# Important Safety Information for GLOPERBA® (colchicine)

- Colchicine 0.6 mg oral solution is contraindicated in patients with renal or hepatic impairment who are currently prescribed drugs that inhibit both P-gp and CYP3A4. Combining these dual inhibitors with colchicine in patients with renal or hepatic impairment has resulted in life-threatening or fatal colchicine toxicity. Patients with both renal and hepatic impairment should not be given GLOPERBA.
- Fatal overdoses have been reported with colchicine in adults and children. Keep GLOPERBA out of the reach of children.
- Blood dyscrasias, such as myelosuppression, leukopenia, granulocytopenia, thrombocytopenia, and aplastic anemia, have been reported with colchicine used in therapeutic doses.
- Drug interactions: 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 and, if present, consider lowering the dose, temporary interruption, or discontinuation of colchicine.
- Neuromuscular toxicity and rhabdomyolysis may occur with chronic treatment with colchicine in therapeutic doses, especially in combination with other drugs known to cause this effect. Patients with impaired renal function and elderly patients (including those with normal renal and hepatic function) are at increased risk. Consider lowering the dose, temporary interruption, or discontinuation of GLOPERBA.
- The most commonly reported adverse reactions with colchicine are gastrointestinal symptoms, including diarrhea, nausea, vomiting, and abdominal pain.

### INDICATION

GLOPERBA 0.6 mg oral solution is indicated for prophylaxis of gout flares in adults. 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.

You are encouraged to report negative side effects of prescription drugs to the FDA. To report suspected adverse reactions, visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see accompanying full Prescribing Information for GLOPERBA.

### **References:**

1. GLOPERBA® (colchicine) oral solution. Prescribing Information. SCILEX Pharmaceuticals; March 2024. 2. Robinson PC, Terkeltaub R, Pillinger MH, et al. Consensus statement regarding the efficacy and safety of long-term low-dose colchicine in gout and cardiovascular disease. Am J Med. 2022;135(1):32-38. doi: 10.1016/j.amjmed.2021.07.025 Epub 2021 Aug 18. 3. Data on file. SCILEX Pharmaceuticals: March 2024.

For gout patients at risk for colchicine toxicity

# How to Prescribe GLOPERBA

# for Gout Flare Prophylaxis

The first and only liquid oral colchicine with precision dosing below 0.6 mg for patients with renal impairment or GI sensitivity.1-3

## **IMPORTANT SAFETY INFORMATION**

### Indication

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GLOPERBA is not an analgesic medication and should not be used to treat pain from

Please see Important Safety Information on back and accompanying full Prescribing



GLOPERBA

with a pre-filled syringe

(colchicine) oral solution

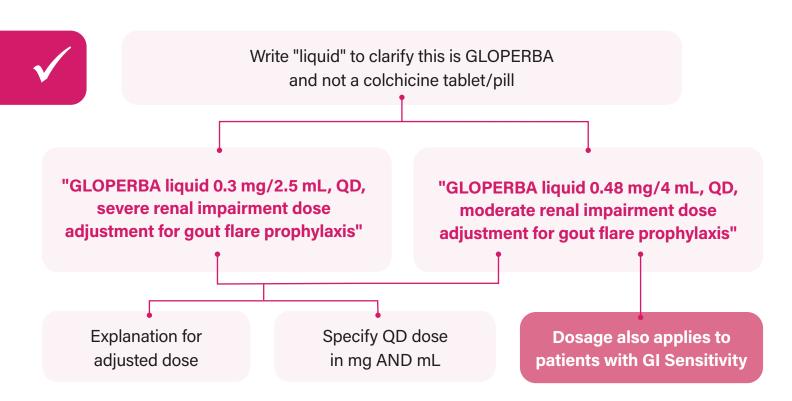
**Precision Dosing** 





# **HOW TO WRITE**

# **HOW TO ENTER IN EMR** (USING EPIC AS AN EXAMPLE)



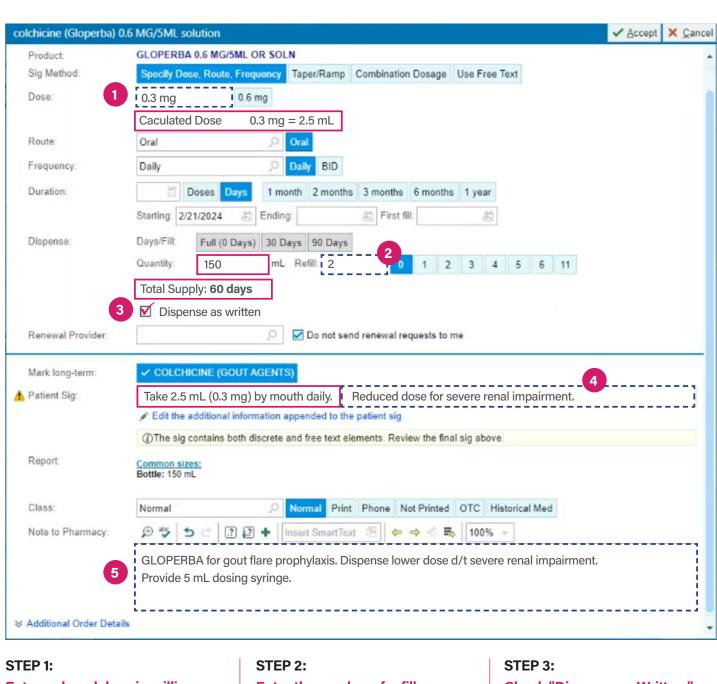
# **Daily Dose Conversion Chart**

Colchicine TABLET (mg) to GLOPERBA® LIQUID (mL) Conversion Table³			
GLOPERBA (mL)	Total Supply	Refills	Dose adjustment
1.0 mL	(150 mL bottle)		
2.0 mL			
2.5 mL	60 days	2	Severe renal impairment
3.0 mL			
4.0 mL	37 days	4	Moderate renal impairmen GI sensitivity
5.0 mL			
	GLOPERBA (mL)  1.0 mL  2.0 mL  2.5 mL  3.0 mL  4.0 mL	GLOPERBA (mL)  1.0 mL  2.0 mL  2.5 mL  3.0 mL  4.0 mL  37 days	GLOPERBA (mL)  1.0 mL  2.0 mL  2.5 mL  3.0 mL  4.0 mL  37 days  Refills  Refills

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# Enter reduced dose in milligrams. Dose can be reduced and is automatically converted to mL to avoid error/ typos.

### STEP 4:

**Enter notes here on downward** dose adjustment. Patient notes are **automatically updated** with dose, route and frequency.

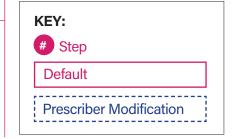
# **Enter the number of refills**

Total supply is automatically calculated based on dose, frequency and quantity.

# STEP 5:

Be sure to provide pharmacist with an explanation for adjusted dose and direction to provide a 5mL dosing syringe.

**Check "Dispense as Written."** 



Please see Important Safety Information on back and accompanying full Prescribing Information for GLOPERBA.