

AIRIS PHARMA Private Limited.
Protocol: 043-1810

16.2.2.4 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 01-001	ALT Increase/Investigations/Alanine aminotransferase increased	2019-05-20		N	DOSE NOT CHANGED	RELATED	NOT RECOVERED/NO T RESOLVED
	AST Increase/Investigations/Aspartate aminotransferase increased	2019-05-20		N	DOSE NOT CHANGED	RELATED	NOT RECOVERED/NO T RESOLVED
	Blood Bilirubin Increase/Investigations/Blood bilirubin increased	2019-05-17		N	DOSE NOT CHANGED	RELATED	NOT RECOVERED/NO T RESOLVED
	Confusion/Psychiatric disorders/Confusional state	2019-05-17		N	DOSE NOT CHANGED	NOT RELATED	NOT RECOVERED/NO T RESOLVED
	Delirium/Psychiatric disorders/Delirium	2019-05-17		N	DOSE NOT CHANGED	NOT RELATED	NOT RECOVERED/NO T RESOLVED
	Diarrhea/Gastrointestinal disorders/Diarrhoea	2019-05-18		N	DOSE NOT CHANGED	RELATED	NOT RECOVERED/NO T RESOLVED
	Worsening Fatigue/General disorders and administration site conditions/Fatigue	2019-05-12		N	DRUG WITHDRAWN	RELATED	NOT RECOVERED/NO T RESOLVED
	Gastroesophageal reflux disease/Gastrointestinal disorders/Gastroesophageal reflux disease	2019-05-09		N	DOSE NOT CHANGED	RELATED	NOT RECOVERED/NO T RESOLVED
	Vomiting/Gastrointestinal disorders/Vomiting	2019-05-10		N	DOSE NOT CHANGED	RELATED	NOT RECOVERED/NO T RESOLVED
043-18101-740 01-002	Tumor pain/Neoplasms benign, malignant and unspecified (incl cysts and polyps)/Tumour pain	2019-06-24		N	NOT APPLICABLE	NOT RELATED	NOT RECOVERED/NO T RESOLVED

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043-18101-740 01-003	Worsening Abdominal pain/Gastrointestinal disorders/Abdominal pain	2019-05-20		N	DOSE NOT CHANGED	RELATED	NOT RECOVERED/NO T RESOLVED
	Anemia/Blood and lymphatic system disorders/Anaemia	2019-05-20	2019-05-22	Y	DRUG WITHDRAWN	RELATED	RECOVERED/RE SOLVED
	AST Increase/Investigations/Aspartate aminotransferase increased	2019-05-20		N	DOSE NOT CHANGED	RELATED	NOT RECOVERED/NO T RESOLVED
	Blood Bilirubin Increase/Investigations/Blood bilirubin increased	2019-05-13	2019-05-19	N	DOSE NOT CHANGED	NOT RELATED	RECOVERED/RE SOLVED WITH SEQUELAE
	Blood Bilirubin Increase/Investigations/Blood bilirubin increased	2019-05-20		N	DOSE NOT CHANGED	RELATED	NOT RECOVERED/NO T RESOLVED
	Worsening Fatigue/General disorders and administration site conditions/Fatigue	2019-05-16		N	DOSE NOT CHANGED	RELATED	NOT RECOVERED/NO T RESOLVED
	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	2019-05-16	2019-05-19	N	DOSE NOT CHANGED	RELATED	NOT RECOVERED/NO T RESOLVED
	Laryngeal Mucositis/Respiratory, thoracic and mediastinal disorders/Laryngeal inflammation	2019-05-20		Y	DOSE NOT CHANGED	RELATED	NOT RECOVERED/NO T RESOLVED
	Nausea/Gastrointestinal disorders/Nausea	2019-05-16		N	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

