

TEAE by Preferred Term - with fisher's exact test p-value
Safety Analysis Set

Preferred Term	Placebo (N=86)	Low Dose (N=84)	High Dose (N=84)	Low dose vs Placebo
	n (%)	n (%)	n (%)	p-value [1]
Overall	65 (75.6%)	77 (91.7%)	76 (90.5%)	0.0065
ABDOMINAL DISCOMFORT	0	0	1 (1.2%)	-
ABDOMINAL PAIN	1 (1.2%)	3 (3.6%)	1 (1.2%)	0.3647
ACROCHORDON EXCISION	0	0	1 (1.2%)	-
ACTINIC KERATOSIS	0	0	1 (1.2%)	-
AGITATION	2 (2.3%)	2 (2.4%)	1 (1.2%)	1.0000
ALCOHOL USE	0	0	1 (1.2%)	-
ALLERGIC GRANULOMATOUS ANGIITIS	0	0	1 (1.2%)	-
ALOPECIA	1 (1.2%)	0	0	1.0000
AMNESIA	0	0	1 (1.2%)	-
ANXIETY	0	3 (3.6%)	0	0.1184
APPLICATION SITE BLEEDING	0	1 (1.2%)	0	0.4941
APPLICATION SITE DERMATITIS	5 (5.8%)	9 (10.7%)	7 (8.3%)	0.2767
APPLICATION SITE DESQUAMATION	0	1 (1.2%)	0	0.4941
APPLICATION SITE DISCHARGE	0	0	1 (1.2%)	-
APPLICATION SITE DISCOLOURATION	0	1 (1.2%)	0	0.4941
APPLICATION SITE ERYTHEMA	3 (3.5%)	12 (14.3%)	15 (17.9%)	0.0152
APPLICATION SITE INDURATION	1 (1.2%)	0	0	1.0000
APPLICATION SITE IRRITATION	3 (3.5%)	9 (10.7%)	9 (10.7%)	0.0783
APPLICATION SITE PAIN	0	0	2 (2.4%)	-
APPLICATION SITE PERSPIRATION	0	0	2 (2.4%)	-
APPLICATION SITE PRURITUS	6 (7.0%)	22 (26.2%)	22 (26.2%)	0.0008
APPLICATION SITE REACTION	1 (1.2%)	0	1 (1.2%)	1.0000
APPLICATION SITE SWELLING	0	1 (1.2%)	2 (2.4%)	0.4941
APPLICATION SITE URTICARIA	0	2 (2.4%)	1 (1.2%)	0.2427
APPLICATION SITE VESICLES	1 (1.2%)	4 (4.8%)	6 (7.1%)	0.2077
APPLICATION SITE WARMTH	0	1 (1.2%)	0	0.4941
ARTHRALGIA	1 (1.2%)	2 (2.4%)	1 (1.2%)	0.6183
ARTHRITIS	0	0	1 (1.2%)	-
ASTHENIA	1 (1.2%)	0	1 (1.2%)	1.0000
atrial fibrillation	1 (1.2%)	1 (1.2%)	3 (3.6%)	1.0000
atrial flutter	0	1 (1.2%)	1 (1.2%)	0.4941
atrial hypertrophy	1 (1.2%)	0	0	1.0000

