

Summary of Treatment-Emergent Adverse Events (TEAE)

System Organ Class Preferred Term	Placebo N = 86¹	Xanomeline High Dose N = 72¹	Xanomeline Low Dose N = 96¹
Any TEAE	65 (76%)	68 (94%)	84 (88%)
CARDIAC DISORDERS	12 (14%)	14 (19%)	14 (15%)
ATRIAL FIBRILLATION	1 (1.2%)	2 (2.8%)	2 (2.1%)
ATRIAL FLUTTER	0 (0%)	1 (1.4%)	1 (1.0%)
ATRIAL HYPERTROPHY	1 (1.2%)	0 (0%)	0 (0%)
ATRIOVENTRICULAR BLOCK FIRST DEGREE	1 (1.2%)	0 (0%)	1 (1.0%)
ATRIOVENTRICULAR BLOCK SECOND DEGREE	1 (1.2%)	0 (0%)	0 (0%)
BRADYCARDIA	1 (1.2%)	0 (0%)	0 (0%)
BUNDLE BRANCH BLOCK LEFT	1 (1.2%)	0 (0%)	0 (0%)
BUNDLE BRANCH BLOCK RIGHT	1 (1.2%)	0 (0%)	1 (1.0%)
CARDIAC DISORDER	0 (0%)	1 (1.4%)	0 (0%)
CARDIAC FAILURE CONGESTIVE	1 (1.2%)	0 (0%)	0 (0%)
MYOCARDIAL INFARCTION	4 (4.7%)	4 (5.6%)	2 (2.1%)
PALPITATIONS	0 (0%)	0 (0%)	2 (2.1%)
SINUS ARRHYTHMIA	1 (1.2%)	0 (0%)	0 (0%)
SINUS BRADYCARDIA	2 (2.3%)	8 (11%)	7 (7.3%)
SUPRAVENTRICULAR EXTRASYSTOLES	1 (1.2%)	1 (1.4%)	1 (1.0%)
SUPRAVENTRICULAR TACHYCARDIA	0 (0%)	0 (0%)	1 (1.0%)
TACHYCARDIA	1 (1.2%)	0 (0%)	0 (0%)
VENTRICULAR EXTRASYSTOLES	0 (0%)	1 (1.4%)	2 (2.1%)
VENTRICULAR HYPERTROPHY	1 (1.2%)	0 (0%)	0 (0%)
WOLFF-PARKINSON-WHITE SYNDROME	0 (0%)	0 (0%)	1 (1.0%)

¹ n (%)

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CONGENITAL, FAMILIAL AND GENETIC DISORDERS	0 (0%)	2 (2.8%)	1 (1.0%)
VENTRICULAR SEPTAL DEFECT	0 (0%)	2 (2.8%)	1 (1.0%)
EAR AND LABYRINTH DISORDERS	1 (1.2%)	1 (1.4%)	2 (2.1%)
CERUMEN IMPACTION	0 (0%)	0 (0%)	1 (1.0%)
EAR PAIN	1 (1.2%)	0 (0%)	0 (0%)
VERTIGO	0 (0%)	1 (1.4%)	1 (1.0%)
EYE DISORDERS	2 (2.3%)	1 (1.4%)	2 (2.1%)
CONJUNCTIVAL HAEMORRHAGE	0 (0%)	0 (0%)	1 (1.0%)
CONJUNCTIVITIS	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%)
VISION BLURRED	0 (0%)	1 (1.4%)	1 (1.0%)
GASTROINTESTINAL DISORDERS	17 (20%)	19 (26%)	15 (16%)
ABDOMINAL DISCOMFORT	0 (0%)	1 (1.4%)	0 (0%)
ABDOMINAL PAIN	1 (1.2%)	1 (1.4%)	3 (3.1%)
CONSTIPATION	1 (1.2%)	0 (0%)	0 (0%)
DIARRHOEA	9 (10%)	3 (4.2%)	5 (5.2%)
DYSPEPSIA	1 (1.2%)	0 (0%)	1 (1.0%)
DYSPHAGIA	0 (0%)	0 (0%)	1 (1.0%)
FLATULENCE	1 (1.2%)	0 (0%)	0 (0%)
GASTROINTESTINAL HAEMORRHAGE	0 (0%)	1 (1.4%)	0 (0%)

