| **Primary System Organ Class**      **Reported Term for the Adverse Event** | **Placebo**  N = 861 | **Xanomeline High Dose**  N = 841 | **Xanomeline Low Dose**  N = 841 |
| --- | --- | --- | --- |
| CARDIAC DISORDERS | 2 (2.3%) | 0 (0%) | 0 (0%) |
| ATRIOVENTRICULAR BLOCK SECOND DEGREE | 1 (1.2%) | 0 (0%) | 0 (0%) |
| BUNDLE BRANCH BLOCK LEFT | 1 (1.2%) | 0 (0%) | 0 (0%) |
| EYE DISORDERS | 1 (1.2%) | 0 (0%) | 0 (0%) |
| EYE ALLERGY | 1 (1.2%) | 0 (0%) | 0 (0%) |
| EYE PRURITUS | 1 (1.2%) | 0 (0%) | 0 (0%) |
| EYE SWELLING | 1 (1.2%) | 0 (0%) | 0 (0%) |
| GASTROINTESTINAL DISORDERS | 2 (2.3%) | 4 (4.8%) | 0 (0%) |
| DIARRHOEA | 1 (1.2%) | 0 (0%) | 0 (0%) |
| DYSPEPSIA | 0 (0%) | 1 (1.2%) | 0 (0%) |
| HIATUS HERNIA | 1 (1.2%) | 0 (0%) | 0 (0%) |
| NAUSEA | 0 (0%) | 1 (1.2%) | 0 (0%) |
| SALIVARY HYPERSECRETION | 0 (0%) | 2 (2.4%) | 0 (0%) |
| VOMITING | 0 (0%) | 2 (2.4%) | 0 (0%) |
| GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS | 2 (2.3%) | 8 (9.5%) | 5 (6.0%) |
| APPLICATION SITE DERMATITIS | 0 (0%) | 0 (0%) | 1 (1.2%) |
| APPLICATION SITE ERYTHEMA | 1 (1.2%) | 6 (7.1%) | 3 (3.6%) |
| APPLICATION SITE IRRITATION | 0 (0%) | 2 (2.4%) | 2 (2.4%) |
| APPLICATION SITE PAIN | 0 (0%) | 1 (1.2%) | 0 (0%) |
| APPLICATION SITE PRURITUS | 1 (1.2%) | 7 (8.3%) | 4 (4.8%) |
| 1n (%) | | | |

| **Primary System Organ Class**      **Reported Term for the Adverse Event** | **Placebo**  N = 861 | **Xanomeline High Dose**  N = 841 | **Xanomeline Low Dose**  N = 841 |
| --- | --- | --- | --- |
| APPLICATION SITE URTICARIA | 0 (0%) | 0 (0%) | 1 (1.2%) |
| APPLICATION SITE VESICLES | 0 (0%) | 2 (2.4%) | 1 (1.2%) |
| FATIGUE | 0 (0%) | 3 (3.6%) | 1 (1.2%) |
| PYREXIA | 1 (1.2%) | 0 (0%) | 0 (0%) |
| SECRETION DISCHARGE | 0 (0%) | 0 (0%) | 1 (1.2%) |
| SUDDEN DEATH | 0 (0%) | 0 (0%) | 1 (1.2%) |
| INFECTIONS AND INFESTATIONS | 2 (2.3%) | 3 (3.6%) | 2 (2.4%) |
| CELLULITIS | 0 (0%) | 0 (0%) | 1 (1.2%) |
| HORDEOLUM | 0 (0%) | 1 (1.2%) | 0 (0%) |
| LOCALISED INFECTION | 0 (0%) | 0 (0%) | 1 (1.2%) |
| LOWER RESPIRATORY TRACT INFECTION | 0 (0%) | 1 (1.2%) | 0 (0%) |
| NASOPHARYNGITIS | 0 (0%) | 1 (1.2%) | 0 (0%) |
| PNEUMONIA | 0 (0%) | 0 (0%) | 1 (1.2%) |
| UPPER RESPIRATORY TRACT INFECTION | 1 (1.2%) | 1 (1.2%) | 0 (0%) |
| URINARY TRACT INFECTION | 1 (1.2%) | 0 (0%) | 0 (0%) |
| INJURY, POISONING AND PROCEDURAL COMPLICATIONS | 0 (0%) | 0 (0%) | 1 (1.2%) |
| JOINT DISLOCATION | 0 (0%) | 0 (0%) | 1 (1.2%) |
| SKIN LACERATION | 0 (0%) | 0 (0%) | 1 (1.2%) |
| INVESTIGATIONS | 0 (0%) | 0 (0%) | 1 (1.2%) |
| NASAL MUCOSA BIOPSY | 0 (0%) | 0 (0%) | 1 (1.2%) |
| 1n (%) | | | |

