

**Treatment-Emergent Adverse Events by Relationship to Study Drug  
Safety Analysis Set**

<b>System Organ Class Preferred Term</b>	<b>Maximum Relationship P</b>	<b>Placebo (N=86) n (%)</b>	<b>Low Dose (N=84) n (%)</b>	<b>High Dose (N=84) n (%)</b>
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%)
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%)
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%)
ATRIAL FLUTTER				
	None	0	0	1 ( 1.2%)
	Unlikely	0	0	0
	Possible	0	1 ( 1.2%)	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	1 ( 1.2%)	1 ( 1.2%)
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
ATRIOVENTRICULAR BLOCK FIRST DEGREE				
	None	0	1 ( 1.2%)	0
	Unlikely	0	0	0

Copyright @ DH

**Treatment-Emergent Adverse Events by Relationship to Study Drug  
Safety Analysis Set**

System Organ Class Preferred Term	Maximum Relationship P	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%)	1 ( 1.2%)	0
ATRIOVENTRICULAR BLOCK SECOND DEGREE	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
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
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
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
CARDIAC DISORDER	None	0	0	1 ( 1.2%)
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0

Copyright @ DH

**Treatment-Emergent Adverse Events by Relationship to Study Drug  
Safety Analysis Set**

System Organ Class Preferred Term	Maximum Relationship p	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	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
	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
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
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%)

Copyright @ DH

**Treatment-Emergent Adverse Events by Relationship to Study Drug  
Safety Analysis Set**

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

Copyright © DH

**Treatment-Emergent Adverse Events by Relationship to Study Drug  
Safety Analysis Set**

System Organ Class Preferred Term	Maximum Relationship P	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	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%)
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
	Possible	0	0	0

Copyright @ DH

**Treatment-Emergent Adverse Events by Relationship to Study Drug  
Safety Analysis Set**

System Organ Class Preferred Term	Maximum Relationship P	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%)	0	0
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%)
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%)
CONJUNCTIVAL HAEMORRHAGE	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
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
EYE ALLERGY	None	1 ( 1.2%)	0	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0

Copyright @ DH

**Treatment-Emergent Adverse Events by Relationship to Study Drug  
Safety Analysis Set**

System Organ Class Preferred Term	Maximum Relationship P	Placebo	Low Dose	High Dose
		(N=86) n (%)	(N=84) n (%)	(N=84) n (%)
	Total	1 ( 1.2%)	0	0
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
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
	Unlikely	0	0	1 ( 1.2%)
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	0	1 ( 1.2%)

Copyright @ DH

**Treatment-Emergent Adverse Events by Relationship to Study Drug  
Safety Analysis Set**

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

Copyright @ DH

**Treatment-Emergent Adverse Events by Relationship to Study Drug  
Safety Analysis Set**

System Organ Class Preferred Term	Maximum Relationship P	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
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
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%)

Copyright @ DH

**Treatment-Emergent Adverse Events by Relationship to Study Drug  
Safety Analysis Set**

System Organ Class Preferred Term	Maximum Relationship p	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	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
	Possible	0	0	3 ( 3.6%)
	Probable	0	0	0
	Missing	0	0	0
	Total	0	0	4 ( 4.8%)
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%)
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%)
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%)
	Missing	0	0	0
	Total	21 ( 24.4%)	47 ( 56.0%)	40 ( 47.6%)

