**INDICATIONS AND USAGE**

GLOPERBA® (colchicine) is indicated for the prevention of gout flares in adults and children 18 years of age and older. It is recommended that GLOPERBA be administered at a minimum dosage of 0.6 mg/day (5 mL) for adults and 0.13 mg/kg/day (1 mL) for children weighing less than 10 kg. The maximum recommended daily dose is 1.2 mg/day (10 mL) for adults and 0.26 mg/kg/day (5 mL) for children weighing 10 kg or more. GLOPERBA is administered orally, without regard to meals.

**DOSAGE FORMS AND STRENGTHS**

- **16.1 Formulations**
  - Ready-to-use solution for oral administration containing 0.6 mg/5 mL of colchicine.

**CLINICAL PHARMACOLOGY**

**5.1 Pharmacokinetics**

Colchicine is rapidly absorbed from the gastrointestinal tract, with peak plasma levels occurring within one week to several months. Patients with impaired renal function and elderly patients, even those with normal renal and hepatic function, are at increased risk of colchicine toxicity.

**5.2 Drug Interactions**

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. Inhibition of both CYP3A4 and P-gp by dual inhibitors (i.e., a substrate that has been reported to produce colchicine-related toxicity or fatal overdoses, both accidental and intentional, have been reported in adults and children who have ingested colchicine). The coadministration with CYP3A4 and P-gp inhibitors is required, the patient's dose of colchicine may need to be reduced or interrupted, and the patient should be monitored carefully for colchicine toxicity.

**5.3 Overdose**

Fatal overdoses, both accidental and intentional, have been reported in adults and children who have ingested colchicine. The coadministration with CYP3A4 and P-gp inhibitors is required, the patient's dose of colchicine may need to be reduced or interrupted, and the patient should be monitored carefully for colchicine toxicity.

**5.4 Use in Specific Subpopulations**

**5.4.1 Geriatric Use**

Use of GLOPERBA in conjunction with drugs that inhibit both CYP3A4 and P-gp is contraindicated in patients with reduced renal function, because concomitant use of GLOPERBA with inhibitors of both CYP3A4 and P-gp is associated with a significant increase in systemic colchicine levels, leading to potentially fatal toxicity.

**ADVERSE REACTIONS**

The most commonly reported adverse reactions with colchicine are gastrointestinal symptoms, including diarrhea, nausea, vomiting, and abdominal pain.

**CONTRAINDICATIONS**

Patients with renal or hepatic impairment should not be given GLOPERBA in conjunction with drugs that inhibit both CYP3A4 and P-gp. A patient should be closely monitored for colchicine toxicity [see Drug Interactions (5.4)].

**WARNINGS AND PRECAUTIONS**

**5.1 Hypersensitivity Reactions**

Hypersensitivity reactions, including anaphylaxis, have been reported with colchicine in adults and children. Keep GLOPERBA out of the reach of children.

**5.2 Blood Dyscrasias**

Blood dyscrasias, including bone marrow depression, thrombocytopenia, agranulocytosis, and aplastic anemia, have been reported with colchicine. Patients with bone marrow depression should be closely monitored for colchicine toxicity.

**5.3 Drug Interactions**

Drug interactions may lead to colchicine-related toxicity. Inhibition of both CYP3A4 and P-gp by dual inhibitors (i.e., a substrate that has been reported to produce colchicine-related toxicity or fatal overdoses, both accidental and intentional, have been reported in adults and children who have ingested colchicine). The coadministration with CYP3A4 and P-gp inhibitors is required, the patient's dose of colchicine may need to be reduced or interrupted, and the patient should be monitored carefully for colchicine toxicity.

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6. ADVERSE REACTIONS

Controversial disorders are for the most commonplace reactions with colchicine. These disorders are distinctive signs of toxicity and may indicate that the drug is not suitable to be reduced or therapy stopped. These indicators include diarrhea, nausea, vomiting, and abdominal pain.

Colchicine has been reported to cause neuromuscular toxicity, which may present in muscle pain, weakness, or headaches.

