

**Treatment-Emergent Adverse Events by Maximum Severity  
Safety Analysis Set**

System Organ Class Preferred Term	Maximum Severity	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
Overall	Mild	36 ( 41.9%)	19 ( 22.6%)	22 ( 26.2%)
	Moderate	24 ( 27.9%)	42 ( 50.0%)	46 ( 54.8%)
	Severe	5 ( 5.8%)	16 ( 19.0%)	8 ( 9.5%)
	Total	65 ( 75.6%)	77 ( 91.7%)	76 ( 90.5%)
CARDIAC DISORDERS	Mild	8 ( 9.3%)	8 ( 9.5%)	9 ( 10.7%)
	Moderate	2 ( 2.3%)	5 ( 6.0%)	5 ( 6.0%)
	Severe	2 ( 2.3%)	0	1 ( 1.2%)
	Total	12 ( 14.0%)	13 ( 15.5%)	15 ( 17.9%)
ATRIAL FIBRILLATION	Mild	0	0	2 ( 2.4%)
	Moderate	1 ( 1.2%)	1 ( 1.2%)	0
	Severe	0	0	1 ( 1.2%)
	Total	1 ( 1.2%)	1 ( 1.2%)	3 ( 3.6%)
ATRIAL FLUTTER	Mild	0	0	1 ( 1.2%)
	Moderate	0	1 ( 1.2%)	0
	Severe	0	0	0
	Total	0	1 ( 1.2%)	1 ( 1.2%)
ATRIAL HYPERTROPHY	Mild	1 ( 1.2%)	0	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	0	0
ATRIOVENTRICULAR BLOCK FIRST DEGREE	Mild	1 ( 1.2%)	1 ( 1.2%)	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	1 ( 1.2%)	0
ATRIOVENTRICULAR BLOCK SECOND DEGREE	Mild	1 ( 1.2%)	0	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	0	0
BRADYCARDIA	Mild	1 ( 1.2%)	0	0
	Moderate	0	0	0

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	Severe	0	0	0
	Total	1 ( 1.2%)	0	0
BUNDLE BRANCH BLOCK LEFT	Mild	1 ( 1.2%)	0	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	0	0
BUNDLE BRANCH BLOCK RIGHT	Mild	1 ( 1.2%)	0	0
	Moderate	0	1 ( 1.2%)	0
	Severe	0	0	0
	Total	1 ( 1.2%)	1 ( 1.2%)	0
CARDIAC DISORDER	Mild	0	0	1 ( 1.2%)
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	0	1 ( 1.2%)
CARDIAC FAILURE CONGESTIVE	Mild	0	0	0
	Moderate	1 ( 1.2%)	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	0	0
MYOCARDIAL INFARCTION	Mild	1 ( 1.2%)	2 ( 2.4%)	3 ( 3.6%)
	Moderate	1 ( 1.2%)	0	1 ( 1.2%)
	Severe	2 ( 2.3%)	0	0
	Total	4 ( 4.7%)	2 ( 2.4%)	4 ( 4.8%)
PALPITATIONS	Mild	0	0	0
	Moderate	0	2 ( 2.4%)	0
	Severe	0	0	0
	Total	0	2 ( 2.4%)	0
SINUS ARRHYTHMIA	Mild	1 ( 1.2%)	0	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	0	0

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SINUS BRADYCARDIA	Mild	1 ( 1.2%)	6 ( 7.1%)	4 ( 4.8%)
	Moderate	1 ( 1.2%)	1 ( 1.2%)	4 ( 4.8%)
	Severe	0	0	0
	Total	2 ( 2.3%)	7 ( 8.3%)	8 ( 9.5%)
SUPRAVENTRICULAR EXTRASYSTOLES	Mild	1 ( 1.2%)	1 ( 1.2%)	1 ( 1.2%)
	Moderate	0	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	1 ( 1.2%)	1 ( 1.2%)
SUPRAVENTRICULAR TACHYCARDIA	Mild	0	0	0
	Moderate	0	1 ( 1.2%)	0
	Severe	0	0	0
	Total	0	1 ( 1.2%)	0
TACHYCARDIA	Mild	0	0	0
	Moderate	1 ( 1.2%)	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	0	0
VENTRICULAR EXTRASYSTOLES	Mild	0	1 ( 1.2%)	1 ( 1.2%)
	Moderate	0	1 ( 1.2%)	0
	Severe	0	0	0
	Total	0	2 ( 2.4%)	1 ( 1.2%)
VENTRICULAR HYPERTROPHY	Mild	1 ( 1.2%)	0	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	0	0
WOLFF-PARKINSON-WHITE SYNDROME	Mild	0	1 ( 1.2%)	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	1 ( 1.2%)	0
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	Mild	0	0	2 ( 2.4%)

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	Moderate	0	1 ( 1.2%)	0
	Severe	0	0	0
	Total	0	1 ( 1.2%)	2 ( 2.4%)
VENTRICULAR SEPTAL DEFECT	Mild	0	0	2 ( 2.4%)
	Moderate	0	1 ( 1.2%)	0
	Severe	0	0	0
	Total	0	1 ( 1.2%)	2 ( 2.4%)
EAR AND LABYRINTH DISORDERS	Mild	1 ( 1.2%)	1 ( 1.2%)	0
	Moderate	0	1 ( 1.2%)	1 ( 1.2%)
	Severe	0	0	0
	Total	1 ( 1.2%)	2 ( 2.4%)	1 ( 1.2%)
CERUMEN IMPACTION	Mild	0	1 ( 1.2%)	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	1 ( 1.2%)	0
EAR PAIN	Mild	1 ( 1.2%)	0	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	0	0
VERTIGO	Mild	0	0	0
	Moderate	0	1 ( 1.2%)	1 ( 1.2%)
	Severe	0	0	0
	Total	0	1 ( 1.2%)	1 ( 1.2%)
EYE DISORDERS	Mild	1 ( 1.2%)	1 ( 1.2%)	0
	Moderate	1 ( 1.2%)	1 ( 1.2%)	1 ( 1.2%)
	Severe	0	0	0
	Total	2 ( 2.3%)	2 ( 2.4%)	1 ( 1.2%)
CONJUNCTIVAL HAEMORRHAGE	Mild	0	0	0
	Moderate	0	1 ( 1.2%)	0
	Severe	0	0	0

