

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

-> group == Standard

ssoccd Soccde  
 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  
 fatalrel Fatalities causally related to treatment number

ssoccd	aeterm	affected	exposed	occurrences	occurrel	fatality	fatalrel
??? (not in SEVAL0.DTA)	Aspiration pneumonia	1	440	1	.	.	.
??? (not in SEVAL0.DTA)	Digestive hemorrhage	1	440	1	1	.	.
??? (not in SEVAL0.DTA)	Ileus	1	440	1	1	1	1
??? (not in SEVAL0.DTA)	Lung infection	1	440	1	.	1	.
??? (not in SEVAL0.DTA)	Sepsis	3	440	3	2	1	1
Blood and lymphatic disorders	Bone Marrow hypocellular	1	440	1	1	.	.
Blood and lymphatic disorders	Febrile neutropenia	1	440	1	1	.	.
Blood and lymphatic disorders	Fever in aplasia	1	440	1	1	.	.
Blood and lymphatic disorders	Neutropenic fever	2	440	3	3	.	.
Blood and lymphatic disorders	Thrombopenia	1	440	1	.	.	.
Cardiac disorders	Acute coronary syndrome	2	440	2	.	.	.
Cardiac disorders	Atrial fibrillation	1	440	1	1	.	.
Cardiac disorders	Cardiac arrest	1	440	1	.	1	.
Cardiac disorders	Heart Failure	1	440	1	1	.	.
Cardiac disorders	Heart failure	2	440	2	2	.	.
Cardiac disorders	Left ventricular systolic dysfunction	1	440	1	1	.	.
Cardiac disorders	Myocardial infection (non SCT elevated)	1	440	1	.	.	.
Cardiac disorders	Myocarditis	1	440	1	1	.	.
Cardiac disorders	Pericarditis	1	440	1	.	.	.
Cardiac disorders	Symptomatic bradycardia with possible circulation arrest	1	440	1	1	.	.
Cardiac disorders	Torsade	1	440	1	.	1	.
Congenital, familial and genetic disorders	Prolonged aplasia	2	440	2	2	.	.
Congenital, familial and genetic disorders	Tachycardic atrial fibrillation	1	440	1	.	.	.
Gastrointestinal disorders	Colitis	3	440	3	2	1	1
Gastrointestinal disorders	Colonic perforation	1	440	1	.	.	.
Gastrointestinal disorders	Constipation	1	440	1	.	.	.
Gastrointestinal disorders	Diarrhea	2	440	2	1	.	.
Gastrointestinal disorders	Enteritis	1	440	1	1	.	.
Gastrointestinal disorders	Enterocolitis	1	440	1	1	.	.
Gastrointestinal disorders	Gastric hemorrhage	1	440	1	1	.	.
Gastrointestinal disorders	Gastric perforation	1	440	1	1	.	.
Gastrointestinal disorders	Ileus	2	440	2	.	2	.
Gastrointestinal disorders	Ileus gr. 4	1	440	1	1	.	.
Gastrointestinal disorders	Infection (Tyflitt)	1	440	1	1	.	.
Gastrointestinal disorders	Neutropenic colitis	2	440	2	2	1	1
Gastrointestinal disorders	Neutropenic enterocolitis	1	440	1	1	1	1
Gastrointestinal disorders	Obstipation	1	440	1	.	.	.
Gastrointestinal disorders	Small intestinal obstruction	1	440	1	1	.	.
General disorders and administration site conditions	Death	1	440	1	.	1	.
General disorders and administration site conditions	Fever	4	440	4	2	.	.
General disorders and administration site conditions	Fever (in the absence of neutropenia)	1	440	1	.	.	.
General disorders and administration site conditions	Fever eci	1	440	1	.	.	.
General disorders and administration site conditions	Fever no focus	1	440	1	1	.	.
General disorders and administration site conditions	Mucositis	1	440	1	1	.	.
General disorders and administration site conditions	Multi organ failure	2	440	2	1	2	1
Hepatobiliary disorders	Cholecystitis	3	440	3	1	.	.
