

## **Colchicine**

**Class:** Antigout Agent

**Indications:** Prevention and treatment of acute gout flares; treatment of familial Mediterranean fever (FMF); Primary biliary cirrhosis (unlabeled); pericarditis (unlabeled).

**Available dosage form in the hospital:** (0.5 mg, 1 mg )Tab

**Trade Names:**

**Dosage:**

**Familial Mediterranean fever (FMF):** Oral: 1.2-2.4 mg/day in 1-2 divided doses. Titration: Increase or decrease dose in 0.3 mg/day increments based on efficacy or adverse effects; maximum: 2.4 mg/day

**Gout:** Oral:

- Flare treatment: Initial: 1.2 mg at the first sign of flare, followed in 1 hour with a single dose of 0.6 mg (maximum: 1.8 mg within 1 hour). Patients receiving prophylaxis therapy may receive treatment dosing; wait 12 hours before resuming prophylaxis dose.
- Prophylaxis: 0.6 mg once or twice daily; maximum: 1.2 mg/day

**Pericarditis post-STEMI (unlabeled use):** Oral: 0.6 mg twice daily

**Recurrent pericarditis due to previous autoimmune or idiopathic cause (unlabeled use):**

- Oral: 0.5-1 mg every 12 hours for 1 day, followed by 0.25-0.5 mg every 12 hours for 6 months (in combination with high-dose aspirin or ibuprofen)
- *Patients <70 kg or unable to tolerate higher dosing regimen:* 0.5 mg every 12 hours for 1 day followed by 0.5 mg once daily.

**Primary biliary cirrhosis (unlabeled use):** Oral: 0.6 mg twice daily (refractory to ursodiol)

**Dosage adjustment for concomitant therapy with CYP3A4 or P-glycoprotein (P-gp) inhibitors:**[ Dosage adjustment also required in patients receiving CYP3A4 or P-gp inhibitors up to 14 days prior to initiation of colchicine. Treatment of gout flare with colchicine is not recommended in patients receiving prophylactic colchicine and CYP3A4 inhibitors.]

**Coadministration of strong CYP3A4 inhibitor** (eg, atazanavir, clarithromycin, darunavir, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, nefazodone, nelfinavir, ritonavir, saquinavir, telithromycin, tipranavir):

- FMF: Maximum dose: 0.6 mg/day (0.3 mg twice daily).
- Gout prophylaxis: If original dose is 0.6 mg twice daily, adjust dose to 0.3 mg once daily; If original dose is 0.6 mg once daily, adjust dose to 0.3 mg every other day
- Gout flare treatment: Initial: 0.6 mg, followed in 1 hour by a single dose of 0.3 mg; do not repeat for at least 3 days

**Coadministration of moderate CYP3A4 inhibitor** (eg, aprepitant, diltiazem, erythromycin, fluconazole, fosamprenavir, grapefruit juice, verapamil):

- FMF: Maximum dose: 1.2 mg/day (0.6 mg twice daily)
- Gout prophylaxis: If original dose is 0.6 mg twice daily, adjust dose to 0.3 mg twice daily **or** 0.6 mg once daily; If original dose is 0.6 mg once daily, adjust dose to 0.3 mg once daily
- Gout flare treatment: 1.2 mg as a single dose; do not repeat for at least 3 days

**Coadministration of P-gp inhibitor (eg, cyclosporine, ranolazine):**

- FMF: Maximum dose: 0.6 mg/day (0.3 mg twice daily)
- Gout prophylaxis: If original dose is 0.6 mg twice daily, adjust dose to 0.3 mg once daily; If original dose is 0.6 mg once daily, adjust dose to 0.3 mg every other day
- Gout flare treatment: Initial: 0.6 mg as a single dose; do not repeat for at least 3 days

## Renal Impairment doses

**Concurrent use of colchicine and P-gp or strong CYP3A4 inhibitors is contraindicated in renal impairment. Fatal toxicity has been reported. Use of colchicine to treat gout flares is not recommended in patients with renal impairment receiving prophylactic colchicine.**

**FMF and Gout prophylaxis:**  $Cl_{cr}$  30-80 mL/minute: Monitor closely for adverse effects; dose reduction may be necessary.  $Cl_{cr}$  <30 mL/minute: Initial dose: 0.3 mg/day; use caution if dose titrated; monitor for adverse effects.

Dialysis (FMF): 0.3 mg as a single dose; use caution if dose titrated; dosing can be increased with close monitoring; monitor for adverse effects. Not removed by dialysis

Dialysis (Gout Prophylaxis): 0.3 mg twice weekly; monitor closely for adverse effects.

### **Gout flare treatment:**

$Cl_{cr}$  30-80 mL/minute: Dosage adjustment not required; monitor closely for adverse effects.

$Cl_{cr}$  <30 mL/minute: Dosage reduction not required but may be considered; treatment course should not be repeated more frequently than every 14 days.

Dialysis: 0.6 mg as a single dose; treatment course should not be repeated more frequently than every 14 days. Not removed by dialysis.

Hemodialysis: Avoid chronic use of colchicine.

## Hepatic Impairment

***Concurrent use of colchicine and P-glycoprotein or strong CYP3A4 inhibitors is contraindicated in hepatic impairment. Fatal toxicity has been reported. Treatment of gout flare with colchicine is not recommended in patients with hepatic impairment receiving prophylactic colchicine.***

*FMF and Gout prophylaxis:* Mild-to-moderate: Use caution; monitor closely for adverse effects; Severe impairment: Consider dosage reduction.

*Gout flare treatment:* Mild-to-moderate impairment: Dosage adjustment not required; monitor closely for adverse effects; Severe impairment: Dosage reduction not required but may be considered; treatment course should not be repeated more frequently than every 14 days.

**Common side effect:**

Gastrointestinal: Gastrointestinal disorders including abdominal pain, cramping, nausea, vomiting, diarrhea

Respiratory: Pharyngolaryngeal pain

**Pregnancy Risk Factor: C**