HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use colchicine safely and effectively. See full prescribing information for COLCRYS™.

COLCRYS™ (colchicine, USP) tablets for Oral use
Initial U.S. Approval: 1961

---------- **INDICATIONS AND USAGE** ----------

COLCRYS (colchicine, USP) tablets are an alkaloid indicated for

- gout flares (1.1)
- Familial Mediterranean fever (FMF) in adults and children 4 years or older (1.2).

COLCRYS is not an analgesic medication and should not be used to treat pain from other causes.

---------- **DOSAGE AND ADMINISTRATION** ----------

- **Gout Flares**: 1.2 mg (2 tablets) at the first sign of a gout flare followed by 0.6 mg (1 tablet) one hour later (2.1).
- **FMF:** Adults and Children older than 12 years 1.2 – 2.4 mg; Children 6 to 12 years 0.9 – 1.8 mg; Children 4 to 6 years 0.3 – 1.8 mg. (2.2, 2.3).
  - Give total daily dose in one or two divided doses (2.2).
  - Increase or decrease the dose as indicated and as tolerated in increments of 0.3 mg/day, not to exceed the maximum recommended daily dose (2.4).
- See full prescribing information for dose adjustment regarding patients with impaired renal function (2.5) or hepatic function (2.6).

---------- **DOSAGE FORMS AND STRENGTHS** ----------

- 0.6 mg tablets (3).

---------- **CONTRAINDICATIONS** ----------

Patients with renal or hepatic impairment should not be given COLCRYS in conjunction with P-gp or strong CYP3A4 inhibitors (5.3). In these patients, life-threatening and fatal colchicine toxicity has been reported with colchicine taken in therapeutic doses (7).

---------- **WARNINGS AND PRECAUTIONS** ----------

- *Fatal overdoses* have been reported with colchicine in adults and children. Keep COLCRYS out of the reach of children (5.1, 10).
- *Blood dyscrasias:* myelosuppression, leukopenia, granulocytopenia, thrombocytopenia, and aplastic anemia have been reported.
- Monitor for toxicity and if present consider temporary interruption or discontinuation of colchicine (5.2, 5.3, 5.4, 6, 10).
- *Drug interaction P-gp and/or CYP3A4 inhibitors:* Coadministration with P-gp and/or strong CYP3A4 inhibitors has resulted in life-threatening interactions and death (5.3, 7).
- *Neuromuscular toxicity:* Myotoxicity including rhabdomyolysis may occur, especially in combination with other drugs known to cause this effect. Consider temporary interruption or discontinuation of COLCRYS. (5.4, 7).

---------- **ADVERSE REACTIONS** ----------

Gout Flares: Most common adverse reaction is diarrhea (23%) and pharyngolaryngeal pain (3%). (6).

FMF: Most common adverse reactions (up to 20%) are abdominal pain, diarrhea, nausea, and vomiting. These effects are usually mild, transient, and reversible upon lowering the dose (6).

To report SUSPECTED ADVERSE REACTIONS, contact Mutual Pharmaceutical Company, Inc. at 1-888-351-3786 or drugsafety@urlpharma.com or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch.*

---------- **DRUG INTERACTIONS** ----------

Coadministration of P-gp and/or CYP3A4 inhibitors (*e.g.*, clarithromycin or cyclosporine) have been demonstrated to alter the concentration of COLCRYS. The potential for drug-drug interactions must be considered prior to and during therapy. See full prescribing information for a complete list of reported and potential interactions (2.4, 5.3, 7).

---------- **USE IN SPECIFIC POPULATIONS** ----------

- In patients with severe hepatic or renal impairment, close monitoring is recommended in both gout flares and FMF patients; a dose reduction may not be needed in gout flares but should be considered in FMF patients, based on the patient's estimated creatinine clearance. (2.5, 2.6, 8.6, 8.7)
- In the presence of renal impairment, dosing for gout flares should be repeated no more than once every two weeks, whereas dosing for FMF should be continued but adjusted based upon the patients estimated creatinine clearance. (2.5, 8.6).
- For patients undergoing dialysis, the total recommended dose for gout flares should be reduced to 0.6 mg (1 tablet) x 1 dose, whereas for FMF patients the starting dose should be 0.3 mg per day. For gout flares, a treatment course should be repeated no more than once every 2 weeks with no increase in dosage but for FMF patients, dosing can be increased with close monitoring. (2.5, 8.6)
- Pregnancy: Use only if the potential benefit justifies the potential risk to the fetus (8.1).
- Nursing Mothers: Caution should be exercised when administered to a nursing woman (8.3).
- Geriatric Use: The recommended dose of colchicine should be based on renal function (2.5, 8.5).

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

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FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed