

Treatment-Emergent Adverse Events by Relationship to Study Drug
Safety Analysis Set
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System Organ Class Preferred Term	Maximum Relationship	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
Overall	None	13 (15.1%)	2 (2.4%)	5 (6.0%)
	Unlikely	9 (10.5%)	2 (2.4%)	1 (1.2%)
	Possible	20 (23.3%)	23 (27.4%)	20 (23.8%)
	Probable	23 (26.7%)	48 (57.1%)	50 (59.5%)
	Missing	0	2 (2.4%)	0
	Total	65 (75.6%)	77 (91.7%)	76 (90.5%)
<hr/>				
CARDIAC DISORDERS	None	1 (1.2%)	2 (2.4%)	8 (9.5%)
	Unlikely	5 (5.8%)	4 (4.8%)	3 (3.6%)
	Possible	6 (7.0%)	5 (6.0%)	4 (4.8%)
	Probable	0	2 (2.4%)	0
	Missing	0	0	0
	Total	12 (14.0%)	13 (15.5%)	15 (17.9%)
<hr/>				
ATRIAL FIBRILLATION	None	0	1 (1.2%)	1 (1.2%)
	Unlikely	0	0	0
	Possible	1 (1.2%)	0	2 (2.4%)
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	1 (1.2%)	3 (3.6%)
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ATRIAL FLUTTER	None	0	0	1 (1.2%)
	Unlikely	0	0	0

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	Possible	0	1 (1.2%)	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	1 (1.2%)	1 (1.2%)
<hr/>				
ATRIAL HYPERTROPHY	None	0	0	0
	Unlikely	1 (1.2%)	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	0
<hr/>				
ATRIOVENTRICULAR BLOCK FIRST DEGREE	None	0	1 (1.2%)	0
	Unlikely	0	0	0
	Possible	1 (1.2%)	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	1 (1.2%)	0
<hr/>				
ATRIOVENTRICULAR BLOCK SECOND DEGREE	None	0	0	0
	Unlikely	0	0	0
	Possible	1 (1.2%)	0	0
	Probable	0	0	0

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System Organ Class Preferred Term	Maximum Relationship ip	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Missing	0	0	0
	Total	1 (1.2%)	0	0
<hr/>				
BRADYCARDIA	None	0	0	0
	Unlikely	0	0	0
	Possible	1 (1.2%)	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	0
<hr/>				
BUNDLE BRANCH BLOCK LEFT	None	1 (1.2%)	0	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	0
<hr/>				
BUNDLE BRANCH BLOCK RIGHT	None	0	0	0
	Unlikely	1 (1.2%)	0	0
	Possible	0	1 (1.2%)	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	1 (1.2%)	0

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System Organ Class Preferred Term	Maximum Relationship ip	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
CARDIAC DISORDER	None	0	0	1 (1.2%)
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	0	1 (1.2%)
CARDIAC FAILURE CONGESTIVE	None	0	0	0
	Unlikely	0	0	0
	Possible	1 (1.2%)	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	0
MYOCARDIAL INFARCTION	None	0	0	2 (2.4%)
	Unlikely	2 (2.3%)	1 (1.2%)	1 (1.2%)
	Possible	2 (2.3%)	1 (1.2%)	1 (1.2%)
	Probable	0	0	0
	Missing	0	0	0
	Total	4 (4.7%)	2 (2.4%)	4 (4.8%)
PALPITATIONS	None	0	0	0

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	Unlikely	0	1 (1.2%)	0
	Possible	0	0	0
	Probable	0	1 (1.2%)	0
	Missing	0	0	0
	Total	0	2 (2.4%)	0
<hr/>				
SINUS ARRHYTHMIA	None	0	0	0
	Unlikely	0	0	0
	Possible	1 (1.2%)	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	0
<hr/>				
SINUS BRADYCARDIA	None	0	2 (2.4%)	5 (6.0%)
	Unlikely	0	3 (3.6%)	3 (3.6%)
	Possible	2 (2.3%)	2 (2.4%)	0
	Probable	0	0	0
	Missing	0	0	0
	Total	2 (2.3%)	7 (8.3%)	8 (9.5%)
<hr/>				
SUPRAVENTRICULAR EXTRASYSTOLES	None	0	0	0
	Unlikely	1 (1.2%)	0	0
	Possible	0	1 (1.2%)	1 (1.2%)

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System Organ Class Preferred Term	Maximum Relationship ip	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	1 (1.2%)	1 (1.2%)
<hr/>				
SUPRAVENTRICULAR TACHYCARDIA	None	0	1 (1.2%)	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	1 (1.2%)	0
<hr/>				
TACHYCARDIA	None	0	0	0
	Unlikely	1 (1.2%)	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	0
<hr/>				
VENTRICULAR EXTRASYSTOLES	None	0	0	1 (1.2%)
	Unlikely	0	1 (1.2%)	0
	Possible	0	0	0
	Probable	0	1 (1.2%)	0
	Missing	0	0	0

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System Organ Class Preferred Term	Maximum Relationsh ip	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Total	0	2 (2.4%)	1 (1.2%)
VENTRICULAR HYPERTROPHY	None	0	0	0
	Unlikely	1 (1.2%)	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	0
WOLFF-PARKINSON-WHITE SYNDROME	None	0	0	0
	Unlikely	0	0	0
	Possible	0	1 (1.2%)	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	1 (1.2%)	0
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	None	0	0	2 (2.4%)
	Unlikely	0	0	0
	Possible	0	1 (1.2%)	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	1 (1.2%)	2 (2.4%)

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System Organ Class Preferred Term	Maximum Relationship	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
VENTRICULAR SEPTAL DEFECT	None	0	0	2 (2.4%)
	Unlikely	0	0	0
	Possible	0	1 (1.2%)	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	1 (1.2%)	2 (2.4%)
EAR AND LABYRINTH DISORDERS	None	1 (1.2%)	1 (1.2%)	0
	Unlikely	0	0	0
	Possible	0	1 (1.2%)	1 (1.2%)
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	2 (2.4%)	1 (1.2%)
CERUMEN IMPACTION	None	0	1 (1.2%)	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	1 (1.2%)	0
EAR PAIN	None	1 (1.2%)	0	0
	Unlikely	0	0	0

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System Organ Class Preferred Term	Maximum Relationship ip	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	0
<hr/>				
VERTIGO	None	0	0	0
	Unlikely	0	0	0
	Possible	0	1 (1.2%)	1 (1.2%)
	Probable	0	0	0
	Missing	0	0	0
	Total	0	1 (1.2%)	1 (1.2%)
<hr/>				
EYE DISORDERS	None	0	0	0
	Unlikely	2 (2.3%)	1 (1.2%)	0
	Possible	0	1 (1.2%)	1 (1.2%)
	Probable	0	0	0
	Missing	0	0	0
	Total	2 (2.3%)	2 (2.4%)	1 (1.2%)
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CONJUNCTIVAL HAEMORRHAGE	None	0	0	0
	Unlikely	0	1 (1.2%)	0
	Possible	0	0	0
	Probable	0	0	0

