

[Skip to main content](#)

Aloprim (Allopurinol Sodium for Injection)

??? ??????: 30 ?????2/????? 2017

In an uncontrolled, compassionate plea protocol, 125 of 1,378 patients reported a total of 301 adverse reactions while receiving ALOPRIM (allopurinol sodium) for Injection. Most of the patients had advanced malignancies or serious underlying diseases and were taking multiple concomitant medications. Side effects directly attributable to ALOPRIM (allopurinol sodium) for Injection were reported in 19 patients. Fifteen of these adverse experiences were allergic in nature (rash, eosinophilia, local injection site reaction). One adverse experience of severe diarrhea and one incidence of nausea were also reported as being possibly attributable to ALOPRIM (allopurinol sodium) for Injection. Two patients had serious adverse experiences (decreased renal function and generalized seizure) reported as being possibly attributable to ALOPRIM (allopurinol sodium) for Injection.

A listing of the adverse reactions regardless of causality reported from clinical trials follows:

Incidence Greater Than 1%

rash (1.5%) **Cutaneous/Dermatologic:**

renal failure/insufficiency (1.2%) **Genitourinary:**

nausea (1.3%), vomiting (1.2%) **Gastrointestinal:**

Incidence Less Than 1%

| | |
|---|--------------------------------|
| fever, pain, chills, alopecia, infection, sepsis, enlarged abdomen, mucositis/pharyngitis, blast crisis, cellulitis, hypervolemia | Body as Whole: |
| heart failure, cardiorespiratory arrest, hypertension, pulmonary embolus, hypotension, decreased venous pressure, flushing, headache, stroke, septic shock, cardiovascular disorder, ECG abnormality, hemorrhage, bradycardia, thrombophlebitis, ventricular fibrillation | Cardiovascular: |
| urticaria, pruritus, local injection site reaction | Cutaneous/Dermatologic: |
| diarrhea, gastrointestinal bleeding, hyperbilirubinemia, splenomegaly, hepatomegaly, intestinal obstruction, jaundice, flatulence, constipation, liver failure, proctitis | Gastrointestinal: |
| hematuria, increased creatinine, oliguria, kidney function abnormality, urinary tract infection | Genitourinary: |
| leukopenia, marrow aplasia, thrombocytopenia, eosinophilia, neutropenia, anemia, pancytopenia, ecchymosis, bone marrow suppression, disseminated intravascular coagulation | Hematologic: |
| hypocalcemia, hyperphosphatemia, hypokalemia, | Metabolic: |

| | |
|---|-------------------------|
| hyperuricemia, electrolyte abnormality, hypercalcemia, hyperglycemia, hypernatremia, hyponatremia, metabolic acidosis, edema, glycosuria, hyperkalemia, lactic acidosis, water intoxication, hypomagnesemia | |
| seizure, status epilepticus, myoclonus, twitching, agitation, mental status changes, cerebral infarction, coma, dystonia, paralysis, tremor | Neurologic: |
| respiratory failure/insufficiency, ARDS, increased respiration rate, apnea | Pulmonary: |
| arthralgia | Musculoskeletal: |
| hypotonia, diaphoresis, tumor lysis syndrome | Other: |

The most frequent adverse reaction to oral allopurinol is skin rash. Skin reactions can be severe and sometimes fatal. Therefore, treatment with ALOPRIM). For further details on **WARNINGS**(allopurinol sodium for injection) (allopurinol sodium) for Injection should be discontinued immediately if a rash develops (see hypersensitivity reactions to treatment with oral allopurinol, refer to the package insert for allopurinol tablets.