

Table 12: Summary of Treatment Emergent Adverse Events

Body System or Organ Class	Dictionary-Derived Term	Placebo	Xanomeline		Total
		(N=86) n (%)	Low Dose (N=96) n (%)	High Dose (N=72) n (%)	(N=254) n (%)
ANY EVENT	ANY EVENT	69 (80%)	86 (90%)	70 (97%)	225 (89%)
CARDIAC DISORDERS	ANY EVENT	13 (15%)	16 (17%)	15 (21%)	44 (17%)
	ATRIAL FIBRILLATION	1 (1%)	2 (2%)	2 (3%)	5 (2%)
	ATRIAL FLUTTER	0 (0%)	1 (1%)	1 (1%)	2 (1%)
	ATRIAL HYPERTROPHY	1 (1%)	0 (0%)	0 (0%)	1 (0%)
	ATRIOVENTRICULAR BLOCK FIRST DEGREE	1 (1%)	1 (1%)	0 (0%)	2 (1%)
	ATRIOVENTRICULAR BLOCK SECOND DEGREE	2 (2%)	2 (2%)	1 (1%)	5 (2%)
	BRADYCARDIA	1 (1%)	0 (0%)	0 (0%)	1 (0%)
	BUNDLE BRANCH BLOCK LEFT	1 (1%)	0 (0%)	0 (0%)	1 (0%)
	BUNDLE BRANCH BLOCK RIGHT	1 (1%)	1 (1%)	0 (0%)	2 (1%)
	CARDIAC DISORDER	0 (0%)	0 (0%)	1 (1%)	1 (0%)
	CARDIAC FAILURE CONGESTIVE	1 (1%)	0 (0%)	0 (0%)	1 (0%)
	MYOCARDIAL INFARCTION	4 (5%)	2 (2%)	4 (6%)	10 (4%)
	PALPITATIONS	0 (0%)	2 (2%)	0 (0%)	2 (1%)
	SINUS ARRHYTHMIA	1 (1%)	0 (0%)	0 (0%)	1 (0%)
	SINUS BRADYCARDIA	2 (2%)	7 (7%)	8 (11%)	17 (7%)

- 1.) Only treatment emergent events related to lipids are displayed.
- 2.) Subjects are only counted once within each body system and preferred term.

Table 12: Summary of Treatment Emergent Adverse Events

Body System or Organ Class	Dictionary-Derived Term	Placebo	Xanomeline		Xanomeline		Total
		(N=86) n (%)	Low Dose (N=96) n (%)	High Dose (N=72) n (%)	Total (N=254) n (%)		
CARDIAC DISORDERS	SUPRAVENTRICULAR EXTRASYSTOLES	1 (1%)	1 (1%)	1 (1%)	3 (1%)		
	SUPRAVENTRICULAR TACHYCARDIA	0 (0%)	1 (1%)	0 (0%)	1 (0%)		
	TACHYCARDIA	1 (1%)	0 (0%)	0 (0%)	1 (0%)		
	VENTRICULAR EXTRASYSTOLES	0 (0%)	2 (2%)	1 (1%)	3 (1%)		
	VENTRICULAR HYPERTROPHY	1 (1%)	0 (0%)	0 (0%)	1 (0%)		
	WOLFF-PARKINSON-WHITE SYNDROME	0 (0%)	1 (1%)	0 (0%)	1 (0%)		
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	ANY EVENT	0 (0%)	1 (1%)	2 (3%)	3 (1%)		
	VENTRICULAR SEPTAL DEFECT	0 (0%)	1 (1%)	2 (3%)	3 (1%)		
EAR AND LABYRINTH DISORDERS	ANY EVENT	1 (1%)	2 (2%)	1 (1%)	4 (2%)		
	CERUMEN IMPACTION	0 (0%)	1 (1%)	0 (0%)	1 (0%)		
	EAR PAIN	1 (1%)	0 (0%)	0 (0%)	1 (0%)		
	TINNITUS	0 (0%)	1 (1%)	0 (0%)	1 (0%)		
	VERTIGO	0 (0%)	1 (1%)	1 (1%)	2 (1%)		

- 1.) Only treatment emergent events related to lipids are displayed.
2.) Subjects are only counted once within each body system and preferred term.