¹ n (%)

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GASTROOESOPHAGEAL REFLUX DISEASE	1 (1.2%)	0 (0%)	0 (0%)
GLOSSITIS	1 (1.2%)	0 (0%)	0 (0%)
HIATUS HERNIA	1 (1.2%)	0 (0%)	0 (0%)
NAUSEA	3 (3.5%)	6 (8.3%)	3 (3.1%)
RECTAL HAEMORRHAGE	0 (0%)	0 (0%)	1 (1.0%)
SALIVARY HYPERSECRETION	0 (0%)	4 (5.6%)	0 (0%)
STOMACH DISCOMFORT	0 (0%)	1 (1.4%)	0 (0%)
VOMITING	3 (3.5%)	6 (8.3%)	4 (4.2%)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	21 (24%)	36 (50%)	51 (53%)
APPLICATION SITE BLEEDING	0 (0%)	0 (0%)	1 (1.0%)
APPLICATION SITE DERMATITIS	5 (5.8%)	7 (9.7%)	9 (9.4%)
APPLICATION SITE DESQUAMATION	0 (0%)	0 (0%)	1 (1.0%)
APPLICATION SITE DISCHARGE	0 (0%)	1 (1.4%)	0 (0%)
APPLICATION SITE DISCOLOURATION	0 (0%)	0 (0%)	1 (1.0%)
APPLICATION SITE ERYTHEMA	3 (3.5%)	14 (19%)	13 (14%)
APPLICATION SITE INDURATION	1 (1.2%)	0 (0%)	0 (0%)
APPLICATION SITE IRRITATION	3 (3.5%)	9 (13%)	9 (9.4%)
APPLICATION SITE PAIN	0 (0%)	2 (2.8%)	0 (0%)
APPLICATION SITE PERSPIRATION	0 (0%)	2 (2.8%)	0 (0%)
APPLICATION SITE PRURITUS	6 (7.0%)	21 (29%)	23 (24%)
APPLICATION SITE REACTION	1 (1.2%)	1 (1.4%)	0 (0%)
APPLICATION SITE SWELLING	0 (0%)	2 (2.8%)	1 (1.0%)
APPLICATION SITE URTICARIA	0 (0%)	1 (1.4%)	2 (2.1%)

¹ n (%)

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APPLICATION SITE VESICLES	1 (1.2%)	5 (6.9%)	5 (5.2%)
APPLICATION SITE WARMTH	0 (0%)	0 (0%)	1 (1.0%)
ASTHENIA	1 (1.2%)	0 (0%)	1 (1.0%)
CHEST DISCOMFORT	0 (0%)	1 (1.4%)	1 (1.0%)
CHEST PAIN	0 (0%)	2 (2.8%)	0 (0%)
CHILLS	1 (1.2%)	1 (1.4%)	1 (1.0%)
FATIGUE	1 (1.2%)	5 (6.9%)	5 (5.2%)
FEELING ABNORMAL	0 (0%)	1 (1.4%)	0 (0%)
FEELING COLD	0 (0%)	1 (1.4%)	0 (0%)
INFLAMMATION	0 (0%)	0 (0%)	1 (1.0%)
MALAISE	0 (0%)	2 (2.8%)	1 (1.0%)
OEDEMA	0 (0%)	0 (0%)	2 (2.1%)
OEDEMA PERIPHERAL	2 (2.3%)	2 (2.8%)	1 (1.0%)
PAIN	0 (0%)	1 (1.4%)	1 (1.0%)
PYREXIA	2 (2.3%)	0 (0%)	1 (1.0%)
SECRETION DISCHARGE	0 (0%)	0 (0%)	1 (1.0%)
SUDDEN DEATH	0 (0%)	0 (0%)	1 (1.0%)
SWELLING	0 (0%)	0 (0%)	1 (1.0%)
ULCER	0 (0%)	0 (0%)	1 (1.0%)
HEPATOBIILIARY DISORDERS	1 (1.2%)	0 (0%)	0 (0%)
HYPERBILIRUBINAEMIA	1 (1.2%)	0 (0%)	0 (0%)
IMMUNE SYSTEM DISORDERS	0 (0%)	0 (0%)	1 (1.0%)
HYPERSENSITIVITY	0 (0%)	0 (0%)	1 (1.0%)
¹ n (%)			

