

Frequently Asked Questions About RELYVRIO™

 **relyvrio™**
(sodium phenylbutyrate and
taurursodiol) for oral
suspension 3 g/1 g

What is RELYVRIO approved to treat?

RELYVRIO is indicated for the treatment of amyotrophic lateral sclerosis (ALS) in adults.

What have researchers learned about RELYVRIO so far?

It is a new prescription oral therapy for adults living with ALS shown to help slow disease progression. RELYVRIO may be taken alone or with other FDA-approved treatments for ALS and can serve as an important part of you and your doctor's plan to manage ALS.

Is there a difference between RELYVRIO and ALBRIOZA™?

No. Each dose of RELYVRIO and ALBRIOZA is made of 3 g of sodium phenylbutyrate and 1 g of taurursodiol (ursodoxicoltaurine), also known as AMX0035. RELYVRIO is the brand name in the United States, and ALBRIOZA is the brand name in Canada.

How should I decide whether RELYVRIO is right for me?

As with any decision regarding your treatment and/or disease management plan, talk to your doctor about whether or not RELYVRIO is right for you.

If I am considering RELYVRIO, where can I get more information?

You can get more information and resources at [RELYVRIO.com](https://www.relyvrio.com). Additionally, you can visit [AmylyxCareTeam.com](https://www.amylyxcareteam.com) to learn more about how the Amylyx Care Team (ACT)™ can help once you have been prescribed RELYVRIO.



Doctors are the best source for treatment information. Everyone should be directed to their doctor for medical advice.

IMPORTANT SAFETY INFORMATION

Before you receive RELYVRIO, tell your doctor about all of your medical conditions, including if you:

- Have pancreas, liver, or intestinal problems
- Have heart failure, including congestive heart failure
- Have high blood pressure
- Have kidney problems

For more information about RELYVRIO, please see the Important Safety Information throughout and the full [Prescribing Information and Medication Guide](#).

How can adults with ALS access RELYVRIO?

The first step to getting on RELYVRIO is to discuss with your doctor if RELYVRIO is right for you. If you and your doctor decide on RELYVRIO, your doctor will complete the RELYVRIO Enrollment Form with you, which enrolls you in the ACT Support Program and also serves as your prescription. The ACT Support Program is a dedicated Amylyx team who can help provide personalized support and communicate on next steps after you consent.

Will RELYVRIO be covered by my insurance?

We are working with all insurers, including Medicare, Veterans Affairs (VA), and commercial health insurance companies, to educate them on RELYVRIO and asking them to cover it. Drug coverage decisions will be made by Medicare, VA, and commercial private insurers. Securing coverage could take up to 45 days or longer, especially within the first 6 months of product approval.

Call ACT to see if there are any programs that may be available for commercially insured eligible adults living with ALS while your insurance is being secured.

How do I get my RELYVRIO prescription delivered to me?

Your RELYVRIO prescription can only be filled by a specialty pharmacy. ACT will send your RELYVRIO prescription to the specialty pharmacy once the insurance benefit investigation and approval are completed. Your specialty pharmacy will contact you directly to coordinate your shipment directly to your home.

What if I can't afford RELYVRIO?

ACT can help you understand your out-of-pocket insurance cost. If you are unable to afford RELYVRIO, ACT can help you learn about programs that you may be eligible for. To learn more about possible financial assistance options, visit [AmylyxCareTeam.com](https://www.amylyxcareteam.com) or call [1-866-318-2989](tel:1-866-318-2989) Monday-Friday, 8:00 AM-8:00 PM ET.

IMPORTANT SAFETY INFORMATION (continued)

Before you receive RELYVRIO, tell your doctor about all of your medical conditions, including if you:

- Are pregnant or plan to become pregnant. It is not known if RELYVRIO will harm your unborn baby
- Are breastfeeding or plan to breastfeed. It is not known if RELYVRIO passes into your breast milk.

You and your doctor should decide the best way to feed your baby

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements and any taurursodiol products, such as tauroursodeoxycholic acid (TUDCA).

For more information about RELYVRIO, please see the Important Safety Information throughout and the full [Prescribing Information](#) and [Medication Guide](#).



What is the recommended dosing for RELYVRIO?

Your doctor will tell you how much RELYVRIO to take and when to take it. The recommended dosing is to take 1 packet once a day for the first 3 weeks. After the first 3 weeks, take 2 packets per day, 1 packet in the morning and 1 packet at night.

I have a feeding tube. Can I use RELYVRIO?

Yes. RELYVRIO can be administered through a feeding tube, as directed by your doctor.

What do I do if I miss a dose of RELYVRIO?

If you forget to take 1 or more doses of RELYVRIO, you should take your next dose at the normal time and in the normal amount. You should not take more than what is prescribed by your doctor. If you have any questions, be sure to speak with your doctor, who is always the best source for treatment information.

How do I transition from an Amylyx clinical trial, Early Access Program, or Compassionate Use Program to the commercial product (RELYVRIO)?

Amylyx is committed to ensuring adults living with ALS have equal access to receiving RELYVRIO. If you are currently enrolled in a clinical trial, the Early Access Program, or the Compassionate Use Program, please contact your Site Coordinator or doctor to transition to the commercially available product, if you and your doctor decide to continue taking RELYVRIO.

IMPORTANT SAFETY INFORMATION (continued)

RELYVRIO may affect the way other medicines work, and other medicines may affect how RELYVRIO works.

What are the possible side effects of RELYVRIO?

RELYVRIO may cause serious side effects, including:

- **Changes in bile acid levels.** RELYVRIO may increase bile acid levels and cause worsening diarrhea if you already have problems with your liver, bile ducts, or pancreas. Your doctor should monitor you for these side effects. Some disorders of the pancreas, bile ducts, or intestines may also make it harder to absorb RELYVRIO
- **Salt (sodium) retention.** RELYVRIO contains a high amount of salt. For people who are sensitive to salt intake, such as people with heart failure, high blood pressure, or kidney problems, limit the amount of salt you eat and drink. Talk to your doctor about the total amount of daily salt that is right for you. Your doctor will monitor you for

signs and symptoms of salt retention during your treatment with RELYVRIO

The most common side effects of RELYVRIO include diarrhea, abdominal pain, nausea, and upper respiratory tract infection.

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of RELYVRIO. Call your doctor for medical advice about side effects.

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.

INDICATION

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