

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 (%)	(N=96) n (%)	(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	1 (1%)	1 (1%)	0 (0%)	2 (1%)
	FIRST DEGREE				
	ATRIOVENTRICULAR BLOCK	2 (2%)	2 (2%)	1 (1%)	5 (2%)
	SECOND DEGREE				
	BRADYCARDIA	1 (1%)	0 (0%)	0 (0%)	1 (0%)
	BUNDLE BRANCH BLOCK	1 (1%)	0 (0%)	0 (0%)	1 (0%)
	LEFT				
	BUNDLE BRANCH BLOCK	1 (1%)	1 (1%)	0 (0%)	2 (1%)
	RIGHT				
	CARDIAC DISORDER	0 (0%)	0 (0%)	1 (1%)	1 (0%)
	CARDIAC FAILURE	1 (1%)	0 (0%)	0 (0%)	1 (0%)
	CONGESTIVE				
	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%)

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Body System or Organ Class	Dictionary-Derived Term	Placebo (N=86) n (%)	Xanomeline	Xanomeline	Total (N=254) n (%)
			Low Dose (N=96) n (%)	High Dose (N=72) 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%)
	ANY EVENT	0 (0%)	1 (1%)	2 (3%)	3 (1%)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	VENTRICULAR SEPTAL DEFECT	0 (0%)	1 (1%)	2 (3%)	3 (1%)
	ANY EVENT	1 (1%)	2 (2%)	1 (1%)	4 (2%)
EAR AND LABYRINTH DISORDERS	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%)

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EYE DISORDERS	ANY EVENT	4 (5%)	2 (2%)	1 (1%)	7 (3%)
	CONJUNCTIVAL	0 (0%)	1 (1%)	0 (0%)	1 (0%)
	HAEMORRHAGE				
	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%)

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GASTROINTESTINAL DISORDERS	HIATUS HERNIA	1 (1%)	0 (0%)	0 (0%)	1 (0%)
	NAUSEA	3 (3%)	3 (3%)	6 (8%)	12 (5%)
	RECTAL HAEMORRHAGE	0 (0%)	1 (1%)	0 (0%)	1 (0%)
	SALIVARY	0 (0%)	0 (0%)	4 (6%)	4 (2%)
	HYPERSECRETION				
	STOMACH DISCOMFORT	0 (0%)	0 (0%)	1 (1%)	1 (0%)
	VOMITING	3 (3%)	4 (4%)	6 (8%)	13 (5%)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ANY EVENT	21 (24%)	51 (53%)	36 (50%)	108 (43%)
	APPLICATION SITE BLEEDING	0 (0%)	1 (1%)	0 (0%)	1 (0%)
	APPLICATION SITE DERMATITIS	5 (6%)	9 (9%)	7 (10%)	21 (8%)
	APPLICATION SITE DESQUAMATION	0 (0%)	1 (1%)	0 (0%)	1 (0%)
	APPLICATION SITE DISCHARGE	0 (0%)	0 (0%)	1 (1%)	1 (0%)
	APPLICATION SITE DISCOLOURATION	0 (0%)	1 (1%)	0 (0%)	1 (0%)
	APPLICATION SITE ERYTHEMA	3 (3%)	13 (14%)	14 (19%)	30 (12%)

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GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	APPLICATION SITE INDURATION	1 (1%)	0 (0%)	0 (0%)	1 (0%)
	APPLICATION SITE IRRITATION	3 (3%)	9 (9%)	9 (12%)	21 (8%)
	APPLICATION SITE PAIN	0 (0%)	0 (0%)	2 (3%)	2 (1%)
	APPLICATION SITE PERSPIRATION	0 (0%)	0 (0%)	2 (3%)	2 (1%)
	APPLICATION SITE PRURITUS	6 (7%)	23 (24%)	21 (29%)	50 (20%)
	APPLICATION SITE REACTION	1 (1%)	0 (0%)	1 (1%)	2 (1%)
	APPLICATION SITE SWELLING	0 (0%)	1 (1%)	2 (3%)	3 (1%)
	APPLICATION SITE URTICARIA	0 (0%)	2 (2%)	1 (1%)	3 (1%)
	APPLICATION SITE VESICLES	1 (1%)	5 (5%)	5 (7%)	11 (4%)
	APPLICATION SITE WARMTH	0 (0%)	1 (1%)	0 (0%)	1 (0%)
	ASTHENIA	1 (1%)	1 (1%)	0 (0%)	2 (1%)

