Report Run Date: 25-Mar-2021

Data Lock Date: 24-Mar-2021 19:00:04

Earliest Reaction Date: 23-Mar-2008 MedDRA 23.1 MedDRA Version:

M-M-R VAXPRO:

All spontaneous UK suspected ADR reports associated with M-M-R VAXPRO up to and including

24/03/2021

Report Run Date: 25-Mar-2021 Data Lock Date: 24-Mar-2021 19:00:04 Earliest Reaction Date: 23-Mar-2008 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Blood disorders		
Anaemias NEC		
Anaemia	1	0
Leukopenias NEC		
Lymphopenia	1	0
Lymphatic system disorders NEC		
Lymphadenopathy	11	0
Thrombocytopenias		
Immune thrombocytopenia	2	0
Blood disorders SOC TOTAL	15	l o

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Reaction Name	Total	Fatal
Cardiac disorders		
Endocarditis NEC		
Endocarditis noninfective	1	1
Noninfectious pericarditis		
Pericarditis	1	0
Pericardial disorders NEC		
Pericardial effusion	1	0
Pulmonary valvular disorders		
Pulmonary valve stenosis	2	0
Rate and rhythm disorders NEC		
Bradycardia	3	0
Cardiac disorders SOC TOTAL	8	1

Earliest Reaction Date: 23-Mar-2008 MedDRA Version: MedDRA 23.	.1	
Reaction Name	<u>Total</u>	<u>Fatal</u>
Congenital disorders		
Anorectal disorders congenital		
Preternatural anus	2	0
Autosomal chromosomal abnormalities		
Trisomy 21	2	0
Cardiac septal defects congenital		
Atrioventricular septal defect	2	0
Congenital disorders NEC		
Congenital anomaly	1	0
Congenital cyst	1	0
VACTERL syndrome	2	0
External ear disorders congenital		
Anomaly of external ear congenital	1	0
Eyelid disorders congenital		
Eyelid ptosis congenital	2	0
Gene mutations and other alterations NEC		
Gene mutation	1	0
Great vessel disorders congenital		
Double outlet right ventricle	2	0
Immune system abnormalities congenital		
Primary immunodeficiency syndrome	3	0
Male reproductive tract disorders congenital		
Cryptorchism	1	0
Hydrocele	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		
Spine malformation	2	0
Neurological disorders congenital NEC		
Spinal muscular atrophy	1	0
Persistent foetal circulation disorders		
Patent ductus arteriosus	1	0
Pulmonary and bronchial disorders congenital		
Congenital pneumonia	1	0
Pulmonary aplasia	2	0
Pulmonary hypoplasia	2	0
Renal disorders congenital		_
Congenital cystic kidney disease	2	0
Skin and subcutaneous tissue disorders congenital NEC		_
Congenital naevus	1	0
Congenital skin dimples	2	0
Tongue disorders congenital		J
Ankyloglossia congenital	2	0
Congenital disorders SOC TOTAL	47	0

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Reaction Name	Total	Fatal
Ear disorders		
Ear disorders NEC		
Ear pain	1	0
Hearing losses		
Deafness	2	0
Hypoacusis	1	0
Inner ear signs and symptoms		
Tinnitus	1	0
Vertigo	3	0
Ear disorders SOC TOTAL	B	o l

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Reaction Name	Total	Fatal
Eye disorders		
Lid, lash and lacrimal infections, irritations and inflammations		
Swelling of eyelid	2	0
Lid, lash and lacrimal structural disorders		
Dacryostenosis acquired	1	0
Ocular disorders NEC		
Eye disorder	1	0
Eye swelling	1	0
Ocular infections, inflammations and associated manifestations		
Eye pruritus	1	0
Ocular nerve and muscle disorders		
Eye movement disorder	3	0
Strabismus	2	0
Ocular sensation disorders		
Asthenopia	1	0
Photophobia	3	0
Pupil disorders		
Mydriasis	1	0
Visual disorders NEC		
Vision blurred	1	0
Visual impairment and blindness (excl colour blindness)		
Visual impairment	1	0
Eve disorders SOC TOTAL	18	l o

