

Exposure Adjusted Subject Incidence Rate by SOC and PT

Safety Analysis Set

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System Organ Class Preferred Term	Placebo (N=86) n [subj-yr] (r)	Low Dose (N=84) n [subj-yr] (r)	High Dose (N=84) n [subj-yr] (r)
Overall	63[14.54] (433.3)	73[6.82] (1070.8)	71[5.47] (1298.6)
HEPATOBILIARY DISORDERS	1[35.10] (2.8)	0[22.77] (0.0)	0[22.86] (0.0)
HYPERBILIRUBINAEMIA	1[35.10] (2.8)	0[22.77] (0.0)	0[22.86] (0.0)
IMMUNE SYSTEM DISORDERS	0[35.10] (0.0)	1[22.68] (4.4)	0[22.86] (0.0)
HYPERSENSITIVITY	0[35.10] (0.0)	1[22.68] (4.4)	0[22.86] (0.0)
EAR AND LABYRINTH DISORDERS	1[34.67] (2.9)	1[22.70] (4.4)	1[22.83] (4.4)
CERUMEN IMPACTION	0[35.10] (0.0)	1[22.78] (4.4)	0[22.86] (0.0)
EAR PAIN	1[34.67] (2.9)	0[22.77] (0.0)	0[22.86] (0.0)
VERTIGO	0[35.10] (0.0)	1[22.70] (4.4)	1[22.83] (4.4)
SOCIAL CIRCUMSTANCES	0[35.10] (0.0)	0[22.77] (0.0)	1[22.82] (4.4)
ALCOHOL USE	0[35.10] (0.0)	0[22.77] (0.0)	1[22.82] (4.4)
VASCULAR DISORDERS	3[34.86] (8.6)	2[22.76] (8.8)	1[22.82] (4.4)
HOT FLUSH	0[35.10] (0.0)	1[22.77] (4.4)	0[22.86] (0.0)
HYPERTENSION	1[35.06] (2.9)	1[22.77] (4.4)	0[22.86] (0.0)
HYPOTENSION	2[34.90] (5.7)	1[22.77] (4.4)	0[22.86] (0.0)
ORTHOSTATIC HYPOTENSION	1[34.95] (2.9)	0[22.77] (0.0)	0[22.86] (0.0)
WOUND HAEMORRHAGE	0[35.10] (0.0)	0[22.77] (0.0)	1[22.82] (4.4)

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	n	[subj-yr] (r)	n	[subj-yr] (r)	n	[subj-yr] (r)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0[35.10]	(0.0)	2[22.52]	(8.9)	1[22.80]	(4.4)
COLON CANCER	0[35.10]	(0.0)	1[22.74]	(4.4)	0[22.86]	(0.0)
MALIGNANT FIBROUS HISTIOCYTOMA	0[35.10]	(0.0)	1[22.55]	(4.4)	0[22.86]	(0.0)
PROSTATE CANCER	0[35.10]	(0.0)	0[22.77]	(0.0)	1[22.80]	(4.4)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	2[34.54]	(5.8)	0[22.77]	(0.0)	1[22.77]	(4.4)
PELVIC PAIN	1[34.78]	(2.9)	0[22.77]	(0.0)	0[22.86]	(0.0)
BENIGN PROSTATIC HYPERPLASIA	1[34.86]	(2.9)	0[22.77]	(0.0)	1[22.77]	(4.4)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	0[35.10]	(0.0)	1[22.76]	(4.4)	2[22.70]	(8.8)
VENTRICULAR SEPTAL DEFECT	0[35.10]	(0.0)	1[22.76]	(4.4)	2[22.70]	(8.8)
SURGICAL AND MEDICAL PROCEDURES	2[34.34]	(5.8)	1[22.73]	(4.4)	2[22.66]	(8.8)
CATARACT OPERATION	1[34.71]	(2.9)	1[22.73]	(4.4)	0[22.86]	(0.0)
EYE LASER SURGERY	1[34.73]	(2.9)	0[22.77]	(0.0)	0[22.86]	(0.0)
ACROCHORDON EXCISION	0[35.10]	(0.0)	0[22.77]	(0.0)	1[22.77]	(4.4)
SKIN LESION EXCISION	0[35.10]	(0.0)	0[22.77]	(0.0)	1[22.75]	(4.4)
EYE DISORDERS	2[34.62]	(5.8)	1[22.77]	(4.4)	1[22.47]	(4.5)
CONJUNCTIVAL HAEMORRHAGE	0[35.10]	(0.0)	1[22.77]	(4.4)	0[22.86]	(0.0)
CONJUNCTIVITIS	1[34.89]	(2.9)	0[22.77]	(0.0)	0[22.86]	(0.0)
EYE ALLERGY	1[34.83]	(2.9)	0[22.77]	(0.0)	0[22.86]	(0.0)
EYE PRURITUS	1[34.86]	(2.9)	0[22.77]	(0.0)	0[22.86]	(0.0)

