

Menitorix Vaccine Analysis Print.

All UK spontaneous suspected Adverse Drug Reaction (ADR) reports associated with the Menitorix vaccine up to and including 14/05/2025.

Report run: 15/05/2025.

Earliest Reaction Date: 28/09/2006

Reaction MedDRA SOC Name	Reaction MedDRA HLT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
Blood and lymphatic system disorders	Platelet disorders	Thrombocytopenias	Immune thrombocytopenia	1	0
	Spleen, lymphatic and reticuloendothelial system disorders	Lymphatic system disorders NEC	Lymphadenopathy	8	0
			Lymphoid tissue hyperplasia	1	0
	Total			10	0
Cardiac disorders	Cardiac arrhythmias	Rate and rhythm disorders NEC	Bradycardia	2	0
			Tachycardia	5	0
		Ventricular arrhythmias and cardiac arrest	Cardiac arrest	1	1
			Cardio-respiratory arrest	1	0
			Ventricular tachycardia	1	0
	Cardiac disorders, signs and symptoms NEC	Cardiac signs and symptoms NEC	Palpitations	2	0
	Heart failures	Heart failures NEC	Cardiac failure	1	0
	Total			13	1
Congenital, familial and genetic disorders	Musculoskeletal and connective tissue disorders congenital	Connective tissue disorders congenital	Hypermobility syndrome	1	0
		Musculoskeletal and connective tissue disorders	Polydactyly	1	0
			Syndactyly	1	0
	Total			3	0
Ear and labyrinth disorders	Aural disorders NEC	Ear disorders NEC	Ear pain	1	0
			Ear swelling	1	0
	External ear disorders (excl congenital)	External ear disorders NEC	Excessive cerumen production	1	0
	Hearing disorders	Hearing losses	Deafness	1	0
	Total			4	0
Eye disorders	Eye disorders NEC	Lacrimation disorders	Lacrimation increased	1	0
		Ocular disorders NEC	Eye disorder	1	0
			Eye oedema	1	0
			Eye swelling	8	0
			Periorbital swelling	1	0
	Ocular infections, irritations and inflammations	Lid, lash and lacrimal infections, irritations and inflammations	Erythema of eyelid	1	0
			Swelling of eyelid	2	0
		Ocular infections, inflammations and associated manifestations	Eye pruritus	2	0
	Ocular neuromuscular disorders	Eyelid movement disorders	Excessive eye blinking	2	0
			Eyelid function disorder	1	0
			Eyelid ptosis	1	0
		Ocular nerve and muscle disorders	Eye movement disorder	3	0
			Strabismus	1	0
		Pupil disorders	Anisocoria	1	0
			Mydriasis	2	0
			Pupil fixed	1	0
	Total			29	0
Gastrointestinal disorders	Gastrointestinal haemorrhages NEC	Non-site specific gastrointestinal disorders	Haematemesis	1	0
			Haematochezia	1	0
	Gastrointestinal motility and defaecation conditions	Diarrhoea (excl infective)	Diarrhoea	62	0
		Gastrointestinal atonic and hypomotility	Constipation	2	0
			Gastrooesophageal reflux disease	2	0