Copyright @ DH

**Treatment-Emergent Adverse Events by Relationship to Study Drug  
Safety Analysis Set**

System Organ Class Preferred Term	Maximum Relationship P	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
APPLICATION SITE BLEEDING				
None	0	0	0	0
Unlikely	0	0	0	0
Possible	0	0	0	0
Probable	0	1 ( 1.2%)	0	0
Missing	0	0	0	0
Total	0	1 ( 1.2%)	0	0
APPLICATION SITE DERMATITIS				
None	0	0	0	0
Unlikely	0	0	0	0
Possible	1 ( 1.2%)	0	0	0
Probable	4 ( 4.7%)	9 ( 10.7%)	7 ( 8.3%)	7 ( 8.3%)
Missing	0	0	0	0
Total	5 ( 5.8%)	9 ( 10.7%)	7 ( 8.3%)	7 ( 8.3%)
APPLICATION SITE DESQUAMATION				
None	0	0	0	0
Unlikely	0	0	0	0
Possible	0	1 ( 1.2%)	0	0
Probable	0	0	0	0
Missing	0	0	0	0
Total	0	1 ( 1.2%)	0	0
APPLICATION SITE DISCHARGE				
None	0	0	0	0
Unlikely	0	0	0	0
Possible	0	0	0	0
Probable	0	0	1 ( 1.2%)	1 ( 1.2%)
Missing	0	0	0	0
Total	0	0	1 ( 1.2%)	1 ( 1.2%)
APPLICATION SITE DISCOLOURATION				
None	0	0	0	0
Unlikely	0	0	0	0
Possible	0	0	0	0
Probable	0	1 ( 1.2%)	0	0
Missing	0	0	0	0
Total	0	1 ( 1.2%)	0	0
APPLICATION SITE ERYTHEMA				
None	0	0	0	0

Copyright @ DH

**Treatment-Emergent Adverse Events by Relationship to Study Drug  
Safety Analysis Set**

<b>System Organ Class Preferred Term</b>	<b>Maximum Relationship P</b>	<b>Placebo (N=86) n (%)</b>	<b>Low Dose (N=84) n (%)</b>	<b>High Dose (N=84) n (%)</b>
	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
	Unlikely	0	0	0
	Possible	1 ( 1.2%)	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 ( 1.2%)	0	0
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%)
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%)
APPLICATION SITE PERSPIRATION	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%)
APPLICATION SITE PRURITUS	None	0	0	0
	Unlikely	0	0	0
	Possible	1 ( 1.2%)	5 ( 6.0%)	2 ( 2.4%)

Copyright @ DH

**Treatment-Emergent Adverse Events by Relationship to Study Drug  
Safety Analysis Set**

<b>System Organ Class Preferred Term</b>	<b>Maximum Relationship P</b>	<b>Placebo (N=86) n (%)</b>	<b>Low Dose (N=84) n (%)</b>	<b>High Dose (N=84) n (%)</b>
	Probable	5 ( 5.8%)	17 ( 20.2%)	20 ( 23.8%)
	Missing	0	0	0
	Total	6 ( 7.0%)	22 ( 26.2%)	22 ( 26.2%)
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%)
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
	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

