

TEAE by PT - Odds Ratio
Safety Analysis Set
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Preferred Term	Placebo (N=86) n (%)	Active (N=84) n (%)	OR (95% CI)
Overall	65 (75.6%)	77 (91.7%)	3.6 (1.4,8.9)
ABDOMINAL DISCOMFORT	0	0	-
ABDOMINAL PAIN	1 (1.2%)	3 (3.6%)	3.1 (0.3,30.9)
ACROCHORDON EXCISION	0	0	-
ACTINIC KERATOSIS	0	0	-
AGITATION	2 (2.3%)	2 (2.4%)	1.0 (0.1,7.4)
ALCOHOL USE	0	0	-
ALLERGIC GRANULOMATOUS ANGIITIS	0	0	-
ALOPECIA	1 (1.2%)	0	-
AMNESIA	0	0	-
ANXIETY	0	3 (3.6%)	-
APPLICATION SITE BLEEDING	0	1 (1.2%)	-
APPLICATION SITE DERMATITIS	5 (5.8%)	9 (10.7%)	1.9 (0.6,6.1)
APPLICATION SITE DESQUAMATION	0	1 (1.2%)	-
APPLICATION SITE DISCHARGE	0	0	-
APPLICATION SITE DISCOLOURATION	0	1 (1.2%)	-
APPLICATION SITE ERYTHEMA	3 (3.5%)	12 (14.3%)	4.6 (1.3,17.0)
APPLICATION SITE INDURATION	1 (1.2%)	0	-
APPLICATION SITE IRRITATION	3 (3.5%)	9 (10.7%)	3.3 (0.9,12.7)
APPLICATION SITE PAIN	0	0	-
APPLICATION SITE PERSPIRATION	0	0	-
APPLICATION SITE PRURITUS	6 (7.0%)	22 (26.2%)	4.7 (1.8,12.4)

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APPLICATION SITE REACTION	1 (1.2%)	0	-
APPLICATION SITE SWELLING	0	1 (1.2%)	-
APPLICATION SITE URTICARIA	0	2 (2.4%)	-
APPLICATION SITE VESICLES	1 (1.2%)	4 (4.8%)	4.3 (0.5,38.8)
APPLICATION SITE WARMTH	0	1 (1.2%)	-
ARTHRALGIA	1 (1.2%)	2 (2.4%)	2.1 (0.2,23.3)
ARTHRITIS	0	0	-
ASTHENIA	1 (1.2%)	0	-
ATRIAL FIBRILLATION	1 (1.2%)	1 (1.2%)	1.0 (0.1,16.6)
ATRIAL FLUTTER	0	1 (1.2%)	-
ATRIAL HYPERTROPHY	1 (1.2%)	0	-
ATRIOVENTRICULAR BLOCK FIRST DEGREE	1 (1.2%)	1 (1.2%)	1.0 (0.1,16.6)
ATRIOVENTRICULAR BLOCK SECOND DEGREE	1 (1.2%)	0	-
BACK PAIN	1 (1.2%)	1 (1.2%)	1.0 (0.1,16.6)
BALANCE DISORDER	0	1 (1.2%)	-
BENIGN PROSTATIC HYPERPLASIA	1 (1.2%)	0	-
BIOPSY	0	0	-
BIOPSY PROSTATE	0	0	-
BLISTER	0	5 (6.0%)	-
BLOOD ALKALINE PHOSPHATASE INCREASED	1 (1.2%)	0	-
BLOOD CHOLESTEROL INCREASED	0	0	-
BLOOD CREATINE PHOSPHOKINASE INCREASED	1 (1.2%)	0	-
BLOOD GLUCOSE INCREASED	0	1 (1.2%)	-