		Gastrointestinal spastic and hypermotility disorders	Irritable bowel syndrome	1	0
	Gastrointestinal signs and symptoms	Faecal abnormalities NEC	Abnormal faeces	1	0
			Faecaloma	1	0
			Faeces discoloured	1	0
			Mucous stools	2	0
		Flatulence, bloating and distension	Abdominal distension	3	0
			Flatulence	1	0
		Gastrointestinal and abdominal pains	Abdominal pain	4	0
			Abdominal pain upper	4	0
		Gastrointestinal signs and symptoms NEC	Abdominal discomfort	2	0
			Dysphagia	1	0
		Nausea and vomiting symptoms	Infantile vomiting	2	0
			Nausea	5	0
			Vomiting	90	0
			Vomiting projectile	8	0
	Oral soft tissue conditions	Oral soft tissue disorders NEC	Chapped lips	1	0
			Lip blister	1	0
		Oral soft tissue signs and symptoms	Oral pain	1	0
		Oral soft tissue swelling and	Lip swelling	3	0
			Mouth swelling	1	0
		Stomatitis and ulceration	Mouth ulceration	2	0
Salivary gland conditions	Oral dryness and saliva altered	Lip dry	1	0	
Tongue conditions	Tongue disorders	Tongue geographic	1	0	
	Total		205	0	
General disorders and administration site conditions	Administration site reactions	Administration site reactions NEC	Administration site erythema	1	0
		Injection site reactions	Injection site bruising	1	0
			Injection site discolouration	2	0
			Injection site erythema	15	0
			Injection site induration	2	0
			Injection site inflammation	5	0
			Injection site irritation	1	0
			Injection site mass	3	0
			Injection site oedema	1	0
			Injection site pain	3	0
			Injection site rash	4	0
			Injection site reaction	5	0
			Injection site swelling	13	0
			Injection site urticaria	3	0
			Injection site warmth	3	0
		Vaccination site reactions	Extensive swelling of vaccinated limb	2	0
			Vaccination site bruising	3	0
			Vaccination site discolouration	1	0
			Vaccination site discomfort	1	0
			Vaccination site erythema	24	0
			Vaccination site induration	4	0
			Vaccination site inflammation	4	0
			Vaccination site mass	13	0
			Vaccination site pain	6	0
			Vaccination site pruritus	1	0
			Vaccination site rash	5	0
			Vaccination site reaction	1	0

Immune system disorders			Vaccination site swelling	25	0	
			Vaccination site vesicles	1	0	
			Vaccination site warmth	5	0	
	Body temperature conditions	Body temperature altered	Hypothermia	1	0	
		Febrile disorders	Pyrexia	216	0	
	Fatal outcomes	Death and sudden death	Death	2	2	
			Sudden death	1	1	
			Sudden infant death syndrome	1	1	
	General system disorders NEC	Asthenic conditions	Asthenia	6	0	
			Decreased activity	1	0	
			Fatigue	18	0	
			Malaise	28	0	
		Feelings and sensations NEC	Chills	12	0	
			Feeling abnormal	4	0	
			Feeling drunk	1	0	
			Feeling hot	4	0	
			Feeling of body temperature change	1	0	
			Thirst	2	0	
			Thirst decreased	2	0	
			Gait disturbances	Gait disturbance	9	0
				Gait inability	10	0
				Loss of control of legs	1	0
		General signs and symptoms NEC	Condition aggravated	2	0	
			Crepitations	1	0	
			Crying	44	0	
			Developmental delay	2	0	
			Developmental regression	1	0	
			Foaming at mouth	1	0	
			Glassy eyes	1	0	
			High-pitched crying	3	0	
			Illness	10	0	
			Induration	2	0	
			Influenza like illness	3	0	
			Irritability postvaccinal	1	0	
			Local reaction	6	0	
			Peripheral swelling	22	0	
			Screaming	13	0	
			Secretion discharge	1	0	
			Swelling	18	0	
			Swelling face	10	0	
			Inflammations	Inflammation	4	0
			Oedema NEC	Oedema peripheral	2	0
		Pain and discomfort NEC	Chest discomfort	1	0	
			Discomfort	2	0	
			Pain	18	0	
			Tenderness	1	0	
		Therapeutic and nontherapeutic effects	Therapeutic and nontherapeutic	Drug ineffective	1	0
				Vaccination failure	13	0
		Tissue disorders NEC	Mass conditions NEC	Mass	1	0
		Total			662	4
Allergic conditions		Allergic conditions NEC	Allergy to metals	1	0	
			Hypersensitivity	12	0	
			Allergies to foods, food additives, drugs and other chemicals	Food allergy	1	0
				Milk allergy	2	0
	Reaction to excipient			1	0	

