

MEDICATION GUIDE
RUZURGI® (rew-ZUR-jee)
(amifampridine)
tablets, for oral use

Read this Medication Guide before you start taking RUZURGI and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment.

What is the most important information I should know about RUZURGI?

RUZURGI can cause seizures.

- You could have a seizure even if you never had a seizure before.
- **Do not** take RUZURGI if you have ever had a seizure.

Stop taking RUZURGI and call your doctor right away if you have a seizure while taking RUZURGI.

What is RUZURGI?

RUZURGI is a prescription medicine used to treat Lambert-Eaton myasthenic syndrome (LEMS) in children 6 to less than 17 years of age.

It is not known if RUZURGI is safe or effective in children less than 6 years of age.

Do not take RUZURGI if you:

- have ever had a seizure.
- are allergic to amifampridine or another aminopyridine. Talk to your doctor if you are not sure.

Before you take RUZURGI, tell your doctor about all of your medical conditions including if you:

- are taking another aminopyridine, such as as compounded 3,4-diaminopyridine (3,4-DAP), 4-aminopyridine, or pyridostigmine.
- have had a seizure.
- have kidney problems.
- have liver problems.
- are pregnant or planning to become pregnant. It is not known if RUZURGI can harm your unborn baby. You and your doctor should decide if you will take RUZURGI while you are pregnant.
- are breastfeeding or plan to breastfeed. It is not known if RUZURGI passes into your breastmilk. Talk to your doctor about the best way to feed your baby while taking RUZURGI.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How should I take RUZURGI?

- **See the detailed “Instructions for Use” on how to take and prepare a suspension of RUZURGI if your dose is less than 5mg, you have trouble swallowing tablets, or you need a feeding tube.**
- Take RUZURGI exactly as your doctor tells you to take it.
- **Do not** change your dose of RUZURGI.
- **Do not** stop taking RUZURGI without first talking to your doctor.
- RUZURGI tablets are scored and can be cut if less than a full tablet is needed for you to get the right dose.
- RUZURGI can be taken with or without food.
- If you miss a dose of RUZURGI, skip that dose and take your next dose at your next scheduled dose time.
- **Do not** take RUZURGI together with other medicines known to increase the risk of seizures such as aminopyridine medicines, including:
 - compounded 3,4-diaminopyridine (amifampridine)
 - amifampridine phosphate
 - 4-aminopyridine
- If you take too much RUZURGI, call your doctor or go to the nearest hospital emergency room right away.

What are the possible side effects of RUZURGI?

RUZURGI may cause serious side effects, including:

- **Seizures.** See “What is the most important information I should know about RUZURGI?”
- **Serious allergic reactions, such as anaphylaxis.** RUZURGI can cause serious allergic reactions. Stop taking RUZURGI and call your doctor right away or get emergency medical help if you have:
 - shortness of breath or trouble breathing
 - swelling of your throat or tongue
 - hives

The most common side effects of RUZURGI include:

- tingling around the mouth, tongue, face, fingers, toes, and other body parts
- stomach pain
- indigestion
- dizziness
- nausea

Tell your doctor if you have any side effect that bothers you or does not go away.

These are not all the possible side effects of RUZURGI.

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 RUZURGI?

- Store RUZURGI tablets in the container from the pharmacy at room temperature between 68°F to 77°F (20°C to 25°C) for up to 3 months.
- Refrigerate prepared RUZURGI oral suspension between doses for up to 24 hours.
- Safely throw away medicine that is no longer needed or out of date.

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

General Information about the safe and effective use of RUZURGI

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use RUZURGI for a condition for which it was not prescribed. Do not give RUZURGI to other people, even if they have the same symptoms that you have. It may harm them.

If you would like more information, talk with your doctor or pharmacist. You can ask your pharmacist or doctor for information about RUZURGI that is written for health professionals.

What are the ingredients in RUZURGI?

Active ingredient: amifampridine (also called 3,4-diaminopyridine)

Inactive ingredients: colloidal silicon dioxide, dibasic calcium phosphate dihydrate, magnesium stearate, microcrystalline cellulose, and sodium starch glycolate

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For more information, go to www.RUZURGI.com or call 609-921-7447.