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atrioventricular block first degree	1 (1.2%)	1 (1.2%)	0	1.0000
atrioventricular block second degree	1 (1.2%)	0	0	1.0000
back pain	1 (1.2%)	1 (1.2%)	3 (3.6%)	1.0000
balance disorder	0	1 (1.2%)	0	0.4941
benign prostatic hyperplasia	1 (1.2%)	0	1 (1.2%)	1.0000
biopsy	0	0	1 (1.2%)	-
biopsy prostate	0	0	1 (1.2%)	-
blister	0	5 (6.0%)	1 (1.2%)	0.0277
blood alkaline phosphatase increased	1 (1.2%)	0	0	1.0000
blood cholesterol increased	0	0	1 (1.2%)	-
blood creatine phosphokinase increased	1 (1.2%)	0	0	1.0000
blood glucose increased	0	1 (1.2%)	1 (1.2%)	0.4941
blood urine present	1 (1.2%)	0	0	1.0000
body temperature increased	0	1 (1.2%)	0	0.4941
bradycardia	1 (1.2%)	0	0	1.0000
bronchitis	1 (1.2%)	0	0	1.0000
bundle branch block left	1 (1.2%)	0	0	1.0000
bundle branch block right	1 (1.2%)	1 (1.2%)	0	1.0000
burning sensation	0	0	2 (2.4%)	-
calculus urethral	0	0	1 (1.2%)	-
cardiac disorder	0	0	1 (1.2%)	-
cardiac failure congestive	1 (1.2%)	0	0	1.0000
cataract operation	1 (1.2%)	1 (1.2%)	0	1.0000
cellulitis	0	1 (1.2%)	0	0.4941
cerumen impaction	0	1 (1.2%)	0	0.4941
cervicitis	1 (1.2%)	0	0	1.0000
chest discomfort	0	0	2 (2.4%)	-
chest pain	0	0	2 (2.4%)	-
chills	1 (1.2%)	1 (1.2%)	1 (1.2%)	1.0000
cognitive disorder	0	0	1 (1.2%)	-
cold sweat	1 (1.2%)	0	0	1.0000
colon cancer	0	1 (1.2%)	0	0.4941
completed suicide	1 (1.2%)	0	0	1.0000
complex partial seizures	0	1 (1.2%)	0	0.4941

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CONFUSIONAL STATE	2 (2.3%)	3 (3.6%)	1 (1.2%)	0.6800
CONJUNCTIVAL HAEMORRHAGE	0	1 (1.2%)	0	0.4941
CONJUNCTIVITIS	1 (1.2%)	0	0	1.0000
CONSTIPATION	1 (1.2%)	0	0	1.0000
CONTUSION	1 (1.2%)	1 (1.2%)	2 (2.4%)	1.0000
COORDINATION ABNORMAL	0	1 (1.2%)	0	0.4941
COUGH	1 (1.2%)	5 (6.0%)	5 (6.0%)	0.1152
CYSTITIS	1 (1.2%)	0	1 (1.2%)	1.0000
CYSTOSCOPY	1 (1.2%)	0	0	1.0000
DECREASED APPETITE	1 (1.2%)	0	1 (1.2%)	1.0000
DEHYDRATION	1 (1.2%)	0	0	1.0000
DELIRIUM	0	0	1 (1.2%)	-
DELUSION	1 (1.2%)	0	1 (1.2%)	1.0000
DEPRESSED MOOD	0	1 (1.2%)	0	0.4941
DERMATITIS CONTACT	0	1 (1.2%)	0	0.4941
DIABETES MELLITUS	1 (1.2%)	0	0	1.0000
DIARRHOEA	9 (10.5%)	4 (4.8%)	4 (4.8%)	0.2482
DISORIENTATION	1 (1.2%)	0	0	1.0000
DIZZINESS	2 (2.3%)	8 (9.5%)	11 (13.1%)	0.0556
DRUG ERUPTION	1 (1.2%)	0	0	1.0000
DYSPEPSIA	1 (1.2%)	1 (1.2%)	0	1.0000
DYSPHAGIA	0	1 (1.2%)	0	0.4941
DYSPHONIA	0	1 (1.2%)	0	0.4941
DYSPNOEA	1 (1.2%)	1 (1.2%)	1 (1.2%)	1.0000
DYSURIA	1 (1.2%)	1 (1.2%)	0	1.0000
EAR INFECTION	2 (2.3%)	0	0	0.4971
EAR PAIN	1 (1.2%)	0	0	1.0000
ELECTROCARDIOGRAM ST SEGMENT DEPRESSION	4 (4.7%)	1 (1.2%)	0	0.3677
ELECTROCARDIOGRAM T WAVE AMPLITUDE DECREASED	1 (1.2%)	1 (1.2%)	0	1.0000
ELECTROCARDIOGRAM T WAVE INVERSION	2 (2.3%)	1 (1.2%)	1 (1.2%)	1.0000
EMPHYSEMA	1 (1.2%)	0	0	1.0000
EPISTAXIS	0	1 (1.2%)	2 (2.4%)	0.4941
ERYTHEMA	8 (9.3%)	14 (16.7%)	14 (16.7%)	0.1754
EXCORIATION	2 (2.3%)	1 (1.2%)	1 (1.2%)	1.0000

