

MEDICATION GUIDE
RAVICTI™ (rah-VIK- tee)
(glycerol phenylbutyrate)
oral liquid

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

RAVICTI may cause serious side effects, including:

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

- sleepiness
- weakness
- lightheadedness
- change in taste
- problems with hearing
- confusion
- problems with memory
- worsening neuropathy (numbness, tingling, or burning in your hands or feet)
- headache

What is RAVICTI?

RAVICTI is a prescription medicine used in adults and children 2 years of age and older for long-term management of high blood levels of ammonia (hyperammonemia) caused by a condition called urea cycle disorder (UCD). Ravicti should be used if the UCD cannot be managed with a low protein diet and dietary supplements alone. RAVICTI must be used along with a low protein diet and in some cases dietary supplements.

RAVICTI is not used for the treatment of hyperammonemia in people with UCD.

It is not known if RAVICTI is safe and effective for the treatment of N-acetylglutamate synthase (NAGS) deficiency.

It is not known if RAVICTI is safe and effective in children 2 months to less than 2 years of age.

Who should not take RAVICTI?

- Children less than 2 months of age should not take RAVICTI because it may not be digested in babies less than 2 months of age.
- Do not take RAVICTI if you are allergic to phenylbutyrate.

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

What should I tell my doctor before taking RAVICTI?

Before you take RAVICTI, tell your doctor if you:

- have liver or kidney problems
- have pancreas or bowel (intestine) problems
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if RAVICTI will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if RAVICTI passes into your breast milk. RAVICTI may harm your baby, so you and your doctor should decide if you will take RAVICTI or breastfeed.

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 RAVICTI?

- Take RAVICTI exactly as your doctor tells you.
- Your doctor will tell you how much RAVICTI to take and when to take it.
- Your doctor may change your dose if needed.
- Take RAVICTI with food.
- RAVICTI is an oral liquid that is taken by mouth using an oral syringe or measuring cup. Ask your pharmacist for an oral syringe or measuring cup if you do not have one.
- Stay on the diet that your doctor gives you.
- If you take too much RAVICTI, call your doctor or go to the nearest hospital emergency room right away.
- Talk to your doctor about participating in a UCD registry. The purpose of this registry is to collect information about people with UCD to improve care. For more information about the registry program call 1-855-823-2595 or visit www.ucdregistry.com.

For people who have a nasogastric or gastric tube in place, RAVICTI should be given as follows:

- Use an oral syringe to withdraw the prescribed dose of RAVICTI from the bottle.
- Place the tip of the syringe into the tip of the nasogastric or gastric tube and push the plunger of the syringe to give RAVICTI into the tube.
- Flush the nasogastric or gastric tube with 30 mL of water and allow the flush to drain.
- Flush the nasogastric or gastric tube a second time with an additional 30 mL of water.

What are the possible side effects of RAVICTI?

RAVICTI may cause serious side effects, including:

- **See “What is the most important information I should know about RAVICTI?”**
- The most common side effects of RAVICTI in adults include:
 - diarrhea
 - gas
 - headache
 - nausea
 - vomiting
 - tiredness
 - decrease appetite
 - high blood levels of ammonia
 - dizziness

The most common side effect of RAVICTI in children include:

- upper abdomen (stomach) pain
- nausea
- vomiting
- diarrhea
- decreased appetite
- high blood levels of ammonia
- headache

Tell your doctor 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 RAVICTI.

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 RAVICTI?

- Store RAVICTI between 68°F to 77°F (20°C to 25°C).

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

General information about the safe and effective use of RAVICTI

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use RAVICTI for a condition for which it was not prescribed. Do not give RAVICTI to other people, even if they have the same symptoms you have. It may harm them.

If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about RAVICTI that is written for health professionals.

For more information call 1-855-823-7878 or go to www.RAVICTI.com.

What are the ingredients in RAVICTI?

Active ingredient: glycerol phenylbutyrate

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

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