

MMRVaxPro Vaccine Analysis Print.

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

Report run: 15/05/2025.

Earliest Reaction Date: 01/01/1991

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
Blood and lymphatic system disorders	Anaemias nonhaemolytic and marrow depression	Anaemias NEC	Anaemia	1	0
	Platelet disorders	Thrombocytopenias	Immune thrombocytopenia	2	0
	Spleen, lymphatic and reticuloendothelial system disorders	Lymphatic system disorders NEC	Lymphadenopathy	12	0
	White blood cell disorders	Leukopenias NEC	Lymphopenia	1	0
	<b>Total</b>			<b>16</b>	<b>0</b>
Cardiac disorders	Cardiac arrhythmias	Rate and rhythm disorders NEC	Bradycardia	3	0
	Cardiac valve disorders	Pulmonary valvular disorders	Pulmonary valve stenosis	2	0
	Endocardial disorders	Endocarditis NEC	Endocarditis noninfective	1	1
	Pericardial disorders	Noninfectious pericarditis	Pericarditis	1	0
		Pericardial disorders NEC	Pericardial effusion	1	0
<b>Total</b>			<b>8</b>	<b>1</b>	
Congenital, familial and genetic disorders	Cardiac and vascular disorders congenital	Cardiac septal defects congenital	Atrioventricular septal defect	2	0
		Great vessel disorders congenital	Double outlet right ventricle	2	0
		Persistent foetal circulation disorders	Patent ductus arteriosus	1	0
	Chromosomal abnormalities, gene alterations and gene variants	Autosomal chromosomal abnormalities	Trisomy 21	2	0
		Gene mutations and other alterations NEC	Gene mutation	1	0
	Congenital and hereditary disorders NEC	Congenital disorders NEC	Congenital anomaly	1	0
			Congenital cyst	1	0
			VACTERL syndrome	2	0

Ear and labyrinthine disorders congenital	External ear disorders congenital	Anomaly of external ear congenital	1	0	
Eye disorders congenital	Eyelid disorders congenital	Eyelid ptosis congenital	2	0	
Gastrointestinal tract disorders congenital	Anorectal disorders congenital	Preternatural anus	2	0	
	Oral cavity disorders congenital NEC	Tethered oral tissue	2	0	
Immune system disorders congenital	Immune system abnormalities congenital	Primary immunodeficiency syndrome	3	0	
Musculoskeletal and connective tissue disorders congenital	Connective tissue disorders congenital	Hypermobility syndrome	1	0	
		Musculoskeletal and connective tissue disorders of limbs congenital	Developmental hip dysplasia	2	0
	Limb hypoplasia congenital		2	0	
	Limb reduction defect		2	0	
	Talipes		3	0	
	Musculoskeletal and connective tissue disorders of skull congenital	Plagiocephaly	1	0	
	Musculoskeletal and connective tissue disorders of spine congenital	Congenital musculoskeletal disorder of spine	2	0	
Renal and urinary tract disorders congenital	Renal disorders congenital	Congenital cystic kidney disease	2	0	
Reproductive tract and breast disorders congenital	Male reproductive tract disorders congenital	Cryptorchism	1	0	
		Hydrocele	1	0	
Respiratory disorders congenital	Pulmonary and bronchial disorders congenital	Congenital pneumonia	1	0	
		Pulmonary aplasia	2	0	
		Pulmonary hypoplasia	2	0	
Skin and subcutaneous tissue disorders congenital	Skin and subcutaneous tissue disorders congenital NEC	Congenital naevus	1	0	
		Congenital skin dimples	2	0	
<b>Total</b>			<b>47</b>	<b>0</b>	
Ear and labyrinth disorders	Aural disorders NEC	Ear disorders NEC	Ear pain	1	0
	Hearing disorders	Hearing losses	Deafness	2	0
			Hypoacusis	1	0
	Inner ear and VIIIth cranial nerve disorders	Inner ear signs and symptoms	Tinnitus	1	0
			Vertigo	3	0
<b>Total</b>			<b>8</b>	<b>0</b>	