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System Organ Class Preferred Term	Placebo (N=86)		Low Dose (N=84)		High Dose (N=84)	
	n	[subj-yr] (r)	n	[subj-yr] (r)	n	[subj-yr] (r)
EYE SWELLING	1[34.83] (2.9)	0[22.77] (0.0)	0[22.86] (0.0)
VISION BLURRED	0[35.10] (0.0)	1[22.77] (4.4)	1[22.47] (4.5)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	4[33.83] (11.8)	4[22.18] (18.0)	4[22.43] (17.8)
FACIAL BONES FRACTURE	0[35.10] (0.0)	0[22.77] (0.0)	1[22.86] (4.4)
FALL	1[34.70] (2.9)	2[22.46] (8.9)	1[22.86] (4.4)
JOINT DISLOCATION	0[35.10] (0.0)	1[22.63] (4.4)	0[22.86] (0.0)
SKIN LACERATION	1[35.09] (2.8)	2[22.68] (8.8)	0[22.86] (0.0)
WOUND	0[35.10] (0.0)	1[22.66] (4.4)	0[22.86] (0.0)
EXCORIATION	2[34.56] (5.8)	1[22.75] (4.4)	1[22.78] (4.4)
CONTUSION	1[35.09] (2.8)	1[22.48] (4.4)	2[22.69] (8.8)
HIP FRACTURE	1[34.77] (2.9)	0[22.77] (0.0)	2[22.67] (8.8)
METABOLISM AND NUTRITION DISORDERS	5[33.65] (14.9)	1[22.58] (4.4)	2[22.35] (9.0)
DEHYDRATION	1[34.93] (2.9)	0[22.77] (0.0)	0[22.86] (0.0)
DIABETES MELLITUS	1[34.72] (2.9)	0[22.77] (0.0)	0[22.86] (0.0)
FOOD CRAVING	1[34.96] (2.9)	1[22.58] (4.4)	0[22.86] (0.0)
HYPONATRAEMIA	1[35.10] (2.8)	0[22.77] (0.0)	0[22.86] (0.0)
DECREASED APPETITE	1[34.76] (2.9)	0[22.77] (0.0)	1[22.84] (4.4)
INCREASED APPETITE	1[34.68] (2.9)	0[22.77] (0.0)	1[22.37] (4.5)
RENAL AND URINARY DISORDERS	4[33.48] (11.9)	3[22.36] (13.4)	3[22.28] (13.5)
DYSURIA	1[34.63] (2.9)	1[22.53] (4.4)	0[22.86] (0.0)

