

***Treatment-Emergent Adverse Events by descending frequency -SOC continued***  
***Safety Analysis Set***  
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<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>
Overall	65 ( 75.6%)	77 ( 91.7%)	76 ( 90.5%)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	21 ( 24.4%)	47 ( 56.0%)	40 ( 47.6%)
APPLICATION SITE PRURITUS	6 ( 7.0%)	22 ( 26.2%)	22 ( 26.2%)
APPLICATION SITE ERYTHEMA	3 ( 3.5%)	12 ( 14.3%)	15 ( 17.9%)
APPLICATION SITE IRRITATION	3 ( 3.5%)	9 ( 10.7%)	9 ( 10.7%)
APPLICATION SITE DERMATITIS	5 ( 5.8%)	9 ( 10.7%)	7 ( 8.3%)
APPLICATION SITE VESICLES	1 ( 1.2%)	4 ( 4.8%)	6 ( 7.1%)
FATIGUE	1 ( 1.2%)	5 ( 6.0%)	5 ( 6.0%)
APPLICATION SITE PAIN	0	0	2 ( 2.4%)
APPLICATION SITE PERSPIRATION	0	0	2 ( 2.4%)
APPLICATION SITE SWELLING	0	1 ( 1.2%)	2 ( 2.4%)
CHEST DISCOMFORT	0	0	2 ( 2.4%)
CHEST PAIN	0	0	2 ( 2.4%)
MALAISE	0	1 ( 1.2%)	2 ( 2.4%)
OEDEMA PERIPHERAL	2 ( 2.3%)	1 ( 1.2%)	2 ( 2.4%)
APPLICATION SITE DISCHARGE	0	0	1 ( 1.2%)
APPLICATION SITE REACTION	1 ( 1.2%)	0	1 ( 1.2%)
APPLICATION SITE URTICARIA	0	2 ( 2.4%)	1 ( 1.2%)
ASTHENIA	1 ( 1.2%)	0	1 ( 1.2%)
CHILLS	1 ( 1.2%)	1 ( 1.2%)	1 ( 1.2%)
FEELING ABNORMAL	0	0	1 ( 1.2%)
FEELING COLD	0	0	1 ( 1.2%)

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PAIN	0	1 ( 1.2%)	1 ( 1.2%)
PYREXIA	2 ( 2.3%)	0	1 ( 1.2%)
APPLICATION SITE BLEEDING	0	1 ( 1.2%)	0

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GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS			
APPLICATION SITE DESQUAMATION	0	1 ( 1.2%)	0
APPLICATION SITE DISCOLOURATION	0	1 ( 1.2%)	0
APPLICATION SITE INDURATION	1 ( 1.2%)	0	0
APPLICATION SITE WARMTH	0	1 ( 1.2%)	0
INFLAMMATION	0	1 ( 1.2%)	0
OEDEMA	0	2 ( 2.4%)	0
SECRETION DISCHARGE	0	1 ( 1.2%)	0
SUDDEN DEATH	0	1 ( 1.2%)	0
SWELLING	0	1 ( 1.2%)	0
ULCER	0	1 ( 1.2%)	0
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	20 ( 23.3%)	39 ( 46.4%)	40 ( 47.6%)
PRURITUS	8 ( 9.3%)	21 ( 25.0%)	26 ( 31.0%)
ERYTHEMA	8 ( 9.3%)	14 ( 16.7%)	14 ( 16.7%)
RASH	5 ( 5.8%)	13 ( 15.5%)	9 ( 10.7%)
HYPERHIDROSIS	2 ( 2.3%)	4 ( 4.8%)	8 ( 9.5%)
SKIN IRRITATION	3 ( 3.5%)	6 ( 7.1%)	5 ( 6.0%)
RASH PRURITIC	0	1 ( 1.2%)	2 ( 2.4%)
ACTINIC KERATOSIS	0	0	1 ( 1.2%)
BLISTER	0	5 ( 6.0%)	1 ( 1.2%)
PRURITUS GENERALISED	0	1 ( 1.2%)	1 ( 1.2%)
RASH MACULO-PAPULAR	0	0	1 ( 1.2%)

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SKIN ODOUR ABNORMAL	0	0	1 ( 1.2%)
URTICARIA	0	1 ( 1.2%)	1 ( 1.2%)
ALOPECIA	1 ( 1.2%)	0	0
COLD SWEAT	1 ( 1.2%)	0	0