Copyright @ DH

**Treatment-Emergent Adverse Events by Relationship to Study Drug  
Safety Analysis Set**

System Organ Class Preferred Term	Maximum Relationship P	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
			Total	Total
ASTHENIA			0 ( 1.2%)	0 ( 0%)
	None	0 ( 0%)	0 ( 0%)	0 ( 0%)
	Unlikely	0 ( 0%)	0 ( 0%)	1 ( 1.2%)
	Possible	1 ( 1.2%)	0 ( 0%)	0 ( 0%)
	Probable	0 ( 0%)	0 ( 0%)	0 ( 0%)
	Missing	0 ( 0%)	0 ( 0%)	0 ( 0%)
	Total	1 ( 1.2%)	0 ( 0%)	1 ( 1.2%)
CHEST DISCOMFORT			0 ( 0%)	1 ( 1.2%)
	None	0 ( 0%)	0 ( 0%)	0 ( 0%)
	Unlikely	0 ( 0%)	0 ( 0%)	0 ( 0%)
	Possible	0 ( 0%)	0 ( 0%)	0 ( 0%)
	Probable	0 ( 0%)	0 ( 0%)	1 ( 1.2%)
	Missing	0 ( 0%)	0 ( 0%)	0 ( 0%)
	Total	0 ( 0%)	0 ( 0%)	2 ( 2.4%)
CHEST PAIN			0 ( 0%)	0 ( 0%)
	None	0 ( 0%)	0 ( 0%)	0 ( 0%)
	Unlikely	0 ( 0%)	0 ( 0%)	2 ( 2.4%)
	Possible	0 ( 0%)	0 ( 0%)	0 ( 0%)
	Probable	0 ( 0%)	0 ( 0%)	0 ( 0%)
	Missing	0 ( 0%)	0 ( 0%)	0 ( 0%)
	Total	0 ( 0%)	0 ( 0%)	2 ( 2.4%)
CHILLS			0 ( 0%)	0 ( 0%)
	None	0 ( 0%)	0 ( 0%)	0 ( 0%)
	Unlikely	0 ( 0%)	0 ( 0%)	1 ( 1.2%)
	Possible	1 ( 1.2%)	1 ( 1.2%)	0 ( 0%)
	Probable	0 ( 0%)	0 ( 0%)	0 ( 0%)
	Missing	0 ( 0%)	0 ( 0%)	0 ( 0%)
	Total	1 ( 1.2%)	1 ( 1.2%)	1 ( 1.2%)
FATIGUE			0 ( 0%)	0 ( 0%)
	None	0 ( 0%)	0 ( 0%)	0 ( 0%)
	Unlikely	0 ( 0%)	3 ( 3.6%)	1 ( 1.2%)
	Possible	1 ( 1.2%)	2 ( 2.4%)	4 ( 4.8%)
	Probable	0 ( 0%)	0 ( 0%)	0 ( 0%)
	Missing	0 ( 0%)	0 ( 0%)	0 ( 0%)
	Total	1 ( 1.2%)	5 ( 6.0%)	5 ( 6.0%)

Copyright @ DH

**Treatment-Emergent Adverse Events by Relationship to Study Drug  
Safety Analysis Set**

<b>System Organ Class Preferred Term</b>	<b>Maximum Relationship P</b>	<b>Placebo (N=86) n (%)</b>	<b>Low Dose (N=84) n (%)</b>	<b>High Dose (N=84) n (%)</b>
FEELING ABNORMAL	None Unlikely Possible Probable Missing Total	0 0 0 0 0 0	0 0 0 0 0 0	0 0 1 ( 1.2%) 0 0 1 ( 1.2%)
FEELING COLD	None Unlikely Possible Probable Missing Total	0 0 0 0 0 0	0 0 0 0 0 0	1 ( 1.2%) 0 0 0 0 1 ( 1.2%)
INFLAMMATION	None Unlikely Possible Probable Missing Total	0 0 0 0 0 0	0 1 ( 1.2%) 0 0 0 1 ( 1.2%)	0 0 0 0 0 0
MALAISE	None Unlikely Possible Probable Missing Total	0 0 0 0 0 0	0 0 1 ( 1.2%) 0 0 1 ( 1.2%)	0 1 ( 1.2%) 1 ( 1.2%) 0 0 2 ( 2.4%)
OEDEMA	None Unlikely Possible Probable Missing Total	0 0 0 0 0 0	0 0 0 2 ( 2.4%) 0 2 ( 2.4%)	0 0 0 0 0 0
OEDEMA PERIPHERAL	None Unlikely	1 ( 1.2%) 1 ( 1.2%)	0 1 ( 1.2%)	1 ( 1.2%) 0

