

AIRIS PHARMA Private Limited.

Protocol: 043-1810

Table 14.1.18 Shift Table from Baseline to End of period (Safety Population)

Parameter category	Parameter (Unit)	Baseline	Treatment end (N=11)		
			Low	Normal	High
CHEMISTRY	Urea Nitrogen (mmol/L)	LOW	1 ( 9.1)	0	0
		NORMAL	0	9 (81.8)	1 ( 9.1)
	Creatinine (umol/L)	LOW	1 ( 9.1)	0	0
		NORMAL	1 ( 9.1)	9 (81.8)	0
	Urate (umol/L)	HIGH	0	0	1 ( 9.1)
		NORMAL	1 ( 9.1)	9 (81.8)	0
	Glucose (mmol/L)	HIGH	0	1 ( 9.1)	1 ( 9.1)
		NORMAL	0	7 (63.6)	2 (18.2)
	Potassium (mmol/L)	NORMAL	1 ( 9.1)	10 (90.9)	0
	Chloride (mmol/L)	HIGH	0	1 ( 9.1)	0
		LOW	0	1 ( 9.1)	0
		NORMAL	1 ( 9.1)	8 (72.7)	0
	Bicarbonate (mmol/L)	NORMAL	0	10 (90.9)	1 ( 9.1)
	Albumin (g/L)	LOW	2 (18.2)	1 ( 9.1)	0
		NORMAL	2 (18.2)	6 (54.5)	0
	Sodium (mmol/L)	HIGH	0	1 ( 9.1)	0
		NORMAL	2 (18.2)	8 (72.7)	0

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			Low	Normal	High
CHEMISTRY	Magnesium (mmol/L)	LOW	0	1 ( 9.1)	0
		NORMAL	3 (27.3)	7 (63.6)	0
	Phosphate (mmol/L)	LOW	1 ( 9.1)	0	0
		NORMAL	1 ( 9.1)	9 (81.8)	0
	Calcium (mmol/L)	NORMAL	3 (27.3)	7 (63.6)	1 ( 9.1)
	Bilirubin (umol/L)	HIGH	0	0	2 (18.2)
		LOW	0	1 ( 9.1)	0
		NORMAL	0	8 (72.7)	0
	Direct Bilirubin (umol/L)	LOW	0	1 ( 9.1)	0
		NORMAL	0	4 (36.4)	1 ( 9.1)
	Aspartate Aminotransferase (U/L)	HIGH	0	1 ( 9.1)	2 (18.2)
		NORMAL	0	5 (45.5)	3 (27.3)
	Alanine Aminotransferase (U/L)	HIGH	0	0	1 ( 9.1)
		LOW	0	1 ( 9.1)	0
		NORMAL	0	6 (54.5)	3 (27.3)
	Alkaline Phosphatase (U/L)	HIGH	0	1 ( 9.1)	5 (45.5)
		NORMAL	0	2 (18.2)	3 (27.3)

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			Low	Normal	High
CHEMISTRY	Protein (g/L)	HIGH	0	0	1 ( 9.1)
		LOW	2 (18.2)	0	0
		NORMAL	1 ( 9.1)	7 (63.6)	0
HEMATOLOGY	Lactate Dehydrogenase (U/L)	HIGH	0	1 ( 9.1)	5 (45.5)
		NORMAL	0	4 (36.4)	1 ( 9.1)
	Follicle Stimulating Hormone (IU/L)	NORMAL	0	1 ( 9.1)	0
	Platelets (10/L)	HIGH	0	0	1 ( 9.1)
		NORMAL	2 (18.2)	7 (63.6)	1 ( 9.1)
	Hemoglobin (g/L)	LOW	10 (90.9)	0	0
		NORMAL	0	1 ( 9.1)	0
	Hematocrit (L/L)	LOW	6 (54.5)	1 ( 9.1)	0
		NORMAL	3 (27.3)	1 ( 9.1)	0
	Ery. Mean Corpuscular Volume (fL)	HIGH	0	2 (18.2)	2 (18.2)
		NORMAL	0	7 (63.6)	0
	Ery. Mean Corpuscular Hemoglobin (pg)	HIGH	0	1 ( 9.1)	1 ( 9.1)
		NORMAL	1 ( 9.1)	7 (63.6)	1 ( 9.1)
	Leukocytes (10/L)	HIGH	1 ( 9.1)	1 ( 9.1)	0

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HEMATOLOGY	Leukocytes (10/L)	LOW	2 (18.2)	0	0
		NORMAL	2 (18.2)	4 (36.4)	1 ( 9.1)
	Neutrophils (10/L)	HIGH	0	2 (18.2)	0
		NORMAL	2 (18.2)	5 (45.5)	2 (18.2)
	Lymphocytes (10/L)	LOW	4 (36.4)	0	1 ( 9.1)
		NORMAL	2 (18.2)	4 (36.4)	0
	Monocytes (10/L)	HIGH	1 ( 9.1)	1 ( 9.1)	0
		NORMAL	1 ( 9.1)	6 (54.5)	2 (18.2)
	Eosinophils (10/L)	NORMAL	0	10 (90.9)	1 ( 9.1)
	Basophils (10/L)	NORMAL	0	11 (100)	0