

Listing of Subjects With Serious Adverse Events ASaT

Trial Number: CDISCPILOT01, Site Number: 701

Subject ID	Rel Day of Onset	Adverse Event	Duration	Intensity	Serious	Related	Action Taken	Outcome
Placebo								
Subject ID = 01-701-1363, Gender = F, Race = BLACK OR AFRICAN AMERICAN, AGE = 81 Years, TRT = Placebo								
01-701-1363	16	NAUSEA	2 DAY	MILD	N	REMOTE		RECOVERED/RESOLVED
	48	APPLICATION SITE PRURITUS	NA	MILD	N	PROBABLE		NOT RECOVERED/NOT RESOLVED
	137	BACK PAIN	3 DAY	MILD	N	NONE		NOT RECOVERED/NOT RESOLVED
		BACK PAIN	3 DAY	MILD	N	NONE		RECOVERED/RESOLVED
		HEADACHE	NA	MODERATE	N	POSSIBLE		NOT RECOVERED/NOT RESOLVED
		HEADACHE	NA	MILD	N	POSSIBLE		NOT RECOVERED/NOT RESOLVED
Subject ID = 01-701-1387, Gender = F, Race = WHITE, AGE = 87 Years, TRT = Placebo								
01-701-1387	7	DIARRHOEA	1 DAY	MILD	N	REMOTE		RECOVERED/RESOLVED
		HYPERHIDROSIS	1 DAY	MILD	N	REMOTE		RECOVERED/RESOLVED

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Subject ID	Rel Day of Onset	Adverse Event	Duration	Intensity	Serious	Related	Action Taken	Outcome
Placebo								
Subject ID = 01-701-1392, Gender = M, Race = WHITE, AGE = 78 Years, TRT = Placebo								
01-701-1392	140	UPPER RESPIRATORY TRACT INFECTION	6 DAY	MILD	N	REMOTE		NOT RECOVERED/NOT RESOLVED
		UPPER RESPIRATORY TRACT INFECTION	6 DAY	MILD	N	REMOTE		RECOVERED/RESOLVED
Subject ID = 01-701-1415, Gender = M, Race = WHITE, AGE = 85 Years, TRT = Placebo								
01-701-1415	29	UPPER RESPIRATORY TRACT INFECTION	15 DAY	MILD	N	NONE		NOT RECOVERED/NOT RESOLVED
		UPPER RESPIRATORY TRACT INFECTION	15 DAY	MILD	N	NONE		RECOVERED/RESOLVED
	71	MICTURITION URGENCY	NA	MILD	N	NONE		NOT RECOVERED/NOT RESOLVED
	121	UPPER RESPIRATORY TRACT INFECTION	21 DAY	MILD	N	REMOTE		NOT RECOVERED/NOT RESOLVED

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Placebo								
Subject ID = 01-701-1415, Gender = M, Race = WHITE, AGE = 85 Years, TRT = Placebo								
01-701-1415	121	UPPER RESPIRATORY TRACT INFECTION	21 DAY	MILD	N	REMOTE		RECOVERED/RESOLVED
	168	DIARRHOEA	1 DAY	MILD	N	NONE		RECOVERED/RESOLVED
Xanomeline High Dose								
Subject ID = 01-701-1360, Gender = M, Race = WHITE, AGE = 67 Years, TRT = Xanomeline High Dose								
01-701-1360	3	APPLICATION SITE PRURITUS	NA	MODERATE	N	PROBABLE		NOT RECOVERED/NOT RESOLVED
	6	APPLICATION SITE VESICLES	NA	MODERATE	N	PROBABLE		NOT RECOVERED/NOT RESOLVED
Subject ID = 01-701-1383, Gender = F, Race = WHITE, AGE = 72 Years, TRT = Xanomeline High Dose								
01-701-1383	4	APPLICATION SITE PRURITUS	1 DAY	MILD	N	PROBABLE		RECOVERED/RESOLVED
		APPLICATION SITE PAIN	1 DAY	MILD	N	PROBABLE		RECOVERED/RESOLVED
	48	APPLICATION SITE ERYTHEMA	4 DAY	MILD	N	POSSIBLE		RECOVERED/RESOLVED
		APPLICATION SITE PRURITUS	NA	MILD	N	POSSIBLE		NOT RECOVERED/NOT RESOLVED