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System Organ Class Preferred Term	Placebo N = 86¹	Xanomeline High Dose N = 72¹	Xanomeline Low Dose N = 96¹
INFECTIONS AND INFESTATIONS	16 (19%)	13 (18%)	9 (9.4%)
BRONCHITIS	1 (1.2%)	0 (0%)	0 (0%)
CELLULITIS	0 (0%)	0 (0%)	1 (1.0%)
CERVICITIS	1 (1.2%)	0 (0%)	0 (0%)
CYSTITIS	1 (1.2%)	1 (1.4%)	0 (0%)
EAR INFECTION	2 (2.3%)	0 (0%)	0 (0%)
GASTROENTERITIS VIRAL	1 (1.2%)	0 (0%)	0 (0%)
HORDEOLUM	0 (0%)	1 (1.4%)	0 (0%)
INFLUENZA	1 (1.2%)	1 (1.4%)	1 (1.0%)
LOCALISED INFECTION	1 (1.2%)	0 (0%)	0 (0%)
LOWER RESPIRATORY TRACT INFECTION	0 (0%)	1 (1.4%)	0 (0%)
NASOPHARYNGITIS	2 (2.3%)	6 (8.3%)	4 (4.2%)
PNEUMONIA	0 (0%)	0 (0%)	1 (1.0%)
RHINITIS	0 (0%)	1 (1.4%)	0 (0%)
UPPER RESPIRATORY TRACT INFECTION	6 (7.0%)	3 (4.2%)	1 (1.0%)
URINARY TRACT INFECTION	2 (2.3%)	1 (1.4%)	0 (0%)
VAGINAL MYCOSIS	1 (1.2%)	0 (0%)	0 (0%)
VIRAL INFECTION	0 (0%)	0 (0%)	1 (1.0%)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	4 (4.7%)	5 (6.9%)	5 (5.2%)
CONTUSION	1 (1.2%)	2 (2.8%)	1 (1.0%)
EXCORIATION	2 (2.3%)	1 (1.4%)	1 (1.0%)
FACIAL BONES FRACTURE	0 (0%)	1 (1.4%)	0 (0%)
FALL	1 (1.2%)	1 (1.4%)	2 (2.1%)

¹ n (%)

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System Organ Class Preferred Term	Placebo N = 86¹	Xanomeline High Dose N = 72¹	Xanomeline Low Dose N = 96¹
HIP FRACTURE	1 (1.2%)	2 (2.8%)	0 (0%)
JOINT DISLOCATION	0 (0%)	0 (0%)	1 (1.0%)
SKIN LACERATION	1 (1.2%)	0 (0%)	2 (2.1%)
WOUND	0 (0%)	0 (0%)	1 (1.0%)
INVESTIGATIONS	10 (12%)	5 (6.9%)	7 (7.3%)
BIOPSY	0 (0%)	1 (1.4%)	0 (0%)
BIOPSY PROSTATE	0 (0%)	1 (1.4%)	0 (0%)
BLOOD ALKALINE PHOSPHATASE INCREASED	1 (1.2%)	0 (0%)	0 (0%)
BLOOD CHOLESTEROL INCREASED	0 (0%)	1 (1.4%)	0 (0%)
BLOOD CREATINE PHOSPHOKINASE INCREASED	1 (1.2%)	0 (0%)	0 (0%)
BLOOD GLUCOSE INCREASED	0 (0%)	1 (1.4%)	1 (1.0%)
BLOOD URINE PRESENT	1 (1.2%)	0 (0%)	0 (0%)
BODY TEMPERATURE INCREASED	0 (0%)	0 (0%)	1 (1.0%)
CYSTOSCOPY	1 (1.2%)	0 (0%)	0 (0%)
ELECTROCARDIOGRAM ST SEGMENT DEPRESSION	4 (4.7%)	0 (0%)	1 (1.0%)
ELECTROCARDIOGRAM T WAVE AMPLITUDE DECREASED	1 (1.2%)	0 (0%)	1 (1.0%)
ELECTROCARDIOGRAM T WAVE INVERSION	2 (2.3%)	1 (1.4%)	1 (1.0%)
HEART RATE INCREASED	1 (1.2%)	0 (0%)	0 (0%)
HEART RATE IRREGULAR	1 (1.2%)	0 (0%)	0 (0%)
NASAL MUCOSA BIOPSY	0 (0%)	0 (0%)	1 (1.0%)
WEIGHT DECREASED	0 (0%)	0 (0%)	1 (1.0%)