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GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST DISCOMFORT	0 (0%)	1 (1%)	1 (1%)	1 (1%)	2 (1%)	
	CHEST PAIN	0 (0%)	0 (0%)	2 (3%)	2 (3%)	2 (1%)	
	CHILLS	1 (1%)	1 (1%)	1 (1%)	1 (1%)	3 (1%)	
	CYST	0 (0%)	1 (1%)	0 (0%)	0 (0%)	1 (0%)	
	FATIGUE	1 (1%)	5 (5%)	5 (7%)	5 (7%)	11 (4%)	
	FEELING ABNORMAL	0 (0%)	0 (0%)	1 (1%)	1 (1%)	1 (0%)	
	FEELING COLD	0 (0%)	0 (0%)	1 (1%)	1 (1%)	1 (0%)	
	INFLAMMATION	0 (0%)	1 (1%)	0 (0%)	0 (0%)	1 (0%)	
	MALAISE	0 (0%)	1 (1%)	2 (3%)	2 (3%)	3 (1%)	
	OEDEMA	0 (0%)	2 (2%)	0 (0%)	0 (0%)	2 (1%)	
	OEDEMA PERIPHERAL	2 (2%)	1 (1%)	2 (3%)	2 (3%)	5 (2%)	

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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%)		
HEPATOBILIARY 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%)		

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INFECTIONS AND INFESTATIONS	CELLULITIS	0 (0%)	1 (1%)	0 (0%)	1 (0%)
	CERVICITIS	1 (1%)	0 (0%)	0 (0%)	1 (0%)
	CYSTITIS	1 (1%)	0 (0%)	1 (1%)	2 (1%)
	EAR INFECTION	2 (2%)	0 (0%)	0 (0%)	2 (1%)
	GASTROENTERITIS VIRAL	1 (1%)	0 (0%)	0 (0%)	1 (0%)
	HORDEOLUM	0 (0%)	0 (0%)	1 (1%)	1 (0%)
	INFLUENZA	1 (1%)	1 (1%)	1 (1%)	3 (1%)
	LOCALISED INFECTION	1 (1%)	1 (1%)	0 (0%)	2 (1%)
	LOWER RESPIRATORY TRACT	0 (0%)	0 (0%)	1 (1%)	1 (0%)
	INFECTION				
	NASOPHARYNGITIS	2 (2%)	4 (4%)	6 (8%)	12 (5%)
	ONYCHOMYCOSIS	0 (0%)	1 (1%)	0 (0%)	1 (0%)
	PNEUMONIA	0 (0%)	1 (1%)	0 (0%)	1 (0%)
	RHINITIS	0 (0%)	0 (0%)	1 (1%)	1 (0%)
	UPPER RESPIRATORY TRACT	6 (7%)	1 (1%)	3 (4%)	10 (4%)
	INFECTION				
	URINARY TRACT INFECTION	2 (2%)	0 (0%)	1 (1%)	3 (1%)
	VAGINAL MYCOSIS	1 (1%)	0 (0%)	0 (0%)	1 (0%)
	VIRAL INFECTION	0 (0%)	1 (1%)	0 (0%)	1 (0%)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ANY EVENT	4 (5%)	5 (5%)	5 (7%)	14 (6%)

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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%)

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INVESTIGATIONS	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%)

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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%)

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MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	FLANK PAIN	0 (0%)	0 (0%)	2 (3%)	2 (3%)	2 (1%)	
	MUSCLE SPASMS	0 (0%)	1 (1%)	1 (1%)	1 (1%)	2 (1%)	
	MUSCULAR WEAKNESS	0 (0%)	1 (1%)	0 (0%)	0 (0%)	1 (0%)	
	MYALGIA	0 (0%)	0 (0%)	1 (1%)	1 (1%)	1 (0%)	
	PAIN IN EXTREMITY	1 (1%)	0 (0%)	0 (0%)	0 (0%)	1 (0%)	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	SHOULDER PAIN	1 (1%)	2 (2%)	0 (0%)	0 (0%)	3 (1%)	
	ANY EVENT	0 (0%)	2 (2%)	1 (1%)	1 (1%)	3 (1%)	
	COLON CANCER	0 (0%)	1 (1%)	0 (0%)	0 (0%)	1 (0%)	
	MALIGNANT FIBROUS HISTIOCYTOMA	0 (0%)	1 (1%)	0 (0%)	0 (0%)	1 (0%)	
	PROSTATE CANCER	0 (0%)	0 (0%)	1 (1%)	1 (1%)	1 (0%)	

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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%)

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NERVOUS SYSTEM DISORDERS	PSYCHOMOTOR HYPERACTIVITY	1 (1%)	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%)

