

MEDICATION GUIDE

GLOPERBA® (colchicine USP) Oral Solution

Read the Medication Guide that comes with GLOPERBA before you start taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or treatment. You and your healthcare provider should talk about GLOPERBA when you start taking it and at regular checkups.

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

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

- Taking certain medicines with GLOPERBA can cause your level of colchicine 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.
- Even 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

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

It is not known if GLOPERBA is safe and effective in children. Keep GLOPERBA out of the reach of children.

Who should not take GLOPERBA?

Do not take GLOPERBA if you have liver or kidney problems and you take certain other medicines. Serious side effects, including death, have been reported in these patients even when taken as directed. See "**What is the most important information that I should know about GLOPERBA?**"

What should I tell my healthcare provider before starting GLOPERBA?

See "**What is the most important information that I should know about GLOPERBA?**"

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

- have liver or kidney problems;
- are pregnant or plan to become pregnant. It is not known if GLOPERBA will harm your unborn baby. Talk to your healthcare provider if you are pregnant or plan to become pregnant.
- are breastfeeding or plan to breastfeed. GLOPERBA passes into your breast milk. You and your healthcare provider should decide if you will take GLOPERBA or breastfeed. If you take GLOPERBA and breastfeed, you should talk to your child's healthcare provider about how to watch for side effects in your child.

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

- Using GLOPERBA with certain other medicines can affect each other, causing serious side effects and/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);
 - cyclosporine ;
 - 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.
- GLOPERBA can be taken with or without food.
- If you take too much GLOPERBA, go to the nearest hospital emergency room right away.
- Do not stop taking GLOPERBA even if you start to feel better, unless your healthcare provider tells you.
- If you take GLOPERBA daily and you miss a dose, then take it as soon as you remember. If it is almost time for your next dose, just skip the missed dose. Take the next dose at your regular time.
- If you have a gout flare while taking GLOPERBA daily, report this to your healthcare provider.

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 or even cause death. See "**What is the most important information that I should know about GLOPERBA?**"

Get medical help right away if you have:

- Muscle weakness or pain
- Numbness or tingling in your fingers or toes
- Unusual bleeding or bruising
- Increased infections
- Feel weak or tired
- Pale or gray color to your lips, tongue or palms of your hands
- Severe diarrhea or vomiting

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. For more information, ask your healthcare provider or pharmacist.

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 at room temperature between 68°F and 77°F (20°C and 25°C).

- **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. This Medication Guide summarizes the most important information about GLOPERBA. 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.

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

R_x ONLY

Issued: 7/2019

Manufactured for:

Avion Pharmaceuticals, LLC

Alpharetta, GA 30005

L-0225 Rev. 1219-01