The following adverse reactions have been reported with colchicine. These adverse reactions have been generally reversible upon interrupting treatment or lowering the dose of colchicine:

- Neurological: headaches, cranial neuropathy, nausea, vomiting
- Dermatological: alopecia, maculopapular rash, purpura
- Gastrointestinal: abdominal cramping, abdominal pain, diarrhea, ileus, hemorrhage, nausea, vomiting
- Hematological: anemia, granulocytopenia, thrombocytopenia, pancytopenia, aplastic anemia
- Renal: elevated BUN, elevated ALT
- Metabolic: myopathy, elevated CPK, myoglobin, muscle weakness, muscle pain, rhabdomyolysis

7. DISCONTINUATIONS

Colchicine is a substrate of the CYP3A4 metabolizing enzyme and the P-glycoprotein (P-gp) efflux transporter. The drug's metabolism and efflux can be altered by co-administration with certain drugs, such as clarithromycin, a dual inhibitor of CYP3A4 and P-gp. Patients have also been reported to experience adverse reactions when colchicine is administered with inhibitors of CYP3A4. Inhibitors of P-gp (e.g., grapefruit juice, erythromycin, qinacrin) or inhibitors of P-gp that may not be potent inhibitors of CYP3A4 may also be considered.

Patients with renal or hepatic impairment should be given GLOPERBA with drugs that inhibit both CYP3A4 and P-glycoprotein (see Contraindications). Combining these dual inhibitors with GLOPERBA in patients with renal or hepatic impairment has resulted in drug interactions that may increase the risk of toxicity.

Care should be taken to reduce or discontinue therapy in patients who show signs or symptoms of toxicity, especially if co-administered drugs are also involved.

8. USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Available literature from published clinical trials on colchicine use in pregnancy over several decades has identified few drug-related adverse effects for major birth defects, miscarriage, or adverse maternal or fetal events (see Warnings and Precautions). Although animal toxicology and development studies exist, no information on the risk-benefit ratio is available.

The following adverse reactions have been reported with colchicine. These adverse reactions have been generally reversible upon interrupting treatment or lowering the dose of colchicine:

- Cardiovascular: hypotension, nausea, vomiting
- Respiratory: respiratory depression

8.2 Lactation

The use of GLOPERBA during breastfeeding is not recommended due to the potential for serious and life-threatening complications in the newborn. However, the results should not be extrapolated to other co-administered drugs. Colchicine plasma levels were normally elevated when GLOPERBA was co-administered with propoxyphene (12.5 mg/kg).

8.3 Pediatric Use

The use of GLOPERBA in children is not recommended due to the potential for serious and life-threatening complications in the newborn. However, the results should not be extrapolated to other co-administered drugs. Colchicine plasma levels were normally elevated when GLOPERBA was co-administered with propoxyphene (12.5 mg/kg).

8.4 Geriatric Use

Because of the increased incidence of decreased renal function in the elderly population, and the higher incidence of other co-morbid conditions in the elderly population, especially the use of other medications, the dosage of colchicine is recommended to be reduced or therapy stopped carefully (see Clinical Pharmacology).

8.5 Renal Impairment

No data is available for the use of colchicine in patients with renal impairment. Colchicine is not excreted by the kidney, and its excretion in this population has not been studied. No information on the use of colchicine in patients with renal impairment is available.

8.6 Hepatic Impairment

No data is available for the use of colchicine in patients with hepatic impairment. Colchicine is not metabolized by the liver, and its excretion in this population has not been studied. No information on the use of colchicine in patients with hepatic impairment is available.

8.7 Hypothyroid Impairment

No data is available for the use of colchicine in patients with hypothyroid impairment. Colchicine is not excreted by the kidney, and its excretion in this population has not been studied. No information on the use of colchicine in patients with hypothyroid impairment is available.

10. OVERDOSAGE

The dose of colchicine that would induce significant toxicity for an individual varies.Fatalities have occurred after ingestion of as little as 5 mg over a 2-hour period, while other patients have survived after receiving up to 50 mg. The symptoms of colchicine overdose are primarily gastrointestinal in nature, including nausea, vomiting, diarrhea, abdominal pain, and peripheral edema. These symptoms may be life-threatening in severe cases, particularly in patients with renal or hepatic impairment.

10.1 General Measures

Gastrointestinal decontamination should be performed if indicated. Activated charcoal may be beneficial, and attempts to control vomiting may be helpful. If the patient survives, recovery is generally rapid. If the patient is unresponsive, the use of dopamine is not recommended.

10.2 Specific Therapy

No specific antidote to colchicine is known. The supportive care of patients with severe colchicine toxicity is crucial.

10.3 Withdrawal

Colchicine has been used as an abortifacient in patients with severe colchicine toxicity. The use of colchicine in pregnant women is not recommended due to the potential for serious and life-threatening complications in the newborn. However, the results should not be extrapolated to other co-administered drugs. Colchicine plasma levels were normally elevated when GLOPERBA was co-administered with propoxyphene (12.5 mg/kg).

