

Table 9: Summary of Treatment Emergent Adverse Events

	Placebo (N=86) n (%)	Xanomeline Low Dose (N=96) n (%)	Xanomeline High Dose (N=72) n (%)	Total (N=254) n (%)
New AEBODSYS Label				
New AEDECOD Label				
ANY EVENT				
ANY EVENT	69 (80%)	86 (90%)	70 (97%)	225 (89%)
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%)

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New AEBODSYS Label				
New AEDECOD Label				
HEPATOBILIARY 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%)
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%)

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New AEBODSYS Label				
New AEDECOD Label				
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%)
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%)

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New AEBODSYS Label				
New AEDECOD Label				
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%)
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%)
POLLAKIURIA	1 (1%)	0 (0%)	0 (0%)	1 (0%)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS				
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%)
SOCIAL CIRCUMSTANCES				
ANY EVENT	0 (0%)	0 (0%)	1 (1%)	1 (0%)
ALCOHOL USE	0 (0%)	0 (0%)	1 (1%)	1 (0%)

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User: cr715052 /mnt/code/vignettes/AE-Tbls.Rmd 2025-07-31 13:51:50

Protocol: ABCXYZPDQ

Population: Safety

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Page 5 of 6

User: cr715052 /mnt/code/vignettes/AE-Tbls.Rmd 2025-07-31 13:51:50

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New AEBODSYS Label				
New AEDECOD Label				
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%)

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