

***** List of reported NON-SERIOUS AE's *****

-> group == placebo

ssoc System Organ Class
aeterm Adverse Event term
affected Subjects affected number
exposed Subjects exposed number
occurrences Occurrences all number

| | ssoc | aeterm | affected | exposed | occurrences |
|--|--------------------------------------|--------|----------|---------|-------------|
| Blood and lymphatic system disorders | Anemia | | 4 | 39 | 5 |
| Blood and lymphatic system disorders | Leucopenia | | 1 | 39 | 1 |
| Blood and lymphatic system disorders | Neutropenia | | 1 | 39 | 2 |
| Cardiac disorders | Artial fibrilladtion | | 1 | 39 | 1 |
| Cardiac disorders | Atrial fibrillation | | 2 | 39 | 3 |
| Cardiac disorders | Bradycardia | | 2 | 39 | 2 |
| Cardiac disorders | Restrictive cardiomyopathy | | 1 | 39 | 1 |
| Cardiac disorders | Sinus Bradycardia | | 1 | 39 | 1 |
| Ear and labyrinth disorders | Vestibular disorder | | 1 | 39 | 1 |
| Eye disorders | Cataract | | 1 | 39 | 1 |
| Eye disorders | Watering eyes | | 1 | 39 | 1 |
| Gastrointestinal disorders | Constipation | | 7 | 39 | 9 |
| Gastrointestinal disorders | Diarrhea | | 1 | 39 | 1 |
| Gastrointestinal disorders | Diarrhea | | 2 | 39 | 2 |
| Gastrointestinal disorders | Dyspepsia | | 1 | 39 | 1 |
| Gastrointestinal disorders | Nausea | | 3 | 39 | 3 |
| Gastrointestinal disorders | Obstipation | | 2 | 39 | 2 |
| Gastrointestinal disorders | Stomach pain | | 1 | 39 | 1 |
| General disorders and administration site conditions | Anorexia | | 1 | 39 | 1 |
| General disorders and administration site conditions | Chills | | 1 | 39 | 1 |
| General disorders and administration site conditions | Edema | | 1 | 39 | 1 |
| General disorders and administration site conditions | Edema - limbs | | 1 | 39 | 1 |
| General disorders and administration site conditions | Edema Limbs | | 1 | 39 | 1 |
| General disorders and administration site conditions | Edema limbs | | 4 | 39 | 4 |
| General disorders and administration site conditions | Fatigue | | 3 | 39 | 3 |
| General disorders and administration site conditions | Fever | | 1 | 39 | 1 |
| General disorders and administration site conditions | Malaise | | 2 | 39 | 2 |
| General disorders and administration site conditions | Oedema limbs | | 1 | 39 | 1 |
| General disorders and administration site conditions | Swollen whole body | | 1 | 39 | 1 |
| Infections and infestations | Bone infection | | 1 | 39 | 1 |
| Infections and infestations | Cold | | 1 | 39 | 1 |
| Infections and infestations | Gastro-enteritis | | 1 | 39 | 1 |
| Infections and infestations | Herpes zoster | | 1 | 39 | 1 |
| Infections and infestations | Infection - unknown origin | | 1 | 39 | 1 |
| Infections and infestations | Infection upper respiratory - cold | | 1 | 39 | 1 |
| Infections and infestations | Pulmonary infection | | 1 | 39 | 1 |
| Infections and infestations | Tooth infection | | 1 | 39 | 1 |
| Infections and infestations | Upper respiratory infection | | 2 | 39 | 2 |
| Injury, poisoning and procedural complications | Fall | | 2 | 39 | 2 |
| Injury, poisoning and procedural complications | Fracture | | 1 | 39 | 1 |
| Injury, poisoning and procedural complications | Fracture on costa 5,6 and 7 | | 1 | 39 | 1 |
| Injury, poisoning and procedural complications | Fracture right lateral os acetabulum | | 1 | 39 | 1 |
| Injury, poisoning and procedural complications | Infected wound on right lower leg | | 1 | 39 | 1 |
| Injury, poisoning and procedural complications | Lost a tooth in the lower jaw | | 1 | 39 | 1 |
| Investigations | Creatinine increased | | 1 | 39 | 1 |
| Investigations | Platelet count decreased | | 1 | 39 | 2 |
| Investigations | Weight gain | | 1 | 39 | 1 |
| Metabolism and nutrition disorders | Anorexia | | 1 | 39 | 1 |
| Metabolism and nutrition disorders | Hyperglycemia | | 2 | 39 | 4 |
| Metabolism and nutrition disorders | Hypokalemia | | 1 | 39 | 1 |
| Musculoskeletal and connective tissue disorders | Arthralgia | | 1 | 39 | 1 |
| Musculoskeletal and connective tissue disorders | Back pain | | 2 | 39 | 2 |
| Musculoskeletal and connective tissue disorders | Generalized muscle weakness | | 1 | 39 | 1 |
| Musculoskeletal and connective tissue disorders | Lower back pain | | 1 | 39 | 1 |
| Musculoskeletal and connective tissue disorders | Myositis | | 1 | 39 | 1 |
| Musculoskeletal and connective tissue disorders | Pain - Right hip | | 1 | 39 | 1 |
| Musculoskeletal and connective tissue disorders | Pain in dthe left hip | | 1 | 39 | 1 |
| Musculoskeletal and connective tissue disorders | Pain left knee | | 1 | 39 | 1 |
| Musculoskeletal and connective tissue disorders | Pain left pelvis | | 1 | 39 | 1 |
| Musculoskeletal and connective tissue disorders | Pain right kne | | 1 | 39 | 1 |
| Nervous system disorders | Dizziness | | 3 | 39 | 3 |
| Nervous system disorders | Memory impairment | | 1 | 39 | 1 |
| Nervous system disorders | Neuropathy | | 2 | 39 | 2 |
| Nervous system disorders | Neuropathy feet | | 1 | 39 | 1 |
| Nervous system disorders | Neuropathy fingers | | 1 | 39 | 1 |