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BLOOD URINE PRESENT	1 (1.2%)	0	-
BODY TEMPERATURE INCREASED	0	1 (1.2%)	-
BRADYCARDIA	1 (1.2%)	0	-
BRONCHITIS	1 (1.2%)	0	-
BUNDLE BRANCH BLOCK LEFT	1 (1.2%)	0	-
BUNDLE BRANCH BLOCK RIGHT	1 (1.2%)	1 (1.2%)	1.0 (0.1,16.6)
BURNING SENSATION	0	0	-
CALCULUS URETHRAL	0	0	-
CARDIAC DISORDER	0	0	-
CARDIAC FAILURE CONGESTIVE	1 (1.2%)	0	-
CATARACT OPERATION	1 (1.2%)	1 (1.2%)	1.0 (0.1,16.6)
CELLULITIS	0	1 (1.2%)	-
CERUMEN IMPACTION	0	1 (1.2%)	-
CERVICITIS	1 (1.2%)	0	-
CHEST DISCOMFORT	0	0	-
CHEST PAIN	0	0	-
CHILLS	1 (1.2%)	1 (1.2%)	1.0 (0.1,16.6)
COGNITIVE DISORDER	0	0	-
COLD SWEAT	1 (1.2%)	0	-
COLON CANCER	0	1 (1.2%)	-
COMPLETED SUICIDE	1 (1.2%)	0	-
COMPLEX PARTIAL SEIZURES	0	1 (1.2%)	-
CONFUSIONAL STATE	2 (2.3%)	3 (3.6%)	1.6 (0.3,9.6)

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CONJUNCTIVAL HAEMORRHAGE	0	1 (1.2%)	-
CONJUNCTIVITIS	1 (1.2%)	0	-
CONSTIPATION	1 (1.2%)	0	-
CONTUSION	1 (1.2%)	1 (1.2%)	1.0 (0.1,16.6)
COORDINATION ABNORMAL	0	1 (1.2%)	-
COUGH	1 (1.2%)	5 (6.0%)	5.4 (0.6,47.1)
CYSTITIS	1 (1.2%)	0	-
CYSTOSCOPY	1 (1.2%)	0	-
DECREASED APPETITE	1 (1.2%)	0	-
DEHYDRATION	1 (1.2%)	0	-
DELIRIUM	0	0	-
DELUSION	1 (1.2%)	0	-
DEPRESSED MOOD	0	1 (1.2%)	-
DERMATITIS CONTACT	0	1 (1.2%)	-
DIABETES MELLITUS	1 (1.2%)	0	-
DIARRHOEA	9 (10.5%)	4 (4.8%)	0.4 (0.1,1.4)
DISORIENTATION	1 (1.2%)	0	-
DIZZINESS	2 (2.3%)	8 (9.5%)	4.4 (0.9,21.5)
DRUG ERUPTION	1 (1.2%)	0	-
DYSPEPSIA	1 (1.2%)	1 (1.2%)	1.0 (0.1,16.6)
DYSPHAGIA	0	1 (1.2%)	-
DYSPHONIA	0	1 (1.2%)	-
DYSPNOEA	1 (1.2%)	1 (1.2%)	1.0 (0.1,16.6)

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DYSURIA	1 (1.2%)	1 (1.2%)	1.0 (0.1,16.6)
EAR INFECTION	2 (2.3%)	0	-
EAR PAIN	1 (1.2%)	0	-
ELECTROCARDIOGRAM ST SEGMENT DEPRESSION	4 (4.7%)	1 (1.2%)	0.2 (0.0,2.3)
ELECTROCARDIOGRAM T WAVE AMPLITUDE DECREASED	1 (1.2%)	1 (1.2%)	1.0 (0.1,16.6)
ELECTROCARDIOGRAM T WAVE INVERSION	2 (2.3%)	1 (1.2%)	0.5 (0.0,5.7)
EMPHYSEMA	1 (1.2%)	0	-
EPISTAXIS	0	1 (1.2%)	-
ERYTHEMA	8 (9.3%)	14 (16.7%)	2.0 (0.8,4.9)
EXCORIATION	2 (2.3%)	1 (1.2%)	0.5 (0.0,5.7)
EYE ALLERGY	1 (1.2%)	0	-
EYE LASER SURGERY	1 (1.2%)	0	-
EYE PRURITUS	1 (1.2%)	0	-
EYE SWELLING	1 (1.2%)	0	-
FACIAL BONES FRACTURE	0	0	-
FALL	1 (1.2%)	2 (2.4%)	2.1 (0.2,23.3)
FATIGUE	1 (1.2%)	5 (6.0%)	5.4 (0.6,47.1)
FEELING ABNORMAL	0	0	-
FEELING COLD	0	0	-
FLANK PAIN	0	0	-
FLATULENCE	1 (1.2%)	0	-
FOOD CRAVING	1 (1.2%)	1 (1.2%)	1.0 (0.1,16.6)
GASTROENTERITIS VIRAL	1 (1.2%)	0	-

