

Viatris Influenza Tetra MYL (QIVe) Vaccine Analysis Print.

All UK spontaneous suspected Adverse Drug Reaction (ADR) reports associated with the Viatris Influenza Tetra MYL (QIVe) vaccine up to and including 21/01/2025.

Report run: 21/01/2025.

Earliest reaction date: 12/09/2018.

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
Blood and lymphatic system disorders	Spleen, lymphatic and reticuloendothelial system disorders	Lymphatic system disorders NEC	Lymph node pain	1	0
			Lymphadenopathy	1	0
	Total			2	0
Cardiac disorders	Cardiac arrhythmias	Rate and rhythm disorders NEC	Arrhythmia	1	0
	Cardiac disorders, signs and symptoms NEC	Cardiac signs and symptoms NEC	Palpitations	1	0
	Total			2	0
Ear and labyrinth disorders	Hearing disorders	Hearing losses	Hypoacusis	2	0
			Sudden hearing loss	1	0
	Inner ear and VIIIth cranial nerve disorders	Inner ear signs and symptoms	Vertigo	2	0
	Total			5	0
Eye disorders	Eye disorders NEC	Ocular disorders NEC	Eye swelling	1	0
	Ocular infections, irritations and inflammations	Ocular infections, inflammations and associated manifestations	Ocular hyperaemia	2	0
	Vision disorders	Visual impairment and blindness (excl colour blindness)	Visual impairment	1	0
	Total			4	0
Gastrointestinal disorders	Gastrointestinal motility and defaecation conditions	Diarrhoea (excl infective)	Diarrhoea	7	0
		Gastrointestinal atonic and hypomotility disorders NEC	Gastrooesophageal reflux disease	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal	
	Gastrointestinal signs and symptoms	Gastrointestinal and abdominal pains (excl oral and throat)	Abdominal pain	3	0	
			Abdominal pain upper	1	0	
		Nausea and vomiting symptoms	Nausea	12	0	
			Vomiting	8	0	
	Oral soft tissue conditions	Oral soft tissue signs and symptoms	Paraesthesia oral	2	0	
		Oral soft tissue swelling and oedema	Lip swelling	1	0	
			Mouth swelling	1	0	
	Total			36	0	
	General disorders and administration site conditions	Administration site reactions	Administration site reactions NEC	Administration site rash	1	0
			Injection site reactions	Injection site erythema	3	0
Injection site pain				2	0	
Injection site pruritus				1	0	
Vaccination site reactions			Shoulder injury related to vaccine administration	2	0	
			Vaccination site erythema	8	0	
			Vaccination site haemorrhage	1	0	
			Vaccination site induration	4	0	
			Vaccination site joint movement impairment	1	0	
			Vaccination site mass	1	0	
			Vaccination site movement impairment	1	0	
			Vaccination site pain	11	0	
			Vaccination site pruritus	4	0	

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			Vaccination site rash	3	0
			Vaccination site reaction	1	0
			Vaccination site swelling	12	0
			Vaccination site vesicles	1	0
			Vaccination site warmth	6	0
	Body temperature conditions	Febrile disorders	Pyrexia	14	0
	General system disorders NEC	Asthenic conditions	Asthenia	4	0
			Fatigue	10	0
			Malaise	9	0
		Feelings and sensations NEC	Chills	3	0
			Feeling abnormal	1	0
			Feeling cold	1	0
			Feeling hot	5	0
			Feeling of body temperature change	1	0
		General signs and symptoms NEC	Influenza like illness	6	0
			Peripheral swelling	4	0
			Swelling	2	0
			Swelling face	3	0
		Pain and discomfort NEC	Axillary pain	1	0
			Chest discomfort	2	0
			Chest pain	2	0
			Pain	7	0

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			Tenderness	1	0
	Total			139	0
Immune system disorders	Allergic conditions	Allergic conditions NEC	Hypersensitivity	4	0
		Allergies to foods, food additives, drugs and other chemicals	Allergy to vaccine	1	0
		Anaphylactic and anaphylactoid responses	Anaphylactic reaction	2	0
			Anaphylactoid reaction	1	0
	Total			8	0
Infections and infestations	Infections - pathogen unspecified	Lower respiratory tract and lung infections	Lower respiratory tract infection	1	0
		Skin structures and soft tissue infections	Vaccination site pustule	1	0
		Upper respiratory tract infections	Nasopharyngitis	2	0
	Viral infectious disorders	Herpes viral infections	Oral herpes	1	0
		Influenza viral infections	Influenza	3	0
	Total			8	0
Injury, poisoning and procedural complications	Exposures, chemical injuries and poisoning	Exposures associated with pregnancy, delivery and lactation	Maternal exposure during pregnancy	1	0
	Injuries NEC	Skin injuries NEC	Contusion	1	0
	Medication errors and other product use errors and issues	Product administration errors and issues	Product administered at inappropriate site	1	0
	Procedural related injuries and complications NEC	Vaccination related complications	Immunisation reaction	1	0
	Total			4	0
Investigations	Cardiac and vascular investigations (excl enzyme tests)	Heart rate and pulse investigations	Heart rate increased	1	0

