

***** 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		3	110	3
Blood and lymphatic system disorders	Disseminated intravascular coagulation		1	110	1
Blood and lymphatic system disorders	Febrile neutropenia		29	110	32
Blood and lymphatic system disorders	Neutropenic fever		3	110	3
Blood and lymphatic system disorders	Overall edema		1	110	1
Blood and lymphatic system disorders	Relapse		1	110	1
Cardiac disorders	Atrial fibrillation		2	110	2
Cardiac disorders	Atriumfibrillation		1	110	1
Cardiac disorders	Bradycard		1	110	1
Cardiac disorders	Decompensatio cordis		2	110	2
Cardiac disorders	Decomptensatio cordis		1	110	1
Cardiac disorders	Hypertension		4	110	4
Cardiac disorders	Pericard effusion		1	110	1
Cardiac disorders	Systolic souffle		1	110	1
Cardiac disorders	Tachycardia		1	110	1
Ear and labyrinth disorders	Otitis		1	110	1
Endocrine disorders	Hyperthyroidism		1	110	1
Endocrine disorders	Hypothyroidism		1	110	1
Eye disorders	Dry eye		1	110	1
Eye disorders	Dry eyes		3	110	3
Eye disorders	GVH uveitis anterior ODS		1	110	1
Gastrointestinal disorders	Abdominal cramps		1	110	1
Gastrointestinal disorders	Anorexia		2	110	2
Gastrointestinal disorders	Bleeding stomach		1	110	1
Gastrointestinal disorders	Constipation		1	110	1
Gastrointestinal disorders	Diarrhea		11	110	11
Gastrointestinal disorders	Diarrhea (episodal)		1	110	1
Gastrointestinal disorders	Diarrhea GVH		1	110	1
Gastrointestinal disorders	Dry mouth		1	110	1
Gastrointestinal disorders	Enterocolitis		1	110	1
Gastrointestinal disorders	Esophagitis		1	110	1
Gastrointestinal disorders	Fecal incontinence		1	110	1
Gastrointestinal disorders	Fissura ani		1	110	1
Gastrointestinal disorders	Gastrointestinal pain		1	110	1
Gastrointestinal disorders	Hemorrhoids		1	110	1
Gastrointestinal disorders	Intestinal mucositis		1	110	1
Gastrointestinal disorders	Mucosal infection		1	110	1
Gastrointestinal disorders	Mucositis		1	110	1
Gastrointestinal disorders	Mucositis mouth		1	110	1
Gastrointestinal disorders	Mucositis small intestine		1	110	1
Gastrointestinal disorders	Nausea		3	110	3
Gastrointestinal disorders	Nausea		1	110	1
Gastrointestinal disorders	Obstipation		1	110	1
Gastrointestinal disorders	Odynofagie		1	110	1
Gastrointestinal disorders	Oesophagitis		1	110	1
Gastrointestinal disorders	Oral mucositis		1	110	1
Gastrointestinal disorders	Pyrosis		3	110	3
Gastrointestinal disorders	Rectal hemorrhoids		1	110	1
Gastrointestinal disorders	Stomach pain		1	110	1
Gastrointestinal disorders	Vomiting		3	110	3
Gastrointestinal disorders	Weight loss		2	110	2
General disorders and administration site conditions	Edema both legs		1	110	1
General disorders and administration site conditions	Edema limbs		2	110	2
General disorders and administration site conditions	Fatigue		6	110	6
General disorders and administration site conditions	Fatigue		3	110	3
General disorders and administration site conditions	Fever		2	110	2
General disorders and administration site conditions	General malaisia		2	110	2
General disorders and administration site conditions	Injection site reaction		1	110	1
General disorders and administration site conditions	Insomnia		1	110	1
General disorders and administration site conditions	Malaise		2	110	2
General disorders and administration site conditions	Pain (legs/heels)		1	110	1
General disorders and administration site conditions	Pain joints		1	110	1
General disorders and administration site conditions	Weightloss		1	110	1
Hepatobiliary disorders	Cholecystitis		1	110	1
Hepatobiliary disorders	Liverchemy		1	110	1

Infections and infestations	Aspargillus infection lung	1	110	1
Infections and infestations	CMV reactivation	12	110	13
Infections and infestations	CMV reactivation with no signs or symptoms of CMV disease	1	110	1
Infections and infestations	Candida esophagus	1	110	1
Infections and infestations	Catheter related	1	110	1
Infections and infestations	Catheter related infection	1	110	1
Infections and infestations	Candida albicans vaginal	1	110	1
