

***** 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		33	61	61
Blood and lymphatic system disorders	Febrile Neutropenia		2	61	2
Blood and lymphatic system disorders	Febrile neutropenia		9	61	9
Blood and lymphatic system disorders	Hemolysis		3	61	3
Blood and lymphatic system disorders	Hemolytic uremic syndrome		1	61	1
Blood and lymphatic system disorders	Neutropenic fever		1	61	1
Blood and lymphatic system disorders	Thrombocytopenic microangiopathy		1	61	1
Cardiac disorders	Bradycardia		1	61	1
Cardiac disorders	Heart failure		1	61	1
Cardiac disorders	Paroximal atrial fibrillation		1	61	1
Cardiac disorders	Paroxysmal atrial tachycardia		1	61	1
Cardiac disorders	Sinus Tachycardia		2	61	2
Cardiac disorders	Sinus bradycardia		1	61	1
Cardiac disorders	Sinus tachycardia		2	61	2
Ear and labyrinth disorders	Hearing impaired		1	61	1
Ear and labyrinth disorders	Pain ears		1	61	1
Eye disorders	Conjunctivitis		1	61	1
Eye disorders	Eye infection		1	61	1
Eye disorders	Flashing lights		1	61	1
Eye disorders	Retinal Vascular Disorder		1	61	1
Gastrointestinal disorders	Abdominal pain		2	61	2
Gastrointestinal disorders	Ascites		1	61	1
Gastrointestinal disorders	Constipation		3	61	3
Gastrointestinal disorders	Diarrhea		12	61	13
Gastrointestinal disorders	Gastric pain		1	61	1
Gastrointestinal disorders	Gastroesophageal reflux disease		1	61	1
Gastrointestinal disorders	Hemorrhoids		1	61	1
Gastrointestinal disorders	Mucositis		5	61	5
Gastrointestinal disorders	Mucositis mouth		1	61	1
Gastrointestinal disorders	Mucositis oral		5	61	5
Gastrointestinal disorders	Nausea		6	61	7
Gastrointestinal disorders	Nausea intermittent		1	61	1
Gastrointestinal disorders	Other; stomatitis		1	61	1
Gastrointestinal disorders	Vomitting		1	61	1
General disorders and administration site conditions	Chills		1	61	1
General disorders and administration site conditions	Edema		1	61	1
General disorders and administration site conditions	Fatigue		10	61	10
General disorders and administration site conditions	Fever		9	61	9
General disorders and administration site conditions	Infusion related reaction		7	61	7
General disorders and administration site conditions	Infusion related reaction (ATG)		1	61	1
General disorders and administration site conditions	Localised edema ; papil		1	61	1
General disorders and administration site conditions	Malaise		2	61	2
General disorders and administration site conditions	Other; condition worsened		1	61	1
General disorders and administration site conditions	Pain		1	61	1
General disorders and administration site conditions	Pain spleen		1	61	1
Hepatobiliary disorders	Cholecystitis		1	61	1
Hepatobiliary disorders	Hepatic Failure		1	61	1
Immune system disorders	Anaphylaxis		1	61	1
Immune system disorders	Cytokine release syndrome		1	61	1
Infections and infestations	Adenovirus infection		1	61	1
Infections and infestations	Bladder infection		1	61	1
Infections and infestations	Catheter related infection		5	61	6
Infections and infestations	Cystitis (E.coli Positive		1	61	1
Infections and infestations	Eye infection (blefaritis)		1	61	1
Infections and infestations	HSV infection mouth		1	61	1
Infections and infestations	Hepatic infection		1	61	1
Infections and infestations	Infection eye		1	61	1
Infections and infestations	Infection muscle		1	61	1
Infections and infestations	Joint infection		1	61	1
Infections and infestations	Lip infection		1	61	1
Infections and infestations	Mucosal infection		1	61	1
Infections and infestations	Other HSV2 infection labia		1	61	1