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043-18101-740 01-004	White blood cell decrease/Investigations/White blood cell count decreased	2019-05-20	2019-05-25	N	DOSE NOT CHANGED	RELATED	RECOVERED/RE SOLVED
	ALT Increase/Investigations/Alanine aminotransferase increased	2019-10-04	2019-10-11	N	DOSE NOT CHANGED	RELATED	RECOVERED/RE SOLVED
	ALT Increase/Investigations/Alanine aminotransferase increased	2019-10-24	2019-12-06	N	DOSE NOT CHANGED	RELATED	RECOVERED/RE SOLVED
	Alopecia/Skin and subcutaneous tissue disorders/Alopecia	2019-11-06		N	DOSE NOT CHANGED	NOT RELATED	NOT RECOVERED/NO T RESOLVED
	Worsening Anemia/Blood and lymphatic system disorders/Anaemia	2019-09-16	2019-09-20	N	DOSE NOT CHANGED	RELATED	RECOVERED/RE SOLVED
	Worsening Anemia/Blood and lymphatic system disorders/Anaemia	2019-10-30		N	DOSE NOT CHANGED	RELATED	NOT RECOVERED/NO T RESOLVED
	AST Increase/Investigations/Aspartate aminotransferase increased	2019-10-04	2019-10-11	N	DOSE NOT CHANGED	RELATED	RECOVERED/RE SOLVED
	AST Increase/Investigations/Aspartate aminotransferase increased	2019-10-24		N	DOSE NOT CHANGED	RELATED	NOT RECOVERED/NO T RESOLVED
	Alkaline phosphatase increase/Investigations/Blood alkaline phosphatase increased	2019-11-06	2019-12-15	N	DOSE NOT CHANGED	RELATED	RECOVERED/RE SOLVED WITH SEQUELAE
	Worsening alkaline phosphatase Increase/Investigations/Blood alkaline phosphatase increased	2019-12-16		N	DOSE NOT CHANGED	NOT RELATED	NOT RECOVERED/NO T RESOLVED
	Diarrhea/Gastrointestinal disorders/Diarrhoea	2019-09-13	2019-09-20	N	DOSE NOT CHANGED	RELATED	RECOVERED/RE SOLVED
	Diarrhea/Gastrointestinal disorders/Diarrhoea	2019-09-30		N	DOSE NOT CHANGED	RELATED	NOT RECOVERED/NO T RESOLVED

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	Dyspnea/Respiratory, thoracic and mediastinal disorders/Dyspnoea	2019-10-29		N	DOSE NOT CHANGED	NOT RELATED	NOT RECOVERED/NO T RESOLVED
	Fatigue/General disorders and administration site conditions/Fatigue	2019-09-14	2019-11-07	N	DOSE NOT CHANGED	NOT RELATED	RECOVERED/RE SOLVED
	Hypercalcemia/Metabolism and nutrition disorders/Hypercalcaemia	2019-10-18	2019-10-24	N	DOSE NOT CHANGED	NOT RELATED	RECOVERED/RE SOLVED
	Hypercalcemia/Metabolism and nutrition disorders/Hypercalcaemia	2019-12-19		Y		NOT RELATED	RECOVERING/R ESOLVING
	Hypoxia/Respiratory, thoracic and mediastinal disorders/Hypoxia	2019-10-29		N	DOSE NOT CHANGED	NOT RELATED	NOT RECOVERED/NO T RESOLVED
	Nausea/Gastrointestinal disorders/Nausea	2019-09-14		N	DOSE NOT CHANGED	RELATED	NOT RECOVERED/NO T RESOLVED
	Pleural effusion/Respiratory, thoracic and mediastinal disorders/Pleural effusion	2019-10-29	2019-11-01	Y	DOSE NOT CHANGED	NOT RELATED	RECOVERED/RE SOLVED
	Oral mucositis/Gastrointestinal disorders/Stomatitis	2019-09-14	2019-11-05	N	DOSE NOT CHANGED	RELATED	RECOVERED/RE SOLVED WITH SEQUELAE
	Worsening oral mucositis/Gastrointestinal disorders/Stomatitis	2019-11-06	2019-11-13	N	DOSE NOT CHANGED	RELATED	RECOVERED/RE SOLVED
	Weight loss/Investigations/Weight decreased	2019-09-18	2019-10-11	N	DOSE NOT CHANGED	RELATED	RECOVERED/RE SOLVED
043-18101-740 01-005	Abdominal pain/Gastrointestinal disorders/Abdominal pain	2019-12-22		N	DOSE NOT CHANGED	NOT RELATED	NOT RECOVERED/NO T RESOLVED
	Alopecia/Skin and subcutaneous tissue disorders/Alopecia	2020-01-09	2020-01-15	N	DOSE NOT CHANGED	NOT RELATED	RECOVERED/RE SOLVED WITH SEQUELAE