Table 12: Summary of Treatment Emergent Adverse Events

Body System or Organ Class	Dictionary-Derived Term	Placebo	Xanomeline		Xanomeline		Total
		(N=86) n (%)	Low Dose	(N=96) n (%)	High Dose	(N=72) n (%)	(N=254) n (%)
EYE DISORDERS	ANY EVENT	4 (5%)	2 (2%)	1 (1%)	7 (3%)		
	CONJUNCTIVAL HAEMORRHAGE	0 (0%)	1 (1%)	0 (0%)	1 (0%)		
	CONJUNCTIVITIS	2 (2%)	0 (0%)	0 (0%)	2 (1%)		
	EYE ALLERGY	1 (1%)	0 (0%)	0 (0%)	1 (0%)		
	EYE PRURITUS	1 (1%)	0 (0%)	0 (0%)	1 (0%)		
	EYE SWELLING	1 (1%)	0 (0%)	0 (0%)	1 (0%)		
	GLAUCOMA	1 (1%)	0 (0%)	0 (0%)	1 (0%)		
	VISION BLURRED	0 (0%)	1 (1%)	1 (1%)	2 (1%)		
GASTROINTESTINAL DISORDERS	ANY EVENT	17 (20%)	16 (17%)	20 (28%)	53 (21%)		
	ABDOMINAL DISCOMFORT	0 (0%)	0 (0%)	1 (1%)	1 (0%)		
	ABDOMINAL PAIN	1 (1%)	3 (3%)	1 (1%)	5 (2%)		
	CONSTIPATION	1 (1%)	0 (0%)	0 (0%)	1 (0%)		
	DIARRHOEA	9 (10%)	6 (6%)	3 (4%)	18 (7%)		
	DYSPEPSIA	1 (1%)	1 (1%)	1 (1%)	3 (1%)		
	DYSPHAGIA	0 (0%)	1 (1%)	0 (0%)	1 (0%)		
	FLATULENCE	1 (1%)	0 (0%)	0 (0%)	1 (0%)		
	GASTROINTESTINAL HAEMORRHAGE	0 (0%)	0 (0%)	1 (1%)	1 (0%)		
	GASTROESOPHAGEAL REFLUX DISEASE	1 (1%)	0 (0%)	0 (0%)	1 (0%)		
	GLOSSITIS	1 (1%)	0 (0%)	0 (0%)	1 (0%)		

- 1.) Only treatment emergent events related to lipids are displayed.
2.) Subjects are only counted once within each body system and preferred term.

Table 12: Summary of Treatment Emergent Adverse Events

Body System or Organ Class	Dictionary-Derived Term	Placebo	Xanomeline		Xanomeline		Total
		(N=86)	Low Dose	(N=96)	High Dose	(N=72)	(N=254)
		n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
GASTROINTESTINAL DISORDERS	HIATUS HERNIA	1 (1%)	0 (0%)	0 (0%)	0 (0%)	1 (0%)	1 (0%)
	NAUSEA	3 (3%)	3 (3%)	6 (8%)	12 (5%)	12 (5%)	12 (5%)
	RECTAL HAEMORRHAGE	0 (0%)	1 (1%)	0 (0%)	1 (0%)	1 (0%)	1 (0%)
	SALIVARY HYPERSECRETION	0 (0%)	0 (0%)	4 (6%)	4 (2%)	4 (2%)	4 (2%)
	STOMACH DISCOMFORT	0 (0%)	0 (0%)	1 (1%)	1 (0%)	1 (0%)	1 (0%)
	VOMITING	3 (3%)	4 (4%)	6 (8%)	13 (5%)	13 (5%)	13 (5%)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ANY EVENT	21 (24%)	51 (53%)	36 (50%)	108 (43%)	108 (43%)	108 (43%)
	APPLICATION SITE BLEEDING	0 (0%)	1 (1%)	0 (0%)	1 (0%)	1 (0%)	1 (0%)
	APPLICATION SITE DERMATITIS	5 (6%)	9 (9%)	7 (10%)	21 (8%)	21 (8%)	21 (8%)
	APPLICATION SITE DESQUAMATION	0 (0%)	1 (1%)	0 (0%)	1 (0%)	1 (0%)	1 (0%)
	APPLICATION SITE DISCHARGE	0 (0%)	0 (0%)	1 (1%)	1 (0%)	1 (0%)	1 (0%)
	APPLICATION SITE DISCOLOURATION	0 (0%)	1 (1%)	0 (0%)	1 (0%)	1 (0%)	1 (0%)
	APPLICATION SITE ERYTHEMA	3 (3%)	13 (14%)	14 (19%)	30 (12%)	30 (12%)	30 (12%)

- 1.) Only treatment emergent events related to lipids are displayed.
- 2.) Subjects are only counted once within each body system and preferred term.