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EYE ALLERGY	1 (1.2%)	0	0	1.0000
EYE LASER SURGERY	1 (1.2%)	0	0	1.0000
EYE PRURITUS	1 (1.2%)	0	0	1.0000
EYE SWELLING	1 (1.2%)	0	0	1.0000
FACIAL BONES FRACTURE	0	0	1 (1.2%)	-
FALL	1 (1.2%)	2 (2.4%)	1 (1.2%)	0.6183
FATIGUE	1 (1.2%)	5 (6.0%)	5 (6.0%)	0.1152
FEELING ABNORMAL	0	0	1 (1.2%)	-
FEELING COLD	0	0	1 (1.2%)	-
FLANK PAIN	0	0	1 (1.2%)	-
FLATULENCE	1 (1.2%)	0	0	1.0000
FOOD CRAVING	1 (1.2%)	1 (1.2%)	0	1.0000
GASTROENTERITIS VIRAL	1 (1.2%)	0	0	1.0000
GASTROINTESTINAL HAEMORRHAGE	0	0	1 (1.2%)	-
GASTROOESOPHAGEAL REFLUX DISEASE	1 (1.2%)	0	0	1.0000
GLOSSITIS	1 (1.2%)	0	0	1.0000
HAEMOPTYSIS	1 (1.2%)	0	0	1.0000
HALLUCINATION	0	0	1 (1.2%)	-
HALLUCINATION, VISUAL	0	0	1 (1.2%)	-
HEADACHE	3 (3.5%)	3 (3.6%)	5 (6.0%)	1.0000
HEART RATE INCREASED	1 (1.2%)	0	0	1.0000
HEART RATE IRREGULAR	1 (1.2%)	0	0	1.0000
HEMIANOPIA HOMONYMOUS	0	1 (1.2%)	0	0.4941
HIATUS HERNIA	1 (1.2%)	0	0	1.0000
HIP FRACTURE	1 (1.2%)	0	2 (2.4%)	1.0000
HORDEOLUM	0	0	1 (1.2%)	-
HOT FLUSH	0	1 (1.2%)	0	0.4941
HYPERBILIRUBINAEMIA	1 (1.2%)	0	0	1.0000
HYPERHIDROSIS	2 (2.3%)	4 (4.8%)	8 (9.5%)	0.4406
HYPERSENSITIVITY	0	1 (1.2%)	0	0.4941
HYPERSOMNIA	0	0	1 (1.2%)	-
HYPERTENSION	1 (1.2%)	1 (1.2%)	0	1.0000
HYPONATRAEMIA	1 (1.2%)	0	0	1.0000
HYPOTENSION	2 (2.3%)	1 (1.2%)	0	1.0000

