

MEDICATION GUIDE

Glycerol Phenylbutyrate (GLIS-er-ol FEN-il-BUE-ti-rate) Oral Liquid

What is the most important information I should know about Glycerol Phenylbutyrate Oral Liquid?

Glycerol phenylbutyrate oral liquid may cause serious side effects, including:

Nervous system problems (Neurotoxicity). Phenylacetate (PAA), a breakdown product of glycerol phenylbutyrate oral liquid, may cause nervous system side effects. Call your doctor or get medical help right away if you get any of these symptoms while taking glycerol phenylbutyrate oral liquid:

- sleepiness
- lightheadedness
- change in taste
- problems with hearing
- confusion
- problems with memory
- worsening of numbness, tingling, or burning in your hands or feet
- headache
- feeling very tired (fatigue)
- nausea
- vomiting

Your doctor may do blood tests to measure the amount of PAA in your blood during your treatment with glycerol phenylbutyrate oral liquid.

What is Glycerol Phenylbutyrate Oral Liquid?

- Glycerol phenylbutyrate oral liquid is a prescription medicine used for long-term management of high blood levels of ammonia (hyperammonemia) caused by a condition called a urea cycle disorder (UCD). Glycerol phenylbutyrate oral liquid should be used if the UCD cannot be managed with a low protein diet and dietary supplements alone. Glycerol phenylbutyrate oral liquid must be used along with a low protein diet and in some cases dietary supplements.
- Glycerol phenylbutyrate oral liquid is not used for the acute treatment of hyperammonemia in people with UCD.
- It is not known if glycerol phenylbutyrate oral liquid is safe and effective for the treatment of N-acetylglutamate synthase (NAGS) deficiency.

Do not take Glycerol Phenylbutyrate Oral Liquid if you are allergic to phenylbutyrate.

Call your doctor or go to the nearest hospital emergency room if you have wheezing, shortness of breath, cough, low blood pressure, flushing, nausea or a rash while taking glycerol phenylbutyrate oral liquid.

Before taking glycerol phenylbutyrate oral liquid, tell your doctor about all of your medical conditions, including if you:

- have liver or kidney problems
- have pancreas or bowel (intestine) problems
- are pregnant or plan to become pregnant. It is not known if glycerol phenylbutyrate oral liquid will harm your unborn baby. If you become pregnant during treatment with glycerol phenylbutyrate oral liquid, call Horizon at 1-800-772-6436 to report the pregnancy.
- are breastfeeding or plan to breastfeed. It is not known if glycerol phenylbutyrate passes into your breast milk. Breastfeeding is not recommended during treatment with glycerol phenylbutyrate oral liquid. Talk to your doctor about the best way to feed your baby if you take glycerol phenylbutyrate oral liquid.

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

Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

How should I take Glycerol Phenylbutyrate Oral Liquid?

- Take glycerol phenylbutyrate oral liquid exactly as your doctor tells you.
- Your doctor will tell you how much glycerol phenylbutyrate oral liquid to take and when to take it.
- Your doctor may change your dose if needed.
- Take glycerol phenylbutyrate oral liquid with food or formula.
- In an infant who is breastfeeding, give glycerol phenylbutyrate oral liquid just before breastfeeding.
- Glycerol phenylbutyrate oral liquid is an oral liquid that is taken by mouth using an oral syringe.
- Ask your pharmacist for oral syringes and a reclosable bottle cap adapter for each bottle you receive if you do not have them
- Use the glycerol phenylbutyrate oral liquid bottle and oral syringe as follows:
 - Use a new reclosable bottle cap adapter with each new glycerol phenylbutyrate oral liquid bottle that is opened.
 - Open the glycerol phenylbutyrate oral liquid bottle and twist on the new reclosable bottle cap adapter.
 - Use a new dry oral syringe to remove each prescribed dose of glycerol phenylbutyrate oral liquid.
 - Throw away (discard) the oral syringe after each dose.
 - Tightly close the tethered tab on the reclosable bottle cap adapter after each use.
 - Do not rinse the reclosable bottle cap adapter.
 - If water or moisture enters the glycerol phenylbutyrate oral liquid bottle, the contents will become cloudy in appearance. If the contents appear cloudy at any time, **do not** use the remaining glycerol phenylbutyrate oral liquid and return the bottle to your pharmacy to throw it away.
 - Throw away the bottle and any unused glycerol phenylbutyrate oral liquid 28 days after opening.
- If you have a nasogastric or gastrostomy tube in place and can swallow, you should take glycerol phenylbutyrate oral liquid by mouth.
- Stay on the diet that your doctor gives you.
- If you take too much glycerol phenylbutyrate oral liquid, call your doctor or your poison control center at 1-800-222-1222 or go to the nearest hospital emergency room right away.