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|---|--|---|----|---|
| Nervous system disorders | Neuropathy legs | 1 | 39 | 1 |
| Nervous system disorders | Neuropathy sensory | 1 | 39 | 1 |
| Nervous system disorders | Neuropathy-sensori | 1 | 39 | 2 |
| Nervous system disorders | Neuropathy-sensory | 4 | 39 | 5 |
| Nervous system disorders | Neuropati | 1 | 39 | 1 |
| Nervous system disorders | PNP | 1 | 39 | 2 |
| Nervous system disorders | Paresthesia | 2 | 39 | 3 |
| Nervous system disorders | Peripheral motor neuropathy | 1 | 39 | 1 |
| Nervous system disorders | Peripheral sensory neuropathy | 4 | 39 | 6 |
| Nervous system disorders | Peripheral sensory neuropath | 1 | 39 | 1 |
| Nervous system disorders | Polyneuropathy | 4 | 39 | 4 |
| Nervous system disorders | Polyneuropathy feet | 2 | 39 | 3 |
| Nervous system disorders | Polyneuropathy fingers | 1 | 39 | 1 |
| Nervous system disorders | Progressive polyneuropathy feet to knees | 1 | 39 | 1 |
| Nervous system disorders | Sensory polyneuropathy feet | 1 | 39 | 1 |
| Nervous system disorders | Sensory polyneuropathy fingers | 1 | 39 | 1 |
| Nervous system disorders | Sensory polyneuropathy hands | 1 | 39 | 1 |
| Nervous system disorders | Short term memory loss | 1 | 39 | 1 |
| Nervous system disorders | Transient ischemic attacks | 1 | 39 | 1 |
| Nervous system disorders | Vasovagal | 1 | 39 | 2 |
| Psychiatric disorders | Agitation | 2 | 39 | 2 |
| Psychiatric disorders | Depression | 2 | 39 | 2 |
| Psychiatric disorders | Hallucinations | 2 | 39 | 2 |
| Psychiatric disorders | Insomnia | 1 | 39 | 1 |
| Renal and urinary disorders | Cystitis | 1 | 39 | 1 |
| Renal and urinary disorders | Urine incontinence | 1 | 39 | 1 |
| Reproductive system and breast disorders | Erectile dysfunction | 1 | 39 | 1 |
| Reproductive system and breast disorders | Prostatic obstruction | 1 | 39 | 1 |
| Reproductive system and breast disorders | Uterine prolapse | 1 | 39 | 1 |
| Reproductive system and breast disorders | Vaginal discharge | 1 | 39 | 1 |
| Respiratory, thoracic and mediastinal disorders | Bronchitis | 1 | 39 | 1 |
| Respiratory, thoracic and mediastinal disorders | Cough | 1 | 39 | 1 |
| Respiratory, thoracic and mediastinal disorders | Dyspnea | 2 | 39 | 2 |
| Respiratory, thoracic and mediastinal disorders | Pneumonia | 2 | 39 | 2 |
| Skin and subcutaneous tissue disorders | Basalioma | 1 | 39 | 1 |
| Skin and subcutaneous tissue disorders | Dry skin | 1 | 39 | 1 |
| Skin and subcutaneous tissue disorders | Eczema | 1 | 39 | 1 |
| Skin and subcutaneous tissue disorders | Herpes Zoster | 1 | 39 | 1 |
| Skin and subcutaneous tissue disorders | Pruritus | 1 | 39 | 1 |
| Skin and subcutaneous tissue disorders | Rash | 3 | 39 | 3 |
| Skin and subcutaneous tissue disorders | Rash (allergic) | 1 | 39 | 1 |
| Skin and subcutaneous tissue disorders | Rash maculo-papular | 3 | 39 | 4 |
| Skin and subcutaneous tissue disorders | Skin reaction, probably after contact with a plant while gardening | 1 | 39 | 1 |
| Skin and subcutaneous tissue disorders | Skin ulceration | 1 | 39 | 1 |
| Skin and subcutaneous tissue disorders | Small bump chest | 1 | 39 | 1 |
| Skin and subcutaneous tissue disorders | Urticaria | 1 | 39 | 1 |
| Vascular disorders | Hypertension | 1 | 39 | 1 |
| Vascular disorders | Hypotension | 1 | 39 | 1 |

