

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
Cardiac disorders	Cardiac arrhythmias	Cardiac conduction disorders	Bundle branch block right	1	0
		Rate and rhythm disorders NEC	Tachycardia	1	0
		Supraventricular arrhythmias	Sinus tachycardia	1	0
	Cardiac disorders, signs and symptoms NEC	Cardiac signs and symptoms NEC	Palpitations	1	0
Ear and labyrinth disorders	Inner ear and VIIIth cranial nerve disorders	Inner ear signs and symptoms	Vertigo	1	0
Endocrine disorders	Endocrine disorders of gonadal function	Endocrine abnormalities of gonadal function NEC	Fertility increased	1	0
Eye disorders	Ocular infections, irritations and inflammations	Ocular infections, inflammations and associated manifestations	Eye irritation	1	0
Gastrointestinal disorders	Gastrointestinal motility and defaecation conditions	Diarrhoea (excl infective)	Diarrhoea	1	0
	Gastrointestinal signs and symptoms	Dyspeptic signs and symptoms	Eructation	1	0
		Faecal abnormalities NEC	Faeces pale	1	0
		Gastrointestinal and abdominal pains (excl oral and throat)	Abdominal pain	1	0
			Gastrointestinal pain	1	0
		Gastrointestinal signs and symptoms NEC	Abdominal discomfort	1	0
			Acute abdomen	1	0
		Nausea and vomiting symptoms	Nausea	1	0
			Vomiting projectile	1	0
General disorders and administration site conditions	General system disorders NEC	Asthenic conditions	Malaise	1	0
		Feelings and sensations NEC	Feeling abnormal	1	0
	Therapeutic and nontherapeutic effects (excl toxicity)	Interactions	Drug interaction	2	0
			Herbal interaction	1	0
Hepatobiliary disorders	Hepatic and hepatobiliary disorders	Cholestasis and jaundice	Cholestasis	1	0
			Hyperbilirubinaemia	1	0
			Jaundice	4	0
			Jaundice cholestatic	1	0
		Hepatic enzymes and function abnormalities	Hepatic function abnormal	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
		Hepatocellular damage and hepatitis NEC	Drug-induced liver injury	2	0
			Liver injury	1	0
Injury, poisoning and procedural complications	Exposures, chemical injuries and poisoning	Exposures associated with pregnancy, delivery and lactation	Maternal exposure during breast feeding	1	0
		Poisoning and toxicity	Toxicity to various agents	1	0
	Injuries NEC	Non-site specific injuries NEC	Fall	1	0
Investigations	Cardiac and vascular investigations (excl enzyme tests)	ECG investigations	QRS axis abnormal	1	0
	Endocrine investigations (incl sex hormones)	Thyroid analyses	Thyroid function test abnormal	1	0
	Enzyme investigations NEC	Tissue enzyme analyses NEC	Blood alkaline phosphatase increased	1	0
	Haematology investigations (incl blood groups)	Platelet analyses	Platelet count decreased	1	0
		Red blood cell analyses	Red cell distribution width increased	1	0
		White blood cell analyses	Monocyte count increased	1	0
			Neutrophil count increased	1	0
			White blood cell count increased	1	0
	Hepatobiliary investigations	Hepatobiliary function diagnostic procedures	Alanine aminotransferase increased	1	0
			Aspartate aminotransferase increased	1	0
			Blood bilirubin increased	3	0
			Liver function test abnormal	5	0
	Lipid analyses	Cholesterol analyses	Blood cholesterol increased	1	0
			High density lipoprotein decreased	1	0
	Renal and urinary tract investigations and urinalyses	Renal function analyses	Blood creatinine increased	1	0
			Blood urea increased	1	0
Metabolism and nutrition disorders	Appetite and general nutritional disorders	Appetite disorders	Decreased appetite	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
	Electrolyte and fluid balance conditions	Sodium imbalance	Hyponatraemia	1	0
Musculoskeletal and connective tissue disorders	Joint disorders	Joint related signs and symptoms	Joint swelling	1	0
	Musculoskeletal and connective tissue disorders NEC	Musculoskeletal and connective tissue pain and discomfort	Musculoskeletal discomfort	1	0
Nervous system disorders	Movement disorders (incl parkinsonism)	Tremor (excl congenital)	Tremor	1	0
	Neurological disorders NEC	Coordination and balance disturbances	Balance disorder	1	0
		Neurological signs and symptoms NEC	Dizziness	2	0
		Paraesthesias and dysaesthesias	Burning sensation	1	0
		Sensory abnormalities NEC	Ageusia	1	0
Pregnancy, puerperium and perinatal conditions	Pregnancy, labour, delivery and postpartum conditions	Unintended pregnancies	Pregnancy on oral contraceptive	1	0
Product issues	Product quality, supply, distribution, manufacturing and quality system issues	Product contamination and sterility issues	Product contamination chemical	1	0
Psychiatric disorders	Anxiety disorders and symptoms	Anxiety symptoms	Anxiety	1	0
			Nervousness	1	0
	Schizophrenia and other psychotic disorders	Psychotic disorder NEC	Psychotic disorder	3	0
Renal and urinary disorders	Renal disorders (excl nephropathies)	Renal failure and impairment	Acute kidney injury	1	0
	Urinary tract signs and symptoms	Bladder and urethral symptoms	Pollakiuria	1	0
		Urinary abnormalities	Chromaturia	1	0
Reproductive system and breast disorders	Menopause related conditions	Menopausal effects on the genitourinary tract	Postmenopausal haemorrhage	2	0
	Sexual function and fertility disorders	Erection and ejaculation conditions and disorders	Priapism	1	0
Skin and subcutaneous tissue disorders	Epidermal and dermal conditions	Pruritus NEC	Pruritus	1	0
	Pigmentation disorders	Pigmentation changes NEC	Pigmentation disorder	1	0
	Skin appendage conditions	Apocrine and eccrine gland disorders	Cold sweat	1	0
			Hyperhidrosis	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
Vascular disorders	Vascular haemorrhagic disorders	Haemorrhages NEC	Haemorrhage	1	0
Total				35	0