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	Total	0	1 ( 1.2%)	0
CONJUNCTIVITIS	Mild	0	0	0
	Moderate	1 ( 1.2%)	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	0	0
EYE ALLERGY	Mild	1 ( 1.2%)	0	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	0	0
EYE PRURITUS	Mild	1 ( 1.2%)	0	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	0	0
EYE SWELLING	Mild	1 ( 1.2%)	0	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	0	0
VISION BLURRED	Mild	0	1 ( 1.2%)	0
	Moderate	0	0	1 ( 1.2%)
	Severe	0	0	0
	Total	0	1 ( 1.2%)	1 ( 1.2%)
GASTROINTESTINAL DISORDERS	Mild	15 ( 17.4%)	10 ( 11.9%)	14 ( 16.7%)
	Moderate	2 ( 2.3%)	4 ( 4.8%)	4 ( 4.8%)
	Severe	0	0	2 ( 2.4%)
	Total	17 ( 19.8%)	14 ( 16.7%)	20 ( 23.8%)
ABDOMINAL DISCOMFORT	Mild	0	0	1 ( 1.2%)
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	0	1 ( 1.2%)

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ABDOMINAL PAIN	Mild	1 ( 1.2%)	2 ( 2.4%)	0
	Moderate	0	1 ( 1.2%)	1 ( 1.2%)
	Severe	0	0	0
	Total	1 ( 1.2%)	3 ( 3.6%)	1 ( 1.2%)
CONSTIPATION	Mild	1 ( 1.2%)	0	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	0	0
DIARRHOEA	Mild	9 ( 10.5%)	4 ( 4.8%)	2 ( 2.4%)
	Moderate	0	0	2 ( 2.4%)
	Severe	0	0	0
	Total	9 ( 10.5%)	4 ( 4.8%)	4 ( 4.8%)
DYSPEPSIA	Mild	1 ( 1.2%)	0	0
	Moderate	0	1 ( 1.2%)	0
	Severe	0	0	0
	Total	1 ( 1.2%)	1 ( 1.2%)	0
DYSPHAGIA	Mild	0	0	0
	Moderate	0	1 ( 1.2%)	0
	Severe	0	0	0
	Total	0	1 ( 1.2%)	0
FLATULENCE	Mild	1 ( 1.2%)	0	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	0	0
GASTROINTESTINAL HAEMORRHAGE	Mild	0	0	0
	Moderate	0	0	0
	Severe	0	0	1 ( 1.2%)
	Total	0	0	1 ( 1.2%)
GASTROESOPHAGEAL REFLUX DISEASE	Mild	1 ( 1.2%)	0	0
	Moderate	0	0	0

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	Severe	0	0	0
	Total	1 ( 1.2%)	0	0
GLOSSITIS	Mild	1 ( 1.2%)	0	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	0	0
HIATUS HERNIA	Mild	0	0	0
	Moderate	1 ( 1.2%)	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	0	0
NAUSEA	Mild	2 ( 2.3%)	2 ( 2.4%)	5 ( 6.0%)
	Moderate	1 ( 1.2%)	1 ( 1.2%)	0
	Severe	0	0	1 ( 1.2%)
	Total	3 ( 3.5%)	3 ( 3.6%)	6 ( 7.1%)
RECTAL HAEMORRHAGE	Mild	0	1 ( 1.2%)	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	1 ( 1.2%)	0
SALIVARY HYPERSECRETION	Mild	0	0	4 ( 4.8%)
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	0	4 ( 4.8%)
STOMACH DISCOMFORT	Mild	0	0	1 ( 1.2%)
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	0	1 ( 1.2%)
VOMITING	Mild	2 ( 2.3%)	2 ( 2.4%)	5 ( 6.0%)
	Moderate	1 ( 1.2%)	1 ( 1.2%)	2 ( 2.4%)
	Severe	0	0	0
	Total	3 ( 3.5%)	3 ( 3.6%)	7 ( 8.3%)

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System Organ Class Preferred Term	Maximum Severity	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Mild	16 ( 18.6%)	19 ( 22.6%)	19 ( 22.6%)
	Moderate	5 ( 5.8%)	21 ( 25.0%)	21 ( 25.0%)
	Severe	0	7 ( 8.3%)	0
	Total	21 ( 24.4%)	47 ( 56.0%)	40 ( 47.6%)
APPLICATION SITE BLEEDING	Mild	0	0	0
	Moderate	0	1 ( 1.2%)	0
	Severe	0	0	0
	Total	0	1 ( 1.2%)	0
APPLICATION SITE DERMATITIS	Mild	5 ( 5.8%)	4 ( 4.8%)	2 ( 2.4%)
	Moderate	0	4 ( 4.8%)	5 ( 6.0%)
	Severe	0	1 ( 1.2%)	0
	Total	5 ( 5.8%)	9 ( 10.7%)	7 ( 8.3%)
APPLICATION SITE DESQUAMATION	Mild	0	1 ( 1.2%)	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	1 ( 1.2%)	0
APPLICATION SITE DISCHARGE	Mild	0	0	0
	Moderate	0	0	1 ( 1.2%)
	Severe	0	0	0
	Total	0	0	1 ( 1.2%)
APPLICATION SITE DISCOLOURATION	Mild	0	0	0
	Moderate	0	1 ( 1.2%)	0
	Severe	0	0	0
	Total	0	1 ( 1.2%)	0
APPLICATION SITE ERYTHEMA	Mild	3 ( 3.5%)	4 ( 4.8%)	9 ( 10.7%)
	Moderate	0	6 ( 7.1%)	6 ( 7.1%)
	Severe	0	2 ( 2.4%)	0
	Total	3 ( 3.5%)	12 ( 14.3%)	15 ( 17.9%)
APPLICATION SITE INDURATION	Mild	1 ( 1.2%)	0	0

