

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

-> group == arm A

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	73	3
Blood and lymphatic system disorders	Febrile Neutropenia		1	73	2
Blood and lymphatic system disorders	Febrile neutropenia		1	73	1
Blood and lymphatic system disorders	Febrile neutropenia		5	73	5
Blood and lymphatic system disorders	Neutropenia		1	73	1
Blood and lymphatic system disorders	Neutropenic fever		2	73	2
Cardiac disorders	Acute coronary syndrome		1	73	1
Cardiac disorders	Atrial fibrillation		5	73	5
Cardiac disorders	Atrial fibrillation (Paroxysmale)		1	73	1
Cardiac disorders	Atrial flutter		1	73	1
Cardiac disorders	Decompensatio cordis		1	73	1
Cardiac disorders	Heart failure		1	73	1
Cardiac disorders	Other: Cardiac decompensation		1	73	1
Cardiac disorders	Pericardial effusion		1	73	1
Ear and labyrinth disorders	Vertigo		1	73	1
Eye disorders	Cataract		2	73	2
Eye disorders	Dry eyes		1	73	1
Eye disorders	Other: Myopia left side		1	73	1
Gastrointestinal disorders	Abdominal pain		1	73	1
Gastrointestinal disorders	Anal hemorrhage		1	73	1
Gastrointestinal disorders	Buccal Ulcer		1	73	1
Gastrointestinal disorders	Constipation		10	73	10
Gastrointestinal disorders	Diarrhea		4	73	4
Gastrointestinal disorders	Dyspepsia		1	73	1
Gastrointestinal disorders	Hemorrhoids		1	73	1
Gastrointestinal disorders	Hemorrhoids (pain)		1	73	1
Gastrointestinal disorders	Lower gastrointestinal hemorrhage		1	73	1
Gastrointestinal disorders	Mucositis oral		4	73	4
Gastrointestinal disorders	Nausea		1	73	2
Gastrointestinal disorders	Obstipation		1	73	1
Gastrointestinal disorders	Oral and digestive mucositis		1	73	1
Gastrointestinal disorders	Oral mucositis		1	73	1
Gastrointestinal disorders	Other, sigmoid diverticulitis		1	73	1
Gastrointestinal disorders	Other: aften lip		1	73	1
Gastrointestinal disorders	Vomiting		1	73	1
General disorders and administration site conditions	Cough		1	73	1
General disorders and administration site conditions	Edema ankles		1	73	1
General disorders and administration site conditions	Edema limbs		2	73	2
General disorders and administration site conditions	Fatigue		10	73	10
General disorders and administration site conditions	Fever		2	73	2
General disorders and administration site conditions	Fever eci		1	73	1
General disorders and administration site conditions	Infusion related reaction		1	73	1
General disorders and administration site conditions	Infusion site extravasation		1	73	1
General disorders and administration site conditions	Localized edema		1	73	1
General disorders and administration site conditions	Malaise		1	73	1
Immune system disorders	Allergic reaction		2	73	2
Infections and infestations	Abces finger		1	73	1
Infections and infestations	Aspergillus infection lung		1	73	1
Infections and infestations	Bacteremia		2	73	2
Infections and infestations	Bacteriemia pseudomonas		1	73	1
Infections and infestations	Blepharitis eye infection		1	73	1
Infections and infestations	Bronchial infection		1	73	1
Infections and infestations	Candida stomatitis		2	73	2
Infections and infestations	Clostridium infection		1	73	1
Infections and infestations	Diverticulitis		1	73	1
Infections and infestations	Enterocolitis infectious clostridium		1	73	1
Infections and infestations	Erysipelas		2	73	2
Infections and infestations	Febrile neutropenia		1	73	1
Infections and infestations	Fungal pneumonia		1	73	1
Infections and infestations	Gum infection		1	73	1
Infections and infestations	HSV infection mouth		1	73	1
Infections and infestations	HSV- infection oral		1	73	1

