

TEAE by PT - Risk Difference

Safety Analysis Set

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Preferred Term	Placebo (N=86) n (%)	Active (N=84) n (%)	RD (95% CI)
Overall	65 (75.6%)	77 (91.7%)	0.161 (0.053,0.269)
ABDOMINAL DISCOMFORT	0	0	-
ABDOMINAL PAIN	1 (1.2%)	3 (3.6%)	0.024 (-0.022,0.070)
ACROCHORDON EXCISION	0	0	-
ACTINIC KERATOSIS	0	0	-
AGITATION	2 (2.3%)	2 (2.4%)	0.001 (-0.045,0.046)
ALCOHOL USE	0	0	-
ALLERGIC GRANULOMATOUS ANGIITIS	0	0	-
ALOPECIA	1 (1.2%)	0	-0.012 (-0.034,0.011)
AMNESIA	0	0	-
ANXIETY	0	3 (3.6%)	0.036 (-0.004,0.075)
APPLICATION SITE BLEEDING	0	1 (1.2%)	0.012 (-0.011,0.035)
APPLICATION SITE DERMATITIS	5 (5.8%)	9 (10.7%)	0.049 (-0.034,0.132)
APPLICATION SITE DESQUAMATION	0	1 (1.2%)	0.012 (-0.011,0.035)
APPLICATION SITE DISCHARGE	0	0	-
APPLICATION SITE DISCOLOURATION	0	1 (1.2%)	0.012 (-0.011,0.035)
APPLICATION SITE ERYTHEMA	3 (3.5%)	12 (14.3%)	0.108 (0.024,0.192)

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Preferred Term	Placebo (N=86) n (%)	Active (N=84) n (%)	RD (95% CI)
APPLICATION SITE INDURATION	1 (1.2%)	0	-0.012 (-0.034,0.011)
APPLICATION SITE IRRITATION	3 (3.5%)	9 (10.7%)	0.072 (-0.004,0.149)
APPLICATION SITE PAIN	0	0	-
APPLICATION SITE PERSPIRATION	0	0	-
APPLICATION SITE PRURITUS	6 (7.0%)	22 (26.2%)	0.192 (0.084,0.300)
APPLICATION SITE REACTION	1 (1.2%)	0	-0.012 (-0.034,0.011)
APPLICATION SITE SWELLING	0	1 (1.2%)	0.012 (-0.011,0.035)
APPLICATION SITE URTICARIA	0	2 (2.4%)	0.024 (-0.009,0.056)
APPLICATION SITE VESICLES	1 (1.2%)	4 (4.8%)	0.036 (-0.015,0.087)
APPLICATION SITE WARMTH	0	1 (1.2%)	0.012 (-0.011,0.035)
ARTHRALGIA	1 (1.2%)	2 (2.4%)	0.012 (-0.028,0.052)
ARTHRITIS	0	0	-
ASTHENIA	1 (1.2%)	0	-0.012 (-0.034,0.011)
ATRIAL FIBRILLATION	1 (1.2%)	1 (1.2%)	0.000 (-0.032,0.033)
ATRIAL FLUTTER	0	1 (1.2%)	0.012 (-0.011,0.035)

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ATRIAL HYPERTROPHY	1 (1.2%)	0	-0.012 (-0.034,0.011)
ATRIOVENTRICULAR BLOCK FIRST DEGREE	1 (1.2%)	1 (1.2%)	0.000 (-0.032,0.033)
ATRIOVENTRICULAR BLOCK SECOND DEGREE	1 (1.2%)	0	-0.012 (-0.034,0.011)
BACK PAIN	1 (1.2%)	1 (1.2%)	0.000 (-0.032,0.033)
BALANCE DISORDER	0	1 (1.2%)	0.012 (-0.011,0.035)
BENIGN PROSTATIC HYPERPLASIA	1 (1.2%)	0	-0.012 (-0.034,0.011)
BIOPSY	0	0	-
BIOPSY PROSTATE	0	0	-
BLISTER	0	5 (6.0%)	0.060 (0.009,0.110)
BLOOD ALKALINE PHOSPHATASE INCREASED	1 (1.2%)	0	-0.012 (-0.034,0.011)
BLOOD CHOLESTEROL INCREASED	0	0	-
BLOOD CREATINE PHOSPHOKINASE INCREASED	1 (1.2%)	0	-0.012 (-0.034,0.011)
BLOOD GLUCOSE INCREASED	0	1 (1.2%)	0.012 (-0.011,0.035)
BLOOD URINE PRESENT	1 (1.2%)	0	-0.012 (-0.034,0.011)
BODY TEMPERATURE INCREASED	0	1 (1.2%)	0.012 (-0.011,0.035)