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	Moderate	0	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	0	0
APPLICATION SITE IRRITATION	Mild	1 ( 1.2%)	3 ( 3.6%)	3 ( 3.6%)
	Moderate	2 ( 2.3%)	3 ( 3.6%)	6 ( 7.1%)
	Severe	0	3 ( 3.6%)	0
	Total	3 ( 3.5%)	9 ( 10.7%)	9 ( 10.7%)
APPLICATION SITE PAIN	Mild	0	0	1 ( 1.2%)
	Moderate	0	0	1 ( 1.2%)
	Severe	0	0	0
	Total	0	0	2 ( 2.4%)
APPLICATION SITE PERSPIRATION	Mild	0	0	1 ( 1.2%)
	Moderate	0	0	1 ( 1.2%)
	Severe	0	0	0
	Total	0	0	2 ( 2.4%)
APPLICATION SITE PRURITUS	Mild	5 ( 5.8%)	13 ( 15.5%)	10 ( 11.9%)
	Moderate	1 ( 1.2%)	8 ( 9.5%)	12 ( 14.3%)
	Severe	0	1 ( 1.2%)	0
	Total	6 ( 7.0%)	22 ( 26.2%)	22 ( 26.2%)
APPLICATION SITE REACTION	Mild	0	0	0
	Moderate	1 ( 1.2%)	0	1 ( 1.2%)
	Severe	0	0	0
	Total	1 ( 1.2%)	0	1 ( 1.2%)
APPLICATION SITE SWELLING	Mild	0	1 ( 1.2%)	1 ( 1.2%)
	Moderate	0	0	1 ( 1.2%)
	Severe	0	0	0
	Total	0	1 ( 1.2%)	2 ( 2.4%)
APPLICATION SITE URTICARIA	Mild	0	2 ( 2.4%)	0
	Moderate	0	0	1 ( 1.2%)
	Severe	0	0	0

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	Total	0	2 ( 2.4%)	1 ( 1.2%)
APPLICATION SITE VESICLES	Mild	1 ( 1.2%)	3 ( 3.6%)	2 ( 2.4%)
	Moderate	0	1 ( 1.2%)	4 ( 4.8%)
	Severe	0	0	0
	Total	1 ( 1.2%)	4 ( 4.8%)	6 ( 7.1%)
APPLICATION SITE WARMTH	Mild	0	0	0
	Moderate	0	0	0
	Severe	0	1 ( 1.2%)	0
	Total	0	1 ( 1.2%)	0
ASTHENIA	Mild	0	0	0
	Moderate	1 ( 1.2%)	0	1 ( 1.2%)
	Severe	0	0	0
	Total	1 ( 1.2%)	0	1 ( 1.2%)
CHEST DISCOMFORT	Mild	0	0	2 ( 2.4%)
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	0	2 ( 2.4%)
CHEST PAIN	Mild	0	0	2 ( 2.4%)
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	0	2 ( 2.4%)
CHILLS	Mild	0	1 ( 1.2%)	1 ( 1.2%)
	Moderate	1 ( 1.2%)	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	1 ( 1.2%)	1 ( 1.2%)
FATIGUE	Mild	1 ( 1.2%)	3 ( 3.6%)	5 ( 6.0%)
	Moderate	0	2 ( 2.4%)	0
	Severe	0	0	0
	Total	1 ( 1.2%)	5 ( 6.0%)	5 ( 6.0%)

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FEELING ABNORMAL	Mild	0	0	1 ( 1.2%)
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	0	1 ( 1.2%)
FEELING COLD	Mild	0	0	1 ( 1.2%)
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	0	1 ( 1.2%)
INFLAMMATION	Mild	0	0	0
	Moderate	0	1 ( 1.2%)	0
	Severe	0	0	0
	Total	0	1 ( 1.2%)	0
MALAISE	Mild	0	1 ( 1.2%)	1 ( 1.2%)
	Moderate	0	0	1 ( 1.2%)
	Severe	0	0	0
	Total	0	1 ( 1.2%)	2 ( 2.4%)
OEDEMA	Mild	0	2 ( 2.4%)	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	2 ( 2.4%)	0
OEDEMA PERIPHERAL	Mild	2 ( 2.3%)	0	1 ( 1.2%)
	Moderate	0	1 ( 1.2%)	1 ( 1.2%)
	Severe	0	0	0
	Total	2 ( 2.3%)	1 ( 1.2%)	2 ( 2.4%)
PAIN	Mild	0	0	1 ( 1.2%)
	Moderate	0	1 ( 1.2%)	0
	Severe	0	0	0
	Total	0	1 ( 1.2%)	1 ( 1.2%)
PYREXIA	Mild	2 ( 2.3%)	0	1 ( 1.2%)
	Moderate	0	0	0

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	Severe	0	0	0
	Total	2 ( 2.3%)	0	1 ( 1.2%)
SECRETION DISCHARGE	Mild	0	1 ( 1.2%)	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	1 ( 1.2%)	0
SUDDEN DEATH	Mild	0	0	0
	Moderate	0	0	0
	Severe	0	1 ( 1.2%)	0
	Total	0	1 ( 1.2%)	0
SWELLING	Mild	0	0	0
	Moderate	0	1 ( 1.2%)	0
	Severe	0	0	0
	Total	0	1 ( 1.2%)	0
ULCER	Mild	0	0	0
	Moderate	0	1 ( 1.2%)	0
	Severe	0	0	0
	Total	0	1 ( 1.2%)	0
HEPATOBIILIARY DISORDERS	Mild	0	0	0
	Moderate	1 ( 1.2%)	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	0	0
HYPERBILIRUBINAEMIA	Mild	0	0	0
	Moderate	1 ( 1.2%)	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	0	0
IMMUNE SYSTEM DISORDERS	Mild	0	1 ( 1.2%)	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	1 ( 1.2%)	0

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HYPERSENSITIVITY	Mild	0	1 ( 1.2%)	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	1 ( 1.2%)	0
INFECTIONS AND INFESTATIONS	Mild	11 ( 12.8%)	6 ( 7.1%)	10 ( 11.9%)
	Moderate	5 ( 5.8%)	2 ( 2.4%)	3 ( 3.6%)
	Severe	0	1 ( 1.2%)	0
	Total	16 ( 18.6%)	9 ( 10.7%)	13 ( 15.5%)
BRONCHITIS	Mild	0	0	0
	Moderate	1 ( 1.2%)	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	0	0
CELLULITIS	Mild	0	0	0
	Moderate	0	1 ( 1.2%)	0
	Severe	0	0	0
	Total	0	1 ( 1.2%)	0
CERVICITIS	Mild	1 ( 1.2%)	0	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	0	0
CYSTITIS	Mild	1 ( 1.2%)	0	1 ( 1.2%)
	Moderate	0	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	0	1 ( 1.2%)
EAR INFECTION	Mild	2 ( 2.3%)	0	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	2 ( 2.3%)	0	0
GASTROENTERITIS VIRAL	Mild	0	0	0