Table 12: Summary of Treatment Emergent Adverse Events

Body System or Organ Class	Dictionary-Derived Term	Placebo	Xanomeline		Xanomeline		Total
		(N=86)	Low Dose	(N=96)	High Dose	(N=72)	(N=254)
		n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	APPLICATION SITE	1 (1%)	0 (0%)	0 (0%)	0 (0%)	1 (0%)	1 (0%)
	INDURATION						
	APPLICATION SITE	3 (3%)	9 (9%)	9 (12%)	21 (8%)		
	IRRITATION						
	APPLICATION SITE PAIN	0 (0%)	0 (0%)	2 (3%)	2 (1%)		
	APPLICATION SITE	0 (0%)	0 (0%)	2 (3%)	2 (1%)		
	PERSPIRATION						
	APPLICATION SITE	6 (7%)	23 (24%)	21 (29%)	50 (20%)		
	PRURITUS						
	APPLICATION SITE	1 (1%)	0 (0%)	1 (1%)	2 (1%)		
	REACTION						
	APPLICATION SITE	0 (0%)	1 (1%)	2 (3%)	3 (1%)		
	SWELLING						
	APPLICATION SITE	0 (0%)	2 (2%)	1 (1%)	3 (1%)		
	URTICARIA						
	APPLICATION SITE	1 (1%)	5 (5%)	5 (7%)	11 (4%)		
	VESICLES						
	APPLICATION SITE WARMTH	0 (0%)	1 (1%)	0 (0%)	1 (0%)		
	ASTHENIA	1 (1%)	1 (1%)	0 (0%)	2 (1%)		

- 1.) Only treatment emergent events related to lipids are displayed.
- 2.) Subjects are only counted once within each body system and preferred term.

Table 12: Summary of Treatment Emergent Adverse Events

Body System or Organ Class	Dictionary-Derived Term	Placebo	Xanomeline		Xanomeline		Total
		(N=86)	Low Dose		High Dose		(N=254)
		n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST DISCOMFORT	0 (0%)	1 (1%)	1 (1%)	1 (1%)	2 (1%)	2 (1%)
	CHEST PAIN	0 (0%)	0 (0%)	2 (3%)	2 (3%)	2 (1%)	2 (1%)
	CHILLS	1 (1%)	1 (1%)	1 (1%)	1 (1%)	3 (1%)	3 (1%)
	CYST	0 (0%)	1 (1%)	0 (0%)	0 (0%)	1 (0%)	1 (0%)
	FATIGUE	1 (1%)	5 (5%)	5 (7%)	5 (7%)	11 (4%)	11 (4%)
	FEELING ABNORMAL	0 (0%)	0 (0%)	1 (1%)	1 (1%)	1 (0%)	1 (0%)
	FEELING COLD	0 (0%)	0 (0%)	1 (1%)	1 (1%)	1 (0%)	1 (0%)
	INFLAMMATION	0 (0%)	1 (1%)	0 (0%)	0 (0%)	1 (0%)	1 (0%)
	MALAISE	0 (0%)	1 (1%)	2 (3%)	2 (3%)	3 (1%)	3 (1%)
	OEDEMA	0 (0%)	2 (2%)	0 (0%)	0 (0%)	2 (1%)	2 (1%)
	OEDEMA PERIPHERAL	2 (2%)	1 (1%)	2 (3%)	2 (3%)	5 (2%)	5 (2%)

- 1.) Only treatment emergent events related to lipids are displayed.
2.) Subjects are only counted once within each body system and preferred term.

Table 12: Summary of Treatment Emergent Adverse Events

Body System or Organ Class	Dictionary-Derived Term	Placebo	Xanomeline		Xanomeline		Total	
		(N=86) n (%)	Low Dose (N=96) n (%)	High Dose (N=72) n (%)	Total (N=254) n (%)			
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PAIN	0 (0%)	1 (1%)	1 (1%)	1 (1%)	2 (1%)		
	PYREXIA	2 (2%)	1 (1%)	0 (0%)	3 (1%)			
	SECRETION DISCHARGE	0 (0%)	1 (1%)	0 (0%)	1 (0%)			
	SUDDEN DEATH	0 (0%)	1 (1%)	0 (0%)	1 (0%)			
	SWELLING	0 (0%)	1 (1%)	0 (0%)	1 (0%)			
	ULCER	0 (0%)	1 (1%)	0 (0%)	1 (0%)			
HEPATOBIILIARY DISORDERS	ANY EVENT	1 (1%)	0 (0%)	0 (0%)	1 (0%)			
	HYPERBILIRUBINAEMIA	1 (1%)	0 (0%)	0 (0%)	1 (0%)			
IMMUNE SYSTEM DISORDERS	ANY EVENT	0 (0%)	1 (1%)	1 (1%)	2 (1%)			
	HYPERSENSITIVITY	0 (0%)	1 (1%)	0 (0%)	1 (0%)			
	SEASONAL ALLERGY	0 (0%)	0 (0%)	1 (1%)	1 (0%)			
INFECTIONS AND INFESTATIONS	ANY EVENT	16 (19%)	10 (10%)	13 (18%)	39 (15%)			
	BRONCHITIS	1 (1%)	0 (0%)	0 (0%)	1 (0%)			

- 1.) Only treatment emergent events related to lipids are displayed.
- 2.) Subjects are only counted once within each body system and preferred term.