¹ n (%)

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System Organ Class Preferred Term	Placebo N = 86[†]	Xanomeline High Dose N = 72[†]	Xanomeline Low Dose N = 96[†]
METABOLISM AND NUTRITION DISORDERS	6 (7.0%)	2 (2.8%)	1 (1.0%)
DECREASED APPETITE	1 (1.2%)	1 (1.4%)	0 (0%)
DEHYDRATION	1 (1.2%)	0 (0%)	0 (0%)
DIABETES MELLITUS	1 (1.2%)	0 (0%)	0 (0%)
FOOD CRAVING	1 (1.2%)	0 (0%)	1 (1.0%)
HYPONATRAEMIA	1 (1.2%)	0 (0%)	0 (0%)
INCREASED APPETITE	1 (1.2%)	1 (1.4%)	0 (0%)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	4 (4.7%)	7 (9.7%)	7 (7.3%)
ARTHRALGIA	1 (1.2%)	1 (1.4%)	2 (2.1%)
ARTHRITIS	0 (0%)	1 (1.4%)	0 (0%)
BACK PAIN	1 (1.2%)	3 (4.2%)	1 (1.0%)
FLANK PAIN	0 (0%)	1 (1.4%)	0 (0%)
MUSCLE SPASMS	0 (0%)	1 (1.4%)	1 (1.0%)
MUSCULAR WEAKNESS	0 (0%)	0 (0%)	1 (1.0%)
MYALGIA	0 (0%)	1 (1.4%)	0 (0%)
PAIN IN EXTREMITY	1 (1.2%)	0 (0%)	0 (0%)
SHOULDER PAIN	1 (1.2%)	0 (0%)	2 (2.1%)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0 (0%)	1 (1.4%)	2 (2.1%)
COLON CANCER	0 (0%)	0 (0%)	1 (1.0%)
MALIGNANT FIBROUS HISTIOCYTOMA	0 (0%)	0 (0%)	1 (1.0%)
PROSTATE CANCER	0 (0%)	1 (1.4%)	0 (0%)
NERVOUS SYSTEM DISORDERS	8 (9.3%)	23 (32%)	22 (23%)
[†] n (%)			