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System Organ Class Preferred Term	Maximum Relationship ip	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Missing	0	0	0
	Total	0	1 (1.2%)	0
<hr/>				
CONJUNCTIVITIS	None	0	0	0
	Unlikely	1 (1.2%)	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	0
<hr/>				
EYE ALLERGY	None	1 (1.2%)	0	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	0
<hr/>				
EYE PRURITUS	None	0	0	0
	Unlikely	1 (1.2%)	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	0

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System Organ Class Preferred Term	Maximum Relationship ip	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
EYE SWELLING	None	1 (1.2%)	0	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	0
VISION BLURRED	None	0	0	0
	Unlikely	0	0	0
	Possible	0	1 (1.2%)	1 (1.2%)
	Probable	0	0	0
	Missing	0	0	0
	Total	0	1 (1.2%)	1 (1.2%)
GASTROINTESTINAL DISORDERS	None	6 (7.0%)	3 (3.6%)	6 (7.1%)
	Unlikely	7 (8.1%)	3 (3.6%)	4 (4.8%)
	Possible	4 (4.7%)	7 (8.3%)	8 (9.5%)
	Probable	0	0	2 (2.4%)
	Missing	0	1 (1.2%)	0
	Total	17 (19.8%)	14 (16.7%)	20 (23.8%)
ABDOMINAL DISCOMFORT	None	0	0	0

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	Unlikely	0	0	1 (1.2%)
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	0	1 (1.2%)
<hr/>				
ABDOMINAL PAIN	None	0	1 (1.2%)	0
	Unlikely	1 (1.2%)	1 (1.2%)	0
	Possible	0	1 (1.2%)	1 (1.2%)
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	3 (3.6%)	1 (1.2%)
<hr/>				
CONSTIPATION	None	0	0	0
	Unlikely	1 (1.2%)	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	0
<hr/>				
DIARRHOEA	None	3 (3.5%)	1 (1.2%)	1 (1.2%)
	Unlikely	3 (3.5%)	1 (1.2%)	1 (1.2%)
	Possible	3 (3.5%)	2 (2.4%)	1 (1.2%)

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System Organ Class Preferred Term	Maximum Relationship ip	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Probable	0	0	1 (1.2%)
	Missing	0	0	0
	Total	9 (10.5%)	4 (4.8%)	4 (4.8%)
<hr/>				
DYSPEPSIA	None	0	0	0
	Unlikely	0	0	0
	Possible	1 (1.2%)	1 (1.2%)	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	1 (1.2%)	0
<hr/>				
DYSPHAGIA	None	0	0	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	1 (1.2%)	0
	Total	0	1 (1.2%)	0
<hr/>				
FLATULENCE	None	1 (1.2%)	0	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0

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	Total	1 (1.2%)	0	0
GASTROINTESTINAL HAEMORRHAGE	None	0	0	1 (1.2%)
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	0	1 (1.2%)
GASTROESOPHAGEAL REFLUX DISEASE	None	0	0	0
	Unlikely	0	0	0
	Possible	1 (1.2%)	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	0
GLOSSITIS	None	1 (1.2%)	0	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	0

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HIATUS HERNIA	None	1 (1.2%)	0	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	0
NAUSEA	None	0	0	1 (1.2%)
	Unlikely	3 (3.5%)	0	2 (2.4%)
	Possible	0	3 (3.6%)	2 (2.4%)
	Probable	0	0	1 (1.2%)
	Missing	0	0	0
	Total	3 (3.5%)	3 (3.6%)	6 (7.1%)
RECTAL HAEMORRHAGE	None	0	1 (1.2%)	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	1 (1.2%)	0
SALIVARY HYPERSECRETION	None	0	0	1 (1.2%)
	Unlikely	0	0	0

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	Possible	0	0	3 (3.6%)
	Probable	0	0	0
	Missing	0	0	0
	Total	0	0	4 (4.8%)
<hr/>				
STOMACH DISCOMFORT	None	0	0	0
	Unlikely	0	0	0
	Possible	0	0	1 (1.2%)
	Probable	0	0	0
	Missing	0	0	0
	Total	0	0	1 (1.2%)
<hr/>				
VOMITING	None	1 (1.2%)	0	2 (2.4%)
	Unlikely	2 (2.3%)	1 (1.2%)	2 (2.4%)
	Possible	0	2 (2.4%)	2 (2.4%)
	Probable	0	0	1 (1.2%)
	Missing	0	0	0
	Total	3 (3.5%)	3 (3.6%)	7 (8.3%)
<hr/>				
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	None	3 (3.5%)	2 (2.4%)	1 (1.2%)
	Unlikely	0	2 (2.4%)	4 (4.8%)
	Possible	5 (5.8%)	9 (10.7%)	4 (4.8%)
	Probable	13 (15.1%)	34 (40.5%)	31 (36.9%)

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	Missing	0	0	0
	Total	21 (24.4%)	47 (56.0%)	40 (47.6%)
<hr/>				
APPLICATION SITE BLEEDING	None	0	0	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	1 (1.2%)	0
	Missing	0	0	0
	Total	0	1 (1.2%)	0
<hr/>				
APPLICATION SITE DERMATITIS	None	0	0	0
	Unlikely	0	0	0
	Possible	1 (1.2%)	0	0
	Probable	4 (4.7%)	9 (10.7%)	7 (8.3%)
	Missing	0	0	0
	Total	5 (5.8%)	9 (10.7%)	7 (8.3%)
<hr/>				
APPLICATION SITE DESQUAMATION	None	0	0	0
	Unlikely	0	0	0
	Possible	0	1 (1.2%)	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	1 (1.2%)	0

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APPLICATION SITE DISCHARGE	None	0	0	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	1 (1.2%)
	Missing	0	0	0
	Total	0	0	1 (1.2%)
APPLICATION SITE DISCOLOURATION	None	0	0	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	1 (1.2%)	0
	Missing	0	0	0
	Total	0	1 (1.2%)	0
APPLICATION SITE ERYTHEMA	None	0	0	0
	Unlikely	0	0	0
	Possible	0	3 (3.6%)	5 (6.0%)
	Probable	3 (3.5%)	9 (10.7%)	10 (11.9%)
	Missing	0	0	0
	Total	3 (3.5%)	12 (14.3%)	15 (17.9%)
APPLICATION SITE INDURATION	None	0	0	0

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	Unlikely	0	0	0
	Possible	1 (1.2%)	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	0
<hr/>				
APPLICATION SITE IRRITATION	None	0	0	0
	Unlikely	0	0	0
	Possible	0	1 (1.2%)	2 (2.4%)
	Probable	3 (3.5%)	8 (9.5%)	7 (8.3%)
	Missing	0	0	0
	Total	3 (3.5%)	9 (10.7%)	9 (10.7%)
<hr/>				
APPLICATION SITE PAIN	None	0	0	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	2 (2.4%)
	Missing	0	0	0
	Total	0	0	2 (2.4%)
<hr/>				
APPLICATION SITE PERSPIRATION	None	0	0	0
	Unlikely	0	0	0
	Possible	0	0	1 (1.2%)

