizure disorders NEC</i></b>		
Acute encephalitis with refractory, repetitive partial seizures	1	0
Epilepsy	2	0
Febrile convulsion	1	0
Seizure	15	0
Seizure anoxic	1	0
Seizure like phenomena	2	0
Status epilepticus	1	1
Tonic clonic movements	2	0
Tonic convulsion	1	0
<b><i>Sensory abnormalities NEC</i></b>		
Neuralgia	1	0
Sensory disturbance	5	0
Sensory loss	4	0
Taste disorder	2	0
<b><i>Speech and language abnormalities</i></b>		
Dysarthria	3	0
Incoherent	1	0
Speech disorder	2	0
<b><i>Tremor (excl congenital)</i></b>		
Tremor	56	0
<b>Nervous system disorders SOC TOTAL</b>	<b>1347</b>	<b>1</b>

## Case Series Drug Analysis Print

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Report Run Date: 09-Mar-2021

Data Lock Date: 04-Mar-2021 19:00:03

Earliest Reaction Date: 03-Mar-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Pregnancy conditions</b>		
<i>Abortions spontaneous</i>		
Abortion spontaneous	2	0
<b>Pregnancy conditions SOC TOTAL</b>	<b>2</b>	<b>0</b>

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Earliest Reaction Date: 03-Mar-2001

MedDRA Version: MedDRA 23.1

<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<i>Device physical property and chemical issues</i>		
Device breakage	1	0
<b>null SOC TOTAL</b>	<b>1</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	2	0
Staring	1	0
<b><i>Anxiety symptoms</i></b>		
Agitation	2	0
Anxiety	11	0
Nervousness	1	0
<b><i>Behaviour and socialisation disturbances</i></b>		
Indifference	1	0
<b><i>Confusion and disorientation</i></b>		
Confusional state	12	0
Disorientation	11	0
<b><i>Deliria</i></b>		
Delirium	7	0
<b><i>Dissociative states</i></b>		
Dissociation	3	0
<b><i>Disturbances in initiating and maintaining sleep</i></b>		
Insomnia	24	0
<b><i>Emotional and mood disturbances NEC</i></b>		
Emotional disorder	3	0
Emotional distress	2	0
Irritability	11	0
Mood altered	1	0
<b><i>Fear symptoms and phobic disorders (incl social phobia)</i></b>		
Fear	1	0
<b><i>Hallucinations (excl sleep-related)</i></b>		
Hallucination	6	0
Hallucination, auditory	1	0
<b><i>Increased physical activity levels</i></b>		
Restlessness	2	0
<b><i>Mood alterations with depressive symptoms</i></b>		
Depressed mood	1	0
Tearfulness	3	0
<b><i>Mood disorders NEC</i></b>		
Apathy	1	0
Listless	3	0
<b><i>Panic attacks and disorders</i></b>		
Panic reaction	1	0
<b><i>Parasomnias</i></b>		
Nightmare	3	0
<b><i>Psychiatric elimination disorders</i></b>		
Enuresis	1	0
<b><i>Sleep disorders NEC</i></b>		
Sleep disorder	7	0
<b><i>Somatic symptom disorders</i></b>		
Somatic symptom disorder	1	0
<b><i>Stereotypies and automatisms</i></b>		
Head banging	1	0
<b><i>Suicidal and self-injurious behaviour</i></b>		
Self-injurious ideation	1	0
<b><i>Tic disorders</i></b>		

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> Psychiatric disorders cont'd		
Tic	1	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>127</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i><b>Bladder and urethral symptoms</b></i>		
Dysuria	1	0
Pollakiuria	1	0
Urinary incontinence	4	0
<i><b>Glomerulonephritis and nephrotic syndrome</b></i>		
Glomerulonephritis acute	1	0
Henoch-Schonlein purpura nephritis	1	0
IgA nephropathy	1	0
<i><b>Renal failure and impairment</b></i>		
Acute kidney injury	1	0
<i><b>Renal failure complications</b></i>		
Azotaemia	1	0
<i><b>Urinary abnormalities</b></i>		
Chromaturia	1	0
Haematuria	2	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>14</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i>Breast signs and symptoms</i>		
Breast swelling	1	0
<i>Menstruation and uterine bleeding NEC</i>		
Menstruation irregular	1	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	1	0
<i>Reproductive tract disorders NEC (excl neoplasms)</i>		
Perineal ulceration	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Genital swelling	1	0
<i>Scrotal disorders NEC</i>		
Scrotal pain	1	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>6</b>	<b>0</b>

