

Table 11: 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 (%)
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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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)	Xanomeline Low Dose (N=96)	Xanomeline High Dose (N=72)	Total (N=254)
	n (%)	n (%)	n (%)	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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	n (%)	n (%)	n (%)	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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	n	(%)	n	(%)	n	(%)	n	(%)
SWELLING	0	(0%)	1	(1%)	0	(0%)	1	(0%)
ULCER	0	(0%)	1	(1%)	0	(0%)	1	(0%)
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%)
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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	n	(%)	n	(%)	n	(%)	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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	n (%)	n (%)		n (%)		n (%)
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%)
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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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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	n	(%)	n	(%)	n	(%)	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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	n (%)	n (%)	n (%)	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%)
POLAKIURIA	1 (1%)	0 (0%)	0 (0%)	1 (0%)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS				

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

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

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 (%)
ALOPECIA	1 (1%)	0 (0%)		0 (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%)

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

Table 11: 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 (%)
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%)

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