Eye disorders

Anterior eye structural change, deposit and degeneration	Lid, lash and lacrimal structural disorders	Dacryostenosis acquired	1	0
Eye disorders NEC	Ocular disorders NEC	Eye disorder	1	0
		Eye pain	1	0
		Eye swelling	1	0
		Periorbital oedema	1	0
Ocular infections, irritations and inflammations	Lid, lash and lacrimal infections, irritations and inflammations	Swelling of eyelid	2	0
	Ocular infections, inflammations and associated manifestations	Eye pruritus	1	0
Ocular neuromuscular disorders	Ocular nerve and muscle disorders	Eye movement disorder	3	0
		Strabismus	2	0
	Pupil disorders	Mydriasis	1	0
Ocular sensory symptoms NEC	Ocular sensation disorders	Asthenopia	1	0
		Photophobia	3	0
Ocular structural change, deposit and degeneration NEC	Choroid and vitreous structural change, deposit and degeneration	Vitreous floaters	1	0
Vision disorders	Visual disorders NEC	Vision blurred	1	0
	Visual impairment and blindness (excl colour blindness)	Visual impairment	1	0
<b>Total</b>			<b>21</b>	<b>0</b>
Gastrointestinal disorders	Abdominal hernias and other abdominal wall conditions	Umbilical hernias	2	0
	Dental and gingival conditions	Gingival disorders, signs and symptoms NEC	1	0
	Gastrointestinal haemorrhages NEC	Gastric and oesophageal haemorrhages	Gastric haemorrhage	1
Oesophageal haemorrhage			1	0

Gastrointestinal motility and defaecation conditions	Diarrhoea (excl infective)	Diarrhoea	17	0	
	Gastrointestinal atonic and hypomotility disorders NEC	Gastrooesophageal reflux disease	3	0	
Gastrointestinal signs and symptoms	Faecal abnormalities NEC	Faeces discoloured	1	0	
		Abdominal pain	2	0	
	Gastrointestinal and abdominal pains (excl oral and throat)	Abdominal pain lower	1	0	
		Abdominal discomfort	1	0	
	Gastrointestinal signs and symptoms NEC	Anal incontinence	1	0	
		Nausea and vomiting symptoms	Nausea	13	0
			Retching	1	0
			Vomiting	21	0
Vomiting projectile	1		0		
Oral soft tissue conditions	Oral soft tissue disorders NEC	Oral disorder	1	0	
		Oral soft tissue signs and symptoms	Oral mucosal blistering	3	0
	Oral soft tissue swelling and oedema	Oral pain	1	0	
		Paraesthesia oral	1	0	
		Lip swelling	6	0	
Stomatitis and ulceration	Mouth ulceration	2	0		
Salivary gland conditions	Salivary gland enlargements	Parotid gland enlargement	3	0	
		Submaxillary gland enlargement	1	0	
Tongue conditions	Tongue signs and symptoms	Strawberry tongue	1	0	
		Tongue eruption	1	0	
<b>Total</b>			<b>87</b>	<b>0</b>	
General disorders and administration site conditions	Administration site reactions	Administration site reactions NEC	Administration site urticaria	2	0
		Injection site reactions	Injection site erythema	10	0
	Injection site inflammation		2	0	
	Injection site irritation		1	0	
	Injection site mass		1	0	
	Injection site pain		3	0	
	Injection site pruritus		1	0	
	Injection site rash	4	0		

		Injection site reaction	2	0
		Injection site swelling	7	0
		Injection site urticaria	1	0
		Injection site vesicles	1	0
		Injection site warmth	1	0
	Vaccination site reactions	Extensive swelling of vaccinated limb	1	0
		Vaccination site bruising	3	0
		Vaccination site discomfort	1	0
		Vaccination site erythema	13	0
		Vaccination site haematoma	1	0
		Vaccination site haemorrhage	1	0
		Vaccination site inflammation	2	0
		Vaccination site mass	4	0
		Vaccination site pain	6	0
		Vaccination site paraesthesia	1	0
		Vaccination site rash	4	0
		Vaccination site reaction	1	0
		Vaccination site swelling	8	0
Body temperature conditions	Febrile disorders	Pyrexia	74	0
General system disorders NEC	Adverse effect absent	No adverse event	3	0
	Asthenic conditions	Asthenia	4	0
		Fatigue	7	0
		Malaise	16	0
	Feelings and sensations NEC	Chills	2	0
		Feeling abnormal	1	0
		Feeling drunk	1	0
		Feeling hot	1	0
		Feeling of body temperature change	1	0
	Gait disturbances	Gait disturbance	1	0
	General signs and symptoms NEC	Condition aggravated	1	0
		Creptitations	1	0

