

*Exposure Adjusted Event Rate by SOC and PT*

*Safety Analysis Set*

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System Organ Class Preferred Term	Placebo (N=86) [Subj-yr=35.1] n (r)	Low Dose (N=84) [Subj-yr=22.77] n (r)	High Dose (N=84) [Subj-yr=22.86] n (r)
Overall	281 ( 800.6)	412 (1809.1)	433 (1894.3)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	46 ( 131.1)	118 ( 518.1)	124 ( 542.5)
APPLICATION SITE PRURITUS	10 ( 28.5)	32 ( 140.5)	35 ( 153.1)
APPLICATION SITE ERYTHEMA	3 ( 8.5)	20 ( 87.8)	23 ( 100.6)
APPLICATION SITE IRRITATION	7 ( 19.9)	18 ( 79.0)	16 ( 70.0)
APPLICATION SITE DERMATITIS	9 ( 25.6)	15 ( 65.9)	12 ( 52.5)
APPLICATION SITE VESICLES	2 ( 5.7)	5 ( 22.0)	6 ( 26.2)
FATIGUE	2 ( 5.7)	5 ( 22.0)	5 ( 21.9)
APPLICATION SITE PERSPIRATION	0	0	3 ( 13.1)
APPLICATION SITE SWELLING	0	1 ( 4.4)	3 ( 13.1)
MALAISE	0	2 ( 8.8)	3 ( 13.1)
OEDEMA PERIPHERAL	3 ( 8.5)	1 ( 4.4)	3 ( 13.1)
APPLICATION SITE PAIN	0	0	2 ( 8.7)
CHEST DISCOMFORT	0	0	2 ( 8.7)
CHEST PAIN	0	0	2 ( 8.7)
APPLICATION SITE DISCHARGE	0	0	1 ( 4.4)
APPLICATION SITE REACTION	2 ( 5.7)	0	1 ( 4.4)
APPLICATION SITE URTICARIA	0	2 ( 8.8)	1 ( 4.4)
ASTHENIA	2 ( 5.7)	0	1 ( 4.4)
CHILLS	3 ( 8.5)	2 ( 8.8)	1 ( 4.4)
FEELING ABNORMAL	0	0	1 ( 4.4)

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FEELING COLD	0	0	1 ( 4.4)
PAIN	0	2 ( 8.8)	1 ( 4.4)
PYREXIA	2 ( 5.7)	0	1 ( 4.4)
APPLICATION SITE BLEEDING	0	1 ( 4.4)	0
APPLICATION SITE DESQUAMATION	0	1 ( 4.4)	0
APPLICATION SITE DISCOLOURATION	0	1 ( 4.4)	0
APPLICATION SITE INDURATION	1 ( 2.8)	0	0
APPLICATION SITE WARMTH	0	2 ( 8.8)	0
INFLAMMATION	0	1 ( 4.4)	0
OEDEMA	0	2 ( 8.8)	0
SECRETION DISCHARGE	0	2 ( 8.8)	0
SUDDEN DEATH	0	1 ( 4.4)	0
SWELLING	0	1 ( 4.4)	0
ULCER	0	1 ( 4.4)	0
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SKIN AND SUBCUTANEOUS TISSUE DISORDERS	45 ( 128.2)	111 ( 487.4)	104 ( 455.0)
PRURITUS	11 ( 31.3)	31 ( 136.1)	38 ( 166.2)
ERYTHEMA	12 ( 34.2)	22 ( 96.6)	22 ( 96.2)
RASH	9 ( 25.6)	18 ( 79.0)	15 ( 65.6)
HYPERHIDROSIS	2 ( 5.7)	5 ( 22.0)	10 ( 43.7)
SKIN IRRITATION	4 ( 11.4)	13 ( 57.1)	8 ( 35.0)
RASH PRURITIC	0	2 ( 8.8)	3 ( 13.1)