		Anaphylactic and anaphylactoid responses	Anaphylactic reaction	5	0
	Immunodeficiency syndromes	Immunodeficiency disorders NEC	Immunodeficiency	1	0
	Total			23	0
Infections and infestations	Bacterial infectious disorders	Bacterial infections NEC	Cellulitis	17	0
			Injection site cellulitis	1	0
			Periorbital cellulitis	1	0
			Skin bacterial infection	2	0
			Vaccination site cellulitis	2	0
		Haemophilus infections	Haemophilus infection	3	1
			Meningitis haemophilus	1	0
		Neisseria infections	Meningitis meningococcal	1	0
			Meningococcal infection	7	0
			Meningococcal sepsis	2	0
	Infections - pathogen unspecified	Abdominal and gastrointestinal infections	Gastroenteritis	1	0
		Bone and joint infections	Intervertebral discitis	1	0
			Osteomyelitis	1	0
		Central nervous system and spinal infections	Encephalitis	2	0
			Meningitis	2	1
		Dental and oral soft tissue infections	Gingivitis	1	0
		Ear infections	Ear infection	4	0
			Otitis media chronic	1	0
		Eye and eyelid infections	Conjunctivitis	3	0
			Eye infection	1	0
		Infections NEC	Infection	2	0
			Localised infection	2	0
			Vaccination site abscess	2	0
			Vaccination site infection	1	0
		Lower respiratory tract and lung infections	Atypical pneumonia	1	0
			Lower respiratory tract infection	5	0
			Pneumonia	2	0
		Sepsis, bacteraemia, viraemia and fungaemia NEC	Sepsis	3	0
		Skin structures and soft tissue infections	Skin infection	1	0
		Upper respiratory tract infections	Croup infectious	1	0
			Epiglottitis	3	0
			Nasopharyngitis	3	0
			Rhinitis	3	0
			Tonsillitis	6	0
			Tracheitis	1	0
			Upper respiratory tract infection	2	0
	Mycobacterial infectious disorders	Tuberculous infections	Erythema induratum	1	0
	Viral infectious disorders	Herpes viral infections	Oral herpes	1	0
			Varicella	1	0
		Influenza viral infections	Influenza	1	0
		Rubeola viral infections	Measles	1	0
		Viral infections NEC	Bronchiolitis	1	0
			Viral rash	3	0
	Total			101	2

Injury, poisoning and procedural complications	Exposures, chemical injuries and poisoning	Exposures associated with pregnancy, delivery and lactation	Exposure via breast milk	1	0
	Injuries NEC	Cerebral injuries NEC	Craniocerebral injury	1	0
		Non-site specific injuries NEC	Fall	1	0
			Injury	1	0
		Skin injuries NEC	Contusion	1	0
			Scar	1	0
			Skin laceration	1	0
	Medication errors and other product use errors and issues	Medication errors, product use errors and issues NEC	Medication error	1	0
			Vaccination error	1	0
			Wrong technique in product usage process	1	0
		Product administration errors and issues	Accidental overdose	2	0
			Expired product administered	1	0
			Extra dose administered	1	0
			Inappropriate schedule of product administration	3	0
			Incorrect dose administered	1	0
			Product administered at inappropriate site	1	0
			Product administered to patient of inappropriate age	2	0
			Wrong product administered	4	0
			Product prescribing error	1	0
		Product prescribing errors and issues			
	Overdoses and underdoses NEC	Overdoses NEC	Overdose	1	0
	Total			27	0
Investigations	Cardiac and vascular investigations (excl blood groups)	Heart rate and pulse investigations	Heart rate abnormal	2	0
			Heart rate increased	7	0
	Haematology investigations (incl blood groups)	Coagulation and bleeding analyses	Bleeding time prolonged	1	0
	Immunology and allergy investigations	Immunoglobulin analyses	Blood immunoglobulin G increased	1	0
	Microbiology and serology investigations	Bacteria identification and serology (excl mycobacteria)	Neisseria test positive	1	0
	Physical examination and organ system status topics	Physical examination procedures and organ system status	Body temperature abnormal	1	0
			Body temperature decreased	2	0
			Body temperature fluctuation	1	0
			Body temperature increased	24	0
			Breath sounds abnormal	1	0
	Protein and chemistry analyses NEC	Chemistry analyses NEC	Inflammatory marker increased	1	0
		Protein analyses NEC	C-reactive protein increased	1	0
	Total			43	0
Metabolism and nutrition disorders	Acid-base disorders	Metabolic acidoses (excl diabetic acidoses)	Metabolic acidosis	1	0
	Appetite and general nutritional disorders	Appetite disorders	Decreased appetite	58	0
			Food refusal	1	0
			Hypophagia	2	0
		General nutritional disorders NEC	Abnormal loss of weight	1	0
			Food aversion	1	0
			Poor feeding infant	2	0

