

Adverse Events by System Organ Class and Preferred Term  
(Safety Analysis Set)

<b>System Organ Class Preferred Term</b>	<b>Placebo (N=86)</b>	<b>Xanomeline Low Dose (N=84)</b>	<b>Xanomeline High Dose (N=84)</b>
Participants in population	86	84	84
Cardiac Disorders			
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
Congenital, Familial And Genetic Disorders			
Ventricular Septal Defect	0	1	2
Ear And Labyrinth Disorders			
Cerumen Impaction	0	1	0
Ear Pain	1	0	0
Tinnitus	0	1	0
Vertigo	0	1	1
Eye Disorders			
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
Gastrointestinal Disorders			
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
General Disorders And Administration Site Conditions			
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
Chest Discomfort	0	0	2

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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
Hepatobiliary 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
Upper Respiratory Tract Infection	6	1	3

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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
Food Craving	1	1	0

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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
Somnolence	2	3	1

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Stupor	0	1	0
Syncope	0	4	3
Syncope Vasovagal	0	0	1
Transient Ischaemic Attack	0	2	1
Psychiatric Disorders			
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
Renal And Urinary Disorders			
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
Reproductive System And Breast Disorders			
Benign Prostatic Hyperplasia	1	0	1
Pelvic Pain	1	0	0
Respiratory, Thoracic And Mediastinal Disorders			
Allergic Granulomatous Angiitis	0	0	1
Cough	3	6	5
Dysphonia	0	1	0
Dyspnoea	1	1	1

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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			
Acrochordon Excision	0	0	1

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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
MedDRA version 25.0. Each participant is counted once within each preferred term and system organ class. Participants with multiple events in the same preferred term are counted only once for that term.			

Source: ADAE Analysis Dataset (Data cutoff: 01JAN2023)