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	n	[subj-yr] (r)	n	[subj-yr] (r)	n	[subj-yr] (r)
INCONTINENCE	0[35.10] (0.0)	1[22.63] (4.4)	0[22.86] (0.0)
POLLAKIURIA	1[34.63] (2.9)	0[22.77] (0.0)	0[22.86] (0.0)
MICTURITION URGENCY	1[34.79] (2.9)	1[22.75] (4.4)	1[22.77] (4.4)
CALCULUS URETHRAL	0[35.10] (0.0)	0[22.77] (0.0)	1[22.68] (4.4)
NEPHROLITHIASIS	1[34.72] (2.9)	0[22.77] (0.0)	1[22.55] (4.4)
INVESTIGATIONS	9[32.30] (27.9)	5[21.66] (23.1)	6[21.72] (27.6)
BLOOD ALKALINE PHOSPHATASE INCREASED	1[34.98] (2.9)	0[22.77] (0.0)	0[22.86] (0.0)
BLOOD CREATINE PHOSPHOKINASE INCREASED	1[34.69] (2.9)	0[22.77] (0.0)	0[22.86] (0.0)
BLOOD URINE PRESENT	1[34.85] (2.9)	0[22.77] (0.0)	0[22.86] (0.0)
BODY TEMPERATURE INCREASED	0[35.10] (0.0)	1[22.77] (4.4)	0[22.86] (0.0)
CYSTOSCOPY	1[34.86] (2.9)	0[22.77] (0.0)	0[22.86] (0.0)
ELECTROCARDIOGRAM ST SEGMENT DEPRESSION	4[34.37] (11.6)	1[22.74] (4.4)	0[22.86] (0.0)
ELECTROCARDIOGRAM T WAVE AMPLITUDE DECREASED	1[34.89] (2.9)	1[22.77] (4.4)	0[22.86] (0.0)
HEART RATE INCREASED	1[34.60] (2.9)	0[22.77] (0.0)	0[22.86] (0.0)
HEART RATE IRREGULAR	1[34.83] (2.9)	0[22.77] (0.0)	0[22.86] (0.0)
NASAL MUCOSA BIOPSY	0[35.10] (0.0)	1[22.31] (4.5)	0[22.86] (0.0)
WEIGHT DECREASED	0[35.10] (0.0)	0[22.77] (0.0)	1[22.86] (4.4)
BLOOD CHOLESTEROL INCREASED	0[35.10] (0.0)	0[22.77] (0.0)	1[22.79] (4.4)
BIOPSY PROSTATE	0[35.10] (0.0)	0[22.77] (0.0)	1[22.75] (4.4)
BLOOD GLUCOSE INCREASED	0[35.10] (0.0)	1[22.37] (4.5)	1[22.64] (4.4)
ELECTROCARDIOGRAM T WAVE INVERSION	2[34.21] (5.8)	1[22.57] (4.4)	1[22.60] (4.4)

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	n [subj-yr] (r)	n [subj-yr] (r)	n [subj-yr] (r)
BIOPSY	0[35.10] (0.0)	0[22.77] (0.0)	1[22.38] (4.5)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	4[34.80] (11.5)	7[21.32] (32.8)	7[21.31] (32.8)
MUSCULAR WEAKNESS	0[35.10] (0.0)	1[22.40] (4.5)	0[22.86] (0.0)
PAIN IN EXTREMITY	1[35.09] (2.9)	0[22.77] (0.0)	0[22.86] (0.0)
SHOULDER PAIN	1[34.94] (2.9)	2[22.43] (8.9)	0[22.86] (0.0)
MYALGIA	0[35.10] (0.0)	0[22.77] (0.0)	1[22.68] (4.4)
FLANK PAIN	0[35.10] (0.0)	0[22.77] (0.0)	1[22.67] (4.4)
ARTHRALGIA	1[35.09] (2.8)	2[22.27] (9.0)	1[22.58] (4.4)
ARTHRITIS	0[35.10] (0.0)	0[22.77] (0.0)	1[22.55] (4.4)
MUSCLE SPASMS	0[35.10] (0.0)	1[22.69] (4.4)	1[22.44] (4.5)
BACK PAIN	1[34.98] (2.9)	1[22.62] (4.4)	3[22.40] (13.4)
PSYCHIATRIC DISORDERS	10[32.24] (31.0)	7[20.82] (33.6)	7[21.20] (33.0)
AGITATION	2[34.69] (5.8)	2[22.79] (8.8)	1[22.86] (4.4)
ANXIETY	0[35.10] (0.0)	3[21.35] (14.0)	0[22.86] (0.0)
COMPLETED SUICIDE	1[35.10] (2.8)	0[22.77] (0.0)	0[22.86] (0.0)
DELIRIUM	0[35.10] (0.0)	0[22.77] (0.0)	1[22.86] (4.4)
DEPRESSED MOOD	0[35.10] (0.0)	1[22.39] (4.5)	0[22.86] (0.0)
DISORIENTATION	1[34.67] (2.9)	0[22.77] (0.0)	0[22.86] (0.0)
IRRITABILITY	1[34.57] (2.9)	1[22.28] (4.5)	0[22.86] (0.0)
RESTLESSNESS	0[35.10] (0.0)	1[22.70] (4.4)	0[22.86] (0.0)
LIBIDO DECREASED	0[35.10] (0.0)	0[22.77] (0.0)	1[22.83] (4.4)