Table 12: Summary of Treatment Emergent Adverse Events

Body System or Organ Class	Dictionary-Derived Term	Placebo	Xanomeline		Xanomeline		Total
		(N=86)	Low Dose	(N=96)	High Dose	(N=72)	(N=254)
		n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
INFECTIONS AND INFESTATIONS	CELLULITIS	0 (0%)	1 (1%)	0 (0%)	1 (1%)	2 (1%)	1 (0%)
	CERVICITIS	1 (1%)	0 (0%)	0 (0%)	0 (0%)	1 (0%)	1 (0%)
	CYSTITIS	1 (1%)	0 (0%)	1 (1%)	1 (1%)	2 (1%)	2 (1%)
	EAR INFECTION	2 (2%)	0 (0%)	0 (0%)	0 (0%)	2 (1%)	2 (1%)
	GASTROENTERITIS VIRAL	1 (1%)	0 (0%)	0 (0%)	0 (0%)	1 (0%)	1 (0%)
	HORDEOLUM	0 (0%)	0 (0%)	1 (1%)	1 (1%)	2 (1%)	1 (0%)
	INFLUENZA	1 (1%)	1 (1%)	1 (1%)	1 (1%)	3 (1%)	3 (1%)
	LOCALISED INFECTION	1 (1%)	1 (1%)	0 (0%)	0 (0%)	2 (1%)	2 (1%)
	LOWER RESPIRATORY TRACT INFECTION	0 (0%)	0 (0%)	1 (1%)	1 (1%)	2 (1%)	1 (0%)
	NASOPHARYNGITIS	2 (2%)	4 (4%)	6 (8%)	6 (8%)	12 (5%)	12 (5%)
	ONYCHOMYCOSIS	0 (0%)	1 (1%)	0 (0%)	0 (0%)	1 (0%)	1 (0%)
	PNEUMONIA	0 (0%)	1 (1%)	0 (0%)	0 (0%)	1 (0%)	1 (0%)
	RHINITIS	0 (0%)	0 (0%)	1 (1%)	1 (1%)	2 (1%)	1 (0%)
	UPPER RESPIRATORY TRACT INFECTION	6 (7%)	1 (1%)	3 (4%)	3 (4%)	10 (4%)	10 (4%)
	URINARY TRACT INFECTION	2 (2%)	0 (0%)	1 (1%)	1 (1%)	3 (1%)	3 (1%)
	VAGINAL MYCOSIS	1 (1%)	0 (0%)	0 (0%)	0 (0%)	1 (0%)	1 (0%)
	VIRAL INFECTION	0 (0%)	1 (1%)	0 (0%)	0 (0%)	1 (0%)	1 (0%)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ANY EVENT	4 (5%)	5 (5%)	5 (7%)	5 (7%)	14 (6%)	14 (6%)

- 1.) Only treatment emergent events related to lipids are displayed.
- 2.) Subjects are only counted once within each body system and preferred term.

Table 12: Summary of Treatment Emergent Adverse Events

Body System or Organ Class	Dictionary-Derived Term	Placebo	Xanomeline		Xanomeline		Total
		(N=86)	Low Dose	(N=96)	High Dose	(N=72)	(N=254)
		n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	CONTUSION	1 (1%)	1 (1%)	2 (3%)	4 (2%)		
	EXCORIATION	2 (2%)	1 (1%)	1 (1%)	4 (2%)		
	FACIAL BONES FRACTURE	0 (0%)	0 (0%)	1 (1%)	1 (0%)		
	FALL	1 (1%)	2 (2%)	1 (1%)	4 (2%)		
	HIP FRACTURE	1 (1%)	0 (0%)	2 (3%)	3 (1%)		
	JOINT DISLOCATION	0 (0%)	1 (1%)	0 (0%)	1 (0%)		
	SKIN LACERATION	1 (1%)	2 (2%)	0 (0%)	3 (1%)		
	WOUND	0 (0%)	1 (1%)	0 (0%)	1 (0%)		
INVESTIGATIONS	ANY EVENT	10 (12%)	8 (8%)	5 (7%)	23 (9%)		
	BIOPSY	0 (0%)	0 (0%)	1 (1%)	1 (0%)		
	BIOPSY PROSTATE	0 (0%)	0 (0%)	1 (1%)	1 (0%)		

- 1.) Only treatment emergent events related to lipids are displayed.
2.) Subjects are only counted once within each body system and preferred term.