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	Worsening Alopecia/Skin and subcutaneous tissue disorders/Alopecia	2020-01-16		N	DOSE NOT CHANGED	NOT RELATED	NOT RECOVERED/NO T RESOLVED
	Bone pain/Musculoskeletal and connective tissue disorders/Bone pain	2020-01-05		N	DOSE NOT CHANGED	NOT RELATED	NOT RECOVERED/NO T RESOLVED
	Bronchial Infection/Infections and infestations/Bronchitis	2020-01-10	2020-01-16	N	DOSE NOT CHANGED	NOT RELATED	RECOVERED/RE SOLVED
	Bladder infection/Infections and infestations/Cystitis	2020-01-28	2020-01-30	N	DOSE NOT CHANGED	NOT RELATED	RECOVERED/RE SOLVED
	Dysesthesia/Nervous system disorders/Dysaesthesia	2020-01-09		N	DOSE NOT CHANGED	NOT RELATED	NOT RECOVERED/NO T RESOLVED
	Fatigue/General disorders and administration site conditions/Fatigue	2020-01-16	2020-01-28	N	DOSE NOT CHANGED	RELATED	RECOVERED/RE SOLVED
	Nausea/Gastrointestinal disorders/Nausea	2019-12-21		N	DOSE NOT CHANGED	RELATED	NOT RECOVERED/NO T RESOLVED
	Neutrophil count decreased/Investigations/Neutrophil count decreased	2020-01-09	2020-02-24	N	DOSE NOT CHANGED	RELATED	RECOVERED/RE SOLVED
	Fever/General disorders and administration site conditions/Pyrexia	2020-01-28	2020-01-29	N	DOSE NOT CHANGED	RELATED	RECOVERED/RE SOLVED
	Skin papiloma/Neoplasms benign, malignant and unspecified (incl cysts and polyps)/Skin papilloma	2020-01-27		N	DOSE NOT CHANGED	NOT RELATED	NOT RECOVERED/NO T RESOLVED
	Vertigo/Ear and labyrinth disorders/Vertigo	2020-02-01		N	DOSE NOT CHANGED	NOT RELATED	NOT RECOVERED/NO T RESOLVED
	White blood cell decreased/Investigations/White blood cell count decreased	2020-01-09		N	DOSE NOT CHANGED		NOT RECOVERED/NO T RESOLVED

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043-18101-740 02-001	Anemia/Blood and lymphatic system disorders/Anaemia	2019-11-14	2019-12-18	N	DOSE NOT CHANGED	NOT RELATED	RECOVERED/RE SOLVED
	Anemia/Blood and lymphatic system disorders/Anaemia	2019-12-19	2020-01-03	N	NOT APPLICABLE	NOT RELATED	RECOVERED/RE SOLVED
	Anemia/Blood and lymphatic system disorders/Anaemia	2020-01-04	2020-01-06	N	DOSE NOT CHANGED	NOT RELATED	RECOVERED/RE SOLVED
	Anemia/Blood and lymphatic system disorders/Anaemia	2020-01-07		N	DOSE NOT CHANGED	NOT RELATED	NOT RECOVERED/NO T RESOLVED
	Hypokalemia/Metabolism and nutrition disorders/Hypokalaemia	2019-12-04	2019-12-11	N	NOT APPLICABLE	RELATED	RECOVERED/RE SOLVED
	Hypokalemia/Metabolism and nutrition disorders/Hypokalaemia	2019-12-19		N	DOSE NOT CHANGED	NOT RELATED	NOT RECOVERED/NO T RESOLVED
	Colonic Obstruction/Gastrointestinal disorders/Large intestinal obstruction	2019-11-23	2019-11-27	Y	DRUG INTERRUPTED	NOT RELATED	RECOVERED/RE SOLVED
	Muscle Cramp - Hands/Musculoskeletal and connective tissue disorders/Muscle spasms	2019-11-10		N	DOSE NOT CHANGED	NOT RELATED	NOT RECOVERED/NO T RESOLVED
	Small Bowel Obstruction/Gastrointestinal disorders/Small intestinal obstruction	2020-01-01	2020-01-08	Y	DOSE NOT CHANGED	NOT RELATED	RECOVERED/RE SOLVED
	Vomiting/Gastrointestinal disorders/Vomiting	2019-11-11		N	DOSE NOT CHANGED	NOT RELATED	NOT RECOVERED/NO T RESOLVED
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
	STROKE/Nervous system disorders/Cerebrovascular accident	2019-12-07		N	NOT APPLICABLE	NOT RELATED	NOT RECOVERED/NO T RESOLVED
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