Copyright @ DH

**Treatment-Emergent Adverse Events by Relationship to Study Drug  
Safety Analysis Set**

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

Copyright @ DH

**Treatment-Emergent Adverse Events by Relationship to Study Drug  
Safety Analysis Set**

System Organ Class Preferred Term	Maximum Relationship p	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
ULCER	Missing	0	0	0
	Total	0	1 ( 1.2%)	0
	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
	None	0	0	0
	Unlikely	1 ( 1.2%)	0	0
	Possible	0	0	0
	Probable	0	0	0
HEPATOBILIARY DISORDERS	Missing	0	0	0
	Total	1 ( 1.2%)	0	0
	None	0	0	0
	Unlikely	1 ( 1.2%)	0	0
	Possible	0	0	0
	Probable	0	0	0
HYPERBILIRUBINAEMIA	Missing	0	0	0
	Total	1 ( 1.2%)	0	0
	None	0	0	0
	Unlikely	1 ( 1.2%)	0	0
	Possible	0	0	0
	Probable	0	0	0
IMMUNE SYSTEM DISORDERS	Missing	0	0	0
	Total	0	1 ( 1.2%)	0
	None	0	1 ( 1.2%)	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
HYPERSENSITIVITY	Missing	0	0	0
	Total	0	1 ( 1.2%)	0
	None	0	1 ( 1.2%)	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0

Copyright @ DH

**Treatment-Emergent Adverse Events by Relationship to Study Drug  
Safety Analysis Set**

System Organ Class Preferred Term	Maximum Relationship P	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
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
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

Copyright @ DH

**Treatment-Emergent Adverse Events by Relationship to Study Drug  
Safety Analysis Set**

System Organ Class Preferred Term	Maximum Relationship P	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	2 ( 2.3%)	0	0
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
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%)
INFLUENZA	None	1 ( 1.2%)	1 ( 1.2%)	1 ( 1.2%)
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 ( 1.2%)	1 ( 1.2%)	1 ( 1.2%)
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
LOWER RESPIRATORY TRACT INFECTION	None	0	0	1 ( 1.2%)
	Unlikely	0	0	0
	Possible	0	0	0

Copyright @ DH

**Treatment-Emergent Adverse Events by Relationship to Study Drug  
Safety Analysis Set**

System Organ Class Preferred Term	Maximum Relationship P	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%)
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%)
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%)
	Unlikely	1 ( 1.2%)	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0

Copyright @ DH

**Treatment-Emergent Adverse Events by Relationship to Study Drug  
Safety Analysis Set**

System Organ Class Preferred Term	Maximum Relationship P	Placebo (N=86)	Low Dose (N=84)	High Dose (N=84)
		n (%)	n (%)	n (%)
	Total	2 ( 2.3%)	0	1 ( 1.2%)
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
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
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
	Probable	0	1 ( 1.2%)	1 ( 1.2%)
	Missing	0	0	0
	Total	4 ( 4.7%)	5 ( 6.0%)	5 ( 6.0%)
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%)
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%)

Copyright @ DH

**Treatment-Emergent Adverse Events by Relationship to Study Drug  
Safety Analysis Set**

<b>System Organ Class Preferred Term</b>	<b>Maximum Relationship P</b>	<b>Placebo (N=86) n (%)</b>	<b>Low Dose (N=84) n (%)</b>	<b>High Dose (N=84) n (%)</b>
FACIAL BONES FRACTURE	None Unlikely Possible Probable Missing Total	0 0 0 0 0 0	0 0 0 0 0 0	1 ( 1.2%)
FALL	None Unlikely Possible Probable Missing Total	1 ( 1.2%) 0 0 0 0 1 ( 1.2%)	0 1 ( 1.2%) 1 ( 1.2%) 0 0 2 ( 2.4%)	1 ( 1.2%) 0 0 0 0 1 ( 1.2%)
HIP FRACTURE	None Unlikely Possible Probable Missing Total	1 ( 1.2%) 0 0 0 0 1 ( 1.2%)	0 0 0 0 0 0	2 ( 2.4%) 0 0 0 0 2 ( 2.4%)
JOINT DISLOCATION	None Unlikely Possible Probable Missing Total	0 0 0 0 0 0	1 ( 1.2%) 0 0 0 0 1 ( 1.2%)	0 0 0 0 0 0
SKIN LACERATION	None Unlikely Possible Probable Missing Total	1 ( 1.2%) 0 0 0 0 1 ( 1.2%)	1 ( 1.2%) 0 1 ( 1.2%) 0 0 2 ( 2.4%)	0 0 0 0 0 0
WOUND	None Unlikely	0 0	0 0	0 0