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	n	[subj-yr] (r)	n	[subj-yr] (r)	n	[subj-yr] (r)
LISTLESS	0[35.10] (0.0)	0[22.77] (0.0)	1[22.83] (4.4)
HALLUCINATION, VISUAL	0[35.10] (0.0)	0[22.77] (0.0)	1[22.69] (4.4)
DELUSION	1[35.02] (2.9)	0[22.77] (0.0)	1[22.60] (4.4)
HALLUCINATION	0[35.10] (0.0)	0[22.77] (0.0)	1[22.60] (4.4)
CONFUSIONAL STATE	2[34.68] (5.8)	3[22.70] (13.2)	1[22.43] (4.5)
NIGHTMARE	0[35.10] (0.0)	0[22.77] (0.0)	1[22.36] (4.5)
INSOMNIA	2[34.11] (5.9)	0[22.77] (0.0)	2[22.16] (9.0)
CARDIAC DISORDERS	10[32.66] (30.6)	10[20.65] (48.4)	11[21.13] (52.1)
atrial hypertrophy	1[34.64] (2.9)	0[22.77] (0.0)	0[22.86] (0.0)
atrioventricular block first degree	1[34.91] (2.9)	1[22.54] (4.4)	0[22.86] (0.0)
atrioventricular block second degree	1[35.08] (2.9)	0[22.77] (0.0)	0[22.86] (0.0)
bradycardia	1[34.65] (2.9)	0[22.77] (0.0)	0[22.86] (0.0)
bundle branch block left	1[35.10] (2.8)	0[22.77] (0.0)	0[22.86] (0.0)
bundle branch block right	1[34.71] (2.9)	1[22.76] (4.4)	0[22.86] (0.0)
cardiac failure congestive	1[35.10] (2.8)	0[22.77] (0.0)	0[22.86] (0.0)
palpitations	0[35.10] (0.0)	2[22.70] (8.8)	0[22.86] (0.0)
sinus arrhythmia	1[34.68] (2.9)	0[22.77] (0.0)	0[22.86] (0.0)
supraventricular tachycardia	0[35.10] (0.0)	1[22.51] (4.4)	0[22.86] (0.0)
tachycardia	1[35.07] (2.9)	0[22.77] (0.0)	0[22.86] (0.0)
ventricular hypertrophy	1[35.06] (2.9)	0[22.77] (0.0)	0[22.86] (0.0)
wolff-parkinson-white syndrome	0[35.10] (0.0)	1[22.78] (4.4)	0[22.86] (0.0)
cardiac disorder	0[35.10] (0.0)	0[22.77] (0.0)	1[22.81] (4.4)