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	Moderate	1 ( 1.2%)	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	0	0
HORDEOLUM	Mild	0	0	1 ( 1.2%)
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	0	1 ( 1.2%)
INFLUENZA	Mild	1 ( 1.2%)	1 ( 1.2%)	1 ( 1.2%)
	Moderate	0	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	1 ( 1.2%)	1 ( 1.2%)
LOCALISED INFECTION	Mild	1 ( 1.2%)	0	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	0	0
LOWER RESPIRATORY TRACT INFECTION	Mild	0	0	0
	Moderate	0	0	1 ( 1.2%)
	Severe	0	0	0
	Total	0	0	1 ( 1.2%)
NASOPHARYNGITIS	Mild	1 ( 1.2%)	3 ( 3.6%)	5 ( 6.0%)
	Moderate	1 ( 1.2%)	0	1 ( 1.2%)
	Severe	0	1 ( 1.2%)	0
	Total	2 ( 2.3%)	4 ( 4.8%)	6 ( 7.1%)
PNEUMONIA	Mild	0	0	0
	Moderate	0	1 ( 1.2%)	0
	Severe	0	0	0
	Total	0	1 ( 1.2%)	0
RHINITIS	Mild	0	0	1 ( 1.2%)
	Moderate	0	0	0
	Severe	0	0	0

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**Treatment-Emergent Adverse Events by Maximum Severity  
Safety Analysis Set**

System Organ Class Preferred Term	Maximum Severity	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Total	0	0	1 ( 1.2%)
UPPER RESPIRATORY TRACT INFECTION	Mild	4 ( 4.7%)	1 ( 1.2%)	2 ( 2.4%)
	Moderate	2 ( 2.3%)	0	1 ( 1.2%)
	Severe	0	0	0
	Total	6 ( 7.0%)	1 ( 1.2%)	3 ( 3.6%)
URINARY TRACT INFECTION	Mild	2 ( 2.3%)	0	1 ( 1.2%)
	Moderate	0	0	0
	Severe	0	0	0
	Total	2 ( 2.3%)	0	1 ( 1.2%)
VAGINAL MYCOSIS	Mild	1 ( 1.2%)	0	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	0	0
VIRAL INFECTION	Mild	0	1 ( 1.2%)	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	1 ( 1.2%)	0
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	Mild	3 ( 3.5%)	1 ( 1.2%)	1 ( 1.2%)
	Moderate	0	4 ( 4.8%)	3 ( 3.6%)
	Severe	1 ( 1.2%)	0	1 ( 1.2%)
	Total	4 ( 4.7%)	5 ( 6.0%)	5 ( 6.0%)
CONTUSION	Mild	1 ( 1.2%)	0	2 ( 2.4%)
	Moderate	0	1 ( 1.2%)	0
	Severe	0	0	0
	Total	1 ( 1.2%)	1 ( 1.2%)	2 ( 2.4%)
EXCORIATION	Mild	2 ( 2.3%)	0	0
	Moderate	0	1 ( 1.2%)	1 ( 1.2%)
	Severe	0	0	0
	Total	2 ( 2.3%)	1 ( 1.2%)	1 ( 1.2%)

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**Treatment-Emergent Adverse Events by Maximum Severity  
Safety Analysis Set**

System Organ Class Preferred Term	Maximum Severity	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
FACIAL BONES FRACTURE	Mild	0	0	0
	Moderate	0	0	1 ( 1.2%)
	Severe	0	0	0
	Total	0	0	1 ( 1.2%)
FALL	Mild	1 ( 1.2%)	1 ( 1.2%)	1 ( 1.2%)
	Moderate	0	1 ( 1.2%)	0
	Severe	0	0	0
	Total	1 ( 1.2%)	2 ( 2.4%)	1 ( 1.2%)
HIP FRACTURE	Mild	0	0	0
	Moderate	0	0	1 ( 1.2%)
	Severe	1 ( 1.2%)	0	1 ( 1.2%)
	Total	1 ( 1.2%)	0	2 ( 2.4%)
JOINT DISLOCATION	Mild	0	0	0
	Moderate	0	1 ( 1.2%)	0
	Severe	0	0	0
	Total	0	1 ( 1.2%)	0
SKIN LACERATION	Mild	1 ( 1.2%)	1 ( 1.2%)	0
	Moderate	0	1 ( 1.2%)	0
	Severe	0	0	0
	Total	1 ( 1.2%)	2 ( 2.4%)	0
WOUND	Mild	0	1 ( 1.2%)	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	1 ( 1.2%)	0
INVESTIGATIONS	Mild	8 ( 9.3%)	6 ( 7.1%)	4 ( 4.8%)
	Moderate	2 ( 2.3%)	0	2 ( 2.4%)
	Severe	0	0	0
	Total	10 ( 11.6%)	6 ( 7.1%)	6 ( 7.1%)
BIOPSY	Mild	0	0	1 ( 1.2%)
	Moderate	0	0	0

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**Treatment-Emergent Adverse Events by Maximum Severity  
Safety Analysis Set**

System Organ Class Preferred Term	Maximum Severity	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Severe	0	0	0
	Total	0	0	1 ( 1.2%)
BIOPSY PROSTATE	Mild	0	0	0
	Moderate	0	0	1 ( 1.2%)
	Severe	0	0	0
	Total	0	0	1 ( 1.2%)
BLOOD ALKALINE PHOSPHATASE INCREASED	Mild	0	0	0
	Moderate	1 ( 1.2%)	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	0	0
BLOOD CHOLESTEROL INCREASED	Mild	0	0	1 ( 1.2%)
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	0	1 ( 1.2%)
BLOOD CREATINE PHOSPHOKINASE INCREASED	Mild	0	0	0
	Moderate	1 ( 1.2%)	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	0	0
BLOOD GLUCOSE INCREASED	Mild	0	1 ( 1.2%)	1 ( 1.2%)
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	1 ( 1.2%)	1 ( 1.2%)
BLOOD URINE PRESENT	Mild	1 ( 1.2%)	0	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	0	0
BODY TEMPERATURE INCREASED	Mild	0	1 ( 1.2%)	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	1 ( 1.2%)	0

