

**Managing a UCD Video: Transcript**

<b>Voiceover</b>	<b>On screen</b>
<p>A urea cycle disorder, also known as a UCD, is a genetic disease that people are born with.</p>	<p>Managing a urea cycle disorder</p> <p>Please listen to the Important Safety Information in this video</p>
<p>As the body digests protein in food throughout the day nitrogen is released and it circulates in the body in the form of ammonia, or NH<sub>3</sub>.</p> <p>Normally most of the ammonia is converted to urea in the liver and the body gets rid of it via the kidneys in the urine.</p>	<p>Liver graphic</p> <p>Ammonia</p> <p>Urea</p>
<p>However, in people with a UCD, ammonia is not as effectively turned into urea and can build up to toxic levels. And spread throughout the body, including the brain.</p> <p>An ammonia-removing medicine may be needed to help bind to ammonia so it can be safely removed from the body.</p>	<p>Liver graphic</p>
<p>RAVICTI (glycerol phenylbutyrate) Oral Liquid may help.</p> <p>RAVICTI is an ammonia removing medicine that is taken 3 or more times per day. And keeps working in your body throughout the day.</p>	<p>RAVICTI logo</p> <p><b>Approved uses for RAVICTI (glycerol phenylbutyrate) Oral Liquid</b></p> <p>RAVICTI (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). 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.</p>
<p>When a dose of RAVICTI travels through the body it is not released right away.</p>	<p>Dosing animation</p> <p><b>Select Important Risk Information</b></p>

<p>A naturally occurring enzyme found in the digestive tract slowly unlocks RAVICTI so it can be absorbed and start working to bind and remove excessive ammonia.</p>	<p>The breakdown of RAVICTI produces the byproduct phenylacetate (PAA), 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, feeling very tired (fatigue); nausea; or vomiting.</p>
<p>Once unlocked, RAVICTI is slowly released and converted to the active substance that binds nitrogen, so that it can control ammonia levels when given as indicated.</p>	<p>Dosing animation</p> <p><b>Select Important Risk Information</b> Do not take RAVICTI if you are allergic to phenylbutyrate.</p>

**APPROVED USES and IMPORTANT SAFETY INFORMATION for RAVICTI**

**What is RAVICTI?**

RAVICTI (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). 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 to treat extremely high levels of ammonia in the blood (hyperammonemic crisis) in people with UCDs.

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

**IMPORTANT SAFETY INFORMATION**

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

**RAVICTI may cause serious side effects, including:**

**Nervous system side effects (Neurotoxicity).** The breakdown of RAVICTI produces the byproduct phenylacetate (PAA), 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
- feeling very tired (fatigue)
- nausea
- vomiting

### **Who should not take RAVICTI?**

**Do not take RAVICTI if you are allergic to phenylbutyrate.** Call your doctor or go to the nearest hospital emergency room if you experience any of the following symptoms of an allergic reaction while taking RAVICTI:

- wheezing
- shortness of breath
- cough
- low blood pressure
- flushing
- nausea
- skin rash

### **What should I tell my doctor before taking RAVICTI?**

**Tell your doctor about any medical conditions and 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.
  - **Pregnancy Registry:** There is a Pregnancy Registry for women who take RAVICTI just before becoming pregnant or who become pregnant during treatment with RAVICTI. The purpose of this registry is to collect information about the health of you and your baby. Talk to your doctor about how you can join the Pregnancy Registry. For more information about this registry, call 1-855-823-2595 or visit [www.ucdregistry.com](http://www.ucdregistry.com).
- 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.

### **What are 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
- abdomen (stomach) pain
- vomiting
- tiredness
- decreased appetite
- indigestion or heartburn

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

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

**The most common side effects of RAVICTI 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 white blood cell count (lymphocytosis)
- diarrhea
- gas
- constipation
- fever
- drowsiness (lethargy)
- irritability
- agitation

These are not all of the possible side effects of RAVICTI. Call your doctor for medical advice about side effects.

**For additional important safety information, please see the [Full Prescribing Information](#) and [Medication Guide](#) available at [RAVICTI.com](http://RAVICTI.com) and discuss with your**

**doctor.**

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

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