			Weight gain poor	1	0
Musculoskeletal and connective tissue disorders	Electrolyte and fluid balance conditions	Fluid intake decreased	Fluid intake reduced	1	0
		Total fluid volume decreased	Dehydration	2	0
	Food intolerance syndromes	Food malabsorption and intolerance	Dairy intolerance	1	0
			Food intolerance	2	0
	Total			73	0
	Joint disorders	Joint related signs and symptoms	Arthralgia	4	0
			Joint stiffness	1	0
			Joint swelling	1	0
	Muscle disorders	Muscle pains	Myalgia	5	0
		Muscle related signs and symptoms NEC	Muscle tightness	1	0
			Muscle twitching	1	0
		Muscle tone abnormalities	Floppy infant	3	0
		Muscle weakness conditions	Muscular weakness	5	0
	Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)	Extremity deformities	Foot deformity	1	0
	Musculoskeletal and connective tissue disorders NEC	Musculoskeletal and connective tissue conditions NEC	Limb mass	1	0
			Mobility decreased	1	0
			Musculoskeletal stiffness	4	0
			Weight bearing difficulty	7	0
		Musculoskeletal and connective tissue pain and discomfort	Back pain	2	0
			Limb discomfort	4	0
			Neck pain	1	0
			Pain in extremity	25	0
	Total			67	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin neoplasms malignant and unspecified	Skin neoplasms malignant and unspecified (excl melanoma)	Neoplasm skin	1	0
	Total			1	0
Nervous system disorders	Central nervous system vascular disorders	Central nervous system vascular disorders NEC	Brain hypoxia	1	0
	Cranial nerve disorders (excl neoplasms)	Facial cranial nerve disorders	Bell's palsy	1	0
	Headaches	Headaches NEC	Headache	9	0
		Migraine headaches	Migraine	1	0
	Increased intracranial pressure and hydrocephalus	Increased intracranial pressure disorders	Brain oedema	1	0
	Movement disorders (incl parkinsonism)	Dyskinesias and movement disorders NEC	Dyskinesia	5	0
			Fine motor delay	1	0
			Hypokinesia	4	0
			Movement disorder	1	0
			Psychomotor	2	0
		Paralysis and paresis (excl cranial nerve)	Hemiparesis	1	0
			Monoplegia	1	0
			Paralysis	2	0
		Tremor (excl congenital)	Tremor	8	0
	Neurological disorders NEC	Coordination and balance disturbances	Balance disorder	5	0
			Coordination abnormal	2	0
			Dysstasia	2	0
			Hand-eye coordination impaired	1	0
		Cortical dysfunction NEC	Aphasia	4	0
			Dyspraxia	1	0