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Safety Analysis Set**

System Organ Class Preferred Term	Maximum Severity	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
CYSTOSCOPY	Mild	1 ( 1.2%)	0	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	0	0
ELECTROCARDIOGRAM ST SEGMENT DEPRESSION	Mild	4 ( 4.7%)	1 ( 1.2%)	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	4 ( 4.7%)	1 ( 1.2%)	0
ELECTROCARDIOGRAM T WAVE AMPLITUDE DECREASED	Mild	1 ( 1.2%)	1 ( 1.2%)	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	1 ( 1.2%)	0
ELECTROCARDIOGRAM T WAVE INVERSION	Mild	2 ( 2.3%)	1 ( 1.2%)	1 ( 1.2%)
	Moderate	0	0	0
	Severe	0	0	0
	Total	2 ( 2.3%)	1 ( 1.2%)	1 ( 1.2%)
HEART RATE INCREASED	Mild	1 ( 1.2%)	0	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	0	0
HEART RATE IRREGULAR	Mild	1 ( 1.2%)	0	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	0	0
NASAL MUCOSA BIOPSY	Mild	0	1 ( 1.2%)	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	1 ( 1.2%)	0
WEIGHT DECREASED	Mild	0	0	0

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Safety Analysis Set**

System Organ Class Preferred Term	Maximum Severity	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Moderate	0	0	1 ( 1.2%)
	Severe	0	0	0
	Total	0	0	1 ( 1.2%)
METABOLISM AND NUTRITION DISORDERS	Mild	4 ( 4.7%)	0	1 ( 1.2%)
	Moderate	2 ( 2.3%)	1 ( 1.2%)	1 ( 1.2%)
	Severe	0	0	0
	Total	6 ( 7.0%)	1 ( 1.2%)	2 ( 2.4%)
DECREASED APPETITE	Mild	0	0	0
	Moderate	1 ( 1.2%)	0	1 ( 1.2%)
	Severe	0	0	0
	Total	1 ( 1.2%)	0	1 ( 1.2%)
DEHYDRATION	Mild	1 ( 1.2%)	0	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	0	0
DIABETES MELLITUS	Mild	1 ( 1.2%)	0	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	0	0
FOOD CRAVING	Mild	1 ( 1.2%)	0	0
	Moderate	0	1 ( 1.2%)	0
	Severe	0	0	0
	Total	1 ( 1.2%)	1 ( 1.2%)	0
HYPONATRAEMIA	Mild	0	0	0
	Moderate	1 ( 1.2%)	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	0	0
INCREASED APPETITE	Mild	1 ( 1.2%)	0	1 ( 1.2%)
	Moderate	0	0	0
	Severe	0	0	0

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Safety Analysis Set**

System Organ Class Preferred Term	Maximum Severity	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Total	1 ( 1.2%)	0	1 ( 1.2%)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	Mild	3 ( 3.5%)	2 ( 2.4%)	3 ( 3.6%)
	Moderate	1 ( 1.2%)	4 ( 4.8%)	4 ( 4.8%)
	Severe	0	1 ( 1.2%)	0
	Total	4 ( 4.7%)	7 ( 8.3%)	7 ( 8.3%)
ARTHRALGIA	Mild	1 ( 1.2%)	0	0
	Moderate	0	2 ( 2.4%)	1 ( 1.2%)
	Severe	0	0	0
	Total	1 ( 1.2%)	2 ( 2.4%)	1 ( 1.2%)
ARTHRITIS	Mild	0	0	0
	Moderate	0	0	1 ( 1.2%)
	Severe	0	0	0
	Total	0	0	1 ( 1.2%)
BACK PAIN	Mild	1 ( 1.2%)	0	2 ( 2.4%)
	Moderate	0	1 ( 1.2%)	1 ( 1.2%)
	Severe	0	0	0
	Total	1 ( 1.2%)	1 ( 1.2%)	3 ( 3.6%)
FLANK PAIN	Mild	0	0	0
	Moderate	0	0	1 ( 1.2%)
	Severe	0	0	0
	Total	0	0	1 ( 1.2%)
MUSCLE SPASMS	Mild	0	0	1 ( 1.2%)
	Moderate	0	0	0
	Severe	0	1 ( 1.2%)	0
	Total	0	1 ( 1.2%)	1 ( 1.2%)
MUSCULAR WEAKNESS	Mild	0	0	0
	Moderate	0	1 ( 1.2%)	0
	Severe	0	0	0
	Total	0	1 ( 1.2%)	0

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Safety Analysis Set**

System Organ Class Preferred Term	Maximum Severity	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
MYALGIA	Mild	0	0	1 ( 1.2%)
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	0	1 ( 1.2%)
PAIN IN EXTREMITY	Mild	1 ( 1.2%)	0	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	0	0
SHOULDER PAIN	Mild	0	2 ( 2.4%)	0
	Moderate	1 ( 1.2%)	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	2 ( 2.4%)	0
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	Mild	0	1 ( 1.2%)	0
	Moderate	0	0	0
	Severe	0	1 ( 1.2%)	1 ( 1.2%)
	Total	0	2 ( 2.4%)	1 ( 1.2%)
COLON CANCER	Mild	0	0	0
	Moderate	0	0	0
	Severe	0	1 ( 1.2%)	0
	Total	0	1 ( 1.2%)	0
MALIGNANT FIBROUS HISTIOCYTOMA	Mild	0	1 ( 1.2%)	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	1 ( 1.2%)	0
PROSTATE CANCER	Mild	0	0	0
	Moderate	0	0	0
	Severe	0	0	1 ( 1.2%)
	Total	0	0	1 ( 1.2%)
NERVOUS SYSTEM DISORDERS	Mild	6 ( 7.0%)	10 ( 11.9%)	13 ( 15.5%)