Reaction Name MedDRA Version: MedDRA 23.1	Total	Fatal
Gastrointestinal disorders	l	i atai
Diarrhoea (excl infective)		
Diarrhoea	15	0
Faecal abnormalities NEC		_
Faeces discoloured	1	0
Gastrointestinal and abdominal pains (excl oral and throat)		
Abdominal pain	2	0
Abdominal pain lower	1	0
Gastrointestinal atonic and hypomotility disorders NEC		
Gastrooesophageal reflux disease	3	0
Gastrointestinal signs and symptoms NEC		
Abdominal discomfort	1	0
Anal incontinence	1	0
Dysphagia	1	0
Gastrointestinal vascular occlusion and infarction		
Intestinal ischaemia	1	0
Gingival disorders, signs and symptoms NEC		
Gingival pain	1	0
Nausea and vomiting symptoms		
Nausea	10	0
Retching	1	0
Vomiting	22	0
Vomiting projectile	1	0
Oral soft tissue disorders NEC		
Oral disorder	1	0
Oral soft tissue signs and symptoms		
Oral mucosal blistering	3	0
Oral pain	1	0
Paraesthesia oral	2	0
Oral soft tissue swelling and oedema		
Lip swelling	6	0
Mouth swelling	1	0
Salivary gland enlargements		
Parotid gland enlargement	3	0
Submaxillary gland enlargement	1	0
Stomatitis and ulceration		
Mouth ulceration	2	0
Tongue signs and symptoms		
Strawberry tongue	1	0
Umbilical hernias		
Umbilical hernia	2	0
Gastrointestinal disorders SOC TOTAL	84	0

Earliest Reaction Date: 23-Mar-2008	MedDRA Version: MedDRA 23.1	
Reaction Name	Total	Fatal
General disorders		
Adverse effect absent		
No adverse event	3	0
Asthenic conditions		
Asthenia	4	. 0
Fatigue	7	0
Malaise	14	. 0
Febrile disorders		
Pyrexia	59	0
Feelings and sensations NEC		
Chills	2	. 0
Feeling abnormal	2	0
Feeling drunk	1	0
Feeling hot	1	0
Gait disturbances		
Gait disturbance	1	0
General signs and symptoms NEC		
Condition aggravated	2	. 0
Crepitations	1	
Crying	4	. 0
Disease complication	1	
Illness	2	
Induration	1	
Influenza like illness	10	0
Irritability postvaccinal	1	
Local reaction	2	
Peripheral swelling	2 9	0
Screaming	2	0
Swelling	2 4	. 0
Swelling face	3	0
Inflammations		
Inflammation	3	0
Injection site reactions		
Injection site erythema	10	0
Injection site inflammation	1	
Injection site irritation	1	_
Injection site mass	1	
Injection site pain	2	
Injection site pruritus	2	0
Injection site rash	2	. 0
Injection site reaction	2 2 7	0
Injection site swelling	7	0
Injection site urticaria	1	
Injection site vesicles		0
Injection site warmth	1	
Mass conditions NEC		
Mass	1	0
Pain and discomfort NEC		
Chest discomfort	3	0
Chest pain	5	0
Pain	5	0
Tenderness	2	. 0
Therapeutic and nontherapeutic responses		
Adverse event	1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Therapy non-responder	2	. 0
Vaccination site reactions		
Extensive swelling of vaccinated limb	1	0
Vaccination site bruising	3	0
Vaccination site discomfort	1	0
Vaccination site erythema	11	0
Vaccination site haematoma	1	0
Vaccination site inflammation	2	. 0
Vaccination site mass	4	. 0
Vaccination site pain	5	0
Vaccination site rash	2	. 0
Vaccination site reaction	1	0
Vaccination site swelling	6	0
General disorders SOC TOTAL	225	sl ol

Reaction Name	Total	Fatal
Hepatic disorders		
Cholecystitis and cholelithiasis		
Cholecystitis	1	0
Hepatocellular damage and hepatitis NEC		
Hepatitis	2	0
Hepatic disorders SOC TOTAL	3	0

Reaction Name	Total	Fatal
Immune system disorders		
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	7	0
Immune and associated conditions NEC		
Haemophagocytic lymphohistiocytosis	1	1
Immune system disorders SOC TOTAL	15	1

