

Oral administration

Section	Frame	Voicover	On-screen text/action
Introduction and welcome	1	Welcome to the RAVICTI® (glycerol phenylbutyrate) Oral Liquid instructional dosing video. In this video you will see step-by-step instructions for the oral administration of RAVICTI for your infant.	RAVICTI logo title card and onscreen text: Instructions for giving RAVICTI to infants by mouth
Approved uses for RAVICTI	2	<p>Use for RAVICTI (glycerol phenylbutyrate) Oral Liquid</p> <p>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.</p> <p>RAVICTI is not used to treat extremely high levels of ammonia in the blood (hyperammonemic crisis) in people with UCDs.</p> <p>It is not known if RAVICTI is safe and effective for the treatment of <i>N</i>-acetylglutamate synthase (NAGS) deficiency.</p> <p>Please listen to the RAVICTI Important Safety Information at the end of this video. For additional important safety information, see the Medication Guide at RAVICTI.com and discuss with your doctor.</p>	<p><i>Scrolling text:</i> Use for RAVICTI® (glycerol phenylbutyrate) Oral Liquid</p> <p>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.</p> <p>RAVICTI is not used to treat extremely high levels of ammonia in the blood (hyperammonemic crisis) in people with UCDs.</p> <p>It is not known if RAVICTI is safe and effective for the treatment of <i>N</i>-acetylglutamate synthase (NAGS) deficiency.</p> <p>Please listen to the RAVICTI Important Safety Information at the end of this video.</p> <p>For additional important safety information, see the Medication Guide at RAVICTI.com and discuss with your doctor.</p>

What to know before getting started	3	<p>This video is intended to complement the instructions you have already received from your doctor. Always give RAVICTI exactly as directed by your doctor.</p> <p>Do not mix RAVICTI with formula or any other liquids.</p> <p>If your child is breastfed, give RAVICTI just prior to breastfeeding.</p> <p>Now, let's get started.</p>	<p><i>Infant and mother onscreen in the background, preparing/getting comfortable</i></p> <p><i>Onscreen text:</i></p> <p>This video is intended to complement the instructions you have already received from your doctor. Always give RAVICTI exactly as directed by your doctor.</p> <p>Do not mix RAVICTI with formula or any other liquids.</p> <p>If your child is breastfed, give RAVICTI just prior to breastfeeding.</p>
Supplies Header	4	N/A	<p><i>Header:</i></p> <p>RAVICTI SUPPLIES</p>
Supplies	5	<p>Your RAVICTI shipment includes a 25-mL bottle of RAVICTI, a blue AdaptaCap Bottle Adapter, and an oral dosing syringe.</p> <p>When dosing RAVICTI, be sure to use the oral dosing syringe provided with the product.</p>	<p><i>Onscreen supplies with labels (left to right):</i></p> <p>ORAL DOSING SYRINGE</p> <p>BOTTLE OF RAVICTI® (glycerol phenylbutyrate) Oral Liquid</p> <p><i>Footnote:</i></p> <p>Vial shown is for demonstration use only.</p> <p>BLUE ADAPTACAP® BOTTLE ADAPTER</p>
Title card	6	N/A	<p><i>Title card:</i></p> <p>STEP 1 PREPARE THE RAVICTI BOTTLE AND ADAPTER</p>
Step 1: Prepare RAVICTI bottle and adapter	7	<p>For the first step, remove the childproof cap on the RAVICTI bottle. To do that, push down on the cap while twisting it to the left.</p> <p>Then, attach the blue AdaptaCap Bottle Adapter onto the bottle. Put it on top of the bottle and twist it to the right.</p> <p>Make sure it is secured tightly on the bottle.</p>	<p><i>Live action of each step</i></p> <p><i>Lower third text:</i></p> <p>Remove childproof cap.</p> <p><i>Lower third text:</i></p> <p>Attach blue AdaptaCap® Bottle Adapter.</p>
Title card	8	N/A	<p><i>Title card:</i></p>