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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
	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	Right upper back pain/Musculoskeletal and connective tissue disorders/Back pain	2019-10-30		N	NOT APPLICABLE	NOT RELATED	NOT RECOVERED/NO T RESOLVED
	Right flank pain/Musculoskeletal and connective tissue disorders/Flank pain	2019-10-30		N	NOT APPLICABLE	NOT RELATED	NOT RECOVERED/NO T RESOLVED
	Tongue Soreness/Gastrointestinal disorders/Glossodynia	2019-11-24	2019-12-30	N	DOSE NOT CHANGED	NOT RELATED	RECOVERED/RE SOLVED
	Numbness to left toes/Nervous system disorders/Hypoaesthesia	2019-10-30		N	NOT APPLICABLE	NOT RELATED	NOT RECOVERED/NO T RESOLVED
	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

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043-18101-740 04-002	ALT Increased/Investigations/Alanine aminotransferase increased	2020-02-25		N	DRUG INTERRUPTED	RELATED	NOT RECOVERED/NO T RESOLVED
	Anxiety/Psychiatric disorders/Anxiety	2020-01-20		N	DOSE NOT CHANGED	NOT RELATED	NOT RECOVERED/NO T RESOLVED
	AST increased/Investigations/Aspartate aminotransferase increased	2020-02-25		N	DRUG INTERRUPTED	RELATED	NOT RECOVERED/NO T RESOLVED
	Atrial Fibrillation/Cardiac disorders/Atrial fibrillation	2020-01-13	2020-01-21	Y	DRUG INTERRUPTED	RELATED	RECOVERED/RE SOLVED
	Alkaline phosphatase increased/Investigations/Blood alkaline phosphatase increased	2020-02-25		N	DRUG INTERRUPTED	RELATED	NOT RECOVERED/NO T RESOLVED
	Bronchial Stricture/Respiratory, thoracic and mediastinal disorders/Bronchostenosis	2020-02-18		N	DOSE NOT CHANGED	NOT RELATED	NOT RECOVERED/NO T RESOLVED
	Constipation/Gastrointestinal disorders/Constipation	2020-01-10	2020-02-10	N	DOSE NOT CHANGED	NOT RELATED	RECOVERED/RE SOLVED
	intermittent Constipation/Gastrointestinal disorders/Constipation	2020-01-10		N	DOSE NOT CHANGED	NOT RELATED	NOT RECOVERED/NO T RESOLVED
	Diarrhea/Gastrointestinal disorders/Diarrhoea	2020-01-24	2020-01-24	N	DOSE NOT CHANGED	RELATED	RECOVERED/RE SOLVED
	Hypermagnesemia/Metabolism and nutrition disorders/Hypermagnesaemia	2020-01-13	2020-01-28	N	DOSE NOT CHANGED	RELATED	RECOVERED/RE SOLVED
	Hypocalcemia/Metabolism and nutrition disorders/Hypocalcaemia	2020-01-21	2020-01-28	N	DOSE NOT CHANGED	RELATED	RECOVERED/RE SOLVED
	Hypocalcemia/Metabolism and nutrition disorders/Hypocalcaemia	2020-02-18		N	DOSE NOT CHANGED	RELATED	NOT RECOVERED/NO T RESOLVED

