

***** 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 disorders	Anemia		5	57	6
Blood and lymphatic disorders	Creatinine elevation		1	57	1
Blood and lymphatic disorders	Edema		1	57	1
Blood and lymphatic disorders	Febrile neutropenia		7	57	7
Blood and lymphatic disorders	Hypoalbuminaemia		1	57	1
Blood and lymphatic disorders	Leukopenia		1	57	1
Blood and lymphatic disorders	Low Hemaglobine		1	57	1
Blood and lymphatic disorders	Low hemoglobine		1	57	1
Blood and lymphatic disorders	Low lymphocytes		1	57	1
Blood and lymphatic disorders	Mediastinal and hilar*		1	57	1
Blood and lymphatic disorders	Neutropenia		1	57	1
Blood and lymphatic disorders	Platelet count decreased*		1	57	1
Blood and lymphatic disorders	Thrombopenia		1	57	1
Cardiac disorders	Aterial fibrillation		1	57	1
Cardiac disorders	Atrial arrhythmia		1	57	1
Cardiac disorders	Atrial fibrillation		3	57	3
Cardiac disorders	Atypical thoracic *		1	57	1
Cardiac disorders	Bradycardia		1	57	1
Cardiac disorders	Chest pain(cardiac)		1	57	1
Cardiac disorders	Decompensatio cordis		1	57	1
Cardiac disorders	Decompensatio cordis(*)		1	57	1
Cardiac disorders	Decompesatio cordis		1	57	1
Cardiac disorders	Dicompensatio cordis		1	57	1
Cardiac disorders	Heart failure		2	57	2
Cardiac disorders	Heart palpitations		1	57	1
Cardiac disorders	Orthostatism		1	57	1
Cardiac disorders	Palpitations		1	57	1
Cardiac disorders	Right + left ventricular		1	57	1
Cardiac disorders	Sinus tachycardia		1	57	1
Cardiac disorders	Ventricular arrhythmia		1	57	1
Cardiac disorders	Ventricular tachycardia*		1	57	1
Eye disorders	Bleeding eye		1	57	1
Eye disorders	Blepharitis		1	57	1
Eye disorders	Blepharitis left eye		1	57	1
Eye disorders	Blurred vision		1	57	1
Eye disorders	Burning eyes		1	57	1
Eye disorders	Conjunctival haemorrhage		1	57	2
Eye disorders	Subconjunctival hemorrhag		1	57	1
Gastrointestinal disorders	Abdominal pain		2	57	2
Gastrointestinal disorders	Acute esophageal necrosis		1	57	1
Gastrointestinal disorders	Ascites		2	57	3
Gastrointestinal disorders	Ascites, drainage not nee		1	57	1
Gastrointestinal disorders	Ascitis abdomen		1	57	1
Gastrointestinal disorders	Bleeding/other: blood *		1	57	1
Gastrointestinal disorders	Bloating		1	57	1
Gastrointestinal disorders	Colitis (CMV)		1	57	1
Gastrointestinal disorders	Colitis (mucositis)		1	57	1
Gastrointestinal disorders	Constipation		11	57	12
Gastrointestinal disorders	Diarrea		1	57	1
Gastrointestinal disorders	Diarrhea		15	57	20
Gastrointestinal disorders	Diarrhea(+melena)		1	57	1
Gastrointestinal disorders	Dysfagia		1	57	1
Gastrointestinal disorders	Dyspepsia		1	57	1
Gastrointestinal disorders	Gastritis		1	57	1
Gastrointestinal disorders	Gastroparese		1	57	1
Gastrointestinal disorders	Heartburn		1	57	1

Gastrointestinal disorders	Hemorrhoids	1	57	1
Gastrointestinal disorders	Ileus	1	57	1
Gastrointestinal disorders	Mucositis	12	57	12
Gastrointestinal disorders	Mucositis (diarrhea)	1	57	1
Gastrointestinal disorders	Mucositis oral	2	57	2
Gastrointestinal disorders	Mucositis (diarrhea)	1	57	1
Gastrointestinal disorders	Mucositis (oral/pharynx)	1	57	1
Gastrointestinal disorders	Nausea	1	57	1
Gastrointestinal disorders	Neuro-constipation	1	57	1
Gastrointestinal disorders	Other: mallory-Weiss *	1	57	1
Gastrointestinal disorders	Pain in epistrio	1	57	1
Gastrointestinal disorders	Rectal hemorrhage	2	57	2
Gastrointestinal disorders	Taste disturbance	1	57	1
Gastrointestinal disorders	Vomiting	1	57	1
General disorders and administration site conditions	Common cold	1	57	1
General disorders and administration site conditions	Diverticulitis	1	57	1
General disorders and administration site conditions	Dizziness	1	57	1
General disorders and administration site conditions	Dyspnea,edema related	1	57	1
General disorders and administration site conditions	Edema	6	57	7
