Case Series Drug Analysis Print

Name: Nimenrix Vaccine

Report Run Date:	09-Apr-2021
Data Lock Date:	08-Apr-2021 18:30:03
Earliest Reaction Date:	31-Oct-2012
MedDRA Version:	MedDRA 23.1
Nimenrix Vaccine:	All UK spontaneous adverse drug reaction (ADR) reports for the Nimenrix vaccine from 01/01/2011-31/12/2020

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Reaction Name	Total	Fatal
Blood disorders		
Anaemias haemolytic NEC		
Haemolytic anaemia	1	0
Lymphatic system disorders NEC		
Lymph node pain	1	0
Lymphadenopathy	17	0
Thrombocytopenias		
Thrombocytopenia	1	0
Blood disorders SOC TOTAL	**20**	**0**

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Reaction Name	Total	Fatal
Cardiac disorders		
Noninfectious myocarditis		
Myocarditis	1	0
Noninfectious pericarditis		
Pericarditis	1	0
Rate and rhythm disorders NEC		
Arrhythmia	2	0
Tachycardia	9	0
Cardiac disorders SOC TOTAL	**13**	**0**

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Reaction Name	Total	Fatal
Ear disorders		
Ear disorders NEC		
Ear discomfort	3	0
Ear pain	4	0
Hearing losses		
Deafness	1	0
Hypoacusis	6	0
Hyperacusia		
Hyperacusis	1	0
Inner ear signs and symptoms		
Tinnitus	4	0
Vertigo	3	0
Tympanic membrane disorders (excl infections)		
Tympanic membrane perforation	1	0
Ear disorders SOC TOTAL	**23**	**0**

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Reaction Name	Total	Fatal
Eye disorders		
Eyelid movement disorders		
Blepharospasm	2	0
Lid, lash and lacrimal infections, irritations and inflammations		
Swelling of eyelid	2	0
Ocular disorders NEC		
Eye pain	7	0
Eye swelling	5	0
Ocular infections, inflammations and associated manifestations		
Eye irritation	1	0
Ocular hyperaemia	2	0
Ocular nerve and muscle disorders		
Eye movement disorder	7	0
Gaze palsy	1	0
Ocular sensation disorders		
Photophobia	18	0
Pupil disorders		
Mydriasis	3	0
Pupil fixed	1	0
Visual disorders NEC		
Photopsia	2	0
Vision blurred	14	0
Visual impairment and blindness (excl colour blindness)		
Visual impairment	8	0
Eye disorders SOC TOTAL	**73**	**0**

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Report Run Date: 09-Apr-2021 Data Lock Date: 08-Apr-2021 18:30:03
Earliest Reaction Date: 31-Oct-2012 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Gastrointestinal disorders		
Colitis (excl infective)		
Colitis ulcerative	2	0
Diarrhoea (excl infective)		
Diarrhoea	38	0
Diarrhoea haemorrhagic	1	0
Gastrointestinal and abdominal pains (excl oral and throat)		
Abdominal pain	12	0
Abdominal pain lower	1	0
Abdominal pain upper	24	0
Gastrointestinal disorders NEC		
Gastric disorder	1	0
Gastrointestinal disorder	1	0
Gastrointestinal dyskinetic disorders		
Gastrointestinal motility disorder	1	0
Gastrointestinal signs and symptoms NEC		
Abdominal discomfort	6	0
Dysphagia	1	0
Gingival disorders, signs and symptoms NEC		
Gingival swelling	1	0
Malabsorption syndromes		
Coeliac disease	2	0
Nausea and vomiting symptoms		
Nausea	213	0
Vomiting	140	0
Non-site specific gastrointestinal haemorrhages		
Haematemesis	2	0
Oral dryness and saliva altered		
Salivary hypersecretion	1	0
Oral soft tissue signs and symptoms		
Hypoaesthesia oral	2	0
Oral discomfort	1	0
Paraesthesia oral	2	0
Oral soft tissue swelling and oedema		
Lip swelling	9	0
Mouth swelling	1	0
Stomatitis and ulceration		
Mouth ulceration	2	0
Tongue disorders		
Tongue ulceration	1	0
Tongue signs and symptoms		
Swollen tongue	4	0
Tongue discolouration	1	0
Tongue eruption	1	0
Gastrointestinal disorders SOC TOTAL	471	0

