

## Summary of Treatment-Emergent Adverse Events by Primary System Organ Class and Preferred Term Safety Analysis Set

<b>System Organ Class Preferred Term</b>	<b>Placebo (N=86) n (%)</b>	<b>Low Dose (N=84) n (%)</b>	<b>High Dose (N=84) n (%)</b>	<b>Total (N=254) n (%)</b>
Overall	65 ( 75.6)	77 ( 91.7)	76 ( 90.5)	218 ( 85.8)
CARDIAC DISORDERS	12 ( 14.0)	13 ( 15.5)	15 ( 17.9)	40 ( 15.7)
ATRIAL FIBRILLATION	1 ( 1.2)	1 ( 1.2)	3 ( 3.6)	5 ( 2.0)
ATRIAL FLUTTER	0	1 ( 1.2)	1 ( 1.2)	2 ( 0.8)
ATRIAL HYPERTROPHY	1 ( 1.2)	0	0	1 ( 0.4)
ATRIOVENTRICULAR BLOCK FIRST DEGREE	1 ( 1.2)	1 ( 1.2)	0	2 ( 0.8)
ATRIOVENTRICULAR BLOCK SECOND DEGREE	1 ( 1.2)	0	0	1 ( 0.4)
BRADYCARDIA	1 ( 1.2)	0	0	1 ( 0.4)
BUNDLE BRANCH BLOCK LEFT	1 ( 1.2)	0	0	1 ( 0.4)
BUNDLE BRANCH BLOCK RIGHT	1 ( 1.2)	1 ( 1.2)	0	2 ( 0.8)
CARDIAC DISORDER	0	0	1 ( 1.2)	1 ( 0.4)
CARDIAC FAILURE CONGESTIVE	1 ( 1.2)	0	0	1 ( 0.4)
MYOCARDIAL INFARCTION	4 ( 4.7)	2 ( 2.4)	4 ( 4.8)	10 ( 3.9)
PALPITATIONS	0	2 ( 2.4)	0	2 ( 0.8)
SINUS ARRHYTHMIA	1 ( 1.2)	0	0	1 ( 0.4)
SINUS BRADYCARDIA	2 ( 2.3)	7 ( 8.3)	8 ( 9.5)	17 ( 6.7)
SUPRAVENTRICULAR EXTRASYSTOLES	1 ( 1.2)	1 ( 1.2)	1 ( 1.2)	3 ( 1.2)
SUPRAVENTRICULAR TACHYCARDIA	0	1 ( 1.2)	0	1 ( 0.4)
TACHYCARDIA	1 ( 1.2)	0	0	1 ( 0.4)
VENTRICULAR EXTRASYSTOLES	0	2 ( 2.4)	1 ( 1.2)	3 ( 1.2)
VENTRICULAR HYPERTROPHY	1 ( 1.2)	0	0	1 ( 0.4)
WOLFF-PARKINSON-WHITE SYNDROME	0	1 ( 1.2)	0	1 ( 0.4)