Table 12: Summary of Treatment Emergent Adverse Events

Body System or Organ Class	Dictionary-Derived Term	Placebo		Xanomeline Low Dose		Xanomeline High Dose		Total	
		(N=86)		(N=96)		(N=72)		(N=254)	
INVESTIGATIONS		n	(%)	n	(%)	n	(%)	n	(%)
	BLOOD ALKALINE PHOSPHATASE INCREASED	1	(1%)	0	(0%)	0	(0%)	1	(0%)
	BLOOD CHOLESTEROL INCREASED	0	(0%)	0	(0%)	1	(1%)	1	(0%)
	BLOOD CREATINE PHOSPHOKINASE INCREASED	1	(1%)	0	(0%)	0	(0%)	1	(0%)
	BLOOD GLUCOSE INCREASED	0	(0%)	1	(1%)	1	(1%)	2	(1%)
	BLOOD URINE PRESENT	1	(1%)	0	(0%)	0	(0%)	1	(0%)
	BODY TEMPERATURE INCREASED	0	(0%)	1	(1%)	0	(0%)	1	(0%)
	CYSTOSCOPY	1	(1%)	0	(0%)	0	(0%)	1	(0%)
	ELECTROCARDIOGRAM ST SEGMENT DEPRESSION	4	(5%)	1	(1%)	0	(0%)	5	(2%)
	ELECTROCARDIOGRAM T WAVE AMPLITUDE DECREASED	1	(1%)	1	(1%)	0	(0%)	2	(1%)
	ELECTROCARDIOGRAM T WAVE INVERSION	2	(2%)	1	(1%)	1	(1%)	4	(2%)
	HEART RATE INCREASED	1	(1%)	0	(0%)	0	(0%)	1	(0%)
	HEART RATE IRREGULAR	1	(1%)	0	(0%)	0	(0%)	1	(0%)
	NASAL MUCOSA BIOPSY	0	(0%)	1	(1%)	0	(0%)	1	(0%)
	NEUTROPHIL COUNT INCREASED	0	(0%)	1	(1%)	0	(0%)	1	(0%)

- 1.) Only treatment emergent events related to lipids are displayed.
- 2.) Subjects are only counted once within each body system and preferred term.

Table 12: Summary of Treatment Emergent Adverse Events

Body System or Organ Class	Dictionary-Derived Term	Placebo	Xanomeline		Xanomeline		Total
		(N=86)	Low Dose	High Dose	Total		
		n (%)	n (%)	n (%)	n (%)	n (%)	
INVESTIGATIONS	URINE ANALYSIS ABNORMAL	0 (0%)	1 (1%)	0 (0%)	1 (0%)		
	WEIGHT DECREASED	0 (0%)	1 (1%)	0 (0%)	1 (0%)		
	WHITE BLOOD CELL COUNT INCREASED	0 (0%)	1 (1%)	0 (0%)	1 (0%)		
METABOLISM AND NUTRITION DISORDERS	ANY EVENT	6 (7%)	1 (1%)	3 (4%)	10 (4%)		
	DECREASED APPETITE	1 (1%)	0 (0%)	1 (1%)	2 (1%)		
	DEHYDRATION	1 (1%)	0 (0%)	0 (0%)	1 (0%)		
	DIABETES MELLITUS	1 (1%)	0 (0%)	0 (0%)	1 (0%)		
	FOOD CRAVING	1 (1%)	1 (1%)	0 (0%)	2 (1%)		
	HYPERCHOLESTEROLAEMIA	0 (0%)	0 (0%)	1 (1%)	1 (0%)		
	HYPONATRAEMIA	1 (1%)	0 (0%)	0 (0%)	1 (0%)		
	INCREASED APPETITE	1 (1%)	0 (0%)	1 (1%)	2 (1%)		
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ANY EVENT	5 (6%)	7 (7%)	8 (11%)	20 (8%)		
	ARTHRALGIA	1 (1%)	2 (2%)	1 (1%)	4 (2%)		
	ARTHRITIS	1 (1%)	0 (0%)	1 (1%)	2 (1%)		
	BACK PAIN	1 (1%)	1 (1%)	3 (4%)	5 (2%)		

- 1.) Only treatment emergent events related to lipids are displayed.
- 2.) Subjects are only counted once within each body system and preferred term.

Table 12: Summary of Treatment Emergent Adverse Events

Body System or Organ Class	Dictionary-Derived Term	Placebo	Xanomeline		Xanomeline		Total
		(N=86) n (%)	Low Dose (N=96) n (%)		High Dose (N=72) n (%)		(N=254) n (%)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	FLANK PAIN	0 (0%)	0	(0%)	2	(3%)	2 (1%)
	MUSCLE SPASMS	0 (0%)	1	(1%)	1	(1%)	2 (1%)
	MUSCULAR WEAKNESS	0 (0%)	1	(1%)	0	(0%)	1 (0%)
	MYALGIA	0 (0%)	0	(0%)	1	(1%)	1 (0%)
	PAIN IN EXTREMITY	1 (1%)	0	(0%)	0	(0%)	1 (0%)
	SHOULDER PAIN	1 (1%)	2	(2%)	0	(0%)	3 (1%)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	ANY EVENT	0 (0%)	2	(2%)	1	(1%)	3 (1%)
	COLON CANCER	0 (0%)	1	(1%)	0	(0%)	1 (0%)
	MALIGNANT FIBROUS HISTIOCYTOMA	0 (0%)	1	(1%)	0	(0%)	1 (0%)
	PROSTATE CANCER	0 (0%)	0	(0%)	1	(1%)	1 (0%)

- 1.) Only treatment emergent events related to lipids are displayed.
2.) Subjects are only counted once within each body system and preferred term.

