

Table 6: Summary of Treatment Emergent Adverse Events

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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	(%)	
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%)
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%)

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

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		n	(%)	n	(%)	
HEPATOBILIARY DISORDERS	ANY EVENT	1	(1%)	0	(0%)	1 (0%)
	HYPERBILIRUBINAEMIA	1	(1%)	0	(0%)	1 (0%)
IMMUNE SYSTEM DISORDERS	ANY EVENT	0	(0%)	1	(1%)	2 (1%)
	HYPERSENSITIVITY	0	(0%)	1	(1%)	1 (0%)
	SEASONAL ALLERGY	0	(0%)	0	(0%)	1 (0%)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ANY EVENT	4	(5%)	5	(5%)	14 (6%)
	CONTUSION	1	(1%)	1	(1%)	4 (2%)
	EXCORIATION	2	(2%)	1	(1%)	4 (2%)
	FACIAL BONES FRACTURE	0	(0%)	0	(0%)	1 (0%)
	FALL	1	(1%)	2	(2%)	4 (2%)
	HIP FRACTURE	1	(1%)	0	(0%)	3 (1%)
	JOINT DISLOCATION	0	(0%)	1	(1%)	1 (0%)
	SKIN LACERATION	1	(1%)	2	(2%)	3 (1%)
	WOUND	0	(0%)	1	(1%)	1 (0%)

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		n	(%)	n	(%)	n	(%)		
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%)
	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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		n	(%)	n	(%)	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	ANY EVENT	0	(0%)	2	(2%)	1 (1%)
	COLON CANCER	0	(0%)	1	(1%)	0 (0%)
	MALIGNANT FIBROUS HISTIOCYTOMA	0	(0%)	1	(1%)	0 (0%)
	PROSTATE CANCER	0	(0%)	0	(0%)	1 (1%)
RENAL AND URINARY DISORDERS	ANY EVENT	4	(5%)	4	(4%)	3 (4%)
	CALCULUS URETHRAL	0	(0%)	0	(0%)	1 (1%)
	DYSURIA	1	(1%)	1	(1%)	0 (0%)
	ENURESIS	0	(0%)	1	(1%)	0 (0%)
	INCONTINENCE	0	(0%)	1	(1%)	0 (0%)
	MICTURITION URGENCY	1	(1%)	1	(1%)	1 (1%)
	NEPHROLITHIASIS	1	(1%)	0	(0%)	1 (1%)
	POLLAKIURIA	1	(1%)	0	(0%)	0 (0%)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	ANY EVENT	2	(2%)	0	(0%)	1 (1%)
	BENIGN PROSTATIC HYPERPLASIA	1	(1%)	0	(0%)	1 (1%)
	PELVIC PAIN	1	(1%)	0	(0%)	0 (0%)

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

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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%)
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%)
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	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%)
	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%)
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	COLON CANCER	0	(0%)	1	(1%)	0 (0%)
	MALIGNANT FIBROUS HISTIOCYTOMA	0	(0%)	1	(1%)	0 (0%)
	PROSTATE CANCER	0	(0%)	0	(0%)	1 (1%)
RENAL AND URINARY DISORDERS	ANY EVENT	4	(5%)	4	(4%)	3 (4%)
	CALCULUS URETHRAL	0	(0%)	0	(0%)	1 (1%)
	DYSURIA	1	(1%)	1	(1%)	0 (0%)
	ENURESIS	0	(0%)	1	(1%)	0 (0%)
	INCONTINENCE	0	(0%)	1	(1%)	0 (0%)
	MICTURITION URGENCY	1	(1%)	1	(1%)	1 (1%)
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	POLLAKIURIA	1	(1%)	0	(0%)	0 (0%)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	ANY EVENT	2	(2%)	0	(0%)	1 (1%)
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	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%)
	HOT FLUSH	0	(0%)	1	(1%)	0	(0%)	1 (0%)
	HYPERTENSION	1	(1%)	2	(2%)	0	(0%)	3 (1%)
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	ORTHOSTATIC HYPOTENSION	1	(1%)	0	(0%)	0	(0%)	1 (0%)
	WOUND HAEMORRHAGE	0	(0%)	0	(0%)	1	(1%)	1 (0%)

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