General disorders and administration site conditions	Edema (Dexa reduced)	1	57	1
General disorders and administration site conditions	Edema -> diurectics iv	1	57	1
General disorders and administration site conditions	Edema back	1	57	1
General disorders and administration site conditions	Edema legs	1	57	1
General disorders and administration site conditions	Edema legs and trunk	1	57	1
General disorders and administration site conditions	Edema limbs	5	57	6
General disorders and administration site conditions	Edema limbs (*)	1	57	1
General disorders and administration site conditions	Edema limbs (gr.1 to gr.2	1	57	1
General disorders and administration site conditions	Edema limos	1	57	1
General disorders and administration site conditions	Fatigue	8	57	9
General disorders and administration site conditions	Fatigue	6	57	6
General disorders and administration site conditions	Feu-eike symptoms	1	57	1
General disorders and administration site conditions	Fever	1	57	1
General disorders and administration site conditions	General deterioration	1	57	1
General disorders and administration site conditions	General malaise	1	57	1
General disorders and administration site conditions	Hematemesis *	1	57	1
General disorders and administration site conditions	Hyperhydratation	1	57	1
General disorders and administration site conditions	Hyperhydration	1	57	1
General disorders and administration site conditions	Malaise	3	57	3
General disorders and administration site conditions	Oedema	1	57	1
General disorders and administration site conditions	Poor condition*	1	57	1
General disorders and administration site conditions	Worsening edema	1	57	1
Hepatobiliary disorders	Ascites	1	57	1
Hepatobiliary disorders	Complaints liver	1	57	1
Immune system disorders	Cytokine release syndrome	1	57	1
Infections and infestations	Bacteremia	1	57	3
Infections and infestations	Bacteremia*	1	57	1
Infections and infestations	Bronchial infection	1	57	1
Infections and infestations	Candida mouth	1	57	1
Infections and infestations	Candidosis oral	1	57	1
Infections and infestations	Cold sores	1	57	1
Infections and infestations	Conjunctivitis	1	57	1
Infections and infestations	Fungal infection groins	1	57	1
Infections and infestations	Gastro intestinal infecti	1	57	1
Infections and infestations	Gastro intestinal*	1	57	1
Infections and infestations	HSV - infection	1	57	1
Infections and infestations	Herpes simplex infection	1	57	1
Infections and infestations	Herpes simplex virus	1	57	1
Infections and infestations	Infection	2	57	2
Infections and infestations	Infection - herpes *	1	57	1
Infections and infestations	Infection campylobacker	1	57	2
Infections and infestations	Infection erysipelas*	1	57	1
Infections and infestations	Infection line (infuus)	1	57	1
Infections and infestations	Infection nos	1	57	1
Infections and infestations	Infection upper jaw	1	57	1
Infections and infestations	Infection-pneumonia	1	57	1
Infections and infestations	Influenza	1	57	1
Infections and infestations	Neutropenic fever	3	57	3
Infections and infestations	Neutropenic virus	1	57	1
Infections and infestations	Oropharynx infec.candidia	1	57	1

Infections and infestations	Other: herpes simplex *	1	57	1
Infections and infestations	Pneumonia	1	57	1
Infections and infestations	Positive blood culture	1	57	1
Infections and infestations	Pulmonary infection	1	57	1
Infections and infestations	Respiratory tract infecti	1	57	1
Infections and infestations	Streptococcus *	1	57	1
Infections and infestations	Upper respiratory tract*	1	57	1
Infections and infestations	Urinary tract infection	1	57	1
Infections and infestations	Varicella zoster*	1	57	1
Injury, poisoning and procedural complications	Fall	1	57	1
Investigations	AF increased	1	57	1
Investigations	ALAT increase	1	57	2
Investigations	ALAT increased	4	57	6