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	Probable	0	0	1 (1.2%)
	Missing	0	0	0
	Total	0	0	2 (2.4%)
<hr/>				
APPLICATION SITE PRURITUS	None	0	0	0
	Unlikely	0	0	0
	Possible	1 (1.2%)	5 (6.0%)	2 (2.4%)
	Probable	5 (5.8%)	17 (20.2%)	20 (23.8%)
	Missing	0	0	0
	Total	6 (7.0%)	22 (26.2%)	22 (26.2%)
<hr/>				
APPLICATION SITE REACTION	None	0	0	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	1 (1.2%)	0	1 (1.2%)
	Missing	0	0	0
	Total	1 (1.2%)	0	1 (1.2%)
<hr/>				
APPLICATION SITE SWELLING	None	0	0	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	1 (1.2%)	2 (2.4%)
	Missing	0	0	0

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System Organ Class Preferred Term	Maximum Relationsh ip	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Total	0	1 (1.2%)	2 (2.4%)
APPLICATION SITE URTICARIA	None	0	0	0
	Unlikely	0	0	0
	Possible	0	1 (1.2%)	0
	Probable	0	1 (1.2%)	1 (1.2%)
	Missing	0	0	0
	Total	0	2 (2.4%)	1 (1.2%)
APPLICATION SITE VESICLES	None	0	0	0
	Unlikely	0	0	0
	Possible	0	0	2 (2.4%)
	Probable	1 (1.2%)	4 (4.8%)	4 (4.8%)
	Missing	0	0	0
	Total	1 (1.2%)	4 (4.8%)	6 (7.1%)
APPLICATION SITE WARMTH	None	0	0	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	1 (1.2%)	0
	Missing	0	0	0
	Total	0	1 (1.2%)	0

Treatment-Emergent Adverse Events by Relationship to Study Drug
Safety Analysis Set
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System Organ Class Preferred Term	Maximum Relationship	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
ASTHENIA	None	0	0	0
	Unlikely	0	0	1 (1.2%)
	Possible	1 (1.2%)	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	1 (1.2%)
CHEST DISCOMFORT	None	0	0	1 (1.2%)
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	1 (1.2%)
	Missing	0	0	0
	Total	0	0	2 (2.4%)
CHEST PAIN	None	0	0	0
	Unlikely	0	0	2 (2.4%)
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	0	2 (2.4%)
CHILLS	None	0	0	0
	Unlikely	0	0	1 (1.2%)

Treatment-Emergent Adverse Events by Relationship to Study Drug
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System Organ Class Preferred Term	Maximum Relationship ip	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Possible	1 (1.2%)	1 (1.2%)	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	1 (1.2%)	1 (1.2%)
<hr/>				
FATIGUE	None	0	0	0
	Unlikely	0	3 (3.6%)	1 (1.2%)
	Possible	1 (1.2%)	2 (2.4%)	4 (4.8%)
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	5 (6.0%)	5 (6.0%)
<hr/>				
FEELING ABNORMAL	None	0	0	0
	Unlikely	0	0	0
	Possible	0	0	1 (1.2%)
	Probable	0	0	0
	Missing	0	0	0
	Total	0	0	1 (1.2%)
<hr/>				
FEELING COLD	None	0	0	1 (1.2%)
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0

Treatment-Emergent Adverse Events by Relationship to Study Drug
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System Organ Class Preferred Term	Maximum Relationship ip	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Missing	0	0	0
	Total	0	0	1 (1.2%)
<hr/>				
INFLAMMATION	None	0	0	0
	Unlikely	0	1 (1.2%)	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	1 (1.2%)	0
<hr/>				
MALAISE	None	0	0	0
	Unlikely	0	0	1 (1.2%)
	Possible	0	1 (1.2%)	1 (1.2%)
	Probable	0	0	0
	Missing	0	0	0
	Total	0	1 (1.2%)	2 (2.4%)
<hr/>				
OEDEMA	None	0	0	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	2 (2.4%)	0
	Missing	0	0	0
	Total	0	2 (2.4%)	0

Treatment-Emergent Adverse Events by Relationship to Study Drug
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System Organ Class Preferred Term	Maximum Relationship ip	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
OEDEMA PERIPHERAL	None	1 (1.2%)	0	1 (1.2%)
	Unlikely	1 (1.2%)	1 (1.2%)	0
	Possible	0	0	1 (1.2%)
	Probable	0	0	0
	Missing	0	0	0
	Total	2 (2.3%)	1 (1.2%)	2 (2.4%)
PAIN	None	0	0	0
	Unlikely	0	0	0
	Possible	0	0	1 (1.2%)
	Probable	0	1 (1.2%)	0
	Missing	0	0	0
	Total	0	1 (1.2%)	1 (1.2%)
PYREXIA	None	2 (2.3%)	0	0
	Unlikely	0	0	1 (1.2%)
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	2 (2.3%)	0	1 (1.2%)
SECRETION DISCHARGE	None	0	1 (1.2%)	0

Treatment-Emergent Adverse Events by Relationship to Study Drug
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System Organ Class Preferred Term	Maximum Relationship	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	1 (1.2%)	0
<hr/>				
SUDDEN DEATH	None	0	1 (1.2%)	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	1 (1.2%)	0
<hr/>				
SWELLING	None	0	1 (1.2%)	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	1 (1.2%)	0
<hr/>				
ULCER	None	0	1 (1.2%)	0
	Unlikely	0	0	0
	Possible	0	0	0

Treatment-Emergent Adverse Events by Relationship to Study Drug
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System Organ Class Preferred Term	Maximum Relationship ip	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Probable	0	0	0
	Missing	0	0	0
	Total	0	1 (1.2%)	0
<hr/>				
HEPATOBILIARY DISORDERS	None	0	0	0
	Unlikely	1 (1.2%)	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	0
<hr/>				
HYPERBILIRUBINAEMIA	None	0	0	0
	Unlikely	1 (1.2%)	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	0
<hr/>				
IMMUNE SYSTEM DISORDERS	None	0	1 (1.2%)	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0

Treatment-Emergent Adverse Events by Relationship to Study Drug
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System Organ Class Preferred Term	Maximum Relationsh ip	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Total	0	1 (1.2%)	0
HYPERSENSITIVITY	None	0	1 (1.2%)	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	1 (1.2%)	0
INFECTIONS AND INFESTATIONS	None	12 (14.0%)	9 (10.7%)	12 (14.3%)
	Unlikely	4 (4.7%)	0	1 (1.2%)
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	16 (18.6%)	9 (10.7%)	13 (15.5%)
BRONCHITIS	None	1 (1.2%)	0	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	0

Treatment-Emergent Adverse Events by Relationship to Study Drug
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System Organ Class Preferred Term	Maximum Relationship	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
CELLULITIS	None	0	1 (1.2%)	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	1 (1.2%)	0
CERVICITIS	None	0	0	0
	Unlikely	1 (1.2%)	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	0
CYSTITIS	None	1 (1.2%)	0	0
	Unlikely	0	0	1 (1.2%)
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	1 (1.2%)
EAR INFECTION	None	2 (2.3%)	0	0
	Unlikely	0	0	0

