

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

-> group == Arm1: Experimental (1 arm only)

ssoc            System Organ Class  
aeterm        Adverse event term (please use CTCAE term)  
affected      Subjects affected number  
exposed       Subjects exposed number  
occurrences   Occurrences all number

	ssoc	aeterm	affected	exposed	occurrences
Blood and lymphatic system disorders	Anemia		5	60	9
Blood and lymphatic system disorders	Febrile neutropenia		1	60	1
Blood and lymphatic system disorders	NEUTROPENIA		1	60	3
Blood and lymphatic system disorders	Neutropenia		2	60	3
Blood and lymphatic system disorders	THROMBOCYTOPENIA		1	60	2
Blood and lymphatic system disorders	Thrombocytopenia		3	60	4
Blood and lymphatic system disorders	Thrombopenia		1	60	1
Cardiac disorders	Atrial fibrillation		1	60	1
Cardiac disorders	Sinus bradycardia		1	60	1
Eye disorders	Cataract		1	60	1
Eye disorders	Conjunctivitis		2	60	2
Gastrointestinal disorders	Constipation		3	60	3
Gastrointestinal disorders	Diarrhea		3	60	3
Gastrointestinal disorders	Dry mouth		1	60	1
Gastrointestinal disorders	Gastritis		1	60	1
Gastrointestinal disorders	Gastroesophageal reflux		1	60	1
Gastrointestinal disorders	Hemorrhoids		1	60	1
Gastrointestinal disorders	Intermittent nausea		1	60	1
Gastrointestinal disorders	Intermittent stomach complaints		1	60	1
Gastrointestinal disorders	Mucositis oral		2	60	2
Gastrointestinal disorders	Nausea		1	60	1
Gastrointestinal disorders	Obstipation		1	60	1
Gastrointestinal disorders	Stomatitis		1	60	1
General disorders and administration site conditions	Chills		1	60	1
General disorders and administration site conditions	Dizziness		1	60	1
General disorders and administration site conditions	Edema face		2	60	2
General disorders and administration site conditions	Edema one hand		1	60	1
General disorders and administration site conditions	Fatigue		9	60	12
General disorders and administration site conditions	Fatigue		1	60	1
General disorders and administration site conditions	Fever		2	60	2
General disorders and administration site conditions	Flu like symptoms		2	60	2
General disorders and administration site conditions	General malaise		1	60	1
General disorders and administration site conditions	Headache		1	60	1
General disorders and administration site conditions	Infusion related reaction		2	60	2
General disorders and administration site conditions	Injection site reaction		4	60	7
General disorders and administration site conditions	Injection site reaction, small swelling		1	60	1
General disorders and administration site conditions	Localized edema eyes		1	60	1
General disorders and administration site conditions	Malaise		1	60	1
General disorders and administration site conditions	Malleolar oedema bilateral		1	60	1
General disorders and administration site conditions	Moderate pain		1	60	1
General disorders and administration site conditions	Mucosal bleeding		1	60	1
General disorders and administration site conditions	Other, night sweats		1	60	1
Immune system disorders	Allergic reaction		3	60	7
Infections and infestations	Abdominal wall infection		1	60	1
Infections and infestations	Bronchial infections		1	60	3
Infections and infestations	Candida stomatitis		1	60	1
Infections and infestations	Erysipelas		1	60	1
Infections and infestations	Herpes zoster		1	60	1
Infections and infestations	Infected mosquito bite lower leg		1	60	1
Infections and infestations	Infection (unknown)		1	60	1
Infections and infestations	Infection upper airway		1	60	1
Infections and infestations	Influenza infection		1	60	1
Infections and infestations	Lung infection		1	60	1
Infections and infestations	Oral candidiasis		1	60	1
Infections and infestations	Pleural empyema		1	60	1
Infections and infestations	Pleural infection		1	60	2
Infections and infestations	Pneumonia		2	60	4
Infections and infestations	Respiratory infection		1	60	2
Infections and infestations	Rhinitis		1	60	1
Infections and infestations	Sinusitis		4	60	4
Infections and infestations	Skin infection		2	60	3
Infections and infestations	Tooth infection		1	60	1

