

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**  
**PATIENT MEDICATION INFORMATION**

**PrRUZURGI®**  
**Amifampridine Tablets**

Read this carefully before you start taking **Ruzurgi** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Ruzurgi**.

**What is Ruzurgi used for?**

Ruzurgi is used to treat the symptoms of Lambert-Eaton myasthenic syndrome (LEMS) in patients 6 years of age and older. It is not known if Ruzurgi works or is safe in children less than 6 years old.

**How does Ruzurgi work?**

The way that Ruzurgi works in patients with LEMS is not fully understood.

**What are the ingredients in Ruzurgi?**

Medicinal ingredients: amifampridine.

Non-medicinal ingredients (listed in alphabetical order): colloidal silicon dioxide, dibasic calcium phosphate dihydrate, magnesium stearate, microcrystalline cellulose and sodium starch glycolate.

**Ruzurgi comes in the following dosage forms:**

10 mg tablets

**Do not use Ruzurgi if:**

- You are allergic to Ruzurgi or any of its ingredients
- You have ever had a seizure (convulsion)
- You are taking other forms of amifampridine or other aminopyridines

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Ruzurgi. Talk about any health conditions or problems you may have, including if you:**

- Have a known gene that may reduce your ability to break down a drug
- Have kidney problems
- Have liver problems
- Have ever had a seizure
- Are pregnant or planning to become pregnant.
  - It is not known if Ruzurgi can harm your unborn baby.
  - You and your healthcare professional will decide if you should take Ruzurgi if you are pregnant.
  - If you are a woman of child bearing potential you must use effective birth control during your treatment with RUZURGI.
- Are breastfeeding or plan to breastfeed. It is not known if Ruzurgi passes into your breast milk. Talk to your healthcare professional about the best way to feed your baby while taking Ruzurgi.

**Other warnings you should know about:**

- RUZURGI can cause problems with your heart rhythm called QTc prolongation, particularly if you have a known gene that may reduce your ability to break down RUZURGI. You may have no symptoms or you may have dizziness, feeling like your heart has skipped or added a beat, fainting or seizures. If these symptoms continue, they can lead to sudden death. You may be more at risk if you have had or have:
  - a heart attack
  - congestive heart failure
  - an irregular heartbeat or heart rhythm
  - a blockage in one or more of your arteries that affects blood flow to your heart
  - an abnormally rapid heart rate
  - heart palpitations (feeling like your heart has skipped a beat or added an extra beat)
  - a family history of sudden cardiac death at less than 50 years of age
  - problems of electrocardiogram (ECG) abnormality called “Long QT syndrome”
  - diabetes
  - imbalances in the electrolytes in your body (potassium, magnesium and calcium)

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with Ruzurgi:**

- Drugs that can interfere with transmission between nerves and muscles, such as pyridostigmine
- Drugs that are known to increase the risk of seizures
- Drugs that can affect the levels of electrolytes (potassium, magnesium and calcium) in your body:
  - Diuretics
  - Laxatives and enemas
  - Certain antibiotics
  - High doses of steroids
- Certain drugs that have an effect on your heart rate, such as:
  - Antiarrhythmics (such as flecainide and propafenone)
  - Antipsychotics (such as chlorpromazine and haloperidol)
  - Antidepressants (such as fluoxetine and amitriptyline)
  - Opioids (such as methadone)
  - Some antibiotics (such as erythromycin, clarithromycin and ciprofloxacin)
  - Antimalarials (such as quinone and chloroquine)
  - Antifungals (such as ketoconazole)
  - Kinase inhibitors (such as sunitinib)
  - Histone deacetylase inhibitors (such as vorinostat)
  - Beta-2 adrenoceptor agonists (such as salmeterol)

**How to take Ruzurgi:**

- Take Ruzurgi exactly how your healthcare professional tells you to take it
- **Do not** change your dose of Ruzurgi
- **Do not** stop taking Ruzurgi without first talking to your healthcare professional
- Ruzurgi can be taken with or without food. Taking RUZURGI with food may help if you have side effects of pain in your stomach, tingling in various parts of your body or nausea.
- Ruzurgi tablets can be cut in half if less than a full tablet is needed for you to get the right dose

- If you require less than half of a tablet to reach your prescribed dose, have difficulty swallowing tablets, or require a feeding tube, you can prepare a 1 mg/mL suspension by following the instructions below:

You will need:



Empty 30 mL Bottle



Sterile Water



10 mL Oral Syringe  
with a Catheter Tip

**Do not** use any foods or liquids other than sterile water to mix Ruzurgi.

Procedure for making a 1 mg/mL suspension (10 mL) if you require **10 mg OR LESS** for each dose:



Place one (1) 10 mg Ruzurgi (amifampridine) tablet in a 30 mL bottle.