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System Organ Class Preferred Term	Placebo N = 86¹	Xanomeline High Dose N = 72¹	Xanomeline Low Dose¹ N = 96¹
AMNESIA	0 (0%)	1 (1.4%)	0 (0%)
BALANCE DISORDER	0 (0%)	0 (0%)	1 (1.0%)
BURNING SENSATION	0 (0%)	2 (2.8%)	0 (0%)
COGNITIVE DISORDER	0 (0%)	1 (1.4%)	0 (0%)
COMPLEX PARTIAL SEIZURES	0 (0%)	0 (0%)	1 (1.0%)
COORDINATION ABNORMAL	0 (0%)	0 (0%)	1 (1.0%)
DIZZINESS	2 (2.3%)	10 (14%)	9 (9.4%)
HEADACHE	3 (3.5%)	5 (6.9%)	3 (3.1%)
HEMIANOPIA HOMONYMOUS	0 (0%)	0 (0%)	1 (1.0%)
HYPERSOMNIA	0 (0%)	1 (1.4%)	0 (0%)
LETHARGY	0 (0%)	1 (1.4%)	1 (1.0%)
PARAESTHESIA	0 (0%)	1 (1.4%)	0 (0%)
PARAESTHESIA ORAL	0 (0%)	0 (0%)	1 (1.0%)
PARKINSON'S DISEASE	1 (1.2%)	0 (0%)	0 (0%)
PAROSMIA	0 (0%)	1 (1.4%)	0 (0%)
PARTIAL SEIZURES WITH SECONDARY GENERALISATION	0 (0%)	1 (1.4%)	0 (0%)
PSYCHOMOTOR HYPERACTIVITY	1 (1.2%)	0 (0%)	0 (0%)
SOMNOLENCE	2 (2.3%)	1 (1.4%)	3 (3.1%)
STUPOR	0 (0%)	0 (0%)	1 (1.0%)
SYNCOPE	0 (0%)	2 (2.8%)	5 (5.2%)
SYNCOPE VASOVAGAL	0 (0%)	1 (1.4%)	0 (0%)
TRANSIENT ISCHAEMIC ATTACK	0 (0%)	1 (1.4%)	2 (2.1%)
PSYCHIATRIC DISORDERS	10 (12%)	7 (9.7%)	11 (11%)

¹ n (%)

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AGITATION	2 (2.3%)	0 (0%)	3 (3.1%)
ANXIETY	0 (0%)	0 (0%)	3 (3.1%)
COMPLETED SUICIDE	1 (1.2%)	0 (0%)	0 (0%)
CONFUSIONAL STATE	2 (2.3%)	1 (1.4%)	3 (3.1%)
DELIRIUM	0 (0%)	1 (1.4%)	0 (0%)
DELUSION	1 (1.2%)	1 (1.4%)	0 (0%)
DEPRESSED MOOD	0 (0%)	0 (0%)	1 (1.0%)
DISORIENTATION	1 (1.2%)	0 (0%)	0 (0%)
HALLUCINATION	0 (0%)	1 (1.4%)	0 (0%)
HALLUCINATION, VISUAL	0 (0%)	1 (1.4%)	0 (0%)
INSOMNIA	2 (2.3%)	2 (2.8%)	0 (0%)
IRRITABILITY	1 (1.2%)	0 (0%)	1 (1.0%)
LIBIDO DECREASED	0 (0%)	1 (1.4%)	0 (0%)
LISTLESS	0 (0%)	1 (1.4%)	0 (0%)
NIGHTMARE	0 (0%)	1 (1.4%)	0 (0%)
RESTLESSNESS	0 (0%)	0 (0%)	1 (1.0%)
RENAL AND URINARY DISORDERS	4 (4.7%)	3 (4.2%)	3 (3.1%)
CALCULUS URETHRAL	0 (0%)	1 (1.4%)	0 (0%)
DYSURIA	1 (1.2%)	0 (0%)	1 (1.0%)
INCONTINENCE	0 (0%)	0 (0%)	1 (1.0%)
MICTURITION URGENCY	1 (1.2%)	1 (1.4%)	1 (1.0%)
NEPHROLITHIASIS	1 (1.2%)	1 (1.4%)	0 (0%)
POLLAKIURIA	1 (1.2%)	0 (0%)	0 (0%)

¹ n (%)