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Preferred Term	Placebo (N=86) n (%)	Active (N=84) n (%)	RD (95% CI)
BRADYCARDIA	1 (1.2%)	0	-0.012 (-0.034,0.011)
BRONCHITIS	1 (1.2%)	0	-0.012 (-0.034,0.011)
BUNDLE BRANCH BLOCK LEFT	1 (1.2%)	0	-0.012 (-0.034,0.011)
BUNDLE BRANCH BLOCK RIGHT	1 (1.2%)	1 (1.2%)	0.000 (-0.032,0.033)
BURNING SENSATION	0	0	-
CALCULUS URETHRAL	0	0	-
CARDIAC DISORDER	0	0	-
CARDIAC FAILURE CONGESTIVE	1 (1.2%)	0	-0.012 (-0.034,0.011)
CATARACT OPERATION	1 (1.2%)	1 (1.2%)	0.000 (-0.032,0.033)
CELLULITIS	0	1 (1.2%)	0.012 (-0.011,0.035)
CERUMEN IMPACTION	0	1 (1.2%)	0.012 (-0.011,0.035)
CERVICITIS	1 (1.2%)	0	-0.012 (-0.034,0.011)
CHEST DISCOMFORT	0	0	-
CHEST PAIN	0	0	-
CHILLS	1 (1.2%)	1 (1.2%)	0.000 (-0.032,0.033)
COGNITIVE DISORDER	0	0	-

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Preferred Term	Placebo (N=86) n (%)	Active (N=84) n (%)	RD (95% CI)
COLD SWEAT	1 (1.2%)	0	-0.012 (-0.034,0.011)
COLON CANCER	0	1 (1.2%)	0.012 (-0.011,0.035)
COMPLETED SUICIDE	1 (1.2%)	0	-0.012 (-0.034,0.011)
COMPLEX PARTIAL SEIZURES	0	1 (1.2%)	0.012 (-0.011,0.035)
CONFUSIONAL STATE	2 (2.3%)	3 (3.6%)	0.012 (-0.038,0.063)
CONJUNCTIVAL HAEMORRHAGE	0	1 (1.2%)	0.012 (-0.011,0.035)
CONJUNCTIVITIS	1 (1.2%)	0	-0.012 (-0.034,0.011)
CONSTIPATION	1 (1.2%)	0	-0.012 (-0.034,0.011)
CONTUSION	1 (1.2%)	1 (1.2%)	0.000 (-0.032,0.033)
COORDINATION ABNORMAL	0	1 (1.2%)	0.012 (-0.011,0.035)
COUGH	1 (1.2%)	5 (6.0%)	0.048 (-0.008,0.103)
CYSTITIS	1 (1.2%)	0	-0.012 (-0.034,0.011)
CYSTOSCOPY	1 (1.2%)	0	-0.012 (-0.034,0.011)
DECREASED APPETITE	1 (1.2%)	0	-0.012 (-0.034,0.011)

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Preferred Term	Placebo (N=86) n (%)	Active (N=84) n (%)	RD (95% CI)
DEHYDRATION	1 (1.2%)	0	-0.012 (-0.034,0.011)
DELIRIUM	0	0	-
DELUSION	1 (1.2%)	0	-0.012 (-0.034,0.011)
DEPRESSED MOOD	0	1 (1.2%)	0.012 (-0.011,0.035)
DERMATITIS CONTACT	0	1 (1.2%)	0.012 (-0.011,0.035)
DIABETES MELLITUS	1 (1.2%)	0	-0.012 (-0.034,0.011)
DIARRHOEA	9 (10.5%)	4 (4.8%)	-0.057 (-0.136,0.022)
DISORIENTATION	1 (1.2%)	0	-0.012 (-0.034,0.011)
DIZZINESS	2 (2.3%)	8 (9.5%)	0.072 (0.002,0.142)
DRUG ERUPTION	1 (1.2%)	0	-0.012 (-0.034,0.011)
DYSPEPSIA	1 (1.2%)	1 (1.2%)	0.000 (-0.032,0.033)
DYSPHAGIA	0	1 (1.2%)	0.012 (-0.011,0.035)
DYSPHONIA	0	1 (1.2%)	0.012 (-0.011,0.035)
DYSPNOEA	1 (1.2%)	1 (1.2%)	0.000 (-0.032,0.033)
DYSURIA	1 (1.2%)	1 (1.2%)	0.000 (-0.032,0.033)

