

***** 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	Diarrea		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

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 neuropathi	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

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	Peripheral sensory neuropathy	2	39	2
Nervous system disorders	Polyneuropathy	4	39	5

Nervous system disorders	Polyneuropathy feet	1	39	2
Nervous system disorders	Polyneuropathy hands	1	39	1
Nervous system disorders	Polyneuropathi	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	Rach 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 (erythematosquamous)	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	Lymf leakage	1	39	1
Vascular disorders	Venous thrombosis left leg	1	39	1