Treatment-Emergent Adverse Events by Relationship to Study Drug
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System Organ Class Preferred Term	Maximum Relationship	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	2 (2.3%)	0	0
<hr/>				
GASTROENTERITIS VIRAL	None	0	0	0
	Unlikely	1 (1.2%)	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	0
<hr/>				
HORDEOLUM	None	0	0	1 (1.2%)
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	0	1 (1.2%)
<hr/>				
INFLUENZA	None	1 (1.2%)	1 (1.2%)	1 (1.2%)
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0

Treatment-Emergent Adverse Events by Relationship to Study Drug
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System Organ Class Preferred Term	Maximum Relationship ip	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Missing	0	0	0
	Total	1 (1.2%)	1 (1.2%)	1 (1.2%)
<hr/>				
LOCALISED INFECTION	None	1 (1.2%)	0	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	0
<hr/>				
LOWER RESPIRATORY TRACT INFECTION	None	0	0	1 (1.2%)
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	0	1 (1.2%)
<hr/>				
NASOPHARYNGITIS	None	2 (2.3%)	4 (4.8%)	6 (7.1%)
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	2 (2.3%)	4 (4.8%)	6 (7.1%)

Treatment-Emergent Adverse Events by Relationship to Study Drug
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System Organ Class Preferred Term	Maximum Relationship ip	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
PNEUMONIA	None	0	1 (1.2%)	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	1 (1.2%)	0
RHINITIS	None	0	0	1 (1.2%)
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	0	1 (1.2%)
UPPER RESPIRATORY TRACT INFECTION	None	3 (3.5%)	1 (1.2%)	3 (3.6%)
	Unlikely	3 (3.5%)	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	6 (7.0%)	1 (1.2%)	3 (3.6%)
URINARY TRACT INFECTION	None	1 (1.2%)	0	1 (1.2%)

Treatment-Emergent Adverse Events by Relationship to Study Drug
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System Organ Class Preferred Term	Maximum Relationship ip	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Unlikely	1 (1.2%)	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	2 (2.3%)	0	1 (1.2%)
<hr/>				
VAGINAL MYCOSIS	None	0	0	0
	Unlikely	1 (1.2%)	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	0
<hr/>				
VIRAL INFECTION	None	0	1 (1.2%)	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	1 (1.2%)	0
<hr/>				
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	None	4 (4.7%)	2 (2.4%)	3 (3.6%)
	Unlikely	0	1 (1.2%)	1 (1.2%)
	Possible	0	1 (1.2%)	0

Treatment-Emergent Adverse Events by Relationship to Study Drug
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System Organ Class Preferred Term	Maximum Relationship ip	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Probable	0	1 (1.2%)	1 (1.2%)
	Missing	0	0	0
	Total	4 (4.7%)	5 (6.0%)	5 (6.0%)
<hr/>				
CONTUSION	None	1 (1.2%)	0	1 (1.2%)
	Unlikely	0	1 (1.2%)	1 (1.2%)
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	1 (1.2%)	2 (2.4%)
<hr/>				
EXCORIATION	None	2 (2.3%)	1 (1.2%)	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	1 (1.2%)
	Missing	0	0	0
	Total	2 (2.3%)	1 (1.2%)	1 (1.2%)
<hr/>				
FACIAL BONES FRACTURE	None	0	0	1 (1.2%)
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0

Treatment-Emergent Adverse Events by Relationship to Study Drug
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System Organ Class Preferred Term	Maximum Relationship ip	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Total	0	0	1 (1.2%)
FALL	None	1 (1.2%)	0	1 (1.2%)
	Unlikely	0	1 (1.2%)	0
	Possible	0	1 (1.2%)	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	2 (2.4%)	1 (1.2%)
HIP FRACTURE	None	1 (1.2%)	0	2 (2.4%)
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	2 (2.4%)
JOINT DISLOCATION	None	0	1 (1.2%)	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	1 (1.2%)	0

Treatment-Emergent Adverse Events by Relationship to Study Drug
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System Organ Class Preferred Term	Maximum Relationship	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
SKIN LACERATION	None	1 (1.2%)	1 (1.2%)	0
	Unlikely	0	0	0
	Possible	0	1 (1.2%)	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	2 (2.4%)	0
WOUND	None	0	0	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	1 (1.2%)	0
	Missing	0	0	0
	Total	0	1 (1.2%)	0
INVESTIGATIONS	None	2 (2.3%)	3 (3.6%)	5 (6.0%)
	Unlikely	4 (4.7%)	1 (1.2%)	0
	Possible	4 (4.7%)	2 (2.4%)	1 (1.2%)
	Probable	0	0	0
	Missing	0	0	0
	Total	10 (11.6%)	6 (7.1%)	6 (7.1%)
BIOPSY	None	0	0	1 (1.2%)
	Unlikely	0	0	0

Treatment-Emergent Adverse Events by Relationship to Study Drug
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System Organ Class Preferred Term	Maximum Relationsh ip	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	0	1 (1.2%)
<hr/>				
BIOPSY PROSTATE	None	0	0	1 (1.2%)
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	0	1 (1.2%)
<hr/>				
BLOOD ALKALINE PHOSPHATASE INCREASED	None	1 (1.2%)	0	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	0
<hr/>				
BLOOD CHOLESTEROL INCREASED	None	0	0	1 (1.2%)
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0

Treatment-Emergent Adverse Events by Relationship to Study Drug
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System Organ Class Preferred Term	Maximum Relationship ip	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Missing	0	0	0
	Total	0	0	1 (1.2%)
<hr/>				
BLOOD CREATINE PHOSPHOKINASE INCREASED	None	0	0	0
	Unlikely	0	0	0
	Possible	1 (1.2%)	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	0
<hr/>				
BLOOD GLUCOSE INCREASED	None	0	1 (1.2%)	1 (1.2%)
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	1 (1.2%)	1 (1.2%)
<hr/>				
BLOOD URINE PRESENT	None	1 (1.2%)	0	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	0

Treatment-Emergent Adverse Events by Relationship to Study Drug
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System Organ Class Preferred Term	Maximum Relationship ip	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
BODY TEMPERATURE INCREASED	None	0	0	0
	Unlikely	0	0	0
	Possible	0	1 (1.2%)	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	1 (1.2%)	0
<hr/>				
CYSTOSCOPY	None	1 (1.2%)	0	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	0
<hr/>				
ELECTROCARDIOGRAM ST SEGMENT DEPRESSION	None	0	0	0
	Unlikely	3 (3.5%)	0	0
	Possible	1 (1.2%)	1 (1.2%)	0
	Probable	0	0	0
	Missing	0	0	0
	Total	4 (4.7%)	1 (1.2%)	0
<hr/>				

Treatment-Emergent Adverse Events by Relationship to Study Drug
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System Organ Class Preferred Term	Maximum Relationship ip	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
ELECTROCARDIOGRAM T WAVE AMPLITUDE DECREASED	None	0	0	0
	Unlikely	1 (1.2%)	1 (1.2%)	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	1 (1.2%)	0
<hr/>				
ELECTROCARDIOGRAM T WAVE INVERSION	None	0	1 (1.2%)	0
	Unlikely	2 (2.3%)	0	0
	Possible	0	0	1 (1.2%)
	Probable	0	0	0
	Missing	0	0	0
	Total	2 (2.3%)	1 (1.2%)	1 (1.2%)
<hr/>				
HEART RATE INCREASED	None	0	0	0
	Unlikely	0	0	0
	Possible	1 (1.2%)	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	0
<hr/>				
HEART RATE IRREGULAR	None	0	0	0
	Unlikely	0	0	0

