NOW APPROVED

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.
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.

• RELYVRIO will be available through specialty pharmacies, which can deliver the therapy right to the patient’s home

• Since RELYVRIO is a newly approved specialty product, it may take time to get the therapy to your patients. This is a normal part of the process for new 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.