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CONGENITAL, FAMILIAL AND GENETIC DISORDERS	0	1 ( 1.2)	2 ( 2.4)	3 ( 1.2)
VENTRICULAR SEPTAL DEFECT	0	1 ( 1.2)	2 ( 2.4)	3 ( 1.2)
EAR AND LABYRINTH DISORDERS	1 ( 1.2)	2 ( 2.4)	1 ( 1.2)	4 ( 1.6)
CERUMEN IMPACTION	0	1 ( 1.2)	0	1 ( 0.4)
EAR PAIN	1 ( 1.2)	0	0	1 ( 0.4)
VERTIGO	0	1 ( 1.2)	1 ( 1.2)	2 ( 0.8)
EYE DISORDERS	2 ( 2.3)	2 ( 2.4)	1 ( 1.2)	5 ( 2.0)
CONJUNCTIVAL HAEMORRHAGE	0	1 ( 1.2)	0	1 ( 0.4)
CONJUNCTIVITIS	1 ( 1.2)	0	0	1 ( 0.4)
EYE ALLERGY	1 ( 1.2)	0	0	1 ( 0.4)
EYE PRURITUS	1 ( 1.2)	0	0	1 ( 0.4)
EYE SWELLING	1 ( 1.2)	0	0	1 ( 0.4)
VISION BLURRED	0	1 ( 1.2)	1 ( 1.2)	2 ( 0.8)
GASTROINTESTINAL DISORDERS	17 ( 19.8)	14 ( 16.7)	20 ( 23.8)	51 ( 20.1)
ABDOMINAL DISCOMFORT	0	0	1 ( 1.2)	1 ( 0.4)
ABDOMINAL PAIN	1 ( 1.2)	3 ( 3.6)	1 ( 1.2)	5 ( 2.0)
CONSTIPATION	1 ( 1.2)	0	0	1 ( 0.4)
DIARRHOEA	9 ( 10.5)	4 ( 4.8)	4 ( 4.8)	17 ( 6.7)
DYSPEPSIA	1 ( 1.2)	1 ( 1.2)	0	2 ( 0.8)
DYSPHAGIA	0	1 ( 1.2)	0	1 ( 0.4)

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FLATULENCE	1 ( 1.2)	0	0	1 ( 0.4)
GASTROINTESTINAL HAEMORRHAGE	0	0	1 ( 1.2)	1 ( 0.4)
GASTROOESOPHAGEAL REFLUX DISEASE	1 ( 1.2)	0	0	1 ( 0.4)
GLOSSITIS	1 ( 1.2)	0	0	1 ( 0.4)
HIATUS HERNIA	1 ( 1.2)	0	0	1 ( 0.4)
NAUSEA	3 ( 3.5)	3 ( 3.6)	6 ( 7.1)	12 ( 4.7)
RECTAL HAEMORRHAGE	0	1 ( 1.2)	0	1 ( 0.4)
SALIVARY HYPERSECRETION	0	0	4 ( 4.8)	4 ( 1.6)
STOMACH DISCOMFORT	0	0	1 ( 1.2)	1 ( 0.4)
VOMITING	3 ( 3.5)	3 ( 3.6)	7 ( 8.3)	13 ( 5.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	21 ( 24.4)	47 ( 56.0)	40 ( 47.6)	108 ( 42.5)
APPLICATION SITE BLEEDING	0	1 ( 1.2)	0	1 ( 0.4)
APPLICATION SITE DERMATITIS	5 ( 5.8)	9 ( 10.7)	7 ( 8.3)	21 ( 8.3)
APPLICATION SITE DESQUAMATION	0	1 ( 1.2)	0	1 ( 0.4)
APPLICATION SITE DISCHARGE	0	0	1 ( 1.2)	1 ( 0.4)
APPLICATION SITE DISCOLOURATION	0	1 ( 1.2)	0	1 ( 0.4)
APPLICATION SITE ERYTHEMA	3 ( 3.5)	12 ( 14.3)	15 ( 17.9)	30 ( 11.8)
APPLICATION SITE INDURATION	1 ( 1.2)	0	0	1 ( 0.4)
APPLICATION SITE IRRITATION	3 ( 3.5)	9 ( 10.7)	9 ( 10.7)	21 ( 8.3)
APPLICATION SITE PAIN	0	0	2 ( 2.4)	2 ( 0.8)
APPLICATION SITE PERSPIRATION	0	0	2 ( 2.4)	2 ( 0.8)
APPLICATION SITE PRURITUS	6 ( 7.0)	22 ( 26.2)	22 ( 26.2)	50 ( 19.7)