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Dyspnoea	37	0
Dyspnoea exertional	1	0
Hyperventilation	5	0
Respiration abnormal	1	0
Respiratory arrest	1	0
Tachypnoea	1	0
<i><b>Bronchospasm and obstruction</b></i>		
Asthma	2	0
Wheezing	9	0
<i><b>Coughing and associated symptoms</b></i>		
Cough	20	0
<i><b>Nasal congestion and inflammations</b></i>		
Nasal congestion	2	0
<i><b>Nasal disorders NEC</b></i>		
Epistaxis	5	0
Nasal pruritus	1	0
<i><b>Pharyngeal disorders (excl infections and neoplasms)</b></i>		
Pharyngeal swelling	5	0
<i><b>Respiratory tract disorders NEC</b></i>		
Respiratory disorder	1	0
<i><b>Upper respiratory tract signs and symptoms</b></i>		
Aphonia	1	0
Dysphonia	1	0
Nasal discomfort	2	0
Oropharyngeal discomfort	1	0
Oropharyngeal pain	41	0
Rhinorrhoea	3	0
Sneezing	1	0
Throat irritation	7	0
Throat tightness	4	0
<b>Respiratory disorders SOC TOTAL</b>	<b>152</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<i><b>Alopecias</b></i>		
Alopecia	2	0
<i><b>Angioedemas</b></i>		
Angioedema	5	0
<i><b>Apocrine and eccrine gland disorders</b></i>		
Cold sweat	18	0
Hyperhidrosis	30	0
Night sweats	3	0
<i><b>Bullous conditions</b></i>		
Blister	5	0
Blister rupture	1	0
Erythema multiforme	2	0
<i><b>Dermal and epidermal conditions NEC</b></i>		
Dry skin	3	0
Pain of skin	4	0
Papule	1	0
Skin burning sensation	1	0
Skin discolouration	7	0
Skin discomfort	1	0
Skin induration	3	0
Skin lesion	2	0
Skin reaction	6	0
Skin sensitisation	1	0
Skin swelling	1	0
Skin texture abnormal	1	0
Skin warm	29	0
<i><b>Dermatitis and eczema</b></i>		
Dermatitis	1	0
Dermatitis allergic	5	0
Eczema	2	0
Skin irritation	1	0
<i><b>Dermatitis ascribed to specific agent</b></i>		
Fixed eruption	1	0
<i><b>Erythemas</b></i>		
Erythema	110	0
<i><b>Exfoliative conditions</b></i>		
Skin exfoliation	2	0
<i><b>Photosensitivity and photodermatitis conditions</b></i>		
Photosensitivity reaction	2	0
<i><b>Pigmentation changes NEC</b></i>		
Pigmentation disorder	1	0
<i><b>Pruritus NEC</b></i>		
Pruritus	53	0
<i><b>Purpura and related conditions</b></i>		
Henoch-Schonlein purpura	2	0
Petechiae	2	0
Purpura	5	0
<i><b>Rashes, eruptions and exanthems NEC</b></i>		
Rash	96	0
Rash erythematous	11	0
Rash macular	14	0
Rash maculo-papular	3	0

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Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Rash papular	7	0
Rash pruritic	13	0
<b><i>Skin and subcutaneous conditions NEC</i></b>		
Subcutaneous emphysema	1	0
<b><i>Skin vasomotor conditions</i></b>		
Livedo reticularis	5	0
<b><i>Urticarias</i></b>		
Urticaria	70	0
<b>Skin disorders SOC TOTAL</b>	<b>533</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<i>Circulatory collapse and shock</i>		
Circulatory collapse	1	0
Shock	2	0
<i>Non-site specific vascular disorders NEC</i>		
Vein disorder	1	0
<i>Peripheral vascular disorders NEC</i>		
Flushing	8	0
Hot flush	2	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	9	0
Raynaud's phenomenon	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	67	0
<i>Vascular hypotensive disorders</i>		
Hypotension	10	0
Orthostatic hypotension	1	0
<b>Vascular disorders SOC TOTAL</b>	<b>102</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>6275</b>	<b>2</b>
<b>TOTAL REPORTS</b>	<b>1841</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>2</b>