

Case Series Drug Analysis Print
Name: Nimenrix Vaccine Analysis Print

Report Run Date: 23-Nov-2022
Data Lock Date: 16-Nov-2022 18:30:05
Earliest Reaction Date: 31-Oct-2012
MedDRA Version: MedDRA 25.1
Nimenrix Vaccine Analysis Print: All UK spontaneous ADR reports for Nimenrix since the start of the Yellow Card system to 11/11/2022

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

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Reaction Name	Total	Fatal
Cardiac disorders		
<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
Cardiac disorders SOC TOTAL	14	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear discomfort	3	0
Ear pain	4	0
<i>Hearing losses</i>		
Deafness	1	0
Hypoacusis	6	0
<i>Hyperacusia</i>		
Hyperacusis	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	5	0
Vertigo	3	0
<i>Tympanic membrane disorders (excl infections)</i>		
Tympanic membrane perforation	1	0
Ear disorders SOC TOTAL	24	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Eyelid movement disorders</i>		
Blepharospasm	2	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Swelling of eyelid	2	0
<i>Ocular disorders NEC</i>		
Eye disorder	1	0
Eye pain	7	0
Eye swelling	6	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye irritation	1	0
Ocular hyperaemia	2	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	9	0
Gaze palsy	1	0
<i>Ocular sensation disorders</i>		
Photophobia	19	0
<i>Pupil disorders</i>		
Mydriasis	3	0
Pupil fixed	1	0
<i>Visual disorders NEC</i>		
Photopsia	2	0
Vision blurred	17	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	1	0
Visual impairment	8	0
Eye disorders SOC TOTAL	82	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Colitis (excl infective)</i>		
Colitis ulcerative	2	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	41	0
Diarrhoea haemorrhagic	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	12	0
Abdominal pain lower	1	0
Abdominal pain upper	24	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	6	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	221	0
Vomiting	144	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 signs and symptoms</i>		
Hypoaesthesia oral	2	0
Oral discomfort	1	0
Paraesthesia oral	2	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	10	0
Mouth swelling	1	0
<i>Stomatitis and ulceration</i>		
Mouth ulceration	2	0
<i>Tongue disorders</i>		
Tongue ulceration	1	0
<i>Tongue signs and symptoms</i>		
Swollen tongue	5	0
Tongue discolouration	1	0
Tongue eruption	1	0
Gastrointestinal disorders SOC TOTAL	488	0

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Reaction Name	Total	Fatal
General disorders		
Administration site reactions NEC		
Administration site pain	1	0
Administration site rash	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	95	0
Malaise	251	0
Febrile disorders		
Hyperpyrexia	1	0
Pyrexia	316	0
Feelings and sensations NEC		
Chills	38	0
Feeling abnormal	8	0
Feeling cold	10	0
Feeling hot	37	0
Feeling of body temperature change	9	0
Hangover	1	0
Thirst	3	0
Gait disturbances		
Gait disturbance	3	0
General signs and symptoms NEC		
Condition aggravated	3	0
Crying	12	0
Illness	25	0
Induration	2	0
Influenza like illness	38	0
Local reaction	1	0
Peripheral swelling	28	0
Swelling	17	0
Swelling face	7	0
Inflammations		
Inflammation	3	0
Injection site reactions		
Injection site discomfort	1	0
Injection site erythema	7	0
Injection site hypoaesthesia	1	0
Injection site inflammation	2	0
Injection site mass	4	0
Injection site pain	12	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	7	0
Discomfort	2	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Pain	55	0
Tenderness	5	0
<i>Therapeutic and nontherapeutic responses</i>		
Adverse drug reaction	6	0
Drug ineffective	1	0
Treatment noncompliance	1	0
<i>Vaccination site reactions</i>		
Vaccination site bruising	1	0
Vaccination site discomfort	4	0
Vaccination site erythema	32	0
Vaccination site induration	6	0
Vaccination site inflammation	8	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	34	0
Vaccination site warmth	10	0
General disorders SOC TOTAL	1205	0

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

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Hypersensitivity	17	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to vaccine	2	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	18	0
<i>Immune and associated conditions NEC</i>		
Immunisation reaction	7	0
Immune system disorders SOC TOTAL	44	0