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APPLICATION SITE REACTION	1 ( 1.2)	0	1 ( 1.2)	2 ( 0.8)
APPLICATION SITE SWELLING	0	1 ( 1.2)	2 ( 2.4)	3 ( 1.2)
APPLICATION SITE URTICARIA	0	2 ( 2.4)	1 ( 1.2)	3 ( 1.2)
APPLICATION SITE VESICLES	1 ( 1.2)	4 ( 4.8)	6 ( 7.1)	11 ( 4.3)
APPLICATION SITE WARMTH	0	1 ( 1.2)	0	1 ( 0.4)
ASTHENIA	1 ( 1.2)	0	1 ( 1.2)	2 ( 0.8)
CHEST DISCOMFORT	0	0	2 ( 2.4)	2 ( 0.8)
CHEST PAIN	0	0	2 ( 2.4)	2 ( 0.8)
CHILLS	1 ( 1.2)	1 ( 1.2)	1 ( 1.2)	3 ( 1.2)
FATIGUE	1 ( 1.2)	5 ( 6.0)	5 ( 6.0)	11 ( 4.3)
FEELING ABNORMAL	0	0	1 ( 1.2)	1 ( 0.4)
FEELING COLD	0	0	1 ( 1.2)	1 ( 0.4)
INFLAMMATION	0	1 ( 1.2)	0	1 ( 0.4)
MALAISE	0	1 ( 1.2)	2 ( 2.4)	3 ( 1.2)
OEDEMA	0	2 ( 2.4)	0	2 ( 0.8)
OEDEMA PERIPHERAL	2 ( 2.3)	1 ( 1.2)	2 ( 2.4)	5 ( 2.0)
PAIN	0	1 ( 1.2)	1 ( 1.2)	2 ( 0.8)
PYREXIA	2 ( 2.3)	0	1 ( 1.2)	3 ( 1.2)
SECRETION DISCHARGE	0	1 ( 1.2)	0	1 ( 0.4)
SUDDEN DEATH	0	1 ( 1.2)	0	1 ( 0.4)
SWELLING	0	1 ( 1.2)	0	1 ( 0.4)
ULCER	0	1 ( 1.2)	0	1 ( 0.4)
HEPATOBILIARY DISORDERS	1 ( 1.2)	0	0	1 ( 0.4)

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HYPERBILIRUBINAEMIA	1 ( 1.2)	0	0	1 ( 0.4)
IMMUNE SYSTEM DISORDERS	0	1 ( 1.2)	0	1 ( 0.4)
HYPERSENSITIVITY	0	1 ( 1.2)	0	1 ( 0.4)
INFECTIONS AND INFESTATIONS	16 ( 18.6)	9 ( 10.7)	13 ( 15.5)	38 ( 15.0)
BRONCHITIS	1 ( 1.2)	0	0	1 ( 0.4)
CELLULITIS	0	1 ( 1.2)	0	1 ( 0.4)
CERVICITIS	1 ( 1.2)	0	0	1 ( 0.4)
CYSTITIS	1 ( 1.2)	0	1 ( 1.2)	2 ( 0.8)
EAR INFECTION	2 ( 2.3)	0	0	2 ( 0.8)
GASTROENTERITIS VIRAL	1 ( 1.2)	0	0	1 ( 0.4)
HORDEOLUM	0	0	1 ( 1.2)	1 ( 0.4)
INFLUENZA	1 ( 1.2)	1 ( 1.2)	1 ( 1.2)	3 ( 1.2)
LOCALISED INFECTION	1 ( 1.2)	0	0	1 ( 0.4)
LOWER RESPIRATORY TRACT INFECTION	0	0	1 ( 1.2)	1 ( 0.4)
NASOPHARYNGITIS	2 ( 2.3)	4 ( 4.8)	6 ( 7.1)	12 ( 4.7)
PNEUMONIA	0	1 ( 1.2)	0	1 ( 0.4)
RHINITIS	0	0	1 ( 1.2)	1 ( 0.4)
UPPER RESPIRATORY TRACT INFECTION	6 ( 7.0)	1 ( 1.2)	3 ( 3.6)	10 ( 3.9)
URINARY TRACT INFECTION	2 ( 2.3)	0	1 ( 1.2)	3 ( 1.2)
VAGINAL MYCOSIS	1 ( 1.2)	0	0	1 ( 0.4)
VIRAL INFECTION	0	1 ( 1.2)	0	1 ( 0.4)