Infections and infestations	Cystitis	1	110	1
Infections and infestations	Enterococ faecialis	1	110	1
Infections and infestations	Enterococcus faecalis infection in BAL fluid	1	110	1
Infections and infestations	Flebitis	1	110	1
Infections and infestations	Flebitis arm	1	110	1
Infections and infestations	Hepatitis E infection	1	110	1
Infections and infestations	Infection GI	3	110	3
Infections and infestations	Infection airway	1	110	1
Infections and infestations	Infection airway RS virus	1	110	1
Infections and infestations	Infection catheter related	13	110	15
Infections and infestations	Infection lung	3	110	3
Infections and infestations	Infection mouth	1	110	1
Infections and infestations	Infection nose	1	110	1
Infections and infestations	Infection upper airway	5	110	5
Infections and infestations	Infection urinary tract	2	110	2
Infections and infestations	Infection; pulmonary aspergillosis	1	110	2
Infections and infestations	Influenza A	1	110	1
Infections and infestations	Influenza B infection	1	110	1
Infections and infestations	Other parainfluenza	1	110	1
Infections and infestations	Other; enterococcus faecium	1	110	1
Infections and infestations	Other; influenza A	1	110	1
Infections and infestations	Other; influenza B	1	110	1
Infections and infestations	Para influenza type 3	1	110	1
Infections and infestations	Parainfluenza 3	1	110	1
Infections and infestations	Parainfluenza virus 3	1	110	1
Infections and infestations	Pharyngitis	1	110	1
Infections and infestations	Pneumonia	1	110	1
Infections and infestations	Proctitis	1	110	1
Infections and infestations	Rhinitis infective	1	110	1
Infections and infestations	Sepsis	1	110	1
Infections and infestations	Sinusitis	1	110	1
Infections and infestations	Staph .epider CVL	1	110	1
Infections and infestations	Staphylococcus epidermis infection in blood	1	110	1
Infections and infestations	Throat infection (Candida)	1	110	1
Infections and infestations	Upper respiratory infection	2	110	2
Infections and infestations	Urinary tract infection	4	110	5
Infections and infestations	Viral infection	1	110	1
Injury, poisoning and procedural complications	Vascular access complication	1	110	1
Injury, poisoning and procedural complications	Vascular acces complication	1	110	1
Investigations	ALT	1	110	2
Investigations	ALT increased	4	110	4
Investigations	AST	1	110	1
Investigations	AST increased	1	110	1
Investigations	Alk fosf increased	1	110	1
Investigations	Alkaline phosphatase	1	110	1
Investigations	Alkaline phospahtase increased	1	110	1
Investigations	Alkaline phosphatase increased	2	110	2
Investigations	Bilirubin increased	2	110	2
Investigations	Bilirubine increased	1	110	1
Investigations	Blood bilirubin increased	5	110	8
Investigations	Creatinine increased	10	110	12
Investigations	Eosinophilia	1	110	1
Investigations	GGT	1	110	2
Investigations	GGT increased	3	110	4
Investigations	Hyperbilirubin	1	110	2
Investigations	Hyperkalemia	3	110	4
Investigations	Hypoalbumania	1	110	1
Investigations	Hypokalemia	1	110	1
Investigations	Hypomagnesemia	2	110	2
Investigations	Hyponatremia	1	110	1
Investigations	Increased GGT	1	110	1
Investigations	Increased creatinine	12	110	13
Investigations	Increased kidney parameters	1	110	1
Investigations	Increased liverenzymes	8	110	9
Investigations	Increased livertests	1	110	1
Investigations	Increased livertests GVH	1	110	1
Investigations	Platelet count decreased	2	110	3
Investigations	Platetelet count decreased	1	110	1
Investigations	Weight loss	3	110	4
Investigations	Weightloss	2	110	2
Investigations	White blood cell decreased	1	110	1

Metabolism and nutrition disorders	Anorexia	2	110	2
Metabolism and nutrition disorders	Hyperglycemia	1	110	1
Metabolism and nutrition disorders	Hyperkalemia	2	110	2
Metabolism and nutrition disorders	Hypoalbuminemia	1	110	1
Metabolism and nutrition disorders	Hypokalemia	7	110	8
Metabolism and nutrition disorders	Hypomagnesemia	9	110	9
Metabolism and nutrition disorders	Hypomagnesia	2	110	2
Metabolism and nutrition disorders	Hyponatremia	2	110	2
