

***** 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 |