

Specific Adverse Events  
(Safety Analysis Population)

	Placebo n	Xanomeline Low Dose n	Xanomeline High Dose n
Participants in population	86	84	84
<b>CARDIAC DISORDERS</b>			
Atrial Fibrillation	1	1	3
Atrial Flutter	0	1	1
Atrial Hypertrophy	1	0	0
Atrioventricular Block First Degree	1	1	0
Atrioventricular Block Second Degree	2	0	3
Bradycardia	1	0	0
Bundle Branch Block Left	1	0	0
Bundle Branch Block Right	1	1	0
Cardiac Disorder	0	0	1
Cardiac Failure Congestive	1	0	0
Myocardial Infarction	4	2	4
Palpitations	0	2	0
Sinus Arrhythmia	1	0	0
Sinus Bradycardia	2	7	8
Supraventricular Extrasystoles	1	1	1
Supraventricular Tachycardia	0	1	0
Tachycardia	1	0	0
Ventricular Extrasystoles	0	2	1
Ventricular Hypertrophy	1	0	0
Wolff-Parkinson-White Syndrome	0	1	0
<b>CONGENITAL, FAMILIAL AND GENETIC DISORDERS</b>			
Ventricular Septal Defect	0	1	2
<b>EAR AND LABYRINTH DISORDERS</b>			
Cerumen Impaction	0	1	0
Ear Pain	1	0	0
Tinnitus	0	1	0
Vertigo	0	1	1
<b>EYE DISORDERS</b>			
Conjunctival Haemorrhage	0	1	0
Conjunctivitis	2	0	0
Eye Allergy	1	0	0
Eye Pruritus	1	0	0
Eye Swelling	1	0	0
Glaucoma	1	0	0

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Vision Blurred	0	1	1
<b>GASTROINTESTINAL DISORDERS</b>			
Abdominal Discomfort	0	0	1
Abdominal Pain	1	3	1
Constipation	1	0	0
Diarrhoea	9	5	4
Dyspepsia	1	1	1
Dysphagia	0	1	0
Flatulence	1	0	0
Gastrointestinal Haemorrhage	0	0	1
Gastrooesophageal Reflux Disease	1	0	0
Glossitis	1	0	0
Hiatus Hernia	1	0	0
Nausea	3	3	6
Rectal Haemorrhage	0	1	0
Salivary Hypersecretion	0	0	4
Stomach Discomfort	0	0	1
Vomiting	3	3	7
<b>GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS</b>			
Application Site Bleeding	0	1	0
Application Site Dermatitis	5	9	7
Application Site Desquamation	0	1	0
Application Site Discharge	0	0	1
Application Site Discolouration	0	1	0
Application Site Erythema	3	12	15
Application Site Induration	1	0	0
Application Site Irritation	3	9	9
Application Site Pain	0	0	2
Application Site Perspiration	0	0	2
Application Site Pruritus	6	22	22
Application Site Reaction	1	0	1
Application Site Swelling	0	1	2
Application Site Urticaria	0	2	1
Application Site Vesicles	1	4	6
Application Site Warmth	0	1	0
Asthenia	1	0	1

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	Placebo n	Xanomeline Low Dose n	Xanomeline High Dose n
Chest Discomfort	0	0	2
Chest Pain	0	0	2
Chills	1	1	1
Cyst	0	1	0
Fatigue	1	5	5
Feeling Abnormal	0	0	1
Feeling Cold	0	0	1
Inflammation	0	1	0
Malaise	0	1	2
Oedema	0	2	0
Oedema Peripheral	2	1	2
Pain	0	1	1
Pyrexia	2	0	1
Secretion Discharge	0	1	0
Sudden Death	0	1	0
Swelling	0	1	0
Ulcer	0	1	0
HEPATOBIILIARY DISORDERS			
Hyperbilirubinaemia	1	0	0
IMMUNE SYSTEM DISORDERS			
Hypersensitivity	0	1	0
Seasonal Allergy	0	0	1
INFECTIONS AND INFESTATIONS			
Bronchitis	1	0	0
Cellulitis	0	1	0
Cervicitis	1	0	0
Cystitis	1	0	1
Ear Infection	2	0	0
Gastroenteritis Viral	1	0	0
Hordeolum	0	0	1
Influenza	1	1	1
Localised Infection	1	1	0
Lower Respiratory Tract Infection	0	0	1
Nasopharyngitis	2	4	6
Onychomycosis	0	1	0
Pneumonia	0	1	0
Rhinitis	0	0	1

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Upper Respiratory Tract Infection	6	1	3
Urinary Tract Infection	2	0	1
Vaginal Mycosis	1	0	0
Viral Infection	0	1	0
INJURY, POISONING AND PROCEDURAL COMPLICATIONS			
Contusion	1	1	2
Excoriation	2	1	1
Facial Bones Fracture	0	0	1
Fall	1	2	1
Hip Fracture	1	0	2
Joint Dislocation	0	1	0
Skin Laceration	1	2	0
Wound	0	1	0
INVESTIGATIONS			
Biopsy	0	0	1
Biopsy Prostate	0	0	1
Blood Alkaline Phosphatase Increased	1	0	0
Blood Cholesterol Increased	0	0	1
Blood Creatine Phosphokinase Increased	1	0	0
Blood Glucose Increased	0	1	1
Blood Urine Present	1	0	0
Body Temperature Increased	0	1	0
Cystoscopy	1	0	0
Electrocardiogram St Segment Depression	4	1	0
Electrocardiogram T Wave Amplitude Decreased	1	1	0
Electrocardiogram T Wave Inversion	2	1	1
Heart Rate Increased	1	0	0
Heart Rate Irregular	1	0	0
Nasal Mucosa Biopsy	0	1	0
Neutrophil Count Increased	0	1	0
Urine Analysis Abnormal	0	1	0
Weight Decreased	0	0	1
White Blood Cell Count Increased	0	1	0
METABOLISM AND NUTRITION DISORDERS			
Decreased Appetite	1	0	1
Dehydration	1	0	0
Diabetes Mellitus	1	0	0