Hepatobiliary disorders	Galbladder necrosis	1	440	1	.	.	.
Hepatobiliary disorders	Toxic hepatic cytolysis	1	440	1	1	.	.
Immune system disorders	Allergic rection	1	440	1	1	.	.
Immune system disorders	Cutaneous GvHD grade 3	1	440	1	.	.	.
Immune system disorders	GvHD	1	440	1	.	1	.
Infections and infestations	(Apergilosis) pulmonary infection	1	440	1	.	1	.
Infections and infestations	Admitted to hospital/spondylodiscitis	1	440	1	1	.	.
Infections and infestations	Aspergilloma (wedge incision)	1	440	1	1	.	.
Infections and infestations	Aspergillosis (infections: other)	1	440	1	1	.	.
Infections and infestations	Bilateral pneumonia	1	440	1	1	.	.
Infections and infestations	Bronchial infection	1	440	1	1	.	.
Infections and infestations	Candida sepsis	1	440	1	1	.	.
Infections and infestations	Catheter related infection	3	440	3	1	.	.
Infections and infestations	Cellulitis	1	440	1	.	1	.
Infections and infestations	E-coli - sepsis	1	440	1	1	1	1
Infections and infestations	Gastro-enteritis	1	440	1	.	.	.

Infections and infestations	Infection	1	440	1	1	.	.
Infections and infestations	Infection (biliary tract)	1	440	1	1	1	1
Infections and infestations	Infection and infestation: Bronchial infection	1	440	1	1	.	.
Infections and infestations	Infection upper airway	1	440	1	.	.	.
Infections and infestations	Infection)	1	440	1	.	1	.
Infections and infestations	Infective myositis	1	440	1	1	.	.
Infections and infestations	Lung infection	9	440	9	9	2	2
Infections and infestations	Lung infection (abscess)	1	440	1	.	.	.
Infections and infestations	Mediastinal infection	1	440	1	1	.	.
Infections and infestations	Necrotizing fasciitis	1	440	1	.	1	.
Infections and infestations	Neutropenic streptococcus sepsis	1	440	1	1	.	.
Infections and infestations	Pneumocystis carinii - pneumonia	1	440	1	1	.	.
Infections and infestations	Pneumonia	9	440	9	9	5	5
Infections and infestations	Pneumosepsis (coli+)	1	440	1	.	1	.
Infections and infestations	Pulmonary infection	1	440	1	1	1	1
Infections and infestations	Pulmonary invasive aspergillosis	1	440	1	1	.	.
Infections and infestations	Sepsis	18	440	20	15	8	5
Infections and infestations	Sepsis (after transfer to ICU)	1	440	1	1	1	1
Infections and infestations	Sepsis (septic pneumonia)	1	440	1	1	.	.
Infections and infestations	Sepsis / Septic shock	1	440	1	1	.	.
Infections and infestations	Sepsis E-Coli ESBL	1	440	1	1	.	.
Infections and infestations	Septic shock	3	440	3	1	2	1
Infections and infestations	Septicemia	1	440	1	1	1	1
Infections and infestations	Sinusitis	1	440	1	1	.	.
Infections and infestations	Sinusitis maxillaris both sides	1	440	1	1	.	.
Infections and infestations	Skin infection	1	440	1	.	.	.
Infections and infestations	Tonsillitis	1	440	1	.	.	.
Injury, poisoning and procedural complications	Fall	1	440	1	.	1	.
Injury, poisoning and procedural complications	Hepatic rupture	1	440	1	.	1	.
Injury, poisoning and procedural complications	Neoral toxicity	1	440	1	.	.	.
Injury, poisoning and procedural complications	Splenic rupture	2	440	2	.	.	.
Injury, poisoning and procedural complications	Tacrolimus intoxication	1	440	1	.	.	.
Investigations	C-difficile toxin intoxication	1	440	1	.	1	.
Investigations	ECG QT time corrected prolonged	1	440	1	1	.	.
Investigations	GGT elevated	1	440	1	.	.	.