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BLISTER	0	8 ( 35.1)	2 ( 8.7)
URTICARIA	0	3 ( 13.2)	2 ( 8.7)
ACTINIC KERATOSIS	0	0	1 ( 4.4)
PRURITUS GENERALISED	0	4 ( 17.6)	1 ( 4.4)
RASH MACULO-PAPULAR	0	0	1 ( 4.4)
SKIN ODOUR ABNORMAL	0	0	1 ( 4.4)
ALOPECIA	1 ( 2.8)	0	0
COLD SWEAT	3 ( 8.5)	0	0
DERMATITIS CONTACT	0	2 ( 8.8)	0
DRUG ERUPTION	1 ( 2.8)	0	0
RASH ERYTHEMATOUS	0	1 ( 4.4)	0
SKIN EXFOLIATION	0	2 ( 8.8)	0
SKIN ULCER	2 ( 5.7)	0	0
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NERVOUS SYSTEM DISORDERS	11 ( 31.3)	40 ( 175.6)	41 ( 179.4)
DIZZINESS	3 ( 8.5)	13 ( 57.1)	15 ( 65.6)
HEADACHE	3 ( 8.5)	4 ( 17.6)	8 ( 35.0)
SYNCOPE	0	6 ( 26.3)	4 ( 17.5)
AMNESIA	0	0	2 ( 8.7)
BURNING SENSATION	0	0	2 ( 8.7)
PAROSMIA	0	0	2 ( 8.7)
COGNITIVE DISORDER	0	0	1 ( 4.4)

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HYPERSOMNIA	0	0	1 ( 4.4)
LETHARGY	0	1 ( 4.4)	1 ( 4.4)
PARAESTHESIA	0	0	1 ( 4.4)
PARTIAL SEIZURES WITH SECONDARY GENERALISATION	0	0	1 ( 4.4)
SOMNOLENCE	3 ( 8.5)	5 ( 22.0)	1 ( 4.4)
SYNCOPE VASOVAGAL	0	0	1 ( 4.4)
TRANSIENT ISCHAEMIC ATTACK	0	3 ( 13.2)	1 ( 4.4)
BALANCE DISORDER	0	3 ( 13.2)	0
COMPLEX PARTIAL SEIZURES	0	1 ( 4.4)	0
COORDINATION ABNORMAL	0	1 ( 4.4)	0
HEMIANOPIA HOMONYMOUS	0	1 ( 4.4)	0
PARAESTHESIA ORAL	0	1 ( 4.4)	0
PARKINSON'S DISEASE	1 ( 2.8)	0	0
PSYCHOMOTOR HYPERACTIVITY	1 ( 2.8)	0	0
STUPOR	0	1 ( 4.4)	0
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GASTROINTESTINAL DISORDERS	26 ( 74.1)	22 ( 96.6)	36 ( 157.5)
NAUSEA	3 ( 8.5)	5 ( 22.0)	13 ( 56.9)
VOMITING	3 ( 8.5)	4 ( 17.6)	9 ( 39.4)
SALIVARY HYPERSECRETION	0	0	5 ( 21.9)
DIARRHOEA	10 ( 28.5)	5 ( 22.0)	4 ( 17.5)
ABDOMINAL PAIN	1 ( 2.8)	3 ( 13.2)	2 ( 8.7)

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ABDOMINAL DISCOMFORT	0	0	1 ( 4.4)
GASTROINTESTINAL HAEMORRHAGE	0	0	1 ( 4.4)
STOMACH DISCOMFORT	0	0	1 ( 4.4)
CONSTIPATION	1 ( 2.8)	0	0
DYSPEPSIA	2 ( 5.7)	2 ( 8.8)	0
DYSPHAGIA	0	1 ( 4.4)	0
FLATULENCE	2 ( 5.7)	0	0
GASTROESOPHAGEAL REFLUX DISEASE	1 ( 2.8)	0	0
GLOSSITIS	1 ( 2.8)	0	0
HIATUS HERNIA	2 ( 5.7)	0	0
RECTAL HAEMORRHAGE	0	2 ( 8.8)	0
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CARDIAC DISORDERS	26 ( 74.1)	30 ( 131.7)	30 ( 131.2)
SINUS BRADYCARDIA	2 ( 5.7)	10 ( 43.9)	12 ( 52.5)
MYOCARDIAL INFARCTION	4 ( 11.4)	4 ( 17.6)	8 ( 35.0)
ATRIAL FIBRILLATION	1 ( 2.8)	1 ( 4.4)	5 ( 21.9)
ATRIAL FLUTTER	0	1 ( 4.4)	2 ( 8.7)
CARDIAC DISORDER	0	0	1 ( 4.4)
SUPRAVENTRICULAR EXTRASYSTOLES	2 ( 5.7)	2 ( 8.8)	1 ( 4.4)
VENTRICULAR EXTRASYSTOLES	0	4 ( 17.6)	1 ( 4.4)
ATRIAL HYPERTROPHY	2 ( 5.7)	0	0
ATRIOVENTRICULAR BLOCK FIRST DEGREE	1 ( 2.8)	1 ( 4.4)	0