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INCONTINENCE	0	1 (1.2%)	0	0.4941
INCREASED APPETITE	1 (1.2%)	0	1 (1.2%)	1.0000
INFLAMMATION	0	1 (1.2%)	0	0.4941
INFLUENZA	1 (1.2%)	1 (1.2%)	1 (1.2%)	1.0000
INSOMNIA	2 (2.3%)	0	2 (2.4%)	0.4971
IRRITABILITY	1 (1.2%)	1 (1.2%)	0	1.0000
JOINT DISLOCATION	0	1 (1.2%)	0	0.4941
LETHARGY	0	1 (1.2%)	1 (1.2%)	0.4941
LIBIDO DECREASED	0	0	1 (1.2%)	-
LISTLESS	0	0	1 (1.2%)	-
LOCALISED INFECTION	1 (1.2%)	0	0	1.0000
LOWER RESPIRATORY TRACT INFECTION	0	0	1 (1.2%)	-
MALAISE	0	1 (1.2%)	2 (2.4%)	0.4941
MALIGNANT FIBROUS HISTIOCYTOMA	0	1 (1.2%)	0	0.4941
MICTURITION URGENCY	1 (1.2%)	1 (1.2%)	1 (1.2%)	1.0000
MUSCLE SPASMS	0	1 (1.2%)	1 (1.2%)	0.4941
MUSCULAR WEAKNESS	0	1 (1.2%)	0	0.4941
MYALGIA	0	0	1 (1.2%)	-
MYOCARDIAL INFARCTION	4 (4.7%)	2 (2.4%)	4 (4.8%)	0.6820
NASAL CONGESTION	3 (3.5%)	1 (1.2%)	3 (3.6%)	0.6206
NASAL MUCOSA BIOPSY	0	1 (1.2%)	0	0.4941
NASOPHARYNGITIS	2 (2.3%)	4 (4.8%)	6 (7.1%)	0.4406
NAUSEA	3 (3.5%)	3 (3.6%)	6 (7.1%)	1.0000
NEPHROLITHIASIS	1 (1.2%)	0	1 (1.2%)	1.0000
NIGHTMARE	0	0	1 (1.2%)	-
OEDEMA	0	2 (2.4%)	0	0.2427
OEDEMA PERIPHERAL	2 (2.3%)	1 (1.2%)	2 (2.4%)	1.0000
ORTHOSTATIC HYPOTENSION	1 (1.2%)	0	0	1.0000
PAIN	0	1 (1.2%)	1 (1.2%)	0.4941
PAIN IN EXTREMITY	1 (1.2%)	0	0	1.0000
PALPITATIONS	0	2 (2.4%)	0	0.2427
PARAESTHESIA	0	0	1 (1.2%)	-
PARAESTHESIA ORAL	0	1 (1.2%)	0	0.4941
PARKINSON'S DISEASE	1 (1.2%)	0	0	1.0000

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PAROSMIA	0	0	1 (1.2%)	-	
PARTIAL SEIZURES WITH SECONDARY GENERALISATION	0	0	1 (1.2%)	-	
PELVIC PAIN	1 (1.2%)	0	0	1.0000	
PHARYNGEAL ERYTHEMA	0	0	1 (1.2%)	-	
PHARYNGOLARYNGEAL PAIN	0	1 (1.2%)	1 (1.2%)	0.4941	
PNEUMONIA	0	1 (1.2%)	0	0.4941	
POLLAKIURIA	1 (1.2%)	0	0	1.0000	
POSTNASAL DRIP	1 (1.2%)	0	0	1.0000	
PRODUCTIVE COUGH	0	0	1 (1.2%)	-	
PROSTATE CANCER	0	0	1 (1.2%)	-	
PRURITUS	8 (9.3%)	21 (25.0%)	26 (31.0%)	0.0078	
PRURITUS GENERALISED	0	1 (1.2%)	1 (1.2%)	0.4941	
PSYCHOMOTOR HYPERACTIVITY	1 (1.2%)	0	0	1.0000	
PYREXIA	2 (2.3%)	0	1 (1.2%)	0.4971	
RALES	1 (1.2%)	0	0	1.0000	
RASH	5 (5.8%)	13 (15.5%)	9 (10.7%)	0.0480	
RASH ERYTHEMATOUS	0	1 (1.2%)	0	0.4941	
RASH MACULO-PAPULAR	0	0	1 (1.2%)	-	
RASH PRURITIC	0	1 (1.2%)	2 (2.4%)	0.4941	
RECTAL HAEMORRHAGE	0	1 (1.2%)	0	0.4941	
RESPIRATORY TRACT CONGESTION	0	0	1 (1.2%)	-	
RESTLESSNESS	0	1 (1.2%)	0	0.4941	
RHINITIS	0	0	1 (1.2%)	-	
RHINORRHOEA	0	1 (1.2%)	1 (1.2%)	0.4941	
SALIVARY HYPERSECRETION	0	0	4 (4.8%)	-	
SECRETION DISCHARGE	0	1 (1.2%)	0	0.4941	
SHOULDER PAIN	1 (1.2%)	2 (2.4%)	0	0.6183	
SINUS ARRHYTHMIA	1 (1.2%)	0	0	1.0000	
SINUS BRADYCARDIA	2 (2.3%)	7 (8.3%)	8 (9.5%)	0.0971	
SKIN EXFOLIATION	0	1 (1.2%)	0	0.4941	
SKIN IRRITATION	3 (3.5%)	6 (7.1%)	5 (6.0%)	0.3261	
SKIN LACERATION	1 (1.2%)	2 (2.4%)	0	0.6183	
SKIN LESION EXCISION	0	0	1 (1.2%)	-	
SKIN ODOUR ABNORMAL	0	0	1 (1.2%)	-	

