

Table 6: Summary of Treatment Emergent Adverse Events

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

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		(N=86)	Low Dose	(N=96)	High Dose	(N=72)	(N=254)
		n (%)	n (%)	n (%)	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=86)	Low Dose	High Dose	(N=72)	(N=254)	
		n (%)	n (%)	n (%)	n (%)	n (%)	
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%)		
	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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		n (%)	n (%)	n (%)	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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		(N=86)	Low Dose	High Dose	High Dose	Total	(N=254)
		n (%)	n (%)	n (%)	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%)		
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HEPATOBIILIARY DISORDERS	ANY EVENT	1 (1%)	0 (0%)	0 (0%)	0 (0%)	1 (0%)	1 (0%)
	HYPERBILIRUBINAEMIA	1 (1%)	0 (0%)	0 (0%)	0 (0%)	1 (0%)	1 (0%)
IMMUNE SYSTEM DISORDERS	ANY EVENT	0 (0%)	1 (1%)	1 (1%)	1 (1%)	2 (1%)	2 (1%)
	HYPERSENSITIVITY	0 (0%)	1 (1%)	0 (0%)	0 (0%)	1 (0%)	1 (0%)
	SEASONAL ALLERGY	0 (0%)	0 (0%)	1 (1%)	1 (1%)	1 (0%)	1 (0%)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ANY EVENT	4 (5%)	5 (5%)	5 (7%)	5 (7%)	14 (6%)	14 (6%)
	CONTUSION	1 (1%)	1 (1%)	2 (3%)	2 (3%)	4 (2%)	4 (2%)
	EXCORIATION	2 (2%)	1 (1%)	1 (1%)	1 (1%)	4 (2%)	4 (2%)
	FACIAL BONES FRACTURE	0 (0%)	0 (0%)	1 (1%)	1 (1%)	1 (0%)	1 (0%)
	FALL	1 (1%)	2 (2%)	1 (1%)	1 (1%)	4 (2%)	4 (2%)
	HIP FRACTURE	1 (1%)	0 (0%)	2 (3%)	2 (3%)	3 (1%)	3 (1%)
	JOINT DISLOCATION	0 (0%)	1 (1%)	0 (0%)	0 (0%)	1 (0%)	1 (0%)
	SKIN LACERATION	1 (1%)	2 (2%)	0 (0%)	0 (0%)	3 (1%)	3 (1%)
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MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ANY EVENT	5 (6%)	7 (7%)	8 (11%)	20 (8%)		
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RENAL AND URINARY DISORDERS	ANY EVENT	4 (5%)	4 (4%)	3 (4%)	11 (4%)		
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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%)		
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