

Protocol: ABCXYZPDQ
Population: Safety

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Table 3: Summary of Treatment Emergent Adverse Events
Gender: Male

No data to report

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

Table 3: Summary of Treatment Emergent Adverse Events
 Gender: Female

Serious AE (Y/N)	Placebo (N=86)	Xanomeline		Total (N=254)
		Low Dose (N=96)	High Dose (N=72)	
Body System or Organ Class	n (%)	n (%)	n (%)	n (%)
Dictionary-Derived Term				
No				
ANY EVENT				
ANY EVENT	69 (80%)	86 (90%)	70 (97%)	225 (89%)
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%)

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Table 3: Summary of Treatment Emergent Adverse Events
 Gender: Female

Serious AE (Y/N) Body System or Organ Class Dictionary-Derived Term	Placebo (N=86)	Xanomeline		Xanomeline High Dose (N=72)	Total (N=254)
		n (%)	n (%)		
No					
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%)	
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%)	

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Table 3: Summary of Treatment Emergent Adverse Events
 Gender: Female

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		Low Dose (N=96)	n (%)		
No					
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%)	
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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Table 3: Summary of Treatment Emergent Adverse Events
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		Low Dose (N=96) n (%)	High Dose (N=72) n (%)	High Dose (N=72) n (%)	High Dose (N=72) n (%)	
No						
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%)		

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		Low Dose (N=96) n (%)	High Dose (N=72) n (%)	High Dose (N=72) n (%)	High Dose (N=72) n (%)	
No						
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%)	
SOCIAL CIRCUMSTANCES						
ANY EVENT	0 (0%)	0 (0%)	1 (1%)	1 (1%)	1 (0%)	
ALCOHOL USE	0 (0%)	0 (0%)	1 (1%)	1 (1%)	1 (0%)	

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		Low Dose (N=96) n (%)	High Dose (N=72) n (%)			
No						
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%)		
Yes						
ANY EVENT	69 (80%)	86 (90%)	70 (97%)	225 (89%)		
CONGENITAL, FAMILIAL AND GENETIC DISORDERS						
ANY EVENT	0 (0%)	1 (1%)	2 (3%)	3 (1%)		
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Yes								
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%)				
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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%)				
HEPATOBILIARY DISORDERS								
ANY EVENT	1 (1%)	0 (0%)	0 (0%)	1 (0%)				
HYPERBILIRUBINAEMIA	1 (1%)	0 (0%)	0 (0%)	1 (0%)				

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IMMUNE SYSTEM DISORDERS								
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HYPERSENSITIVITY	0 (0%)	1 (1%)	0 (0%)	1 (0%)				
SEASONAL ALLERGY	0 (0%)	0 (0%)	1 (1%)	1 (0%)				
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ANY EVENT	4 (5%)	5 (5%)	5 (7%)	14 (6%)				
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JOINT DISLOCATION	0 (0%)	1 (1%)	0 (0%)	1 (0%)				
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DEHYDRATION	1 (1%)	0 (0%)	0 (0%)	1 (0%)				
DIABETES MELLITUS	1 (1%)	0 (0%)	0 (0%)	1 (0%)				
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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%)				

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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%)
RENAL AND URINARY DISORDERS				
ANY EVENT	4 (5%)	4 (4%)	3 (4%)	11 (4%)
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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%)
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Yes						
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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