

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 (PAA), 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
- 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 RAVICTI.

What is RAVICTI?

- RAVICTI 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). 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 acute 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.

Do not take RAVICTI 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 RAVICTI.

Before taking RAVICTI, 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 RAVICTI will harm your unborn baby. If you become pregnant during treatment with RAVICTI, call Amgen Inc. at 1-800-77-AMGEN (1-800-772-6436) to report the pregnancy.
- 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.

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 or formula.
- In an infant who is breastfeeding, give RAVICTI just before breastfeeding.
- RAVICTI 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 RAVICTI bottle and oral syringe as follows:
 - Use a new reclosable bottle cap adapter with each new RAVICTI bottle that is opened.
 - Open the RAVICTI bottle and twist on the new reclosable bottle cap adapter.
 - Use a new dry oral syringe to remove each prescribed dose of RAVICTI.
 - 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 RAVICTI bottle, the contents will become cloudy in appearance. If the contents appear cloudy at any time, **do not** use the remaining RAVICTI and return the bottle to your pharmacy to throw it away.
 - Throw away the bottle and any unused RAVICTI 28 days after opening.
- If you have a nasogastric or gastrostomy tube in place and can swallow, you should take RAVICTI by mouth.
- Stay on the diet that your doctor gives you.

- If you take too much RAVICTI, 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, RAVICTI should be given as follows:

- Use a new dry oral syringe to withdraw each prescribed dose of RAVICTI from the bottle.
- Place the tip of the syringe into the nasogastric or gastrostomy tube and push the plunger of the syringe to give RAVICTI 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 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:

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

The most common side effects of RAVICTI in children 2 years to 17 years of age include:

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

The most common side effects of RAVICTI in children 2 months to less than 2 years of age include:

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

The most common side effects of RAVICTI in children less than 2 months of age include:

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

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.

You may also report side effects to Amgen Inc. at 1-800-77-AMGEN (1-800-772-6436).

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. You can ask your doctor or pharmacist for information about RAVICTI that is written for health professionals.

What are the ingredients in RAVICTI?

Active ingredient: glycerol phenylbutyrate

Manufactured for: Horizon Therapeutics US Holdings, LLC, 1 Horizon Way, Deerfield, IL 60015.

For more information, go to www.RAVICTI.com or call 1-800-77-AMGEN (1-800-772-6436).