

AIRIS PHARMA Private Limited.

Protocol: 043-1810

Table 14.1.20 Medical History by Treatment, System Organ Class and Preferred Term (Safety Population)

MedDRA?System Organ Class MedDRA?Preferred Term	DRUG A (N = 3)	DRUG B (N = 3)	DRUG C (N = 3)	DRUG D (N = 2)
Number of Subjects with one Medical History	3 (100)	3 (100)	1 (33.3)	0
Blood and lymphatic system disorders	3 (100)	1 (33.3)	0	0
Anaemia	1 (33.3)	1 (33.3)	0	0
Lymphopenia	2 (66.7)	0	0	0
Cardiac disorders	1 (33.3)	1 (33.3)	0	0
Atrial fibrillation	1 (33.3)	0	0	0
Tachycardia	0	1 (33.3)	0	0
Ear and labyrinth disorders	1 (33.3)	0	0	0
Deafness bilateral	1 (33.3)	0	0	0
Endocrine disorders	0	0	1 (33.3)	0
Hypothyroidism	0	0	1 (33.3)	0
Gastrointestinal disorders	3 (100)	2 (66.7)	1 (33.3)	0
Abdominal pain	2 (66.7)	0	0	0
Constipation	1 (33.3)	1 (33.3)	0	0
Diarrhoea	2 (66.7)	0	0	0
Flatulence	1 (33.3)	0	0	0
Gastroesophageal reflux disease	0	1 (33.3)	0	0

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Inguinal hernia	1 (33.3)	0	0	0
Irritable bowel syndrome	0	1 (33.3)	0	0
Nausea	2 (66.7)	1 (33.3)	1 (33.3)	0
General disorders and administration site conditions	3 (100)	1 (33.3)	0	0
Fatigue	2 (66.7)	0	0	0
Pain	1 (33.3)	0	0	0
Pyrexia	1 (33.3)	1 (33.3)	0	0
Immune system disorders	2 (66.7)	2 (66.7)	1 (33.3)	0
Contrast media allergy	0	1 (33.3)	0	0
Drug hypersensitivity	2 (66.7)	1 (33.3)	1 (33.3)	0
Metabolism and nutrition disorders	2 (66.7)	1 (33.3)	1 (33.3)	0
Gout	1 (33.3)	1 (33.3)	0	0
Hypercholesterolaemia	2 (66.7)	0	1 (33.3)	0
Hyperglycaemia	1 (33.3)	0	0	0
Hyperlipidaemia	0	1 (33.3)	0	0
Hypokalaemia	0	1 (33.3)	0	0
Hypomagnesaemia	0	1 (33.3)	0	0

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Musculoskeletal and connective tissue disorders	2 (66.7)	1 (33.3)	1 (33.3)	0
Back pain	2 (66.7)	0	0	0
Flank pain	0	1 (33.3)	0	0
Muscle spasms	0	0	1 (33.3)	0
Osteoarthritis	1 (33.3)	0	0	0
Osteoporosis	1 (33.3)	0	0	0
Rheumatoid arthritis	1 (33.3)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3 (100)	0	1 (33.3)	0
Malignant melanoma	1 (33.3)	0	0	0
Prostate cancer	1 (33.3)	0	0	0
Tumour pain	3 (100)	0	1 (33.3)	0
Nervous system disorders	0	1 (33.3)	1 (33.3)	0
Narcolepsy	0	0	1 (33.3)	0
Paraesthesia	0	1 (33.3)	0	0
Psychiatric disorders	0	1 (33.3)	1 (33.3)	0
Anxiety	0	1 (33.3)	1 (33.3)	0
Depression	0	1 (33.3)	1 (33.3)	0

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Insomnia	0	1 (33.3)	1 (33.3)	0
Schizoaffective disorder	0	1 (33.3)	0	0
Respiratory, thoracic and mediastinal disorders	0	1 (33.3)	1 (33.3)	0
Cough	0	1 (33.3)	0	0
Dyspnoea	0	1 (33.3)	0	0
Pneumonitis	0	0	1 (33.3)	0
Pulmonary embolism	0	0	1 (33.3)	0
Surgical and medical procedures	2 (66.7)	2 (66.7)	1 (33.3)	0
Bile duct stent insertion	1 (33.3)	0	0	0
Cardiac pacemaker insertion	1 (33.3)	0	0	0
Cholecystectomy	0	0	1 (33.3)	0
Gastric banding	0	0	1 (33.3)	0
Hysterectomy	0	1 (33.3)	1 (33.3)	0
Large intestinal polypectomy	1 (33.3)	0	0	0
Nephrostomy	0	1 (33.3)	0	0
Spinal fusion surgery	0	0	1 (33.3)	0
Spinal operation	1 (33.3)	0	0	0

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Tonsillectomy	0	1 (33.3)	0	0
Vena cava filter insertion	0	0	1 (33.3)	0
Vascular disorders	1 (33.3)	1 (33.3)	1 (33.3)	0
Deep vein thrombosis	1 (33.3)	0	1 (33.3)	0
Hypertension	0	1 (33.3)	1 (33.3)	0