Table 12: Summary of Treatment Emergent Adverse Events

Body System or Organ Class	Dictionary-Derived Term	Placebo	Xanomeline		Xanomeline		Total
		(N=86)	Low Dose	(N=96)	High Dose	(N=72)	(N=254)
		n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)							
NERVOUS SYSTEM DISORDERS	ANY EVENT	12 (14%)	22 (23%)	25 (35%)	59 (23%)		
	AMNESIA	0 (0%)	0 (0%)	1 (1%)	1 (0%)		
	BALANCE DISORDER	0 (0%)	1 (1%)	0 (0%)	1 (0%)		
	BURNING SENSATION	0 (0%)	0 (0%)	2 (3%)	2 (1%)		
	COGNITIVE DISORDER	0 (0%)	0 (0%)	1 (1%)	1 (0%)		
	COMPLEX PARTIAL SEIZURES	0 (0%)	1 (1%)	0 (0%)	1 (0%)		
	COORDINATION ABNORMAL	0 (0%)	1 (1%)	0 (0%)	1 (0%)		
	DIZZINESS	2 (2%)	9 (9%)	11 (15%)	22 (9%)		
	HEADACHE	7 (8%)	3 (3%)	6 (8%)	16 (6%)		
	HEMIANOPIA HOMONYMOUS	0 (0%)	1 (1%)	0 (0%)	1 (0%)		
	HYPERSOMNIA	0 (0%)	0 (0%)	1 (1%)	1 (0%)		
	LETHARGY	0 (0%)	1 (1%)	1 (1%)	2 (1%)		
	PARAESTHESIA	0 (0%)	0 (0%)	1 (1%)	1 (0%)		
	PARAESTHESIA ORAL	0 (0%)	1 (1%)	0 (0%)	1 (0%)		
	PARKINSON'S DISEASE	1 (1%)	0 (0%)	0 (0%)	1 (0%)		
	PAROSMIA	0 (0%)	0 (0%)	1 (1%)	1 (0%)		
	PARTIAL SEIZURES WITH SECONDARY GENERALISATION	0 (0%)	0 (0%)	1 (1%)	1 (0%)		

- 1.) Only treatment emergent events related to lipids are displayed.
- 2.) Subjects are only counted once within each body system and preferred term.

Table 12: Summary of Treatment Emergent Adverse Events

Body System or Organ Class	Dictionary-Derived Term	Placebo	Xanomeline		Xanomeline		Total
		(N=86) n (%)	Low Dose (N=96) n (%)	High Dose (N=72) n (%)	Total (N=254) n (%)		
NERVOUS SYSTEM DISORDERS	PSYCHOMOTOR HYPERACTIVITY	1 (1%)	0 (0%)	0 (0%)	0 (0%)	1 (0%)	
	SOMNOLENCE	2 (2%)	3 (3%)	1 (1%)	6 (2%)		
	STUPOR	0 (0%)	1 (1%)	0 (0%)	1 (0%)		
	SYNCOPE	0 (0%)	5 (5%)	2 (3%)	7 (3%)		
	SYNCOPE VASOVAGAL	0 (0%)	0 (0%)	1 (1%)	1 (0%)		
	TRANSIENT ISCHAEMIC ATTACK	0 (0%)	2 (2%)	1 (1%)	3 (1%)		
PSYCHIATRIC DISORDERS	ANY EVENT	10 (12%)	11 (11%)	8 (11%)	29 (11%)		
	AGITATION	2 (2%)	3 (3%)	0 (0%)	5 (2%)		
	ANXIETY	1 (1%)	3 (3%)	0 (0%)	4 (2%)		
	COMPLETED SUICIDE	1 (1%)	0 (0%)	0 (0%)	1 (0%)		
	CONFUSIONAL STATE	2 (2%)	3 (3%)	1 (1%)	6 (2%)		
	DELIRIUM	0 (0%)	0 (0%)	1 (1%)	1 (0%)		
	DELUSION	1 (1%)	0 (0%)	1 (1%)	2 (1%)		
	DEPRESSED MOOD	0 (0%)	1 (1%)	1 (1%)	2 (1%)		
	DISORIENTATION	1 (1%)	0 (0%)	0 (0%)	1 (0%)		
	HALLUCINATION	0 (0%)	0 (0%)	1 (1%)	1 (0%)		
	HALLUCINATION, VISUAL	0 (0%)	0 (0%)	1 (1%)	1 (0%)		
	INSOMNIA	2 (2%)	0 (0%)	2 (3%)	4 (2%)		
	IRRITABILITY	1 (1%)	1 (1%)	0 (0%)	2 (1%)		
	LIBIDO DECREASED	0 (0%)	0 (0%)	1 (1%)	1 (0%)		

- 1.) Only treatment emergent events related to lipids are displayed.
- 2.) Subjects are only counted once within each body system and preferred term.

