# Adverse Events by Body System

|  | Adverse Event Term | Placebo | Xanomeline High Dose | level |
| --- | --- | --- | --- | --- |
|  | ABDOMINAL DISCOMFORT | 0 | 1 | 2 |
|  | ABDOMINAL PAIN | 1 | 1 | 2 |
|  | ACROCHORDON EXCISION | 0 | 1 | 2 |
|  | ACTINIC KERATOSIS | 0 | 1 | 2 |
|  | AGITATION | 2 | 1 | 2 |
|  | ALCOHOL USE | 0 | 1 | 2 |
|  | ALLERGIC GRANULOMATOUS ANGIITIS | 0 | 1 | 2 |
|  | ALOPECIA | 1 | 0 | 2 |
|  | AMNESIA | 0 | 1 | 2 |
|  | APPLICATION SITE DERMATITIS | 5 | 7 | 2 |
|  | APPLICATION SITE DISCHARGE | 0 | 1 | 2 |
|  | APPLICATION SITE ERYTHEMA | 3 | 14 | 2 |
|  | APPLICATION SITE INDURATION | 1 | 0 | 2 |
|  | APPLICATION SITE IRRITATION | 3 | 9 | 2 |
|  | APPLICATION SITE PAIN | 0 | 2 | 2 |
|  | APPLICATION SITE PERSPIRATION | 0 | 2 | 2 |
|  | APPLICATION SITE PRURITUS | 6 | 21 | 2 |
|  | APPLICATION SITE REACTION | 1 | 1 | 2 |
|  | APPLICATION SITE SWELLING | 0 | 2 | 2 |
|  | APPLICATION SITE URTICARIA | 0 | 1 | 2 |
|  | APPLICATION SITE VESICLES | 1 | 5 | 2 |
|  | ARTHRALGIA | 1 | 1 | 2 |
|  | ARTHRITIS | 0 | 1 | 2 |
|  | ASTHENIA | 1 | 1 | 2 |
|  | ATRIAL FIBRILLATION | 1 | 3 | 2 |
|  | ATRIAL FLUTTER | 0 | 1 | 2 |
|  | ATRIAL HYPERTROPHY | 1 | 0 | 2 |
|  | ATRIOVENTRICULAR BLOCK FIRST DEGREE | 1 | 0 | 2 |
|  | ATRIOVENTRICULAR BLOCK SECOND DEGREE | 1 | 0 | 2 |
|  | BACK PAIN | 1 | 3 | 2 |
|  | BENIGN PROSTATIC HYPERPLASIA | 1 | 1 | 2 |
|  | BIOPSY | 0 | 1 | 2 |
|  | BIOPSY PROSTATE | 0 | 1 | 2 |
|  | BLISTER | 0 | 1 | 2 |
|  | BLOOD ALKALINE PHOSPHATASE INCREASED | 1 | 0 | 2 |
|  | BLOOD CHOLESTEROL INCREASED | 0 | 1 | 2 |
|  | BLOOD CREATINE PHOSPHOKINASE INCREASED | 1 | 0 | 2 |
|  | BLOOD GLUCOSE INCREASED | 0 | 1 | 2 |
|  | BLOOD URINE PRESENT | 1 | 0 | 2 |
|  | BRADYCARDIA | 1 | 0 | 2 |
|  | BRONCHITIS | 1 | 0 | 2 |
|  | BUNDLE BRANCH BLOCK RIGHT | 1 | 0 | 2 |
|  | BURNING SENSATION | 0 | 2 | 2 |
|  | CALCULUS URETHRAL | 0 | 1 | 2 |
|  | CARDIAC DISORDER | 0 | 1 | 2 |
|  | CATARACT OPERATION | 1 | 0 | 2 |
|  | CERVICITIS | 1 | 0 | 2 |
|  | CHEST DISCOMFORT | 0 | 1 | 2 |
|  | CHEST PAIN | 0 | 2 | 2 |
|  | CHILLS | 1 | 1 | 2 |
|  | COGNITIVE DISORDER | 0 | 1 | 2 |
|  | COLD SWEAT | 1 | 0 | 2 |
|  | COMPLETED SUICIDE | 1 | 0 | 2 |
|  | CONFUSIONAL STATE | 2 | 1 | 2 |
|  | CONJUNCTIVITIS | 1 | 0 | 2 |
|  | CONSTIPATION | 1 | 0 | 2 |
|  | CONTUSION | 1 | 2 | 2 |
|  | COUGH | 1 | 5 | 2 |
|  | CYSTITIS | 1 | 1 | 2 |
|  | CYSTOSCOPY | 1 | 0 | 2 |
|  | DECREASED APPETITE | 1 | 1 | 2 |
|  | DEHYDRATION | 1 | 0 | 2 |
|  | DELIRIUM | 0 | 1 | 2 |
|  | DELUSION | 1 | 1 | 2 |
|  | DIABETES MELLITUS | 1 | 0 | 2 |
|  | DIARRHOEA | 9 | 4 | 2 |
|  | DISORIENTATION | 1 | 0 | 2 |
|  | DIZZINESS | 2 | 11 | 2 |