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INJURY, POISONING AND PROCEDURAL COMPLICATIONS	4 ( 4.7)	5 ( 6.0)	5 ( 6.0)	14 ( 5.5)
CONTUSION	1 ( 1.2)	1 ( 1.2)	2 ( 2.4)	4 ( 1.6)
EXCORIATION	2 ( 2.3)	1 ( 1.2)	1 ( 1.2)	4 ( 1.6)
FACIAL BONES FRACTURE	0	0	1 ( 1.2)	1 ( 0.4)
FALL	1 ( 1.2)	2 ( 2.4)	1 ( 1.2)	4 ( 1.6)
HIP FRACTURE	1 ( 1.2)	0	2 ( 2.4)	3 ( 1.2)
JOINT DISLOCATION	0	1 ( 1.2)	0	1 ( 0.4)
SKIN LACERATION	1 ( 1.2)	2 ( 2.4)	0	3 ( 1.2)
WOUND	0	1 ( 1.2)	0	1 ( 0.4)
INVESTIGATIONS	10 ( 11.6)	6 ( 7.1)	6 ( 7.1)	22 ( 8.7)
BIOPSY	0	0	1 ( 1.2)	1 ( 0.4)
BIOPSY PROSTATE	0	0	1 ( 1.2)	1 ( 0.4)
BLOOD ALKALINE PHOSPHATASE INCREASED	1 ( 1.2)	0	0	1 ( 0.4)
BLOOD CHOLESTEROL INCREASED	0	0	1 ( 1.2)	1 ( 0.4)
BLOOD CREATINE PHOSPHOKINASE INCREASED	1 ( 1.2)	0	0	1 ( 0.4)
BLOOD GLUCOSE INCREASED	0	1 ( 1.2)	1 ( 1.2)	2 ( 0.8)
BLOOD URINE PRESENT	1 ( 1.2)	0	0	1 ( 0.4)
BODY TEMPERATURE INCREASED	0	1 ( 1.2)	0	1 ( 0.4)
CYSTOSCOPY	1 ( 1.2)	0	0	1 ( 0.4)
ELECTROCARDIOGRAM ST SEGMENT DEPRESSION	4 ( 4.7)	1 ( 1.2)	0	5 ( 2.0)

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ELECTROCARDIOGRAM T WAVE AMPLITUDE DECREASED	1 ( 1.2)	1 ( 1.2)	0	2 ( 0.8)
ELECTROCARDIOGRAM T WAVE INVERSION	2 ( 2.3)	1 ( 1.2)	1 ( 1.2)	4 ( 1.6)
HEART RATE INCREASED	1 ( 1.2)	0	0	1 ( 0.4)
HEART RATE IRREGULAR	1 ( 1.2)	0	0	1 ( 0.4)
NASAL MUCOSA BIOPSY	0	1 ( 1.2)	0	1 ( 0.4)
WEIGHT DECREASED	0	0	1 ( 1.2)	1 ( 0.4)
 METABOLISM AND NUTRITION DISORDERS	 6 ( 7.0)	 1 ( 1.2)	 2 ( 2.4)	 9 ( 3.5)
DECREASED APPETITE	1 ( 1.2)	0	1 ( 1.2)	2 ( 0.8)
DEHYDRATION	1 ( 1.2)	0	0	1 ( 0.4)
DIABETES MELLITUS	1 ( 1.2)	0	0	1 ( 0.4)
FOOD CRAVING	1 ( 1.2)	1 ( 1.2)	0	2 ( 0.8)
HYPONATRAEMIA	1 ( 1.2)	0	0	1 ( 0.4)
INCREASED APPETITE	1 ( 1.2)	0	1 ( 1.2)	2 ( 0.8)
 MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	 4 ( 4.7)	 7 ( 8.3)	 7 ( 8.3)	 18 ( 7.1)
ARTHRALGIA	1 ( 1.2)	2 ( 2.4)	1 ( 1.2)	4 ( 1.6)
ARTHRITIS	0	0	1 ( 1.2)	1 ( 0.4)
BACK PAIN	1 ( 1.2)	1 ( 1.2)	3 ( 3.6)	5 ( 2.0)
FLANK PAIN	0	0	1 ( 1.2)	1 ( 0.4)
MUSCLE SPASMS	0	1 ( 1.2)	1 ( 1.2)	2 ( 0.8)
MUSCULAR WEAKNESS	0	1 ( 1.2)	0	1 ( 0.4)
MYALGIA	0	0	1 ( 1.2)	1 ( 0.4)

