

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

-> group == Arm1: Experimental (1 arm only)

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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

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	ssoccd	aeterm	affected	exposed	occurrences	occurrel	fatality	fatalrel
??? (not in SEVAL0.DTA)	Heart failure		1	57	1	1	.	.
Blood and lymphatic disorders	Trombopenia		1	57	1	1	.	.
Cardiac disorders	Cardiac arrest		2	57	2	2	2	2
Cardiac disorders	Cardiac right ventricular dysfunction		1	57	1	1	.	.
Cardiac disorders	Complete atrioventricular block		1	57	1	.	.	.
Cardiac disorders	Heart failure		4	57	5	3	.	.
Cardiac disorders	Myocardial infarction		1	57	1	.	.	.
Gastrointestinal disorders	Colitis		1	57	1	1	.	.
Gastrointestinal disorders	Diarrhea		1	57	1	.	.	.
Gastrointestinal disorders	Gastro-intestinal necrosis		1	57	1	.	.	.
Gastrointestinal disorders	Ischemic colitis		1	57	1	.	.	.
Gastrointestinal disorders	Pancreatitis		1	57	1	.	.	.
General disorders and administration site conditions	Edema		1	57	1	1	.	.
General disorders and administration site conditions	General malaise		1	57	1	.	.	.
General disorders and administration site conditions	Oedema		1	57	1	1	.	.
Hepatobiliary disorders	Cholecystitis		1	57	1	.	.	.
Hepatobiliary disorders	Hepato-Renal syndrome		1	57	1	.	1	.
Infections and infestations	Community acquired pneumonia		1	57	1	.	.	.
Infections and infestations	Gastro-intestinal infection		1	57	1	.	.	.
Infections and infestations	Gastrointestinal infection		1	57	1	.	.	.
Infections and infestations	Lung infection		1	57	1	1	.	.
Infections and infestations	Pneumonia		4	57	4	3	.	.
Infections and infestations	Pneumosepsis		1	57	1	.	.	.
Infections and infestations	Sepsis		3	57	3	3	.	.
Infections and infestations	Viral infection		1	57	1	1	.	.
Injury, poisoning and procedural complications	Sinusitis		1	57	1	.	.	.
Metabolism and nutrition disorders	Dehydration		1	57	2	2	.	.
Metabolism and nutrition disorders	Fluid overflow		1	57	1	1	.	.
Metabolism and nutrition disorders	Fluid retention		1	57	1	1	.	.
Metabolism and nutrition disorders	Hypoglycemia		1	57	1	.	.	.
Metabolism and nutrition disorders	Hyponatremia		1	57	1	1	.	.
Musculoskeletal and connective tissue disorders	Muscle weakness arms and legs		1	57	1	1	.	.
Nervous system disorders	Intercranial hemorrhage		1	57	1	1	.	.
Nervous system disorders	Near syncope		1	57	1	.	.	.
Nervous system disorders	Poly neuropathy		1	57	1	1	.	.
Renal and urinary disorders	Acute kidney injury		1	57	1	1	.	.
Renal and urinary disorders	Acute tubulus necrosis		1	57	1	1	.	.
Renal and urinary disorders	Progress. of renal insufficiency		1	57	1	.	.	.
Renal and urinary disorders	Renal insufficiency		2	57	2	.	.	.
Respiratory, thoracic and mediastinal disorders	Dyspnea/ bronchial hyperreactivity		1	57	1	1	.	.
Respiratory, thoracic and mediastinal disorders	Pulmonary bleeding		1	57	1	.	.	.
Respiratory, thoracic and mediastinal disorders	Pulmonary embolism		2	57	2	1	.	.
Vascular disorders	Hypotension		1	57	1	1	.	.
Vascular disorders	Orthostatic hypotension		1	57	1	1	.	.
Vascular disorders	Symptomatic hypotension		1	57	1	1	.	.