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Reaction Name	Total	Fatal
General disorders		
Administration site reactions NEC		
Administration site pain	1	0
Administration site swelling	1	0
Application and instillation site reactions		
Application site pain	1	0
Application site pruritus	1	0
Asthenic conditions		
Asthenia	24	0
Chronic fatigue syndrome	1	0
Fatigue	89	0
Malaise	249	0
Febrile disorders		
Hyperpyrexia	1	0
Pyrexia	305	0
Feelings and sensations NEC		
Chills	37	0
Feeling abnormal	8	0
Feeling cold	9	0
Feeling hot	35	0
Feeling of body temperature change	8	0
Hangover	1	0
Thirst	3	0
Gait disturbances		
Gait disturbance	2	0
General signs and symptoms NEC		
Condition aggravated	2	0
Crying	11	0
Illness	25	0
Induration	2	0
Influenza like illness	38	0
Local reaction	1	0
Peripheral swelling	27	0
Swelling	17	0
Swelling face	7	0
Inflammations		
Inflammation	3	0
Injection site reactions		
Injection site discomfort	1	0
Injection site erythema	6	0
Injection site hypoaesthesia	1	0
Injection site inflammation	2	0
Injection site mass	4	0
Injection site pain	11	0
Injection site pruritus	2	0
Injection site swelling	4	0
Mass conditions NEC		
Mass	2	0
Pain and discomfort NEC		
Axillary pain	10	0
Chest discomfort	7	0
Chest pain	6	0
Discomfort	2	0
Pain	52	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Tenderness	5	0
Therapeutic and nontherapeutic responses		
Drug ineffective	1	0
Treatment noncompliance	1	0
Vaccination site reactions		
Vaccination site bruising	1	0
Vaccination site discomfort	4	0
Vaccination site erythema	32	0
Vaccination site induration	6	0
Vaccination site inflammation	7	0
Vaccination site irritation	1	0
Vaccination site joint pain	2	0
Vaccination site mass	1	0
Vaccination site movement impairment	3	0
Vaccination site nodule	1	0
Vaccination site pain	27	0
Vaccination site paraesthesia	1	0
Vaccination site pruritus	2	0
Vaccination site rash	3	0
Vaccination site reaction	2	0
Vaccination site swelling	33	0
Vaccination site warmth	10	0
General disorders SOC TOTAL	**1162**	**0**

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Reaction Name	Total	Fatal
Hepatic disorders		
Bile duct infections and inflammations		
Cholangitis sclerosing	1	0
Cholestasis and jaundice		
Jaundice	3	0
Hepatobiliary signs and symptoms		
Hepatomegaly	1	0
Hepatic disorders SOC TOTAL	**5**	**0**

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Reaction Name	Total	Fatal
Immune system disorders		
Allergic conditions NEC		
Hypersensitivity	15	0
Anaphylactic and anaphylactoid responses		
Anaphylactic reaction	16	0
Immune system disorders SOC TOTAL	**31**	**0**