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GASTROINTESTINAL HAEMORRHAGE	0	0	-
GASTROESOPHAGEAL REFLUX DISEASE	1 (1.2%)	0	-
GLOSSITIS	1 (1.2%)	0	-
HAEMOPTYSIS	1 (1.2%)	0	-
HALLUCINATION	0	0	-
HALLUCINATION, VISUAL	0	0	-
HEADACHE	3 (3.5%)	3 (3.6%)	1.0 (0.2,5.2)
HEART RATE INCREASED	1 (1.2%)	0	-
HEART RATE IRREGULAR	1 (1.2%)	0	-
HEMIANOPIA HOMONYMOUS	0	1 (1.2%)	-
HIATUS HERNIA	1 (1.2%)	0	-
HIP FRACTURE	1 (1.2%)	0	-
HORDEOLUM	0	0	-
HOT FLUSH	0	1 (1.2%)	-
HYPERBILIRUBINAEMIA	1 (1.2%)	0	-
HYPERHIDROSIS	2 (2.3%)	4 (4.8%)	2.1 (0.4,11.8)
HYPERSENSITIVITY	0	1 (1.2%)	-
HYPERSOMNIA	0	0	-
HYPERTENSION	1 (1.2%)	1 (1.2%)	1.0 (0.1,16.6)
HYPONATRAEMIA	1 (1.2%)	0	-
HYPOTENSION	2 (2.3%)	1 (1.2%)	0.5 (0.0,5.7)
INCONTINENCE	0	1 (1.2%)	-
INCREASED APPETITE	1 (1.2%)	0	-

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INFLAMMATION	0	1 (1.2%)	-
INFLUENZA	1 (1.2%)	1 (1.2%)	1.0 (0.1,16.6)
INSOMNIA	2 (2.3%)	0	-
IRRITABILITY	1 (1.2%)	1 (1.2%)	1.0 (0.1,16.6)
JOINT DISLOCATION	0	1 (1.2%)	-
LETHARGY	0	1 (1.2%)	-
LIBIDO DECREASED	0	0	-
LISTLESS	0	0	-
LOCALISED INFECTION	1 (1.2%)	0	-
LOWER RESPIRATORY TRACT INFECTION	0	0	-
MALAISE	0	1 (1.2%)	-
MALIGNANT FIBROUS HISTIOCYTOMA	0	1 (1.2%)	-
MICTURITION URGENCY	1 (1.2%)	1 (1.2%)	1.0 (0.1,16.6)
MUSCLE SPASMS	0	1 (1.2%)	-
MUSCULAR WEAKNESS	0	1 (1.2%)	-
MYALGIA	0	0	-
MYOCARDIAL INFARCTION	4 (4.7%)	2 (2.4%)	0.5 (0.1,2.8)
NASAL CONGESTION	3 (3.5%)	1 (1.2%)	0.3 (0.0,3.3)
NASAL MUCOSA BIOPSY	0	1 (1.2%)	-
NASOPHARYNGITIS	2 (2.3%)	4 (4.8%)	2.1 (0.4,11.8)
NAUSEA	3 (3.5%)	3 (3.6%)	1.0 (0.2,5.2)
NEPHROLITHIASIS	1 (1.2%)	0	-
NIGHTMARE	0	0	-