Metabolism and nutrition disorders	Hypophosphatemia	1	110	1
Metabolism and nutrition disorders	Iron overload	1	110	1
Metabolism and nutrition disorders	Metabolic acidosis	1	110	1
Metabolism and nutrition disorders	Weight loss	1	110	1
Musculoskeletal and connective tissue disorders	Achillodynie	1	110	1
Musculoskeletal and connective tissue disorders	Arthralgia	1	110	1
Musculoskeletal and connective tissue disorders	Arthritis	1	110	1
Musculoskeletal and connective tissue disorders	Buttock pain	1	110	1
Musculoskeletal and connective tissue disorders	Myalgia knees	1	110	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benigne prostatic hyperplasia	1	110	1
Nervous system disorders	Carpal tunnel syndrome	1	110	1
Nervous system disorders	Collaps	1	110	1
Nervous system disorders	Delerium	2	110	2
Nervous system disorders	Dizziness	1	110	1
Nervous system disorders	Dizzyness	1	110	1
Nervous system disorders	Gegeneralised epileptic insult	1	110	1
Nervous system disorders	Headache	6	110	6
Nervous system disorders	Hiccough	1	110	1
Nervous system disorders	PNP	1	110	1
Nervous system disorders	Polyneuropathy hands and feet	1	110	1
Nervous system disorders	Syncope, orthostatic collaps	1	110	1
Nervous system disorders	Tremor	1	110	1
Psychiatric disorders	Anxiety	1	110	1
Psychiatric disorders	Delirium	1	110	1
Psychiatric disorders	Depression	1	110	1
Renal and urinary disorders	Acute kidney injury	2	110	2
Renal and urinary disorders	Cystitis noninfective	1	110	1
Renal and urinary disorders	Cystitis	1	110	1
Renal and urinary disorders	Dysurie	1	110	1
Renal and urinary disorders	Hematuria	1	110	1
Renal and urinary disorders	Kidneyinsufficiency, biochemy	1	110	1
Renal and urinary disorders	Other; eGFR decreased	1	110	1
Renal and urinary disorders	Renal disorder; decrease eGFR	1	110	1
Renal and urinary disorders	Renal disorder; eGFR decreased	1	110	1
Renal and urinary disorders	Renal faillure (eGFR disorder)	1	110	1
Renal and urinary disorders	Renal insufficiency	1	110	1
Renal and urinary disorders	Retention	1	110	1
Renal and urinary disorders	Urinary frequency	1	110	1
Renal and urinary disorders	Urinary retention	1	110	1
Reproductive system and breast disorders	Erectile dysfunction	1	110	1
Reproductive system and breast disorders	Irregular mentruation	1	110	1
Respiratory, thoracic and mediastinal disorders	Cough with sputa	1	110	1
Respiratory, thoracic and mediastinal disorders	Hiccups	1	110	1
Respiratory, thoracic and mediastinal disorders	Metabolic acidose	1	110	1
Respiratory, thoracic and mediastinal disorders	Nasal congestion	1	110	1
Respiratory, thoracic and mediastinal disorders	Pleural effusion	1	110	1
Respiratory, thoracic and mediastinal disorders	Pneumonia	1	110	1
Respiratory, thoracic and mediastinal disorders	Pulmonary fibrosis	1	110	1
Respiratory, thoracic and mediastinal disorders	Respiratoir insufficiency	1	110	1
Respiratory, thoracic and mediastinal disorders	Respiratory depression	1	110	1
Respiratory, thoracic and mediastinal disorders	Respiratory infection	1	110	1
Respiratory, thoracic and mediastinal disorders	Thoracle pain	1	110	1
Skin and subcutaneous tissue disorders	Dermatitis	1	110	1
Skin and subcutaneous tissue disorders	Erythema	1	110	1
Skin and subcutaneous tissue disorders	Erythema GVH	1	110	1
Skin and subcutaneous tissue disorders	Erythema multiforma	3	110	3
Skin and subcutaneous tissue disorders	Exanthema	1	110	2
Skin and subcutaneous tissue disorders	Exanthema aGVH	1	110	1
Skin and subcutaneous tissue disorders	Exanthema skin GVH	1	110	1
Skin and subcutaneous tissue disorders	Folliculitis	1	110	1
Skin and subcutaneous tissue disorders	Other; redness	1	110	1
Skin and subcutaneous tissue disorders	Rash	4	110	4
Skin and subcutaneous tissue disorders	Rash maculo papular	1	110	1
Skin and subcutaneous tissue disorders	Rash maculo-papular	1	110	1
Vascular disorders	Edema	3	110	3
Vascular disorders	Hypertension	14	110	14
Vascular disorders	Hypotension	1	110	1
Vascular disorders	Thromboembolic event	2	110	2