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Preferred Term	Placebo (N=86) n (%)	Active (N=84) n (%)	RD (95% CI)
EAR INFECTION	2 (2.3%)	0	-0.023 (-0.055,0.009)
EAR PAIN	1 (1.2%)	0	-0.012 (-0.034,0.011)
ELECTROCARDIOGRAM ST SEGMENT DEPRESSION	4 (4.7%)	1 (1.2%)	-0.035 (-0.085,0.016)
ELECTROCARDIOGRAM T WAVE AMPLITUDE DECREASED	1 (1.2%)	1 (1.2%)	0.000 (-0.032,0.033)
ELECTROCARDIOGRAM T WAVE INVERSION	2 (2.3%)	1 (1.2%)	-0.011 (-0.051,0.028)
EMPHYSEMA	1 (1.2%)	0	-0.012 (-0.034,0.011)
EPISTAXIS	0	1 (1.2%)	0.012 (-0.011,0.035)
ERYTHEMA	8 (9.3%)	14 (16.7%)	0.074 (-0.027,0.174)
EXCORIATION	2 (2.3%)	1 (1.2%)	-0.011 (-0.051,0.028)
EYE ALLERGY	1 (1.2%)	0	-0.012 (-0.034,0.011)
EYE LASER SURGERY	1 (1.2%)	0	-0.012 (-0.034,0.011)
EYE PRURITUS	1 (1.2%)	0	-0.012 (-0.034,0.011)
EYE SWELLING	1 (1.2%)	0	-0.012 (-0.034,0.011)
FACIAL BONES FRACTURE	0	0	-

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FALL	1 (1.2%)	2 (2.4%)	0.012 (-0.028,0.052)
FATIGUE	1 (1.2%)	5 (6.0%)	0.048 (-0.008,0.103)
FEELING ABNORMAL	0	0	-
FEELING COLD	0	0	-
FLANK PAIN	0	0	-
FLATULENCE	1 (1.2%)	0	-0.012 (-0.034,0.011)
FOOD CRAVING	1 (1.2%)	1 (1.2%)	0.000 (-0.032,0.033)
GASTROENTERITIS VIRAL	1 (1.2%)	0	-0.012 (-0.034,0.011)
GASTROINTESTINAL HAEMORRHAGE	0	0	-
GASTROESOPHAGEAL REFLUX DISEASE	1 (1.2%)	0	-0.012 (-0.034,0.011)
GLOSSITIS	1 (1.2%)	0	-0.012 (-0.034,0.011)
HAEMOPTYSIS	1 (1.2%)	0	-0.012 (-0.034,0.011)
HALLUCINATION	0	0	-
HALLUCINATION, VISUAL	0	0	-
HEADACHE	3 (3.5%)	3 (3.6%)	0.001 (-0.055,0.056)
HEART RATE INCREASED	1 (1.2%)	0	-0.012 (-0.034,0.011)

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HEART RATE IRREGULAR	1 (1.2%)	0	-0.012 (-0.034,0.011)
HEMIANOPIA HOMONYMOUS	0	1 (1.2%)	0.012 (-0.011,0.035)
HIATUS HERNIA	1 (1.2%)	0	-0.012 (-0.034,0.011)
HIP FRACTURE	1 (1.2%)	0	-0.012 (-0.034,0.011)
HORDEOLUM	0	0	-
HOT FLUSH	0	1 (1.2%)	0.012 (-0.011,0.035)
HYPERBILIRUBINAEMIA	1 (1.2%)	0	-0.012 (-0.034,0.011)
HYPERHIDROSIS	2 (2.3%)	4 (4.8%)	0.024 (-0.031,0.080)
HYPERSENSITIVITY	0	1 (1.2%)	0.012 (-0.011,0.035)
HYPERSOMNIA	0	0	-
HYPERTENSION	1 (1.2%)	1 (1.2%)	0.000 (-0.032,0.033)
HYPONATRAEMIA	1 (1.2%)	0	-0.012 (-0.034,0.011)
HYPOTENSION	2 (2.3%)	1 (1.2%)	-0.011 (-0.051,0.028)
INCONTINENCE	0	1 (1.2%)	0.012 (-0.011,0.035)
INCREASED APPETITE	1 (1.2%)	0	-0.012 (-0.034,0.011)