## Step 1



Fill an oral syringe with 10 mL of sterile water and empty the contents into the 30 mL bottle.

## Step 2



Secure the cap onto the bottle and shake well for 30 seconds.

## Step 3

Procedure for making a 1 mg/mL suspension (30 mL) if you require **MORE than 10 mg for each dose:**



Place three (3) 10 mg Ruzurgi (amifampridine) tablets in a 30 mL bottle.

## Step 1



Fill an oral syringe with 10 mL of sterile water and empty the contents into the 30 mL bottle. This step must be performed for a total of three (3) times to create a volume of 30 mL which is equal to a 30 mg dose.

## Step 2



Secure the cap onto the bottle and shake well for 30 seconds.

## Step 3

Prepare fresh suspensions every day. Refrigerate the suspension between uses and shake well before taking your dose. Discard any unused suspension after 24 hours.

Procedure for taking Ruzurqi by mouth:



Remove the bottle cap and use an oral syringe with a catheter tip to measure the prescribed dose.

## Step 4



Administer by mouth. For patients requiring more than 10 mg for each dose, repeat steps 4 and 5 until the prescribed dose is given.

## Step 5

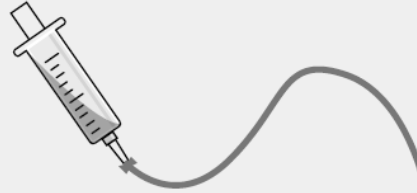
Procedure for taking Ruzurgi through a feeding tube:

Use only an oral syringe with a catheter tip. Talk to your healthcare professional about the size and the type of catheter you should use.



Remove the bottle cap and use an oral syringe with a catheter tip to measure the prescribed dose.

## Step 4



Empty the medicine using the oral syringe with a catheter tip into the feeding tube right away. For patients requiring more than 10 mg for each dose, repeat steps 4 and 5 until the prescribed dose is given.

## Step 5



To flush the feeding tube, refill the syringe with 10 mL of sterile water.

## Step 6



Shake the syringe, insert the catheter tip into the feeding tube to flush any remaining medicine from the feeding tube into the stomach.

## Step 7

**Usual Dose:**

- Your dose will be decided by your doctor based on your condition and how you react to RUZURGI.
- You will likely take RUZURGI 2 to 3 times a day and up to 5 times a day.

**Overdose:**

If you think you have taken too much Ruzurgi, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

**Missed Dose:**

If you miss your dose by a few hours and you are feeling weak, take your missed dose as soon as possible. If you missed your dose and it is close to your next dose, take it at your next dose.

**Do not** double your dose to make up for the missed dose.

## What are possible side effects from using Ruzurgi?

These are not all the possible side effects you may feel when taking Ruzurgi. If you experience any side effects not listed here, contact your healthcare professional.

The most common side effects of Ruzurgi are:

- Tingling around the mouth, tongue, face, fingers, toes, and other body parts
- Change in sense of taste (numbness or tingling in the mouth, on the lips or tongue)
- Change or reduction in sense of touch (numbness or tingling in the fingers)
- Stomach pain
- Indigestion
- Dizziness
- Nausea
- Diarrhea

Serious Side Effects and What to do About Them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>COMMON</b> <b>Seizures</b>			✓
<b>UNCOMMON</b> <b>Hypersensitivity reaction:</b> rash, itchiness along with difficulty breathing with or without swelling of the face, lips, tongue and throat.			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

### Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### Storage:

Store Ruzurgi in the container from the pharmacy at room temperature between 20°C to 25°C

for up to 3 months. Protect from moisture.

Refrigerate prepared Ruzurgi oral suspension between doses for up to 24 hours. Discard any unused portion of the suspension after 24 hours.

Keep out of reach and sight of children.

**If you want more information about Ruzurgi:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); the manufacturer's website (<https://www.medunikcanada.com/en/>), or by calling 1-855-633-8645.

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