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Reaction Name	Total	<u> Fatal</u>
Infections		
Abdominal and gastrointestinal infections		
Gastroenteritis	1	0
Bacterial infections NEC		
Cellulitis	9	0
Injection site cellulitis	1	0
Respiratory tract infection bacterial	1	0
Vaccination site cellulitis	3	0
Borrelial infections		
Lyme disease	1	0
Central nervous system and spinal infections		
Encephalitis	5	0
Meningitis aseptic	1	0
Ear infections		
Ear infection	1	0
Otitis media	2	2 0
Epstein-Barr viral infections		
Infectious mononucleosis		0
Eye and eyelid infections		
Conjunctivitis	3	0
Herpes viral infections		
Human herpesvirus 6 infection		0
Varicella	1	0
Infections NEC		
Infection	1	0
Respiratory tract infection	1	0
Vaccination site infection	2	2 0
Vestibulitis	1	0
Lower respiratory tract and lung infections		
Pneumonia	2	<u> </u> 0
Male reproductive tract infections		
Orchitis		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		0
Sepsis, bacteraemia, viraemia and fungaemia NEC		
Sepsis neonatal	1	0
Streptococcal infections		
Pneumococcal sepsis	1	0
Upper respiratory tract infections		
Nasopharyngitis	2	2 0
Rhinitis	2	0
Tonsillitis	2	<u> </u> 0
Upper respiratory tract infection	2	2 0
Urinary tract infections		
Urinary tract infection	1	0
Viral infections NEC		
Bronchiolitis	2	2 0
Encephalitis viral	1	

Reaction Name	Total	Fatal
Infections Infections cont'd		
Gastroenteritis viral	1	0
Viral infection	2	0
Infections SOC TOTAL	69	0

Earliest Reaction Date: 23-Mar-2008 MedDRA Version: MedDRA 23.1	Tatal	Fatal
Reaction Name	Total	<u>Fatal</u>
Injuries		
Accidental exposures to product		_
_Accidental exposure to product	1	0
Exposures associated with pregnancy, delivery and lactation		
Exposure during pregnancy	35	
Foetal exposure during pregnancy	26	0
Maternal exposure before pregnancy	9	0
Maternal exposure timing unspecified	1	0
Medication errors, product use errors and issues NEC		
Inadequate aseptic technique in use of product	1	0
Medication error	2	0
Vaccination error	2	0
Non-site specific injuries NEC		
Fall	1	0
Injury	1	0
Occupational exposures		
Occupational exposure to product	1	0
Pathways and sources of exposure		
Exposure via skin contact	1	0
Product administration errors and issues		
Booster dose missed	2	0
Extra dose administered	1	0
Inappropriate schedule of product administration	4	0
Wrong patient received product	1	0
Wrong product administered	2	0
Reproductive system and breast injuries		
Perineal injury	1	0
Skin injuries NEC		
Contusion	1	0
Skin laceration	1	0
Vaccination related complications		
Vaccination failure	1	0
Injuries SOC TOTAL	95	0

Earliest Reaction Date: 23-Mar-2008 MedDRA Version: MedDRA 2	3.1	
Reaction Name	Total_	Fatal
Investigations		
Carbohydrate tolerance analyses (incl diabetes)		
Blood glucose fluctuation	1	0
Cardiac auscultatory investigations		
Cardiac murmur	2	0
Foetal and neonatal diagnostic procedures		
Foetal heart rate decreased	1	0
Foetal monitoring abnormal	1	0
Haematological analyses NEC		
Red blood cell sedimentation rate increased	1	0
Heart rate and pulse investigations		
Heart rate decreased	2	0
Heart rate increased	1	0
Heart rate irregular	2	0
Liver function analyses		
Transaminases increased	1	0
Physical examination procedures and organ system status		
Body temperature decreased	1	0
Body temperature increased	3	0
Platelet analyses		
Platelet count decreased	1	0
Respiratory tract and thoracic imaging procedures		
Chest X-ray abnormal	1	0
Urinalysis NEC		
Protein urine	1	0
Vascular tests NEC (incl blood pressure)		
Blood pressure decreased	1	0
Blood pressure increased	2	0
Virus identification and serology		
Measles antibody positive	1	0
Mumps antibody test negative	2	0
Investigations SOC TOTAL	25	0