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REPRODUCTIVE SYSTEM AND BREAST DISORDERS	2 (2.3%)	1 (1.4%)	0 (0%)
BENIGN PROSTATIC HYPERPLASIA	1 (1.2%)	1 (1.4%)	0 (0%)
PELVIC PAIN	1 (1.2%)	0 (0%)	0 (0%)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	8 (9.3%)	10 (14%)	9 (9.4%)
ALLERGIC GRANULOMATOUS ANGIITIS	0 (0%)	1 (1.4%)	0 (0%)
COUGH	1 (1.2%)	5 (6.9%)	5 (5.2%)
DYSPHONIA	0 (0%)	0 (0%)	1 (1.0%)
DYSPNOEA	1 (1.2%)	1 (1.4%)	1 (1.0%)
EMPHYSEMA	1 (1.2%)	0 (0%)	0 (0%)
EPISTAXIS	0 (0%)	2 (2.8%)	1 (1.0%)
HAEMOPTYSIS	1 (1.2%)	0 (0%)	0 (0%)
NASAL CONGESTION	3 (3.5%)	3 (4.2%)	1 (1.0%)
PHARYNGEAL ERYTHEMA	0 (0%)	1 (1.4%)	0 (0%)
PHARYNGOLARYNGEAL PAIN	0 (0%)	1 (1.4%)	1 (1.0%)
POSTNASAL DRIP	1 (1.2%)	0 (0%)	0 (0%)
PRODUCTIVE COUGH	0 (0%)	1 (1.4%)	0 (0%)
RALES	1 (1.2%)	0 (0%)	0 (0%)
RESPIRATORY TRACT CONGESTION	0 (0%)	1 (1.4%)	0 (0%)
RHINORRHOEA	0 (0%)	1 (1.4%)	1 (1.0%)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	20 (23%)	39 (54%)	39 (41%)
ACTINIC KERATOSIS	0 (0%)	1 (1.4%)	0 (0%)
ALOPECIA	1 (1.2%)	0 (0%)	0 (0%)

¹ n (%)

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BLISTER	0 (0%)	1 (1.4%)	5 (5.2%)
COLD SWEAT	1 (1.2%)	0 (0%)	0 (0%)
DERMATITIS CONTACT	0 (0%)	0 (0%)	1 (1.0%)
DRUG ERUPTION	1 (1.2%)	0 (0%)	0 (0%)
ERYTHEMA	8 (9.3%)	14 (19%)	14 (15%)
HYPERHIDROSIS	2 (2.3%)	8 (11%)	4 (4.2%)
PRURITUS	8 (9.3%)	25 (35%)	21 (22%)
PRURITUS GENERALISED	0 (0%)	1 (1.4%)	1 (1.0%)
RASH	5 (5.8%)	8 (11%)	13 (14%)
RASH ERYTHEMATOUS	0 (0%)	0 (0%)	1 (1.0%)
RASH MACULO-PAPULAR	0 (0%)	1 (1.4%)	0 (0%)
RASH PRURITIC	0 (0%)	2 (2.8%)	1 (1.0%)
SKIN EXFOLIATION	0 (0%)	0 (0%)	1 (1.0%)
SKIN IRRITATION	3 (3.5%)	5 (6.9%)	6 (6.3%)
SKIN ODOUR ABNORMAL	0 (0%)	1 (1.4%)	0 (0%)
SKIN ULCER	1 (1.2%)	0 (0%)	0 (0%)
URTICARIA	0 (0%)	1 (1.4%)	1 (1.0%)
SOCIAL CIRCUMSTANCES	0 (0%)	1 (1.4%)	0 (0%)
ALCOHOL USE	0 (0%)	1 (1.4%)	0 (0%)
SURGICAL AND MEDICAL PROCEDURES	2 (2.3%)	2 (2.8%)	1 (1.0%)
ACROCHORDON EXCISION	0 (0%)	1 (1.4%)	0 (0%)
CATARACT OPERATION	1 (1.2%)	0 (0%)	1 (1.0%)
EYE LASER SURGERY	1 (1.2%)	0 (0%)	0 (0%)

¹ n (%)

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SKIN LESION EXCISION	0 (0%)	1 (1.4%)	0 (0%)
VASCULAR DISORDERS	3 (3.5%)	1 (1.4%)	3 (3.1%)
HOT FLUSH	0 (0%)	0 (0%)	1 (1.0%)
HYPERTENSION	1 (1.2%)	0 (0%)	1 (1.0%)
HYPOTENSION	2 (2.3%)	0 (0%)	1 (1.0%)
ORTHOSTATIC HYPOTENSION	1 (1.2%)	0 (0%)	0 (0%)
WOUND HAEMORRHAGE	0 (0%)	1 (1.4%)	0 (0%)

¹ n (%)