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SKIN AND SUBCUTANEOUS TISSUE DISORDERS			
DERMATITIS CONTACT	0	1 ( 1.2%)	0
DRUG ERUPTION	1 ( 1.2%)	0	0
RASH ERYTHEMATOUS	0	1 ( 1.2%)	0
SKIN EXFOLIATION	0	1 ( 1.2%)	0
SKIN ULCER	1 ( 1.2%)	0	0
NERVOUS SYSTEM DISORDERS	8 ( 9.3%)	20 ( 23.8%)	25 ( 29.8%)
DIZZINESS	2 ( 2.3%)	8 ( 9.5%)	11 ( 13.1%)
HEADACHE	3 ( 3.5%)	3 ( 3.6%)	5 ( 6.0%)
SYNCOPE	0	4 ( 4.8%)	3 ( 3.6%)
BURNING SENSATION	0	0	2 ( 2.4%)
AMNESIA	0	0	1 ( 1.2%)
COGNITIVE DISORDER	0	0	1 ( 1.2%)
HYPERSOMNIA	0	0	1 ( 1.2%)
LETHARGY	0	1 ( 1.2%)	1 ( 1.2%)
PARAESTHESIA	0	0	1 ( 1.2%)
PAROSMIA	0	0	1 ( 1.2%)
PARTIAL SEIZURES WITH SECONDARY GENERALISATION	0	0	1 ( 1.2%)
SOMNOLENCE	2 ( 2.3%)	3 ( 3.6%)	1 ( 1.2%)
SYNCOPE VASOVAGAL	0	0	1 ( 1.2%)
TRANSIENT ISCHAEMIC ATTACK	0	2 ( 2.4%)	1 ( 1.2%)
BALANCE DISORDER	0	1 ( 1.2%)	0

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COMPLEX PARTIAL SEIZURES	0	1 ( 1.2%)	0
COORDINATION ABNORMAL	0	1 ( 1.2%)	0
HEMIANOPIA HOMONYMOUS	0	1 ( 1.2%)	0
PARAESTHESIA ORAL	0	1 ( 1.2%)	0

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NERVOUS SYSTEM DISORDERS			
PARKINSON'S DISEASE	1 ( 1.2%)	0	0
PSYCHOMOTOR HYPERACTIVITY	1 ( 1.2%)	0	0
STUPOR	0	1 ( 1.2%)	0
GASTROINTESTINAL DISORDERS	17 ( 19.8%)	14 ( 16.7%)	20 ( 23.8%)
VOMITING	3 ( 3.5%)	3 ( 3.6%)	7 ( 8.3%)
NAUSEA	3 ( 3.5%)	3 ( 3.6%)	6 ( 7.1%)
DIARRHOEA	9 ( 10.5%)	4 ( 4.8%)	4 ( 4.8%)
SALIVARY HYPERSECRETION	0	0	4 ( 4.8%)
ABDOMINAL DISCOMFORT	0	0	1 ( 1.2%)
ABDOMINAL PAIN	1 ( 1.2%)	3 ( 3.6%)	1 ( 1.2%)
GASTROINTESTINAL HAEMORRHAGE	0	0	1 ( 1.2%)
STOMACH DISCOMFORT	0	0	1 ( 1.2%)
CONSTIPATION	1 ( 1.2%)	0	0
DYSPEPSIA	1 ( 1.2%)	1 ( 1.2%)	0
DYSPHAGIA	0	1 ( 1.2%)	0
FLATULENCE	1 ( 1.2%)	0	0
GASTROOESOPHAGEAL REFLUX DISEASE	1 ( 1.2%)	0	0
GLOSSITIS	1 ( 1.2%)	0	0
HIATUS HERNIA	1 ( 1.2%)	0	0
RECTAL HAEMORRHAGE	0	1 ( 1.2%)	0

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CARDIAC DISORDERS	12 ( 14.0%)	13 ( 15.5%)	15 ( 17.9%)
SINUS BRADYCARDIA	2 ( 2.3%)	7 ( 8.3%)	8 ( 9.5%)
MYOCARDIAL INFARCTION	4 ( 4.7%)	2 ( 2.4%)	4 ( 4.8%)
ATRIAL FIBRILLATION	1 ( 1.2%)	1 ( 1.2%)	3 ( 3.6%)
ATRIAL FLUTTER	0	1 ( 1.2%)	1 ( 1.2%)