			STEP 2 PREPARE THE DOSE
Step 2: Prepare the dose	9	While holding the RAVICTI bottle securely, place the tip of the oral dosing syringe into the AdaptaCap Bottle Adapter.	<i>Live action of each step</i> <i>Lower third:</i> Place tip of the oral dosing syringe into AdaptaCap® Bottle Adapter.
	10	Turn the bottle upside down with the oral dosing syringe still inserted. Now, you're ready to fill the oral dosing syringe with RAVICTI. Get the medicine into the oral dosing syringe by pulling the plunger back slowly. Pulling slowly will help avoid large air bubbles from forming in the medicine.	<i>Lower third:</i> Turn bottle upside down. <i>Lower third:</i> Pull plunger back slowly.
	11	Pull the plunger back until the stopper is even with the dosing mark. The dosing marks are on the barrel of the oral dosing syringe. Match the dosing mark with the amount of medicine prescribed by your doctor.	
	12	Then, turn the bottle upright again. If there are large air bubbles, push the medicine back into the bottle. Do this slowly. Then, draw up the medicine again.	<i>Lower third:</i> Turn bottle upright. <i>Lower third:</i> Check for large air bubbles.
	13	Once the dose is ready, close the tab on the AdaptaCap Bottle Adapter. Make sure it's closed tightly.	<i>Lower third:</i> Close tab on AdaptaCap® Bottle Adapter.
Title card	14	N/A	<i>Title card:</i> STEP 3 GIVE RAVICTI
Step 3: Give RAVICTI	15	Once you have the oral dosing syringe prepared, place it into your child's mouth. Push the plunger to squirt the medicine directly into the mouth. Make sure all of the medicine is pushed out of the oral dosing syringe and swallowed.	<i>Live action of each step</i> <i>Lower third:</i> Do not mix RAVICTI with formula or any other liquids. <i>Lower third:</i> Squirt medicine into mouth.

	16	Feed your child right after giving them RAVICTI. This helps ensure that all of the medicine is swallowed.	<i>Lower third:</i> Feed your child right after giving RAVICTI.
Giving multiple daily doses	17	RAVICTI should be given multiple times throughout the day, based on the dosing schedule prescribed by your doctor. Follow these instructions and tips for giving multiple daily doses.	<i>Mother comforts/brings infant to her shoulder</i>
	18	<p>Give all RAVICTI doses with feedings, 3 or more times per day.</p> <p>If your child is breastfed, give RAVICTI just prior to breastfeeding.</p> <p>You can use 1 oral dosing syringe and 1 blue AdaptaCap Bottle Adapter for all doses each day.</p> <p>You can also choose to use a new oral dosing syringe with each dose.</p> <p>Do not rinse the AdaptaCap Bottle Adapter or oral dosing syringe between doses.</p> <p>After the last dose of the day, dispose of the oral dosing syringe.</p>	<p><i>Background action of mother holding infant</i></p> <p><i>Static onscreen text:</i> GIVING MULTIPLE DAILY DOSES</p> <ul style="list-style-type: none"> • Give all RAVICTI doses with feedings, 3 or more times per day • If your child is breastfed, give RAVICTI just prior to breastfeeding • 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
IMPORTANT REMINDERS	19	<p>If you give too much RAVICTI, call your doctor or go to the nearest hospital emergency room right away.</p> <p>You should consult your child's doctor if they have missed a dose of RAVICTI.</p> <p>Do not mix RAVICTI with formula or any other liquids.</p>	<p><i>Static onscreen text:</i> IMPORTANT REMINDERS</p> <ul style="list-style-type: none"> • If you give too much RAVICTI, call your doctor or go to the nearest hospital emergency room right away • You should consult your child's doctor if they have missed a dose of RAVICTI • Do not mix RAVICTI with formula or any other liquids
IMPORTANT SAFETY INFORMATION	20	Important Safety Information	<p><i>Scrolling onscreen text:</i> IMPORTANT SAFETY INFORMATION</p>