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Subject ID	Rel Day of Onset	Adverse Event	Duration	Intensity	Serious	Related	Action Taken	Outcome
Xanomeline High Dose								
Subject ID = 01-701-1383, Gender = F, Race = WHITE, AGE = 72 Years, TRT = Xanomeline High Dose								
01-701-1383	48	APPLICATION SITE PRURITUS	NA	MODERATE	N	POSSIBLE		NOT RECOVERED/NOT RESOLVED
	68	APPLICATION SITE ERYTHEMA	NA	MILD	N	POSSIBLE		NOT RECOVERED/NOT RESOLVED
		APPLICATION SITE IRRITATION	NA	MILD	N	POSSIBLE		NOT RECOVERED/NOT RESOLVED
		APPLICATION SITE IRRITATION	NA	MODERATE	N	POSSIBLE		NOT RECOVERED/NOT RESOLVED
	93	APPLICATION SITE VESICLES	18 DAY	MILD	N	POSSIBLE		RECOVERED/RESOLVED
	141	CHEST DISCOMFORT	1 DAY	MILD	N	NONE		RECOVERED/RESOLVED
		HEADACHE	1 DAY	MILD	N	NONE		RECOVERED/RESOLVED
	164	COUGH	10 DAY	MODERATE	N	NONE		RECOVERED/RESOLVED
Subject ID = 01-701-1444, Gender = M, Race = WHITE, AGE = 63 Years, TRT = Xanomeline High Dose								
01-701-1444	15	APPLICATION SITE ERYTHEMA	NA	MILD	N	POSSIBLE		NOT RECOVERED/NOT RESOLVED

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Subject ID	Rel Day of Onset	Adverse Event	Duration	Intensity	Serious	Related	Action Taken	Outcome
Xanomeline High Dose								
Subject ID = 01-701-1444, Gender = M, Race = WHITE, AGE = 63 Years, TRT = Xanomeline High Dose								
01-701-1444	15	APPLICATION SITE PRURITUS	NA	MILD	N	PROBABLE		NOT RECOVERED/NOT RESOLVED
		SALIVARY HYPERSECRETION	NA	MILD	N	POSSIBLE		NOT RECOVERED/NOT RESOLVED
		APPLICATION SITE ERYTHEMA	NA	MODERATE	N	POSSIBLE		NOT RECOVERED/NOT RESOLVED
		APPLICATION SITE PRURITUS	NA	MODERATE	N	PROBABLE		NOT RECOVERED/NOT RESOLVED
	31	APPLICATION SITE IRRITATION	NA	MODERATE	N	PROBABLE		NOT RECOVERED/NOT RESOLVED
		APPLICATION SITE VESICLES	NA	MODERATE	N	PROBABLE		NOT RECOVERED/NOT RESOLVED
	35	PARAESTHESIA	1 DAY	MILD	N	NONE		RECOVERED/RESOLVED
Xanomeline Low Dose								
Subject ID = 01-701-1442, Gender = F, Race = BLACK OR AFRICAN AMERICAN, AGE = 57 Years, TRT = Xanomeline Low Dose								
01-701-1442	77	APPLICATION SITE PRURITUS	NA	MILD	N	PROBABLE		NOT RECOVERED/NOT RESOLVED

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Trial Number: CDISCPILOT01, Site Number: 702

Subject ID	Rel Day of Onset	Adverse Event	Duration	Intensity	Serious	Related	Action Taken	Outcome
Xanomeline Low Dose								
Subject ID = 01-702-1082, Gender = F, Race = WHITE, AGE = 84 Years, TRT = Xanomeline Low Dose								
01-702-1082	-19	WHITE BLOOD CELL COUNT INCREASED	20 DAY	MILD	N	NONE		NOT RECOVERED/NOT RESOLVED
		NEUTROPHIL COUNT INCREASED	20 DAY	MILD	N	NONE		NOT RECOVERED/NOT RESOLVED
		URINE ANALYSIS ABNORMAL	18 DAY	MILD	N	NONE		NOT RECOVERED/NOT RESOLVED
		URINE ANALYSIS ABNORMAL	18 DAY	MILD	N	NONE		RECOVERED/RESOLVED
		WHITE BLOOD CELL COUNT INCREASED	20 DAY	MILD	N	NONE		RECOVERED/RESOLVED
		NEUTROPHIL COUNT INCREASED	20 DAY	MILD	N	NONE		RECOVERED/RESOLVED