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ATRIOVENTRICULAR BLOCK SECOND DEGREE	1 ( 2.8)	0	0
BRADYCARDIA	4 ( 11.4)	0	0
BUNDLE BRANCH BLOCK LEFT	1 ( 2.8)	0	0
BUNDLE BRANCH BLOCK RIGHT	2 ( 5.7)	1 ( 4.4)	0
CARDIAC FAILURE CONGESTIVE	1 ( 2.8)	0	0
PALPITATIONS	0	2 ( 8.8)	0
SINUS ARRHYTHMIA	2 ( 5.7)	0	0
SUPRAVENTRICULAR TACHYCARDIA	0	2 ( 8.8)	0
TACHYCARDIA	2 ( 5.7)	0	0
VENTRICULAR HYPERTROPHY	1 ( 2.8)	0	0
WOLFF-PARKINSON-WHITE SYNDROME	0	2 ( 8.8)	0
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RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	12 ( 34.2)	14 ( 61.5)	22 ( 96.2)
COUGH	1 ( 2.8)	7 ( 30.7)	7 ( 30.6)
NASAL CONGESTION	3 ( 8.5)	1 ( 4.4)	4 ( 17.5)
EPISTAXIS	0	1 ( 4.4)	2 ( 8.7)
PHARYNGEAL ERYTHEMA	0	0	2 ( 8.7)
RHINORRHOEA	0	2 ( 8.8)	2 ( 8.7)
ALLERGIC GRANULOMATOUS ANGIITIS	0	0	1 ( 4.4)
DYSPNOEA	1 ( 2.8)	1 ( 4.4)	1 ( 4.4)
PHARYNGOLARYNGEAL PAIN	0	1 ( 4.4)	1 ( 4.4)
PRODUCTIVE COUGH	0	0	1 ( 4.4)

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RESPIRATORY TRACT CONGESTION	0	0	1 ( 4.4)
DYSPHONIA	0	1 ( 4.4)	0
EMPHYSEMA	1 ( 2.8)	0	0
HAEMOPTYSIS	2 ( 5.7)	0	0
POSTNASAL DRIP	2 ( 5.7)	0	0
RALES	2 ( 5.7)	0	0
INFECTIONS AND INFESTATIONS	35 ( 99.7)	16 ( 70.3)	20 ( 87.5)
NASOPHARYNGITIS	4 ( 11.4)	9 ( 39.5)	8 ( 35.0)
UPPER RESPIRATORY TRACT INFECTION	12 ( 34.2)	2 ( 8.8)	5 ( 21.9)
LOWER RESPIRATORY TRACT INFECTION	0	0	2 ( 8.7)
CYSTITIS	1 ( 2.8)	0	1 ( 4.4)
HORDEOLUM	0	0	1 ( 4.4)
INFLUENZA	2 ( 5.7)	1 ( 4.4)	1 ( 4.4)
RHINITIS	0	0	1 ( 4.4)
URINARY TRACT INFECTION	4 ( 11.4)	0	1 ( 4.4)
BRONCHITIS	1 ( 2.8)	0	0
CELLULITIS	0	1 ( 4.4)	0
CERVICITIS	2 ( 5.7)	0	0
EAR INFECTION	4 ( 11.4)	0	0
GASTROENTERITIS VIRAL	1 ( 2.8)	0	0
LOCALISED INFECTION	2 ( 5.7)	0	0