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PAIN IN EXTREMITY	1 ( 1.2)	0	0	1 ( 0.4)
SHOULDER PAIN	1 ( 1.2)	2 ( 2.4)	0	3 ( 1.2)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	2 ( 2.4)	1 ( 1.2)	3 ( 1.2)
COLON CANCER	0	1 ( 1.2)	0	1 ( 0.4)
MALIGNANT FIBROUS HISTIOCYTOMA	0	1 ( 1.2)	0	1 ( 0.4)
PROSTATE CANCER	0	0	1 ( 1.2)	1 ( 0.4)
NERVOUS SYSTEM DISORDERS	8 ( 9.3)	20 ( 23.8)	25 ( 29.8)	53 ( 20.9)
AMNESIA	0	0	1 ( 1.2)	1 ( 0.4)
BALANCE DISORDER	0	1 ( 1.2)	0	1 ( 0.4)
BURNING SENSATION	0	0	2 ( 2.4)	2 ( 0.8)
COGNITIVE DISORDER	0	0	1 ( 1.2)	1 ( 0.4)
COMPLEX PARTIAL SEIZURES	0	1 ( 1.2)	0	1 ( 0.4)
COORDINATION ABNORMAL	0	1 ( 1.2)	0	1 ( 0.4)
DIZZINESS	2 ( 2.3)	8 ( 9.5)	11 ( 13.1)	21 ( 8.3)
HEADACHE	3 ( 3.5)	3 ( 3.6)	5 ( 6.0)	11 ( 4.3)
HEMIANOPIA HOMONYMOUS	0	1 ( 1.2)	0	1 ( 0.4)
HYPERSOMNIA	0	0	1 ( 1.2)	1 ( 0.4)
LETHARGY	0	1 ( 1.2)	1 ( 1.2)	2 ( 0.8)
PARAESTHESIA	0	0	1 ( 1.2)	1 ( 0.4)
PARAESTHESIA ORAL	0	1 ( 1.2)	0	1 ( 0.4)
PARKINSON'S DISEASE	1 ( 1.2)	0	0	1 ( 0.4)