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	n	[subj-yr] (r)	n	[subj-yr] (r)	n	[subj-yr] (r)
ATRIAL FIBRILLATION	1[35.10] (2.8)	1[22.77] (4.4)	3[22.75] (13.2)
ATRIAL FLUTTER	0[35.10] (0.0)	1[22.76] (4.4)	1[22.75] (4.4)
VENTRICULAR EXTRASYSTOLES	0[35.10] (0.0)	2[22.69] (8.8)	1[22.58] (4.4)
SUPRAVENTRICULAR EXTRASYSTOLES	1[34.73] (2.9)	1[22.69] (4.4)	1[22.56] (4.4)
MYOCARDIAL INFARCTION	4[34.65] (11.5)	2[21.86] (9.1)	4[22.25] (18.0)
SINUS BRADYCARDIA	2[34.92] (5.7)	7[21.75] (32.2)	8[22.18] (36.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	7[33.17] (21.1)	9[21.09] (42.7)	10[21.02] (47.6)
DYSPHONIA	0[35.10] (0.0)	1[22.73] (4.4)	0[22.86] (0.0)
EMPHYSEMA	1[35.00] (2.9)	0[22.77] (0.0)	0[22.86] (0.0)
HAEMOPTYSIS	1[34.79] (2.9)	0[22.77] (0.0)	0[22.86] (0.0)
POSTNASAL DRIP	1[34.70] (2.9)	0[22.77] (0.0)	0[22.86] (0.0)
RALES	1[34.83] (2.9)	0[22.77] (0.0)	0[22.86] (0.0)
DYSPNOEA	1[35.10] (2.8)	1[22.77] (4.4)	1[22.83] (4.4)
RESPIRATORY TRACT CONGESTION	0[35.10] (0.0)	0[22.77] (0.0)	1[22.82] (4.4)
RHINORRHOEA	0[35.10] (0.0)	1[22.28] (4.5)	1[22.81] (4.4)
PHARYNGEAL ERYTHEMA	0[35.10] (0.0)	0[22.77] (0.0)	1[22.74] (4.4)
PHARYNGOLARYNGEAL PAIN	0[35.10] (0.0)	1[22.55] (4.4)	1[22.68] (4.4)
PRODUCTIVE COUGH	0[35.10] (0.0)	0[22.77] (0.0)	1[22.68] (4.4)
EPISTAXIS	0[35.10] (0.0)	1[22.71] (4.4)	2[22.63] (8.8)
ALLERGIC GRANULOMATOUS ANGIITIS	0[35.10] (0.0)	0[22.77] (0.0)	1[22.40] (4.5)
NASAL CONGESTION	3[34.25] (8.8)	1[22.55] (4.4)	3[21.96] (13.7)
COUGH	1[34.82] (2.9)	5[21.42] (23.3)	5[21.90] (22.8)

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INFECTIONS AND INFESTATIONS	16[29.85] (53.6)	9[21.48] (41.9)	13[19.70] (66.0)
BRONCHITIS	1[34.85] (2.9)	0[22.77] (0.0)	0[22.86] (0.0)
CELLULITIS	0[35.10] (0.0)	1[22.77] (4.4)	0[22.86] (0.0)
CERVICITIS	1[34.90] (2.9)	0[22.77] (0.0)	0[22.86] (0.0)
EAR INFECTION	2[34.33] (5.8)	0[22.77] (0.0)	0[22.86] (0.0)
GASTROENTERITIS VIRAL	1[34.78] (2.9)	0[22.77] (0.0)	0[22.86] (0.0)
LOCALISED INFECTION	1[34.75] (2.9)	0[22.77] (0.0)	0[22.86] (0.0)
PNEUMONIA	0[35.10] (0.0)	1[22.40] (4.5)	0[22.86] (0.0)
VAGINAL MYCOSIS	1[34.90] (2.9)	0[22.77] (0.0)	0[22.86] (0.0)
VIRAL INFECTION	0[35.10] (0.0)	1[22.76] (4.4)	0[22.86] (0.0)
CYSTITIS	1[34.74] (2.9)	0[22.77] (0.0)	1[22.82] (4.4)
RHINITIS	0[35.10] (0.0)	0[22.77] (0.0)	1[22.82] (4.4)
INFLUENZA	1[34.58] (2.9)	1[22.69] (4.4)	1[22.81] (4.4)
HORDEOLUM	0[35.10] (0.0)	0[22.77] (0.0)	1[22.58] (4.4)
URINARY TRACT INFECTION	2[34.22] (5.8)	0[22.77] (0.0)	1[22.55] (4.4)
LOWER RESPIRATORY TRACT INFECTION	0[35.10] (0.0)	0[22.77] (0.0)	1[22.50] (4.4)
UPPER RESPIRATORY TRACT INFECTION	6[33.40] (18.0)	1[22.31] (4.5)	3[21.90] (13.7)
NASOPHARYNGITIS	2[34.67] (5.8)	4[22.42] (17.8)	6[21.41] (28.0)
NERVOUS SYSTEM DISORDERS	8[33.03] (24.2)	17[20.07] (84.7)	21[18.85] (111.4)
BALANCE DISORDER	0[35.10] (0.0)	1[22.46] (4.5)	0[22.86] (0.0)
COMPLEX PARTIAL SEIZURES	0[35.10] (0.0)	1[22.77] (4.4)	0[22.86] (0.0)