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PNEUMONIA	0	2 ( 8.8)	0
VAGINAL MYCOSIS	2 ( 5.7)	0	0
VIRAL INFECTION	0	1 ( 4.4)	0
PSYCHIATRIC DISORDERS	12 ( 34.2)	14 ( 61.5)	11 ( 48.1)
INSOMNIA	3 ( 8.5)	0	2 ( 8.7)
AGITATION	2 ( 5.7)	2 ( 8.8)	1 ( 4.4)
CONFUSIONAL STATE	2 ( 5.7)	3 ( 13.2)	1 ( 4.4)
DELIRIUM	0	0	1 ( 4.4)
DELUSION	1 ( 2.8)	0	1 ( 4.4)
HALLUCINATION	0	0	1 ( 4.4)
HALLUCINATION, VISUAL	0	0	1 ( 4.4)
LIBIDO DECREASED	0	0	1 ( 4.4)
LISTLESS	0	0	1 ( 4.4)
NIGHTMARE	0	0	1 ( 4.4)
ANXIETY	0	4 ( 17.6)	0
COMPLETED SUICIDE	1 ( 2.8)	0	0
DEPRESSED MOOD	0	2 ( 8.8)	0
DISORIENTATION	1 ( 2.8)	0	0
IRRITABILITY	2 ( 5.7)	1 ( 4.4)	0
RESTLESSNESS	0	2 ( 8.8)	0

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MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	6 ( 17.1)	10 ( 43.9)	10 ( 43.7)
BACK PAIN	2 ( 5.7)	1 ( 4.4)	4 ( 17.5)
MUSCLE SPASMS	0	1 ( 4.4)	2 ( 8.7)
ARTHRALGIA	1 ( 2.8)	4 ( 17.6)	1 ( 4.4)
ARTHRITIS	0	0	1 ( 4.4)
FLANK PAIN	0	0	1 ( 4.4)
MYALGIA	0	0	1 ( 4.4)
MUSCULAR WEAKNESS	0	2 ( 8.8)	0
PAIN IN EXTREMITY	1 ( 2.8)	0	0
SHOULDER PAIN	2 ( 5.7)	2 ( 8.8)	0
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INJURY, POISONING AND PROCEDURAL COMPLICATIONS	9 ( 25.6)	12 ( 52.7)	8 ( 35.0)
CONTUSION	1 ( 2.8)	3 ( 13.2)	3 ( 13.1)
HIP FRACTURE	2 ( 5.7)	0	2 ( 8.7)
EXCORIATION	3 ( 8.5)	2 ( 8.8)	1 ( 4.4)
FACIAL BONES FRACTURE	0	0	1 ( 4.4)
FALL	2 ( 5.7)	2 ( 8.8)	1 ( 4.4)
JOINT DISLOCATION	0	1 ( 4.4)	0
SKIN LACERATION	1 ( 2.8)	2 ( 8.8)	0
WOUND	0	2 ( 8.8)	0

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INVESTIGATIONS	19 ( 54.1)	7 ( 30.7)	8 ( 35.0)
BLOOD GLUCOSE INCREASED	0	1 ( 4.4)	2 ( 8.7)
WEIGHT DECREASED	0	0	2 ( 8.7)
BIOPSY	0	0	1 ( 4.4)
BIOPSY PROSTATE	0	0	1 ( 4.4)
BLOOD CHOLESTEROL INCREASED	0	0	1 ( 4.4)
ELECTROCARDIOGRAM T WAVE INVERSION	3 ( 8.5)	1 ( 4.4)	1 ( 4.4)
BLOOD ALKALINE PHOSPHATASE INCREASED	1 ( 2.8)	0	0
BLOOD CREATINE PHOSPHOKINASE INCREASED	2 ( 5.7)	0	0
BLOOD URINE PRESENT	1 ( 2.8)	0	0
BODY TEMPERATURE INCREASED	0	1 ( 4.4)	0
CYSTOSCOPY	1 ( 2.8)	0	0
ELECTROCARDIOGRAM ST SEGMENT DEPRESSION	4 ( 11.4)	2 ( 8.8)	0
ELECTROCARDIOGRAM T WAVE AMPLITUDE DECREASED	1 ( 2.8)	1 ( 4.4)	0
HEART RATE INCREASED	2 ( 5.7)	0	0
HEART RATE IRREGULAR	4 ( 11.4)	0	0
NASAL MUCOSA BIOPSY	0	1 ( 4.4)	0
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METABOLISM AND NUTRITION DISORDERS	8 ( 22.8)	1 ( 4.4)	4 ( 17.5)
DECREASED APPETITE	2 ( 5.7)	0	2 ( 8.7)
INCREASED APPETITE	2 ( 5.7)	0	2 ( 8.7)