-> group == Ixa

ssoc System Organ Class
aeterm Adverse Event term
affected Subjects affected number
exposed Subjects exposed number
occurrences Occurrences all number

| | ssoc | aeterm | affected | exposed | occurrences |
|--------------------------------------|--|--------|----------|---------|-------------|
| Blood and lymphatic system disorders | Anemia | | 4 | 39 | 6 |
| Blood and lymphatic system disorders | Neutropenia | | 1 | 39 | 1 |
| Blood and lymphatic system disorders | Trombocytopeni | | 1 | 39 | 1 |
| Blood and lymphatic system disorders | Trombocytopeni | | 1 | 39 | 2 |
| Blood and lymphatic system disorders | Trombocytopenia | | 1 | 39 | 1 |
| Cardiac disorders | Atrial fibrillation | | 1 | 39 | 1 |
| Cardiac disorders | Palpitations | | 1 | 39 | 1 |
| Cardiac disorders | Tachycardia | | 2 | 39 | 2 |
| Ear and labyrinth disorders | Benign paroxysmal positional vertigo | | 1 | 39 | 1 |
| Ear and labyrinth disorders | Hearing impaired | | 1 | 39 | 2 |
| Ear and labyrinth disorders | Vertigo | | 1 | 39 | 1 |
| Ear and labyrinth disorders | Vestibular disorder | | 1 | 39 | 1 |
| Eye disorders | Blurred vision | | 1 | 39 | 1 |
| Eye disorders | Burning eyes | | 1 | 39 | 1 |
| Eye disorders | Cataract | | 3 | 39 | 4 |
| Eye disorders | Double vision | | 1 | 39 | 1 |
| Eye disorders | Drye eyes | | 1 | 39 | 1 |
| Eye disorders | Other; dry eyes | | 1 | 39 | 1 |
| Eye disorders | Short period of blindness after trauma | | 1 | 39 | 1 |
| Eye disorders | Uveitis | | 1 | 39 | 1 |

