

Table 11: Summary of Treatment Emergent Adverse Events

Body System or Organ Class Dictionary-Derived Term	Placebo (N=86)	Xanomeline Low Dose (N=96)	Xanomeline High Dose (N=72)	Total (N=254)
	n (%)	n (%)	n (%)	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%)
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%)

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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 (%)
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%)
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%)

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Body System or Organ Class Dictionary-Derived Term	Placebo (N=86) n (%)	Xanomeline		Total (N=254) n (%)
		Low Dose (N=96) n (%)	High Dose (N=72) n (%)	
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%)
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 HYPERSECRETION	0 (0%)	0 (0%)	4 (6%)	4 (2%)
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%)
APPLICATION SITE INDURATION	1 (1%)	0 (0%)	0 (0%)	1 (0%)

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Body System or Organ Class Dictionary-Derived Term	Placebo (N=86) n (%)	Xanomeline		Total (N=254) n (%)
		Low Dose (N=96) n (%)	High Dose (N=72) n (%)	
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%)
CHEST DISCOMFORT	0 (0%)	1 (1%)	1 (1%)	2 (1%)
CHEST PAIN	0 (0%)	0 (0%)	2 (3%)	2 (1%)
CHILLS	1 (1%)	1 (1%)	1 (1%)	3 (1%)
CYST	0 (0%)	1 (1%)	0 (0%)	1 (0%)
FATIGUE	1 (1%)	5 (5%)	5 (7%)	11 (4%)
FEELING ABNORMAL	0 (0%)	0 (0%)	1 (1%)	1 (0%)
FEELING COLD	0 (0%)	0 (0%)	1 (1%)	1 (0%)
INFLAMMATION	0 (0%)	1 (1%)	0 (0%)	1 (0%)
MALAISE	0 (0%)	1 (1%)	2 (3%)	3 (1%)
OEDEMA	0 (0%)	2 (2%)	0 (0%)	2 (1%)
OEDEMA PERIPHERAL	2 (2%)	1 (1%)	2 (3%)	5 (2%)
PAIN	0 (0%)	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%)

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Body System or Organ Class Dictionary-Derived Term	Placebo (N=86) n (%)	Xanomeline		Total (N=254) n (%)
		Low Dose (N=96) n (%)	High Dose (N=72) n (%)	
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%)
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 INFECTION	0 (0%)	0 (0%)	1 (1%)	1 (0%)
NASOPHARYNGITIS	2 (2%)	4 (4%)	6 (8%)	12 (5%)

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		Low Dose (N=96) n (%)					
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 INFECTION	6 (7%)	1	(1%)	3 (4%)	10 (4%)		
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%)		
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%)		
BLOOD ALKALINE PHOSPHATASE INCREASED	1 (1%)	0	(0%)	0 (0%)	1 (0%)		
BLOOD CHOLESTEROL INCREASED	0 (0%)	0	(0%)	1 (1%)	1 (0%)		

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		Low Dose (N=96) n (%)					
BLOOD CREATINE PHOSPHOKINASE INCREASED	1 (1%)	0 (0%)	0 (0%)	1 (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%)			
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%)			

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	n (%)	n (%)	n (%)	n (%)
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%)
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%)
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%)

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		Low Dose (N=96) n (%)			
		High Dose (N=72) n (%)			
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%)	
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%)	

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		Low Dose (N=96) n (%)	High Dose (N=72) n (%)	
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%)
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				

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		Low Dose (N=96) n (%)	High Dose (N=72) n (%)	
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%)
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%)
POSTNASAL DRIP	1 (1%)	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%)

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Table 11: Summary of Treatment Emergent Adverse Events

Body System or Organ Class Dictionary-Derived Term	Placebo (N=86) n (%)	Xanomeline		Xanomeline High Dose (N=72) n (%)	Total (N=254) n (%)		
		Low Dose (N=96) n (%)					
		n (%)	n (%)				
ALOPECIA	1 (1%)	0 (0%)	0 (0%)	1 (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%)			
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%)			

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Table 11: Summary of Treatment Emergent Adverse Events

Body System or Organ Class Dictionary-Derived Term	Placebo (N=86) n (%)	Xanomeline		Total (N=254) n (%)
		Low Dose (N=96) n (%)	High Dose (N=72) n (%)	
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%)
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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