Table 12: Summary of Treatment Emergent Adverse Events

Body System or Organ Class	Dictionary-Derived Term	Placebo	Xanomeline		Xanomeline		Total	
		(N=86)	Low Dose	High Dose	Total	(N=254)		
		n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
PSYCHIATRIC DISORDERS	LISTLESS	0 (0%)	0 (0%)	1 (1%)	1 (1%)	1 (0%)		
	NIGHTMARE	0 (0%)	0 (0%)	1 (1%)	1 (1%)	1 (0%)		
	RESTLESSNESS	0 (0%)	1 (1%)	0 (0%)	0 (0%)	1 (0%)		
RENAL AND URINARY DISORDERS	ANY EVENT	4 (5%)	4 (4%)	3 (4%)	3 (4%)	11 (4%)		
	CALCULUS URETHRAL	0 (0%)	0 (0%)	1 (1%)	1 (1%)	1 (0%)		
	DYSURIA	1 (1%)	1 (1%)	0 (0%)	0 (0%)	2 (1%)		
	ENURESIS	0 (0%)	1 (1%)	0 (0%)	0 (0%)	1 (0%)		
	INCONTINENCE	0 (0%)	1 (1%)	0 (0%)	0 (0%)	1 (0%)		
	MICTURITION URGENCY	1 (1%)	1 (1%)	1 (1%)	1 (1%)	3 (1%)		
	NEPHROLITHIASIS	1 (1%)	0 (0%)	1 (1%)	1 (1%)	2 (1%)		
	POLLAKIURIA	1 (1%)	0 (0%)	0 (0%)	0 (0%)	1 (0%)		
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	ANY EVENT	2 (2%)	0 (0%)	1 (1%)	1 (1%)	3 (1%)		
	BENIGN PROSTATIC HYPERPLASIA	1 (1%)	0 (0%)	1 (1%)	1 (1%)	2 (1%)		
	PELVIC PAIN	1 (1%)	0 (0%)	0 (0%)	0 (0%)	1 (0%)		

- 1.) Only treatment emergent events related to lipids are displayed.
- 2.) Subjects are only counted once within each body system and preferred term.

Table 12: Summary of Treatment Emergent Adverse Events

Body System or Organ Class	Dictionary-Derived Term	Placebo	Xanomeline		Xanomeline		Total
		(N=86) n (%)	Low Dose	(N=96) n (%)	High Dose	(N=72) n (%)	(N=254) n (%)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ANY EVENT	10 (12%)	10 (10%)	10 (14%)	30 (12%)		
	ALLERGIC GRANULOMATOUS ANGIITIS	0 (0%)	0 (0%)	1 (1%)	1 (0%)		
	COUGH	3 (3%)	6 (6%)	5 (7%)	14 (6%)		
	DYSPHONIA	0 (0%)	1 (1%)	0 (0%)	1 (0%)		
	DYSPNOEA	1 (1%)	1 (1%)	1 (1%)	3 (1%)		
	EMPHYSEMA	1 (1%)	0 (0%)	0 (0%)	1 (0%)		
	EPISTAXIS	0 (0%)	1 (1%)	2 (3%)	3 (1%)		
	HAEMOPTYSIS	1 (1%)	0 (0%)	0 (0%)	1 (0%)		
	NASAL CONGESTION	3 (3%)	1 (1%)	3 (4%)	7 (3%)		
	PHARYNGEAL ERYTHEMA	0 (0%)	0 (0%)	1 (1%)	1 (0%)		
	PHARYNGOLARYNGEAL PAIN	0 (0%)	1 (1%)	1 (1%)	2 (1%)		

- 1.) Only treatment emergent events related to lipids are displayed.
- 2.) Subjects are only counted once within each body system and preferred term.