Reaction Name	Total	Fatal
Metabolic disorders		
Appetite disorders		
Decreased appetite	11	0
Hypophagia	2	0
Fluid intake increased		
Polydipsia	1	0
Food malabsorption and intolerance syndromes (excl sugar intolerance)		
Dairy intolerance	1	0
Food intolerance	1	0
General nutritional disorders NEC		
Failure to thrive	1	0
Metabolic disorders NEC		
Metabolic disorder	1	0
Sodium imbalance		
Hyponatraemia	1	0
Total fluid volume decreased		
Dehydration	1	0
Metabolic disorders SOC TOTAL	20	0

Earliest Reaction Date: 23-Mar-2008	Medura Version: Medura 23.1		
Reaction Name		<u> Fotal</u>	Fatal
Muscle & tissue disorders			
Arthropathies NEC			
Arthritis		1	0
Joint related disorders NEC			
Hypermobility syndrome		1	0
Joint related signs and symptoms			
Arthralgia		15	0
Joint stiffness		1	0
Joint swelling		1	0
Muscle pains			
Myalgia		7	0
Muscle related signs and symptoms NEC			
Muscle fatigue		1	0
Muscle spasms		1	0
Muscle twitching		2	0
Muscle weakness conditions			
Muscular weakness		5	0
Musculoskeletal and connective tissue condi	tions NEC		
Musculoskeletal stiffness		1	0
Weight bearing difficulty		3	0
Musculoskeletal and connective tissue pain a	and discomfort		
Back pain		3	0
Neck pain		6	0
Pain in extremity		9	0
Soft tissue disorders NEC			
Groin pain		1	0
Muscle & tissue disorders SOC TOTAL		58	0

Reaction Name	Total	Fatal
Neoplasms		
Reproductive neoplasms female benign NEC		
Benign hydatidiform mole	1	0
Neoplasms SOC TOTAL	1	l o

Earliest Reaction Date: 23-Mar-2008	MedDRA Version: MedDRA 23.1		
Reaction Name		Total	Fatal
Nervous system disorders			
Central nervous system haemorrhages and	cerebrovascular accidents		
Cerebral infarction		1	0
Cerebral ischaemia		1	0
Central nervous system inflammatory disord	ers NEC		
Arachnoiditis		1	0
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		6	0
Loss of consciousness		2	0
Somnolence		2	0
Syncope		6	0
Dyskinesias and movement disorders NEC			
Dyskinesia		2	0
Hypokinesia		1	0
Motor dysfunction		1	0
Psychomotor hyperactivity		1	0
Dystonias			
Opisthotonus		1	0
Encephalopathies NEC			
Encephalopathy neonatal		1	0
Hypoxic-ischaemic encephalopathy		1	0
Facial cranial nerve disorders			
Facial paralysis		1	0
Headaches NEC			
Headache		14	0
Memory loss (excl dementia)			
Amnesia		1	0
Mental impairment (excl dementia and mem	orv loss)		
Disturbance in attention	,,	1	0
Migraine headaches			
Migraine		4	0
Muscle tone abnormal			
Hypotonia		4	0
Neurological signs and symptoms NEC			
Dizziness		11	0
Drooling		1	0
Head discomfort		1	0
Unresponsive to stimuli		3	0
Paraesthesias and dysaesthesias		Ŭ	
Burning sensation		1	0
Hypoaesthesia		3	0
Paraesthesia		7	0
Paralysis and paresis (excl cranial nerve)		,	J
Paralysis		1	0
Seizures and seizure disorders NEC			Ŭ
Epilepsy		3	0

Reaction Name	Total	Fatal
Nervous system disorders us system disorders cont'd		
Neonatal seizure	1	0
Partial seizures	1	0
Seizure	8	0
Sensory abnormalities NEC		
Dysgeusia	1	0
Sensory loss	1	0
Speech and language abnormalities		
Dysarthria	1	0
Slow speech	1	0
Structural brain disorders NEC		
Brain injury	1	0
Tremor (excl congenital)		
Tremor	1	0
Nervous system disorders SOC TOTAL	107	0