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Food Craving	1	1	0
Hypercholesterolaemia	0	0	1
Hyponatraemia	1	0	0
Increased Appetite	1	0	1
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS			
Arthralgia	1	2	1
Arthritis	1	0	1
Back Pain	1	1	3
Flank Pain	0	0	2
Muscle Spasms	0	1	1
Muscular Weakness	0	1	0
Myalgia	0	0	1
Pain In Extremity	1	0	0
Shoulder Pain	1	2	0
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)			
Colon Cancer	0	1	0
Malignant Fibrous Histiocytoma	0	1	0
Prostate Cancer	0	0	1
NERVOUS SYSTEM DISORDERS			
Amnesia	0	0	1
Balance Disorder	0	1	0
Burning Sensation	0	0	2
Cognitive Disorder	0	0	1
Complex Partial Seizures	0	1	0
Coordination Abnormal	0	1	0
Dizziness	2	8	12
Headache	7	3	6
Hemianopia Homonymous	0	1	0
Hypersomnia	0	0	1
Lethargy	0	1	1
Paraesthesia	0	0	1
Paraesthesia Oral	0	1	0
Parkinson'S Disease	1	0	0
Parosmia	0	0	1
Partial Seizures With Secondary Generalisation	0	0	1
Psychomotor Hyperactivity	1	0	0

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	Placebo n	Xanomeline Low Dose n	Xanomeline High Dose n
Somnolence	2	3	1
Stupor	0	1	0
Syncope	0	4	3
Syncope Vasovagal	0	0	1
Transient Ischaemic Attack	0	2	1
<b>PSYCHIATRIC DISORDERS</b>			
Agitation	2	2	1
Anxiety	1	3	0
Completed Suicide	1	0	0
Confusional State	2	3	1
Delirium	0	0	1
Delusion	1	0	1
Depressed Mood	0	1	1
Disorientation	1	0	0
Hallucination	0	0	1
Hallucination, Visual	0	0	1
Insomnia	2	0	2
Irritability	1	1	0
Libido Decreased	0	0	1
Listless	0	0	1
Nightmare	0	0	1
Restlessness	0	1	0
<b>RENAL AND URINARY DISORDERS</b>			
Calculus Urethral	0	0	1
Dysuria	1	1	0
Enuresis	0	1	0
Incontinence	0	1	0
Micturition Urgency	1	1	1
Nephrolithiasis	1	0	1
Pollakiuria	1	0	0
<b>REPRODUCTIVE SYSTEM AND BREAST DISORDERS</b>			
Benign Prostatic Hyperplasia	1	0	1
Pelvic Pain	1	0	0
<b>RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS</b>			
Allergic Granulomatous Angiitis	0	0	1
Cough	3	6	5
Dysphonia	0	1	0

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	Placebo n	Xanomeline Low Dose n	Xanomeline High Dose n
Dyspnoea	1	1	1
Emphysema	1	0	0
Epistaxis	0	1	2
Haemoptysis	1	0	0
Nasal Congestion	3	1	3
Pharyngeal Erythema	0	0	1
Pharyngolaryngeal Pain	0	1	1
Postnasal Drip	1	0	0
Productive Cough	0	0	1
Rales	1	0	0
Respiratory Tract Congestion	0	0	1
Rhinorrhoea	0	1	1
SKIN AND SUBCUTANEOUS TISSUE DISORDERS			
Actinic Keratosis	0	0	1
Alopecia	1	0	0
Blister	0	5	1
Cold Sweat	1	0	0
Dermatitis Atopic	1	0	0
Dermatitis Contact	0	1	0
Drug Eruption	1	0	0
Erythema	9	15	14
Hyperhidrosis	2	4	8
Pruritus	8	23	26
Pruritus Generalised	0	1	1
Rash	5	13	11
Rash Erythematous	0	2	0
Rash Maculo-Papular	0	0	1
Rash Papular	0	0	1
Rash Pruritic	0	1	2
Skin Exfoliation	0	1	0
Skin Irritation	3	6	5
Skin Odour Abnormal	0	0	1
Skin Ulcer	1	0	0
Urticaria	0	1	1
SOCIAL CIRCUMSTANCES			
Alcohol Use	0	0	1
SURGICAL AND MEDICAL PROCEDURES			

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	Placebo n	Xanomeline Low Dose n	Xanomeline High Dose n
Acrochordon Excision	0	0	1
Cataract Operation	1	1	0
Eye Laser Surgery	1	0	0
Skin Lesion Excision	0	0	1
VASCULAR DISORDERS			
Hot Flush	0	1	0
Hypertension	1	1	1
Hypotension	2	1	0
Orthostatic Hypotension	1	0	0
Wound Haemorrhage	0	0	1
Number of participants with specific adverse events.			

Source: ADSL and ADAE datasets