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Reaction Name	Total	Fatal
Infections		
<i>Bacterial infections NEC</i>		
Cellulitis	1	0
Meningitis bacterial	1	0
Skin bacterial infection	1	0
Vaccination site cellulitis	1	0
<i>Central nervous system and spinal infections</i>		
Encephalitis	3	0
Meningitis	2	0
<i>Ear infections</i>		
Ear infection	2	0
<i>Epstein-Barr viral infections</i>		
Infectious mononucleosis	1	0
<i>Herpes viral infections</i>		
Herpes zoster	1	0
<i>Infections NEC</i>		
Abscess	1	0
Infection	1	0
Injection site infection	1	0
Vaccination site infection	2	0
<i>Influenza viral infections</i>		
Influenza	4	0
<i>Lower respiratory tract and lung infections</i>		
Lower respiratory tract infection	1	0
<i>Neisseria infections</i>		
Meningococcal infection	1	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Sepsis	1	0
<i>Skin structures and soft tissue infections</i>		
Pustule	1	0
Vaccination site pustule	1	0
<i>Staphylococcal infections</i>		
Bullous impetigo	1	0
<i>Upper respiratory tract infections</i>		
Nasopharyngitis	11	0
Peritonsillar abscess	1	0
Pharyngitis	1	0
Rhinitis	1	0
Sinusitis	1	0
Tonsillitis	2	0
<i>Viral infections NEC</i>		
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		
<i>Accidental exposures to product</i>		
Accidental exposure to product	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Maternal exposure during pregnancy	1	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	1	0
<i>Non-site specific procedural complications</i>		
Shunt malfunction	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>		
Wrong product administered	1	0
<i>Skin injuries NEC</i>		
Contusion	2	0
Skin abrasion	1	0
Injuries SOC TOTAL	10	0

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Reaction Name	Total	Fatal
Investigations		
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose decreased	1	0
Blood glucose increased	1	0
<i>Coagulation and bleeding analyses</i>		
International normalised ratio increased	1	0
<i>ECG investigations</i>		
Electrocardiogram abnormal	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate increased	8	0
Heart rate irregular	3	0
Pulse abnormal	7	0
<i>Hepatobiliary function diagnostic procedures</i>		
Blood bilirubin increased	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature abnormal	2	0
Body temperature fluctuation	1	0
Body temperature increased	58	0
Respiratory rate increased	5	0
<i>Platelet analyses</i>		
Platelet count decreased	1	0
<i>Red blood cell analyses</i>		
Haemoglobin decreased	1	0
<i>Skeletal and cardiac muscle analyses</i>		
Troponin increased	1	0
<i>Urinalysis NEC</i>		
Blood urine present	2	0
Investigations SOC TOTAL	94	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	47	0
<i>Diabetes mellitus (incl subtypes)</i>		
Type 1 diabetes mellitus	1	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	1	0
<i>Total fluid volume decreased</i>		
Dehydration	1	0
Metabolic disorders SOC TOTAL	50	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Bone related signs and symptoms</i>		
Bone pain	1	0
Spinal pain	1	0
<i>Joint related disorders NEC</i>		
Periarthritis	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	24	0
Joint stiffness	1	0
Joint swelling	3	0
<i>Muscle pains</i>		
Myalgia	51	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle spasms	7	0
Muscle swelling	4	0
Muscle twitching	6	0
<i>Muscle tone abnormalities</i>		
Muscle rigidity	7	0
Trismus	1	0
<i>Muscle weakness conditions</i>		
Muscular weakness	7	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Growth retardation	1	0
Musculoskeletal stiffness	31	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	38	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	133	0
<i>Soft tissue disorders NEC</i>		
Axillary mass	3	0
Neck mass	1	0
Muscle & tissue disorders SOC TOTAL	362	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>Leukaemias NEC</i>		
Leukaemia	1	0
Neoplasms SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	3	0
<i>Coordination and balance disturbances</i>		
Ataxia	1	0
Balance disorder	1	0
Cerebellar ataxia	1	0
Coordination abnormal	1	0
<i>Cortical dysfunction NEC</i>		
Aphasia	1	0
<i>Disturbances in consciousness NEC</i>		
Altered state of consciousness	1	0
Consciousness fluctuating	1	0
Depressed level of consciousness	1	0
Lethargy	36	0
Loss of consciousness	13	0
Somnolence	31	0
Syncope	105	0
<i>Dyskinesias and movement disorders NEC</i>		
Dyskinesia	11	0
Psychomotor hyperactivity	2	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	1	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	4	0
<i>Headaches NEC</i>		
Cluster headache	1	0
Headache	350	0
Medication overuse headache	1	0
Tension headache	3	0
<i>Lumbar spinal cord and nerve root disorders</i>		
Sciatica	1	0
<i>Memory loss (excl dementia)</i>		
Amnesia	2	0
Memory impairment	1	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Disturbance in attention	2	0
<i>Migraine headaches</i>		
Migraine	9	0
Migraine with aura	1	0
<i>Muscle tone abnormal</i>		
Hypotonia	2	0
<i>Myelitis (incl infective)</i>		
Myelitis transverse	1	0
<i>Narcolepsy and hypersomnia</i>		
Hypersomnia	1	0
<i>Nervous system disorders NEC</i>		
Central nervous system lesion	1	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	235	0
Dizziness postural	6	0
Head discomfort	3	0
Hyporesponsive to stimuli	1	0
Meningism	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Neurological symptom	1	0
Presyncope	10	0
Unresponsive to stimuli	7	0
<i>Paraesthesias and dysaesthesias</i>		
Burning sensation	1	0
Hyperaesthesia	4	0
Hypoaesthesia	16	0
Paraesthesia	22	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Paralysis	3	0
<i>Seizures and seizure disorders NEC</i>		
Acute encephalitis with refractory, repetitive partial seizures	1	0
Seizure	12	0
Seizure anoxic	1	0
Seizure like phenomena	2	0
Tonic clonic movements	3	0
Tonic convulsion	1	0
<i>Sensory abnormalities NEC</i>		
Electric shock sensation	1	0
Sensory loss	1	0
<i>Speech and language abnormalities</i>		
Dysarthria	3	0
Incoherent	1	0
Speech disorder	1	0
<i>Tremor (excl congenital)</i>		
Tremor	40	0
Nervous system disorders SOC TOTAL	967	0