Infections and infestations	Herpes (oral)	1	73	1
Infections and infestations	Herpes lip	1	73	1
Infections and infestations	Herpes simplex infection oral	1	73	1
Infections and infestations	Herpes zoster (abdominal)	1	73	1
Infections and infestations	Infection nos	1	73	1
Infections and infestations	Infectious enterocolitis	1	73	1
Infections and infestations	Lip infection	1	73	1
Infections and infestations	Lung infection	6	73	6
Infections and infestations	Lunginfection	1	73	1
Infections and infestations	Mouth (candida)	1	73	1
Infections and infestations	Mucositis oral	1	73	1
Infections and infestations	Oral candida	1	73	1
Infections and infestations	Oral candida infection	1	73	1
Infections and infestations	Other; bursitis (hip joint)	1	73	1
Infections and infestations	Pneumonia	3	73	3
Infections and infestations	Positive blood culture bacteroides fragilis	1	73	1
Infections and infestations	Positive blood culture e.coli	1	73	1
Infections and infestations	Positive bloodculture staph epi	1	73	1
Infections and infestations	Possible aspergillose lunginfection	1	73	1
Infections and infestations	Psittacosis	1	73	1
Infections and infestations	Rash, diffuse	1	73	1
Infections and infestations	Skin infection	1	73	1
Infections and infestations	Suspicion of lung infection	1	73	1
Infections and infestations	Suspiscin of fungus infection in sphnemoidal sinus	1	73	1
Infections and infestations	Thoot abcess	1	73	1
Infections and infestations	Tooth infection	2	73	2
Infections and infestations	Upper airway infection with neutropenia	1	73	1
Infections and infestations	Upper respiratory: pneumonia	1	73	1
Infections and infestations	Urinary tract infection	2	73	2
Infections and infestations	Viral infection: diarrhea	1	73	1
Injury, poisoning and procedural complications	Infusion related reaction	1	73	1
Investigations	ALAT	1	73	2
Investigations	ASAT	1	73	1
Investigations	Bilirubin increased	1	73	1
Investigations	Blood bilirubin increased	2	73	2
Investigations	Creatinine increased	2	73	2
Investigations	GGT increased	1	73	1
Investigations	Hypokalemia	2	73	3
Investigations	Increased ASAT	1	73	2
Investigations	Increased GGT	1	73	1
Investigations	Neutropenia	1	73	1
Investigations	Neutrophil count decreased	7	73	11
Investigations	Neutrophil count decreases	1	73	1
Investigations	Neutrophil counts decreased	1	73	1
Investigations	Other; jaundice	1	73	1
Investigations	Platelet count decreased	4	73	5
Investigations	Positive haemocultures (gram positive bacilli)	1	73	1
Investigations	Weight loss	2	73	2
Investigations	White blood cell decreased	2	73	2
Investigations	White bloodcell count decreased	1	73	1
Metabolism and nutrition disorders	Anorexia	4	73	4
Metabolism and nutrition disorders	Diabetes	1	73	1
Metabolism and nutrition disorders	Hypernatremia	1	73	2
Metabolism and nutrition disorders	Hypoalbuminemia	4	73	4
Metabolism and nutrition disorders	Hypocalcemia	1	73	1
Metabolism and nutrition disorders	Hypoglycemia	1	73	1
Metabolism and nutrition disorders	Hypokalemia	3	73	5
Metabolism and nutrition disorders	Hyponatremia	1	73	1
Metabolism and nutrition disorders	Hypophosphatemia	1	73	1
Metabolism and nutrition disorders	Hypophosphatemia	1	73	1
Musculoskeletal and connective tissue disorders	Arthritis	1	73	1
Musculoskeletal and connective tissue disorders	Back pain	3	73	3
Musculoskeletal and connective tissue disorders	Bone pain	1	73	1
Musculoskeletal and connective tissue disorders	Chest/thorax pain	1	73	1
Musculoskeletal and connective tissue disorders	Left superior arm pain	1	73	1
Musculoskeletal and connective tissue disorders	Nape pain	1	73	1
Musculoskeletal and connective tissue disorders	Other: tendomyogenic pain	1	73	1
Musculoskeletal and connective tissue disorders	Tendinitis	1	73	2
Musculoskeletal and connective tissue disorders	Worsening of medical condition: back pain induced by canal stenosis	1	73	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Other; myoom	1	73	1
Nervous system disorders	Cognitive disturbance	1	73	1
Nervous system disorders	Concentration impairment	1	73	1
Nervous system disorders	Facial paralysis	1	73	1
Nervous system disorders	Headache	2	73	2
Nervous system disorders	Memory impairment	1	73	1