Copyright @ DH

**Treatment-Emergent Adverse Events by Relationship to Study Drug  
Safety Analysis Set**

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

Copyright @ DH

**Treatment-Emergent Adverse Events by Relationship to Study Drug  
Safety Analysis Set**

System Organ Class Preferred Term	Maximum Relationship p	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Missing	0	0	0
	Total	0	0	1 ( 1.2%)
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
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%)
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
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
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

Copyright @ DH

**Treatment-Emergent Adverse Events by Relationship to Study Drug  
Safety Analysis Set**

System Organ Class Preferred Term	Maximum Relationship P	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
ELECTROCARDIOGRAM ST SEGMENT DEPRESSION	None Unlikely Possible Probable Missing Total	0 3 ( 3.5%) 1 ( 1.2%) 0 0 4 ( 4.7%)	0 0 1 ( 1.2%) 0 0 1 ( 1.2%)	0 0 0 0 0 0
ELECTROCARDIOGRAM T WAVE AMPLITUDE DECREASED	None Unlikely Possible Probable Missing Total	0 1 ( 1.2%) 0 0 0 1 ( 1.2%)	0 1 ( 1.2%) 0 0 0 1 ( 1.2%)	0 0 0 0 0 0
ELECTROCARDIOGRAM T WAVE INVERSION	None Unlikely Possible Probable Missing Total	0 2 ( 2.3%) 0 0 0 2 ( 2.3%)	1 ( 1.2%) 0 0 0 0 1 ( 1.2%)	0 0 1 ( 1.2%) 0 0 1 ( 1.2%)
HEART RATE INCREASED	None Unlikely Possible Probable Missing Total	0 0 1 ( 1.2%) 0 0 1 ( 1.2%)	0 0 0 0 0 0	0 0 0 0 0 0
HEART RATE IRREGULAR	None Unlikely Possible Probable Missing Total	0 0 1 ( 1.2%) 0 0 1 ( 1.2%)	0 0 0 0 0 0	0 0 0 0 0 0
NASAL MUCOSA BIOPSY	None	0	1 ( 1.2%)	0

Copyright @ DH

**Treatment-Emergent Adverse Events by Relationship to Study Drug  
Safety Analysis Set**

System Organ Class Preferred Term	Maximum Relationship P	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
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%)
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
	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

Copyright @ DH

**Treatment-Emergent Adverse Events by Relationship to Study Drug  
Safety Analysis Set**

System Organ Class Preferred Term	Maximum Relationship P	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%)	0	0
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%)
	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%)
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

Copyright @ DH

**Treatment-Emergent Adverse Events by Relationship to Study Drug  
Safety Analysis Set**

System Organ Class Preferred Term	Maximum Relationship P	Placebo	Low Dose	High Dose
		(N=86) n (%)	(N=84) n (%)	(N=84) n (%)
	Total	1 ( 1.2%)	2 ( 2.4%)	1 ( 1.2%)
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%)
BACK PAIN	None	1 ( 1.2%)	1 ( 1.2%)	2 ( 2.4%)
	Unlikely	0	0	1 ( 1.2%)
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 ( 1.2%)	1 ( 1.2%)	3 ( 3.6%)
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%)
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%)
MUSCULAR WEAKNESS	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

Copyright @ DH

**Treatment-Emergent Adverse Events by Relationship to Study Drug  
Safety Analysis Set**

<b>System Organ Class Preferred Term</b>	<b>Maximum Relationship P</b>	<b>Placebo (N=86) n (%)</b>	<b>Low Dose (N=84) n (%)</b>	<b>High Dose (N=84) n (%)</b>
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
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND None POLYPS)		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%)
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
MALIGNANT FIBROUS HISTIOCYTOMA		None	0	1 ( 1.2%)
				0

Copyright @ DH

**Treatment-Emergent Adverse Events by Relationship to Study Drug  
Safety Analysis Set**

System Organ Class Preferred Term	Maximum Relationship P	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
PROSTATE CANCER	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%)
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%)
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%)
BALANCE DISORDER	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
BURNING SENSATION	None	0	0	0
	Unlikely	0	0	0
	Possible	0	0	1 ( 1.2%)