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CARDIAC DISORDERS			
CARDIAC DISORDER	0	0	1 ( 1.2%)
SUPRAVENTRICULAR EXTRASYSTOLES	1 ( 1.2%)	1 ( 1.2%)	1 ( 1.2%)
VENTRICULAR EXTRASYSTOLES	0	2 ( 2.4%)	1 ( 1.2%)
ATRIAL HYPERTROPHY	1 ( 1.2%)	0	0
ATRIOVENTRICULAR BLOCK FIRST DEGREE	1 ( 1.2%)	1 ( 1.2%)	0
ATRIOVENTRICULAR BLOCK SECOND DEGREE	1 ( 1.2%)	0	0
BRADYCARDIA	1 ( 1.2%)	0	0
BUNDLE BRANCH BLOCK LEFT	1 ( 1.2%)	0	0
BUNDLE BRANCH BLOCK RIGHT	1 ( 1.2%)	1 ( 1.2%)	0
CARDIAC FAILURE CONGESTIVE	1 ( 1.2%)	0	0
PALPITATIONS	0	2 ( 2.4%)	0
SINUS ARRHYTHMIA	1 ( 1.2%)	0	0
SUPRAVENTRICULAR TACHYCARDIA	0	1 ( 1.2%)	0
TACHYCARDIA	1 ( 1.2%)	0	0
VENTRICULAR HYPERTROPHY	1 ( 1.2%)	0	0
WOLFF-PARKINSON-WHITE SYNDROME	0	1 ( 1.2%)	0
INFECTIONS AND INFESTATIONS	16 ( 18.6%)	9 ( 10.7%)	13 ( 15.5%)
NASOPHARYNGITIS	2 ( 2.3%)	4 ( 4.8%)	6 ( 7.1%)
UPPER RESPIRATORY TRACT INFECTION	6 ( 7.0%)	1 ( 1.2%)	3 ( 3.6%)
CYSTITIS	1 ( 1.2%)	0	1 ( 1.2%)
HORDEOLUM	0	0	1 ( 1.2%)

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INFLUENZA	1 ( 1.2%)	1 ( 1.2%)	1 ( 1.2%)
LOWER RESPIRATORY TRACT INFECTION	0	0	1 ( 1.2%)
RHINITIS	0	0	1 ( 1.2%)
URINARY TRACT INFECTION	2 ( 2.3%)	0	1 ( 1.2%)

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INFECTIONS AND INFESTATIONS			
BRONCHITIS	1 ( 1.2%)	0	0
CELLULITIS	0	1 ( 1.2%)	0
CERVICITIS	1 ( 1.2%)	0	0
EAR INFECTION	2 ( 2.3%)	0	0
GASTROENTERITIS VIRAL	1 ( 1.2%)	0	0
LOCALISED INFECTION	1 ( 1.2%)	0	0
PNEUMONIA	0	1 ( 1.2%)	0
VAGINAL MYCOSIS	1 ( 1.2%)	0	0
VIRAL INFECTION	0	1 ( 1.2%)	0
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	8 ( 9.3%)	9 ( 10.7%)	10 ( 11.9%)
COUGH	1 ( 1.2%)	5 ( 6.0%)	5 ( 6.0%)
NASAL CONGESTION	3 ( 3.5%)	1 ( 1.2%)	3 ( 3.6%)
EPISTAXIS	0	1 ( 1.2%)	2 ( 2.4%)
ALLERGIC GRANULOMATOUS ANGIITIS	0	0	1 ( 1.2%)
DYSPNOEA	1 ( 1.2%)	1 ( 1.2%)	1 ( 1.2%)
PHARYNGEAL ERYTHEMA	0	0	1 ( 1.2%)
PHARYNGOLARYNGEAL PAIN	0	1 ( 1.2%)	1 ( 1.2%)
PRODUCTIVE COUGH	0	0	1 ( 1.2%)
RESPIRATORY TRACT CONGESTION	0	0	1 ( 1.2%)
RHINORRHOEA	0	1 ( 1.2%)	1 ( 1.2%)
DYSPHONIA	0	1 ( 1.2%)	0

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EMPHYSEMA	1 ( 1.2%)	0	0
HAEMOPTYSIS	1 ( 1.2%)	0	0
POSTNASAL DRIP	1 ( 1.2%)	0	0
RALES	1 ( 1.2%)	0	0