Nervous system disorders	Peripheral neuropathy	1	73	1
Nervous system disorders	Stroke	1	73	1
Nervous system disorders	Syncope	1	73	1
Nervous system disorders	Syncope: collapse	1	73	1
Psychiatric disorders	Delirium	3	73	4
Renal and urinary disorders	Acute kidney injury	1	73	1
Renal and urinary disorders	Acute renal failure	1	73	1
Renal and urinary disorders	Renal failure	1	73	1
Renal and urinary disorders	Urinary retention	2	73	2
Respiratory, thoracic and mediastinal disorders	COP	1	73	1
Respiratory, thoracic and mediastinal disorders	Dyspnea	4	73	4
Respiratory, thoracic and mediastinal disorders	Epistaxis	1	73	1
Respiratory, thoracic and mediastinal disorders	Hoarseness	1	73	1
Respiratory, thoracic and mediastinal disorders	Hypoxia	2	73	2
Respiratory, thoracic and mediastinal disorders	Pleural effusion	1	73	1
Respiratory, thoracic and mediastinal disorders	Pneumonitis	2	73	2
Skin and subcutaneous tissue disorders	Bed sore	1	73	1
Skin and subcutaneous tissue disorders	Morbus Sweet	1	73	1
Skin and subcutaneous tissue disorders	Palmar-plantar erythrodysesthesia syndrome	1	73	1
Skin and subcutaneous tissue disorders	Rash	1	73	1
Skin and subcutaneous tissue disorders	Rash (exanthema)	1	73	1
Skin and subcutaneous tissue disorders	Rash maculo-papular	1	73	1
Skin and subcutaneous tissue disorders	Skin ulceration scrotum	1	73	1
Skin and subcutaneous tissue disorders	Ulcer /wound right buttock	1	73	1
Surgical and medical procedures	Incision artheroomcyste	1	73	1
Surgical and medical procedures	Tooth extraction	1	73	1
Vascular disorders	Edema	1	73	1
Vascular disorders	Edema limbs	1	73	1
Vascular disorders	Flebitis	1	73	1
Vascular disorders	Hypertension	2	73	2
Vascular disorders	Hypotension	2	73	2
Vascular disorders	Left superior arm thrombo-phlebitis	1	73	1
Vascular disorders	Phlebitis	4	73	4
Vascular disorders	Stenosis left intern carotid arteria	1	73	1
Vascular disorders	Superficial thromboflebitis	1	73	1
Vascular disorders	Thrombophlebitis	1	73	1

-> group == arm B ibrutinib 560 mg/day

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	71	3
Blood and lymphatic system disorders	Bleeding nose		1	71	2
Blood and lymphatic system disorders	Febrile Neutropenia		2	71	2
Blood and lymphatic system disorders	Febrile neturopenia		1	71	1
Blood and lymphatic system disorders	Febrile neutropenia		7	71	8
Blood and lymphatic system disorders	Hemorrhagic diathesis		1	71	1
Blood and lymphatic system disorders	Neutropenic fever		3	71	3
Blood and lymphatic system disorders	Platelet count decreased		1	71	1
Blood and lymphatic system disorders	Trombopenia		1	71	1
Cardiac disorders	Atrial Fibrillation		1	71	1
Cardiac disorders	Atrial fibrillation		8	71	9
Cardiac disorders	Atrial frbrillation		1	71	1
Cardiac disorders	Decompensatio cordis		1	71	1
Cardiac disorders	Left Ventricular systolic dysfunction		1	71	1
Cardiac disorders	Pericardial effusion		1	71	1
Cardiac disorders	Prolonged QTc		1	71	1
Cardiac disorders	Supraventricular tachycardia		1	71	1
Cardiac disorders	Ventricular arrhythmia		1	71	1
Ear and labyrinth disorders	External ear inflammation		1	71	1
Ear and labyrinth disorders	Hearing impaired		1	71	1
Gastrointestinal disorders	Abdominal pain		2	71	2
Gastrointestinal disorders	Bleeding oesophagal ulcera, gastroscopy: clipping		1	71	1
Gastrointestinal disorders	Constipation		5	71	7
Gastrointestinal disorders	Diarrhea		6	71	6
Gastrointestinal disorders	Dysphagia		1	71	1
Gastrointestinal disorders	Esophagitis		1	71	1
Gastrointestinal disorders	Heartburn		2	71	2
Gastrointestinal disorders	Hemorrhoids		2	71	2
Gastrointestinal disorders	Mucositis oral		3	71	3