	<p>What is the most important safety information I should know about RAVICTI?</p> <p>RAVICTI may cause serious side effects, including:</p> <p>Nervous system side effects (Neurotoxicity). The breakdown of RAVICTI produces the byproduct phenylacetate (PAA), which may cause nervous system side effects.</p> <p>Call your doctor or get medical help right away if you have any of these symptoms while taking RAVICTI:</p> <ul style="list-style-type: none"> • 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 <p>Who should not take RAVICTI?</p> <p>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:</p> <ul style="list-style-type: none"> • wheezing • shortness of breath • cough • low blood pressure • flushing • nausea • skin rash 	<p><u>What is the most important safety information I should know about RAVICTI?</u></p> <p>RAVICTI may cause serious side effects, including:</p> <p>Nervous system side effects (Neurotoxicity). The breakdown of RAVICTI produces the byproduct phenylacetate (PAA), which may cause nervous system side effects.</p> <p>Call your doctor or get medical help right away if you have any of these symptoms while taking RAVICTI:</p> <ul style="list-style-type: none"> • 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 <p><u>Who should not take RAVICTI?</u></p> <p>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:</p> <ul style="list-style-type: none"> • wheezing • shortness of breath • cough • low blood pressure • flushing
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	<p>What should I tell my doctor before taking RAVICTI?</p> <p>Tell your doctor about any medical conditions and if you:</p> <ul style="list-style-type: none"> • 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. <ul style="list-style-type: none"> ○ 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. • 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. <p>What are possible side effects of RAVICTI?</p> <p>RAVICTI may cause serious side effects, including:</p> <ul style="list-style-type: none"> • See “What is the most important information I should know about RAVICTI?” <p>The most common side effects of RAVICTI in adults include:</p> <ul style="list-style-type: none"> • diarrhea • gas 	<ul style="list-style-type: none"> • nausea • skin rash <p><u>What should I tell my doctor before taking RAVICTI?</u></p> <p>Tell your doctor about any medical conditions and if you:</p> <ul style="list-style-type: none"> • 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. <ul style="list-style-type: none"> ○ 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. • 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. <p><u>What are possible side effects of RAVICTI?</u></p>
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	<ul style="list-style-type: none"> • headache • abdomen (stomach) pain • vomiting • tiredness • decreased appetite • indigestion or heartburn <p>The most common side effects of RAVICTI in children 2 years to 17 years of age include:</p> <ul style="list-style-type: none"> • upper abdomen (stomach) pain • rash • nausea • vomiting • diarrhea • decreased appetite • headache <p>The most common side effects of RAVICTI in children 2 months to less than 2 years of age include:</p> <ul style="list-style-type: none"> • low white blood cell count (neutropenia) • vomiting • constipation • diarrhea • fever • reduced food intake • cough • stuffy nose • runny nose • skin rash • small round bumps on the skin <p>The most common side effects of RAVICTI in children less than 2 months of age include:</p> <ul style="list-style-type: none"> • 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 	<p>RAVICTI may cause serious side effects, including:</p> <ul style="list-style-type: none"> • See <u>“What is the most important information I should know about RAVICTI?”</u> <p>The most common side effects of RAVICTI in adults include:</p> <ul style="list-style-type: none"> • diarrhea • gas • headache • abdomen (stomach) pain • vomiting • tiredness • decreased appetite • indigestion or heartburn <p>The most common side effects of RAVICTI in children 2 years to 17 years of age include:</p> <ul style="list-style-type: none"> • upper abdomen (stomach) pain • rash • nausea • vomiting • diarrhea • decreased appetite • headache <p>The most common side effects of RAVICTI in children 2 months to less than 2 years of age include:</p> <ul style="list-style-type: none"> • low white blood cell count (neutropenia) • vomiting • constipation • diarrhea • fever • reduced food intake • cough • stuffy nose • runny nose • skin rash
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	<ul style="list-style-type: none"> • 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 <p>These are not all of the possible side effects of RAVICTI. Call your doctor for medical advice about side effects.</p> <p>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.</p> <p>For additional important safety information, please review the Medication Guide at RAVICTI.com and discuss with your doctor.</p>	<ul style="list-style-type: none"> • small round bumps on the skin <p>The most common side effects of RAVICTI in children less than 2 months of age include:</p> <ul style="list-style-type: none"> • 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 <p>These are not all of the possible side effects of RAVICTI. Call your doctor for medical advice about side effects.</p> <p>You are encouraged to report negative side effects of prescription drugs to the FDA. Visit</p>
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			<p>www.fda.gov/medwatch or call 1-800-FDA-1088.</p> <p>For additional important safety information, please review the Medication Guide at RAVICTI.com and discuss with your doctor.</p>
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Final screen: Horizon Logo	22	N/A	<p><i>Title card:</i> [HORIZON logo]</p>