

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

| MedDRA Preferred Term Reaction | Count | % Rpts |
|---------------------------------------|--------------|---------------|
| FLUSHING | 84 | 0.6% |
| EOSINOPHILIA | 83 | 0.6% |
| INFECTION | 83 | 0.6% |
| INJECTION SITE ERYTHEMA | 83 | 0.6% |
| ARRHYTHMIA | 82 | 0.6% |
| DEAFNESS | 82 | 0.6% |
| DRUG ERUPTION | 82 | 0.6% |
| BALANCE DISORDER | 81 | 0.5% |
| BLISTER | 80 | 0.5% |
| PROTHROMBIN TIME PROLONGED | 80 | 0.5% |
| STAPHYLOCOCCAL INFECTION | 80 | 0.5% |
| SOMNOLENCE | 79 | 0.5% |
| CHOLESTASIS | 78 | 0.5% |
| GRAND MAL CONVULSION | 78 | 0.5% |
| NERVOUSNESS | 77 | 0.5% |
| CONTUSION | 76 | 0.5% |
| SKIN DISCOLOURATION | 76 | 0.5% |
| LETHARGY | 76 | 0.5% |
| GASTROINTESTINAL HAEMORRHAGE | 75 | 0.5% |
| DYSSTASIA | 74 | 0.5% |
| SPEECH DISORDER | 74 | 0.5% |
| PLEURAL EFFUSION | 74 | 0.5% |
| BRONCHITIS | 73 | 0.5% |
| HYPOKALAEMIA | 73 | 0.5% |
| MEMORY IMPAIRMENT | 73 | 0.5% |
| CEREBROVASCULAR ACCIDENT | 72 | 0.5% |
| PHARYNGEAL OEDEMA | 72 | 0.5% |
| BLOOD ALKALINE PHOSPHATASE INCREASED | 71 | 0.5% |
| HYPONATRAEMIA | 71 | 0.5% |
| CARDIO-RESPIRATORY ARREST | 71 | 0.5% |
| DYSPEPSIA | 70 | 0.5% |
| MUSCLE RUPTURE | 70 | 0.5% |
| SINUSITIS | 70 | 0.5% |
| METABOLIC ACIDOSIS | 70 | 0.5% |
| FEELING HOT | 70 | 0.5% |
| CHRONIC OBSTRUCTIVE PULMONARY DISEASE | 69 | 0.5% |
| OSTEOARTHRITIS | 69 | 0.5% |
| CONSTIPATION | 68 | 0.5% |
| ANOSMIA | 67 | 0.5% |
| SUICIDAL IDEATION | 67 | 0.5% |
| PURPURA | 67 | 0.5% |
| OVERDOSE | 67 | 0.5% |
| BRADYCARDIA | 67 | 0.5% |
| COORDINATION ABNORMAL | 66 | 0.4% |
| HAEMATOCRIT DECREASED | 66 | 0.4% |
| INFLAMMATION | 66 | 0.4% |
| LEUKOCYTOSIS | 66 | 0.4% |
| SHOCK | 66 | 0.4% |
| PARANOIA | 66 | 0.4% |
| INJECTION SITE REACTION | 66 | 0.4% |
| HAEMOLYTIC ANAEMIA | 66 | 0.4% |
| BLOOD GLUCOSE INCREASED | 65 | 0.4% |
| CARDIAC FAILURE CONGESTIVE | 65 | 0.4% |