Report Run Date: 27-Sep-2021

Data Lock Date: 26-Sep-2021 18:30:04

Earliest Reaction Date: 21-Sep-2002 MedDRA 24.0 MedDRA Version:

Priorix product analysis print. All UK spontaneous reports between 01/01/2019-31/12/2020 **Priorix Product**

Analysis Print:

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Reaction Name	Total	Fatal
Blood disorders		
Lymphatic system disorders NEC		
Lymphadenopathy	3	0
Thrombocytopenias		
Immune thrombocytopenia	1	0
Blood disorders SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Congenital disorders		
Lymphatic system disorders congenital		
Cystic lymphangioma	1	1
Congenital disorders SOC TOTAL	1	1

Reaction Name	Total	Fatal
Ear disorders		
Ear disorders NEC		
Ear swelling	1	0 ا
Hearing losses		
Deafness	2	0
Inner ear signs and symptoms		
Tinnitus	1	ı o
Vertigo	1	ı o
Ear disorders SOC TOTAL		5 0

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Reaction Name	Total	Fatal
Eve disorders		
Ocular disorders NEC		
Eye pain	1	0
Ocular infections, inflammations and associated manifestations		
Eye irritation	1	0
Eve disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Diarrhoea (excl infective)		
Diarrhoea	4	0
Gastrointestinal and abdominal pains (excl oral and throat)		
Abdominal pain upper	2	0
Gastrointestinal atonic and hypomotility disorders NEC		
Constipation	1	0
Gastrointestinal disorders NEC		
Gastrointestinal disorder	1	0
Gastrointestinal signs and symptoms NEC		
Abdominal discomfort	1	0
Anal incontinence	1	0
Intestinal haemorrhages		
Rectal haemorrhage	1	0
Nausea and vomiting symptoms		
Nausea	2	0
Vomiting	2	0
Rectal inflammations NEC		
Proctitis	1	0
Stomatitis and ulceration		
Stomatitis	1	0
Gastrointestinal disorders SOC TOTAL	17	0

Reaction Name	 Total	Fatal
General disorders		
Asthenic conditions		
Asthenia	1	0
Fatigue	3	0
Febrile disorders		
Pyrexia	17	0
Feelings and sensations NEC		
Chills	1	0
General signs and symptoms NEC		
Crying	1	0
Developmental delay	1	0
Developmental regression	2	0
Peripheral swelling	3	0
Swelling face	2	0
Injection site reactions		
Injection site pain	1	0
Injection site swelling	1	0
Pain and discomfort NEC		
Pain	3	0
Vaccination site reactions		
Vaccination site bruising	1	0
Vaccination site erythema	4	0
Vaccination site pain	2	0
Vaccination site rash	2	0
Vaccination site reaction	1	0
Vaccination site swelling	4	0
Vaccination site vesicles	1	C
Vaccination site warmth	2	C
General disorders SOC TOTAL	53	(

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Reaction Name	Total	Fatal
Immune system disorders		
Allergic conditions NEC		
Hypersensitivity	1	0
Anaphylactic and anaphylactoid responses		
Anaphylactic reaction	1	0
Immune system disorders SOC TOTAL	2	0

Reaction Name	Total	Fatal
Infections		
Bacterial infections NEC		
Cellulitis	2	0
Candida infections		
Candida infection	1	0
Dental and oral soft tissue infections		
Parotitis	1	0
Male reproductive tract infections		
Orchitis	1	0
Rubeola viral infections		
Measles	1	0
Upper respiratory tract infections		
Nasopharyngitis	1	0
Infections SOC TOTAL	7	l o

Reaction Name	Total	Fatal
Injuries		
Exposures associated with pregnancy, delivery and lactation		
Foetal exposure during pregnancy	1	0
Injuries SOC TOTAL	1	0

Reaction Name	Total	Fatal
Investigations		
Physical examination procedures and organ system status		
Body temperature decreased	1	0
Platelet analyses		
Platelet count decreased	1	0
Toxicology laboratory analyses		
Blood heavy metal increased	1	0
Investigations SOC TOTAL	3	l o