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DEHYDRATION	1 ( 2.8)	0	0
DIABETES MELLITUS	1 ( 2.8)	0	0
FOOD CRAVING	1 ( 2.8)	1 ( 4.4)	0
HYPONATRAEMIA	1 ( 2.8)	0	0
RENAL AND URINARY DISORDERS	5 ( 14.2)	3 ( 13.2)	4 ( 17.5)
MICTURITION URGENCY	1 ( 2.8)	1 ( 4.4)	2 ( 8.7)
CALCULUS URETHRAL	0	0	1 ( 4.4)
NEPHROLITHIASIS	1 ( 2.8)	0	1 ( 4.4)
DYSURIA	1 ( 2.8)	1 ( 4.4)	0
INCONTINENCE	0	1 ( 4.4)	0
POLLAKIURIA	2 ( 5.7)	0	0
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	0	1 ( 4.4)	2 ( 8.7)
VENTRICULAR SEPTAL DEFECT	0	1 ( 4.4)	2 ( 8.7)
EYE DISORDERS	5 ( 14.2)	2 ( 8.8)	2 ( 8.7)
VISION BLURRED	0	1 ( 4.4)	2 ( 8.7)
CONJUNCTIVAL HAEMORRHAGE	0	1 ( 4.4)	0
CONJUNCTIVITIS	2 ( 5.7)	0	0
EYE ALLERGY	1 ( 2.8)	0	0
EYE PRURITUS	1 ( 2.8)	0	0

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EYE SWELLING	1 ( 2.8)	0	0
SURGICAL AND MEDICAL PROCEDURES	2 ( 5.7)	1 ( 4.4)	2 ( 8.7)
ACROCHORDON EXCISION	0	0	1 ( 4.4)
SKIN LESION EXCISION	0	0	1 ( 4.4)
CATARACT OPERATION	1 ( 2.8)	1 ( 4.4)	0
EYE LASER SURGERY	1 ( 2.8)	0	0
EAR AND LABYRINTH DISORDERS	2 ( 5.7)	2 ( 8.8)	1 ( 4.4)
VERTIGO	0	1 ( 4.4)	1 ( 4.4)
CERUMEN IMPACTION	0	1 ( 4.4)	0
EAR PAIN	2 ( 5.7)	0	0
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	3 ( 13.2)	1 ( 4.4)
PROSTATE CANCER	0	0	1 ( 4.4)
COLON CANCER	0	1 ( 4.4)	0
MALIGNANT FIBROUS HISTIOCYTOMA	0	2 ( 8.8)	0
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	4 ( 11.4)	0	1 ( 4.4)
BENIGN PROSTATIC HYPERPLASIA	2 ( 5.7)	0	1 ( 4.4)
PELVIC PAIN	2 ( 5.7)	0	0

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SOCIAL CIRCUMSTANCES	0	0	1 ( 4.4)
ALCOHOL USE	0	0	1 ( 4.4)
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VASCULAR DISORDERS	7 ( 19.9)	3 ( 13.2)	1 ( 4.4)
WOUND HAEMORRHAGE	0	0	1 ( 4.4)
HOT FLUSH	0	1 ( 4.4)	0
HYPERTENSION	2 ( 5.7)	1 ( 4.4)	0
HYPOTENSION	3 ( 8.5)	1 ( 4.4)	0
ORTHOSTATIC HYPOTENSION	2 ( 5.7)	0	0
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HEPATOBILIARY DISORDERS	1 ( 2.8)	0	0
HYPERBILIRUBINAEMIA	1 ( 2.8)	0	0
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IMMUNE SYSTEM DISORDERS	0	2 ( 8.8)	0
HYPERSENSITIVITY	0	2 ( 8.8)	0
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