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		Vascular tests NEC (incl blood pressure)	Blood pressure decreased	1	0
	Haematology investigations (incl blood groups)	White blood cell analyses	Neutrophil count increased	1	0
			White blood cell count increased	1	0
	Investigations, imaging and histopathology procedures NEC	Investigations NEC	Blood test abnormal	1	0
	Physical examination and organ system status topics	Physical examination procedures and organ system status	Body temperature increased	1	0
	Renal and urinary tract investigations and urinalyses	Urinary tract function analyses NEC	Urine output decreased	1	0
	Total			7	0
Metabolism and nutrition disorders	Appetite and general nutritional disorders	Appetite disorders	Decreased appetite	3	0
	Purine and pyrimidine metabolism disorders	Disorders of purine metabolism	Gout	1	0
	Total			4	0
Musculoskeletal and connective tissue disorders	Joint disorders	Joint related signs and symptoms	Arthralgia	6	0
	Muscle disorders	Muscle pains	Myalgia	10	0
		Muscle weakness conditions	Muscular weakness	1	0
	Musculoskeletal and connective tissue disorders NEC	Musculoskeletal and connective tissue conditions NEC	Musculoskeletal stiffness	1	0
			Back pain	2	0
			Musculoskeletal discomfort	1	0
			Neck pain	1	0
			Pain in extremity	7	0
	Tendon, ligament and cartilage disorders	Cartilage disorders	Costochondritis	1	0

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	Total			30	0
Nervous system disorders	Cranial nerve disorders (excl neoplasms)	Facial cranial nerve disorders	Bell's palsy	1	0
	Headaches	Headaches NEC	Headache	12	0
		Migraine headaches	Migraine	1	0
	Movement disorders (incl parkinsonism)	Dyskinesias and movement disorders NEC	Dyskinesia	1	0
		Tremor (excl congenital)	Tremor	2	0
	Neurological disorders NEC	Disturbances in consciousness NEC	Lethargy	1	0
			Somnolence	3	0
			Syncope	7	0
		Neurological signs and symptoms NEC	Dizziness	13	0
			Presyncope	2	0
		Paraesthesias and dysaesthesias	Burning sensation	1	0
			Dysaesthesia	1	0
			Hypoaesthesia	3	0
			Paraesthesia	5	0
		Sensory abnormalities NEC	Dysgeusia	1	0
			Neuralgia	2	0
		Speech and language abnormalities	Speech disorder	1	0
	Peripheral neuropathies	Peripheral neuropathies NEC	Peripheral sensory neuropathy	1	0
	Seizures (incl subtypes)	Seizures and seizure disorders NEC	Seizure	1	0
			Tonic clonic movements	1	0

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	Spinal cord and nerve root disorders	Spinal cord and nerve root disorders NEC	Radiculitis brachial	1	0
	Total			61	0
Psychiatric disorders	Deliria (incl confusion)	Confusion and disorientation	Confusional state	3	0
	Depressed mood disorders and disturbances	Mood alterations with depressive symptoms	Negative thoughts	1	0
	Sleep disorders and disturbances	Disturbances in initiating and maintaining sleep	Insomnia	1	0
		Parasomnias	Nightmare	1	0
	Total			6	0
Respiratory, thoracic and mediastinal disorders	Bronchial disorders (excl neoplasms)	Bronchospasm and obstruction	Asthma	1	0
			Wheezing	5	0
	Respiratory disorders NEC	Breathing abnormalities	Dyspnoea	5	0
			Respiratory arrest	1	0
			Respiratory distress	1	0
		Coughing and associated symptoms	Cough	1	0
	Respiratory tract signs and symptoms	Upper respiratory tract signs and symptoms	Dry throat	1	0
			Oropharyngeal pain	2	0
			Rhinorrhoea	1	0
			Throat irritation	1	0
			Throat tightness	1	0
	Upper respiratory tract disorders (excl infections)	Paranasal sinus disorders (excl infections and neoplasms)	Sinus congestion	1	0
		Pharyngeal disorders (excl infections and neoplasms)	Pharyngeal paraesthesia	1	0

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			Pharyngeal swelling	2	0
	Total			24	0
Skin and subcutaneous tissue disorders	Angioedema and urticaria	Angioedemas	Angioedema	1	0
		Urticarias	Idiopathic urticaria	1	0
			Urticaria	4	0
	Epidermal and dermal conditions	Dermal and epidermal conditions NEC	Skin discolouration	2	0
			Skin reaction	1	0
		Dermatitis and eczema	Dermatitis allergic	3	0
			Skin irritation	1	0
		Erythemas	Erythema	4	0
		Pruritus NEC	Pruritus	11	0
		Rashes, eruptions and exanthems NEC	Rash	8	0
			Rash maculo-papular	1	0
			Rash papular	3	0
			Rash pruritic	2	0
	Skin appendage conditions	Acnes	Acne	1	0
		Apocrine and eccrine gland disorders	Cold sweat	2	0
			Hyperhidrosis	5	0
	Skin vascular abnormalities	Skin vasculitides	Vasculitic rash	1	0
	Total			51	0
Vascular disorders	Decreased and nonspecific blood pressure disorders and shock	Blood pressure disorders NEC	Blood pressure fluctuation	1	0
		Vascular hypotensive disorders	Hypotension	3	0

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	Vascular disorders NEC	Peripheral vascular disorders NEC	Flushing	1	0
		Site specific vascular disorders NEC	Pallor	2	0
	Vascular haemorrhagic disorders	Haemorrhages NEC	Haematoma	1	0
	Vascular hypertensive disorders	Vascular hypertensive disorders NEC	Hypertension	1	0
	Total			9	0
Total				400	0

Number of ADR Reports

124