Reaction Name	Total	Fatal
Metabolic disorders		
Appetite disorders		
Decreased appetite	5	0
Metabolic disorders NEC		
Metabolic disorder	1	0
Metabolic disorders SOC TOTAL	6	0

Reaction Name	Total	Fatal
Muscle & tissue disorders		
Joint related signs and symptoms		
Arthralgia	1	0
Musculoskeletal and connective tissue conditions NEC		
Musculoskeletal stiffness	1	0
Weight bearing difficulty	1	0
Musculoskeletal and connective tissue pain and discomfort		
Back pain	1	0
Neck pain	1	0
Pain in extremity	4	0
Muscle & tissue disorders SOC TOTAL	9	0

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Reaction Name		Total	Fatal
Nervous system disorders			
Absence seizures			
Petit mal epilepsy		1	0
Cortical dysfunction NEC			
Aphasia		2	0
Disturbances in consciousness NEC			
Lethargy		2	0
Syncope		1	0
Headaches NEC			
Headache		3	0
Nervous system disorders NEC			
Nervous system disorder		1	0
Neurological signs and symptoms NEC			
Dizziness		1	0
Dizziness postural		1	0
Neuromuscular disorders NEC			
Hypotonic-hyporesponsive episode		1	0
Paraesthesias and dysaesthesias			
Hypoaesthesia		2	0
Paraesthesia		1	0
Paralysis and paresis (excl cranial nerve)			
Paralysis		1	0
Seizures and seizure disorders NEC			
Myoclonic epilepsy		1	0
Partial seizures		1	0
Speech and language abnormalities			
Dysarthria		1	0
Tremor (excl congenital)			
Tremor		1	0
Nervous system disorders SOC TOTAL		21	0

Reaction Name	Total	Fatal
Psychiatric disorders		
Abnormal behaviour NEC		
Abnormal behaviour	1	0
Behaviour and socialisation disturbances		
Social avoidant behaviour	1	0
Disturbances in initiating and maintaining sleep		
Insomnia	1	0
Emotional and mood disturbances NEC		
Irritability	2	0
Fear symptoms and phobic disorders (incl social phobia)		
Social anxiety disorder	1	0
Mood alterations with depressive symptoms		
Depressed mood	1	0
Pervasive developmental disorders NEC		
Autism spectrum disorder	4	0
Speech articulation and rhythm disturbances		
Lack of spontaneous speech	1	0
Psychiatric disorders SOC TOTAL	12	0

Reaction Name	Total	Fatal
Renal & urinary disorders		
Bladder and urethral symptoms		
Urinary incontinence	1	0
Renal & urinary disorders SOC TOTAL	1	0

Reaction Name	Total	Fatal
Respiratory disorders		
Breathing abnormalities		
Dyspnoea	1	0
Respiration abnormal	1	0
Bronchospasm and obstruction		
Wheezing	1	0
Coughing and associated symptoms		
Cough	1	0
Nasal congestion and inflammations		
Nasal congestion	1	0
Upper respiratory tract signs and symptoms		
Rhinorrhoea	1	0
Respiratory disorders SOC TOTAL	6	o l

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Reaction Name		Total	<u>Fatal</u>
Skin disorders			
Apocrine and eccrine gland disorders			
Night sweats		1	0
Dermal and epidermal conditions NEC			
Papule		1	0
Skin warm		1	0
Dermatitis and eczema			
Eczema		1	0
Erythemas			
Erythema		4	0
Pruritus NEC			
Pruritus		2	0
Rashes, eruptions and exanthems NEC			
Rash		7	0
Rash erythematous		1	0
Rash morbilliform		1	0
Rash papular		1	0
Rash pruritic		1	0
Rash scarlatiniform		1	0
Urticarias			
Urticaria		2	0
Skin disorders SOC TOTAL		24	0
TOTAL REACTIONS FOR DRUG		174	1
TOTAL REPORTS		46	
TOTAL FATAL OUTCOME REPORTS			1