| **Primary System Organ Class**      **Reported Term for the Adverse Event** | **Placebo**  N = 861 | **Xanomeline High Dose**  N = 841 | **Xanomeline Low Dose**  N = 841 |
| --- | --- | --- | --- |
| METABOLISM AND NUTRITION DISORDERS | 1 (1.2%) | 0 (0%) | 0 (0%) |
| INCREASED APPETITE | 1 (1.2%) | 0 (0%) | 0 (0%) |
| MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS | 0 (0%) | 1 (1.2%) | 3 (3.6%) |
| ARTHRALGIA | 0 (0%) | 0 (0%) | 1 (1.2%) |
| FLANK PAIN | 0 (0%) | 1 (1.2%) | 0 (0%) |
| MUSCULAR WEAKNESS | 0 (0%) | 0 (0%) | 1 (1.2%) |
| SHOULDER PAIN | 0 (0%) | 0 (0%) | 1 (1.2%) |
| NERVOUS SYSTEM DISORDERS | 0 (0%) | 2 (2.4%) | 0 (0%) |
| HEADACHE | 0 (0%) | 1 (1.2%) | 0 (0%) |
| PAROSMIA | 0 (0%) | 1 (1.2%) | 0 (0%) |
| PSYCHIATRIC DISORDERS | 0 (0%) | 2 (2.4%) | 1 (1.2%) |
| AGITATION | 0 (0%) | 1 (1.2%) | 0 (0%) |
| CONFUSIONAL STATE | 0 (0%) | 0 (0%) | 1 (1.2%) |
| DEPRESSED MOOD | 0 (0%) | 1 (1.2%) | 0 (0%) |
| RENAL AND URINARY DISORDERS | 0 (0%) | 2 (2.4%) | 2 (2.4%) |
| CALCULUS URETHRAL | 0 (0%) | 1 (1.2%) | 0 (0%) |
| INCONTINENCE | 0 (0%) | 0 (0%) | 1 (1.2%) |
| MICTURITION URGENCY | 0 (0%) | 1 (1.2%) | 1 (1.2%) |
| RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS | 2 (2.3%) | 3 (3.6%) | 3 (3.6%) |
| COUGH | 1 (1.2%) | 1 (1.2%) | 1 (1.2%) |
| 1n (%) | | | |

| **Primary System Organ Class**      **Reported Term for the Adverse Event** | **Placebo**  N = 861 | **Xanomeline High Dose**  N = 841 | **Xanomeline Low Dose**  N = 841 |
| --- | --- | --- | --- |
| DYSPNOEA | 0 (0%) | 0 (0%) | 1 (1.2%) |
| EPISTAXIS | 0 (0%) | 1 (1.2%) | 0 (0%) |
| NASAL CONGESTION | 1 (1.2%) | 1 (1.2%) | 1 (1.2%) |
| PHARYNGOLARYNGEAL PAIN | 0 (0%) | 0 (0%) | 1 (1.2%) |
| RHINORRHOEA | 0 (0%) | 1 (1.2%) | 0 (0%) |
| SKIN AND SUBCUTANEOUS TISSUE DISORDERS | 2 (2.3%) | 4 (4.8%) | 4 (4.8%) |
| ACTINIC KERATOSIS | 0 (0%) | 1 (1.2%) | 0 (0%) |
| ERYTHEMA | 1 (1.2%) | 2 (2.4%) | 4 (4.8%) |
| PRURITUS | 1 (1.2%) | 2 (2.4%) | 2 (2.4%) |
| PRURITUS GENERALISED | 0 (0%) | 0 (0%) | 1 (1.2%) |
| RASH | 0 (0%) | 1 (1.2%) | 0 (0%) |
| SKIN ODOUR ABNORMAL | 0 (0%) | 1 (1.2%) | 0 (0%) |
| URTICARIA | 0 (0%) | 0 (0%) | 1 (1.2%) |
| SURGICAL AND MEDICAL PROCEDURES | 1 (1.2%) | 0 (0%) | 0 (0%) |
| EYE LASER SURGERY | 1 (1.2%) | 0 (0%) | 0 (0%) |
| 1n (%) | | | |