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Safety Analysis Set*

System Organ Class Preferred Term	Maximum Severity	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Moderate	2 ( 2.3%)	7 ( 8.3%)	8 ( 9.5%)
	Severe	0	3 ( 3.6%)	4 ( 4.8%)
	Total	8 ( 9.3%)	20 ( 23.8%)	25 ( 29.8%)
AMNESIA	Mild	0	0	1 ( 1.2%)
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	0	1 ( 1.2%)
BALANCE DISORDER	Mild	0	0	0
	Moderate	0	1 ( 1.2%)	0
	Severe	0	0	0
	Total	0	1 ( 1.2%)	0
BURNING SENSATION	Mild	0	0	1 ( 1.2%)
	Moderate	0	0	1 ( 1.2%)
	Severe	0	0	0
	Total	0	0	2 ( 2.4%)
COGNITIVE DISORDER	Mild	0	0	1 ( 1.2%)
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	0	1 ( 1.2%)
COMPLEX PARTIAL SEIZURES	Mild	0	0	0
	Moderate	0	1 ( 1.2%)	0
	Severe	0	0	0
	Total	0	1 ( 1.2%)	0
COORDINATION ABNORMAL	Mild	0	1 ( 1.2%)	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	1 ( 1.2%)	0
DIZZINESS	Mild	2 ( 2.3%)	5 ( 6.0%)	7 ( 8.3%)
	Moderate	0	3 ( 3.6%)	3 ( 3.6%)
	Severe	0	0	1 ( 1.2%)

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Safety Analysis Set**

System Organ Class Preferred Term	Maximum Severity	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Total	2 ( 2.3%)	8 ( 9.5%)	11 ( 13.1%)
HEADACHE	Mild	3 ( 3.5%)	2 ( 2.4%)	4 ( 4.8%)
	Moderate	0	0	1 ( 1.2%)
	Severe	0	1 ( 1.2%)	0
	Total	3 ( 3.5%)	3 ( 3.6%)	5 ( 6.0%)
HEMIANOPIA HOMONYMOUS	Mild	0	1 ( 1.2%)	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	1 ( 1.2%)	0
HYPERSONMIA	Mild	0	0	1 ( 1.2%)
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	0	1 ( 1.2%)
LETHARGY	Mild	0	0	0
	Moderate	0	1 ( 1.2%)	1 ( 1.2%)
	Severe	0	0	0
	Total	0	1 ( 1.2%)	1 ( 1.2%)
PARAESTHESIA	Mild	0	0	1 ( 1.2%)
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	0	1 ( 1.2%)
PARAESTHESIA ORAL	Mild	0	1 ( 1.2%)	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	1 ( 1.2%)	0
PARKINSON'S DISEASE	Mild	1 ( 1.2%)	0	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	0	0

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Safety Analysis Set**

System Organ Class Preferred Term	Maximum Severity	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
PAROSMIA	Mild	0	0	1 ( 1.2%)
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	0	1 ( 1.2%)
PARTIAL SEIZURES WITH SECONDARY GENERALISATION	Mild	0	0	0
	Moderate	0	0	0
	Severe	0	0	1 ( 1.2%)
	Total	0	0	1 ( 1.2%)
PSYCHOMOTOR HYPERACTIVITY	Mild	1 ( 1.2%)	0	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	0	0
SOMNOLENCE	Mild	0	1 ( 1.2%)	1 ( 1.2%)
	Moderate	2 ( 2.3%)	2 ( 2.4%)	0
	Severe	0	0	0
	Total	2 ( 2.3%)	3 ( 3.6%)	1 ( 1.2%)
STUPOR	Mild	0	0	0
	Moderate	0	0	0
	Severe	0	1 ( 1.2%)	0
	Total	0	1 ( 1.2%)	0
SYNCOPE	Mild	0	1 ( 1.2%)	0
	Moderate	0	1 ( 1.2%)	2 ( 2.4%)
	Severe	0	2 ( 2.4%)	1 ( 1.2%)
	Total	0	4 ( 4.8%)	3 ( 3.6%)
SYNCOPE VASOVAGAL	Mild	0	0	0
	Moderate	0	0	1 ( 1.2%)
	Severe	0	0	0
	Total	0	0	1 ( 1.2%)
TRANSIENT ISCHAEMIC ATTACK	Mild	0	1 ( 1.2%)	0
	Moderate	0	0	0

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**Treatment-Emergent Adverse Events by Maximum Severity  
Safety Analysis Set**

System Organ Class Preferred Term	Maximum Severity	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Severe	0	1 ( 1.2%)	1 ( 1.2%)
	Total	0	2 ( 2.4%)	1 ( 1.2%)
PSYCHIATRIC DISORDERS	Mild	7 ( 8.1%)	3 ( 3.6%)	4 ( 4.8%)
	Moderate	2 ( 2.3%)	6 ( 7.1%)	4 ( 4.8%)
	Severe	1 ( 1.2%)	1 ( 1.2%)	0
	Total	10 ( 11.6%)	10 ( 11.9%)	8 ( 9.5%)
AGITATION	Mild	2 ( 2.3%)	0	0
	Moderate	0	1 ( 1.2%)	1 ( 1.2%)
	Severe	0	1 ( 1.2%)	0
	Total	2 ( 2.3%)	2 ( 2.4%)	1 ( 1.2%)
ANXIETY	Mild	0	3 ( 3.6%)	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	3 ( 3.6%)	0
COMPLETED SUICIDE	Mild	0	0	0
	Moderate	0	0	0
	Severe	1 ( 1.2%)	0	0
	Total	1 ( 1.2%)	0	0
CONFUSIONAL STATE	Mild	1 ( 1.2%)	0	1 ( 1.2%)
	Moderate	1 ( 1.2%)	3 ( 3.6%)	0
	Severe	0	0	0
	Total	2 ( 2.3%)	3 ( 3.6%)	1 ( 1.2%)
DELIRIUM	Mild	0	0	0
	Moderate	0	0	1 ( 1.2%)
	Severe	0	0	0
	Total	0	0	1 ( 1.2%)
DELUSION	Mild	1 ( 1.2%)	0	0
	Moderate	0	0	1 ( 1.2%)
	Severe	0	0	0
	Total	1 ( 1.2%)	0	1 ( 1.2%)

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Safety Analysis Set**

System Organ Class Preferred Term	Maximum Severity	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
DEPRESSED MOOD	Mild	0	0	0
	Moderate	0	1 ( 1.2%)	0
	Severe	0	0	0
	Total	0	1 ( 1.2%)	0
DISORIENTATION	Mild	1 ( 1.2%)	0	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	0	0
HALLUCINATION	Mild	0	0	0
	Moderate	0	0	1 ( 1.2%)
	Severe	0	0	0
	Total	0	0	1 ( 1.2%)
HALLUCINATION, VISUAL	Mild	0	0	0
	Moderate	0	0	1 ( 1.2%)
	Severe	0	0	0
	Total	0	0	1 ( 1.2%)
INSOMNIA	Mild	2 ( 2.3%)	0	2 ( 2.4%)
	Moderate	0	0	0
	Severe	0	0	0
	Total	2 ( 2.3%)	0	2 ( 2.4%)
IRRITABILITY	Mild	0	1 ( 1.2%)	0
	Moderate	1 ( 1.2%)	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	1 ( 1.2%)	0
LIBIDO DECREASED	Mild	0	0	1 ( 1.2%)
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	0	1 ( 1.2%)
LISTLESS	Mild	0	0	1 ( 1.2%)

