

AIRIS PHARMA Private Limited.
Protocol: 043-1810

16.2.2.3 Serious Adverse Events

Subj. No.	Adverse Event/Primary System Organ Class/ Preferred term	Start Date/Time	End Date/Time	Serious Event	Action taken	Relationship to Study Drug	Outcome
043-18101-740 01-003	Anemia/Blood and lymphatic system disorders/Anaemia	2019-05-20	2019-05-22	Y	DRUG WITHDRAWN	RELATED	RECOVERED/RE SOLVED
	Hepatic Failure/Hepatobiliary disorders/Hepatic failure	2019-05-20	2019-05-26	Y	NOT APPLICABLE	RELATED	FATAL
	Laryngeal Mucositis/Respiratory, thoracic and mediastinal disorders/Laryngeal inflammation	2019-05-20		Y	DOSE NOT CHANGED	RELATED	NOT RECOVERED/NO T RESOLVED
	Neutropenia/Blood and lymphatic system disorders/Neutropenia	2019-05-20	2019-05-25	Y	DRUG WITHDRAWN	RELATED	RECOVERED/RE SOLVED
	Thrombocytopenia/Blood and lymphatic system disorders/Thrombocytopenia	2019-05-20		Y	DRUG WITHDRAWN	RELATED	NOT RECOVERED/NO T RESOLVED
043-18101-740 01-004	Hypercalcemia/Metabolism and nutrition disorders/Hypercalcaemia	2019-12-19		Y		NOT RELATED	RECOVERING/R ESOLVING
	Pleural effusion/Respiratory, thoracic and mediastinal disorders/Pleural effusion	2019-10-29	2019-11-01	Y	DOSE NOT CHANGED	NOT RELATED	RECOVERED/RE SOLVED
043-18101-740 02-001	Colonic Obstruction/Gastrointestinal disorders/Large intestinal obstruction	2019-11-23	2019-11-27	Y	DRUG INTERRUPTED	NOT RELATED	RECOVERED/RE SOLVED
	Small Bowel Obstruction/Gastrointestinal disorders/Small intestinal obstruction	2020-01-01	2020-01-08	Y	DOSE NOT CHANGED	NOT RELATED	RECOVERED/RE SOLVED
043-18101-740 02-002	STROKE/Nervous system disorders/Cerebrovascular accident	2019-12-02	2019-12-06	Y	NOT APPLICABLE	NOT RELATED	RECOVERED/RE SOLVED
043-18101-740 03-001	Upper Gastrointestinal Bleed/Gastrointestinal disorders/Upper gastrointestinal haemorrhage	2019-09-29	2019-10-03	Y	NOT APPLICABLE	NOT RELATED	RECOVERED/RE SOLVED
043-18101-740 03-002	Small Bowel Obstruction/Gastrointestinal disorders/Small intestinal obstruction	2019-10-08	2019-10-20	Y	NOT APPLICABLE	NOT RELATED	RECOVERED/RE SOLVED
043-18101-740 03-003	Small Bowel Obstruction/Gastrointestinal disorders/Small intestinal obstruction	2019-10-16	2019-10-21	Y	NOT APPLICABLE	NOT RELATED	RECOVERED/RE SOLVED

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	Small Bowel Obstruction/Gastrointestinal disorders/Small intestinal obstruction	2019-10-23	2019-11-11	Y	NOT APPLICABLE	NOT RELATED	RECOVERED/RE SOLVED
043-18101-740 03-004	Paralysis of Left Vocal Fold/Nervous system disorders/Vocal cord paralysis	2020-01-28	2020-01-28	Y	NOT APPLICABLE	NOT RELATED	RECOVERED/RE SOLVED
043-18101-740 03-005	Atrial Fibrillation with rapid ventricular response/Cardiac disorders/Atrial fibrillation	2019-11-26	2019-12-02	Y	NOT APPLICABLE	NOT RELATED	RECOVERED/RE SOLVED
	Variceal Bleed/Gastrointestinal disorders/Oesophageal varices haemorrhage	2019-12-06	2019-12-13	Y	NOT APPLICABLE	NOT RELATED	RECOVERED/RE SOLVED
043-18101-740 03-006	Malignant obstructive jaundice/Hepatobiliary disorders/Jaundice cholestatic	2019-12-13	2019-12-15	Y	NOT APPLICABLE	NOT RELATED	RECOVERED/RE SOLVED
043-18101-740 04-002	Atrial Fibrillation/Cardiac disorders/Atrial fibrillation	2020-01-13	2020-01-21	Y	DRUG INTERRUPTED	RELATED	RECOVERED/RE SOLVED
043-18101-740 04-003	Hemoptysis/Respiratory, thoracic and mediastinal disorders/Haemoptysis	2020-02-13	2020-02-13	Y	DRUG INTERRUPTED	NOT RELATED	RECOVERED/RE SOLVED