

Directions for taking RAVICTI® (glycerol phenylbutyrate) Oral Liquid by mouth

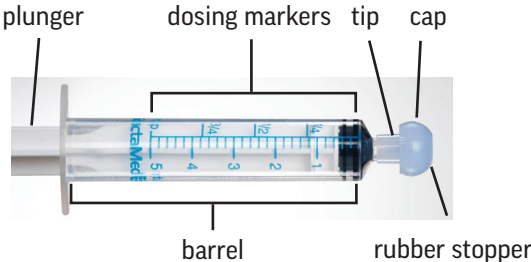
Items in your RAVICTI shipment



Bottle of RAVICTI



Blue AdaptaCap™
Bottle Adapter



Oral dosing syringe

Attention:
If you can swallow liquids, it is recommended you take RAVICTI by mouth.



1 Open the bottle of RAVICTI. To open, push down on the cap while twisting it to the left.



2 Twist the blue AdaptaCap Bottle Adapter onto the bottle. You do this by turning it to the right. Make sure it is tightly on the bottle.



3 Place the tip of the oral dosing syringe into the AdaptaCap Bottle Adapter.



4 Turn the bottle upside down with the oral dosing syringe still inserted.

EXAMPLE: If your prescribed dose is 3 mL, the first line of the rubber stopper should be even with the 3 mL dosing mark on the barrel of the oral dosing syringe.

NOTE: Pull the plunger slowly. This will help keep large air bubbles from forming in the medicine.

Approved Uses for RAVICTI® (glycerol phenylbutyrate) Oral Liquid

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

RAVICTI is not used to treat extremely high levels of ammonia in the blood (hyperammonemic crises) in people with UCDs as they may require rapidly acting medication.

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 for children younger than 2 months.

Please see the Important Safety Information for RAVICTI on page 3 and the Full Prescribing Information and Medication Guide available at RAVICTI.com.

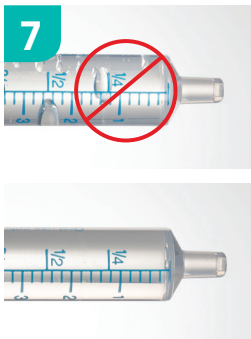
RAVICTI[®]
(glycerol phenylbutyrate) Oral Liquid



5 Get the medicine into the oral dosing syringe by pulling the plunger back. Pull until the first line of the black rubber stopper is even with the dosing mark. The dosing marks are on the barrel of the oral dosing syringe. Match the dosing mark to the amount of medicine prescribed by your doctor.



6 Turn the bottle back to its upright position.



7 **If there are large air bubbles**, push the medicine back into the bottle. Do this slowly. Draw up the medicine again (repeat steps 3-6).



8 Place the oral dosing syringe into the mouth. Push the plunger to squirt the medicine into the mouth. Make sure all of the medicine is pushed out of the oral dosing syringe. Put the cap on the oral dosing syringe.



9 After taking RAVICTI, it is suggested to drink liquid or eat some food to help make sure all of the medicine is swallowed.



10 Close the tab on the AdaptaCap™ Bottle Adapter. Make sure it is closed tightly.

IMPORTANT TO REMEMBER:

- Take the exact amount of RAVICTI as instructed by your doctor
- RAVICTI is taken 3 or more times per day in equally divided doses and should be taken with food or formula
- When dosing RAVICTI, be sure to use the provided oral dosing syringe

NOTE: You can use 1 oral dosing syringe and 1 blue AdaptaCap Bottle Adapter for all doses each day.

- You can also choose to use a new oral dosing syringe with each dose

- Do not rinse the AdaptaCap Bottle Adapter or oral dosing syringe between doses
- After the last dose of the day, dispose of the oral dosing syringe

If you take too much RAVICTI, call your doctor or go to the nearest hospital emergency room right away. Do not stop taking RAVICTI unless your doctor tells you to stop.

- **If you miss a dose of RAVICTI, take it as soon as possible**
- **Do not take 2 doses of RAVICTI at the same time**
- **If you miss more than 1 dose and are not feeling well, call your doctor or nurse right away**

If you still have questions about how to take RAVICTI with an oral dosing syringe, please contact your doctor for more information.

IMPORTANT SAFETY INFORMATION

Approved Uses for RAVICTI® (glycerol phenylbutyrate) Oral Liquid

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RAVICTI is not used to treat extremely high levels of ammonia in the blood (hyperammonemic crises) in people with UCDs as they may require rapidly acting medication.

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 for children younger than 2 months.

Detailed Important Safety Information

Who should not take RAVICTI:

Children younger than 2 months should not take RAVICTI because they may not be able to digest it.

Do not take RAVICTI if you are allergic to phenylbutyrate. Call your doctor or go to the nearest hospital emergency room if you have symptoms of an allergic reaction, such as wheezing, shortness of breath, cough, low blood pressure, flushing, nausea, or rash while taking RAVICTI.

RAVICTI may cause serious side effects:

The breakdown of RAVICTI produces the byproduct phenylacetate, which may cause nervous system side effects. Call your doctor or get medical help right away if you have any of these symptoms while taking RAVICTI: sleepiness; lightheadedness; change in taste; problems with hearing; confusion; problems with memory; worsening of numbness, tingling, or burning in your hands or feet; headache, tiredness; nausea; or vomiting.

What are the possible side effects of RAVICTI?

The most common side effects of RAVICTI in adults include diarrhea, gas, headache, nausea, vomiting, tiredness, decreased appetite, and dizziness.

The most common side effects of RAVICTI in children ages 2 to 17 years include stomach pain, nausea, vomiting, diarrhea, decreased appetite, and headache.

The most common side effects of RAVICTI in children ages 2 months to younger than 2 years include decreased level of a type of white blood cell, vomiting, diarrhea, fever, decreased appetite, cough, nasal congestion, runny nose, and rash.

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.

Before you take RAVICTI:

Tell your doctor if you have liver or kidney problems, pancreas or bowel (intestine) problems, or any other medical conditions. Tell your doctor if you are pregnant or plan to become pregnant. It is not known if RAVICTI will harm your unborn baby. Tell your doctor if you are breastfeeding or plan to breastfeed. It is not known if RAVICTI passes into your breast milk. Breastfeeding is not recommended during treatment with RAVICTI. Talk to your doctor about the best way to feed your baby if you take RAVICTI.

Talk to your doctor about participating in a UCD registry. The purpose of this registry is to collect information about people with UCDs to improve care. For more information about the registry program, call 1-855-823-2595 or visit www.ucdregistry.com.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

This information is not comprehensive. To learn more, talk to your healthcare provider or pharmacist. The FDA-approved product labeling, including the Medication Guide, can be found at Ravicti.com.