

MEDICATION GUIDE
GLOPERBA® (Glow per' bah)
(colchicine) Oral Solution

What is the most important information I should know about GLOPERBA?

GLOPERBA can cause serious side effects or death if levels of GLOPERBA are too high in your body.

- Taking certain medicines with GLOPERBA can cause your level of GLOPERBA to be too high, especially if you have kidney or liver problems.
- Tell your healthcare provider about all your medical conditions, including if you have kidney or liver problems. Your dose of GLOPERBA may need to be changed.
- Tell your healthcare provider about all the medicines you take, including prescription and nonprescription medicines, vitamins and herbal supplements.
- Medicines that you take for a short period of time, such as antibiotics, can interact with GLOPERBA and cause serious side effects or death.
- Talk to your healthcare provider or pharmacist before taking any new medicine.

What is GLOPERBA?

GLOPERBA is a prescription medicine used to prevent gout flares in adults.

It is not known if GLOPERBA is safe and effective for the treatment of sudden (acute) gout flares.

GLOPERBA is not a pain medicine, and it should not be taken to treat pain related to other medical conditions unless specifically prescribed for those conditions.

It is not known if GLOPERBA is safe and effective in children.

Do not take GLOPERBA if you:

- have liver or kidney problems and you take certain other medicines, unless directed to by a healthcare provider. Serious side effects, including death, have happened in people even when GLOPERBA is taken as directed.
- have liver and kidney problems.

See “What is the most important information that I should know about GLOPERBA?”

Before taking GLOPERBA, tell your healthcare provider about all of your medical conditions, including if you:

- are pregnant or plan to become pregnant. It is not known if GLOPERBA can harm your unborn baby.
- are breastfeeding or plan to breastfeed. GLOPERBA can pass into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take GLOPERBA.
- are a **male** with a female partner who can become pregnant. Receiving treatment with GLOPERBA may be related to infertility in some men that is reversible when treatment is stopped.

Tell your healthcare provider about all the medicines you take, including prescription, over-the-counter medicines, vitamins, and herbal supplements.

- Using GLOPERBA with certain other medicines can affect each other, causing serious side effects or death.
- **Do not** take GLOPERBA with other medicines unless your healthcare provider tells you to.
- Know the medicines you take. Keep a list of your medicines with you to show your healthcare provider and pharmacist each time you get a new medicine.
- Especially tell your healthcare provider if you take:
 - medicines that may affect how your liver works (CYP3A4 inhibitors)
 - a medicine called cyclosporine (Noeral, Gengraf, Sandimmune)
 - cholesterol lowering medicines, or
 - antibiotics

Ask your healthcare provider or pharmacist if you are not sure if you take any of the medicines listed above. This is not a complete list of all the medicines that can affect GLOPERBA.

How should I take GLOPERBA?

- Take GLOPERBA exactly as your healthcare provider tells you to take it. If you are not sure about your dosing, call your healthcare provider.
- Measure GLOPERBA with an accurate milliliter measuring device. **A household teaspoon is not an accurate measuring device.** Ask your pharmacist to recommend a measuring device and for instructions on how to measure the correct dose.
- GLOPERBA can be taken with or without food.
- If you take too much GLOPERBA, call your healthcare provider or go to the nearest hospital emergency room right away.
- **Do not stop taking GLOPERBA unless your healthcare provider tells you.**
- If you miss a dose of GLOPERBA, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose. Take the next dose at your regular time. Do not take 2 doses at the same time.

What should I avoid while taking GLOPERBA?

Avoid eating grapefruit or drinking grapefruit juice while taking GLOPERBA. It can increase your chances of having serious side effects.

What are the possible side effects of GLOPERBA?

GLOPERBA can cause serious side effects, including:

See “What is the most important information that I should know about GLOPERBA?”

- **Blood problems.** Blood problems have happened in some people taking GLOPERBA. Get medical help right away if you have any of these symptoms:
 - pale or gray color to your lips, tongue or palms of your hands.
 - feel weak or tired
 - unusual bleeding or bruising
 - increased infections
- **Muscle weakness (neuromuscular toxicity).** Muscle weakness has happened in some people taking GLOPERBA. Get medical help right away if you have any of these symptoms:
 - muscle weakness or pain
 - numbness or tingling in your fingers or toes

The most common side effects of GLOPERBA include:

- diarrhea
- nausea
- vomiting
- abdominal (stomach) pain

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of GLOPERBA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store GLOPERBA?

Store GLOPERBA between 20°-25°C (68° - 77°F); excursions permitted to 15°-30°C (59°-86°F). [See USP Controlled Room Temperature.]

Keep GLOPERBA and all medicines out of the reach of children.

General information about the safe and effective use of GLOPERBA.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use GLOPERBA for a condition for which it was not prescribed. Do not give GLOPERBA to other people, even if they have the same symptoms that you have. It may harm them. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about GLOPERBA that is written for healthcare professionals.

What are the ingredients in GLOPERBA?

Active Ingredient: colchicine

Inactive Ingredients: benzyl alcohol, FD&C Red No. 40, artificial cherry flavor, anhydrous citric acid, dibasic sodium phosphate, glycerin, propylene glycol, sucralose, xanthan gum and purified water.

Rx ONLY**Manufactured for:**

SCILEX Pharmaceuticals, Inc.

Palo Alto, California

For more information, visit scilexholding.com or call 1-866-SCILEX3.

This Medication Guide has been approved by the U.S. Food and Drug Administration

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