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INFLAMMATION	0	1 (1.2%)	0.012 (-0.011,0.035)
INFLUENZA	1 (1.2%)	1 (1.2%)	0.000 (-0.032,0.033)
INSOMNIA	2 (2.3%)	0	-0.023 (-0.055,0.009)
IRRITABILITY	1 (1.2%)	1 (1.2%)	0.000 (-0.032,0.033)
JOINT DISLOCATION	0	1 (1.2%)	0.012 (-0.011,0.035)
LETHARGY	0	1 (1.2%)	0.012 (-0.011,0.035)
LIBIDO DECREASED	0	0	-
LISTLESS	0	0	-
LOCALISED INFECTION	1 (1.2%)	0	-0.012 (-0.034,0.011)
LOWER RESPIRATORY TRACT INFECTION	0	0	-
MALAISE	0	1 (1.2%)	0.012 (-0.011,0.035)
MALIGNANT FIBROUS HISTIOCYTOMA	0	1 (1.2%)	0.012 (-0.011,0.035)
MICTURITION URGENCY	1 (1.2%)	1 (1.2%)	0.000 (-0.032,0.033)
MUSCLE SPASMS	0	1 (1.2%)	0.012 (-0.011,0.035)
MUSCULAR WEAKNESS	0	1 (1.2%)	0.012 (-0.011,0.035)

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MYALGIA	0	0	-
MYOCARDIAL INFARCTION	4 (4.7%)	2 (2.4%)	-0.023 (-0.078,0.032)
NASAL CONGESTION	3 (3.5%)	1 (1.2%)	-0.023 (-0.068,0.022)
NASAL MUCOSA BIOPSY	0	1 (1.2%)	0.012 (-0.011,0.035)
NASOPHARYNGITIS	2 (2.3%)	4 (4.8%)	0.024 (-0.031,0.080)
NAUSEA	3 (3.5%)	3 (3.6%)	0.001 (-0.055,0.056)
NEPHROLITHIASIS	1 (1.2%)	0	-0.012 (-0.034,0.011)
NIGHTMARE	0	0	-
OEDEMA	0	2 (2.4%)	0.024 (-0.009,0.056)
OEDEMA PERIPHERAL	2 (2.3%)	1 (1.2%)	-0.011 (-0.051,0.028)
ORTHOSTATIC HYPOTENSION	1 (1.2%)	0	-0.012 (-0.034,0.011)
PAIN	0	1 (1.2%)	0.012 (-0.011,0.035)
PAIN IN EXTREMITY	1 (1.2%)	0	-0.012 (-0.034,0.011)
PALPITATIONS	0	2 (2.4%)	0.024 (-0.009,0.056)
PARAESTHESIA	0	0	-

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PARAESTHESIA ORAL	0	1 (1.2%)	0.012 (-0.011,0.035)
PARKINSON'S DISEASE	1 (1.2%)	0	-0.012 (-0.034,0.011)
PAROSMIA	0	0	-
PARTIAL SEIZURES WITH SECONDARY GENERALISATION	0	0	-
PELVIC PAIN	1 (1.2%)	0	-0.012 (-0.034,0.011)
PHARYNGEAL ERYTHEMA	0	0	-
PHARYNGOLARYNGEAL PAIN	0	1 (1.2%)	0.012 (-0.011,0.035)
PNEUMONIA	0	1 (1.2%)	0.012 (-0.011,0.035)
POLLAKIURIA	1 (1.2%)	0	-0.012 (-0.034,0.011)
POSTNASAL DRIP	1 (1.2%)	0	-0.012 (-0.034,0.011)
PRODUCTIVE COUGH	0	0	-
PROSTATE CANCER	0	0	-
PRURITUS	8 (9.3%)	21 (25.0%)	0.157 (0.046,0.268)
PRURITUS GENERALISED	0	1 (1.2%)	0.012 (-0.011,0.035)
PSYCHOMOTOR HYPERACTIVITY	1 (1.2%)	0	-0.012 (-0.034,0.011)
PYREXIA	2 (2.3%)	0	-0.023 (-0.055,0.009)