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Reaction Name	Total	Fatal
Infections		
Bacterial infections NEC		
Cellulitis	1	0
Meningitis bacterial	1	0
Skin bacterial infection	1	0
Vaccination site cellulitis	1	0
Central nervous system and spinal infections		
Encephalitis	3	0
Meningitis	2	0
Ear infections		
Ear infection	2	0
Epstein-Barr viral infections		
Infectious mononucleosis	1	0
Herpes viral infections		
Herpes zoster	1	0
Infections NEC		
Abscess	1	0
Infection	1	0
Injection site infection	1	0
Vaccination site infection	2	0
Influenza viral infections		
Influenza	4	0
Lower respiratory tract and lung infections		
Lower respiratory tract infection	1	0
Neisseria infections		
Meningococcal infection	1	0
Sepsis, bacteraemia, viraemia and fungaemia NEC		
Sepsis	1	0
Skin structures and soft tissue infections		
Pustule	1	0
Vaccination site pustule	1	0
Staphylococcal infections		
Bullous impetigo	1	0
Upper respiratory tract infections		
Nasopharyngitis	11	0
Peritonsillar abscess	1	0
Pharyngitis	1	0
Rhinitis	1	0
Sinusitis	1	0
Tonsillitis	2	0
Viral infections NEC		
Meningitis viral	1	0
Viral infection	1	0
Viral rash	1	0
Infections SOC TOTAL	48	0

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Reaction Name	Total	Fatal
Injuries		
Accidental exposures to product		
Accidental exposure to product	1	0
Exposures associated with pregnancy, delivery and lactation		
Maternal exposure during pregnancy	1	0
Non-site specific procedural complications		
Shunt malfunction	1	0
Pathways and sources of exposure		
Exposure via skin contact	1	0
Poisoning and toxicity		
Toxicity to various agents	1	0
Product administration errors and issues		
Wrong product administered	1	0
Skin injuries NEC		
Contusion	2	0
Skin abrasion	1	0
Vaccination related complications		
Vaccination complication	7	0
Injuries SOC TOTAL	**16**	**0**

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Reaction Name	Total	Fatal
Investigations		
Carbohydrate tolerance analyses (incl diabetes)		
Blood glucose decreased	1	0
Coagulation and bleeding analyses		
International normalised ratio increased	1	0
ECG investigations		
Electrocardiogram abnormal	1	0
Heart rate and pulse investigations		
Heart rate increased	8	0
Heart rate irregular	3	0
Pulse abnormal	7	0
Liver function analyses		
Blood bilirubin increased	1	0
Physical examination procedures and organ system status		
Body temperature abnormal	2	0
Body temperature fluctuation	1	0
Body temperature increased	57	0
Respiratory rate increased	5	0
Platelet analyses		
Platelet count decreased	1	0
Red blood cell analyses		
Haemoglobin decreased	1	0
Skeletal and cardiac muscle analyses		
Troponin increased	1	0
Urinalysis NEC		
Blood urine present	2	0
Investigations SOC TOTAL	92	0

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Reaction Name	Total	Fatal
Metabolic disorders		
Appetite disorders		
Decreased appetite	45	0
Diabetes mellitus (incl subtypes)		
Type 1 diabetes mellitus	1	0
Hypoglycaemic conditions NEC		
Hypoglycaemia	1	0
Total fluid volume decreased		
Dehydration	1	0
Metabolic disorders SOC TOTAL	48	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Bone related signs and symptoms		
Bone pain	1	0
Spinal pain	1	0
Joint related signs and symptoms		
Arthralgia	23	0
Joint stiffness	1	0
Joint swelling	3	0
Muscle pains		
Myalgia	47	0
Muscle related signs and symptoms NEC		
Muscle spasms	6	0
Muscle swelling	3	0
Muscle twitching	4	0
Muscle tone abnormalities		
Muscle rigidity	6	0
Muscle weakness conditions		
Muscular weakness	7	0
Musculoskeletal and connective tissue conditions NEC		
Growth retardation	1	0
Musculoskeletal stiffness	29	0
Musculoskeletal and connective tissue pain and discomfort		
Back pain	34	0
Limb discomfort	16	0
Musculoskeletal chest pain	1	0
Musculoskeletal discomfort	2	0
Musculoskeletal pain	1	0
Neck pain	21	0
Pain in extremity	124	0
Soft tissue disorders NEC		
Axillary mass	3	0
Neck mass	1	0
Muscle & tissue disorders SOC TOTAL	335	0