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PAROSMIA	0	0	1 ( 1.2)	1 ( 0.4)
PARTIAL SEIZURES WITH SECONDARY GENERALISATION	0	0	1 ( 1.2)	1 ( 0.4)
PSYCHOMOTOR HYPERACTIVITY	1 ( 1.2)	0	0	1 ( 0.4)
SOMNOLENCE	2 ( 2.3)	3 ( 3.6)	1 ( 1.2)	6 ( 2.4)
STUPOR	0	1 ( 1.2)	0	1 ( 0.4)
SYNCOPE	0	4 ( 4.8)	3 ( 3.6)	7 ( 2.8)
SYNCOPE VASOVAGAL	0	0	1 ( 1.2)	1 ( 0.4)
TRANSIENT ISCHAEMIC ATTACK	0	2 ( 2.4)	1 ( 1.2)	3 ( 1.2)
PSYCHIATRIC DISORDERS	10 ( 11.6)	10 ( 11.9)	8 ( 9.5)	28 ( 11.0)
AGITATION	2 ( 2.3)	2 ( 2.4)	1 ( 1.2)	5 ( 2.0)
ANXIETY	0	3 ( 3.6)	0	3 ( 1.2)
COMPLETED SUICIDE	1 ( 1.2)	0	0	1 ( 0.4)
CONFUSIONAL STATE	2 ( 2.3)	3 ( 3.6)	1 ( 1.2)	6 ( 2.4)
DELIRIUM	0	0	1 ( 1.2)	1 ( 0.4)
DELUSION	1 ( 1.2)	0	1 ( 1.2)	2 ( 0.8)
DEPRESSED MOOD	0	1 ( 1.2)	0	1 ( 0.4)
DISORIENTATION	1 ( 1.2)	0	0	1 ( 0.4)
HALLUCINATION	0	0	1 ( 1.2)	1 ( 0.4)
HALLUCINATION, VISUAL	0	0	1 ( 1.2)	1 ( 0.4)
INSOMNIA	2 ( 2.3)	0	2 ( 2.4)	4 ( 1.6)
IRRITABILITY	1 ( 1.2)	1 ( 1.2)	0	2 ( 0.8)
LIBIDO DECREASED	0	0	1 ( 1.2)	1 ( 0.4)

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LISTLESS	0	0	1 ( 1.2)	1 ( 0.4)
NIGHTMARE	0	0	1 ( 1.2)	1 ( 0.4)
RESTLESSNESS	0	1 ( 1.2)	0	1 ( 0.4)
RENAL AND URINARY DISORDERS	4 ( 4.7)	3 ( 3.6)	3 ( 3.6)	10 ( 3.9)
CALCULUS URETHRAL	0	0	1 ( 1.2)	1 ( 0.4)
DYSURIA	1 ( 1.2)	1 ( 1.2)	0	2 ( 0.8)
INCONTINENCE	0	1 ( 1.2)	0	1 ( 0.4)
MICTURITION URGENCY	1 ( 1.2)	1 ( 1.2)	1 ( 1.2)	3 ( 1.2)
NEPHROLITHIASIS	1 ( 1.2)	0	1 ( 1.2)	2 ( 0.8)
POLLAKIURIA	1 ( 1.2)	0	0	1 ( 0.4)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	2 ( 2.3)	0	1 ( 1.2)	3 ( 1.2)
BENIGN PROSTATIC HYPERPLASIA	1 ( 1.2)	0	1 ( 1.2)	2 ( 0.8)
PELVIC PAIN	1 ( 1.2)	0	0	1 ( 0.4)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	8 ( 9.3)	9 ( 10.7)	10 ( 11.9)	27 ( 10.6)
ALLERGIC GRANULOMATOUS ANGIITIS	0	0	1 ( 1.2)	1 ( 0.4)
COUGH	1 ( 1.2)	5 ( 6.0)	5 ( 6.0)	11 ( 4.3)
DYSPHONIA	0	1 ( 1.2)	0	1 ( 0.4)
DYSPNOEA	1 ( 1.2)	1 ( 1.2)	1 ( 1.2)	3 ( 1.2)
EMPHYSEMA	1 ( 1.2)	0	0	1 ( 0.4)
EPISTAXIS	0	1 ( 1.2)	2 ( 2.4)	3 ( 1.2)