			Sensory processing disorder	1	0
		Disturbances in consciousness NEC	Depressed level of consciousness	2	0
			Lethargy	23	0
			Loss of consciousness	3	0
			Somnolence	21	0
			Syncope	2	0
			Nervous system disorders NEC	Nervous system disorder	1
		Neurological signs and symptoms NEC	Dizziness	4	0
			Dizziness postural	1	0
			Drizzling	1	0
			Exaggerated startle response	1	0
			Inability to crawl	1	0
			Infant irritability	3	0
			Meningism	1	0
			Presyncope	3	0
			Unresponsive to stimuli	11	0
			Sensory abnormalities NEC	Aura	1
		Speech and language abnormalities	Language disorder	1	0
			Speech disorder	2	0
			Speech disorder developmental	2	0
	Neuromuscular disorders	Muscle tone abnormal	Hypotonia	12	0
		Neuromuscular disorders NEC	Hypotonic-hyporesponsive episode	1	0
	Seizures (incl subtypes)	Generalised tonic-clonic seizures	Generalised tonic-clonic seizure	1	0
		Seizures and seizure disorders NEC	Epilepsy	1	0
			Febrile convulsion	18	0
			Partial seizures	2	0
			Seizure	11	0
			Seizure anoxic	1	0
			Status epilepticus	1	0
	Sleep disturbances (incl subtypes)	Narcolepsy and hypersomnia	Hypersomnia	3	0
		Sleep disturbances NEC	Sleep deficit	1	0
	Total			190	0
	Product issues	Product quality, supply, distribution, manufacturing and	Product label issues	Product lot number issue	1
Product quality issues NEC			Product complaint	1	0
Total			2	0	
Psychiatric disorders	Anxiety disorders and symptoms	Anxiety symptoms	Agitation	3	0
			Anxiety	2	0
		Obsessive-compulsive disorders and symptoms	Obsessive-compulsive symptom	1	0
	Changes in physical activity	Decreased physical activity levels	Catatonia	1	0
		Increased physical activity levels	Restlessness	10	0
		Tic disorders	Tic	1	0
	Deliria (incl confusion)	Confusion and disorientation	Confusional state	2	0
			Disorientation	1	0
		Deliria	Delirium	1	0
	Depressed mood disorders and	Mood alterations with depressive	Depressed mood	2	0
			Tearfulness	1	0
	Developmental disorders NEC	Pervasive developmental disorders NEC	Autism spectrum disorder	7	0

	Eating disorders and disturbances	Eating disorders NEC	Eating disorder	1	0
	Mood disorders and disturbances NEC	Emotional and mood disturbances NEC	Emotional distress	9	0
			Irritability	48	0
			Mood altered	1	0
		Fluctuating mood symptoms	Mood swings	1	0
		Mood disorders NEC	Listless	4	0
	Personality disorders and disturbances in behaviour	Behaviour and socialisation disturbances	Aggression	5	0
			Disturbance in social behaviour	1	0
			Personality change	3	0
			Social avoidant behaviour	1	0
	Psychiatric and behavioural symptoms NEC	Abnormal behaviour NEC	Abnormal behaviour	9	0
			Breath holding	3	0
			Staring	2	0
		Psychiatric symptoms NEC	Decreased eye contact	2	0
	Psychiatric disorders NEC	Mental disorders NEC	Mental disorder	2	0
	Sleep disorders and disturbances	Disturbances in initiating and maintaining sleep	Initial insomnia	1	0
			Insomnia	12	0
			Middle insomnia	2	0
		Dyssomnias	Poor quality sleep	2	0
		Parasomnias	Sleep terror	1	0
		Sleep disorders NEC	Sleep disorder	6	0
	Suicidal and self-injurious behaviours NEC	Suicidal and self-injurious behaviour	Self-injurious ideation	1	0
	Total			149	0
Renal and urinary disorders	Nephropathies	Glomerulonephritis and nephrotic syndrome	Nephrotic syndrome	1	0
	Renal disorders (excl nephropathies)	Renal disorders NEC	Renal disorder	1	0
		Renal failure and impairment	Acute kidney injury	1	0
	Urinary tract signs and symptoms	Urinary tract signs and symptoms NEC	Renal pain	1	0
	Total			4	0
Reproductive system and breast disorders	Penile and scrotal disorders (excl infections and inflammations)	Scrotal disorders NEC	Scrotal swelling	1	0
	Reproductive tract disorders NEC	Reproductive tract signs and symptoms NEC	Genital rash	1	0
			Genital swelling	1	0
	Vulvovaginal disorders (excl infections and inflammations)	Vulvovaginal disorders NEC	Vaginal haemorrhage	1	0
	Total			4	0
Respiratory, thoracic and mediastinal disorders	Bronchial disorders (excl neoplasms)	Bronchospasm and obstruction	Wheezing	7	0
	Lower respiratory tract disorders (excl obstruction and	Parenchymal lung disorders NEC	Lung consolidation	1	0
		Pulmonary oedemas	Pulmonary oedema	1	0
	Neonatal respiratory disorders	Neonatal hypoxic conditions	Brief resolved unexplained event	1	0
	Respiratory disorders NEC	Breathing abnormalities	Apnoeic attack	1	0
			Dyspnoea	8	0
			Grunting	1	0
			Hyperventilation	1	0
			Respiratory arrest	2	1
			Tachypnoea	1	0