Infections and infestations	Upper respiratory infection	4	60	6
Infections and infestations	Upper respiratory tract infection	1	60	1
Infections and infestations	Urinary tract infection	2	60	2
Infections and infestations	Urosepsis	1	60	1
Infections and infestations	Varicella zoster infection	1	60	1
Infections and infestations	Viral infection	1	60	1
Injury, poisoning and procedural complications	Fracture shoulder	1	60	1
Investigations	ALAT increased	1	60	1
Investigations	ASAT increased	1	60	1
Investigations	GGT increased	2	60	2
Investigations	Gamma GT increased	1	60	1
Investigations	Lymphocyte count decreased	1	60	1
Investigations	Neutropenia	1	60	1
Investigations	Neutrophil count decreased	10	60	15
Investigations	Platelet count decreased	7	60	13
Investigations	Platelet count decreased	1	60	3
Investigations	Weight gain	3	60	3
Investigations	White blood cell count decreased	1	60	1
Investigations	White blood cell decreased	5	60	9
Metabolism and nutrition disorders	Anorexia	2	60	2
Metabolism and nutrition disorders	Hyperglucemia	1	60	1
Metabolism and nutrition disorders	Hyperglycemia	2	60	2
Musculoskeletal and connective tissue disorders	Arthritis left ankle	1	60	1
Musculoskeletal and connective tissue disorders	Avascular necrosis	1	60	1
Musculoskeletal and connective tissue disorders	Avascular necrosis hip	1	60	1
Musculoskeletal and connective tissue disorders	Back pain	1	60	1
Musculoskeletal and connective tissue disorders	Lower back pain	1	60	1
Musculoskeletal and connective tissue disorders	Lower backpain	1	60	1
Musculoskeletal and connective tissue disorders	Lumbar pain	1	60	1
Musculoskeletal and connective tissue disorders	Muscle pain	2	60	3
Musculoskeletal and connective tissue disorders	Neck pain (trapezium syndrome)	1	60	1
Musculoskeletal and connective tissue disorders	OSTEOPOROSIS	1	60	1
Musculoskeletal and connective tissue disorders	Other: cramp	1	60	1
Musculoskeletal and connective tissue disorders	Pain hips	1	60	1
Musculoskeletal and connective tissue disorders	Pain leg	1	60	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basalcel carcinoma shoulder	1	60	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Granuloma pyogenicum	1	60	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Schwannoma at right arm	1	60	1
Nervous system disorders	Bing-Neel Syndrome	1	60	1
Nervous system disorders	Carpal tunnel syndrome	1	60	1
Nervous system disorders	Cramps in fingers	1	60	1
Nervous system disorders	Headache	1	60	1
Nervous system disorders	Headache (migraine)	1	60	1
Nervous system disorders	ISCHEMIC ATTACK	1	60	1
Nervous system disorders	Intermittent headache	1	60	1
Nervous system disorders	NEUROPATHY	1	60	1
Nervous system disorders	Neurological absence	1	60	1
Nervous system disorders	Neuropathy	1	60	1
Nervous system disorders	Neuropathy hand	1	60	1
Nervous system disorders	Neuropathy-sensory	1	60	2
Nervous system disorders	Other: balance disorder	1	60	1
Nervous system disorders	PNP	3	60	4
Nervous system disorders	Paresthesia at right arm	1	60	1
Nervous system disorders	Perhipheral sensory neuropathy	1	60	1
Nervous system disorders	Peripheral motor neuropathy	1	60	1
Nervous system disorders	Peripheral motoric neuropathy	1	60	1
Nervous system disorders	Peripheral neuropathy	1	60	1
Nervous system disorders	Peripheral neutropathy	1	60	1
Nervous system disorders	Peripheral sensory neuropathy	4	60	6
Nervous system disorders	Pheripheral sensory neutropenia	1	60	1
Nervous system disorders	Polyneuropathy	3	60	3
Nervous system disorders	Polyneuropathy at both hands	1	60	1
Nervous system disorders	Polyneuropathy at feet	1	60	1
Nervous system disorders	Polyneuropathy fingers	1	60	1
Nervous system disorders	Polyneuropathy toes	1	60	1
Nervous system disorders	Shaking	1	60	1
Nervous system disorders	Small fiber PNP	1	60	1
Nervous system disorders	Syncope	2	60	3
Nervous system disorders	Tingling of the fingers	1	60	1
Nervous system disorders	Vasovagal reaction	1	60	1
Nervous system disorders	Worsening of polyneuropathy	1	60	1
Nervous system disorders	Worsening polyneuropathy with pain	1	60	1
Psychiatric disorders	Agitation	3	60	3
Psychiatric disorders	Insomnia	4	60	4
Psychiatric disorders	Intermittent insomnia	2	60	4