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|---|---|---|----|----|
| Gastrointestinal disorders | Acid reflux disease | 1 | 39 | 1 |
| Gastrointestinal disorders | Bloating | 1 | 39 | 1 |
| Gastrointestinal disorders | Constipation | 8 | 39 | 11 |
| Gastrointestinal disorders | Diarrhea | 3 | 39 | 3 |
| Gastrointestinal disorders | Heartburn | 1 | 39 | 1 |
| Gastrointestinal disorders | Nausea | 8 | 39 | 9 |
| Gastrointestinal disorders | Stomachflu | 1 | 39 | 1 |
| Gastrointestinal disorders | Tooth infection | 1 | 39 | 1 |
| Gastrointestinal disorders | Vomiting | 3 | 39 | 3 |
| General disorders and administration site conditions | Edema | 4 | 39 | 4 |
| General disorders and administration site conditions | Edema ankles | 1 | 39 | 1 |
| General disorders and administration site conditions | Edema feet | 1 | 39 | 1 |
| General disorders and administration site conditions | Edema limbs | 1 | 39 | 1 |
| General disorders and administration site conditions | Fatigue | 2 | 39 | 2 |
| General disorders and administration site conditions | Fatigue (worsening) | 1 | 39 | 1 |
| General disorders and administration site conditions | Fatigue | 3 | 39 | 3 |
| General disorders and administration site conditions | Fever | 1 | 39 | 3 |
| General disorders and administration site conditions | Malaise | 2 | 39 | 2 |
| General disorders and administration site conditions | Oedema limbs | 1 | 39 | 1 |
| General disorders and administration site conditions | Pain | 1 | 39 | 1 |
| General disorders and administration site conditions | Pain, in relation to multiple myeloma lesions | 1 | 39 | 1 |
| Infections and infestations | Bronchial infection | 1 | 39 | 1 |
| Infections and infestations | Bronchitis | 1 | 39 | 1 |
| Infections and infestations | Common cold | 1 | 39 | 1 |
| Infections and infestations | Flu | 1 | 39 | 1 |
| Infections and infestations | Herpes Zoster | 1 | 39 | 1 |
| Infections and infestations | Herpes zoster infection | 1 | 39 | 1 |
| Infections and infestations | Nailinfection | 1 | 39 | 1 |
| Infections and infestations | Nasopharyngitis | 1 | 39 | 1 |
| Infections and infestations | Respiratory infection | 1 | 39 | 1 |
| Infections and infestations | Sinusitis inflammation | 1 | 39 | 1 |
| Infections and infestations | Skin infection | 1 | 39 | 1 |
| Infections and infestations | Swollen lymphnode throat | 1 | 39 | 1 |
| Infections and infestations | Upper respiratory infection | 1 | 39 | 1 |
| Infections and infestations | Upper respiratory infection | 2 | 39 | 2 |
| Infections and infestations | Urine tract infection | 1 | 39 | 2 |
| Investigations | Gamma GT Increased | 1 | 39 | 1 |
| Investigations | Leukopenia | 1 | 39 | 1 |
| Investigations | Neutropenia | 1 | 39 | 1 |
| Investigations | Thrombopenia | 1 | 39 | 2 |
| Investigations | Weight loss | 1 | 39 | 1 |
| Metabolism and nutrition disorders | Anorexia | 2 | 39 | 2 |
| Metabolism and nutrition disorders | Dehydration | 1 | 39 | 1 |
| Metabolism and nutrition disorders | Hyperglycemia | 1 | 39 | 1 |
| Metabolism and nutrition disorders | Hyponatremia | 1 | 39 | 1 |
| Metabolism and nutrition disorders | Hypophosphatemia | 1 | 39 | 1 |
| Musculoskeletal and connective tissue disorders | Arthralgia | 1 | 39 | 1 |
| Musculoskeletal and connective tissue disorders | Arthralgia knee | 1 | 39 | 1 |
| Musculoskeletal and connective tissue disorders | Back pain | 3 | 39 | 3 |
| Musculoskeletal and connective tissue disorders | Hip pain | 1 | 39 | 1 |
| Musculoskeletal and connective tissue disorders | Muscle Cramps | 1 | 39 | 1 |
| Musculoskeletal and connective tissue disorders | Muscleweakness | 1 | 39 | 1 |
| Musculoskeletal and connective tissue disorders | Myopathy | 2 | 39 | 2 |
| Musculoskeletal and connective tissue disorders | Osteonecrosis of jaw, peri implanitis | 1 | 39 | 1 |
| Musculoskeletal and connective tissue disorders | Osteonecrosis of the jaw | 1 | 39 | 1 |
| Musculoskeletal and connective tissue disorders | Pain back after trauma | 1 | 39 | 1 |
| Musculoskeletal and connective tissue disorders | Pain tailbone after fall | 1 | 39 | 1 |
| Musculoskeletal and connective tissue disorders | Pain thorax | 1 | 39 | 1 |
| Musculoskeletal and connective tissue disorders | Progressive pain thorax | 1 | 39 | 1 |
| Musculoskeletal and connective tissue disorders | Tenosynovitis | 1 | 39 | 1 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | Tumor collum glandula parotis dext | 1 | 39 | 1 |
| Nervous system disorders | Carpal tunnel syndrome | 1 | 39 | 1 |
| Nervous system disorders | Dizziness | 1 | 39 | 1 |
| Nervous system disorders | Dizziness | 4 | 39 | 5 |
| Nervous system disorders | Faintness | 1 | 39 | 1 |
| Nervous system disorders | Headache | 1 | 39 | 2 |
| Nervous system disorders | Neuropathy | 1 | 39 | 1 |
| Nervous system disorders | Neuropathy feet | 1 | 39 | 1 |
| Nervous system disorders | Neuropathy sensori | 1 | 39 | 1 |
| Nervous system disorders | Neuropathy sensory | 1 | 39 | 2 |
| Nervous system disorders | Neuropathy-sensory | 1 | 39 | 1 |
| Nervous system disorders | PNP | 3 | 39 | 7 |
| Nervous system disorders | Peripheral motor neuropath | 1 | 39 | 1 |
| Nervous system disorders | Peripheral motor neuropathy | 4 | 39 | 4 |
| Nervous system disorders | Peripheral sensory Neuropathy | 1 | 39 | 1 |
| Nervous system disorders | Peripheral sensory neuropathy | 9 | 39 | 12 |
| Nervous system disorders | Pheripheral sensory neuropathy | 2 | 39 | 2 |
| Nervous system disorders | Polyneuropathy | 4 | 39 | 5 |