			Crying	5	0		
			Illness	2	0		
			Induration	1	0		
			Influenza like illness	10	0		
			Irritability postvaccinal	1	0		
			Local reaction	2	0		
			Peripheral swelling	11	0		
			Screaming	2	0		
			Swelling	4	0		
			Swelling face	4	0		
	Inflammations	Inflammation		3	0		
	Pain and discomfort NEC	Chest discomfort		4	0		
		Chest pain		6	0		
		Discomfort		1	0		
		Pain		5	0		
		Tenderness		2	0		
Therapeutic and nontherapeutic effects (excl toxicity)	Therapeutic and nontherapeutic responses	Adverse event		1	0		
		Therapy non- responder		2	0		
		Vaccination failure		1	0		
Tissue disorders NEC	Mass conditions NEC	Mass		1	0		
<b>Total</b>				<b>263</b>	<b>0</b>		
Hepatobiliary disorders	Gallbladder disorders	Cholecystitis and cholelithiasis	Cholecystitis		1	0	
	Hepatic and hepatobiliary disorders	Hepatic enzymes and function abnormalities	Hypertransaminasae mia		1	0	
			Hepatocellular damage and hepatitis NEC	Hepatitis		2	0
	<b>Total</b>				<b>4</b>	<b>0</b>	
Immune system disorders	Allergic conditions	Allergic conditions NEC	Hypersensitivity		4	0	
			Allergies to foods, food additives, drugs and other chemicals	Food allergy		1	0
				Milk allergy		1	0
				Reaction to excipient		1	0
		Anaphylactic and anaphylactoid responses	Anaphylactic reaction		10	0	
	Autoimmune disorders	Autoimmune disorders NEC	Autoimmune disorder		1	0	
Immune disorders NEC	Immune and associated conditions NEC	Haemophagocytic lymphohistiocytosis		1	1		
<b>Total</b>				<b>19</b>	<b>1</b>		
Infections and infestations	Bacterial infectious disorders	Bacterial infections NEC	Cellulitis		10	0	
			Injection site cellulitis		1	0	

		Vaccination site cellulitis	3	0
	Borrelial infections	Lyme disease	1	0
Infections - pathogen unspecified	Abdominal and gastrointestinal infections	Gastroenteritis	1	0
		Large intestine infection	1	1
	Central nervous system and spinal infections	Encephalitis	5	0
		Meningitis aseptic	1	0
	Ear infections	Ear infection	2	0
		Otitis media	2	0
	Eye and eyelid infections	Conjunctivitis	4	0
		Eye infection	1	0
	Infections NEC	Infection	1	0
		Respiratory tract infection	1	0
		Vaccination site infection	2	0
		Vestibulitis	1	0
	Lower respiratory tract and lung infections	Lower respiratory tract infection	1	0
		Pneumonia	1	0
	Male reproductive tract infections	Orchitis	1	0
	Sepsis, bacteraemia, viraemia and fungaemia NEC	Sepsis neonatal	1	0
	Upper respiratory tract infections	Nasopharyngitis	2	0
		Rhinitis	1	0
		Tonsillitis	2	0
Upper respiratory tract infection		2	0	
Urinary tract infections	Urinary tract infection	1	0	
Viral infectious disorders	Epstein-Barr viral infections	Infectious mononucleosis	1	0
	Herpes viral infections	Herpes zoster	1	0
		Human herpesvirus 6 infection	1	0
		Varicella	3	0
	Mumps viral infections	Encephalitis mumps	1	0
		Mumps	3	0
	Rubella viral infections	Encephalomyelitis rubella	1	0
	Rubeola viral infections	Measles	8	0
		Measles post vaccine	1	0
	Viral infections NEC	Bronchiolitis	3	0
		Encephalitis viral	1	0

