

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
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
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
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
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
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
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
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)
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
HEPATOBIILIARY DISORDERS	1 (2.8)	0	0
HYPERBILIRUBINAEMIA	1 (2.8)	0	0
IMMUNE SYSTEM DISORDERS	0	2 (8.8)	0
HYPERSENSITIVITY	0	2 (8.8)	0