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	Hyponatremia/Metabolism and nutrition disorders/Hyponatraemia	2020-02-10		N	DOSE NOT CHANGED	RELATED	NOT RECOVERED/NO T RESOLVED
	Hypophosphatemia/Metabolism and nutrition disorders/Hypophosphataemia	2020-01-13	2020-01-21	N	DOSE NOT CHANGED	RELATED	RECOVERED/RE SOLVED
	Hypophosphatemia/Metabolism and nutrition disorders/Hypophosphataemia	2020-01-21		N	DOSE NOT CHANGED	RELATED	NOT RECOVERED/NO T RESOLVED
	subclinical hypothyroidism/Endocrine disorders/Hypothyroidism	2020-01-13		N	DOSE NOT CHANGED	NOT RELATED	NOT RECOVERED/NO T RESOLVED
	Insomnia/Psychiatric disorders/Insomnia	2020-01-21		N	DOSE NOT CHANGED	NOT RELATED	NOT RECOVERED/NO T RESOLVED
	Leg Cramps/Musculoskeletal and connective tissue disorders/Muscle spasms	2020-02-06		N	DOSE NOT CHANGED	RELATED	NOT RECOVERED/NO T RESOLVED
	Muscle cramp-left calf/Musculoskeletal and connective tissue disorders/Muscle spasms	2020-02-06		N	DOSE NOT CHANGED	NOT RELATED	NOT RECOVERED/NO T RESOLVED
	intermittent Nausea/Gastrointestinal disorders/Nausea	2020-01-07		N	DOSE NOT CHANGED	RELATED	NOT RECOVERED/NO T RESOLVED
	nausea/Gastrointestinal disorders/Nausea	2020-01-30		N	DOSE NOT CHANGED	RELATED	NOT RECOVERED/NO T RESOLVED
	Edema limbs (bilateral ankles)/General disorders and administration site conditions/Oedema peripheral	2020-02-17		N	DOSE NOT CHANGED	RELATED	NOT RECOVERED/NO T RESOLVED
	Paresthesia/Nervous system disorders/Paraesthesia	2020-01-14	2020-01-25	N	DOSE NOT CHANGED	NOT RELATED	RECOVERED/RE SOLVED

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	Paresthesia-Tingling - right axilla and right hip/Nervous system disorders/Paraesthesia	2020-01-14	2020-01-25	N	DOSE NOT CHANGED	NOT RELATED	RECOVERED/RE SOLVED
	Platelet count decreased/Investigations/Platelet count decreased	2020-02-25		N	DRUG INTERRUPTED	RELATED	NOT RECOVERED/NO T RESOLVED
	Vomiting/Gastrointestinal disorders/Vomiting	2020-01-08	2020-01-08	N	DOSE NOT CHANGED	RELATED	RECOVERED/RE SOLVED
	White blood cell count decreased/Investigations/White blood cell count decreased	2020-02-25		N	DRUG INTERRUPTED	RELATED	NOT RECOVERED/NO T RESOLVED
043-18101-740 04-003	Constipation/Gastrointestinal disorders/Constipation	2020-02-10	2020-02-11	N	DOSE NOT CHANGED	RELATED	RECOVERED/RE SOLVED
	appetite loss/Metabolism and nutrition disorders/Decreased appetite	2020-01-29		N	DOSE NOT CHANGED	RELATED	NOT RECOVERED/NO T RESOLVED
	Diarrhea/Gastrointestinal disorders/Diarrhoea	2020-02-12		N	DOSE NOT CHANGED	RELATED	NOT RECOVERED/NO T RESOLVED
	belching after oric dose/Gastrointestinal disorders/Eructation	2020-01-28		N	DOSE NOT CHANGED	NOT RELATED	NOT RECOVERED/NO T RESOLVED
	fatigue/General disorders and administration site conditions/Fatigue	2020-02-06	2020-02-10	N	DOSE NOT CHANGED	RELATED	RECOVERED/RE SOLVED
	Hemoptysis/Respiratory, thoracic and mediastinal disorders/Haemoptysis	2020-02-13	2020-02-13	Y	DRUG INTERRUPTED	NOT RELATED	RECOVERED/RE SOLVED
	Subclinical hypothyroidism/Endocrine disorders/Hypothyroidism	2020-02-18		N	DOSE NOT CHANGED	NOT RELATED	NOT RECOVERED/NO T RESOLVED
	Nausea/Gastrointestinal disorders/Nausea	2020-02-04	2020-02-06	N	DOSE NOT CHANGED	RELATED	RECOVERED/RE SOLVED