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PSYCHIATRIC DISORDERS	10 ( 11.6%)	10 ( 11.9%)	8 ( 9.5%)
INSOMNIA	2 ( 2.3%)	0	2 ( 2.4%)
AGITATION	2 ( 2.3%)	2 ( 2.4%)	1 ( 1.2%)
CONFUSIONAL STATE	2 ( 2.3%)	3 ( 3.6%)	1 ( 1.2%)
DELIRIUM	0	0	1 ( 1.2%)
DELUSION	1 ( 1.2%)	0	1 ( 1.2%)
HALLUCINATION	0	0	1 ( 1.2%)
HALLUCINATION, VISUAL	0	0	1 ( 1.2%)
LIBIDO DECREASED	0	0	1 ( 1.2%)
LISTLESS	0	0	1 ( 1.2%)
NIGHTMARE	0	0	1 ( 1.2%)
ANXIETY	0	3 ( 3.6%)	0
COMPLETED SUICIDE	1 ( 1.2%)	0	0
DEPRESSED MOOD	0	1 ( 1.2%)	0
DISORIENTATION	1 ( 1.2%)	0	0
IRRITABILITY	1 ( 1.2%)	1 ( 1.2%)	0
RESTLESSNESS	0	1 ( 1.2%)	0
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	4 ( 4.7%)	7 ( 8.3%)	7 ( 8.3%)
BACK PAIN	1 ( 1.2%)	1 ( 1.2%)	3 ( 3.6%)
ARTHRALGIA	1 ( 1.2%)	2 ( 2.4%)	1 ( 1.2%)
ARTHRITIS	0	0	1 ( 1.2%)
FLANK PAIN	0	0	1 ( 1.2%)

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MUSCLE SPASMS	0	1 ( 1.2%)	1 ( 1.2%)
MYALGIA	0	0	1 ( 1.2%)
MUSCULAR WEAKNESS	0	1 ( 1.2%)	0

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MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS			
PAIN IN EXTREMITY	1 ( 1.2%)	0	0
SHOULDER PAIN	1 ( 1.2%)	2 ( 2.4%)	0
INVESTIGATIONS	10 ( 11.6%)	6 ( 7.1%)	6 ( 7.1%)
BIOPSY	0	0	1 ( 1.2%)
BIOPSY PROSTATE	0	0	1 ( 1.2%)
BLOOD CHOLESTEROL INCREASED	0	0	1 ( 1.2%)
BLOOD GLUCOSE INCREASED	0	1 ( 1.2%)	1 ( 1.2%)
ELECTROCARDIOGRAM T WAVE INVERSION	2 ( 2.3%)	1 ( 1.2%)	1 ( 1.2%)
WEIGHT DECREASED	0	0	1 ( 1.2%)
BLOOD ALKALINE PHOSPHATASE INCREASED	1 ( 1.2%)	0	0
BLOOD CREATINE PHOSPHOKINASE INCREASED	1 ( 1.2%)	0	0
BLOOD URINE PRESENT	1 ( 1.2%)	0	0
BODY TEMPERATURE INCREASED	0	1 ( 1.2%)	0
CYSTOSCOPY	1 ( 1.2%)	0	0
ELECTROCARDIOGRAM ST SEGMENT DEPRESSION	4 ( 4.7%)	1 ( 1.2%)	0
ELECTROCARDIOGRAM T WAVE AMPLITUDE DECREASED	1 ( 1.2%)	1 ( 1.2%)	0
HEART RATE INCREASED	1 ( 1.2%)	0	0
HEART RATE IRREGULAR	1 ( 1.2%)	0	0
NASAL MUCOSA BIOPSY	0	1 ( 1.2%)	0

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INJURY, POISONING AND PROCEDURAL COMPLICATIONS	4 ( 4.7%)	5 ( 6.0%)	5 ( 6.0%)
CONTUSION	1 ( 1.2%)	1 ( 1.2%)	2 ( 2.4%)
HIP FRACTURE	1 ( 1.2%)	0	2 ( 2.4%)
EXCORIATION	2 ( 2.3%)	1 ( 1.2%)	1 ( 1.2%)
FACIAL BONES FRACTURE	0	0	1 ( 1.2%)
FALL	1 ( 1.2%)	2 ( 2.4%)	1 ( 1.2%)