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System Organ Class Preferred Term	Maximum Severity	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	0	1 ( 1.2%)
NIGHTMARE	Mild	0	0	1 ( 1.2%)
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	0	1 ( 1.2%)
RESTLESSNESS	Mild	0	0	0
	Moderate	0	1 ( 1.2%)	0
	Severe	0	0	0
	Total	0	1 ( 1.2%)	0
RENAL AND URINARY DISORDERS	Mild	3 ( 3.5%)	3 ( 3.6%)	1 ( 1.2%)
	Moderate	1 ( 1.2%)	0	2 ( 2.4%)
	Severe	0	0	0
	Total	4 ( 4.7%)	3 ( 3.6%)	3 ( 3.6%)
CALCULUS URETHRAL	Mild	0	0	0
	Moderate	0	0	1 ( 1.2%)
	Severe	0	0	0
	Total	0	0	1 ( 1.2%)
DYSURIA	Mild	1 ( 1.2%)	1 ( 1.2%)	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	1 ( 1.2%)	0
INCONTINENCE	Mild	0	1 ( 1.2%)	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	1 ( 1.2%)	0
MICTURITION URGENCY	Mild	1 ( 1.2%)	1 ( 1.2%)	1 ( 1.2%)
	Moderate	0	0	0
	Severe	0	0	0

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Safety Analysis Set**

System Organ Class Preferred Term	Maximum Severity	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Total	1 ( 1.2%)	1 ( 1.2%)	1 ( 1.2%)
NEPHROLITHIASIS	Mild	0	0	0
	Moderate	1 ( 1.2%)	0	1 ( 1.2%)
	Severe	0	0	0
	Total	1 ( 1.2%)	0	1 ( 1.2%)
POLLAKIURIA	Mild	1 ( 1.2%)	0	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	0	0
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	Mild	1 ( 1.2%)	0	0
	Moderate	0	0	1 ( 1.2%)
	Severe	1 ( 1.2%)	0	0
	Total	2 ( 2.3%)	0	1 ( 1.2%)
BENIGN PROSTATIC HYPERPLASIA	Mild	0	0	0
	Moderate	0	0	1 ( 1.2%)
	Severe	1 ( 1.2%)	0	0
	Total	1 ( 1.2%)	0	1 ( 1.2%)
PELVIC PAIN	Mild	1 ( 1.2%)	0	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	0	0
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	Mild	7 ( 8.1%)	6 ( 7.1%)	8 ( 9.5%)
	Moderate	1 ( 1.2%)	3 ( 3.6%)	2 ( 2.4%)
	Severe	0	0	0
	Total	8 ( 9.3%)	9 ( 10.7%)	10 ( 11.9%)
ALLERGIC GRANULOMATOUS ANGIITIS	Mild	0	0	1 ( 1.2%)
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	0	1 ( 1.2%)

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**Treatment-Emergent Adverse Events by Maximum Severity  
Safety Analysis Set**

System Organ Class Preferred Term	Maximum Severity	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
COUGH	Mild	1 ( 1.2%)	3 ( 3.6%)	3 ( 3.6%)
	Moderate	0	2 ( 2.4%)	2 ( 2.4%)
	Severe	0	0	0
	Total	1 ( 1.2%)	5 ( 6.0%)	5 ( 6.0%)
DYSPHONIA	Mild	0	1 ( 1.2%)	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	1 ( 1.2%)	0
DYSPNOEA	Mild	0	0	1 ( 1.2%)
	Moderate	1 ( 1.2%)	1 ( 1.2%)	0
	Severe	0	0	0
	Total	1 ( 1.2%)	1 ( 1.2%)	1 ( 1.2%)
EMPHYSEMA	Mild	1 ( 1.2%)	0	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	0	0
EPISTAXIS	Mild	0	1 ( 1.2%)	2 ( 2.4%)
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	1 ( 1.2%)	2 ( 2.4%)
HAEMOPTYSIS	Mild	1 ( 1.2%)	0	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	0	0
NASAL CONGESTION	Mild	3 ( 3.5%)	1 ( 1.2%)	3 ( 3.6%)
	Moderate	0	0	0
	Severe	0	0	0
	Total	3 ( 3.5%)	1 ( 1.2%)	3 ( 3.6%)
PHARYNGEAL ERYTHEMA	Mild	0	0	1 ( 1.2%)
	Moderate	0	0	0

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System Organ Class Preferred Term	Maximum Severity	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Severe	0	0	0
	Total	0	0	1 ( 1.2%)
PHARYNGOLARYNGEAL PAIN	Mild	0	1 ( 1.2%)	1 ( 1.2%)
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	1 ( 1.2%)	1 ( 1.2%)
POSTNASAL DRIP	Mild	1 ( 1.2%)	0	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	0	0
PRODUCTIVE COUGH	Mild	0	0	1 ( 1.2%)
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	0	1 ( 1.2%)
RALES	Mild	1 ( 1.2%)	0	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	0	0
RESPIRATORY TRACT CONGESTION	Mild	0	0	1 ( 1.2%)
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	0	1 ( 1.2%)
RHINORRHOEA	Mild	0	1 ( 1.2%)	1 ( 1.2%)
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	1 ( 1.2%)	1 ( 1.2%)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Mild	12 ( 14.0%)	12 ( 14.3%)	24 ( 28.6%)
	Moderate	8 ( 9.3%)	23 ( 27.4%)	15 ( 17.9%)
	Severe	0	4 ( 4.8%)	1 ( 1.2%)
	Total	20 ( 23.3%)	39 ( 46.4%)	40 ( 47.6%)