Gastrointestinal disorders	Nausea	5	71	7
Gastrointestinal disorders	Obstipation	2	71	2
Gastrointestinal disorders	Oral mucositis	1	71	1
Gastrointestinal disorders	Oral pain	1	71	2
Gastrointestinal disorders	Pain Tooth	1	71	1
Gastrointestinal disorders	Stomatitis	1	71	1
General disorders and administration site conditions	Edema limbs	2	71	2
General disorders and administration site conditions	Fatigue	9	71	11
General disorders and administration site conditions	Fever	1	71	1
General disorders and administration site conditions	Fever - intermittant	1	71	1
General disorders and administration site conditions	Fever eci	1	71	1
General disorders and administration site conditions	General deterioration	1	71	1
General disorders and administration site conditions	General edema	1	71	1
General disorders and administration site conditions	Generalized Edema	1	71	1
General disorders and administration site conditions	Malaise	4	71	4
General disorders and administration site conditions	Oedema	1	71	1
Hepatobiliary disorders	Disturbed liver function	1	71	1
Hepatobiliary disorders	Reduced liver function	1	71	2
Immune system disorders	Allergic reaction	1	71	1
Infections and infestations	Abces	1	71	1
Infections and infestations	Abdominal infection	1	71	1
Infections and infestations	Bacteremia	1	71	1
Infections and infestations	Bacteriemy streptococcus pneumonia	1	71	1
Infections and infestations	Big toe skindefect	1	71	1
Infections and infestations	Candida oesophagitis	1	71	1
Infections and infestations	Catheter related infection	1	71	1
Infections and infestations	Cellulitis	1	71	1
Infections and infestations	Fungal pneumonia	1	71	1
Infections and infestations	HSV Infection mouth	1	71	1
Infections and infestations	Herpes Simplex Infection Mouth	1	71	1
Infections and infestations	Herpes simplex mouth	1	71	1
Infections and infestations	Herpetic lip infection	1	71	1
Infections and infestations	Infection blood S. Aureus	1	71	1
Infections and infestations	Infection cheek	1	71	1
Infections and infestations	Infection lung	1	71	1
Infections and infestations	Infection lung right lower lobe	1	71	1
Infections and infestations	Infection mouuth	1	71	1
Infections and infestations	Infection tongue	1	71	1
Infections and infestations	Infection-nos	1	71	1
Infections and infestations	Infection: aspergillus lung	1	71	1
Infections and infestations	Influenza A	1	71	1
Infections and infestations	Invasive aspergillose lungs	1	71	1
Infections and infestations	Lip infection	3	71	3
Infections and infestations	Lunginfection (aspergillus)	1	71	1
Infections and infestations	Mouth HSV infection	1	71	1
Infections and infestations	Mucosal infection	1	71	1
Infections and infestations	Mucosal infection cheek/mouth	1	71	1
Infections and infestations	Mycosis scrotum	1	71	1
Infections and infestations	Oral candidiasis causing pain throath	1	71	1
Infections and infestations	Oral herpes infection	1	71	1
Infections and infestations	Other, specify: Ecthyma gangrenosum	1	71	1
Infections and infestations	Para influenza	1	71	1
Infections and infestations	Pharyngitis	1	71	1
Infections and infestations	Plebitis	1	71	1
Infections and infestations	Pneumonia	2	71	2
Infections and infestations	Positive bloodculture rothia mucilaginosa	1	71	1
Infections and infestations	Pulmonal	1	71	1
Infections and infestations	RSV virus positive	1	71	1
Infections and infestations	Scrotal infection (epidymitis)	1	71	1
Infections and infestations	Serum aspergillus galactomannan positive	1	71	1
Infections and infestations	Sinusitis	1	71	1
Infections and infestations	Skin infection	1	71	1
Infections and infestations	Skin infection (HSV chin)	1	71	1
Infections and infestations	Skin infection (cellulitis)	1	71	1
Infections and infestations	Streptococcus pneumoniae bacteriemia	1	71	1
Infections and infestations	Urinary tract infection	1	71	2
Injury, poisoning and procedural complications	Drug interaction Ibrutinib (CYP3A4) and Noxafil (CYP3A4 inhibitor)	1	71	1
Injury, poisoning and procedural complications	Femoral fracture	1	71	1
Injury, poisoning and procedural complications	Other- rotator cuff rupture	1	71	1
Injury, poisoning and procedural complications	Positive bloodculture pseudomonas	1	71	1
Injury, poisoning and procedural complications	Vascular access complication	1	71	1
Investigations	Alkaline phosphatase increased	2	71	2
Investigations	Blood bilirubin increased	3	71	3
Investigations	Creatinine increased	1	71	1
Investigations	Fluctuant hemoglobin	1	71	1

