

MedDRA version 15.1		CTCAE grade					
System Organ Class	Preferred Term	All Grades	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Blood and lymphatic system disorders	Febrile neutropenia	3	0	1	2	0	0
	Lymph node pain	1	1	0	0	0	0
	Thrombocytopenia	1	0	0	0	1	0
<b>Sub-total number of patients</b>		<b>4</b>	<b>1</b>	<b>1</b>	<b>2</b>	<b>1</b>	<b>0</b>
Cardiac disorders	Atrial flutter	1	0	0	1	0	0
	Tachycardia	1	0	1	0	0	0
	Tachycardia paroxysmal	1	0	1	0	0	0
<b>Sub-total number of patients</b>		<b>2</b>	<b>0</b>	<b>2</b>	<b>1</b>	<b>0</b>	<b>0</b>
Gastrointestinal disorders	Abdominal distension	2	2	0	0	0	0
	Abdominal pain	2	2	0	0	0	0
	Abdominal pain upper	2	1	1	0	0	0
	Anal fissure	2	1	1	0	0	0
	Constipation	4	3	1	0	0	0
	Diarrhoea	10	8	1	1	0	0
	Dry mouth	2	2	0	0	0	0
	Eructation	1	1	0	0	0	0
	Gingival bleeding	1	1	0	0	0	0
	Mouth haemorrhage	3	3	0	0	0	0
	Nausea	7	5	2	0	0	0
	Oral mucosal erythema	1	1	0	0	0	0
	Oral pain	1	1	0	0	0	0
	Proctalgia	1	0	0	1	0	0
	Rectal haemorrhage	1	1	0	0	0	0
Vomiting	7	6	1	0	0	0	
<b>Sub-total number of patients</b>		<b>11</b>	<b>11</b>	<b>4</b>	<b>2</b>	<b>0</b>	<b>0</b>
General disorders and administration site conditions	Asthenia	3	3	0	0	0	0
	Chest pain	1	1	0	0	0	0

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	Chills	2	2	0	0	0	0
	Fatigue	1	1	0	0	0	0
	Oedema peripheral	5	4	1	0	0	0
	Pyrexia	6	4	2	0	0	0
<b>Sub-total number of patients</b>		<b>7</b>	<b>6</b>	<b>2</b>	<b>0</b>	<b>0</b>	<b>0</b>
Infections and infestations	Gastrointestinal infection	1	0	0	0	0	1
	Nasopharyngitis	1	1	0	0	0	0
	Oral herpes	1	1	0	0	0	0
	Paronychia	1	1	0	0	0	0
	Pneumonia	1	0	1	0	0	0
	Soft tissue infection	1	1	0	0	0	0
<b>Sub-total number of patients</b>		<b>5</b>	<b>3</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>1</b>
Injury, poisoning and procedural complications	Periorbital haematoma	1	1	0	0	0	0
<b>Sub-total number of patients</b>		<b>1</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
Investigations	Blood alkaline phosphatase increased	1	1	0	0	0	0
	Blood bilirubin increased	2	1	1	0	0	0
	Blood creatinine increased	1	0	0	1	0	0
	Blood urea increased	1	0	0	1	0	0
	Blood uric acid increased	1	1	0	0	0	0
	Heart rate irregular	1	1	0	0	0	0
	Oxygen saturation decreased	1	1	0	0	0	0
<b>Sub-total number of patients</b>		<b>4</b>	<b>4</b>	<b>1</b>	<b>1</b>	<b>0</b>	<b>0</b>
Metabolism and nutrition disorders	Decreased appetite	4	4	0	0	0	0
	Dehydration	1	0	0	1	0	0
	Hypercalcaemia	1	0	0	0	0	1
	Hyperuricaemia	1	0	0	1	0	0

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<b>Sub-total number of patients</b>		<b>5</b>	<b>4</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>1</b>
Musculoskeletal and connective tissue disorders	Arthralgia	2	1	1	0	0	0
	Back pain	3	2	1	0	0	0
	Joint swelling	1	1	0	0	0	0
	Muscular weakness	1	1	0	0	0	0
	Musculoskeletal chest pain	1	1	0	0	0	0
	Musculoskeletal pain	1	1	0	0	0	0
	Pain in extremity	2	2	0	0	0	0
<b>Sub-total number of patients</b>		<b>6</b>	<b>6</b>	<b>2</b>	<b>0</b>	<b>0</b>	<b>0</b>
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Acute myeloid leukaemia	1	0	0	0	0	1
<b>Sub-total number of patients</b>		<b>1</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>
Nervous system disorders	Dizziness	1	1	0	0	0	0
	Dysgeusia	1	1	0	0	0	0
	Headache	2	2	0	0	0	0
	Hypotonia	2	2	0	0	0	0
	Paraesthesia	2	2	0	0	0	0
	Tremor	1	1	0	0	0	0
<b>Sub-total number of patients</b>		<b>6</b>	<b>6</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
Psychiatric disorders	Disorientation	1	0	1	0	0	0
	Restlessness	4	3	1	0	0	0
<b>Sub-total number of patients</b>		<b>4</b>	<b>3</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>0</b>
Renal and urinary disorders	Pollakiuria	1	1	0	0	0	0
	Renal failure acute	1	0	0	1	0	0
<b>Sub-total number of patients</b>		<b>2</b>	<b>1</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>0</b>
Respiratory, thoracic and mediastinal disorders	Cough	2	1	1	0	0	0
	Dyspnoea	3	2	1	0	0	0

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	Dyspnoea exertional	1	0	1	0	0	0
	Epistaxis	3	1	2	0	0	0
	Oropharyngeal pain	1	1	0	0	0	0
	Pharyngeal erythema	1	1	0	0	0	0
<b>Sub-total number of patients</b>		<b>8</b>	<b>6</b>	<b>5</b>	<b>0</b>	<b>0</b>	<b>0</b>
Skin and subcutaneous tissue disorders	Dry skin	2	2	0	0	0	0
	Night sweats	1	1	0	0	0	0
	Petechiae	1	1	0	0	0	0
	Rash	1	1	0	0	0	0
	Skin ulcer	1	1	0	0	0	0
<b>Sub-total number of patients</b>		<b>3</b>	<b>3</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
Vascular disorders	Haematoma	1	1	0	0	0	0
	Hypertension	1	1	0	0	0	0
	Intra-abdominal haematoma	1	1	0	0	0	0
	Peripheral coldness	1	1	0	0	0	0
<b>Sub-total number of patients</b>		<b>4</b>	<b>4</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>Total number of patients</b>		<b>12</b>	<b>12</b>	<b>9</b>	<b>5</b>	<b>1</b>	<b>3</b>