10.4 Disposition

The nature of colchicine toxicity is not altered by the use of dialysis or hemoperfusion. The use of dialysis or hemoperfusion is not recommended.
**11 DESCRIPTION**

Colchicine is a naturally derived constituent of several species of Colchicum. The chemical name for colchicine is 12,13-dihydroxy-1,2,3,13-tetramethoxy-9-oxobenzo[**a**]heptalen-7-yl acetamide (considered a weak CYP3A4 inhibitor) increased AUC by approximately 3-fold.

**12 CLINICAL PHARMACOLOGY**

**12.1 Mechanism of Action**

Colchicine is effective as a prophylactic treatment for gout, although it is not always successful in all patients. Colchicine works by inhibiting the formation of neutrophil granules, which are responsible for the inflammatory response in gout flares.

**12.2 Pharmacodynamics**

The pharmacodynamics of colchicine are not fully understood. It is known to inhibit the formation of neutrophil granules and to have anti-inflammatory properties.

**12.3 Pharmacokinetics**

Absorption

Colchicine is well absorbed following oral administration. The absolute bioavailability of colchicine is approximately 80%.

Distribution

Colchicine is extensively distributed throughout the body. The mean volume of distribution of colchicine in healthy adults is approximately 2 liters/kg.

Elimination

Colchicine is primarily excreted in the urine. The mean elimination half-life of colchicine in healthy adults is 31 hours.

**Drug Interactions**

Colchicine is a substrate of the P-glycoprotein (P-gp) and the cytochrome P450 (CYP3A4) systems. Co-administration of colchicine with P-gp and CYP3A4 inhibitors may result in increased serum levels of colchicine, while co-administration with P-gp and CYP3A4 inducers may result in decreased serum levels of colchicine.

**13 NONCLINICAL TOXICOLOGY**

**13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility**

Carcinogenesis

No studies have been conducted on the carcinogenic potential of colchicine in animals.

Mutagenesis

No studies have been conducted on the mutagenic potential of colchicine.

Impairment of Fertility

There were no studies conducted on the effects of colchicine on fertility in animals.

**14 CLINICAL STUDIES**

The studies for the efficacy of colchicine in the prevention of gout flares included a randomized, double-blind, placebo-controlled trial in patients with gouty arthritis. The study demonstrated that colchicine significantly reduced the frequency of gout flares.

**15 HOW SUPPLIED/STORAGE AND HANDLING**

**15.1 How Supplied**

GLOPERBA (colchicine oral solution) is supplied as a 150 mL bottle, containing 4 mg/mL of the active ingredient colchicine USP. Each 5 mL dose of GLOPERBA consists of propylene glycol, propylene glycol, FD&C Red No. 40, artificial cherry flavor, anhydrous citric acid, dibasic sodium phosphate, sucralose, and purified water.
Risk of Infertility

Infertility may occur with GLOPERBA alone or when it is used with certain other drugs. Patients should be informed that muscle pain or weakness, tingling or numbness in fingers or toes may occur with GLOPERBA. Patients should be notified that muscle pain or weakness, tingling or numbness in fingers or toes may also occur with nonsteroidal anti-inflammatory drugs (NSAIDs) and that some interactions could be fatal.

Bleeding Problems

Blood dyscrasias have happened in some people taking GLOPERBA. Patients should be informed that bone marrow depression with agranulocytosis, aplastic anemia and pancytopenia have occurred in some people taking GLOPERBA. Patients should also be advised to report any signs of infection or symptoms of bone marrow depression (eg, fever, unusual bleeding or bruising) to their healthcare provider. Patients should also be advised that many drugs or other substances may interact with GLOPERBA and that patients may experience bleeding problems when taking GLOPERBA.

Fatal Overdose

Patients should be informed that muscle pain or weakness, tingling or numbness in fingers or toes may occur with GLOPERBA. Patients should be notified that muscle pain or weakness, tingling or numbness in fingers or toes may also occur with nonsteroidal anti-inflammatory drugs (NSAIDs) and that some interactions could be fatal.

Drug and Food Interactions

Patients who take drugs or other substances may interact with GLOPERBA and some interactions could be fatal. Therefore, patients should report to their healthcare provider all of the prescription and over-the-counter (nonprescription) drugs they are taking and check with their healthcare provider before starting any new medication, including herbal or vitamin supplements. Patients should also be advised to report to their healthcare provider all nonprescription medications (eg, dietary supplements, inorganic or organic supplements, vitamins or herbal products) that they are taking. Patients should also be informed that many drugs or other substances may interact with GLOPERBA and that some interactions could be fatal. Patients should also be advised to report to their healthcare provider all nonprescription medications (eg, dietary supplements, inorganic or organic supplements, vitamins or herbal products) that they are taking.