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Reaction Name	Total	Fatal
Neoplasms		
Leukaemias NEC		
Leukaemia	1	0
Neoplasms SOC TOTAL	**1**	**0**

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Reaction Name	Total	Fatal
Nervous system disorders		
Acute polyneuropathies		
Guillain-Barre syndrome	2	0
Coordination and balance disturbances		
Ataxia	1	0
Balance disorder	1	0
Cerebellar ataxia	1	0
Coordination abnormal	1	0
Cortical dysfunction NEC		
Aphasia	1	0
Disturbances in consciousness NEC		
Altered state of consciousness	1	0
Consciousness fluctuating	1	0
Depressed level of consciousness	1	0
Lethargy	35	0
Loss of consciousness	12	0
Somnolence	28	0
Syncope	99	0
Dyskinesias and movement disorders NEC		
Dyskinesia	8	0
Psychomotor hyperactivity	2	0
Facial cranial nerve disorders		
Facial paralysis	1	0
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	4	0
Headaches NEC		
Headache	340	0
Medication overuse headache	1	0
Tension headache	2	0
Lumbar spinal cord and nerve root disorders		
Sciatica	1	0
Memory loss (excl dementia)		
Amnesia	1	0
Mental impairment (excl dementia and memory loss)		
Disturbance in attention	2	0
Migraine headaches		
Migraine	7	0
Migraine with aura	1	0
Muscle tone abnormal		
Hypotonia	2	0
Myelitis (incl infective)		
Myelitis transverse	1	0
Narcolepsy and hypersomnia		
Hypersomnia	1	0
Nervous system disorders NEC		
Central nervous system lesion	1	0
Neurological signs and symptoms NEC		
Dizziness	228	0
Dizziness postural	6	0
Head discomfort	3	0
Hyporesponsive to stimuli	1	0
Meningism	1	0
Neurological symptom	1	0
Presyncope	10	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Unresponsive to stimuli	7	0
Paraesthesias and dysaesthesias		
Burning sensation	1	0
Hyperaesthesia	3	0
Hypoaesthesia	14	0
Paraesthesia	21	0
Paralysis and paresis (excl cranial nerve)		
Paralysis	2	0
Seizures and seizure disorders NEC		
Acute encephalitis with refractory, repetitive partial seizures	1	0
Seizure	10	0
Seizure anoxic	1	0
Seizure like phenomena	2	0
Tonic clonic movements	2	0
Tonic convulsion	1	0
Sensory abnormalities NEC		
Sensory loss	1	0
Speech and language abnormalities		
Dysarthria	2	0
Incoherent	1	0
Speech disorder	1	0
Tremor (excl congenital)		
Tremor	38	0
Nervous system disorders SOC TOTAL	**917**	**0**

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Reaction Name	Total	Fatal
Pregnancy conditions		
Abortions spontaneous		
Abortion spontaneous	1	0
Pregnancy conditions SOC TOTAL	**1**	**0**

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Reaction Name	Total	Fatal
Device physical property and chemical issues		
Device breakage	1	0
null SOC TOTAL	**1**	**0**