Investigations	Low Potassium	1	440	1	1	.	.
Investigations	Platelet count decreased to ctcae grade IV	1	440	1	1	.	.
Investigations	Prolonged QT time	1	440	1	1	.	.
Metabolism and nutrition disorders	Diabetic ketoacidosis in diabetes I	1	440	1	.	.	.
Metabolism and nutrition disorders	Hypokalemia	1	440	1	1	.	.
Musculoskeletal and connective tissue disorders	Fasciitis	1	440	1	1	.	.
Nervous system disorders	Ataxia with presyncope	1	440	1	1	.	.
Nervous system disorders	CVA	1	440	1	1	1	1
Nervous system disorders	Carbonarcosis	1	440	1	.	1	.
Nervous system disorders	Cognitive disturbance	1	440	1	.	.	.
Nervous system disorders	Encephalopathy	1	440	1	1	.	.
Nervous system disorders	Epilepsy crisis	1	440	1	.	.	.
Nervous system disorders	Intercranial hemmorage	1	440	1	1	.	.
Nervous system disorders	Intracranial hemorrhage	3	440	3	2	2	2
Nervous system disorders	Plexitis right thigh	1	440	1	1	.	.
Nervous system disorders	Seizure	1	440	1	.	.	.
Nervous system disorders	Stroke	1	440	1	.	1	.
Psychiatric disorders	Delirium	1	440	1	.	.	.
Renal and urinary disorders	Acute kidney injury	1	440	1	.	1	.
Renal and urinary disorders	Acute renal insufficiency	1	440	1	1	.	.
Renal and urinary disorders	Kidney insufficiency	1	440	1	.	.	.
Renal and urinary disorders	Renal failure	1	440	1	.	.	.
Respiratory, thoracic and mediastinal disorders	ARDS adult respiratory distress syndrom	1	440	1	1	.	.
Respiratory, thoracic and mediastinal disorders	Adult respiratory distress syndrome	1	440	1	1	.	.
Respiratory, thoracic and mediastinal disorders	Airway obstruction due to swollen mucosa oral cavity	1	440	1	1	.	.
Respiratory, thoracic and mediastinal disorders	Atelectasis right lung	1	440	1	1	.	.
Respiratory, thoracic and mediastinal disorders	Dyspnea	5	440	5	1	1	.
Respiratory, thoracic and mediastinal disorders	Dyspnoe	1	440	1	.	.	.
Respiratory, thoracic and mediastinal disorders	Hemophthisis	1	440	1	.	.	.
Respiratory, thoracic and mediastinal disorders	Interstitial pneumonia	1	440	1	.	.	.
Respiratory, thoracic and mediastinal disorders	Pneumonitis	2	440	2	2	.	.
Respiratory, thoracic and mediastinal disorders	Respiratory Failure	2	440	2	.	.	.
Respiratory, thoracic and mediastinal disorders	Respiratory distress	1	440	1	1	1	1
Respiratory, thoracic and mediastinal disorders	Respiratory failure	5	440	5	4	1	1
Respiratory, thoracic and mediastinal disorders	Respiratory insuff	1	440	1	1	1	1
Respiratory, thoracic and mediastinal disorders	Respiratory insufficiency	4	440	4	3	1	1
Respiratory, thoracic and mediastinal disorders	Respiratory insufficiency	1	440	1	1	.	.
Surgical and medical procedures	Reversal of colostomy right and jejunostomy left	1	440	1	.	.	.
Vascular disorders	Acute vascular leak syndrome	1	440	1	1	.	.
Vascular disorders	Catheter related infection and thrombosis	1	440	1	.	.	.
Vascular disorders	Hemorrhage	1	440	1	.	1	.
Vascular disorders	Hemorrhagic shock	1	440	1	1	.	.
Vascular disorders	Thrombo-embolic event	1	440	1	1	.	.

Vascular disorders	Thrombotic event	1	440	1	.	.	.