			Gastroenteritis viral	1	0	
			Viral infection	2	0	
			<b>Total</b>	<b>76</b>	<b>1</b>	
Injury, poisoning and procedural complications	Exposures, chemical injuries and poisoning	Exposures associated with pregnancy, delivery and lactation	Exposure during pregnancy	36	0	
			Foetal exposure during pregnancy	26	0	
			Maternal exposure before pregnancy	9	0	
			Maternal exposure during pregnancy	1	0	
			Maternal exposure timing unspecified	1	0	
		Occupational exposures	Occupational exposure to product	1	0	
		Pathways and sources of exposure	Exposure via skin contact	1	0	
	Injuries NEC	Non-site specific injuries NEC	Fall	1	0	
			Reproductive system and breast injuries	Perineal injury	1	0
		Skin injuries NEC	Contusion	1	0	
	Skin laceration		1	0		
	Medication errors and other product use errors and issues	Accidental exposures to product	Accidental exposure to product	2	0	
			Medication errors, product use errors and issues NEC	Inadequate aseptic technique in use of product	1	0
				Medication error	2	0
				Poor quality device used	1	0
				Vaccination error	2	0
			Wrong technique in product usage process	1	0	
Product administration errors and issues		Accidental underdose	1	0		
		Booster dose missed	2	0		
		Extra dose administered	1	0		
		Inappropriate schedule of product administration	4	0		

		Incorrect dose administered by product	1	0	
		Wrong patient received product	1	0	
		Wrong product administered	2	0	
	Product monitoring errors and issues	Labelled drug-drug interaction issue	1	0	
	<b>Total</b>		<b>101</b>	<b>0</b>	
Investigations	Cardiac and vascular investigations (excl enzyme tests)	Cardiac auscultatory investigations	Cardiac murmur	2	0
		Heart rate and pulse investigations	Heart rate decreased	2	0
			Heart rate increased	1	0
			Heart rate irregular	2	0
		Vascular tests NEC (incl blood pressure)	Blood pressure decreased	1	0
			Blood pressure increased	2	0
	Foetal and neonatal investigations	Foetal and neonatal diagnostic procedures	Foetal heart rate decreased	1	0
			Foetal monitoring abnormal	1	0
	Haematology investigations (incl blood groups)	Haematological analyses NEC	Red blood cell sedimentation rate increased	1	0
		Platelet analyses	Platelet count decreased	1	0
	Metabolic, nutritional and blood gas investigations	Carbohydrate tolerance analyses (incl diabetes)	Blood glucose fluctuation	1	0
	Microbiology and serology investigations	Virus identification and serology	Measles antibody positive	1	0
			Mumps antibody test negative	2	0
	Physical examination and organ system status topics	Physical examination procedures and organ system status	Body temperature increased	2	0
	Renal and urinary tract investigations and urinalyses	Urinalysis NEC	Protein urine	1	0
	<b>Total</b>		<b>21</b>	<b>0</b>	

Metabolism and nutrition disorders	Appetite and general nutritional disorders	Appetite disorders	Decreased appetite	17	0	
			Hypophagia	2	0	
		General nutritional disorders NEC	Failure to thrive	1	0	
	Electrolyte and fluid balance conditions	Fluid intake increased	Polydipsia	1	0	
		Sodium imbalance	Hyponatraemia	1	0	
	Food intolerance syndromes	Food malabsorption and intolerance syndromes (excl sugar intolerance)	Dairy intolerance	1	0	
			Food intolerance	1	0	
	<b>Total</b>			<b>24</b>	<b>0</b>	
	Musculoskeletal and connective tissue disorders	Joint disorders	Arthropathies NEC	Arthritis	1	0
			Joint related signs and symptoms	Arthralgia	17	0
Joint stiffness				1	0	
Joint swelling				1	0	
Rheumatoid arthropathies			Rheumatoid arthritis	1	0	
Muscle disorders		Muscle pains	Myalgia	8	0	
		Muscle related signs and symptoms NEC	Muscle fatigue	1	0	
			Muscle spasms	1	0	
			Muscle twitching	2	0	
Muscle weakness conditions		Muscular weakness	4	0		
Musculoskeletal and connective tissue disorders NEC		Musculoskeletal and connective tissue conditions NEC	Musculoskeletal stiffness	1	0	
			Weight bearing difficulty	3	0	
		Musculoskeletal and connective tissue pain and discomfort	Back pain	3	0	
			Neck pain	5	0	
			Pain in extremity	11	0	
Soft tissue disorders NEC		Groin pain	1	0		
<b>Total</b>			<b>61</b>	<b>0</b>		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Reproductive neoplasms female benign	Reproductive neoplasms female benign NEC	Benign hydatidiform mole	1	0
		<b>Total</b>			<b>1</b>	<b>0</b>
Nervous system disorders		Central nervous system infections and inflammations	Central nervous system inflammatory disorders NEC	Arachnoiditis	1	0
	Central nervous system vascular disorders	Central nervous system haemorrhages and cerebrovascular accidents	Cerebral infarction	1	0	