Earliest Reaction Date: 23-Mar-2008	MedDRA Version: MedDRA 23.1		
Reaction Name		<u>Total</u>	<u>Fatal</u>
Pregnancy conditions			
Abortions spontaneous			
Abortion spontaneous		20	0
Abortion threatened		1	0
Imminent abortion		1	0
Amniotic fluid and cavity disorders of pregn	ancy NEC		
Oligohydramnios		1	0
Foetal complications NEC			
Foetal distress syndrome		1	0
Foetal hypokinesia		1	0
Foetal growth complications			
Foetal growth restriction		3	0
Foetal position and presentation abnormali	ties		
Breech presentation		1	0
Gestational age and weight conditions			
Premature baby		5	0
Haemorrhagic complications of pregnancy			
Premature separation of placenta		1	0
Hypertension associated disorders of pregr	nancy		
Pre-eclampsia	•	3	0
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 NEC			
Complication of pregnancy		1	0
Multiple pregnancies			
Multiple pregnancy		2	0
Neonatal gastrointestinal disorders			
Meconium increased		1	0
Neonatal hepatobiliary disorders			
Jaundice neonatal		1	0
Normal newborn status			
Normal newborn		1	0
Normal pregnancy, labour and delivery			
Pregnancy		2	0
Postpartum complications NEC			
Postpartum haemorrhage		2	0
Pregnancy complicated by maternal disord	ers		
Gestational diabetes		1	0
Stillbirth and foetal death			
Stillbirth		2	2
Pregnancy conditions SOC TOTAL		62	2

Reaction Name	Total	Fatal
Device physical property and chemical issues		
Syringe issue	1	0
Product quality issues NEC		
Product quality issue	1	0
null SOC TOTAL	2	0

Reaction Name MedDRA Version: MedDRA 23.1	Total	Fatal
Psychiatric disorders	Iolai	i alai
Abnormal behaviour NEC		
Abnormal behaviour	2	0
Staring	1	0
Affect alterations NEC	'	J
Affect lability	1	0
Anxiety symptoms	'	J
Agitation	1	0
Anxiety	4	0
Behaviour and socialisation disturbances	4	U
Aggression	1	0
Confusion and disorientation		U
Confusion and disoneritation Confusional state	1	0
	1	0
Disorientation	2	0
Depressive disorders	4	0
Depression Picturbances in initiating and maintaining close	1	0
Disturbances in initiating and maintaining sleep	_	0
Insomnia	2	0
Eating disorders NEC	4	0
Selective eating disorder	1	0
Emotional and mood disturbances NEC	4	0
Dysphoria	1	0
Emotional distress	2	0
Irritability	5	0
Increased physical activity levels	_	_
Restlessness	1	0
Mood alterations with depressive symptoms	_	_
Anhedonia	1	0
Depressed mood	2	0
Tearfulness	2	0
Obsessive-compulsive disorders and symptoms	_	_
Obsessive-compulsive disorder	1	0
Obsessive-compulsive symptom	1	0
Pervasive developmental disorders NEC	_	
Autism spectrum disorder	6	0
Psychotic disorder NEC		
Psychotic disorder	1	0
Sleep disorders NEC	_	
Sleep disorder	3	0
Stereotypies and automatisms		
Head banging	1	0
Posturing	1	0
Psychiatric disorders SOC TOTAL	45	0

Reaction Name	Total	Fatal
Renal & urinary disorders		
Bladder and urethral symptoms		
Pollakiuria	1	0
Urinary incontinence	1	0
Urinary abnormalities		
Proteinuria	1	0
Urinary tract signs and symptoms NEC		
Renal pain	1	0
Renal & urinary disorders SOC TOTAL	4	0

Reaction Name	Total	Fatal
Reproductive & breast disorders		
Breast infections and inflammations		
Nipple inflammation	1	0
Vulvovaginal disorders NEC		
Vaginal haemorrhage	5	0
Reproductive & breast disorders SOC TOTAL	6	0

