

SYSTEM ORGAN CLASS (%) REFERRED TERM (%)	PLACEBO N=27	ACTIVE DRUG A N=28
TOTAL SUBJECCTS WITH AN EVENT	27 (100%)	28 (100%)
Blood and lymphatic system disorders	5 (18.5)	6 (22.2)
Anaemia	5 (18.5)	6 (22.2)
Cardiac disorders	3 (11.1)	2 (7.4)
Atrial fibrillation	1 (3.7)	1 (3.7)
Palpitations	1 (3.7)	1 (3.7)
Pericardial effusion	1 (3.7)	0
Ear and labyrinth disorders	0	1 (3.7)
Vertigo	0	1 (3.7)
Endocrine disorders	1 (3.7)	4 (14.8)
Hyperthyroidism	1 (3.7)	2 (7.4)
Hypothyroidism	0	2 (7.4)
Eye disorders	3 (11.1)	2 (7.4)
Lacrimation increased	2 (7.4)	1 (3.7)
Vision blurred	1 (3.7)	1 (3.7)
Gastrointestinal disorders	11 (40.7)	16 (59.3)
Ascites	0	2 (7.4)
Constipation	2 (7.4)	3 (11.1)
Diarrhoea	2 (7.4)	2 (7.4)
Dry mouth	1 (3.7)	1 (3.7)
Gastrooesophageal reflux disease	1 (3.7)	2 (7.4)
Haematochezia	0	1 (3.7)
Ileus	0	1 (3.7)
Nausea	4 (14.8)	6 (22.2)
Vomiting	2 (7.4)	2 (7.4)
General disorders and administration site conditions	14 (51.9)	14 (51.9)
Chills	3 (11.1)	2 (7.4)
Disease progression	1 (3.7)	0
Fatigue	4 (14.8)	8 (29.6)
Feeling hot	1 (3.7)	0

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Generalised oedema	0	1 (3.7)
Non-cardiac chest pain	1 (3.7)	0
Oedema peripheral	2 (7.4)	1 (3.7)
Pyrexia	2 (7.4)	4 (14.8)
Hepatobiliary disorders	1 (3.7)	0
Cholelithiasis	1 (3.7)	0
Immune system disorders	1 (3.7)	1 (3.7)
Drug hypersensitivity	1 (3.7)	1 (3.7)
Infections and infestations	6 (22.2)	8 (29.6)
Bronchitis	1 (3.7)	1 (3.7)
Cellulitis	1 (3.7)	0
Eye infection	0	1 (3.7)
Fungal skin infection	1 (3.7)	1 (3.7)
Pharyngitis	1 (3.7)	0
Pneumonia	1 (3.7)	3 (11.1)
Sepsis	0	1 (3.7)
Sinusitis	1 (3.7)	0
Tinea cruris	0	1 (3.7)
Upper respiratory tract infection	0	1 (3.7)
Injury, poisoning and procedural complications	0	1 (3.7)
Infusion related reaction	0	1 (3.7)
Investigations	6 (22.2)	8 (29.6)
Alanine aminotransferase increased	0	1 (3.7)
Aspartate aminotransferase increased	1 (3.7)	3 (11.1)
Blood creatinine increased	2 (7.4)	2 (7.4)
Blood urea increased	1 (3.7)	1 (3.7)
International normalised ratio increased	1 (3.7)	0
Platelet count decreased	1 (3.7)	1 (3.7)
Weight decreased	2 (7.4)	3 (11.1)
Weight increased	1 (3.7)	0
Metabolism and nutrition disorders	10 (37.0)	17 (63.0)
Decreased appetite	4 (14.8)	6 (22.2)

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Dehydration	3 (11.1)	3 (11.1)
Diabetic ketoacidosis	0	1 (3.7)
Hypercalcaemia	1 (3.7)	0
Hyperglycaemia	1 (3.7)	2 (7.4)
Hyperkalaemia	2 (7.4)	2 (7.4)
Hyperuricaemia	1 (3.7)	1 (3.7)
Hypoglycaemia	0	1 (3.7)
Hypokalaemia	2 (7.4)	2 (7.4)
Hypomagnesaemia	0	1 (3.7)
Hyponatraemia	2 (7.4)	4 (14.8)
Musculoskeletal and connective tissue disorders	13 (48.1)	13 (48.1)
Arthralgia	1 (3.7)	2 (7.4)
Back pain	5 (18.5)	6 (22.2)
Bone pain	2 (7.4)	1 (3.7)
Flank pain	2 (7.4)	1 (3.7)
Muscular weakness	1 (3.7)	1 (3.7)
Musculoskeletal chest pain	1 (3.7)	2 (7.4)
Myalgia	2 (7.4)	1 (3.7)
Neck pain	0	1 (3.7)
Pain in extremity	0	2 (7.4)
Soft tissue swelling	0	1 (3.7)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (3.7)	3 (11.1)
Brain neoplasm malignant	0	1 (3.7)
Malignant neoplasm progression	1 (3.7)	2 (7.4)
Nervous system disorders	5 (18.5)	5 (18.5)
Ataxia	1 (3.7)	0
Dizziness	1 (3.7)	0
Dysgeusia	0	1 (3.7)
Headache	2 (7.4)	3 (11.1)
Ischaemic stroke	1 (3.7)	0
Migraine	1 (3.7)	1 (3.7)
Somnolence	0	1 (3.7)
Psychiatric disorders	5 (18.5)	8 (29.6)
Agitation	0	1 (3.7)

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Anxiety	0	2 (7.4)
Confusional state	0	1 (3.7)
Depression	1 (3.7)	1 (3.7)
Emotional disorder	1 (3.7)	1 (3.7)
Hallucination	1 (3.7)	0
Insomnia	2 (7.4)	3 (11.1)
Renal and urinary disorders	1 (3.7)	3 (11.1)
Chromaturia	0	1 (3.7)
Haematuria	1 (3.7)	1 (3.7)
Urinary tract pain	0	1 (3.7)
Reproductive system and breast disorders	1 (3.7)	1 (3.7)
Testicular swelling	1 (3.7)	1 (3.7)
Respiratory, thoracic and mediastinal disorders	12 (44.4)	15 (55.6)
Cough	2 (7.4)	4 (14.8)
Dyspnoea	3 (11.1)	3 (11.1)
Epistaxis	0	1 (3.7)
Haemoptysis	1 (3.7)	1 (3.7)
Hiccups	1 (3.7)	0
Hypoxia	2 (7.4)	3 (11.1)
Nasal congestion	0	1 (3.7)
Oropharyngeal pain	1 (3.7)	2 (7.4)
Pleural effusion	0	1 (3.7)
Pneumonia aspiration	1 (3.7)	0
Pneumonitis	0	1 (3.7)
Productive cough	1 (3.7)	1 (3.7)
Upper-airway cough syndrome	2 (7.4)	0
Skin and subcutaneous tissue disorders	6 (22.2)	10 (37.0)
Hyperhidrosis	0	1 (3.7)
Night sweats	1 (3.7)	0
Pruritus	5 (18.5)	7 (25.9)
Rash	0	2 (7.4)