Copyright @ DH

**Treatment-Emergent Adverse Events by Relationship to Study Drug  
Safety Analysis Set**

System Organ Class Preferred Term	Maximum Relationship P	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	0	0	2 ( 2.4%)
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%)
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
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

Copyright @ DH

**Treatment-Emergent Adverse Events by Relationship to Study Drug  
Safety Analysis Set**

System Organ Class Preferred Term	Maximum Relationship P	Placebo	Low Dose	High Dose
		(N=86) n (%)	(N=84) n (%)	(N=84) n (%)
	Total	3 ( 3.5%)	3 ( 3.6%)	5 ( 6.0%)
HEMIANOPIA HOMONYMOUS	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
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%)
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%)
PARAESTHESIA	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%)
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

Copyright @ DH

**Treatment-Emergent Adverse Events by Relationship to Study Drug  
Safety Analysis Set**

<b>System Organ Class Preferred Term</b>	<b>Maximum Relationship P</b>	<b>Placebo (N=86) n (%)</b>	<b>Low Dose (N=84) n (%)</b>	<b>High Dose (N=84) n (%)</b>
PARKINSON'S DISEASE	None Unlikely Possible Probable Missing Total	1 ( 1.2%) 0 0 0 0 1 ( 1.2%)	0 0 0 0 0 0	0 0 0 0 0 0
PAROSMIA	None Unlikely Possible Probable Missing Total	0 0 0 0 0 0	0 0 0 0 0 0	0 0 1 ( 1.2%) 0 0 1 ( 1.2%)
PARTIAL SEIZURES WITH SECONDARY GENERALISATION	None Unlikely Possible Probable Missing Total	0 0 0 0 0 0	0 0 0 0 0 0	1 ( 1.2%) 0 0 0 0 1 ( 1.2%)
PSYCHOMOTOR HYPERACTIVITY	None Unlikely Possible Probable Missing Total	0 1 ( 1.2%) 0 0 0 1 ( 1.2%)	0 0 0 0 0 0	0 0 0 0 0 0
SOMNOLENCE	None Unlikely Possible Probable Missing Total	1 ( 1.2%) 0 1 ( 1.2%) 0 0 2 ( 2.3%)	1 ( 1.2%) 2 ( 2.4%) 0 0 0 3 ( 3.6%)	0 1 ( 1.2%) 0 0 0 1 ( 1.2%)
STUPOR	None Unlikely	0 0	0 0	0 0

Copyright @ DH

**Treatment-Emergent Adverse Events by Relationship to Study Drug  
Safety Analysis Set**

System Organ Class Preferred Term	Maximum Relationship P	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	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
	Possible	0	1 ( 1.2%)	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	2 ( 2.4%)	1 ( 1.2%)
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%)
AGITATION	None	0	0	1 ( 1.2%)
	Unlikely	2 ( 2.3%)	0	0
	Possible	0	2 ( 2.4%)	0
	Probable	0	0	0

Copyright @ DH

**Treatment-Emergent Adverse Events by Relationship to Study Drug  
Safety Analysis Set**

System Organ Class Preferred Term	Maximum Relationship p	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Missing	0	0	0
	Total	2 ( 2.3%)	2 ( 2.4%)	1 ( 1.2%)
ANXIETY	None	0	0	0
	Unlikely	0	0	0
	Possible	0	3 ( 3.6%)	0
	Probable	0	0	0
	Missing	0	0	0
	Total	0	3 ( 3.6%)	0
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
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%)
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%)
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%)