Vascular disorders	Vascular disorders - aneurism of a carotis interna	1	440	1	1	1	1

-> group == Clofa 10mg

ssoccd            Soccod  
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  
fatalrel          Fatalities causally related to treatment number

	ssoccd	aeterm	affected	exposed	occurrences	occurrel	fatality	fatalrel
??? (not in SEVAL0.DTA)	Death		1	407	1	.	1	.
??? (not in SEVAL0.DTA)	Death due to pneumonia		1	407	1	.	1	.
??? (not in SEVAL0.DTA)	Dyspnea (grade III)		1	407	1	.	.	.
??? (not in SEVAL0.DTA)	Erythroderma		1	407	1	1	.	.
??? (not in SEVAL0.DTA)	Febrile neutropenia		1	407	1	.	.	.
??? (not in SEVAL0.DTA)	Fever		1	407	1	.	.	.
??? (not in SEVAL0.DTA)	Gall bladder inflammation		1	407	1	.	.	.
??? (not in SEVAL0.DTA)	Hematuria		1	407	1	1	.	.
??? (not in SEVAL0.DTA)	Neutropenic fever		1	407	1	1	.	.
??? (not in SEVAL0.DTA)	Pericardial effusion		1	407	1	1	.	.
??? (not in SEVAL0.DTA)	Respiratory insufficiency		2	407	2	2	2	2
??? (not in SEVAL0.DTA)	Thrombosis of Hickman Line		1	407	1	1	.	.
Blood and lymphatic disorders	Agranulocytosis		1	407	1	1	.	.
Blood and lymphatic disorders	Disseminated intravascular coagulation		1	407	1	1	.	.
Blood and lymphatic disorders	Febrile neutropenia		1	407	1	.	.	.
Blood and lymphatic disorders	Febrile neutropenia with catheter related infection		1	407	1	.	.	.
Blood and lymphatic disorders	Neutropenic fever (candido krusei)		1	407	1	1	1	1
Blood and lymphatic disorders	Pancytopenia		3	407	3	2	.	.
Blood and lymphatic disorders	Prolonged severe thrombocytopenia due to purpura post transf		1	407	1	.	.	.
Blood and lymphatic disorders	Worsening DIC		1	407	1	1	.	.
Cardiac disorders	Acute coronary syndrome		1	407	1	.	.	.
Cardiac disorders	Asystole		1	407	1	1	.	.
Cardiac disorders	Atrioventricular block		1	407	1	1	.	.
Cardiac disorders	Atrioventricular block with pulse of 30/min		1	407	1	1	.	.
Cardiac disorders	Cardiac arrest		2	407	2	1	1	.
Cardiac disorders	Cardial ischemia		1	407	1	1	.	.
Cardiac disorders	Cardiomyopathie		1	407	1	1	.	.
Cardiac disorders	Heart failure		4	407	4	4	2	2
Cardiac disorders	Myocarditis		1	407	1	.	.	.
Cardiac disorders	Pericardial Effusion		1	407	1	1	.	.
Cardiac disorders	Pericarditis		1	407	1	1	.	.
Cardiac disorders	Ventricular fibrillation		1	407	1	.	.	.
Congenital, familial and genetic disorders	Prolonged aplasia		1	407	1	1	.	.
Endocrine disorders	S I A D H		1	407	1	1	.	.
Eye disorders	Mononuclear diplopia		1	407	1	1	.	.
Gastrointestinal disorders	Acute abdominal pain		1	407	1	1	1	1
Gastrointestinal disorders	Constipation		1	407	1	.	.	.
Gastrointestinal disorders	Diarrhea		3	407	3	3	1	1
Gastrointestinal disorders	Duodenal ulcer		1	407	1	1	.	.
Gastrointestinal disorders	Enteritis		1	407	1	1	1	1
Gastrointestinal disorders	Enterocolitis		1	407	1	1	.	.
Gastrointestinal disorders	Enterocolitis Infectious		1	407	1	1	.	.
Gastrointestinal disorders	Esophagal hemorrhage		1	407	1	1	.	.
Gastrointestinal disorders	Fever in neutropenic colitis		1	407	1	1	.	.