Renal and urinary disorders	Chronic kidney disease	1	60	1
Respiratory, thoracic and mediastinal disorders	Bronchitis	1	60	1
Respiratory, thoracic and mediastinal disorders	Cough	1	60	1
Respiratory, thoracic and mediastinal disorders	Dyspnoe d'effort	1	60	1
Respiratory, thoracic and mediastinal disorders	Epistaxis	2	60	3
Respiratory, thoracic and mediastinal disorders	Exacerbation of Chronic obstructive pulmonary disease	1	60	1
Respiratory, thoracic and mediastinal disorders	Fatigue	1	60	1
Respiratory, thoracic and mediastinal disorders	Mucosal cough	1	60	1
Respiratory, thoracic and mediastinal disorders	Pleuritic pain	1	60	1
Respiratory, thoracic and mediastinal disorders	Pneumonia	1	60	1
Respiratory, thoracic and mediastinal disorders	Pneumonitis	1	60	1
Respiratory, thoracic and mediastinal disorders	Pulmonary infection	1	60	1
Respiratory, thoracic and mediastinal disorders	UPPER RESPIRATORY TRACT INFECTION	1	60	1
Skin and subcutaneous tissue disorders	Dermatose, M.Grover	1	60	1
Skin and subcutaneous tissue disorders	Dry skin	1	60	1
Skin and subcutaneous tissue disorders	Erythema palmare	1	60	1
Skin and subcutaneous tissue disorders	Infection feet fungal	1	60	1
Skin and subcutaneous tissue disorders	Intermittent rash	1	60	1
Skin and subcutaneous tissue disorders	Itch at limbs	1	60	1
Skin and subcutaneous tissue disorders	Itching at back	1	60	1
Skin and subcutaneous tissue disorders	Itchy intermittent	1	60	1
Skin and subcutaneous tissue disorders	Itchy sensation on the head	1	60	1
Skin and subcutaneous tissue disorders	Pruritus	2	60	2
Skin and subcutaneous tissue disorders	Rash / eczema	1	60	1
Skin and subcutaneous tissue disorders	Rash at limbs	1	60	1
Skin and subcutaneous tissue disorders	Rash infusion site	1	60	1
Skin and subcutaneous tissue disorders	Red local disclorouration of skin	1	60	1
Skin and subcutaneous tissue disorders	Rosacea	1	60	1
Skin and subcutaneous tissue disorders	Winter toes	1	60	1
Surgical and medical procedures	Other; tooth extraction	1	60	1
Vascular disorders	Claudication intermittens	1	60	1
Vascular disorders	Collaps	1	60	1
Vascular disorders	Deep Vein Thrombosis	1	60	1
Vascular disorders	Hypertension	1	60	1
Vascular disorders	Hypotension	2	60	2