Skin and subcutaneous tissue disorders		Conditions associated with abnormal gas exchange	Asphyxia	1	0
	Respiratory tract signs and symptoms	Coughing and associated symptoms	Cough	11	0
			Productive cough	2	0
		Lower respiratory tract signs and symptoms	Rales	1	0
		Upper respiratory tract signs and symptoms	Choking	1	0
			Oropharyngeal pain	5	0
			Rhinorrhoea	10	0
			Throat tightness	1	0
	Upper respiratory tract disorders (excl infections)	Nasal congestion and inflammations	Nasal congestion	3	0
		Nasal disorders NEC	Epistaxis	1	0
		Pharyngeal disorders (excl infections and	Pharyngeal erythema	1	0
			Pharyngeal swelling	1	0
	Total			62	1
	Angioedema and urticaria	Angioedemas	Angioedema	2	0
		Urticarias	Urticaria	38	0
	Epidermal and dermal conditions	Bullous conditions	Blister	8	0
			Blood blister	1	0
			Erythema multiforme	4	0
		Dermal and epidermal conditions NEC	Dry skin	2	0
			Macule	1	0
			Pain of skin	1	0
			Papule	4	0
			Scab	1	0
			Sensitive skin	1	0
			Skin burning sensation	1	0
			Skin disorder	2	0
			Skin induration	1	0
			Skin lesion	1	0
			Skin reaction	1	0
			Skin tightness	1	0
			Skin warm	8	0
		Dermatitis and eczema	Dermatitis	1	0
			Dermatitis allergic	7	0
			Dermatitis atopic	1	0
			Dermatitis diaper	2	0
			Eczema	8	0
			Eczema weeping	1	0
		Dermatitis ascribed to specific agent	Drug eruption	1	0
		Erythemas	Erythema	44	0
		Pruritus NEC	Pruritus	10	0
		Rashes, eruptions and exanthems NEC	Rash	120	0
			Rash erythematous	15	0
			Rash macular	11	0
			Rash maculo-papular	8	0
			Rash morbilliform	14	0
			Rash papular	9	0
			Rash pruritic	5	0
			Rash rubelliform	2	0
			Rash vesicular	1	0
			Systemic lupus erythematosus rash	1	0
	Pigmentation disorders	Pigmentation changes NEC	Pigmentation disorder	1	0
	Skin appendage	Apocrine and	Cold sweat	2	0

	conditions	eccrine gland disorders	Hyperhidrosis	5	0
			Miliaria	1	0
		Pilar disorders NEC	Hair growth abnormal	1	0
	Skin vascular abnormalities	Purpura and related conditions	Henoch-Schonlein purpura	1	0
			Purpura	1	0
		Skin vasomotor conditions	Livedo reticularis	1	0
	Total			352	0
Social circumstances	Lifestyle issues	Disability issues	Immobile	2	0
	Total			2	0
Vascular disorders	Arteriosclerosis, stenosis, vascular insufficiency and necrosis	Peripheral vasoconstriction, necrosis and vascular insufficiency	Peripheral coldness	2	0
	Vascular disorders NEC	Peripheral vascular disorders NEC	Cyanosis	6	0
			Flushing	2	0
			Hot flush	1	0
	Vascular haemorrhagic disorders	Haemorrhages NEC	Pallor	15	0
			Haematoma	2	0
			Haemorrhage	1	0
	Total			29	0
Total Reactions for Drug				2,055	
Total Reports				680	
Total Fatal Outcome Reports					8