Table 12: Summary of Treatment Emergent Adverse Events

Body System or Organ Class	Dictionary-Derived Term	Placebo	Xanomeline		Xanomeline		Total
		(N=86)	Low Dose	High Dose	Total		
		n (%)	n (%)	n (%)	n (%)	n (%)	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	POSTNASAL DRIP	1 (1%)	0 (0%)	0 (0%)	0 (0%)	1 (0%)	
	PRODUCTIVE COUGH	0 (0%)	0 (0%)	1 (1%)	1 (0%)		
	RALES	1 (1%)	0 (0%)	0 (0%)	1 (0%)		
	RESPIRATORY TRACT CONGESTION	0 (0%)	0 (0%)	1 (1%)	1 (0%)		
	RHINORRHOEA	0 (0%)	1 (1%)	1 (1%)	2 (1%)		
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ANY EVENT	21 (24%)	42 (44%)	42 (58%)	105 (41%)		
	ACTINIC KERATOSIS	0 (0%)	0 (0%)	1 (1%)	1 (0%)		
	ALOPECIA	1 (1%)	0 (0%)	0 (0%)	1 (0%)		
	BLISTER	0 (0%)	5 (5%)	1 (1%)	6 (2%)		
	COLD SWEAT	1 (1%)	0 (0%)	0 (0%)	1 (0%)		
	DERMATITIS ATOPIC	1 (1%)	0 (0%)	0 (0%)	1 (0%)		
	DERMATITIS CONTACT	0 (0%)	1 (1%)	0 (0%)	1 (0%)		
	DRUG ERUPTION	1 (1%)	0 (0%)	0 (0%)	1 (0%)		
	ERYTHEMA	9 (10%)	15 (16%)	14 (19%)	38 (15%)		
	HYPERHIDROSIS	2 (2%)	4 (4%)	8 (11%)	14 (6%)		
	PRURITUS	8 (9%)	23 (24%)	26 (36%)	57 (22%)		

- 1.) Only treatment emergent events related to lipids are displayed.
- 2.) Subjects are only counted once within each body system and preferred term.

Table 12: Summary of Treatment Emergent Adverse Events

Body System or Organ Class	Dictionary-Derived Term	Placebo		Xanomeline Low Dose		Xanomeline High Dose		Total	
		(N=86)		(N=96)		(N=72)		(N=254)	
		n	(%)	n	(%)	n	(%)	n	(%)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS GENERALISED	0	(0%)	1	(1%)	1	(1%)	2	(1%)
	RASH	5	(6%)	13	(14%)	11	(15%)	29	(11%)
	RASH ERYTHEMATOUS	0	(0%)	2	(2%)	0	(0%)	2	(1%)
	RASH MACULO-PAPULAR	0	(0%)	0	(0%)	1	(1%)	1	(0%)
	RASH PAPULAR	0	(0%)	0	(0%)	1	(1%)	1	(0%)
	RASH PRURITIC	0	(0%)	1	(1%)	2	(3%)	3	(1%)
	SKIN EXFOLIATION	0	(0%)	1	(1%)	0	(0%)	1	(0%)
	SKIN IRRITATION	3	(3%)	6	(6%)	5	(7%)	14	(6%)
	SKIN ODOUR ABNORMAL	0	(0%)	0	(0%)	1	(1%)	1	(0%)
	SKIN ULCER	1	(1%)	0	(0%)	0	(0%)	1	(0%)
	URTICARIA	0	(0%)	1	(1%)	1	(1%)	2	(1%)
SOCIAL CIRCUMSTANCES	ANY EVENT	0	(0%)	0	(0%)	1	(1%)	1	(0%)
	ALCOHOL USE	0	(0%)	0	(0%)	1	(1%)	1	(0%)
SURGICAL AND MEDICAL PROCEDURES	ANY EVENT	2	(2%)	1	(1%)	2	(3%)	5	(2%)
	ACROCHORDON EXCISION	0	(0%)	0	(0%)	1	(1%)	1	(0%)
	CATARACT OPERATION	1	(1%)	1	(1%)	0	(0%)	2	(1%)
	EYE LASER SURGERY	1	(1%)	0	(0%)	0	(0%)	1	(0%)
	SKIN LESION EXCISION	0	(0%)	0	(0%)	1	(1%)	1	(0%)
VASCULAR DISORDERS	ANY EVENT	3	(3%)	4	(4%)	1	(1%)	8	(3%)

- 1.) Only treatment emergent events related to lipids are displayed.
2.) Subjects are only counted once within each body system and preferred term.

Table 12: Summary of Treatment Emergent Adverse Events

Body System or Organ Class	Dictionary-Derived Term	Placebo	Xanomeline		Xanomeline		Total
		(N=86)	Low Dose	High Dose	High Dose	High Dose	(N=254)
		n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
VASCULAR DISORDERS	HOT FLUSH	0 (0%)	1 (1%)	0 (0%)	0 (0%)	1 (0%)	1 (0%)
	HYPERTENSION	1 (1%)	2 (2%)	0 (0%)	0 (0%)	3 (1%)	3 (1%)
	HYPOTENSION	2 (2%)	1 (1%)	0 (0%)	0 (0%)	3 (1%)	3 (1%)
	ORTHOSTATIC HYPOTENSION	1 (1%)	0 (0%)	0 (0%)	0 (0%)	1 (0%)	1 (0%)
	WOUND HAEMORRHAGE	0 (0%)	0 (0%)	1 (1%)	1 (1%)	1 (0%)	1 (0%)

- 1.) Only treatment emergent events related to lipids are displayed.
- 2.) Subjects are only counted once within each body system and preferred term.