

**GLOPERBA  
(colchicine)****RATIONALE FOR INCLUSION IN PA PROGRAM****Background**

Gloperba (colchicine)'s effectiveness as a prophylactic treatment for gout has been postulated to be due to its ability to block neutrophil-mediated inflammatory responses induced by monosodium urate crystals in synovial fluid. Colchicine disrupts the polymerization of  $\beta$ -tubulin into microtubules, thereby preventing the activation, degranulation, and migration of neutrophils to site of inflammation. Colchicine also interferes with the inflammasome complex found in neutrophils and monocytes that mediates interleukin-1 $\beta$  (IL-1  $\beta$ ) activation (1).

**Regulatory Status**

FDA-approved indication: Gloperba (colchicine) is indicated for the prophylaxis of gout flares in adults (1).

Limitations of Use:

The safety and effectiveness of Gloperba for acute treatment of gout flares during prophylaxis has not been studied. Gloperba is not an analgesic medication and should not be used to treat pain from other causes (1).

Myelosuppression, leukopenia, granulocytopenia, thrombocytopenia, pancytopenia, and aplastic anemia have been reported with colchicine used in therapeutic doses (1).

Because colchicine is a substrate for both the CYP3A4 metabolizing enzyme and the P-gp efflux transporter, inhibition of either of these pathways may lead to colchicine-related toxicity.

Concomitant use of Gloperba with inhibitors of both CYP3A4 and P-gp should be avoided. If treatment with colchicine is necessary, a reduced daily dose should be considered and the patient should be closely monitored for colchicine toxicity. Use of Gloperba in conjunction with drugs that inhibit both CYP3A4 and P-gp is contraindicated in patients with renal or hepatic impairment (1).

The safety and effectiveness of Gloperba in pediatric patients less than 18 years of age have not been established (1).

**Summary**

**GLOPERBA  
(colchicine)**

The effectiveness of Gloperba (colchicine) as a prophylactic treatment for gout has been postulated to be due to its ability to block neutrophil-mediated inflammatory responses induced by monosodium urate crystals in synovial fluid. Colchicine disrupts the polymerization of  $\beta$ -tubulin into microtubules, thereby preventing the activation, degranulation, and migration of neutrophils to site of inflammation. Colchicine also interferes with the inflammasome complex found in neutrophils and monocytes that mediates interleukin-1 $\beta$  (IL-1  $\beta$ ) activation. The safety and effectiveness of Gloperba in pediatric patients less than 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Gloperba while maintaining optimal therapeutic outcomes.

**References**

1. Gloperba [package insert]. Alpharetta, GA: Avion Pharmaceuticals, LLC; August 2024.