Gastrointestinal disorders	Gastric hemorrhage		1	407	1	1	1	1
Gastrointestinal disorders	Gastro-intestinal disorders,other-small bowel ischaemia		1	407	1	1	1	1
Gastrointestinal disorders	Ileus		1	407	1	.	.	.
Gastrointestinal disorders	Intestinal obstruction		1	407	1	.	.	.
Gastrointestinal disorders	Jejunal Hemorrhage		1	407	1	1	.	.
Gastrointestinal disorders	Mallory Weiss syndrome		1	407	1	1	.	.
Gastrointestinal disorders	Nausea		1	407	1	1	.	.
Gastrointestinal disorders	Neutropenic Enterokolitis		1	407	1	1	.	.
Gastrointestinal disorders	Neutropenic colitis		1	407	1	1	.	.
Gastrointestinal disorders	Neutropenic enteritis		1	407	1	1	.	.
Gastrointestinal disorders	Neutropenic enterocolitis		1	407	1	1	.	.
Gastrointestinal disorders	Paralytic Ileus		1	407	1	.	.	.
Gastrointestinal disorders	Typhilitis		1	407	1	1	1	1
Gastrointestinal disorders	Typhlitis		3	407	3	3	.	.
General disorders and administration site conditions	Death		2	407	2	.	2	.
General disorders and administration site conditions	Fever		4	407	4	2	.	.
General disorders and administration site conditions	Fever (with cough)		1	407	1	1	.	.
General disorders and administration site conditions	Malaise		1	407	1	.	.	.
General disorders and administration site conditions	Mucositis		2	407	2	1	.	.

General disorders and administration site conditions	Multi organ failure	1	407	1	.	1	.
General disorders and administration site conditions	Multiple organ failure	1	407	1	1	1	1
General disorders and administration site conditions	Progression	1	407	1	.	.	.
General disorders and administration site conditions	SIRS	1	407	1	1	.	.
Hepatobiliary disorders	Cholecystitis	2	407	2	1	1	1
Hepatobiliary disorders	Hepathotoxicity	1	407	1	1	.	.
Hepatobiliary disorders	Hepatic failure	1	407	1	1	1	1
Hepatobiliary disorders	Hepatic toxicity	1	407	1	1	.	.
Hepatobiliary disorders	Hepatotoxicity	1	407	2	2	.	.
Hepatobiliary disorders	Hyperbilirubinemia	1	407	1	1	.	.
Hepatobiliary disorders	Liver dysfunction	1	407	1	1	.	.
Hepatobiliary disorders	Toxic hepatitis	1	407	1	1	.	.
Immune system disorders	GVHD	1	407	1	.	.	.
Infections and infestations	Adeno viremia	1	407	1	.	1	.
Infections and infestations	Bacteremia (CTC4.0?)	1	407	1	.	.	.
Infections and infestations	Bilateral pneumonia	1	407	1	1	.	.
Infections and infestations	Bronchopulmonary infection	1	407	1	.	.	.
Infections and infestations	Candidemia	1	407	1	1	.	.
Infections and infestations	Catheter related infection	2	407	2	1	.	.
Infections and infestations	Cerebral aspergillosis	1	407	1	.	.	.
Infections and infestations	Cerebral fungal infection	1	407	1	1	1	1
Infections and infestations	Ebv reactivation after allogenic sct	1	407	1	.	.	.
Infections and infestations	Endophthalmitis (eye disorder)	1	407	1	1	.	.
Infections and infestations	Ethmoiditis	1	407	1	.	.	.
Infections and infestations	Fever with pos.blood cultures: Staphyloc. epiderm.	1	407	1	.	.	.
Infections and infestations	Fungal infection of the periorbitas	1	407	1	1	.	.
Infections and infestations	Fungal lung infection	1	407	1	1	.	.
Infections and infestations	Fungal pneumonia	3	407	3	3	1	1
Infections and infestations	Fusaria infection	1	407	1	1	.	.
Infections and infestations	Hepatic infection	1	407	1	1	.	.