For people who cannot swallow and who have a nasogastric or gastrostomy tube in place, glycerol phenylbutyrate oral liquid should be given as follows:

- Use a new dry oral syringe to withdraw each prescribed dose of glycerol phenylbutyrate oral liquid from the bottle.
- Place the tip of the syringe into the nasogastric or gastrostomy tube and push the plunger of the syringe to give glycerol phenylbutyrate oral liquid into the tube.
- Use a separate syringe to flush the nasogastric or gastrostomy tube. Add 10 mL of water or formula to the syringe and push the plunger of the syringe to flush any remaining medicine from the nasogastric or gastrostomy tube into the stomach.

- If needed, flush the nasogastric or gastrostomy tube again with 10 mL of water or formula to clear the nasogastric or gastrostomy tube.

What are the possible side effects of Glycerol Phenylbutyrate Oral Liquid?

Glycerol phenylbutyrate oral liquid may cause serious side effects, including:

- See “**What is the most important information I should know about Glycerol Phenylbutyrate Oral Liquid?**”

The most common side effects of glycerol phenylbutyrate oral liquid in adults include:

- diarrhea
- gas
- headache
- abdomen (stomach) pain
- vomiting
- tiredness
- decreased appetite
- indigestion or heartburn

The most common side effects of glycerol phenylbutyrate oral liquid in children 2 years to 17 years of age include:

- upper abdomen (stomach) pain
- rash
- nausea
- vomiting
- diarrhea
- decreased appetite
- headache

The most common side effects of glycerol phenylbutyrate oral liquid in children 2 months to less than 2 years of age include:

- low white blood cell count (neutropenia)
- vomiting
- constipation
- diarrhea
- fever
- reduced food intake
- cough
- stuffy nose
- runny nose
- skin rash
- small round bumps on the skin

The most common side effects of glycerol phenylbutyrate oral liquid in children less than 2 months of age include:

- vomiting
- rash
- gastroesophageal reflux
- increased levels of liver enzymes in the blood
- decreased appetite and reduced food intake
- low red blood cell count (anemia)
- cough
- loss of too much body fluid (dehydration)
- too much acid in the blood (acidosis)
- high blood platelet count (thrombocytosis)
- low blood platelet count (thrombocytopenia)
- low blood neutrophil count (type of white blood cell) (neutropenia)
- high blood white blood cell count (lymphocytosis)
- diarrhea
- gas
- constipation
- fever
- drowsiness (lethargy)
- irritability
- agitation

These are not all of the possible side effects of glycerol phenylbutyrate oral liquid.

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 Glycerol Phenylbutyrate Oral Liquid?

Store glycerol phenylbutyrate oral liquid between 68°F to 77°F (20°C to 25°C).

Keep glycerol phenylbutyrate oral liquid and all medicines out of the reach of children.

General information about the safe and effective use of glycerol phenylbutyrate oral liquid

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use glycerol phenylbutyrate oral liquid for a condition for which it was not prescribed. Do not give glycerol phenylbutyrate oral liquid to other people, even if they have the same symptoms you have. It may harm them. You can ask your doctor or pharmacist for information about glycerol phenylbutyrate oral liquid that is written for health professionals.

What are the ingredients in Glycerol Phenylbutyrate Oral Liquid?

Active ingredient: glycerol phenylbutyrate

For more information, call 1-800-772-6436.

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

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