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				n (%)	
SKIN ULCER	1 (1.2%)	0	0		1.0000
SOMNOLENCE	2 (2.3%)	3 (3.6%)	1 (1.2%)		0.6800
STOMACH DISCOMFORT	0	0	1 (1.2%)		-
STUPOR	0	1 (1.2%)	0		0.4941
SUDDEN DEATH	0	1 (1.2%)	0		0.4941
SUPRAVENTRICULAR EXTRASYSTOLES	1 (1.2%)	1 (1.2%)	1 (1.2%)		1.0000
SUPRAVENTRICULAR TACHYCARDIA	0	1 (1.2%)	0		0.4941
SWELLING	0	1 (1.2%)	0		0.4941
SYNCOPE	0	4 (4.8%)	3 (3.6%)		0.0575
SYNCOPE VASOVAGAL	0	0	1 (1.2%)		-
TACHYCARDIA	1 (1.2%)	0	0		1.0000
TRANSIENT ISCHAEMIC ATTACK	0	2 (2.4%)	1 (1.2%)		0.2427
ULCER	0	1 (1.2%)	0		0.4941
UPPER RESPIRATORY TRACT INFECTION	6 (7.0%)	1 (1.2%)	3 (3.6%)		0.1174
URINARY TRACT INFECTION	2 (2.3%)	0	1 (1.2%)		0.4971
URTICARIA	0	1 (1.2%)	1 (1.2%)		0.4941
VAGINAL MYCOSIS	1 (1.2%)	0	0		1.0000
VENTRICULAR EXTRASYSTOLES	0	2 (2.4%)	1 (1.2%)		0.2427
VENTRICULAR HYPERTROPHY	1 (1.2%)	0	0		1.0000
VENTRICULAR SEPTAL DEFECT	0	1 (1.2%)	2 (2.4%)		0.4941
VERTIGO	0	1 (1.2%)	1 (1.2%)		0.4941
VIRAL INFECTION	0	1 (1.2%)	0		0.4941
VISION BLURRED	0	1 (1.2%)	1 (1.2%)		0.4941
VOMITING	3 (3.5%)	3 (3.6%)	7 (8.3%)		1.0000
WEIGHT DECREASED	0	0	1 (1.2%)		-
WOLFF-PARKINSON-WHITE SYNDROME	0	1 (1.2%)	0		0.4941
WOUND	0	1 (1.2%)	0		0.4941
WOUND HAEMORRHAGE	0	0	1 (1.2%)		-

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