



SUMMARY OF INFORMATION ABOUT RELYVRIO (Re-LIV-rio)

This summary is meant to provide you with important information about RELYVRIO. However, it does not replace your doctor, who is your best source of treatment information.

What is RELYVRIO?

- RELYVRIO is a prescription medicine used to treat adults with amyotrophic lateral sclerosis (ALS).
- It is not known if RELYVRIO is safe and effective in children.

Before taking RELYVRIO, tell your healthcare provider 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.
- 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 healthcare provider should decide the best way to feed your baby.

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

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

How should I take RELYVRIO?

- Your healthcare provider will tell you how much RELYVRIO to take and when to take it.
- Empty 1 packet of RELYVRIO in a cup (8 ounces) of room temperature water and stir well.
- RELYVRIO can be taken by mouth or through a feeding tube within 1 hour of preparing. Throw away (discard) any unused RELYVRIO after 1 hour.
- RELYVRIO should be taken before a snack or meal.
- Avoid taking antacids that contain aluminum while you are receiving treatment with RELYVRIO. If you need an antacid, talk to your healthcare provider about the best one for you to take.

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 healthcare provider 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 healthcare provider about the total amount of daily salt that is right for you. Your healthcare provider 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
- upper respiratory tract infection

Tell your healthcare provider 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 may report side effects to FDA at 1-800-FDA-1088.

How should I store RELYVRIO?

- Store RELYVRIO at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep RELYVRIO packets away from moisture.

Keep RELYVRIO and all medicines out of the reach of children.

General information about the safe and effective use of RELYVRIO.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use RELYVRIO for a condition for which it was not prescribed. Do not give RELYVRIO to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about RELYVRIO that is written for health professionals.

What are the ingredients in RELYVRIO?

- **Active ingredients:** sodium phenylbutyrate, taurursodiol
- **Inactive ingredients:** acacia, dibasic sodium phosphate maltodextrin, medium-chain triglycerides, mixed berry flavoring, other flavoring ingredients, silicon dioxide, sodium stearyl fumarate, sorbitol, and sucralose.

To see the full Prescribing Information, scan this QR code or visit [RELYVRIO.com/PI](https://www.relyvrio.com/PI).