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System Organ Class Preferred Term	Placebo (N=86)		Low Dose (N=84)		High Dose (N=84)	
	n	[subj-yr] (r)	n	[subj-yr] (r)	n	[subj-yr] (r)
COORDINATION ABNORMAL	0[35.10] (0.0)	1[22.56] (4.4)	0[22.86] (0.0)
HEMIANOPIA HOMONYMOUS	0[35.10] (0.0)	1[22.67] (4.4)	0[22.86] (0.0)
PARAESTHESIA ORAL	0[35.10] (0.0)	1[22.64] (4.4)	0[22.86] (0.0)
PARKINSON'S DISEASE	1[35.09] (2.8)	0[22.77] (0.0)	0[22.86] (0.0)
PSYCHOMOTOR HYPERACTIVITY	1[35.02] (2.9)	0[22.77] (0.0)	0[22.86] (0.0)
STUPOR	0[35.10] (0.0)	1[22.77] (4.4)	0[22.86] (0.0)
SYNCOPE VASOVAGAL	0[35.10] (0.0)	0[22.77] (0.0)	1[22.86] (4.4)
TRANSIENT ISCHAEMIC ATTACK	0[35.10] (0.0)	2[22.77] (8.8)	1[22.86] (4.4)
PARAESTHESIA	0[35.10] (0.0)	0[22.77] (0.0)	1[22.85] (4.4)
BURNING SENSATION	0[35.10] (0.0)	0[22.77] (0.0)	2[22.82] (8.8)
HYPERSOMNIA	0[35.10] (0.0)	0[22.77] (0.0)	1[22.81] (4.4)
SYNCOPE	0[35.10] (0.0)	4[22.41] (17.9)	3[22.81] (13.1)
LETHARGY	0[35.10] (0.0)	1[22.70] (4.4)	1[22.76] (4.4)
AMNESIA	0[35.10] (0.0)	0[22.77] (0.0)	1[22.75] (4.4)
SOMNOLENCE	2[34.38] (5.8)	3[21.93] (13.7)	1[22.74] (4.4)
PARTIAL SEIZURES WITH SECONDARY GENERALISATION	0[35.10] (0.0)	0[22.77] (0.0)	1[22.69] (4.4)
COGNITIVE DISORDER	0[35.10] (0.0)	0[22.77] (0.0)	1[22.65] (4.4)
PAROSMIA	0[35.10] (0.0)	0[22.77] (0.0)	1[22.60] (4.4)
HEADACHE	3[34.28] (8.8)	3[22.66] (13.2)	5[22.17] (22.6)
DIZZINESS	2[34.46] (5.8)	8[21.96] (36.4)	11[20.36] (54.0)
GASTROINTESTINAL DISORDERS	17[30.32] (56.1)	13[19.84] (65.5)	17[18.30] (92.9)
GASTROINTESTINAL HAEMORRHAGE	0[35.10] (0.0)	0[22.77] (0.0)	1[22.90] (4.4)