Investigations	ASAT increased	2	57	2
Investigations	Alat ^	1	57	1
Investigations	Asat ^	1	57	1
Investigations	Asat increase	1	57	1
Investigations	Asat increased	1	57	1
Investigations	Billirubin increased	1	57	1
Investigations	Cholesterol high	1	57	1
Investigations	GGT increase (grade 3 *	1	57	1
Investigations	GGT increased	6	57	6
Investigations	GGT-increased	1	57	1
Investigations	Gamma GT increase	1	57	1
Investigations	Gamma GT increased	1	57	1
Investigations	Increase GGT	1	57	2
Investigations	Increase alkaline phospho	1	57	1
Investigations	Increased GGT	1	57	1
Investigations	JGT increase *	1	57	1
Investigations	Leucopenia	3	57	4
Investigations	Leukopenia	1	57	1
Investigations	Low hemoglobine (anemia)	1	57	1
Investigations	Neutropenia	3	57	3
Investigations	Platelet count decreased	1	57	1
Investigations	Thrombopenia	4	57	4
Investigations	Weight loss	4	57	4
Metabolism and nutrition disorders	Anorexia	19	57	21
Metabolism and nutrition disorders	Anorexia -> TPN	1	57	1
Metabolism and nutrition disorders	Anorexia -> nutridrink*	1	57	1
Metabolism and nutrition disorders	Cushing	1	57	1
Metabolism and nutrition disorders	Hypcalcemia	1	57	1
Metabolism and nutrition disorders	Hyperglycemia	3	57	3
Metabolism and nutrition disorders	Hyperkalemia	1	57	1
Metabolism and nutrition disorders	Hypernatremia	3	57	4
Metabolism and nutrition disorders	Hypo albuminemia	4	57	4
Metabolism and nutrition disorders	Hypo calcemia	1	57	1
Metabolism and nutrition disorders	Hypoalbuminemia	2	57	2
Metabolism and nutrition disorders	Hypocalcemia	3	57	3
Metabolism and nutrition disorders	Hypokalemia	7	57	11
Metabolism and nutrition disorders	Hypokalemia (2nd episode)	1	57	1
Metabolism and nutrition disorders	Hypokalemia (1st episode)	1	57	1
Metabolism and nutrition disorders	Hyponatremia	5	57	5
Metabolism and nutrition disorders	Hypophosphatemia	2	57	2
Musculoskeletal and connective tissue disorders	Back pain	1	57	1
Musculoskeletal and connective tissue disorders	Back pain intermittent	1	57	1
Musculoskeletal and connective tissue disorders	Bone Pain	1	57	1
Musculoskeletal and connective tissue disorders	Bone pain(*)	1	57	1
Musculoskeletal and connective tissue disorders	Joint pain	1	57	1
Musculoskeletal and connective tissue disorders	Muscle wakness arm	1	57	1
Musculoskeletal and connective tissue disorders	Myalgia legs	1	57	1
Musculoskeletal and connective tissue disorders	Myopathy	2	57	2
Musculoskeletal and connective tissue disorders	Myopathy (muscle weakness	1	57	1
Musculoskeletal and connective tissue disorders	Tendinitis	1	57	1
Neoplasms benign, malignant and unspecified	Chondrotumour	1	57	1
Neoplasms benign, malignant and unspecified	Neoplasma malignant *	1	57	1
Nervous system disorders	Ataxia	1	57	1
Nervous system disorders	Autonomic neuropathy	2	57	2
Nervous system disorders	Benigne *	1	57	1
Nervous system disorders	Collapse	1	57	1

Nervous system disorders	Constipation	1	57	1
Nervous system disorders	Dizziness	2	57	2
Nervous system disorders	Insomnia	1	57	1
Nervous system disorders	Neuropathic pain	5	57	6
Nervous system disorders	Neuropathy	2	57	2
Nervous system disorders	Neuropathy - sensory	3	57	3
Nervous system disorders	Neuropathy - sensory/ *	1	57	1
Nervous system disorders	Neuropathy -sensory	1	57	1
Nervous system disorders	Neuropathy motory	1	57	1
Nervous system disorders	Neuropathy sensory	2	57	3
Nervous system disorders	Neuropathy-sensory	1	57	2
Nervous system disorders	Neuropatic pain	1	57	1
Nervous system disorders	Orthostatic collapse	1	57	1
Nervous system disorders	PNP	2	57	2
Nervous system disorders	PNP arms	1	57	1
Nervous system disorders	PNP legs	1	57	1
Nervous system disorders	Paresthesia *	1	57	1
Nervous system disorders	Paresthesia/*	1	57	1
Nervous system disorders	Peripheral motor neuropat	1	57	1