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Reaction Name	<u> Total</u>	<u>Fatal</u>
Respiratory disorders		
Breathing abnormalities		
Dyspnoea	6	0
Respiratory arrest	2 2	0
Tachypnoea	2	0
Bronchospasm and obstruction		
Asthma	2	0
Wheezing	3	0
Conditions associated with abnormal gas exchange		
Asphyxia	1	0
Hypoxia	1	0
Coughing and associated symptoms		
Cough	10	0
Sputum increased	1	0
Lower respiratory tract inflammatory and immunologic conditions		
Alveolitis	1	0
Pneumonia aspiration	1	0
Pneumonitis	1	0
Lower respiratory tract signs and symptoms		
Increased bronchial secretion	1	0
Nasal congestion and inflammations		
Nasal congestion	3	0
Nasal disorders NEC		
Epistaxis	1	0
Neonatal hypoxic conditions		
Neonatal respiratory distress syndrome	2	0
Newborn respiratory disorders NEC		
Bronchopulmonary dysplasia	1	0
Transient tachypnoea of the newborn	1	0
Parenchymal lung disorders NEC		
Atelectasis	1	0
Interstitial lung disease	2	0
Lung consolidation	2	0
Organising pneumonia	1	0
Pulmonary alveolar haemorrhage	1	0
Pharyngeal disorders (excl infections and neoplasms)		
Pharyngeal swelling	3	0
Tonsillar hypertrophy	1	0
Pleural conditions NEC		
Pleural adhesion	1	0
Pneumothorax and pleural effusions NEC		
Pleural effusion	1	0
Pulmonary oedemas		
Acute lung injury	1	0
Acute respiratory distress syndrome	1	0
Pulmonary congestion	1	0
Pulmonary oedema	1	0
Pulmonary thrombotic and embolic conditions		
Pulmonary embolism	1	0
Respiratory failures (excl neonatal)		
Respiratory failure	1	0
Upper respiratory tract signs and symptoms		
Catarrh	1	0
Oropharyngeal discomfort	1	0

Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Oropharyngeal pain	8	0
Rhinorrhoea	2	0
Snoring	1	0
Throat irritation	1	0
Throat tightness	1	0
Vascular pulmonary disorders NEC		
Pulmonary arteriopathy	2	0
Respiratory disorders SOC TOTAL	76	0

Reaction Name	 Total	Fatal
Skin disorders		
Angioedemas		
Angioedema	2	C
Apocrine and eccrine gland disorders		
Cold sweat	2	C
Hyperhidrosis	3	(
Bullous conditions		
Blister	1	C
Erythema multiforme	1	C
Dermal and epidermal conditions NEC		
Papule	2	(
Skin discolouration	1	(
Skin reaction	1	(
Skin warm	1	C
Dermatitis and eczema		
Dermatitis allergic	1	C
Eczema	2	C
Skin irritation	1	C
Erythemas		
Erythema	13	(
Pruritus NEC		
Pruritus	13	(
Rashes, eruptions and exanthems NEC		
Rash	50	(
Rash erythematous	4	C
Rash macular	5	(
Rash maculo-papular	3	(
Rash morbilliform	11	C
Rash papular	3	(
Rash pruritic	1	(
Urticarias		
Urticaria	19	(
Skin disorders SOC TOTAL	140	(

Reaction Name	Total	Fatal
Social circumstances		
Family and partner issues		
Multiple birth sibling	2	0
Social issues NEC		
Contraindication to vaccination	1	0
Social circumstances SOC TOTAL	3	0

Reaction Name	Total	Fatal
Surgical & medical 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
Therapeutic procedures NEC		
Resuscitation	1	0
Surgical & medical procedures SOC TOTAL	16	0

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Reaction Name	Total	Fatal
Vascular disorders		
Circulatory collapse and shock		
Circulatory collapse	2	1
Haemorrhages NEC		
Haemorrhage	1	0
Peripheral vascular disorders NEC		
Cyanosis	3	0
Flushing	2	0
Peripheral vasoconstriction, necrosis and vascular insufficiency		
Peripheral coldness	2	0
Site specific vascular disorders NEC		
Pallor	7	0
Vascular hypertensive disorders NEC		
Hypertension	2	0
Vascular disorders SOC TOTAL	19	1
TOTAL REACTIONS FOR DRUG	1171	5
TOTAL REPORTS	347	
TOTAL FATAL OUTCOME REPORTS		5