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System Organ Class Preferred Term	Placebo (N=86)		Low Dose (N=84)		High Dose (N=84)	
	n	[subj-yr] (r)	n	[subj-yr] (r)	n	[subj-yr] (r)
CONSTIPATION	1[35.05] (2.9)	0[22.77] (0.0)	0[22.86] (0.0)
DYSPEPSIA	1[34.64] (2.9)	1[22.74] (4.4)	0[22.86] (0.0)
DYSPHAGIA	0[35.10] (0.0)	1[22.58] (4.4)	0[22.86] (0.0)
FLATULENCE	1[34.63] (2.9)	0[22.77] (0.0)	0[22.86] (0.0)
GASTROOESOPHAGEAL REFLUX DISEASE	1[34.78] (2.9)	0[22.77] (0.0)	0[22.86] (0.0)
GLOSSITIS	1[34.60] (2.9)	0[22.77] (0.0)	0[22.86] (0.0)
HIATUS HERNIA	1[35.03] (2.9)	0[22.77] (0.0)	0[22.86] (0.0)
RECTAL HAEMORRHAGE	0[35.10] (0.0)	1[22.66] (4.4)	0[22.86] (0.0)
ABDOMINAL DISCOMFORT	0[35.10] (0.0)	0[22.77] (0.0)	1[22.70] (4.4)
STOMACH DISCOMFORT	0[35.10] (0.0)	0[22.77] (0.0)	1[22.67] (4.4)
ABDOMINAL PAIN	1[35.05] (2.9)	3[21.83] (13.7)	1[22.38] (4.5)
DIARRHOEA	9[32.78] (27.5)	4[21.82] (18.3)	4[22.14] (18.1)
NAUSEA	3[34.19] (8.8)	3[22.18] (13.5)	6[21.86] (27.5)
SALIVARY HYPERSECRETION	0[35.10] (0.0)	0[22.77] (0.0)	4[21.59] (18.5)
VOMITING	3[34.64] (8.7)	3[21.82] (13.8)	7[21.34] (32.8)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	21[28.19] (74.5)	45[14.12] (318.6)	35[14.54] (240.7)
APPLICATION SITE BLEEDING	0[35.10] (0.0)	1[22.45] (4.5)	0[22.86] (0.0)
APPLICATION SITE DESQUAMATION	0[35.10] (0.0)	1[22.73] (4.4)	0[22.86] (0.0)
APPLICATION SITE DISCOLOURATION	0[35.10] (0.0)	1[22.37] (4.5)	0[22.86] (0.0)
APPLICATION SITE INDURATION	1[34.65] (2.9)	0[22.77] (0.0)	0[22.86] (0.0)
APPLICATION SITE REACTION	1[34.92] (2.9)	0[22.77] (0.0)	1[22.86] (4.4)
APPLICATION SITE URTICARIA	0[35.10] (0.0)	2[22.35] (8.9)	1[22.86] (4.4)

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System Organ Class Preferred Term	Placebo (N=86)		Low Dose (N=84)		High Dose (N=84)	
	n	[subj-yr] (r)	n	[subj-yr] (r)	n	[subj-yr] (r)
APPLICATION SITE WARMTH	0[35.10] (0.0)	1[22.76] (4.4)	0[22.86] (0.0)
ASTHENIA	1[34.68] (2.9)	0[22.77] (0.0)	1[22.86] (4.4)
INFLAMMATION	0[35.10] (0.0)	1[22.81] (4.4)	0[22.86] (0.0)
OEDEMA	0[35.10] (0.0)	2[22.40] (8.9)	0[22.86] (0.0)
PYREXIA	2[34.49] (5.8)	0[22.77] (0.0)	1[22.86] (4.4)
SECRETION DISCHARGE	0[35.10] (0.0)	1[22.32] (4.5)	0[22.86] (0.0)
SUDDEN DEATH	0[35.10] (0.0)	1[22.78] (4.4)	0[22.86] (0.0)
SWELLING	0[35.10] (0.0)	1[22.37] (4.5)	0[22.86] (0.0)
ULCER	0[35.10] (0.0)	1[22.64] (4.4)	0[22.86] (0.0)
APPLICATION SITE SWELLING	0[35.10] (0.0)	1[22.69] (4.4)	2[22.83] (8.8)
FEELING ABNORMAL	0[35.10] (0.0)	0[22.77] (0.0)	1[22.83] (4.4)
CHILLS	1[35.07] (2.9)	1[22.62] (4.4)	1[22.76] (4.4)
CHEST DISCOMFORT	0[35.10] (0.0)	0[22.77] (0.0)	2[22.75] (8.8)
PAIN	0[35.10] (0.0)	1[22.64] (4.4)	1[22.68] (4.4)
APPLICATION SITE DISCHARGE	0[35.10] (0.0)	0[22.77] (0.0)	1[22.67] (4.4)
CHEST PAIN	0[35.10] (0.0)	0[22.77] (0.0)	2[22.61] (8.8)
FEELING COLD	0[35.10] (0.0)	0[22.77] (0.0)	1[22.57] (4.4)
MALAISE	0[35.10] (0.0)	1[22.72] (4.4)	2[22.57] (8.9)
OEDEMA PERIPHERAL	2[34.78] (5.8)	1[22.78] (4.4)	2[22.44] (8.9)
APPLICATION SITE PAIN	0[35.10] (0.0)	0[22.77] (0.0)	2[22.35] (8.9)
APPLICATION SITE PERSPIRATION	0[35.10] (0.0)	0[22.77] (0.0)	2[22.33] (9.0)
APPLICATION SITE VESICLES	1[34.91] (2.9)	4[22.11] (18.1)	6[22.14] (27.1)
FATIGUE	1[34.99] (2.9)	5[21.86] (22.9)	5[22.00] (22.7)

