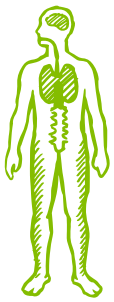
BEFORE INITIATING THERAPY,

It's important to let patients know what to expect

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

IMPORTANT INFORMATION ABOUT RELYVRIO™ THERAPY



OUTCOMES

RELYVRIO has been shown to help slow the loss of physical function. It does not stop the progression of amyotrophic lateral sclerosis (ALS).[1]

TOLERABILITY

RELYVRIO is generally well-tolerated. The most common adverse events were diarrhea, abdominal pain, nausea, and upper respiratory tract infection. Gastrointestinal side effects occurred throughout the study but were more frequent during the first 3 weeks of treatment.[1]

ADMINISTRATION

FIRST 3 WEEKS

1 packet per day[1]

AFTER 3 WEEKS

1 packet in the morning and 1 at night[1]

RELYVRIO may be taken alone or with other FDA-approved treatments for ALS.[1]

The taste of RELYVRIO can vary from person to person[2]

- RELYVRIO may have a bitter aftertaste. In the clinical trial, participants were allowed to try to lessen or remove the bitter aftertaste by:
  - using mint-flavored mouth strips or mouth spray immediately before or after taking the medicine
  - eating a small snack or honey after taking RELYVRIO
  - drinking milk after taking RELYVRIO
  - avoiding fruit juice immediately afterwards, as it can make the aftertaste worse

INDICATION

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

Please see full Important Safety Information on back and full Prescribing Information for RELYVRIO.

Establishing clear expectations about access

HELPFUL TIPS WHEN GETTING PATIENTS STARTED

When you fill out the RELYVRIO™ Enrollment Form for your patients, it will serve as a prescription and bring them into the Amylyx Care Team (ACT)™ Support Program.

ACT™ Amylyx Care Team

- RELYVRIO will be available through specialty pharmacies, which can deliver the therapy right to the patient's home
- Since RELYVRIO is a specialty product, it may take time to get the therapy to your patients. This is a normal part of the process for specialty products
- ACT will communicate updates to you and your patients to help them get access as soon as possible

For more information about how to enroll your patients in ACT, call 866-318-2989, visit AmylyxCareTeam.com, or scan this QR code.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Risk in Patients With Enterohepatic Circulation Disorders, Pancreatic Disorders, or Intestinal Disorders

RELYVRIO contains taurursodiol, which is a bile acid. In patients with disorders that interfere with bile acid circulation, there may be an increased risk for worsening diarrhea, and patients should be monitored appropriately for this adverse reaction. Pancreatic insufficiency, intestinal malabsorption, or intestinal diseases that may alter the concentration of bile acids may also lead to decreased absorption of either of the components of RELYVRIO. Because different enterohepatic circulation, pancreatic, and intestinal disorders have varying degrees of severity, consider consulting with a specialist. Patients with disorders of enterohepatic circulation (eg, biliary infection, active cholecystitis), severe pancreatic disorders (eg, pancreatitis), and intestinal disorders that may alter concentrations of bile acids (eg, ileal resection, regional ileitis) were excluded from the study; therefore, there is no clinical experience in these conditions.

Use in Patients Sensitive to High Sodium Intake

RELYVRIO has a high salt content. Each initial daily dosage of 1 packet contains 464 mg of sodium; each maintenance dosage of 2 packets daily contains 928 mg of sodium. In patients sensitive to salt intake (eg, those with heart failure, hypertension, or renal impairment), consider the amount of daily sodium intake in each dose of RELYVRIO and monitor appropriately.

CONTRAINDICATIONS

None.

ADVERSE REACTIONS

The most common adverse reactions (at least 15% and at least 5% greater than placebo) with RELYVRIO were diarrhea, abdominal pain, nausea, and upper respiratory tract infection. Gastrointestinal-related adverse reactions occurred throughout the study but were more frequent during the first 3 weeks of treatment.

You may report side effects to FDA at 1-800-FDA-1088.

For additional information about RELYVRIO, please see the full Prescribing Information.

References: 1. RELYVRIO. Package insert. Amylyx Pharmaceuticals Inc; 2022. **2.** Paganoni S, Macklin EA, Hendrix S, et al. Trial of sodium phenylbutyrate-taurursodiol for amyotrophic lateral sclerosis. *N Engl J Med.* 2020;383(10)(suppl):919-930. Accessed December 13, 2021. https://www.nejm.org/doi/suppl/10.1056/NEJMoa1916945/suppl_file/nejmoa1916945_appendix.pdf

AMYLYX® Rooted in Connection

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