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PSYCHIATRIC DISORDERS	LISTLESS	0 (0%)	0 (0%)	1 (1%)	1 (0%)
	NIGHTMARE	0 (0%)	0 (0%)	1 (1%)	1 (0%)
	RESTLESSNESS	0 (0%)	1 (1%)	0 (0%)	1 (0%)
RENAL AND URINARY DISORDERS	ANY EVENT	4 (5%)	4 (4%)	3 (4%)	11 (4%)
	CALCULUS URETHRAL	0 (0%)	0 (0%)	1 (1%)	1 (0%)
	DYSURIA	1 (1%)	1 (1%)	0 (0%)	2 (1%)
	ENURESIS	0 (0%)	1 (1%)	0 (0%)	1 (0%)
	INCONTINENCE	0 (0%)	1 (1%)	0 (0%)	1 (0%)
	MICTURITION URGENCY	1 (1%)	1 (1%)	1 (1%)	3 (1%)
	NEPHROLITHIASIS	1 (1%)	0 (0%)	1 (1%)	2 (1%)
	POLLAKIURIA	1 (1%)	0 (0%)	0 (0%)	1 (0%)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	ANY EVENT	2 (2%)	0 (0%)	1 (1%)	3 (1%)
	BENIGN PROSTATIC HYPERPLASIA	1 (1%)	0 (0%)	1 (1%)	2 (1%)
	PELVIC PAIN	1 (1%)	0 (0%)	0 (0%)	1 (0%)

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 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 (N=86) n (%)	Xanomeline	Xanomeline	Total (N=254) n (%)
			Low Dose (N=96) n (%)	High Dose (N=72) 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%)

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Table 12: Summary of Treatment Emergent Adverse Events

Body System or Organ Class	Dictionary-Derived Term	Placebo (N=86) n (%)	Xanomeline		Xanomeline		Total (N=254) n (%)
			Low Dose (N=96) n (%)	High Dose (N=72) n (%)	High Dose (N=72) n (%)	High Dose (N=72) n (%)	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	POSTNASAL DRIP	1 (1%)	0 (0%)	0 (0%)	0 (0%)	1 (0%)	1 (0%)
	PRODUCTIVE COUGH	0 (0%)	0 (0%)	1 (1%)	1 (1%)	1 (0%)	
	RALES	1 (1%)	0 (0%)	0 (0%)	0 (0%)	1 (0%)	
	RESPIRATORY TRACT CONGESTION	0 (0%)	0 (0%)	1 (1%)	1 (1%)	1 (0%)	
	RHINORRHOEA	0 (0%)	1 (1%)	1 (1%)	1 (1%)	2 (1%)	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ANY EVENT	21 (24%)	42 (44%)	42 (58%)	42 (58%)	105 (41%)	
	ACTINIC KERATOSIS	0 (0%)	0 (0%)	1 (1%)	1 (1%)	1 (0%)	
	ALOPECIA	1 (1%)	0 (0%)	0 (0%)	0 (0%)	1 (0%)	
	BLISTER	0 (0%)	5 (5%)	1 (1%)	1 (1%)	6 (2%)	
	COLD SWEAT	1 (1%)	0 (0%)	0 (0%)	0 (0%)	1 (0%)	
	DERMATITIS ATOPIC	1 (1%)	0 (0%)	0 (0%)	0 (0%)	1 (0%)	
	DERMATITIS CONTACT	0 (0%)	1 (1%)	0 (0%)	0 (0%)	1 (0%)	
	DRUG ERUPTION	1 (1%)	0 (0%)	0 (0%)	0 (0%)	1 (0%)	
	ERYTHEMA	9 (10%)	15 (16%)	14 (19%)	14 (19%)	38 (15%)	
	HYPERHIDROSIS	2 (2%)	4 (4%)	8 (11%)	8 (11%)	14 (6%)	
	PRURITUS	8 (9%)	23 (24%)	26 (36%)	26 (36%)	57 (22%)	

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Table 12: Summary of Treatment Emergent Adverse Events

Body System or Organ Class	Dictionary-Derived Term	Placebo (N=86) n (%)	Xanomeline Low Dose (N=96) n (%)	Xanomeline High Dose (N=72) n (%)	Total (N=254) n (%)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS GENERALISED	0 (0%)	1 (1%)	1 (1%)	2 (1%)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	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%)

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Table 12: Summary of Treatment Emergent Adverse Events

Body System or Organ Class	Dictionary-Derived Term	Placebo (N=86) n (%)	Xanomeline Low Dose (N=96) n (%)	Xanomeline High Dose (N=72) n (%)	Total (N=254) n (%)
VASCULAR DISORDERS	HOT FLUSH	0 (0%)	1 (1%)	0 (0%)	1 (0%)
	HYPERTENSION	1 (1%)	2 (2%)	0 (0%)	3 (1%)
	HYPOTENSION	2 (2%)	1 (1%)	0 (0%)	3 (1%)
	ORTHOSTATIC HYPOTENSION	1 (1%)	0 (0%)	0 (0%)	1 (0%)
	WOUND HAEMORRHAGE	0 (0%)	0 (0%)	1 (1%)	1 (0%)

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