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System Organ Class Preferred Term	Placebo (N=86)		Low Dose (N=84)		High Dose (N=84)	
	n	[subj-yr] (r)	n	[subj-yr] (r)	n	[subj-yr] (r)
APPLICATION SITE DERMATITIS	5[33.08] (15.1)	9[21.36] (42.1)	7[21.64] (32.4)
APPLICATION SITE IRRITATION	3[34.17] (8.8)	9[21.77] (41.3)	9[20.84] (43.2)
APPLICATION SITE ERYTHEMA	3[34.09] (8.8)	12[20.33] (59.0)	15[19.95] (75.2)
APPLICATION SITE PRURITUS	6[32.88] (18.2)	22[18.17] (121.1)	22[17.82] (123.5)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	19[30.69] (61.9)	37[15.39] (240.4)	40[13.75] (290.9)
ALOPECIA	1[35.00] (2.9)	0[22.77] (0.0)	0[22.86] (0.0)
COLD SWEAT	1[35.07] (2.9)	0[22.77] (0.0)	0[22.86] (0.0)
DERMATITIS CONTACT	0[35.10] (0.0)	1[22.77] (4.4)	0[22.86] (0.0)
DRUG ERUPTION	1[35.03] (2.9)	0[22.77] (0.0)	0[22.86] (0.0)
RASH ERYTHEMATOUS	0[35.10] (0.0)	1[22.76] (4.4)	0[22.86] (0.0)
SKIN EXFOLIATION	0[35.10] (0.0)	1[22.77] (4.4)	0[22.86] (0.0)
SKIN ULCER	1[34.62] (2.9)	0[22.77] (0.0)	0[22.86] (0.0)
ACTINIC KERATOSIS	0[35.10] (0.0)	0[22.77] (0.0)	1[22.84] (4.4)
BLISTER	0[35.10] (0.0)	5[22.00] (22.7)	1[22.80] (4.4)
RASH PRURITIC	0[35.10] (0.0)	1[22.77] (4.4)	2[22.64] (8.8)
PRURITUS GENERALISED	0[35.10] (0.0)	1[22.39] (4.5)	1[22.46] (4.5)
SKIN ODOUR ABNORMAL	0[35.10] (0.0)	0[22.77] (0.0)	1[22.37] (4.5)
RASH MACULO-PAPULAR	0[35.10] (0.0)	0[22.77] (0.0)	1[22.36] (4.5)
URTICARIA	0[35.10] (0.0)	1[22.72] (4.4)	1[22.31] (4.5)
RASH	5[34.52] (14.5)	13[20.58] (63.2)	9[21.58] (41.7)
HYPERHIDROSIS	2[34.58] (5.8)	4[22.03] (18.2)	8[21.14] (37.8)
SKIN IRRITATION	3[34.09] (8.8)	6[21.52] (27.9)	5[20.98] (23.8)

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System Organ Class Preferred Term	Placebo (N=86)	Low Dose (N=84)	High Dose (N=84)
	n [subj-yr] (r)	n [subj-yr] (r)	n [subj-yr] (r)
ERYTHEMA	8[34.00] (23.5)	14[19.71] (71.0)	14[18.85] (74.3)
PRURITUS	8[32.70] (24.5)	21[19.62] (107.0)	26[17.61] (147.6)