Investigations	GGT	1	71	2
Investigations	GGT increased	3	71	4
Investigations	Increased CRP	1	71	1
Investigations	Neutrophil count decrease	1	71	1
Investigations	Platelet	1	71	2
Investigations	Platelet count decreased	2	71	5
Investigations	Weight gain	1	71	1
Investigations	Weight loss	4	71	4
Metabolism and nutrition disorders	Acute arthritis urica Dig I left foot	1	71	1
Metabolism and nutrition disorders	Acute arthritis urica Dig III left foot	1	71	1
Metabolism and nutrition disorders	Anorexia	8	71	10
Metabolism and nutrition disorders	Glucose intolerance	1	71	1
Metabolism and nutrition disorders	Hyperglycemia	1	71	1
Metabolism and nutrition disorders	Hypernatremia	1	71	1
Metabolism and nutrition disorders	Hypoalbuminemia	5	71	6
Metabolism and nutrition disorders	Hypokalemia	5	71	6
Metabolism and nutrition disorders	Hyponatremia	5	71	6
Metabolism and nutrition disorders	Hyponatrimia	1	71	1
Musculoskeletal and connective tissue disorders	Pain back & legs	1	71	1
Musculoskeletal and connective tissue disorders	Pain bone (jaw)	1	71	1
Musculoskeletal and connective tissue disorders	Pain: ribcage	1	71	1
Musculoskeletal and connective tissue disorders	Pyoderma	1	71	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neoplasm malignant, possible metastases lungcarcinoma	1	71	1
Nervous system disorders	Colaps (syncope)	1	71	1
Nervous system disorders	Dizziness	1	71	1
Nervous system disorders	Dizziness causing fall	1	71	1
Nervous system disorders	Dropfoot radiculopathy L5left	1	71	1
Nervous system disorders	Headache	3	71	3
Nervous system disorders	Peripheral motor neuropathy	1	71	1
Nervous system disorders	Syncope	2	71	2
Nervous system disorders	Syncope / collapse	1	71	1
Psychiatric disorders	Anxiety	1	71	1
Psychiatric disorders	Delirium	1	71	1
Psychiatric disorders	Hallucinations	2	71	2
Psychiatric disorders	Insomnia	2	71	2
Renal and urinary disorders	Acute after chronic kidney disease	1	71	1
Renal and urinary disorders	Acute kidney injury	1	71	1
Renal and urinary disorders	Impaired kidney function	1	71	1
Renal and urinary disorders	Urinary retention	2	71	2
Renal and urinary disorders	Urinary tract infection	1	71	1
Reproductive system and breast disorders	Vaginal hemorrhage	1	71	1
Respiratory, thoracic and mediastinal disorders	Cough	2	71	2
Respiratory, thoracic and mediastinal disorders	Dyspnea	4	71	4
Respiratory, thoracic and mediastinal disorders	Dyspnea due to overfilling	1	71	1
Respiratory, thoracic and mediastinal disorders	Epistaxis	1	71	1
Respiratory, thoracic and mediastinal disorders	Hypoxia	1	71	2
Respiratory, thoracic and mediastinal disorders	Pleural effusion	1	71	1
Respiratory, thoracic and mediastinal disorders	Pneumonia	1	71	1
Respiratory, thoracic and mediastinal disorders	Purpura	1	71	1
Respiratory, thoracic and mediastinal disorders	Respiratoy tract infection	1	71	1
Skin and subcutaneous tissue disorders	Actinic Keratosis	1	71	1
Skin and subcutaneous tissue disorders	Dermohypodermite of the left arm	1	71	1
Skin and subcutaneous tissue disorders	Erythema	1	71	1
Skin and subcutaneous tissue disorders	Erythema multiforma	1	71	1
Skin and subcutaneous tissue disorders	Erythematouze maculae/rash/toxicodermie	1	71	1
Skin and subcutaneous tissue disorders	Fissure anus bleeding and pain	1	71	1
Skin and subcutaneous tissue disorders	Maculopapular rash	1	71	1
Skin and subcutaneous tissue disorders	Purpera	1	71	1
Skin and subcutaneous tissue disorders	Purpura	2	71	2
Skin and subcutaneous tissue disorders	Rash	3	71	3
Skin and subcutaneous tissue disorders	Rash hands	1	71	1
Skin and subcutaneous tissue disorders	Rash macullo-papular	1	71	1
Skin and subcutaneous tissue disorders	Small abscess on the back	1	71	1
Skin and subcutaneous tissue disorders	Cerebral ischemia causing hemiparalyse right	1	71	1
Vascular disorders	Hematoma at port ? chat inserction	1	71	1
Vascular disorders	Hypertension	3	71	3
Vascular disorders	Hypotension	2	71	2
Vascular disorders	Hyprtension	1	71	1
Vascular disorders	Other: petechial bleeding	1	71	1
Vascular disorders	Phlebitis	3	71	3
Vascular disorders	Thrombophlebitis	1	71	1
Vascular disorders	Thrombosis piccline	1	71	1