Cranial nerve disorders (excl neoplasms)	Facial cranial nerve disorders	Facial paralysis	1	0
Encephalopathies	Encephalopathies NEC	Encephalopathy neonatal	1	0
		Hypoxic-ischaemic encephalopathy	1	0
Headaches	Headaches NEC	Headache	14	0
	Migraine headaches	Migraine	4	0
Mental impairment disorders	Memory loss (excl dementia)	Amnesia	1	0
	Mental impairment (excl dementia and memory loss)	Disturbance in attention	1	0
Movement disorders (incl parkinsonism)	Dyskinesias and movement disorders NEC	Dyskinesia	2	0
		Hypokinesia	1	0
		Psychomotor hyperactivity	1	0
	Dystonias	Opisthotonus	1	0
	Paralysis and paresis (excl cranial nerve)	Paralysis	1	0
	Tremor (excl congenital)	Tremor	2	0
Neurological disorders NEC	Coordination and balance disturbances	Balance disorder	2	0
		Coordination abnormal	1	0
		Hand-eye coordination impaired	1	0
	Cortical dysfunction NEC	Aphasia	1	0
		Dyspraxia	1	0
	Disturbances in consciousness NEC	Depressed level of consciousness	2	0
		Lethargy	7	0
		Loss of consciousness	2	0
		Somnolence	4	0
		Syncope	6	0
	Neurological signs and symptoms NEC	Brain fog	1	0
		Dizziness	12	0
		Drooling	2	0
		Head discomfort	1	0
		Unresponsive to stimuli	3	0
	Paraesthesias and dysaesthesias	Burning sensation	1	0
		Hypoaesthesia	3	0
		Paraesthesia	8	0
	Sensory	Dysgeusia	1	0

	abnormalities NEC	Sensory loss	1	0	
	Speech and language abnormalities	Dysarthria	1	0	
		Slow speech	1	0	
		Speech disorder developmental	1	0	
	Neuromuscular disorders	Muscle tone abnormal	Hypotonia	4	0
	Seizures (incl subtypes)	Seizures and seizure disorders NEC	Epilepsy	3	0
			Neonatal seizure	1	0
			Partial seizures	1	0
			Seizure	8	0
	<b>Total</b>		<b>113</b>	<b>0</b>	
Pregnancy, puerperium and perinatal conditions	Abortions and stillbirth	Abortions spontaneous	Abortion spontaneous	20	0
			Abortion threatened	1	0
			Imminent abortion	1	0
			Stillbirth and foetal death	Stillbirth	2
	Foetal complications	Foetal complications NEC	Foetal distress syndrome	1	0
			Foetal hypokinesia	1	0
		Foetal growth complications	Foetal growth restriction	3	0
		Foetal position and presentation abnormalities	Breech presentation	1	0
	Maternal complications of labour and delivery	Labour onset and length abnormalities	Premature delivery	1	0
			Premature labour	2	0
			Premature rupture of membranes	1	0
			Prolonged labour	6	0
		Maternal complications of labour NEC	Labour complication	1	0
	Maternal complications of pregnancy	Haemorrhagic complications of pregnancy	Premature separation of placenta	1	0
		Hypertension associated disorders of pregnancy	Pre-eclampsia	3	0
		Maternal complications of pregnancy NEC	Complication of pregnancy	1	0
		Pregnancy complicated by maternal disorders	Gestational diabetes	1	0