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System Organ Class Preferred Term	Maximum Severity	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
ACTINIC KERATOSIS	Mild	0	0	1 ( 1.2%)
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	0	1 ( 1.2%)
ALOPECIA	Mild	1 ( 1.2%)	0	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	0	0
BLISTER	Mild	0	1 ( 1.2%)	1 ( 1.2%)
	Moderate	0	3 ( 3.6%)	0
	Severe	0	1 ( 1.2%)	0
	Total	0	5 ( 6.0%)	1 ( 1.2%)
COLD SWEAT	Mild	0	0	0
	Moderate	1 ( 1.2%)	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	0	0
DERMATITIS CONTACT	Mild	0	0	0
	Moderate	0	1 ( 1.2%)	0
	Severe	0	0	0
	Total	0	1 ( 1.2%)	0
DRUG ERUPTION	Mild	1 ( 1.2%)	0	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	0	0
ERYTHEMA	Mild	4 ( 4.7%)	6 ( 7.1%)	10 ( 11.9%)
	Moderate	4 ( 4.7%)	8 ( 9.5%)	4 ( 4.8%)
	Severe	0	0	0
	Total	8 ( 9.3%)	14 ( 16.7%)	14 ( 16.7%)
HYPERHIDROSIS	Mild	2 ( 2.3%)	1 ( 1.2%)	8 ( 9.5%)

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Safety Analysis Set**

System Organ Class Preferred Term	Maximum Severity	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Moderate	0	3 ( 3.6%)	0
	Severe	0	0	0
	Total	2 ( 2.3%)	4 ( 4.8%)	8 ( 9.5%)
PRURITUS	Mild	7 ( 8.1%)	9 ( 10.7%)	17 ( 20.2%)
	Moderate	1 ( 1.2%)	11 ( 13.1%)	9 ( 10.7%)
	Severe	0	1 ( 1.2%)	0
	Total	8 ( 9.3%)	21 ( 25.0%)	26 ( 31.0%)
PRURITUS GENERALISED	Mild	0	0	1 ( 1.2%)
	Moderate	0	1 ( 1.2%)	0
	Severe	0	0	0
	Total	0	1 ( 1.2%)	1 ( 1.2%)
RASH	Mild	2 ( 2.3%)	9 ( 10.7%)	5 ( 6.0%)
	Moderate	3 ( 3.5%)	3 ( 3.6%)	3 ( 3.6%)
	Severe	0	1 ( 1.2%)	1 ( 1.2%)
	Total	5 ( 5.8%)	13 ( 15.5%)	9 ( 10.7%)
RASH ERYTHEMATOUS	Mild	0	0	0
	Moderate	0	1 ( 1.2%)	0
	Severe	0	0	0
	Total	0	1 ( 1.2%)	0
RASH MACULO-PAPULAR	Mild	0	0	1 ( 1.2%)
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	0	1 ( 1.2%)
RASH PRURITIC	Mild	0	0	1 ( 1.2%)
	Moderate	0	1 ( 1.2%)	1 ( 1.2%)
	Severe	0	0	0
	Total	0	1 ( 1.2%)	2 ( 2.4%)
SKIN EXFOLIATION	Mild	0	0	0
	Moderate	0	1 ( 1.2%)	0
	Severe	0	0	0

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System Organ Class Preferred Term	Maximum Severity	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Total	0	1 ( 1.2%)	0
SKIN IRRITATION	Mild	2 ( 2.3%)	2 ( 2.4%)	3 ( 3.6%)
	Moderate	1 ( 1.2%)	3 ( 3.6%)	2 ( 2.4%)
	Severe	0	1 ( 1.2%)	0
	Total	3 ( 3.5%)	6 ( 7.1%)	5 ( 6.0%)
SKIN ODOUR ABNORMAL	Mild	0	0	1 ( 1.2%)
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	0	1 ( 1.2%)
SKIN ULCER	Mild	0	0	0
	Moderate	1 ( 1.2%)	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	0	0
URTICARIA	Mild	0	0	1 ( 1.2%)
	Moderate	0	1 ( 1.2%)	0
	Severe	0	0	0
	Total	0	1 ( 1.2%)	1 ( 1.2%)
SOCIAL CIRCUMSTANCES	Mild	0	0	1 ( 1.2%)
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	0	1 ( 1.2%)
ALCOHOL USE	Mild	0	0	1 ( 1.2%)
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	0	1 ( 1.2%)
SURGICAL AND MEDICAL PROCEDURES	Mild	1 ( 1.2%)	1 ( 1.2%)	2 ( 2.4%)
	Moderate	1 ( 1.2%)	0	0
	Severe	0	0	0
	Total	2 ( 2.3%)	1 ( 1.2%)	2 ( 2.4%)

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System Organ Class Preferred Term	Maximum Severity	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
ACROCHORDON EXCISION	Mild	0	0	1 ( 1.2%)
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	0	1 ( 1.2%)
CATARACT OPERATION	Mild	0	1 ( 1.2%)	0
	Moderate	1 ( 1.2%)	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	1 ( 1.2%)	0
EYE LASER SURGERY	Mild	1 ( 1.2%)	0	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	0	0
SKIN LESION EXCISION	Mild	0	0	1 ( 1.2%)
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	0	1 ( 1.2%)
VASCULAR DISORDERS	Mild	1 ( 1.2%)	3 ( 3.6%)	0
	Moderate	2 ( 2.3%)	0	1 ( 1.2%)
	Severe	0	0	0
	Total	3 ( 3.5%)	3 ( 3.6%)	1 ( 1.2%)
HOT FLUSH	Mild	0	1 ( 1.2%)	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	0	1 ( 1.2%)	0
HYPERTENSION	Mild	0	1 ( 1.2%)	0
	Moderate	1 ( 1.2%)	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	1 ( 1.2%)	0
HYPOTENSION	Mild	1 ( 1.2%)	1 ( 1.2%)	0
	Moderate	1 ( 1.2%)	0	0

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System Organ Class Preferred Term	Maximum Severity	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Severe	0	0	0
	Total	2 ( 2.3%)	1 ( 1.2%)	0
ORTHOSTATIC HYPOTENSION	Mild	1 ( 1.2%)	0	0
	Moderate	0	0	0
	Severe	0	0	0
	Total	1 ( 1.2%)	0	0
WOUND HAEMORRHAGE	Mild	0	0	0
	Moderate	0	0	1 ( 1.2%)
	Severe	0	0	0
	Total	0	0	1 ( 1.2%)