Bleeding problems have happened in some people taking GLOPERBA. Patients should be informed that many drugs or other substances may interact with GLOPERBA and that patients may experience bleeding problems when taking GLOPERBA. Patients should also be advised to report any signs of infection or symptoms of bone marrow depression (eg, fever, unusual bleeding or bruising) to their healthcare provider. Patients should also be advised that many drugs or other substances may interact with GLOPERBA and that patients may experience bleeding problems when taking GLOPERBA.

GLOPERBA can cause serious side effects or death in people with colchicine hypersensitivity. Patients should be informed that muscle pain or weakness, tingling or numbness in fingers or toes may occur with GLOPERBA. Patients should be notified that muscle pain or weakness, tingling or numbness in fingers or toes may also occur with nonsteroidal anti-inflammatory drugs (NSAIDs) and that some interactions could be fatal.

Muscle weakness (neuromuscular toxicity)

Muscle weakness has happened in some people taking GLOPERBA. Patients should be informed that muscle pain or weakness, tingling or numbness in fingers or toes may occur with GLOPERBA. Patients should be notified that muscle pain or weakness, tingling or numbness in fingers or toes may also occur with nonsteroidal anti-inflammatory drugs (NSAIDs) and that some interactions could be fatal.

Muscle weakness (myopathy)

Muscle weakness has happened in some people taking GLOPERBA. Patients should be informed that muscle pain or weakness, tingling or numbness in fingers or toes may occur with GLOPERBA. Patients should be notified that muscle pain or weakness, tingling or numbness in fingers or toes may also occur with nonsteroidal anti-inflammatory drugs (NSAIDs) and that some interactions could be fatal.

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Agranulocytosis

Agranulocytosis has happened in some people taking GLOPERBA. Patients should be informed that muscle pain or weakness, tingling or numbness in fingers or toes may occur with GLOPERBA. Patients should be notified that muscle pain or weakness, tingling or numbness in fingers or toes may also occur with nonsteroidal anti-inflammatory drugs (NSAIDs) and that some interactions could be fatal.

Aplastic anemia

Aplastic anemia has happened in some people taking GLOPERBA. Patients should be informed that muscle pain or weakness, tingling or numbness in fingers or toes may occur with GLOPERBA. Patients should be notified that muscle pain or weakness, tingling or numbness in fingers or toes may also occur with nonsteroidal anti-inflammatory drugs (NSAIDs) and that some interactions could be fatal.

Pancytopenia

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Bone marrow depression

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Gastrointestinal problems

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Nausea

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Vomiting

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Anaphylaxis

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Bacterial infections

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Skin reactions

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Metabolic acidosis

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Other side effects

Other side effects have happened in some people taking GLOPERBA. Patients should be informed that muscle pain or weakness, tingling or numbness in fingers or toes may occur with GLOPERBA. Patients should be notified that muscle pain or weakness, tingling or numbness in fingers or toes may also occur with nonsteroidal anti-inflammatory drugs (NSAIDs) and that some interactions could be fatal.

GLOPERBA should be taken exactly as directed. Do not take more GLOPERBA or take it more often than prescribed by your healthcare provider. If you take too much GLOPERBA, call your healthcare provider or local poison control center right away.

Store GLOPERBA at room temperature between 68°F and 77°F (20°C and 25°C). Store GLOPERBA in a tightly closed container.

Keep GLOPERBA and all other medicines out of the reach of children.
### Product Information

**Product Type:** Human Prescription Drug  
**Item Code (Source):** NDC:72690-010

### Route of Administration

**ORAL**

### Active Ingredient/Active Moiety

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<th>Ingredient Name</th>
<th>Basis of Strength</th>
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<tr>
<td>COLCHICINE</td>
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### Inactive Ingredients

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<td>WATER</td>
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<td>CHERRY</td>
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### Product Characteristics

- **Color:** RED (slightly Hazy)
- **Shape:** 
- **Size:** 
- **Flavor:** CHERRY
- **Imprint Code:**

### Packaging

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### Marketing Information

- **Marketing Category:** 
- **Application Number or Monograph Citation:  
- **Marketing Start Date:** 08/01/2019
- **Marketing End Date:** |

### Labeler

ROMEG Therapeutics, LLC (090845416)