

COVID-19 AA
Protocol: 043

16.2.2.4 Adverse Events

Subject Number	Adverse Event/Primary System			Serious Event	Relationship to			Outcome
	Organ Class/	Preferred term	Start Date/Time		Action taken	Study Drug		
AA-2020-06-104001	hypotension/Vascular disorders/Hypotension		2021-04-02	2021-04-02	N	Dose Not Changed	Possibly related	RECOVERED/RESO LVED
AA-2020-06-104004	acute bronchitis/Infections and infestations/Bronchitis		2021-05-10	2021-06-01	N	Dose Not Changed	Not related	RECOVERED/RESO LVED
AA-2020-06-104007	decreased hematocrit/Investigations/Haemoglobin	hematocrit decreased	2021-09-02T16:35		N	Not Applicable	Possibly related	NOT RECOVERED/NOT RESOLVED
	decreased hemoglobin/Investigations/Haemoglobin	hemoglobin decreased	2021-09-02T16:35		N	Not Applicable	Possibly related	NOT RECOVERED/NOT RESOLVED
	decreased red blood cells/Investigations/Red blood cell count decreased	red blood cells/Investigations/Red blood cell count decreased	2021-09-02T16:35		N	Not Applicable	Possibly related	NOT RECOVERED/NOT RESOLVED
AA-2020-06-105001	Left Upper Quadrant Abdominal Pain/Gastrointestinal disorders/Abdominal pain upper	Nose Bleed/Respiratory, thoracic and mediastinal disorders/Epistaxis	2021-03-14	2021-03-14	N	Dose Not Changed	Unlikely related	RECOVERED/RESO LVED
			2021-03-15	2021-03-15	N	Dose Not Changed	Unlikely related	RECOVERED/RESO LVED

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AA-2020-06-105001	Bradyarrhythmia/Cardiac disorders/Bradyarrhythmia	2021-03-16T18:00	2021-03-16T19:30		N	Dose Not Changed	Unlikely related	RECOVERED/RESO LVED
	COVID-19 Pneumonia/Infections and infestations/COVID-19 pneumonia	2021-03-16	2021-03-25		Y	Drug Withdrawn	Unlikely related	RECOVERED/RESO LVED
	Syncope/Nervous system disorders/Syncope	2021-03-16T18:00	2021-03-16T19:30		N	Dose Not Changed	Unlikely related	RECOVERED/RESO LVED
	Acute Hypertension of unknown etiology/Vascular disorders/Hypertension	2021-08-12	2021-08-17		N	Not Applicable	Unlikely related	RECOVERED/RESO LVED
AA-2020-06-105009	Hypokalemia/Metabolism and nutrition disorders/Hypokalaemia	2021-08-12	2021-08-17		N	Not Applicable	Unlikely related	RECOVERED/RESO LVED
	diarrhea/Gastrointestinal disorders/Diarrhoea	2021-08-02	2021-08-17		N	Drug Withdrawn	Possibly related	RECOVERED/RESO LVED
	vomiting	2021-08-04	2021-08-17		N	Not Applicable	Possibly related	RECOVERED/RESO LVED

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AA-2020-06-105009	COVID-19 pneumonia/Infections and infestations/COVID-19 pneumonia	2021-08-12T10:21	2021-08-17	Y	Drug Withdrawn	Unlikely related	RECOVERED/RESO LVED	
	Shortness of Breath/Respiratory, thoracic and mediastinal disorders/Dyspnoea	2021-08-12	2021-08-17	N	Not Applicable	Unlikely related	RECOVERED/RESO LVED	
	Transaminitis/Investigations /Transaminases increased	2021-08-12	2021-08-17	N	Not Applicable	Unlikely related	RECOVERED/RESO LVED	
AA-2020-06-105011	diarrhea/Gastrointestinal disorders/Diarrhoea	2021-09-03	2021-09-05	N	Dose Not Changed	Possibly related	RECOVERED/RESO LVED	
	vomiting/Gastrointestinal disorders/Vomiting	2021-09-03	2021-09-05	N	Dose Not Changed	Possibly related	RECOVERED/RESO LVED	
AA-2020-06-105012	panic attacks/Psychiatric disorders/Panic attack	2021-09-02	2021-09-15	N	Dose Not Changed	Not related	RECOVERED/RESO LVED	
AA-2020-06-105014	sinus congestion/Respiratory, thoracic and mediastinal disorders/Sinus congestion	2021-09-13	2021-09-22	N	Dose Not Changed	Not related	RECOVERED/RESO LVED	

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AA-2020-06-109001	Elevated ALT blood level/Investigations/Alanine aminotransferase increased		2021-04-26	2021-06-04	N	Not Applicable	Unlikely related	RECOVERED/RESOLVED
AA-2020-06-117025	COVID-19 Pneumonia/Infections and infestations/COVID-19 pneumonia	COVID-19 Pneumonia/Infections	2021-08-25	2021-09-02	Y	Drug Withdrawn	Not related	RECOVERED/RESOLVED
	Trasaminitis		2021-08-25	2021-09-02	N	Drug Withdrawn	Not related	RECOVERED/RESOLVED
AA-2020-06-119014	Generalized Rash/Skin and subcutaneous tissue disorders/Rash	Generalized Rash/Skin and subcutaneous tissue disorders/Rash	2021-08-23	2021-08-23	N	Dose Not Changed	Possibly related	RECOVERED/RESOLVED
AA-2020-06-119021	Dizziness/Nervous system disorders/Dizziness	Dizziness/Nervous system disorders/Dizziness	2021-08-20	2021-08-20	N	Dose Not Changed	Not related	RECOVERED/RESOLVED