Infections and infestations	Other; infection mouth	1	61	1
Infections and infestations	Other; rsv infection	1	61	1
Infections and infestations	Pneumonia	1	61	1
Infections and infestations	Pulmonal infection	1	61	1
Infections and infestations	Red, Painfull, Sore left forearm	1	61	1
Infections and infestations	Tooth infection	1	61	1
Infections and infestations	Upper respiratory infection	3	61	3
Infections and infestations	Urinary tract infection	1	61	1
Injury, poisoning and procedural complications	Infusion related reactie	1	61	1
Injury, poisoning and procedural complications	Infusion related reaction	1	61	1
Investigations	Alanine aminotranferase increased	1	61	1
Investigations	Alanine aminotransferase increased	13	61	19
Investigations	Alanine transaminase increased	2	61	2
Investigations	Alkaline fosfatase increased	2	61	2
Investigations	Alkaline phosphatase increased	2	61	2
Investigations	Anemia	1	61	1
Investigations	Asparate aminotransferase increased	1	61	1
Investigations	Aspartase aminotransferase increased	1	61	1
Investigations	Aspartate aminotransferase increased	7	61	10
Investigations	Bilirubin increased	3	61	4
Investigations	Bilirubine increased	1	61	1
Investigations	Bilurubine increased	1	61	1
Investigations	Blood Bilirubin increased	1	61	1
Investigations	Blood biliribin increased	1	61	1
Investigations	Blood bilirubin increased	8	61	8
Investigations	Blood bilirubine increased	2	61	2
Investigations	CPK Increased	1	61	1
Investigations	Creatinin increased	1	61	1
Investigations	Creatinine increased	8	61	9
Investigations	Creatinine increased intermittend	1	61	1
Investigations	GGT increased	14	61	21
Investigations	Gamma Gt increased	2	61	2
Investigations	Gamma gt increased	2	61	5
Investigations	Ggt increased	2	61	3
Investigations	Increased creatinine	1	61	1
Investigations	Leucopenia	1	61	1
Investigations	Lymphocyte count decreased	2	61	2
Investigations	Neurophile count decreased	1	61	1
Investigations	Neutropenia	1	61	1
Investigations	Neutrophil Count Decreased intermittend	1	61	1
Investigations	Neutrophil count decreased	17	61	34
Investigations	Neutrophile count decerased	1	61	1
Investigations	Neutrophile count decreased	17	61	33
Investigations	Other; folic acid increased	1	61	1
Investigations	Platelet Count Decreased	1	61	1
Investigations	Platelet Count decreased	1	61	1
Investigations	Platelet count Decreased	1	61	2
Investigations	Platelet count cecreased	1	61	1
Investigations	Platelet count decreased	36	61	82
Investigations	Platelet cpount decreased	1	61	1
Investigations	Plateletcount decreased	1	61	1
Investigations	Thrombocytopenia	1	61	1
Investigations	Trombocytopenia	1	61	1
Investigations	Weight loss	5	61	6
Investigations	White blood cell count decreased	6	61	7
Investigations	White blood cell decrease	3	61	8
Investigations	White blood cell decreased	8	61	14
Investigations	White blood cells decreased	5	61	9
Investigations	White blood count decreased	1	61	2
Investigations	White bloodcell count decreased	2	61	2
Investigations	White bloodcell decreased	3	61	3
Investigations	White bloodcells decreased	8	61	14
Investigations	White cells decreased	1	61	1
Metabolism and nutrition disorders	Acidosis	1	61	1
Metabolism and nutrition disorders	Anorexia	5	61	6
Metabolism and nutrition disorders	Glucose intolerance	3	61	4
Metabolism and nutrition disorders	Hyperglycemia	3	61	3
Metabolism and nutrition disorders	Hyperkalemia	4	61	5
Metabolism and nutrition disorders	Hypervolemia intermittent	1	61	1
Metabolism and nutrition disorders	Hypokalemia	1	61	1
Metabolism and nutrition disorders	Hypomagnesemia	1	61	1
Musculoskeletal and connective tissue disorders	Arthritis	1	61	1
Musculoskeletal and connective tissue disorders	Arthritis feet	1	61	1
Musculoskeletal and connective tissue disorders	Generalized muscle weakness	1	61	1
Musculoskeletal and connective tissue disorders	Myalgia	1	61	1

Musculoskeletal and connective tissue disorders	Other ; muscle cramps	1	61	1
Musculoskeletal and connective tissue disorders	Other: joint pain knees	1	61	1
Musculoskeletal and connective tissue disorders	Pain upperlegs	1	61	1
Neoplasms benign, malignant and unspecified (including cysts and polyp	Polyps	1	61	1
Nervous system disorders	Ataxia	1	61	1
Nervous system disorders	Depressed level of consciousness	1	61	1
Nervous system disorders	Dizziness	1	61	1
Nervous system disorders	Headache	6	61	7
Nervous system disorders	Peripheral motor neuropathy	1	61	1
Nervous system disorders	Syncope	1	61	1
Nervous system disorders	Tremor	1	61	1
Nervous system disorders	Vasovagal reaction	1	61	1
Psychiatric disorders	Agitation	1	61	1
Psychiatric disorders	Psychiatric disorders - Other, specify (emotional distress)	2	61	2
Renal and urinary disorders	Acute kidney injury	1	61	1
Renal and urinary disorders	Chronic kidney disease	2	61	4
Renal and urinary disorders	Renal tubulair acidosis	1	61	1
Renal and urinary disorders	Urinary Tract Infection: Klebsiella Pneumoniae - Proteus Mirabilis	1	61	1
Renal and urinary disorders	Urinary Tract Infection: Pyuria	1	61	1
Respiratory, thoracic and mediastinal disorders	Dyspnea	1	61	1
Respiratory, thoracic and mediastinal disorders	Epistaxis	2	61	2
Respiratory, thoracic and mediastinal disorders	Hypoxia	3	61	3
Skin and subcutaneous tissue disorders	Cold Sore	1	61	1
Skin and subcutaneous tissue disorders	Hyperpigmentation	1	61	1
Skin and subcutaneous tissue disorders	Rash head	1	61	1
Vascular disorders	Eyenerveinfarct (NAION	1	61	1
Vascular disorders	Hydrocoele left testis	1	61	1
Vascular disorders	Hypertension	10	61	11
Vascular disorders	Hypotension	3	61	3