Nervous system disorders	Peripheral neuropathy	1	57	1
Nervous system disorders	Peripheral sensory	1	57	2
Nervous system disorders	Peripheral sensory *	4	57	5
Nervous system disorders	Peripheral sensory neurop	1	57	1
Nervous system disorders	Peripheral sensory*	4	57	5
Nervous system disorders	Polyneuropathy	2	57	4
Nervous system disorders	Polyneuropathy sensory	1	57	1
Nervous system disorders	Restless legs intermitten	1	57	1
Nervous system disorders	Sensomotoric polyneuropat	1	57	1
Nervous system disorders	Sensory polyneuro feet	1	57	1
Nervous system disorders	Somnolence	1	57	1
Nervous system disorders	Syncope	1	57	1
Nervous system disorders	Syncope/orthosatic*	1	57	1
Nervous system disorders	Tingling fingers	1	57	1
Psychiatric disorders	Delirium	2	57	2
Psychiatric disorders	Depression	1	57	1
Psychiatric disorders	Insomnia	8	57	8
Psychiatric disorders	Psychoses	1	57	1
Psychiatric disorders	Restlessness(legs)	1	57	1
Psychiatric disorders	Worrying	1	57	1
Renal and urinary disorders	Acute kidney injury	1	57	1
Renal and urinary disorders	Chronic kidney disease *	1	57	1
Renal and urinary disorders	Chronic kidney disease*	1	57	1
Renal and urinary disorders	Hematuria	1	57	2
Renal and urinary disorders	Kidney disease *	1	57	1
Renal and urinary disorders	Renal failure	1	57	1
Renal and urinary disorders	Urinary retention	1	57	1
Reproductive system and breast disorders	Erectile dysfunction	1	57	1
Respiratory, thoracic and mediastinal disorders	Cold attended with fever	1	57	1
Respiratory, thoracic and mediastinal disorders	Cough	1	57	1
Respiratory, thoracic and mediastinal disorders	Dyspnea	1	57	1
Respiratory, thoracic and mediastinal disorders	Dyspnea	5	57	6
Respiratory, thoracic and mediastinal disorders	Dyspnea d'effort	1	57	1
Respiratory, thoracic and mediastinal disorders	Epistaxis	1	57	1
Respiratory, thoracic and mediastinal disorders	Hiccups	1	57	1
Respiratory, thoracic and mediastinal disorders	Pleural effusion	3	57	3
Respiratory, thoracic and mediastinal disorders	Pneumonitis	1	57	1
Respiratory, thoracic and mediastinal disorders	Pneumonia	1	57	1
Respiratory, thoracic and mediastinal disorders	Pneumonia (possible)	1	57	1
Respiratory, thoracic and mediastinal disorders	Pneumonia aspergillosis	1	57	1
Respiratory, thoracic and mediastinal disorders	Pulmonary edema	1	57	1
Skin and subcutaneous tissue disorders	Blistering bulleuze *	1	57	1
Skin and subcutaneous tissue disorders	Erythroderma	1	57	1
Skin and subcutaneous tissue disorders	Exanthema	1	57	1
Skin and subcutaneous tissue disorders	Infection sirte reaction	1	57	1
Skin and subcutaneous tissue disorders	Inject site react Fragmin	1	57	1
Skin and subcutaneous tissue disorders	Inject.site react Fragmin	1	57	1
Skin and subcutaneous tissue disorders	Injection site reaction	1	57	1
Skin and subcutaneous tissue disorders	Injection site reaction *	1	57	1
Skin and subcutaneous tissue disorders	Injection site reaction*	1	57	1

Skin and subcutaneous tissue disorders	Other, superficial *	1	57	1
Skin and subcutaneous tissue disorders	Purpura *	1	57	1
Skin and subcutaneous tissue disorders	Purpura hands	1	57	1
Skin and subcutaneous tissue disorders	Rash	3	57	3
Skin and subcutaneous tissue disorders	Rash (livedo)	1	57	1
Skin and subcutaneous tissue disorders	Rash maculo-papular	1	57	1
Skin and subcutaneous tissue disorders	Rash, exanthema	1	57	1
Skin and subcutaneous tissue disorders	Toxicodermi (pruritus)	1	57	1
Vascular disorders	Collapse	1	57	1
Vascular disorders	Hematoma (raccoon eyes)	1	57	1
Vascular disorders	Hypotension (*)	1	57	1
Vascular disorders	Hypotensia	1	57	1
Vascular disorders	Hypotension	5	57	5
Vascular disorders	Lymphedema	1	57	1
Vascular disorders	Oedema	1	57	1
Vascular disorders	Orthostatic hypotension	6	57	7
Vascular disorders	Thromboembolic *	1	57	1
Vascular disorders	Thrombosis	1	57	1