

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new. Please report side effects. See the [full CMI](#) for further details.

1. Why am I taking RUZURGI?

RUZURGI contains the active ingredient amifampridine. RUZURGI is used to treat Lambert-Eaton myasthenic syndrome (LEMS) in adults and children aged 6 years and above.

For more information, see Section [1. Why am I taking RUZURGI?](#) in the full CMI.

2. What should I know before I take RUZURGI?

Do not take if you have ever had an allergic reaction to amifampridine, fampridine or other aminopyridines, or any of the ingredients listed at the end of the CMI. Do not take if you have a history of seizures, fits or convulsions.

Talk to your doctor if you have any other medical conditions, including problems with your kidneys or liver, heart, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I take RUZURGI?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with RUZURGI and increase the side effects of RUZURGI when taken together.

See Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take RUZURGI?

- Follow the instructions provided and use until your doctor tells you to stop.
- How much RUZURGI you should take will depend upon your weight and whether you have any other medical conditions such as problems with your liver or kidneys. Your doctor will determine the right dose for you and how often you should take it.
- You may need to split the tablets or prepare an oral suspension of RUZURGI tablets to get the right dose for you.
- If you have problems taking tablets or require a feeding tube, you may need to prepare an oral suspension of RUZURGI tablets.

More instructions can be found in Section [4. How do I take RUZURGI?](#) in the full CMI.

5. What should I know while taking RUZURGI?

Things you should do	<ul style="list-style-type: none">• Tell your doctor straight away if you are pregnant or planning to become pregnant.• Take RUZURGI exactly as prescribed by your doctor.• Remind any doctor, dentist, or pharmacist you visit that you are taking RUZURGI.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking this medicine or change the dose without first checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how RUZURGI affects you.
Looking after your medicine	<ul style="list-style-type: none">• Store RUZURGI tablets below 25°C for up to 3 months. Do not refrigerate.• Keep your tablets in the bottle and tightly closed until you're ready to take them.

For more information, see Section [5. What should I know while taking RUZURGI?](#) in the full CMI.

6. Are there any side effects?

Less serious side effects include, numbness, burning, prickling, or tingling sensations on any part of the body, stomach or gut pain, indigestion, dizziness, nausea, back pain, muscle spasms. Serious side effects include seizures, fits or convulsions, or an allergic reaction to the medicine.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

RUZURGI® (rew-ZUR-jee)

Active ingredient: *amifampridine* (a-mee-fam-pri-deen)

Consumer Medicine Information (CMI)

This leaflet provides important information about using RUZURGI. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking RUZURGI.**

Where to find information in this leaflet:

1. [Why am I taking RUZURGI?](#)
2. [What should I know before I take RUZURGI?](#)
3. [What if I am taking other medicines?](#)
4. [How do I take RUZURGI?](#)
5. [What should I know while taking RUZURGI?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I taking RUZURGI?

RUZURGI contains the active ingredient amifampridine. RUZURGI is a potassium channel blocker. It is thought to help restore the normal connection between nerves and muscles, which may help to reduce muscle weakness.

RUZURGI is used to treat Lambert-Eaton myasthenic syndrome (LEMS) in adults and children aged 6 years and above.

2. What should I know before I take RUZURGI?

Warnings

Do not take RUZURGI if:

- you are allergic to amifampridine, fampridine or other aminopyridines, or any of the ingredients listed at the end of this leaflet.
- you are taking other forms of amifampridine or other aminopyridines
- Always check the ingredients to make sure you can use this medicine.
- you have a history of seizures, fits or convulsions.

Check with your doctor if you:

- have any other medical conditions including
 - a history of seizures, fits, or convulsions
 - problems with your liver
 - problems with your kidneys
 - problems with your heart such as torsades de pointes
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Effective birth control (contraception) should be used if you are taking RUZURGI.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Children

RUZURGI should not be taken by children less than 6 years of age.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may lead to an increased risk of seizures or other side effects when taken with RUZURGI.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect RUZURGI.

4. How do I take RUZURGI

How much to take

- Follow the instructions provided and use until your doctor tells you to stop.
- How much RUZURGI you should take will depend upon your weight and whether you have any other medical conditions such as problems with your liver or kidneys.
Your doctor will determine the right dose for you and how often you should take it.
- Your doctor may tell you to split the tablets in half, or prepare an oral suspension of the tablets, to get the right dose for you. Information on how to prepare an oral suspension of RUZURGI is provided below.
- Patients who have difficulty swallowing tablets, require feeding tubes or require a dose that cannot be achieved by taking the tablet can prepare an oral suspension of the tablets.
- If the patient weighs less than 45 kg, the maximum daily dose is 4 whole tablets (40 mg) in divided doses.

