

***** List of reported SAE's *****

-> group == placebo

ssoccd SOC code
aeterm Event term
affected Subjects affected number
exposed Subjects exposed number
occurrences Occurrences all number
occurrel Occurrences causally related to treatment number
fatality Fatalities number

** Not listed since missing: fatalrel **

	ssoccd	aeterm	affected	exposed	occurrences	occurrel	fatality
Cardiac disorders	Myocardial infarction		1	39	2	.	1
Gastrointestinal disorders	Colitis, perforated		1	39	1	1	.
Gastrointestinal disorders	Diverticular disease		1	39	1	1	.
Gastrointestinal disorders	Nausea and vomiting		1	39	1	1	.
General disorders and administration site conditions	Fever e.c.i		1	39	1	.	.
Immune system disorders	AL Amyloidosis (disease progression until)		1	39	1	.	.
Infections and infestations	Candida albicans disseminated infection		1	39	1	1	.
Infections and infestations	Eneritis caused by campylobacter		1	39	1	.	.
Infections and infestations	Enterohemorrhagic Ecoli Infection		1	39	1	1	.
Infections and infestations	Gastroenteritis		1	39	1	.	.
Infections and infestations	Lung infection		1	39	1	1	.
Infections and infestations	Pneumonia		5	39	6	4	.
Infections and infestations	Sepsis		1	39	1	1	.
Infections and infestations	Urinary tract infection		1	39	1	1	.
Infections and infestations	Urinary tract infection(E-faecalis)		1	39	1	1	.
Injury, poisoning and procedural complications	Fracture humerus and patella left side		1	39	1	.	.
Injury, poisoning and procedural complications	Hip fracture		1	39	1	1	.
Injury, poisoning and procedural complications	Pertrochanteric fracture of femur, closed		1	39	1	1	.
Injury, poisoning and procedural complications	Spinal compression fracture		1	39	1	.	.
Metabolism and nutrition disorders	Hypercalcemia		1	39	1	.	.
Metabolism and nutrition disorders	Tumor lysis syndrome		1	39	1	1	.
Musculoskeletal and connective tissue disorders	Back pain, worsening		1	39	1	.	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bladder cancer		1	39	1	.	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lymphoplasmacytic lymphoma		1	39	1	.	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate Adenocarcinoma		1	39	1	.	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma		1	39	1	.	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma pancreas		1	39	1	.	1
Nervous system disorders	Intracranial bleeding		1	39	1	.	.
Nervous system disorders	Lethargy/somnolence		1	39	1	1	.
Nervous system disorders	Vasovagal reaction at diarrhea		1	39	1	.	.
Renal and urinary disorders	Acute renal failure		1	39	1	.	.
Renal and urinary disorders	Renal insufficiency		1	39	1	.	.
Respiratory, thoracic and mediastinal disorders	Pneumocystis jiroveci infection		1	39	1	.	.
Skin and subcutaneous tissue disorders	Rash Maculo - Papular		1	39	1	.	.
Vascular disorders	Thromboembolic event		1	39	1	.	.

-> group == Ixa

ssoccd SOC code
aeterm Event term
affected Subjects affected number
exposed Subjects exposed number
occurrences Occurrences all number
occurrel Occurrences causally related to treatment number

** Not listed since missing: fatality fatalrel **

	ssoccd	aeterm	affected	exposed	occurrences	occurrel
Cardiac disorders	Angina Pectoris	1	39	1	.	
Cardiac disorders	Atrium fibrilleren de novo	1	39	1	.	
Cardiac disorders	Decompensatio cordis	1	39	1	1	
Gastrointestinal disorders	Acute hemorrhagic gastritis	1	39	1	1	
Gastrointestinal disorders	Constipation	2	39	2	2	
Gastrointestinal disorders	Diarrhea	1	39	1	1	
General disorders and administration site conditions	Chest pain	1	39	1	.	
General disorders and administration site conditions	Fever	2	39	4	2	
General disorders and administration site conditions	Fever eci	1	39	1	.	
General disorders and administration site conditions	Pain	2	39	2	.	
Infections and infestations	Blefarconjunctivitis	1	39	1	1	
Infections and infestations	E. coli urosepsis	1	39	1	.	
Infections and infestations	Infection urinary tract	1	39	1	.	
Infections and infestations	Influenza	1	39	1	1	
Infections and infestations	Lung infection	1	39	1	1	
Infections and infestations	Pneumonia	5	39	7	5	
Infections and infestations	Pneumonie	1	39	1	.	
Infections and infestations	Urine tract infection	1	39	1	1	
Injury, poisoning and procedural complications	Ankle fracture after trauma	1	39	1	1	
Metabolism and nutrition disorders	Dehydration	2	39	2	1	
Musculoskeletal and connective tissue disorders	(pain in left knee,)osteoarthritis	1	39	1	.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	1	39	1	1	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bladder cancer	1	39	1	.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Melanoma	1	39	1	.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Melanoma in situ (SPM)	1	39	1	1	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreas carcinoma	1	39	1	1	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	SPM: Squamous cell carcinoma car-right	1	39	1	1	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	1	39	1	1	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma in situ	1	39	1	.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Worsening basal cell carcinoma	1	39	1	.	
Nervous system disorders	Medullar compression Th9	1	39	1	.	
Nervous system disorders	Neuropathy (left arm)	1	39	1	1	
Renal and urinary disorders	Renal failure	1	39	1	1	
Respiratory, thoracic and mediastinal disorders	COPD exacerbation	1	39	1	1	