	Neonatal and perinatal conditions	Gestational age and weight conditions	Premature baby	5	0
		Neonatal gastrointestinal disorders	Meconium increased	1	0
		Neonatal hepatobiliary disorders	Jaundice neonatal	1	0
	Placental, amniotic and cavity disorders (excl haemorrhages)	Amniotic fluid and cavity disorders of pregnancy NEC	Oligohydramnios	1	0
	Postpartum and puerperal disorders	Postpartum complications NEC	Postpartum haemorrhage	2	0
	Pregnancy, labour, delivery and postpartum conditions	Multiple pregnancies	Multiple pregnancy	2	0
		Normal newborn status	Normal newborn	1	0
		Normal pregnancy, labour and delivery	Pregnancy	2	0
	<b>Total</b>			<b>62</b>	<b>2</b>
	Product issues	Device issues	Device issues NEC	Device connection issue	2
Device physical property and chemical issues			Needle issue	1	0
			Syringe issue	2	0
Product quality, supply, distribution, manufacturing and quality system issues		Product quality issues NEC	Product quality issue	2	0
<b>Total</b>			<b>7</b>	<b>0</b>	
Psychiatric disorders	Anxiety disorders and symptoms	Anxiety symptoms	Agitation	1	0
			Anxiety	4	0
		Obsessive-compulsive disorders and symptoms	Obsessive-compulsive disorder	1	0
			Obsessive-compulsive symptom	1	0
	Changes in physical activity	Increased physical activity levels	Restlessness	1	0
		Stereotypies and automatisms	Head banging	1	0
			Posturing	1	0
	Cognitive and attention disorders and disturbances	Attention deficit and disruptive behaviour disorders	Attention deficit hyperactivity disorder	1	0
Deliria (incl confusion)	Confusion and disorientation	Confusional state	1	0	

		Disorientation	2	0	
Depressed mood disorders and disturbances	Depressive disorders	Depression	1	0	
	Mood alterations with depressive symptoms	Anhedonia	1	0	
		Depressed mood	2	0	
		Tearfulness	2	0	
Developmental disorders NEC	Pervasive developmental disorders NEC	Autism spectrum disorder	6	0	
Eating disorders and disturbances	Eating disorders NEC	Selective eating disorder	1	0	
Mood disorders and disturbances NEC	Affect alterations NEC	Affect lability	1	0	
	Emotional and mood disturbances NEC	Dysphoria	1	0	
		Emotional distress	3	0	
		Irritability	7	0	
Personality disorders and disturbances in behaviour	Behaviour and socialisation disturbances	Aggression	2	0	
		Attention-seeking behaviour	1	0	
Psychiatric and behavioural symptoms NEC	Abnormal behaviour NEC	Abnormal behaviour	4	0	
		Regressive behaviour	1	0	
		Staring	1	0	
Schizophrenia and other psychotic disorders	Psychotic disorder NEC	Psychotic disorder	1	0	
Sleep disorders and disturbances	Disturbances in initiating and maintaining sleep	Insomnia	2	0	
	Dyssomnias	Poor quality sleep	1	0	
	Sleep disorders NEC	Sleep disorder	3	0	
<b>Total</b>			<b>55</b>	<b>0</b>	
Renal and urinary disorders	Urinary tract signs and symptoms	Pollakiuria	1	0	
		Urinary incontinence	1	0	
	Urinary abnormalities	Proteinuria	1	0	
	Urinary tract signs and symptoms NEC	Renal pain	1	0	
	<b>Total</b>			<b>4</b>	<b>0</b>
Reproductive system and breast disorders	Breast disorders	Breast infections and inflammations	Nipple inflammation	1	0
	Vulvovaginal disorders (excl infections and inflammations)	Vulvovaginal disorders NEC	Vaginal haemorrhage	6	0

<b>Total</b>			<b>7</b>	<b>0</b>		
Respiratory, thoracic and mediastinal disorders	Bronchial disorders (excl neoplasms)	Bronchospasm and obstruction	Asthma	2	0	
			Wheezing	3	0	
	Lower respiratory tract disorders (excl obstruction and infection)	Lower respiratory tract inflammatory		Alveolitis	1	0
				Pneumonitis	1	0
		Parenchymal lung disorders NEC		Interstitial lung disease	1	0
				Lung consolidation	1	0
				Organising pneumonia	1	0
				Pulmonary alveolar haemorrhage	1	0
		Pulmonary oedemas		Acute lung injury	1	0
				Acute respiratory distress syndrome	1	0
				Pulmonary congestion	1	0
				Pulmonary oedema	1	0
	Neonatal respiratory disorders	Neonatal hypoxic conditions	Neonatal respiratory distress syndrome	2	0	
		Newborn respiratory disorders NEC		Bronchopulmonary dysplasia	1	0
				Transient tachypnoea of the newborn	1	0
	Pleural disorders	Pleural conditions NEC	Pleural adhesion	1	0	
		Pneumothorax and pleural effusions NEC	Pleural effusion	1	0	
	Pulmonary vascular disorders	Pulmonary thrombotic and embolic conditions	Pulmonary embolism	1	0	
		Vascular pulmonary disorders NEC	Pulmonary arteriopathy	2	0	
	Respiratory disorders NEC	Breathing abnormalities		Dyspnoea	7	0
			Respiratory arrest	1	0	
			Tachypnoea	1	0	
Conditions associated with			Asphyxia	1	0	
			Hypoxia	1	0	
Coughing and associated symptoms		Cough	11	0		
Respiratory failures (excl neonatal)	Respiratory failure	1	0			