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RALES	1 (1.2%)	0	-0.012 (-0.034,0.011)
RASH	5 (5.8%)	13 (15.5%)	0.097 (0.005,0.188)
RASH ERYTHEMATOUS	0	1 (1.2%)	0.012 (-0.011,0.035)
RASH MACULO-PAPULAR	0	0	-
RASH PRURITIC	0	1 (1.2%)	0.012 (-0.011,0.035)
RECTAL HAEMORRHAGE	0	1 (1.2%)	0.012 (-0.011,0.035)
RESPIRATORY TRACT CONGESTION	0	0	-
RESTLESSNESS	0	1 (1.2%)	0.012 (-0.011,0.035)
RHINITIS	0	0	-
RHINORRHOEA	0	1 (1.2%)	0.012 (-0.011,0.035)
SALIVARY HYPERSECRETION	0	0	-
SECRETION DISCHARGE	0	1 (1.2%)	0.012 (-0.011,0.035)
SHOULDER PAIN	1 (1.2%)	2 (2.4%)	0.012 (-0.028,0.052)
SINUS ARRHYTHMIA	1 (1.2%)	0	-0.012 (-0.034,0.011)
SINUS BRADYCARDIA	2 (2.3%)	7 (8.3%)	0.060 (-0.007,0.127)
SKIN EXFOLIATION	0	1 (1.2%)	0.012 (-0.011,0.035)

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SKIN IRRITATION	3 (3.5%)	6 (7.1%)	0.037 (-0.031,0.104)
SKIN LACERATION	1 (1.2%)	2 (2.4%)	0.012 (-0.028,0.052)
SKIN LESION EXCISION	0	0	-
SKIN ODOUR ABNORMAL	0	0	-
SKIN ULCER	1 (1.2%)	0	-0.012 (-0.034,0.011)
SOMNOLENCE	2 (2.3%)	3 (3.6%)	0.012 (-0.038,0.063)
STOMACH DISCOMFORT	0	0	-
STUPOR	0	1 (1.2%)	0.012 (-0.011,0.035)
SUDDEN DEATH	0	1 (1.2%)	0.012 (-0.011,0.035)
SUPRAVENTRICULAR EXTRASYSTOLES	1 (1.2%)	1 (1.2%)	0.000 (-0.032,0.033)
SUPRAVENTRICULAR TACHYCARDIA	0	1 (1.2%)	0.012 (-0.011,0.035)
SWELLING	0	1 (1.2%)	0.012 (-0.011,0.035)
SYNCOPE	0	4 (4.8%)	0.048 (0.002,0.093)
SYNCOPE VASOVAGAL	0	0	-
TACHYCARDIA	1 (1.2%)	0	-0.012 (-0.034,0.011)
TRANSIENT ISCHAEMIC ATTACK	0	2 (2.4%)	0.024 (-0.009,0.056)

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ULCER	0	1 (1.2%)	0.012 (-0.011,0.035)
UPPER RESPIRATORY TRACT INFECTION	6 (7.0%)	1 (1.2%)	-0.058 (-0.116,0.001)
URINARY TRACT INFECTION	2 (2.3%)	0	-0.023 (-0.055,0.009)
URTICARIA	0	1 (1.2%)	0.012 (-0.011,0.035)
VAGINAL MYCOSIS	1 (1.2%)	0	-0.012 (-0.034,0.011)
VENTRICULAR EXTRASYSTOLES	0	2 (2.4%)	0.024 (-0.009,0.056)
VENTRICULAR HYPERTROPHY	1 (1.2%)	0	-0.012 (-0.034,0.011)
VENTRICULAR SEPTAL DEFECT	0	1 (1.2%)	0.012 (-0.011,0.035)
VERTIGO	0	1 (1.2%)	0.012 (-0.011,0.035)
VIRAL INFECTION	0	1 (1.2%)	0.012 (-0.011,0.035)
VISION BLURRED	0	1 (1.2%)	0.012 (-0.011,0.035)
VOMITING	3 (3.5%)	3 (3.6%)	0.001 (-0.055,0.056)
WEIGHT DECREASED	0	0	-
WOLFF-PARKINSON-WHITE SYNDROME	0	1 (1.2%)	0.012 (-0.011,0.035)

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WOUND	0	1 (1.2%)	0.012 (-0.011,0.035)
WOUND HAEMORRHAGE	0	0	-