

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

<b>MedDRA Preferred Term Reaction</b>	<b>Count</b>	<b>%Rpts</b>
ABDOMINAL PAIN	211	1.4%
DERMATITIS	211	1.4%
CHEST PAIN	210	1.4%
WEIGHT DECREASED	205	1.4%
HEART RATE INCREASED	201	1.4%
HYPOGLYCAEMIA	193	1.3%
FALL	192	1.3%
STEVENS-JOHNSON SYNDROME	192	1.3%
PALPITATIONS	191	1.3%
ASPARTATE AMINOTRANSFERASE INCREASED	189	1.3%
VISUAL IMPAIRMENT	188	1.3%
TINNITUS	186	1.3%
DRUG HYPERSENSITIVITY	185	1.3%
SEPSIS	185	1.3%
ANAEMIA	183	1.2%
LOSS OF CONSCIOUSNESS	183	1.2%
ANAPHYLACTIC REACTION	177	1.2%
DEATH	176	1.2%
RHABDOMYOLYSIS	174	1.2%
TORSADE DE POINTES	174	1.2%
TOXIC EPIDERMAL NECROLYSIS	174	1.2%
DEHYDRATION	172	1.2%
ALANINE AMINOTRANSFERASE INCREASED	168	1.1%
INTERSTITIAL LUNG DISEASE	166	1.1%
BLOOD CREATININE INCREASED	163	1.1%
HAEMOGLOBIN DECREASED	160	1.1%
HYPERHIDROSIS	159	1.1%
CHILLS	158	1.1%
RESPIRATORY FAILURE	157	1.1%
URINARY TRACT INFECTION	151	1.0%
ABASIA	150	1.0%
MYOCARDIAL INFARCTION	150	1.0%
TACHYCARDIA	150	1.0%
HYPERTENSION	148	1.0%
HEPATIC FUNCTION ABNORMAL	147	1.0%
LIVER FUNCTION TEST ABNORMAL	146	1.0%
COUGH	144	1.0%
SWELLING	144	1.0%
CLOSTRIDIUM COLITIS	142	1.0%
VISION BLURRED	141	1.0%
ARTHROPATHY	140	0.9%
CARDIAC ARREST	139	0.9%
MEDICATION ERROR	138	0.9%
VENTRICULAR TACHYCARDIA	138	0.9%
MUSCULOSKELETAL STIFFNESS	136	0.9%
RASH ERYTHEMATOUS	136	0.9%
NIGHTMARE	134	0.9%
PSYCHOTIC DISORDER	133	0.9%
BLOOD UREA INCREASED	132	0.9%
DISORIENTATION	132	0.9%
HEPATITIS	130	0.9%
ATRIAL FIBRILLATION	129	0.9%
NERVOUS SYSTEM DISORDER	127	0.9%