Copyright @ DH

**Treatment-Emergent Adverse Events by Relationship to Study Drug  
Safety Analysis Set**

System Organ Class Preferred Term	Maximum Relationship P	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
DEPRESSED MOOD				
None	0	0	0	0
Unlikely	0	0	0	0
Possible	0	1 ( 1.2%)	0	0
Probable	0	0	0	0
Missing	0	0	0	0
Total	0	1 ( 1.2%)	0	0
DISORIENTATION				
None	0	0	0	0
Unlikely	1 ( 1.2%)	0	0	0
Possible	0	0	0	0
Probable	0	0	0	0
Missing	0	0	0	0
Total	1 ( 1.2%)	0	0	0
HALLUCINATION				
None	0	0	1 ( 1.2%)	0
Unlikely	0	0	0	0
Possible	0	0	0	0
Probable	0	0	0	0
Missing	0	0	0	0
Total	0	0	1 ( 1.2%)	0
HALLUCINATION, VISUAL				
None	0	0	0	0
Unlikely	0	0	0	0
Possible	0	0	1 ( 1.2%)	0
Probable	0	0	0	0
Missing	0	0	0	0
Total	0	0	1 ( 1.2%)	0
INSOMNIA				
None	1 ( 1.2%)	0	0	0
Unlikely	1 ( 1.2%)	0	0	0
Possible	0	0	2 ( 2.4%)	0
Probable	0	0	0	0
Missing	0	0	0	0
Total	2 ( 2.3%)	0	2 ( 2.4%)	0
IRRITABILITY				
None	0	0	0	0

Copyright @ DH

**Treatment-Emergent Adverse Events by Relationship to Study Drug  
Safety Analysis Set**

System Organ Class Preferred Term	Maximum Relationship P	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	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
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%)
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%)
NIGHTMARE	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%)
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%)

Copyright @ DH

**Treatment-Emergent Adverse Events by Relationship to Study Drug  
Safety Analysis Set**

System Organ Class Preferred Term	Maximum Relationship P	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	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%)
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
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0

Copyright @ DH

**Treatment-Emergent Adverse Events by Relationship to Study Drug  
Safety Analysis Set**

<b>System Organ Class Preferred Term</b>	<b>Maximum Relationship P</b>	<b>Placebo (N=86) n (%)</b>	<b>Low Dose (N=84) n (%)</b>	<b>High Dose (N=84) n (%)</b>
		Total	1 ( 1.2%)	0
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
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%)
BENIGN PROSTATIC HYPERPLASIA	None	1 ( 1.2%)	0	1 ( 1.2%)
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 ( 1.2%)	0	1 ( 1.2%)
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
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%)

Copyright @ DH

**Treatment-Emergent Adverse Events by Relationship to Study Drug  
Safety Analysis Set**

<b>System Organ Class Preferred Term</b>	<b>Maximum Relationship P</b>	<b>Placebo (N=86) n (%)</b>	<b>Low Dose (N=84) n (%)</b>	<b>High Dose (N=84) n (%)</b>
ALLERGIC GRANULOMATOUS ANGIITIS	None Unlikely Possible Probable Missing Total	0 0 0 0 0 0	0 0 0 0 0 0	1 ( 1.2%)
COUGH	None Unlikely Possible Probable Missing Total	0 1 ( 1.2%) 0 0 0 1 ( 1.2%)	4 ( 4.8%) 1 ( 1.2%) 0 0 0 5 ( 6.0%)	5 ( 6.0%) 0 0 0 5 ( 6.0%)
DYSPHONIA	None Unlikely Possible Probable Missing Total	0 0 0 0 0 0	0 1 ( 1.2%) 0 0 0 1 ( 1.2%)	0 0 0 0 0 0
DYSPNOEA	None Unlikely Possible Probable Missing Total	0 0 1 ( 1.2%) 0 0 1 ( 1.2%)	1 ( 1.2%) 0 0 0 0 1 ( 1.2%)	1 ( 1.2%) 0 0 0 1 ( 1.2%)
EMPHYSEMA	None Unlikely Possible Probable Missing Total	0 0 0 1 ( 1.2%) 0 1 ( 1.2%)	0 0 0 0 0 0	0 0 0 0 0 0
EPISTAXIS	None Unlikely	0 0	0 1 ( 1.2%)	1 ( 1.2%) 1 ( 1.2%)