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OEDEMA	0	2 (2.4%)	-
OEDEMA PERIPHERAL	2 (2.3%)	1 (1.2%)	0.5 (0.0,5.7)
ORTHOSTATIC HYPOTENSION	1 (1.2%)	0	-
PAIN	0	1 (1.2%)	-
PAIN IN EXTREMITY	1 (1.2%)	0	-
PALPITATIONS	0	2 (2.4%)	-
PARAESTHESIA	0	0	-
PARAESTHESIA ORAL	0	1 (1.2%)	-
PARKINSON'S DISEASE	1 (1.2%)	0	-
PAROSMIA	0	0	-
PARTIAL SEIZURES WITH SECONDARY GENERALISATION	0	0	-
PELVIC PAIN	1 (1.2%)	0	-
PHARYNGEAL ERYTHEMA	0	0	-
PHARYNGOLARYNGEAL PAIN	0	1 (1.2%)	-
PNEUMONIA	0	1 (1.2%)	-
POLLAKIURIA	1 (1.2%)	0	-
POSTNASAL DRIP	1 (1.2%)	0	-
PRODUCTIVE COUGH	0	0	-
PROSTATE CANCER	0	0	-
PRURITUS	8 (9.3%)	21 (25.0%)	3.3 (1.3,7.8)
PRURITUS GENERALISED	0	1 (1.2%)	-
PSYCHOMOTOR HYPERACTIVITY	1 (1.2%)	0	-
PYREXIA	2 (2.3%)	0	-

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RALES	1 (1.2%)	0	-
RASH	5 (5.8%)	13 (15.5%)	3.0 (1.0,8.7)
RASH ERYTHEMATOUS	0	1 (1.2%)	-
RASH MACULO-PAPULAR	0	0	-
RASH PRURITIC	0	1 (1.2%)	-
RECTAL HAEMORRHAGE	0	1 (1.2%)	-
RESPIRATORY TRACT CONGESTION	0	0	-
RESTLESSNESS	0	1 (1.2%)	-
RHINITIS	0	0	-
RHINORRHOEA	0	1 (1.2%)	-
SALIVARY HYPERSECRETION	0	0	-
SECRETION DISCHARGE	0	1 (1.2%)	-
SHOULDER PAIN	1 (1.2%)	2 (2.4%)	2.1 (0.2,23.3)
SINUS ARRHYTHMIA	1 (1.2%)	0	-
SINUS BRADYCARDIA	2 (2.3%)	7 (8.3%)	3.8 (0.8,18.9)
SKIN EXFOLIATION	0	1 (1.2%)	-
SKIN IRRITATION	3 (3.5%)	6 (7.1%)	2.1 (0.5,8.8)
SKIN LACERATION	1 (1.2%)	2 (2.4%)	2.1 (0.2,23.3)
SKIN LESION EXCISION	0	0	-
SKIN ODOUR ABNORMAL	0	0	-
SKIN ULCER	1 (1.2%)	0	-
SOMNOLENCE	2 (2.3%)	3 (3.6%)	1.6 (0.3,9.6)
STOMACH DISCOMFORT	0	0	-

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STUPOR	0	1 (1.2%)	-
SUDDEN DEATH	0	1 (1.2%)	-
SUPRAVENTRICULAR EXTRASYSTOLES	1 (1.2%)	1 (1.2%)	1.0 (0.1,16.6)
SUPRAVENTRICULAR TACHYCARDIA	0	1 (1.2%)	-
SWELLING	0	1 (1.2%)	-
SYNCOPE	0	4 (4.8%)	-
SYNCOPE VASOVAGAL	0	0	-
TACHYCARDIA	1 (1.2%)	0	-
TRANSIENT ISCHAEMIC ATTACK	0	2 (2.4%)	-
ULCER	0	1 (1.2%)	-
UPPER RESPIRATORY TRACT INFECTION	6 (7.0%)	1 (1.2%)	0.2 (0.0,1.4)
URINARY TRACT INFECTION	2 (2.3%)	0	-
URTICARIA	0	1 (1.2%)	-
VAGINAL MYCOSIS	1 (1.2%)	0	-
VENTRICULAR EXTRASYSTOLES	0	2 (2.4%)	-
VENTRICULAR HYPERTROPHY	1 (1.2%)	0	-
VENTRICULAR SEPTAL DEFECT	0	1 (1.2%)	-
VERTIGO	0	1 (1.2%)	-
VIRAL INFECTION	0	1 (1.2%)	-
VISION BLURRED	0	1 (1.2%)	-
VOMITING	3 (3.5%)	3 (3.6%)	1.0 (0.2,5.2)
WEIGHT DECREASED	0	0	-
WOLFF-PARKINSON-WHITE SYNDROME	0	1 (1.2%)	-

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WOUND	0	1 (1.2%)	-
WOUND HAEMORRHAGE	0	0	-