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Reaction Name	Total	Fatal
Psychiatric disorders		
Abnormal behaviour NEC		
Abnormal behaviour	1	0
Breath holding	1	0
Staring	1	0
Anxiety symptoms		
Agitation	2	0
Anxiety	7	0
Nervousness	1	0
Behaviour and socialisation disturbances		
Indifference	1	0
Confusion and disorientation		
Confusional state	5	0
Disorientation	6	0
Deliria		
Delirium	4	0
Dissociative states		
Dissociation	1	0
Disturbances in initiating and maintaining sleep		
Insomnia	18	0
Emotional and mood disturbances NEC		
Emotional disorder	2	0
Emotional distress	1	0
Irritability	4	0
Fear symptoms and phobic disorders (incl social phobia)		
Fear	1	0
Hallucinations (excl sleep-related)		
Hallucination	4	0
Increased physical activity levels		
Restlessness	1	0
Mood alterations with depressive symptoms		
Tearfulness	2	0
Mood disorders NEC		
Apathy	1	0
Listless	2	0
Panic attacks and disorders		
Panic reaction	1	0
Psychiatric elimination disorders		
Enuresis	1	0
Sleep disorders NEC		
Sleep disorder	5	0
Somatic symptom disorders		
Somatic symptom disorder	1	0
Tic disorders		
Tic	1	0
Psychiatric disorders SOC TOTAL	75	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
Bladder and urethral symptoms		
Urinary incontinence	2	0
Renal failure complications		
Azotaemia	1	0
Urinary abnormalities		
Chromaturia	1	0
Renal & urinary disorders SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
Menstruation with decreased bleeding		
Amenorrhoea	1	0
Reproductive tract disorders NEC (excl neoplasms)		
Perineal ulceration	1	0
Reproductive & breast disorders SOC TOTAL	**2**	**0**

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Reaction Name	Total	Fatal
Respiratory disorders		
Breathing abnormalities		
Dyspnoea	17	0
Hyperventilation	4	0
Bronchospasm and obstruction		
Asthma	1	0
Wheezing	3	0
Coughing and associated symptoms		
Cough	5	0
Nasal disorders NEC		
Epistaxis	2	0
Pharyngeal disorders (excl infections and neoplasms)		
Pharyngeal swelling	3	0
Upper respiratory tract signs and symptoms		
Dysphonia	1	0
Nasal discomfort	1	0
Oropharyngeal discomfort	1	0
Oropharyngeal pain	25	0
Rhinorrhoea	2	0
Throat irritation	5	0
Throat tightness	2	0
Respiratory disorders SOC TOTAL	72	0

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Reaction Name	Total	Fatal
Skin disorders		
Apocrine and eccrine gland disorders		
Cold sweat	12	0
Hyperhidrosis	21	0
Night sweats	2	0
Bullous conditions		
Blister	2	0
Erythema multiforme	2	0
Dermal and epidermal conditions NEC		
Pain of skin	3	0
Skin burning sensation	1	0
Skin discolouration	3	0
Skin discomfort	1	0
Skin reaction	1	0
Skin sensitisation	1	0
Skin warm	9	0
Dermatitis and eczema		
Dermatitis	1	0
Dermatitis allergic	4	0
Eczema	1	0
Skin irritation	1	0
Erythemas		
Erythema	25	0
Photosensitivity and photodermatosis conditions		
Photosensitivity reaction	2	0
Pruritus NEC		
Pruritus	23	0
Purpura and related conditions		
Henoch-Schonlein purpura	1	0
Petechiae	1	0
Purpura	3	0
Rashes, eruptions and exanthems NEC		
Rash	46	0
Rash erythematous	5	0
Rash macular	7	0
Rash maculo-papular	1	0
Rash papular	4	0
Rash pruritic	4	0
Skin vasomotor conditions		
Livedo reticularis	3	0
Urticarias		
Urticaria	20	0
Skin disorders SOC TOTAL	210	0

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Reaction Name	Total	Fatal
Vascular disorders		
Circulatory collapse and shock		
Shock	2	0
Peripheral vascular disorders NEC		
Flushing	5	0
Hot flush	1	0
Peripheral vasoconstriction, necrosis and vascular insufficiency		
Peripheral coldness	3	0
Site specific vascular disorders NEC		
Pallor	47	0
Vascular hypotensive disorders		
Hypotension	3	0
Orthostatic hypotension	1	0
Vascular disorders SOC TOTAL	62	0
TOTAL REACTIONS FOR DRUG	3682	0
TOTAL REPORTS	1117	