Infections and infestations	Herpes zoster reactivation	1	407	1	.	.	.
Infections and infestations	Infection	3	407	4	4	.	.
Infections and infestations	Infection and infestation, other (CMV infection)	1	407	1	1	1	1
Infections and infestations	Infection other- Blood	1	407	1	1	.	.
Infections and infestations	Infection-blood	1	407	1	1	.	.
Infections and infestations	Invasive aspergillosis	1	407	1	1	1	1
Infections and infestations	Invasive aspergillosis	1	407	1	1	.	.
Infections and infestations	Invasive infection cerebral	1	407	1	1	.	.
Infections and infestations	Invasive pulmonary aspergillosis (EORTC criteria possible)	1	407	1	1	.	.
Infections and infestations	Lung Infection	1	407	1	.	.	.
Infections and infestations	Lung infection	1	407	1	1	.	.
Infections and infestations	Mediastinal infection (mediastinitis)	1	407	1	.	.	.
Infections and infestations	Meningo-encephalitis	1	407	1	.	1	.
Infections and infestations	Mucormycosis	1	407	1	1	1	1
Infections and infestations	Mucosal infection	1	407	1	1	.	.
Infections and infestations	Other Infections: CMV reactivation	1	407	1	.	.	.
Infections and infestations	Parainfluenza type 3	1	407	1	1	.	.
Infections and infestations	Pneumonia	7	407	8	8	5	5
Infections and infestations	Pneumonia due to pneumocystis carinii	1	407	1	1	.	.
Infections and infestations	Pneumonia lung infection	1	407	1	.	.	.
Infections and infestations	Pneumoniae (cmv)-> lung infection	1	407	1	1	.	.
Infections and infestations	Pulmonary aspergilloma	1	407	1	.	.	.
Infections and infestations	Pulmonary fungal infection	1	407	1	1	.	.
Infections and infestations	Pulmonary infection	1	407	1	.	1	.
Infections and infestations	Pulmonary invasive aspergillosis	1	407	1	1	1	1
Infections and infestations	Relapse of fungal pneumonia	1	407	1	1	.	.
Infections and infestations	Sepsis	24	407	27	23	11	9
Infections and infestations	Sepsis (with unknown focus)	1	407	1	1	1	1
Infections and infestations	Sepsis (E.coli)	1	407	1	1	.	.
Infections and infestations	Sepsis (candida albicans yeast infection)	1	407	1	1	.	.
Infections and infestations	Sepsis due to (candida) fungal infection confirmed by autopsy	1	407	1	1	.	.
Infections and infestations	Sepsis in aplasia	1	407	1	1	.	.
Infections and infestations	Sepsis with clostridium tertium	1	407	1	1	.	.
Infections and infestations	Sepsis with enterococcus faecium	1	407	1	1	.	.
Infections and infestations	Septic shock	10	407	10	6	4	2
Infections and infestations	Septicemia (staphylococcus haemolyticus)	1	407	1	1	.	.
Infections and infestations	Soft tissue infection both thighs	1	407	1	.	.	.
Infections and infestations	Spondylodiscitis caused by candida	1	407	1	1	.	.
Infections and infestations	Subcutaneous abscesses	1	407	1	1	.	.
Infections and infestations	Suspicion of pulmonary aspergillosis	1	407	1	1	.	.
Infections and infestations	Zona	1	407	1	1	.	.
Infections and infestations	Zygomycetes infection	1	407	1	1	1	1
Injury, poisoning and procedural complications	Drug toxicity	1	407	1	1	.	.
Injury, poisoning and procedural complications	Hip fracture - right	1	407	1	.	.	.
Injury, poisoning and procedural complications	Iatrogenic pneumothorax	1	407	1	.	.	.
Investigations	Electrocardiogram QT interval prolonged	1	407	1	1	.	.
Investigations	Increased liver values	1	407	1	1	.	.
Investigations	Investigations: increased aspergillus antigen	1	407	1	1	.	.

Investigations	Weight loss	1	407	1	1	.	.
