

Welcome to the Lupin Glycerol Phenylbutyrate Oral Liquid 1.1 gm/mL Savings Program

# COMMERCIALLY INSURED PATIENTS MAY PAY AS LITTLE AS \$0\*

\*Per fill. Not valid for any person eligible for reimbursement of prescriptions, in whole or in part, by any state or federally funded program, including Medicare, Medigap, or Medicaid, or where prohibited, taxed or otherwise restricted by law.

SEE BELOW FOR FULL TERMS AND CONDITIONS THAT APPLY



# **Use and Important Safety Information**

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

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

Nervous system side effects (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 have 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.

# What are 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

ash

nausea

diarrhea

decreased appetite

headache

· vomiting

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

cough

stuffy nose

· runny nose

· skin rash

small round bumps on the skin

reduced food intake

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)

 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

· high blood platelet count (thrombocytosis)

low blood platelet count (thrombocytopenia)

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.

For additional Important Safety Information, click here for the Medication Guide and discuss with your doctor.

## **Eligibility Requirements:**

- Not valid for any person eligible for reimbursement of prescriptions, in whole or in part, by any state or federally funded program. This
  includes
- Medicare, Medigap, Medicaid, TRICARE®, Veterans Affairs (VA) or Department of Defense (DoD) health coverage, Employer Group Waiver Plans, or where prohibited, taxed or otherwise restricted by law.
- Must be a US resident.
- Must be 18 years of age or older to redeem this offer for yourself or a minor.

### **Terms and Conditions:**

- · Offer valid for up to 12 fills.
- A commercially insured patient with plan coverage for glycerol phenylbutyrate may pay as little as \$0.
- Patient out-of-pocket costs may vary. Patient is responsible for any remaining balance after offer is applied and applicable taxes, if any.
- This co-pay card is not valid when the entire cost of a patient's prescription drug is eligible for reimbursement from a private insurance plan or other private health or pharmacy benefit programs.
- Patient and pharmacy agree not to seek reimbursement for all or any part of the benefit received by the patient through this offer from any third party payer and are each responsible for making any required reports of use of this offer to any third-party payer who pays any part of the prescription filled.
- Valid only at participating pharmacies in the US and Puerto Rico.
- No other purchase is necessary.
- · This card and offer are not health insurance.
- The selling, purchasing, trading, or counterfeiting of this offer is prohibited by law. Void if reproduced.
- Not valid with other offers. This offer has no cash value. No cash back.
- · Lupin Pharmaceuticals, Inc. reserves the right to amend, revoke or terminate this offer without notice.
- By applying this offer, pharmacist is certifying that: (i) the patient meets the eligibility criteria, (ii) you have not submitted and will not submit a claim for reimbursement under any state or federally funded program for this prescription; and (iii) participation is not contrary to pharmacy agreements with third-party payers or laws or regulations applicable to pharmacies.
- Patient and pharmacist understand and agree to comply with the eligibility requirements and terms and conditions of this offer as described above.

For questions about this program, please call (347) 252-3204.

# **Pharmacy Instructions:**

- For a patient with an eligible third party payer, submit the claim to the primary third-party payer first and then submit the balance due as a Secondary Payer COB [coordination of benefits with patient responsibility amount and a valid Other Coverage Code, (e.g. 8)].
- The patient's out-of-pocket expense will be reduced up to the maximum savings limit for the program. Valid Other Coverage Code required.
- For any questions regarding online processing please call 1-347-252-3204.