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|---|--------------------------------|---|----|---|
| Nervous system disorders | Polyneuropathy feet | 1 | 39 | 2 |
| Nervous system disorders | Polyneuropathy hands | 1 | 39 | 1 |
| Nervous system disorders | Polyneuropathy | 1 | 39 | 2 |
| Nervous system disorders | Sensory polyneuropathy feet | 4 | 39 | 4 |
| Nervous system disorders | Sensory polyneuropathy fingers | 1 | 39 | 1 |
| Nervous system disorders | Sensory polyneuropathy hand | 1 | 39 | 1 |
| Nervous system disorders | Tremor | 2 | 39 | 2 |
| Nervous system disorders | Vasovagal reaction | 1 | 39 | 1 |
| Psychiatric disorders | Agitation | 1 | 39 | 2 |
| Psychiatric disorders | Confusion | 1 | 39 | 1 |
| Psychiatric disorders | Disoriented | 1 | 39 | 1 |
| Psychiatric disorders | Nightmares | 1 | 39 | 1 |
| Renal and urinary disorders | Acute kidney injury | 1 | 39 | 1 |
| Renal and urinary disorders | Recurrent urinary infection | 1 | 39 | 1 |
| Renal and urinary disorders | Urinary retention | 1 | 39 | 1 |
| Renal and urinary disorders | Urination | 1 | 39 | 1 |
| Reproductive system and breast disorders | Uterine prolapse | 1 | 39 | 1 |
| Respiratory, thoracic and mediastinal disorders | Cough | 1 | 39 | 1 |
| Respiratory, thoracic and mediastinal disorders | Pneumonia | 1 | 39 | 1 |
| Respiratory, thoracic and mediastinal disorders | Pneumonitis | 1 | 39 | 1 |
| Respiratory, thoracic and mediastinal disorders | Respiratory infection | 2 | 39 | 3 |
| Respiratory, thoracic and mediastinal disorders | Upper respiratory infection | 1 | 39 | 1 |
| Skin and subcutaneous tissue disorders | Abscess groin | 1 | 39 | 1 |
| Skin and subcutaneous tissue disorders | Erythema multiforme | 1 | 39 | 1 |
| Skin and subcutaneous tissue disorders | Rash acneiform | 1 | 39 | 1 |
| Skin and subcutaneous tissue disorders | Rash | 1 | 39 | 1 |
| Skin and subcutaneous tissue disorders | Rash (desquamierende) | 1 | 39 | 1 |
| Skin and subcutaneous tissue disorders | Rash (erythematous squamous) | 1 | 39 | 1 |
| Skin and subcutaneous tissue disorders | Rash maculo-papular | 3 | 39 | 3 |
| Skin and subcutaneous tissue disorders | Urticaria | 1 | 39 | 1 |
| Surgical and medical procedures | Cataract left | 1 | 39 | 1 |
| Surgical and medical procedures | Cataract right | 1 | 39 | 1 |
| Vascular disorders | Hypertension | 2 | 39 | 2 |
| Vascular disorders | Hypotension | 1 | 39 | 1 |
| Vascular disorders | Lymph leakage | 1 | 39 | 1 |
| Vascular disorders | Venous thrombosis left leg | 1 | 39 | 1 |