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System Organ Class Preferred Term	Maximum Relationship ip	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Possible	1 (1.2%)	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	0
<hr/>				
NASAL MUCOSA BIOPSY	None	0	1 (1.2%)	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	1 (1.2%)	0
<hr/>				
WEIGHT DECREASED	None	0	0	1 (1.2%)
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	0	1 (1.2%)
<hr/>				
METABOLISM AND NUTRITION DISORDERS	None	2 (2.3%)	0	0
	Unlikely	1 (1.2%)	0	1 (1.2%)
	Possible	3 (3.5%)	0	1 (1.2%)
	Probable	0	0	0

Treatment-Emergent Adverse Events by Relationship to Study Drug
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System Organ Class Preferred Term	Maximum Relationsh ip	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Missing	0	1 (1.2%)	0
	Total	6 (7.0%)	1 (1.2%)	2 (2.4%)
DECREASED APPETITE	None	0	0	0
	Unlikely	0	0	0
	Possible	1 (1.2%)	0	1 (1.2%)
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	1 (1.2%)
DEHYDRATION	None	1 (1.2%)	0	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	0
DIABETES MELLITUS	None	1 (1.2%)	0	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	0

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System Organ Class Preferred Term	Maximum Relationship ip	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
FOOD CRAVING	None	0	0	0
	Unlikely	0	0	0
	Possible	1 (1.2%)	0	0
	Probable	0	0	0
	Missing	0	1 (1.2%)	0
	Total	1 (1.2%)	1 (1.2%)	0
HYPONATRAEMIA	None	0	0	0
	Unlikely	1 (1.2%)	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	0
INCREASED APPETITE	None	0	0	0
	Unlikely	0	0	1 (1.2%)
	Possible	1 (1.2%)	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	1 (1.2%)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	None	2 (2.3%)	7 (8.3%)	4 (4.8%)

Treatment-Emergent Adverse Events by Relationship to Study Drug
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System Organ Class Preferred Term	Maximum Relationship	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Unlikely	1 (1.2%)	0	2 (2.4%)
	Possible	1 (1.2%)	0	1 (1.2%)
	Probable	0	0	0
	Missing	0	0	0
	Total	4 (4.7%)	7 (8.3%)	7 (8.3%)
<hr/>				
ARTHRALGIA	None	1 (1.2%)	2 (2.4%)	1 (1.2%)
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	2 (2.4%)	1 (1.2%)
<hr/>				
ARTHRITIS	None	0	0	1 (1.2%)
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	0	1 (1.2%)
<hr/>				
BACK PAIN	None	1 (1.2%)	1 (1.2%)	2 (2.4%)
	Unlikely	0	0	1 (1.2%)
	Possible	0	0	0

Treatment-Emergent Adverse Events by Relationship to Study Drug
Safety Analysis Set
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System Organ Class Preferred Term	Maximum Relationsh ip	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	1 (1.2%)	3 (3.6%)
<hr/>				
FLANK PAIN	None	0	0	1 (1.2%)
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	0	1 (1.2%)
<hr/>				
MUSCLE SPASMS	None	0	1 (1.2%)	0
	Unlikely	0	0	1 (1.2%)
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	1 (1.2%)	1 (1.2%)
<hr/>				
MUSCULAR WEAKNESS	None	0	1 (1.2%)	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0

Treatment-Emergent Adverse Events by Relationship to Study Drug
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System Organ Class Preferred Term	Maximum Relationsh ip	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Total	0	1 (1.2%)	0
MYALGIA	None	0	0	0
	Unlikely	0	0	0
	Possible	0	0	1 (1.2%)
	Probable	0	0	0
	Missing	0	0	0
	Total	0	0	1 (1.2%)
PAIN IN EXTREMITY	None	0	0	0
	Unlikely	1 (1.2%)	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	0
SHOULDER PAIN	None	0	2 (2.4%)	0
	Unlikely	0	0	0
	Possible	1 (1.2%)	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	2 (2.4%)	0

Treatment-Emergent Adverse Events by Relationship to Study Drug
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System Organ Class Preferred Term	Maximum Relationship	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	None	0	2 (2.4%)	1 (1.2%)
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	2 (2.4%)	1 (1.2%)
<hr/>				
COLON CANCER	None	0	1 (1.2%)	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	1 (1.2%)	0
<hr/>				
MALIGNANT FIBROUS HISTIOCYTOMA	None	0	1 (1.2%)	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	1 (1.2%)	0
<hr/>				
PROSTATE CANCER	None	0	0	1 (1.2%)
	Unlikely	0	0	0

Treatment-Emergent Adverse Events by Relationship to Study Drug
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System Organ Class Preferred Term	Maximum Relationship	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	0	1 (1.2%)
<hr/>				
NERVOUS SYSTEM DISORDERS	None	3 (3.5%)	3 (3.6%)	7 (8.3%)
	Unlikely	1 (1.2%)	5 (6.0%)	3 (3.6%)
	Possible	4 (4.7%)	9 (10.7%)	12 (14.3%)
	Probable	0	3 (3.6%)	3 (3.6%)
	Missing	0	0	0
	Total	8 (9.3%)	20 (23.8%)	25 (29.8%)
<hr/>				
AMNESIA	None	0	0	1 (1.2%)
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	0	1 (1.2%)
<hr/>				
BALANCE DISORDER	None	0	0	0
	Unlikely	0	0	0
	Possible	0	1 (1.2%)	0
	Probable	0	0	0

Treatment-Emergent Adverse Events by Relationship to Study Drug
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System Organ Class Preferred Term	Maximum Relationship ip	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Missing	0	0	0
	Total	0	1 (1.2%)	0
<hr/>				
BURNING SENSATION	None	0	0	0
	Unlikely	0	0	0
	Possible	0	0	1 (1.2%)
	Probable	0	0	1 (1.2%)
	Missing	0	0	0
	Total	0	0	2 (2.4%)
<hr/>				
COGNITIVE DISORDER	None	0	0	1 (1.2%)
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	0	1 (1.2%)
<hr/>				
COMPLEX PARTIAL SEIZURES	None	0	0	0
	Unlikely	0	0	0
	Possible	0	1 (1.2%)	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	1 (1.2%)	0