Metabolism and nutrition disorders	Anorexia	1	407	1	1	.	.
Metabolism and nutrition disorders	Hypokalemia	2	407	2	2	.	.
Metabolism and nutrition disorders	Tumor lysis syndrome	1	407	1	1	1	1
Musculoskeletal and connective tissue disorders	CPK increased	1	407	1	1	1	1
Musculoskeletal and connective tissue disorders	Fasciitis extending to mediastinum	1	407	1	1	.	.
Musculoskeletal and connective tissue disorders	Myositis	1	407	1	.	.	.
Musculoskeletal and connective tissue disorders	Osteonecrosis of the jaw	1	407	1	1	.	.
Neoplasms benign, malignant and unspecified	Adenocarcinoma in lung	1	407	1	.	1	.
Neoplasms benign, malignant and unspecified	Diffuse large b-cell lymphoma	1	407	1	1	.	.
Neoplasms benign, malignant and unspecified	Osteosarcoma	1	407	1	.	1	.
Neoplasms benign, malignant and unspecified	Solitary fibrous tumor of pleura	1	407	1	.	.	.
Nervous system disorders	CNS hemorrhage	1	407	1	1	.	.
Nervous system disorders	CVA (CNS cerebrovascular ischemia)	1	407	1	.	.	.
Nervous system disorders	Cerebral bleeding	1	407	1	1	1	1
Nervous system disorders	Cerebral edema	1	407	1	.	1	.
Nervous system disorders	Cerebral hemorrhage	2	407	2	2	2	2
Nervous system disorders	Cerebrovascular accident	1	407	1	.	1	.
Nervous system disorders	Dysarthria	1	407	1	1	.	.
Nervous system disorders	Encephalopathy	2	407	2	2	.	.
Nervous system disorders	Epileptic insult	1	407	1	1	1	1
Nervous system disorders	Intracranial hemorrhage	1	407	1	1	.	.
Nervous system disorders	Intracranial hemorrhage	2	407	2	2	.	.
Nervous system disorders	Neurologic toxicity	1	407	1	1	.	.
Nervous system disorders	Peripheral motor neuropathy	1	407	1	.	.	.
Nervous system disorders	Syncope	1	407	1	1	.	.
Psychiatric disorders	Acute psychosis	1	407	1	.	.	.
Renal and urinary disorders	Hemorrhagic Cystitis	1	407	1	.	.	.
Respiratory, thoracic and mediastinal disorders	Adult respiratory distress syndrome	2	407	2	2	.	.
Respiratory, thoracic and mediastinal disorders	Bronchopulmonary hemorrhage	1	407	1	1	1	1
Respiratory, thoracic and mediastinal disorders	Hemoptysis	1	407	1	1	.	.
Respiratory, thoracic and mediastinal disorders	Hypoxia	1	407	1	1	.	.
Respiratory, thoracic and mediastinal disorders	Lung embolism	1	407	1	.	.	.
Respiratory, thoracic and mediastinal disorders	Pleural effusion	1	407	1	1	.	.
Respiratory, thoracic and mediastinal disorders	Pneumonitis	1	407	1	1	.	.
Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	1	407	1	.	.	.
Respiratory, thoracic and mediastinal disorders	Pulmonary infection	1	407	1	1	.	.
Respiratory, thoracic and mediastinal disorders	Pulmonary infiltrates	1	407	1	1	.	.
Respiratory, thoracic and mediastinal disorders	Respiratoire insuf.	1	407	1	1	1	1
Respiratory, thoracic and mediastinal disorders	Respiratory failure	3	407	3	3	2	2
Respiratory, thoracic and mediastinal disorders	Respiratory failure due to pulmonary edema	1	407	1	.	.	.
Respiratory, thoracic and mediastinal disorders	Respiratory insuff.	1	407	1	1	.	.
Respiratory, thoracic and mediastinal disorders	Respiratory insufficiency	13	407	13	10	2	1
Respiratory, thoracic and mediastinal disorders	Respiratory insufficiency	2	407	2	2	.	.