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HAEMOPTYSIS	1 ( 1.2)	0	0	1 ( 0.4)
NASAL CONGESTION	3 ( 3.5)	1 ( 1.2)	3 ( 3.6)	7 ( 2.8)
PHARYNGEAL ERYTHEMA	0	0	1 ( 1.2)	1 ( 0.4)
PHARYNGOLARYNGEAL PAIN	0	1 ( 1.2)	1 ( 1.2)	2 ( 0.8)
POSTNASAL DRIP	1 ( 1.2)	0	0	1 ( 0.4)
PRODUCTIVE COUGH	0	0	1 ( 1.2)	1 ( 0.4)
RALES	1 ( 1.2)	0	0	1 ( 0.4)
RESPIRATORY TRACT CONGESTION	0	0	1 ( 1.2)	1 ( 0.4)
RHINORRHoeA	0	1 ( 1.2)	1 ( 1.2)	2 ( 0.8)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	20 ( 23.3)	39 ( 46.4)	40 ( 47.6)	99 ( 39.0)
ACTINIC KERATOSIS	0	0	1 ( 1.2)	1 ( 0.4)
ALOPECIA	1 ( 1.2)	0	0	1 ( 0.4)
BLISTER	0	5 ( 6.0)	1 ( 1.2)	6 ( 2.4)
COLD SWEAT	1 ( 1.2)	0	0	1 ( 0.4)
DERMATITIS CONTACT	0	1 ( 1.2)	0	1 ( 0.4)
DRUG ERUPTION	1 ( 1.2)	0	0	1 ( 0.4)
ERYTHEMA	8 ( 9.3)	14 ( 16.7)	14 ( 16.7)	36 ( 14.2)
HYPERHIDROSIS	2 ( 2.3)	4 ( 4.8)	8 ( 9.5)	14 ( 5.5)
PRURITUS	8 ( 9.3)	21 ( 25.0)	26 ( 31.0)	55 ( 21.7)
PRURITUS GENERALISED	0	1 ( 1.2)	1 ( 1.2)	2 ( 0.8)
RASH	5 ( 5.8)	13 ( 15.5)	9 ( 10.7)	27 ( 10.6)
RASH ERYTHEMATOUS	0	1 ( 1.2)	0	1 ( 0.4)
RASH MACULO-PAPULAR	0	0	1 ( 1.2)	1 ( 0.4)

## Summary of Treatment-Emergent Adverse Events by Primary System Organ Class and Preferred Term Safety Analysis Set

<b>System Organ Class Preferred Term</b>	<b>Placebo (N=86) n (%)</b>	<b>Low Dose (N=84) n (%)</b>	<b>High Dose (N=84) n (%)</b>	<b>Total (N=254) n (%)</b>
RASH PRURITIC	0	1 ( 1.2)	2 ( 2.4)	3 ( 1.2)
SKIN EXFOLIATION	0	1 ( 1.2)	0	1 ( 0.4)
SKIN IRRITATION	3 ( 3.5)	6 ( 7.1)	5 ( 6.0)	14 ( 5.5)
SKIN ODOUR ABNORMAL	0	0	1 ( 1.2)	1 ( 0.4)
SKIN ULCER	1 ( 1.2)	0	0	1 ( 0.4)
URTICARIA	0	1 ( 1.2)	1 ( 1.2)	2 ( 0.8)
SOCIAL CIRCUMSTANCES	0	0	1 ( 1.2)	1 ( 0.4)
ALCOHOL USE	0	0	1 ( 1.2)	1 ( 0.4)
SURGICAL AND MEDICAL PROCEDURES	2 ( 2.3)	1 ( 1.2)	2 ( 2.4)	5 ( 2.0)
ACROCHORDON EXCISION	0	0	1 ( 1.2)	1 ( 0.4)
CATARACT OPERATION	1 ( 1.2)	1 ( 1.2)	0	2 ( 0.8)
EYE LASER SURGERY	1 ( 1.2)	0	0	1 ( 0.4)
SKIN LESION EXCISION	0	0	1 ( 1.2)	1 ( 0.4)
VASCULAR DISORDERS	3 ( 3.5)	3 ( 3.6)	1 ( 1.2)	7 ( 2.8)
HOT FLUSH	0	1 ( 1.2)	0	1 ( 0.4)
HYPERTENSION	1 ( 1.2)	1 ( 1.2)	0	2 ( 0.8)
HYPOTENSION	2 ( 2.3)	1 ( 1.2)	0	3 ( 1.2)
ORTHOSTATIC HYPOTENSION	1 ( 1.2)	0	0	1 ( 0.4)
WOUND HAEMORRHAGE	0	0	1 ( 1.2)	1 ( 0.4)