Treatment-Emergent Adverse Events by Relationship to Study Drug
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System Organ Class Preferred Term	Maximum Relationship ip	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
COORDINATION ABNORMAL	None	0	0	0
	Unlikely	0	0	0
	Possible	0	1 (1.2%)	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	1 (1.2%)	0
DIZZINESS	None	0	0	2 (2.4%)
	Unlikely	0	2 (2.4%)	3 (3.6%)
	Possible	2 (2.3%)	5 (6.0%)	6 (7.1%)
	Probable	0	1 (1.2%)	0
	Missing	0	0	0
	Total	2 (2.3%)	8 (9.5%)	11 (13.1%)
HEADACHE	None	2 (2.3%)	1 (1.2%)	2 (2.4%)
	Unlikely	0	1 (1.2%)	2 (2.4%)
	Possible	1 (1.2%)	1 (1.2%)	1 (1.2%)
	Probable	0	0	0
	Missing	0	0	0
	Total	3 (3.5%)	3 (3.6%)	5 (6.0%)
HEMIANOPIA HOMONYMOUS	None	0	1 (1.2%)	0

Treatment-Emergent Adverse Events by Relationship to Study Drug
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System Organ Class Preferred Term	Maximum Relationship	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	1 (1.2%)	0
<hr/>				
HYPERSOMNIA	None	0	0	0
	Unlikely	0	0	0
	Possible	0	0	1 (1.2%)
	Probable	0	0	0
	Missing	0	0	0
	Total	0	0	1 (1.2%)
<hr/>				
LETHARGY	None	0	0	0
	Unlikely	0	0	0
	Possible	0	0	1 (1.2%)
	Probable	0	1 (1.2%)	0
	Missing	0	0	0
	Total	0	1 (1.2%)	1 (1.2%)
<hr/>				
PARAESTHESIA	None	0	0	1 (1.2%)
	Unlikely	0	0	0
	Possible	0	0	0

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System Organ Class Preferred Term	Maximum Relationship ip	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Probable	0	0	0
	Missing	0	0	0
	Total	0	0	1 (1.2%)
<hr/>				
PARAESTHESIA ORAL	None	0	0	0
	Unlikely	0	0	0
	Possible	0	1 (1.2%)	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	1 (1.2%)	0
<hr/>				
PARKINSON'S DISEASE	None	1 (1.2%)	0	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	0
<hr/>				
PAROSMIA	None	0	0	0
	Unlikely	0	0	0
	Possible	0	0	1 (1.2%)
	Probable	0	0	0
	Missing	0	0	0

Treatment-Emergent Adverse Events by Relationship to Study Drug
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System Organ Class Preferred Term	Maximum Relationship ip	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Total	0	0	1 (1.2%)
PARTIAL SEIZURES WITH SECONDARY GENERALISATION	None	0	0	1 (1.2%)
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	0	1 (1.2%)
PSYCHOMOTOR HYPERACTIVITY	None	0	0	0
	Unlikely	1 (1.2%)	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	0
SOMNOLENCE	None	1 (1.2%)	1 (1.2%)	0
	Unlikely	0	2 (2.4%)	1 (1.2%)
	Possible	1 (1.2%)	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	2 (2.3%)	3 (3.6%)	1 (1.2%)

Treatment-Emergent Adverse Events by Relationship to Study Drug
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System Organ Class Preferred Term	Maximum Relationship	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
STUPOR	None	0	0	0
	Unlikely	0	0	0
	Possible	0	1 (1.2%)	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	1 (1.2%)	0
SYNCOPE	None	0	0	0
	Unlikely	0	0	0
	Possible	0	3 (3.6%)	1 (1.2%)
	Probable	0	1 (1.2%)	2 (2.4%)
	Missing	0	0	0
	Total	0	4 (4.8%)	3 (3.6%)
SYNCOPE VASOVAGAL	None	0	0	0
	Unlikely	0	0	0
	Possible	0	0	1 (1.2%)
	Probable	0	0	0
	Missing	0	0	0
	Total	0	0	1 (1.2%)
TRANSIENT ISCHAEMIC ATTACK	None	0	0	1 (1.2%)
	Unlikely	0	1 (1.2%)	0

Treatment-Emergent Adverse Events by Relationship to Study Drug
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System Organ Class Preferred Term	Maximum Relationship	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Possible	0	1 (1.2%)	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	2 (2.4%)	1 (1.2%)
<hr/>				
PSYCHIATRIC DISORDERS	None	2 (2.3%)	1 (1.2%)	2 (2.4%)
	Unlikely	6 (7.0%)	0	1 (1.2%)
	Possible	2 (2.3%)	7 (8.3%)	5 (6.0%)
	Probable	0	2 (2.4%)	0
	Missing	0	0	0
	Total	10 (11.6%)	10 (11.9%)	8 (9.5%)
<hr/>				
AGITATION	None	0	0	1 (1.2%)
	Unlikely	2 (2.3%)	0	0
	Possible	0	2 (2.4%)	0
	Probable	0	0	0
	Missing	0	0	0
	Total	2 (2.3%)	2 (2.4%)	1 (1.2%)
<hr/>				
ANXIETY	None	0	0	0
	Unlikely	0	0	0
	Possible	0	3 (3.6%)	0
	Probable	0	0	0

Treatment-Emergent Adverse Events by Relationship to Study Drug
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System Organ Class Preferred Term	Maximum Relationship ip	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Missing	0	0	0
	Total	0	3 (3.6%)	0
<hr/>				
COMPLETED SUICIDE	None	1 (1.2%)	0	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	0
<hr/>				
CONFUSIONAL STATE	None	0	1 (1.2%)	0
	Unlikely	1 (1.2%)	0	1 (1.2%)
	Possible	1 (1.2%)	1 (1.2%)	0
	Probable	0	1 (1.2%)	0
	Missing	0	0	0
	Total	2 (2.3%)	3 (3.6%)	1 (1.2%)
<hr/>				
DELIRIUM	None	0	0	0
	Unlikely	0	0	0
	Possible	0	0	1 (1.2%)
	Probable	0	0	0
	Missing	0	0	0
	Total	0	0	1 (1.2%)

Treatment-Emergent Adverse Events by Relationship to Study Drug
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System Organ Class Preferred Term	Maximum Relationship ip	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
DELUSION	None	0	0	1 (1.2%)
	Unlikely	1 (1.2%)	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	1 (1.2%)
DEPRESSED MOOD	None	0	0	0
	Unlikely	0	0	0
	Possible	0	1 (1.2%)	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	1 (1.2%)	0
DISORIENTATION	None	0	0	0
	Unlikely	1 (1.2%)	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	0
HALLUCINATION	None	0	0	1 (1.2%)

Treatment-Emergent Adverse Events by Relationship to Study Drug
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System Organ Class Preferred Term	Maximum Relationship	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	0	1 (1.2%)
<hr/>				
HALLUCINATION, VISUAL	None	0	0	0
	Unlikely	0	0	0
	Possible	0	0	1 (1.2%)
	Probable	0	0	0
	Missing	0	0	0
	Total	0	0	1 (1.2%)
<hr/>				
INSOMNIA	None	1 (1.2%)	0	0
	Unlikely	1 (1.2%)	0	0
	Possible	0	0	2 (2.4%)
	Probable	0	0	0
	Missing	0	0	0
	Total	2 (2.3%)	0	2 (2.4%)
<hr/>				
IRRITABILITY	None	0	0	0
	Unlikely	0	0	0
	Possible	1 (1.2%)	1 (1.2%)	0

