

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 congenital	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	
		Ocular infections, irritations and inflammations	Lid, lash and lacrimal infections, inflammations and associated manifestations	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	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
	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			

		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	
Immune system disorders	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	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 errors and issues	Product prescribing error	1	0	
	Overdoses and underdoses NEC	Overdoses NEC	Overdose	1	0
Total			27	0	
Investigations	Cardiac and vascular investigations (excl ...)	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	General nutritional disorders NEC	Abnormal loss of weight	1	0
			Food aversion	1	0
Poor feeding infant			2	0	

			Weight gain poor	1	0				
Electrolyte and fluid balance conditions	Fluid intake decreased		Fluid intake reduced	1	0				
			Dehydration	2	0				
Food intolerance syndromes	Food malabsorption and intolerance		Dairy intolerance	1	0				
			Food intolerance	2	0				
Total				73	0				
Musculoskeletal and connective tissue disorders	Joint disorders	Joint related signs and symptoms	Arthralgia	4	0				
			Joint stiffness	1	0				
			Joint swelling	1	0				
	Muscle disorders	Muscle pains	Muscle related signs and symptoms NEC	Myalgia	5	0			
				Muscle tightness	1	0			
				Muscle twitching	1	0			
				Muscle weakness conditions	5	0			
	Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)	Extremity deformities		Foot deformity	1	0			
				Musculoskeletal and connective tissue conditions NEC	Musculoskeletal and connective tissue pain and discomfort	Limb mass	1	0	
						Mobility decreased	1	0	
						Musculoskeletal stiffness	4	0	
	Weight bearing difficulty	7	0						
	Musculoskeletal and connective tissue disorders NEC			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				
Neurological disorders NEC		Tremor (excl congenital)		Tremor	8	0			
				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	0	
	Neurological signs and symptoms NEC	Dizziness	4	0	
		Dizziness postural	1	0	
		Droling	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	0
	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	0
		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

	Conditions associated with abnormal gas exchange	Asphyxia	1	0
	Coughing and associated symptoms	Cough	11	0
		Productive cough	2	0
Respiratory tract signs and symptoms	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)	Pharyngeal erythema	1	0
Pharyngeal swelling		1	0	
Total			62	1
Skin and subcutaneous tissue disorders	Angioedema and urticaria	Angioedemas	2	0
		Urticarias	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
	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 eccrine disorders	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
		Site specific vascular disorders NEC	Pallor	15	0
	Vascular haemorrhagic disorders	Haemorrhages NEC	Haematoma	2	0
Haemorrhage			1	0	
Total			29	0	
Total Reactions for Drug				2,055	
Total Reports				680	
Total Fatal Outcome Reports					8