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	1	0
Pregnancy conditions SOC TOTAL	1	0

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Reaction Name	Total	Fatal
<i>Device physical property and chemical issues</i>		
Device breakage	1	0
null SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	1	0
Breath holding	1	0
Staring	1	0
<i>Anxiety symptoms</i>		
Agitation	4	0
Anxiety	8	0
Nervousness	1	0
<i>Behaviour and socialisation disturbances</i>		
Indifference	1	0
<i>Confusion and disorientation</i>		
Confusional state	6	0
Disorientation	6	0
<i>Deliria</i>		
Delirium	4	0
<i>Dissociative states</i>		
Dissociation	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	22	0
<i>Emotional and mood disturbances NEC</i>		
Emotional disorder	2	0
Emotional distress	1	0
Irritability	7	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Fear	1	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	4	0
<i>Increased physical activity levels</i>		
Restlessness	2	0
<i>Mental disorders NEC</i>		
Mental disorder	1	0
<i>Mood alterations with depressive symptoms</i>		
Tearfulness	3	0
<i>Mood disorders NEC</i>		
Apathy	1	0
Listless	2	0
<i>Panic attacks and disorders</i>		
Panic reaction	1	0
<i>Psychiatric elimination disorders</i>		
Enuresis	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	7	0
<i>Somatic symptom disorders</i>		
Somatic symptom disorder	1	0
<i>Tic disorders</i>		
Tic	1	0
Psychiatric disorders SOC TOTAL	91	0

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

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<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>		
Pelvic pain	1	0
Reproductive & breast disorders SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	18	0
Hyperventilation	4	0
<i>Bronchospasm and obstruction</i>		
Asthma	1	0
Wheezing	3	0
<i>Coughing and associated symptoms</i>		
Cough	5	0
<i>Nasal disorders NEC</i>		
Epistaxis	2	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal swelling	3	0
<i>Upper respiratory tract signs and symptoms</i>		
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	73	0

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Skin disorders		
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	14	0
Hyperhidrosis	22	0
Night sweats	2	0
<i>Bullous conditions</i>		
Blister	2	0
Erythema multiforme	2	0
<i>Dermal and epidermal conditions NEC</i>		
Pain of skin	3	0
Skin burning sensation	1	0
Skin discolouration	4	0
Skin discomfort	1	0
Skin reaction	1	0
Skin sensitisation	1	0
Skin warm	9	0
<i>Dermatitis and eczema</i>		
Dermatitis	1	0
Dermatitis allergic	4	0
Eczema	1	0
Skin irritation	1	0
<i>Erythemas</i>		
Erythema	28	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	2	0
<i>Pruritus NEC</i>		
Pruritus	23	0
<i>Purpura and related conditions</i>		
Henoch-Schonlein purpura	1	0
Petechiae	1	0
Purpura	3	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	53	0
Rash erythematous	5	0
Rash macular	7	0
Rash maculo-papular	1	0
Rash papular	4	0
Rash pruritic	5	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	3	0
<i>Urticarias</i>		
Urticaria	21	0
Skin disorders SOC TOTAL	226	0

Case Series Drug Analysis Print

Name: Nimenrix Vaccine Analysis Print

Report Run Date: 23-Nov-2022
 Earliest Reaction Date: 31-Oct-2012

Data Lock Date: 16-Nov-2022 18:30:05
 MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Vascular disorders		
<i>Circulatory collapse and shock</i>		
Shock	2	0
<i>Peripheral vascular disorders NEC</i>		
Flushing	5	0
Hot flush	2	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	3	0
<i>Site specific vascular disorders NEC</i>		
Pallor	48	0
<i>Vascular hypotensive disorders</i>		
Hypotension	3	0
Orthostatic hypotension	1	0
Vascular disorders SOC TOTAL	64	0
TOTAL REACTIONS FOR DRUG	3877	0
TOTAL REPORTS	1190	