Treatment-Emergent Adverse Events by Relationship to Study Drug
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System Organ Class Preferred Term	Maximum Relationship ip	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	1 (1.2%)	0
<hr/>				
LIBIDO DECREASED	None	0	0	0
	Unlikely	0	0	0
	Possible	0	0	1 (1.2%)
	Probable	0	0	0
	Missing	0	0	0
	Total	0	0	1 (1.2%)
<hr/>				
LISTLESS	None	0	0	0
	Unlikely	0	0	0
	Possible	0	0	1 (1.2%)
	Probable	0	0	0
	Missing	0	0	0
	Total	0	0	1 (1.2%)
<hr/>				
NIGHTMARE	None	0	0	0
	Unlikely	0	0	1 (1.2%)
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0

Treatment-Emergent Adverse Events by Relationship to Study Drug
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System Organ Class Preferred Term	Maximum Relationsh ip	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Total	0	0	1 (1.2%)
RESTLESSNESS	None	0	0	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	1 (1.2%)	0
	Missing	0	0	0
	Total	0	1 (1.2%)	0
RENAL AND URINARY DISORDERS	None	3 (3.5%)	2 (2.4%)	2 (2.4%)
	Unlikely	1 (1.2%)	1 (1.2%)	0
	Possible	0	0	1 (1.2%)
	Probable	0	0	0
	Missing	0	0	0
	Total	4 (4.7%)	3 (3.6%)	3 (3.6%)
CALCULUS URETHRAL	None	0	0	1 (1.2%)
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	0	1 (1.2%)

Treatment-Emergent Adverse Events by Relationship to Study Drug
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System Organ Class Preferred Term	Maximum Relationship	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
DYSURIA	None	0	0	0
	Unlikely	1 (1.2%)	1 (1.2%)	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	1 (1.2%)	0
INCONTINENCE	None	0	1 (1.2%)	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	1 (1.2%)	0
MICTURITION URGENCY	None	1 (1.2%)	1 (1.2%)	0
	Unlikely	0	0	0
	Possible	0	0	1 (1.2%)
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	1 (1.2%)	1 (1.2%)
NEPHROLITHIASIS	None	1 (1.2%)	0	1 (1.2%)
	Unlikely	0	0	0

Treatment-Emergent Adverse Events by Relationship to Study Drug
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System Organ Class Preferred Term	Maximum Relationship	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	1 (1.2%)
<hr/>				
POLLAKIURIA	None	1 (1.2%)	0	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	0
<hr/>				
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	None	1 (1.2%)	0	1 (1.2%)
	Unlikely	0	0	0
	Possible	1 (1.2%)	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	2 (2.3%)	0	1 (1.2%)
<hr/>				
BENIGN PROSTATIC HYPERPLASIA	None	1 (1.2%)	0	1 (1.2%)
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0

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System Organ Class Preferred Term	Maximum Relationsh ip	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Missing	0	0	0
	Total	1 (1.2%)	0	1 (1.2%)
<hr/>				
PELVIC PAIN	None	0	0	0
	Unlikely	0	0	0
	Possible	1 (1.2%)	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	0
<hr/>				
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	None	3 (3.5%)	6 (7.1%)	8 (9.5%)
	Unlikely	3 (3.5%)	3 (3.6%)	2 (2.4%)
	Possible	1 (1.2%)	0	0
	Probable	1 (1.2%)	0	0
	Missing	0	0	0
	Total	8 (9.3%)	9 (10.7%)	10 (11.9%)
<hr/>				
ALLERGIC GRANULOMATOUS ANGIITIS	None	0	0	1 (1.2%)
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	0	1 (1.2%)

Treatment-Emergent Adverse Events by Relationship to Study Drug
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System Organ Class Preferred Term	Maximum Relationship ip	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
COUGH	None	0	4 (4.8%)	5 (6.0%)
	Unlikely	1 (1.2%)	1 (1.2%)	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	5 (6.0%)	5 (6.0%)
DYSPHONIA	None	0	0	0
	Unlikely	0	1 (1.2%)	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	1 (1.2%)	0
DYSPNOEA	None	0	1 (1.2%)	1 (1.2%)
	Unlikely	0	0	0
	Possible	1 (1.2%)	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	1 (1.2%)	1 (1.2%)
EMPHYSEMA	None	0	0	0

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System Organ Class Preferred Term	Maximum Relationship	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	1 (1.2%)	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	0
<hr/>				
PISTAXIS	None	0	0	1 (1.2%)
	Unlikely	0	1 (1.2%)	1 (1.2%)
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	1 (1.2%)	2 (2.4%)
<hr/>				
HAEMOPTYSIS	None	1 (1.2%)	0	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	0
<hr/>				
NASAL CONGESTION	None	1 (1.2%)	1 (1.2%)	2 (2.4%)
	Unlikely	2 (2.3%)	0	1 (1.2%)
	Possible	0	0	0

Treatment-Emergent Adverse Events by Relationship to Study Drug
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System Organ Class Preferred Term	Maximum Relationship	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Probable	0	0	0
	Missing	0	0	0
	Total	3 (3.5%)	1 (1.2%)	3 (3.6%)
<hr/>				
PHARYNGEAL ERYTHEMA	None	0	0	1 (1.2%)
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	0	1 (1.2%)
<hr/>				
PHARYNGOLARYNGEAL PAIN	None	0	1 (1.2%)	1 (1.2%)
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	1 (1.2%)	1 (1.2%)
<hr/>				
POSTNASAL DRIP	None	1 (1.2%)	0	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0

Treatment-Emergent Adverse Events by Relationship to Study Drug
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System Organ Class Preferred Term	Maximum Relationsh ip	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Total	1 (1.2%)	0	0
PRODUCTIVE COUGH	None	0	0	1 (1.2%)
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	0	1 (1.2%)
RALES	None	1 (1.2%)	0	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	0
RESPIRATORY TRACT CONGESTION	None	0	0	1 (1.2%)
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	0	1 (1.2%)

Treatment-Emergent Adverse Events by Relationship to Study Drug
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System Organ Class Preferred Term	Maximum Relationship	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
RHINORRHOEA	None	0	0	1 (1.2%)
	Unlikely	0	1 (1.2%)	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	1 (1.2%)	1 (1.2%)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	None	1 (1.2%)	1 (1.2%)	1 (1.2%)
	Unlikely	3 (3.5%)	0	0
	Possible	5 (5.8%)	14 (16.7%)	18 (21.4%)
	Probable	11 (12.8%)	23 (27.4%)	21 (25.0%)
	Missing	0	1 (1.2%)	0
	Total	20 (23.3%)	39 (46.4%)	40 (47.6%)
ACTINIC KERATOSIS	None	0	0	1 (1.2%)
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	0	1 (1.2%)
ALOPECIA	None	0	0	0
	Unlikely	1 (1.2%)	0	0

Treatment-Emergent Adverse Events by Relationship to Study Drug
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System Organ Class Preferred Term	Maximum Relationship	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	0
<hr/>				
BLISTER	None	0	0	0
	Unlikely	0	0	0
	Possible	0	3 (3.6%)	0
	Probable	0	2 (2.4%)	1 (1.2%)
	Missing	0	0	0
	Total	0	5 (6.0%)	1 (1.2%)
<hr/>				
COLD SWEAT	None	0	0	0
	Unlikely	0	0	0
	Possible	1 (1.2%)	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	0
<hr/>				
DERMATITIS CONTACT	None	0	0	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	1 (1.2%)	0

