

**FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report
Standard Report - All Preferred Terms in Cases**

MedDRA Preferred Term Reaction	Count	% Rpts
ARTHRALGIA	1470	9.9%
PAIN IN EXTREMITY	898	6.1%
TENDONITIS	868	5.9%
TENDON RUPTURE	823	5.6%
MYALGIA	701	4.7%
DYSPNOEA	689	4.7%
INSOMNIA	679	4.6%
TENDON DISORDER	650	4.4%
PAIN	645	4.4%
DIZZINESS	595	4.0%
NAUSEA	592	4.0%
GAIT DISTURBANCE	565	3.8%
ASTHENIA	552	3.7%
PYREXIA	550	3.7%
DRUG INTERACTION	511	3.5%
PARAESTHESIA	509	3.4%
HEADACHE	470	3.2%
ANXIETY	452	3.1%
DIARRHOEA	448	3.0%
CONVULSION	440	3.0%
RASH	428	2.9%
FATIGUE	391	2.6%
OEDEMA PERIPHERAL	390	2.6%
PNEUMONIA	381	2.6%
CONFUSIONAL STATE	376	2.5%
TREMOR	374	2.5%
VOMITING	371	2.5%
PRURITUS	354	2.4%
HYPOAESTHESIA	343	2.3%
URTICARIA	309	2.1%
INTERNATIONAL NORMALISED RATIO INCREASED	282	1.9%
JOINT SWELLING	274	1.9%
HYPERSENSITIVITY	273	1.8%
RENAL FAILURE ACUTE	270	1.8%
TENDON PAIN	257	1.7%
DEPRESSION	256	1.7%
THROMBOCYTOPENIA	255	1.7%
FEELING ABNORMAL	253	1.7%
MUSCULOSKELETAL PAIN	251	1.7%
BACK PAIN	249	1.7%
BURNING SENSATION	245	1.7%
ERYTHEMA	245	1.7%
CONDITION AGGRAVATED	244	1.6%
DECREASED APPETITE	241	1.6%
MALAISE	237	1.6%
MUSCLE SPASMS	237	1.6%
MUSCULAR WEAKNESS	236	1.6%
NEUROPATHY PERIPHERAL	226	1.5%
HALLUCINATION	221	1.5%
RENAL FAILURE	220	1.5%
DRUG INEFFECTIVE	219	1.5%
ELECTROCARDIOGRAM QT PROLONGED	213	1.4%
HYPOTENSION	213	1.4%