Respiratory tract signs and symptoms	Lower respiratory tract signs and symptoms	Pulmonary haemorrhage	1	0	
	Upper respiratory tract signs and symptoms	Catarrh	1	0	
		Oropharyngeal discomfort	1	0	
		Oropharyngeal pain	9	0	
		Rhinorrhoea	5	0	
		Snoring	1	0	
		Throat irritation	2	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 neoplasms)	Pharyngeal swelling	3	0
			Tonsillar hypertrophy	1	0
	<b>Total</b>			<b>76</b>	<b>0</b>
Skin and subcutaneous tissue disorders	Angioedema and urticaria	Angioedemas	Angioedema	2	0
		Urticarias	Mechanical urticaria	1	0
	Urticaria		22	0	
Epidermal and dermal conditions	Bullous conditions	Blister	1	0	
		Erythema multiforme	1	0	
	Dermal and epidermal conditions NEC	Macule	1	0	
		Pain of skin	1	0	
		Papule	2	0	
		Scab	1	0	
		Skin discolouration	1	0	
		Skin reaction	1	0	
		Skin warm	1	0	
	Dermatitis and eczema	Dermatitis allergic	2	0	
		Eczema	2	0	
		Skin irritation	1	0	
	Erythemas	Erythema	14	0	
	Pruritus NEC	Pruritus	14	0	
	Rashes, eruptions and exanthems NEC	Rash	63	0	
		Rash erythematous	8	0	
		Rash macular	5	0	
		Rash maculo-papular	3	0	
		Rash morbilliform	14	0	
		Rash papular	5	0	
Rash pruritic		1	0		

			Rash rubelliform	1	0	
			Rash vesicular	1	0	
	Skin appendage conditions	Apocrine and eccrine gland disorders	Cold sweat	2	0	
			Hyperhidrosis	3	0	
	Skin vascular abnormalities	Skin vasomotor conditions	Livedo reticularis	1	0	
	<b>Total</b>			<b>175</b>	<b>0</b>	
Social circumstances	Family issues	Family and partner issues	Multiple birth sibling	2	0	
	Lifestyle issues	Social issues NEC	Contraindication to vaccination	1	0	
	<b>Total</b>			<b>3</b>	<b>0</b>	
Surgical and medical procedures	Endocrine gland therapeutic procedures	Hormonal therapeutic procedures NEC	Steroid therapy	1	0	
	Obstetric and gynaecological therapeutic procedures	Induced abortions	Abortion induced	1	0	
			Obstetric therapeutic procedures	Caesarean section	11	0
				Episiotomy	1	0
				Forceps delivery	1	0
				Labour stimulation	1	0
	<b>Total</b>			<b>16</b>	<b>0</b>	
Vascular disorders	Arteriosclerosis, stenosis, vascular insufficiency and necrosis	Peripheral vasoconstriction, necrosis and vascular insufficiency	Peripheral coldness	2	0	
	Decreased and nonspecific blood pressure disorders and shock	Circulatory collapse and shock	Circulatory collapse	1	0	
	Vascular disorders NEC	Peripheral vascular disorders NEC	Cyanosis	4	0	
			Flushing	2	0	
			Site specific vascular disorders NEC	Pallor	7	0
	Vascular haemorrhagic disorders	Haemorrhages NEC	Haemorrhage	1	0	
	Vascular hypertensive disorders	Vascular hypertensive disorders NEC	Hypertension	2	0	
	<b>Total</b>			<b>19</b>	<b>0</b>	
<b>Total Reactions for Drug</b>				<b>1,294</b>		
<b>Total Reports</b>				<b>415</b>		
<b>Total Fatal Outcome Reports</b>					<b>5</b>	