Skin and subcutaneous tissue disorders	Bullous dermatitis	1	407	1	1	.	.
Skin and subcutaneous tissue disorders	Leucocytoclastic vasculitis	1	407	1	1	.	.
Skin and subcutaneous tissue disorders	Palmar-plantar erythema	1	407	1	1	.	.
Skin and subcutaneous tissue disorders	Palmar-plantar erythrodysthesia syndrome	2	407	2	2	.	.
Skin and subcutaneous tissue disorders	Rash	1	407	1	1	.	.
Skin and subcutaneous tissue disorders	Skin toxicity	1	407	1	1	.	.
Surgical and medical procedures	Surgical procedure: biopsy vertbral body	1	407	1	.	.	.
Vascular disorders	Capillary leak	1	407	1	1	.	.
Vascular disorders	Embolism with ARDS	1	407	1	1	.	.
Vascular disorders	Orthostatic Hypotension	1	407	1	1	.	.
Vascular disorders	Thromboembolic event	1	407	1	1	.	.

-> group == Clofa 15mg

ssoccd	Soccode
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
fatalrel	Fatalities causally related to treatment number

	ssoccd	aeterm	affected	exposed	occurrences	occurrel	fatality	fatalrel
??? (not in SEVAL0.DTA)	AST, ALT increased	1		32	1	1	.	.
??? (not in SEVAL0.DTA)	Multi organ failure	1		32	1	1	.	.
??? (not in SEVAL0.DTA)	Neutropenic colitis	1		32	1	1	1	1
??? (not in SEVAL0.DTA)	Typhylitis	1		32	1	1	1	1
Blood and lymphatic disorders	Delay in repopulation	1		32	1	1	.	.
Blood and lymphatic disorders	Prolongation of thrombocytopenia *	1		32	1	1	.	.
Blood and lymphatic disorders	Prolonged pancytopenia	1		32	1	1	.	.
Blood and lymphatic disorders	Prolonged thrombocytopenia	1		32	1	1	.	.
Cardiac disorders	Cardiac arrhythmia grade 4	1		32	1	1	.	.
Gastrointestinal disorders	Intestinal obstruction	1		32	1	.	.	.
General disorders and administration site conditions	Multi organ failure	1		32	1	1	1	1
Hepatobiliary disorders	Cholecystitis	1		32	1	.	.	.
Infections and infestations	Aspergillus pneumoniae	1		32	1	1	1	1
Infections and infestations	Herpes zoster (thorax)	1		32	1	1	.	.
Infections and infestations	Infection other-blood	1		32	1	1	1	1
Infections and infestations	Infection (invasive aspergillosis suspicion)	1		32	1	1	.	.
Infections and infestations	Lung infection	1		32	1	1	.	.
Infections and infestations	Pneumonia	1		32	1	1	.	.
Infections and infestations	Pneumonitis (fungal)	1		32	1	.	.	.
Infections and infestations	Sepsis	2		32	3	3	1	1
Investigations	Elevated liverenzymes	1		32	1	1	.	.
Investigations	GGT increased	1		32	1	.	.	.
Metabolism and nutrition disorders	Hypokalemia	1		32	1	.	.	.
Nervous system disorders	Encephalopathy	1		32	1	.	.	.
Renal and urinary disorders	Hematuria	1		32	1	.	.	.
Renal and urinary disorders	Nephrolithiasis	1		32	1	1	.	.
Respiratory, thoracic and mediastinal disorders	Acute dyspnoe due to pulmonary oedema	1		32	1	.	.	.
Respiratory, thoracic and mediastinal disorders	Bilateral acute pulmonary embolism	1		32	1	.	1	.
Respiratory, thoracic and mediastinal disorders	Dyspnea	1		32	1	1	1	1
Respiratory, thoracic and mediastinal disorders	Epistaxis	1		32	1	1	.	.
Respiratory, thoracic and mediastinal disorders	Respiratory insuff.	1		32	1	1	1	1
Vascular disorders	Shock	1		32	1	1	.	.