

**Exposure Adjusted Subject Incidence Rate by SOC and PT**  
**Safety Analysis Set**

<b>System Organ Class Preferred Term</b>	<b>Placebo (N=86)</b>			<b>Low Dose (N=84)</b>			<b>High Dose (N=84)</b>		
	<b>n</b>	<b>[subj-yr]</b>	<b>(r)</b>	<b>n</b>	<b>[subj-yr]</b>	<b>(r)</b>	<b>n</b>	<b>[subj-yr]</b>	<b>(r)</b>
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)
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)

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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)
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)
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)
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)

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	n	[subj-yr]	(r)	n	[subj-yr]	(r)	n	[subj-yr]	(r)
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)
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)

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	n	[subj-yr]	(r)	n	[subj-yr]	(r)	n	[subj-yr]	(r)
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)
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									
ATRIAL HYPERTROPHY	10[	32.66]	( 30.6)	10[	20.65]	( 48.4)	11[	21.13]	( 52.1)
ATRIOVENTRICULAR BLOCK FIRST DEGREE	1[	34.64]	( 2.9)	0[	22.77]	( 0.0)	0[	22.86]	( 0.0)
ATRIOVENTRICULAR BLOCK SECOND DEGREE	1[	34.91]	( 2.9)	1[	22.54]	( 4.4)	0[	22.86]	( 0.0)
BRADYCARDIA	1[	35.08]	( 2.9)	0[	22.77]	( 0.0)	0[	22.86]	( 0.0)
BUNDLE BRANCH BLOCK LEFT	1[	34.65]	( 2.9)	0[	22.77]	( 0.0)	0[	22.86]	( 0.0)
BUNDLE BRANCH BLOCK RIGHT	1[	35.10]	( 2.8)	0[	22.77]	( 0.0)	0[	22.86]	( 0.0)
CARDIAC FAILURE CONGESTIVE	1[	34.71]	( 2.9)	1[	22.76]	( 4.4)	0[	22.86]	( 0.0)
PALPITATIONS	1[	35.10]	( 2.8)	0[	22.77]	( 0.0)	0[	22.86]	( 0.0)
SINUS ARRHYTHMIA	1[	35.10]	( 0.0)	2[	22.70]	( 8.8)	0[	22.86]	( 0.0)
SUPRAVENTRICULAR TACHYCARDIA	1[	34.68]	( 2.9)	0[	22.77]	( 0.0)	0[	22.86]	( 0.0)
TACHYCARDIA	0[	35.10]	( 0.0)	1[	22.51]	( 4.4)	0[	22.86]	( 0.0)
VENTRICULAR HYPERTROPHY	1[	35.07]	( 2.9)	0[	22.77]	( 0.0)	0[	22.86]	( 0.0)
WOLFF-PARKINSON-WHITE SYNDROME	1[	35.06]	( 2.9)	0[	22.77]	( 0.0)	0[	22.86]	( 0.0)
CARDIAC DISORDER	0[	35.10]	( 0.0)	1[	22.78]	( 4.4)	0[	22.86]	( 0.0)
ATRIAL FIBRILLATION	0[	35.10]	( 0.0)	0[	22.77]	( 0.0)	1[	22.81]	( 4.4)
ATRIAL FLUTTER	1[	35.10]	( 2.8)	1[	22.77]	( 4.4)	3[	22.75]	( 13.2)
VENTRICULAR EXTRASYSTOLES	0[	35.10]	( 0.0)	1[	22.76]	( 4.4)	1[	22.75]	( 4.4)
SUPRAVENTRICULAR EXTRASYSTOLES	0[	35.10]	( 0.0)	2[	22.69]	( 8.8)	1[	22.58]	( 4.4)
MYOCARDIAL INFARCTION	1[	34.73]	( 2.9)	1[	22.69]	( 4.4)	1[	22.56]	( 4.4)
SINUS BRADYCARDIA	4[	34.65]	( 11.5)	2[	21.86]	( 9.1)	4[	22.25]	( 18.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	2[	34.92]	( 5.7)	7[	21.75]	( 32.2)	8[	22.18]	( 36.1)
DYSPHONIA	7[	33.17]	( 21.1)	9[	21.09]	( 42.7)	10[	21.02]	( 47.6)
EMPHYSEMA	0[	35.10]	( 0.0)	1[	22.73]	( 4.4)	0[	22.86]	( 0.0)
	1[	35.00]	( 2.9)	0[	22.77]	( 0.0)	0[	22.86]	( 0.0)

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	n	[subj-yr]	(r)	n	[subj-yr]	(r)	n	[subj-yr]	(r)
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)
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)
COORDINATION ABNORMAL	0[	35.10]	( 0.0)	1[	22.56]	( 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)
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)
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)

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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)
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)
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)
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)

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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)
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)
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)