Treatment-Emergent Adverse Events by Relationship to Study Drug
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System Organ Class Preferred Term	Maximum Relationship ip	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Missing	0	0	0
	Total	0	1 (1.2%)	0
<hr/>				
DRUG ERUPTION	None	1 (1.2%)	0	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	0
<hr/>				
ERYTHEMA	None	0	1 (1.2%)	0
	Unlikely	0	0	0
	Possible	1 (1.2%)	4 (4.8%)	6 (7.1%)
	Probable	7 (8.1%)	9 (10.7%)	8 (9.5%)
	Missing	0	0	0
	Total	8 (9.3%)	14 (16.7%)	14 (16.7%)
<hr/>				
HYPERHIDROSIS	None	0	0	0
	Unlikely	1 (1.2%)	0	0
	Possible	1 (1.2%)	2 (2.4%)	8 (9.5%)
	Probable	0	2 (2.4%)	0
	Missing	0	0	0
	Total	2 (2.3%)	4 (4.8%)	8 (9.5%)

Treatment-Emergent Adverse Events by Relationship to Study Drug
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System Organ Class Preferred Term	Maximum Relationship ip	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
PRURITUS	None	0	1 (1.2%)	0
	Unlikely	1 (1.2%)	0	0
	Possible	4 (4.7%)	6 (7.1%)	11 (13.1%)
	Probable	3 (3.5%)	14 (16.7%)	15 (17.9%)
	Missing	0	0	0
	Total	8 (9.3%)	21 (25.0%)	26 (31.0%)
PRURITUS GENERALISED	None	0	0	0
	Unlikely	0	0	0
	Possible	0	1 (1.2%)	0
	Probable	0	0	1 (1.2%)
	Missing	0	0	0
	Total	0	1 (1.2%)	1 (1.2%)
RASH	None	1 (1.2%)	0	1 (1.2%)
	Unlikely	1 (1.2%)	1 (1.2%)	1 (1.2%)
	Possible	2 (2.3%)	6 (7.1%)	2 (2.4%)
	Probable	1 (1.2%)	5 (6.0%)	5 (6.0%)
	Missing	0	1 (1.2%)	0
	Total	5 (5.8%)	13 (15.5%)	9 (10.7%)
RASH ERYTHEMATOUS	None	0	0	0

Treatment-Emergent Adverse Events by Relationship to Study Drug
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System Organ Class Preferred Term	Maximum Relationship ip	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	1 (1.2%)	0
	Missing	0	0	0
	Total	0	1 (1.2%)	0
<hr/>				
RASH MACULO-PAPULAR	None	0	0	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	1 (1.2%)
	Missing	0	0	0
	Total	0	0	1 (1.2%)
<hr/>				
RASH PRURITIC	None	0	0	0
	Unlikely	0	0	0
	Possible	0	0	1 (1.2%)
	Probable	0	1 (1.2%)	1 (1.2%)
	Missing	0	0	0
	Total	0	1 (1.2%)	2 (2.4%)
<hr/>				
SKIN EXFOLIATION	None	0	0	0
	Unlikely	0	0	0
	Possible	0	1 (1.2%)	0

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System Organ Class Preferred Term	Maximum Relationsh ip	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Probable	0	0	0
	Missing	0	0	0
	Total	0	1 (1.2%)	0
<hr/>				
SKIN IRRITATION	None	1 (1.2%)	0	0
	Unlikely	0	0	0
	Possible	1 (1.2%)	3 (3.6%)	1 (1.2%)
	Probable	1 (1.2%)	3 (3.6%)	4 (4.8%)
	Missing	0	0	0
	Total	3 (3.5%)	6 (7.1%)	5 (6.0%)
<hr/>				
SKIN ODOUR ABNORMAL	None	0	0	0
	Unlikely	0	0	1 (1.2%)
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	0	1 (1.2%)
<hr/>				
SKIN ULCER	None	0	0	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	1 (1.2%)	0	0
	Missing	0	0	0

Treatment-Emergent Adverse Events by Relationship to Study Drug
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System Organ Class Preferred Term	Maximum Relationsh ip	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Total	1 (1.2%)	0	0
URTICARIA	None	0	0	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	1 (1.2%)	1 (1.2%)
	Missing	0	0	0
	Total	0	1 (1.2%)	1 (1.2%)
SOCIAL CIRCUMSTANCES	None	0	0	1 (1.2%)
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	0	1 (1.2%)
ALCOHOL USE	None	0	0	1 (1.2%)
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	0	1 (1.2%)

Treatment-Emergent Adverse Events by Relationship to Study Drug
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System Organ Class Preferred Term	Maximum Relationship	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
SURGICAL AND MEDICAL PROCEDURES	None	2 (2.3%)	1 (1.2%)	2 (2.4%)
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	2 (2.3%)	1 (1.2%)	2 (2.4%)
ACROCHORDON EXCISION	None	0	0	1 (1.2%)
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	0	1 (1.2%)
CATARACT OPERATION	None	1 (1.2%)	1 (1.2%)	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	1 (1.2%)	0
EYE LASER SURGERY	None	1 (1.2%)	0	0
	Unlikely	0	0	0

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System Organ Class Preferred Term	Maximum Relationship ip	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	0
<hr/>				
SKIN LESION EXCISION	None	0	0	1 (1.2%)
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	0	1 (1.2%)
<hr/>				
VASCULAR DISORDERS	None	0	1 (1.2%)	0
	Unlikely	2 (2.3%)	0	0
	Possible	1 (1.2%)	2 (2.4%)	1 (1.2%)
	Probable	0	0	0
	Missing	0	0	0
	Total	3 (3.5%)	3 (3.6%)	1 (1.2%)
<hr/>				
HOT FLUSH	None	0	1 (1.2%)	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0

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System Organ Class Preferred Term	Maximum Relationship ip	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Missing	0	0	0
	Total	0	1 (1.2%)	0
<hr/>				
HYPERTENSION	None	0	0	0
	Unlikely	1 (1.2%)	0	0
	Possible	0	1 (1.2%)	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	1 (1.2%)	0
<hr/>				
HYPOTENSION	None	0	0	0
	Unlikely	1 (1.2%)	0	0
	Possible	1 (1.2%)	1 (1.2%)	0
	Probable	0	0	0
	Missing	0	0	0
	Total	2 (2.3%)	1 (1.2%)	0
<hr/>				
ORTHOSTATIC HYPOTENSION	None	0	0	0
	Unlikely	0	0	0
	Possible	1 (1.2%)	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 (1.2%)	0	0

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System Organ Class Preferred Term	Maximum Relationship ip	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
WOUND HAEMORRHAGE	None	0	0	0
	Unlikely	0	0	0
	Possible	0	0	1 (1.2%)
	Probable	0	0	0
	Missing	0	0	0
	Total	0	0	1 (1.2%)