Copyright @ DH

**Treatment-Emergent Adverse Events by Relationship to Study Drug  
Safety Analysis Set**

System Organ Class Preferred Term	Maximum Relationship P	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	1 ( 1.2%)	2 ( 2.4%)
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
NASAL CONGESTION	None	1 ( 1.2%)	1 ( 1.2%)	2 ( 2.4%)
	Unlikely	2 ( 2.3%)	0	1 ( 1.2%)
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	3 ( 3.5%)	1 ( 1.2%)	3 ( 3.6%)
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%)
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%)
POSTNASAL DRIP	None	1 ( 1.2%)	0	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	0	0

Copyright @ DH

**Treatment-Emergent Adverse Events by Relationship to Study Drug  
Safety Analysis Set**

System Organ Class Preferred Term	Maximum Relationship p	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
	Missing	0	0	0
	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%)
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%)

Copyright @ DH

**Treatment-Emergent Adverse Events by Relationship to Study Drug  
Safety Analysis Set**

System Organ Class Preferred Term	Maximum Relationship P	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
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
Possible		0	0	0
Probable		0	0	0
Missing		0	0	0
Total		1 ( 1.2%)	0	0
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%)
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
DERMATITIS CONTACT				
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
DRUG ERUPTION				
None		1 ( 1.2%)	0	0

Copyright @ DH

**Treatment-Emergent Adverse Events by Relationship to Study Drug  
Safety Analysis Set**

System Organ Class Preferred Term	Maximum Relationship p	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	1 ( 1.2%)	0	0
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%)
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%)
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%)

Copyright @ DH

**Treatment-Emergent Adverse Events by Relationship to Study Drug  
Safety Analysis Set**

<b>System Organ Class Preferred Term</b>	<b>Maximum Relationship P</b>	<b>Placebo (N=86) n (%)</b>	<b>Low Dose (N=84) n (%)</b>	<b>High Dose (N=84) n (%)</b>
	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
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	0	1 ( 1.2%)	0
	Missing	0	0	0
	Total	0	1 ( 1.2%)	0
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%)
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%)
SKIN EXFOLIATION	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
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

Copyright @ DH

**Treatment-Emergent Adverse Events by Relationship to Study Drug  
Safety Analysis Set**

System Organ Class Preferred Term	Maximum Relationship P	Placebo (N=86) n (%)	Low Dose	High Dose
			(N=84) n (%)	(N=84) n (%)
	Total	3 ( 3.5%)	6 ( 7.1%)	5 ( 6.0%)
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%)
SKIN ULCER	None	0	0	0
	Unlikely	0	0	0
	Possible	0	0	0
	Probable	1 ( 1.2%)	0	0
	Missing	0	0	0
	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%)

Copyright @ DH

**Treatment-Emergent Adverse Events by Relationship to Study Drug  
Safety Analysis Set**

<b>System Organ Class Preferred Term</b>	<b>Maximum Relationship P</b>	<b>Placebo (N=86) n (%)</b>	<b>Low Dose (N=84) n (%)</b>	<b>High Dose (N=84) n (%)</b>
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
	Possible	0	0	0
	Probable	0	0	0
	Missing	0	0	0
	Total	1 ( 1.2%)	0	0
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%)
VASCULAR DISORDERS	None	0	1 ( 1.2%)	0
	Unlikely	2 ( 2.3%)	0	0

Copyright @ DH

**Treatment-Emergent Adverse Events by Relationship to Study Drug  
Safety Analysis Set**

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

Copyright @ DH

**Treatment-Emergent Adverse Events by Relationship to Study Drug  
Safety Analysis Set**

System Organ Class Preferred Term	Maximum Relationship p	Placebo (N=86) n (%)	Low Dose (N=84) n (%)	High Dose (N=84) n (%)
Missing		0	0	0
Total		0	0	1 ( 1.2%)

Copyright @ DH