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INJURY, POISONING AND PROCEDURAL COMPLICATIONS			
JOINT DISLOCATION	0	1 ( 1.2%)	0
SKIN LACERATION	1 ( 1.2%)	2 ( 2.4%)	0
WOUND	0	1 ( 1.2%)	0
RENAL AND URINARY DISORDERS	4 ( 4.7%)	3 ( 3.6%)	3 ( 3.6%)
CALCULUS URETHRAL	0	0	1 ( 1.2%)
MICTURITION URGENCY	1 ( 1.2%)	1 ( 1.2%)	1 ( 1.2%)
NEPHROLITHIASIS	1 ( 1.2%)	0	1 ( 1.2%)
DYSURIA	1 ( 1.2%)	1 ( 1.2%)	0
INCONTINENCE	0	1 ( 1.2%)	0
POLLAKIURIA	1 ( 1.2%)	0	0
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	0	1 ( 1.2%)	2 ( 2.4%)
VENTRICULAR SEPTAL DEFECT	0	1 ( 1.2%)	2 ( 2.4%)
METABOLISM AND NUTRITION DISORDERS	6 ( 7.0%)	1 ( 1.2%)	2 ( 2.4%)
DECREASED APPETITE	1 ( 1.2%)	0	1 ( 1.2%)
INCREASED APPETITE	1 ( 1.2%)	0	1 ( 1.2%)
DEHYDRATION	1 ( 1.2%)	0	0
DIABETES MELLITUS	1 ( 1.2%)	0	0
FOOD CRAVING	1 ( 1.2%)	1 ( 1.2%)	0
HYPONATRAEMIA	1 ( 1.2%)	0	0

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SURGICAL AND MEDICAL PROCEDURES	2 ( 2.3%)	1 ( 1.2%)	2 ( 2.4%)
ACROCHORDON EXCISION	0	0	1 ( 1.2%)
SKIN LESION EXCISION	0	0	1 ( 1.2%)
CATARACT OPERATION	1 ( 1.2%)	1 ( 1.2%)	0
EYE LASER SURGERY	1 ( 1.2%)	0	0
EAR AND LABYRINTH DISORDERS	1 ( 1.2%)	2 ( 2.4%)	1 ( 1.2%)

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EAR AND LABYRINTH DISORDERS			
VERTIGO	0	1 ( 1.2%)	1 ( 1.2%)
CERUMEN IMPACTION	0	1 ( 1.2%)	0
EAR PAIN	1 ( 1.2%)	0	0
EYE DISORDERS	2 ( 2.3%)	2 ( 2.4%)	1 ( 1.2%)
VISION BLURRED	0	1 ( 1.2%)	1 ( 1.2%)
CONJUNCTIVAL HAEMORRHAGE	0	1 ( 1.2%)	0
CONJUNCTIVITIS	1 ( 1.2%)	0	0
EYE ALLERGY	1 ( 1.2%)	0	0
EYE PRURITUS	1 ( 1.2%)	0	0
EYE SWELLING	1 ( 1.2%)	0	0
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	2 ( 2.4%)	1 ( 1.2%)
PROSTATE CANCER	0	0	1 ( 1.2%)
COLON CANCER	0	1 ( 1.2%)	0
MALIGNANT FIBROUS HISTIOCYTOMA	0	1 ( 1.2%)	0
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	2 ( 2.3%)	0	1 ( 1.2%)
BENIGN PROSTATIC HYPERPLASIA	1 ( 1.2%)	0	1 ( 1.2%)
PELVIC PAIN	1 ( 1.2%)	0	0
SOCIAL CIRCUMSTANCES	0	0	1 ( 1.2%)

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ALCOHOL USE	0	0	1 ( 1.2%)
VASCULAR DISORDERS	3 ( 3.5%)	3 ( 3.6%)	1 ( 1.2%)
WOUND HAEMORRHAGE	0	0	1 ( 1.2%)
HOT FLUSH	0	1 ( 1.2%)	0
HYPERTENSION	1 ( 1.2%)	1 ( 1.2%)	0
HYPOTENSION	2 ( 2.3%)	1 ( 1.2%)	0
ORTHOSTATIC HYPOTENSION	1 ( 1.2%)	0	0

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HEPATOBILIARY DISORDERS	1 ( 1.2%)	0	0
HYPERBILIRUBINAEMIA	1 ( 1.2%)	0	0
IMMUNE SYSTEM DISORDERS	0	1 ( 1.2%)	0
HYPERSENSITIVITY	0	1 ( 1.2%)	0