|  | DRUG ERUPTION | 1 | 0 | 2 |
|  | DYSPEPSIA | 1 | 0 | 2 |
|  | DYSPNOEA | 1 | 1 | 2 |
|  | DYSURIA | 1 | 0 | 2 |
|  | EAR INFECTION | 2 | 0 | 2 |
|  | EAR PAIN | 1 | 0 | 2 |
|  | ELECTROCARDIOGRAM ST SEGMENT DEPRESSION | 4 | 0 | 2 |
|  | ELECTROCARDIOGRAM T WAVE AMPLITUDE DECREASED | 1 | 0 | 2 |
|  | ELECTROCARDIOGRAM T WAVE INVERSION | 2 | 1 | 2 |
|  | EMPHYSEMA | 1 | 0 | 2 |
|  | EPISTAXIS | 0 | 2 | 2 |
|  | ERYTHEMA | 7 | 14 | 2 |
|  | EXCORIATION | 2 | 1 | 2 |
|  | EYE ALLERGY | 1 | 0 | 2 |
|  | EYE LASER SURGERY | 1 | 0 | 2 |
|  | EYE PRURITUS | 1 | 0 | 2 |
|  | EYE SWELLING | 1 | 0 | 2 |
|  | FACIAL BONES FRACTURE | 0 | 1 | 2 |
|  | FALL | 1 | 1 | 2 |
|  | FATIGUE | 1 | 5 | 2 |
|  | FEELING ABNORMAL | 0 | 1 | 2 |
|  | FEELING COLD | 0 | 1 | 2 |
|  | FLANK PAIN | 0 | 1 | 2 |
|  | FLATULENCE | 1 | 0 | 2 |
|  | FOOD CRAVING | 1 | 0 | 2 |
|  | GASTROENTERITIS VIRAL | 1 | 0 | 2 |
|  | GASTROOESOPHAGEAL REFLUX DISEASE | 1 | 0 | 2 |
|  | GLOSSITIS | 1 | 0 | 2 |
|  | HAEMOPTYSIS | 1 | 0 | 2 |
|  | HALLUCINATION | 0 | 1 | 2 |
|  | HALLUCINATION, VISUAL | 0 | 1 | 2 |
|  | HEADACHE | 3 | 5 | 2 |
|  | HEART RATE INCREASED | 1 | 0 | 2 |
|  | HEART RATE IRREGULAR | 1 | 0 | 2 |
|  | HIATUS HERNIA | 1 | 0 | 2 |
|  | HIP FRACTURE | 1 | 2 | 2 |
|  | HORDEOLUM | 0 | 1 | 2 |
|  | HYPERBILIRUBINAEMIA | 1 | 0 | 2 |
|  | HYPERHIDROSIS | 2 | 8 | 2 |
|  | HYPERSOMNIA | 0 | 1 | 2 |
|  | HYPERTENSION | 1 | 0 | 2 |
|  | HYPOTENSION | 2 | 0 | 2 |
|  | INCREASED APPETITE | 1 | 1 | 2 |
|  | INFLUENZA | 1 | 1 | 2 |
|  | INSOMNIA | 2 | 2 | 2 |
|  | IRRITABILITY | 1 | 0 | 2 |
|  | LETHARGY | 0 | 1 | 2 |
|  | LIBIDO DECREASED | 0 | 1 | 2 |
|  | LISTLESS | 0 | 1 | 2 |
|  | LOCALISED INFECTION | 1 | 0 | 2 |
|  | LOWER RESPIRATORY TRACT INFECTION | 0 | 1 | 2 |
|  | MALAISE | 0 | 2 | 2 |
|  | MICTURITION URGENCY | 1 | 1 | 2 |
|  | MUSCLE SPASMS | 0 | 1 | 2 |
|  | MYALGIA | 0 | 1 | 2 |
|  | MYOCARDIAL INFARCTION | 3 | 4 | 2 |
|  | NASAL CONGESTION | 3 | 3 | 2 |
|  | NASOPHARYNGITIS | 2 | 6 | 2 |
|  | NAUSEA | 3 | 6 | 2 |
|  | NEPHROLITHIASIS | 1 | 1 | 2 |
|  | NIGHTMARE | 0 | 1 | 2 |
|  | OEDEMA PERIPHERAL | 2 | 2 | 2 |
|  | ORTHOSTATIC HYPOTENSION | 1 | 0 | 2 |
|  | PAIN | 0 | 1 | 2 |
|  | PAIN IN EXTREMITY | 1 | 0 | 2 |
|  | PARAESTHESIA | 0 | 1 | 2 |
|  | PARKINSON'S DISEASE | 1 | 0 | 2 |
|  | PAROSMIA | 0 | 1 | 2 |
|  | PARTIAL SEIZURES WITH SECONDARY GENERALISATION | 0 | 1 | 2 |
|  | PELVIC PAIN | 1 | 0 | 2 |
|  | PHARYNGEAL ERYTHEMA | 0 | 1 | 2 |
|  | PHARYNGOLARYNGEAL PAIN | 0 | 1 | 2 |
|  | POLLAKIURIA | 1 | 0 | 2 |
|  | POSTNASAL DRIP | 1 | 0 | 2 |
|  | PRODUCTIVE COUGH | 0 | 1 | 2 |
|  | PROSTATE CANCER | 0 | 1 | 2 |
|  | PRURITUS | 8 | 26 | 2 |
