

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal	
Blood and lymphatic system disorders	Coagulopathies and bleeding diatheses (excl thrombocytopenic)	Coagulopathies	Coagulopathy	2	0	
Cardiac disorders	Cardiac arrhythmias	Rate and rhythm disorders NEC	Bradycardia	1	0	
Congenital, familial and genetic disorders	Musculoskeletal and connective tissue disorders congenital	Musculoskeletal and connective tissue disorders of limbs congenital	Developmental hip dysplasia	1	0	
Gastrointestinal disorders	Gastrointestinal haemorrhages NEC	Intestinal haemorrhages	Intestinal haemorrhage	1	0	
		Non-site specific gastrointestinal haemorrhages	Haematochezia	1	0	
	Gastrointestinal signs and symptoms	Faecal abnormalities NEC	Mucous stools	1	0	
General disorders and administration site conditions	Administration site reactions	Injection site reactions	Injection site haematoma	1	0	
			Injection site mass	1	0	
			Injection site necrosis	3	0	
			Injection site swelling	1	0	
	Therapeutic and nontherapeutic effects (excl toxicity)	Therapeutic and nontherapeutic responses	Drug ineffective	1	0	
	Tissue disorders NEC	Mass conditions NEC	Cyst	1	0	
Hepatobiliary disorders	Hepatic and hepatobiliary disorders	Cholestasis and jaundice	Jaundice	6	0	
Immune system disorders	Allergic conditions	Allergies to foods, food additives, drugs and other chemicals	Food allergy	1	0	
			Anaphylactic and anaphylactoid responses	Anaphylactoid reaction	1	0
				Anaphylactoid shock	1	0
Infections and infestations	Bacterial infectious disorders	Bacterial infections NEC	Cellulitis	1	0	
	Infections - pathogen unspecified	Infections NEC	Abscess	1	0	
Injury, poisoning and procedural complications	Exposures, chemical injuries and poisoning	Exposures associated with pregnancy, delivery and lactation	Foetal exposure during pregnancy	1	0	
			Maternal exposure timing unspecified	1	0	
	Injuries NEC	Cerebral injuries NEC	Subdural haemorrhage	1	0	
Metabolism and nutrition disorders	Food intolerance syndromes	Food malabsorption and intolerance syndromes (excl sugar intolerance)	Dairy intolerance	1	0	
			Gluten sensitivity	1	0	
			Milk soy protein intolerance	1	0	
			Sugar intolerance (excl glucose intolerance)	Lactose intolerance	1	0
	Vitamin related disorders	Fat soluble vitamin deficiencies and disorders	Vitamin K deficiency	2	0	
Nervous system disorders	Central nervous system vascular disorders	Central nervous system haemorrhages and cerebrovascular disorders	Cerebral infarction	1	0	
			Subarachnoid haemorrhage	1	0	
	Movement disorders (incl parkinsonism)	Tremor (excl congenital)	Tremor	1	0	
	Seizures (incl subtypes)	Seizures and seizure disorders NEC	Seizure	1	0	

Pregnancy, puerperium and perinatal conditions	Neonatal and perinatal conditions	Neonatal hepatobiliary disorders	Jaundice neonatal	1	0
Respiratory, thoracic and mediastinal disorders	Respiratory disorders NEC	Breathing abnormalities	Respiratory arrest	1	0
Skin and subcutaneous tissue disorders	Epidermal and dermal conditions	Dermal and epidermal conditions NEC	Pain of skin	1	0
			Skin discolouration	1	0
			Skin plaque	1	0
			Skin warm	1	0
	Dermatitis and eczema	Eczema	1	0	
	Rashes, eruptions and exanthems NEC	Rash erythematous	1	0	
		Rash macular	1	0	
	Pigmentation disorders	Pigmentation changes NEC	Pigmentation disorder	1	0
Skin and subcutaneous tissue disorders NEC	Skin and subcutaneous conditions NEC	Skin mass	1	0	
Skin vascular abnormalities	Purpura and related conditions	Petechiae	1	0	
Vascular disorders	Vascular disorders NEC	Peripheral vascular disorders NEC	Cyanosis	1	0
	Vascular haemorrhagic disorders	Haemorrhages NEC	Haemorrhage	1	0
<b>Total number of reactions</b>				<b>53</b>	
<b>Total number of reports</b>				<b>26</b>	
<b>Total number of fatal reports</b>					<b>0</b>