

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

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

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		9	85	10
Blood and lymphatic system disorders	Hypokalemia		1	85	1
Blood and lymphatic system disorders	Neutrophil count decreased		3	85	4
Blood and lymphatic system disorders	Platelet count decreased		1	85	1
Blood and lymphatic system disorders	White blood cell decreased		3	85	3
Cardiac disorders	Atrial fibrillation		2	85	2
Cardiac disorders	Atrial fibrillation de novo		1	85	1
Cardiac disorders	Atrialfibrillation		1	85	1
Cardiac disorders	Cardiomyopathy		1	85	1
Cardiac disorders	Mitral valve disease		1	85	1
Cardiac disorders	Other: cardiac arrhythmias		1	85	1
Cardiac disorders	Tricuspidal valve disease		1	85	1
Ear and labyrinth disorders	Ear pain		1	85	1
Ear and labyrinth disorders	Hearing impaired		1	85	1
Ear and labyrinth disorders	Impaired hearing		1	85	1
Ear and labyrinth disorders	Tinnitus		2	85	2
Eye disorders	Cataract		1	85	1
Eye disorders	Conjunctivitis		1	85	1
Eye disorders	Other; vision impaired		1	85	1
Gastrointestinal disorders	Abdominal pain		2	85	2
Gastrointestinal disorders	Angular cheilitis		1	85	1
Gastrointestinal disorders	Constipation		1	85	1
Gastrointestinal disorders	Constipation		3	85	3
Gastrointestinal disorders	Diarrhea		6	85	6
Gastrointestinal disorders	Dyspepsia		3	85	3
Gastrointestinal disorders	Hemorrhoids		1	85	1
Gastrointestinal disorders	Mucositis		1	85	1
Gastrointestinal disorders	Mucositis (oral)		1	85	1
Gastrointestinal disorders	Mucositis oral		1	85	1
Gastrointestinal disorders	Nausea		5	85	6
Gastrointestinal disorders	Obstipatie		1	85	1
Gastrointestinal disorders	Obstipation		1	85	1
Gastrointestinal disorders	Oral mucositis		1	85	1
Gastrointestinal disorders	Other; mouth ulcers		1	85	1
Gastrointestinal disorders	Stomach pain		1	85	1
Gastrointestinal disorders	Vomiting		2	85	2
General disorders and administration site conditions	Fatigue		5	85	6
General disorders and administration site conditions	Fever		2	85	2
General disorders and administration site conditions	Flu like symptoms		2	85	2
General disorders and administration site conditions	Injection site pain		1	85	1
General disorders and administration site conditions	Injection site reaction thrombophlebitis		1	85	1
General disorders and administration site conditions	Non-cardiac chest pain		1	85	1
General disorders and administration site conditions	Other; influenza B		1	85	1
General disorders and administration site conditions	Pain		1	85	1
General disorders and administration site conditions	Pain right leg		1	85	1
Hepatobiliary disorders	Stenosis choledochus (compression from outside)		1	85	1
Infections and infestations	Bladder infection		1	85	1
Infections and infestations	Bronchial infection		1	85	1
Infections and infestations	Bursitis		1	85	1
Infections and infestations	HSV infection mouth		1	85	1
Infections and infestations	Hepatitis viral		1	85	1
Infections and infestations	Herpes simplwx reactivation		1	85	1
Infections and infestations	Infection lip		1	85	1
Infections and infestations	Infection mouth due to candida		1	85	1
Infections and infestations	Lip infection		1	85	1
Infections and infestations	Neutropenic gram-negative sepsis		1	85	1
Infections and infestations	Oral candida		1	85	1
Infections and infestations	Oral herpes		1	85	1
Infections and infestations	Oral infection		1	85	2
Infections and infestations	Other, mold tongue		1	85	1
Infections and infestations	Other: Hidradenitis suppurativa		1	85	1
Infections and infestations	Other: Jaw abscess		1	85	1
Infections and infestations	Other; candida infection labia		1	85	1
Infections and infestations	Other; candida infection orofaryngeaal		1	85	1
Infections and infestations	Pneumonia		2	85	2