|  | PRURITUS GENERALISED | 0 | 1 | 2 |
|  | PSYCHOMOTOR HYPERACTIVITY | 1 | 0 | 2 |
|  | PYREXIA | 2 | 1 | 2 |
|  | RALES | 1 | 0 | 2 |
|  | RASH | 5 | 9 | 2 |
|  | RASH MACULO-PAPULAR | 0 | 1 | 2 |
|  | RASH PRURITIC | 0 | 2 | 2 |
|  | RESPIRATORY TRACT CONGESTION | 0 | 1 | 2 |
|  | RHINITIS | 0 | 1 | 2 |
|  | RHINORRHOEA | 0 | 1 | 2 |
|  | SALIVARY HYPERSECRETION | 0 | 4 | 2 |
|  | SHOULDER PAIN | 1 | 0 | 2 |
|  | SINUS ARRHYTHMIA | 1 | 0 | 2 |
|  | SINUS BRADYCARDIA | 1 | 4 | 2 |
|  | SKIN IRRITATION | 3 | 5 | 2 |
|  | SKIN LACERATION | 1 | 0 | 2 |
|  | SKIN LESION EXCISION | 0 | 1 | 2 |
|  | SKIN ODOUR ABNORMAL | 0 | 1 | 2 |
|  | SKIN ULCER | 1 | 0 | 2 |
|  | SOMNOLENCE | 2 | 1 | 2 |
|  | STOMACH DISCOMFORT | 0 | 1 | 2 |
|  | SUPRAVENTRICULAR EXTRASYSTOLES | 1 | 1 | 2 |
|  | SYNCOPE | 0 | 3 | 2 |
|  | SYNCOPE VASOVAGAL | 0 | 1 | 2 |
|  | TACHYCARDIA | 1 | 0 | 2 |
|  | TRANSIENT ISCHAEMIC ATTACK | 0 | 1 | 2 |
|  | UPPER RESPIRATORY TRACT INFECTION | 6 | 3 | 2 |
|  | URINARY TRACT INFECTION | 2 | 1 | 2 |
|  | URTICARIA | 0 | 1 | 2 |
|  | VAGINAL MYCOSIS | 1 | 0 | 2 |
|  | VENTRICULAR EXTRASYSTOLES | 0 | 1 | 2 |
|  | VENTRICULAR HYPERTROPHY | 1 | 0 | 2 |
|  | VENTRICULAR SEPTAL DEFECT | 0 | 2 | 2 |
|  | VERTIGO | 0 | 1 | 2 |
|  | VISION BLURRED | 0 | 1 | 2 |
|  | VOMITING | 3 | 6 | 2 |
|  | WEIGHT DECREASED | 0 | 1 | 2 |
|  | WOUND HAEMORRHAGE | 0 | 1 | 2 |
| **CARDIAC DISORDERS** |  |  |  | **1** |
| **CONGENITAL, FAMILIAL AND GENETIC DISORDERS** |  |  |  | **1** |
| **EAR AND LABYRINTH DISORDERS** |  |  |  | **1** |
| **EYE DISORDERS** |  |  |  | **1** |
| **GASTROINTESTINAL DISORDERS** |  |  |  | **1** |
| **GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS** |  |  |  | **1** |
| **HEPATOBILIARY DISORDERS** |  |  |  | **1** |
| **INFECTIONS AND INFESTATIONS** |  |  |  | **1** |
| **INJURY, POISONING AND PROCEDURAL COMPLICATIONS** |  |  |  | **1** |
| **INVESTIGATIONS** |  |  |  | **1** |
| **METABOLISM AND NUTRITION DISORDERS** |  |  |  | **1** |
| **MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS** |  |  |  | **1** |
| **NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)** |  |  |  | **1** |
| **NERVOUS SYSTEM DISORDERS** |  |  |  | **1** |
| **PSYCHIATRIC DISORDERS** |  |  |  | **1** |
| **RENAL AND URINARY DISORDERS** |  |  |  | **1** |
| **REPRODUCTIVE SYSTEM AND BREAST DISORDERS** |  |  |  | **1** |
| **RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS** |  |  |  | **1** |
| **SKIN AND SUBCUTANEOUS TISSUE DISORDERS** |  |  |  | **1** |
| **SOCIAL CIRCUMSTANCES** |  |  |  | **1** |
| **SURGICAL AND MEDICAL PROCEDURES** |  |  |  | **1** |
| **VASCULAR DISORDERS** |  |  |  | **1** |