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Trial Number: CDISCPILOT01, Site Number: 702

Subject ID	Rel Day of Onset	Adverse Event	Duration	Intensity	Serious	Related	Action Taken	Outcome
Xanomeline Low Dose								
Subject ID = 01-702-1082, Gender = F, Race = WHITE, AGE = 84 Years, TRT = Xanomeline Low Dose								
01-702-1082	39	RECTAL HAEMORRHAGE	5 DAY	MILD	N	NONE		NOT RECOVERED/NOT RESOLVED
		RECTAL HAEMORRHAGE	5 DAY	MILD	N	NONE		RECOVERED/RESOLVED
	46	APPLICATION SITE IRRITATION	16 DAY	MILD	N	PROBABLE		RECOVERED/RESOLVED
	79	SKIN IRRITATION	20 DAY	MODERATE	N	PROBABLE		RECOVERED/RESOLVED

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Trial Number: CDISCPLOT01, Site Number: 703

Subject ID	Rel Day of Onset	Adverse Event	Duration	Intensity	Serious	Related	Action Taken	Outcome
Placebo								
Subject ID = 01-703-1042, Gender = M, Race = WHITE, AGE = 64 Years, TRT = Placebo								
01-703-1042	3	DIARRHOEA	2 DAY	MILD	N	POSSIBLE		RECOVERED/RESOLVED
	4	INSOMNIA	2 DAY	MILD	N	REMOTE		RECOVERED/RESOLVED
Xanomeline High Dose								
Subject ID = 01-703-1076, Gender = M, Race = WHITE, AGE = 69 Years, TRT = Xanomeline High Dose								
01-703-1076	23	BIOPSY PROSTATE	1 DAY	MODERATE	N	NONE		RECOVERED/RESOLVED
	27	BENIGN PROSTATIC HYPERPLASIA	NA	MODERATE	N	NONE		NOT RECOVERED/NOT RESOLVED
	30	APPLICATION SITE PRURITUS	NA	MILD	N	PROBABLE		NOT RECOVERED/NOT RESOLVED
		APPLICATION SITE DERMATITIS	NA	MILD	N	PROBABLE		NOT RECOVERED/NOT RESOLVED
		APPLICATION SITE PRURITUS	NA	MODERATE	N	PROBABLE		NOT RECOVERED/NOT RESOLVED

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Trial Number: CDISCPLOT01, Site Number: 703

Subject ID	Rel Day of Onset	Adverse Event	Duration	Intensity	Serious	Related	Action Taken	Outcome
Xanomeline High Dose								
Subject ID = 01-703-1076, Gender = M, Race = WHITE, AGE = 69 Years, TRT = Xanomeline High Dose								
01-703-1076	32	HYPERHIDROSIS	NA	MILD	N	POSSIBLE		NOT RECOVERED/NOT RESOLVED
		HYPERCHOLESTERO LAEMIA	NA	MODERATE	N	NONE		NOT RECOVERED/NOT RESOLVED
Xanomeline Low Dose								
Subject ID = 01-703-1086, Gender = M, Race = WHITE, AGE = 71 Years, TRT = Xanomeline Low Dose								
01-703-1086	12	APPLICATION SITE IRRITATION	112 DAY	MILD	N	PROBABLE		NOT RECOVERED/NOT RESOLVED
		APPLICATION SITE IRRITATION	112 DAY	MODERATE	N	PROBABLE		NOT RECOVERED/NOT RESOLVED
		APPLICATION SITE IRRITATION	112 DAY	SEVERE	N	PROBABLE		NOT RECOVERED/NOT RESOLVED
This is footnote 1 This is footnote 2								

Source: [Study MK9999P001: adam-adae]

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