Infections and infestations	Respiratory infection	1	85	1
Infections and infestations	Respiratory infection	2	85	2
Infections and infestations	Sinusitis	1	85	1
Infections and infestations	Skin infection	1	85	1
Infections and infestations	Skin infection	1	85	1
Infections and infestations	Tooth infection	1	85	1
Infections and infestations	Upper respiratory infection	1	85	1
Infections and infestations	Urinary tract infection	1	85	1
Infections and infestations	Urinarytract infection	1	85	1
Infections and infestations	Viral infection	1	85	1
Investigations	ALAT increased	1	85	1
Investigations	ALT increased	2	85	3
Investigations	ASAT increased	1	85	1
Investigations	AST increased	2	85	2
Investigations	Alanine aminotransferase increased	1	85	1
Investigations	Alkaline phosphatase	1	85	1
Investigations	Alkaline phosphatase increased	1	85	1
Investigations	Anemia	1	85	2
Investigations	Blood bilirubin increased	2	85	2
Investigations	GGT increased	2	85	3
Investigations	Gamma GT increased	1	85	1
Investigations	Neutropenia	2	85	2
Investigations	Neutropenia, neutrophil count decreased	1	85	1
Investigations	Neutrophil count decreased	8	85	20
Investigations	Platelet count decreased	6	85	8
Investigations	Thrombopenia	1	85	1
Investigations	Thrombopenia	1	85	1
Investigations	Weight loss	1	85	1
Investigations	White blood cell decreased	4	85	9
Investigations	White blood celll decreased	1	85	1
Investigations	White blood cells decreased	1	85	1
Metabolism and nutrition disorders	Anorexia	5	85	5
Metabolism and nutrition disorders	Hypocalcemia	1	85	1
Metabolism and nutrition disorders	Hypokalemia	4	85	5
Metabolism and nutrition disorders	Tumor lysis	1	85	1
Metabolism and nutrition disorders	Tumor lysis syndrome	1	85	1
Musculoskeletal and connective tissue disorders	Arthritis	1	85	1
Musculoskeletal and connective tissue disorders	Bacjk pain	1	85	1
Musculoskeletal and connective tissue disorders	Back pain due to vertebral collaps	1	85	1
Musculoskeletal and connective tissue disorders	Flank pain	1	85	1
Musculoskeletal and connective tissue disorders	Flank pain right	1	85	1
Musculoskeletal and connective tissue disorders	Neck pain	1	85	1
Musculoskeletal and connective tissue disorders	Oligoarthritis	1	85	1
Musculoskeletal and connective tissue disorders	Pain in extremity	1	85	1
Musculoskeletal and connective tissue disorders	Pain in leg	1	85	1
Musculoskeletal and connective tissue disorders	Spinal fracture	1	85	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neoplasms benign (cysts) temporal)	1	85	1
Nervous system disorders	Cognitive disturbance	1	85	1
Nervous system disorders	Dizziness	1	85	1
Nervous system disorders	Dysgeusia	1	85	1
Nervous system disorders	Headache	9	85	10
Nervous system disorders	Headache (after LP)	1	85	1
Nervous system disorders	Headache (post punction)	1	85	1
Nervous system disorders	Neuropathy	1	85	1
Nervous system disorders	Neuropathy-sensory	1	85	1
Nervous system disorders	Nuropathy-sensory	1	85	1
Nervous system disorders	Periferal sensory neuropathy	1	85	1
Nervous system disorders	Peripheral motor neuropathy	1	85	1
Nervous system disorders	Peripheral neuropathy sensory	1	85	1
Nervous system disorders	Peripheral sensory	1	85	1
Nervous system disorders	Peripheral sensory neuropathy	9	85	9
Nervous system disorders	Peripheral sensory neuropaty	1	85	1
Nervous system disorders	Polyneuropathy	2	85	2
Nervous system disorders	Polyneuropathy in fingers	1	85	1
Nervous system disorders	Syncope	1	85	1
Nervous system disorders	Vasovagal reaction	2	85	2
Psychiatric disorders	Anxiety	1	85	1
Renal and urinary disorders	Acute kidney injury	1	85	1
Renal and urinary disorders	Kidney injury	1	85	1
Renal and urinary disorders	Post renal obstruction	1	85	1
Renal and urinary disorders	Renal calculi	1	85	1
Renal and urinary disorders	Urinary tract infection	1	85	1
Reproductive system and breast disorders	Vaginal blood loss	1	85	1
Respiratory, thoracic and mediastinal disorders	Cough	1	85	1
Respiratory, thoracic and mediastinal disorders	Coughing	1	85	1
Respiratory, thoracic and mediastinal disorders	Dyspnea	2	85	2
Respiratory, thoracic and mediastinal disorders	Hoarseness	1	85	1
Respiratory, thoracic and mediastinal disorders	Productive cough	1	85	1

Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	1	85	1
Respiratory, thoracic and mediastinal disorders	Thoracic pressure	1	85	1
Respiratory, thoracic and mediastinal disorders	Voice alteration	1	85	1
Skin and subcutaneous tissue disorders	Alopecia	1	85	1
Skin and subcutaneous tissue disorders	Decubitus	1	85	1
Skin and subcutaneous tissue disorders	Rash	3	85	3
Skin and subcutaneous tissue disorders	Rash acneiform	1	85	1
Surgical and medical procedures	Polypectomy	1	85	1
Vascular disorders	DVT, thromboembolic event	1	85	1
Vascular disorders	Edema both legs	1	85	1
Vascular disorders	Hypertension	1	85	1
Vascular disorders	Hypotension	1	85	1
Vascular disorders	Other; lobar hemorrhage left	1	85	1
Vascular disorders	Phlebitis	1	85	1
Vascular disorders	Pulmonary embolism	1	85	1
Vascular disorders	Superficial thrombophlebitis	1	85	1
Vascular disorders	Thrombo phlebitis right arm	1	85	1
Vascular disorders	Thromboembolic event	2	85	2
Vascular disorders	Thrombophlebitis	1	85	1
Vascular disorders	Venous thrombosis	1	85	1