- If the patient weighs 45 kg or more, the maximum daily dose is 10 whole tablets (100 mg) in divided doses

How to take RUZURGI

- RUZURGI should be taken with a glass of water.
- RUZURGI can be taken with or without food.

How to prepare a 1 mg per 1 mL of oral suspension of RUZURGI for patients requiring 10 mg or less per dose

You will need:

- one 30 mL bottle,
- one 10 mL syringe, and
- 10 mL of sterile water.

You can get all these supplies from your local pharmacy.

Follow the steps below to make up the suspension:

1. Place one (1) 10 mg RUZURGI (amifampridine) tablet in the 30 mL bottle.



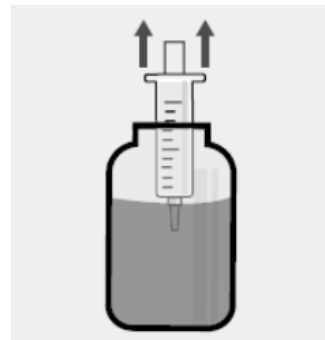
2. Add 10 mL of sterile water to the bottle using the syringe. Do not use any food or other liquids.



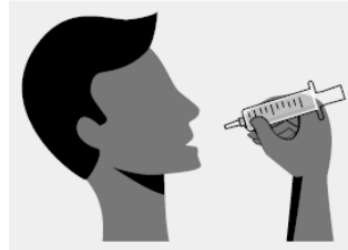
3. Secure the cap on the bottle and shake well for 30 seconds.



4. Using the syringe withdraw the prescribed dose from the bottle.



5. Take the prescribed dose by injecting the suspension into your mouth.



6. Refrigerate the suspension between doses and discard any unused suspension after 24 hours.

How to prepare a 1 mg per 1 mL of oral suspension of RUZURGI for patients requiring 10 mg or more per dose

You will need:

- one 30 mL bottle,
- one 10 mL syringe, and
- 30 mL of sterile water.

You can get all these supplies from your local pharmacy.

Follow the steps below to make up the suspension:

1. Place three (3) 10 mg RUZURGI tablets in the 30 mL bottle.



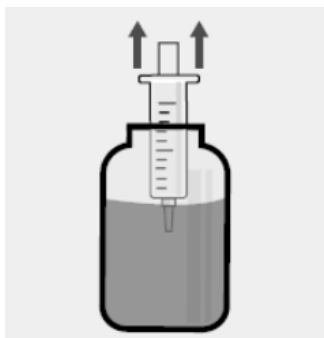
2. Add 30 mL of sterile water to the bottle using the syringe. **You will need to fill the syringe 3 times to create a volume of 30 mL.** Do not use any food or other liquids.



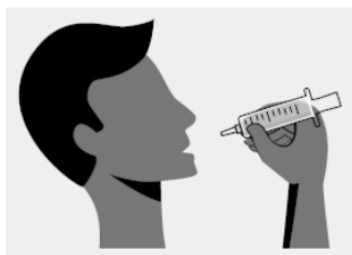
- Secure the cap on the bottle and shake well for 30 seconds.



- Using the syringe withdraw the prescribed dose from the bottle.



- Take the dose by injecting the suspension into your mouth.



- Repeat steps 4 and 5 until you have taken the prescribed dose.
- Refrigerate the suspension between doses and discard any unused suspension after 24 hours.

How to prepare a 1 mg per 1 mL of oral suspension of RUZURGI for patients who require a feeding tube

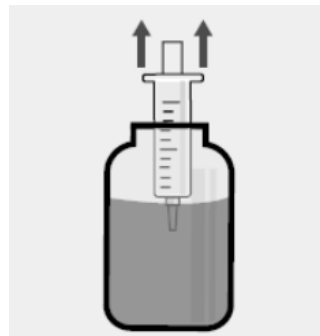
You will need:

- one 30 mL bottle,
- one 10 mL syringe **with a catheter tip**, and
- 30 mL of sterile water and extra to flush the feeding tube.

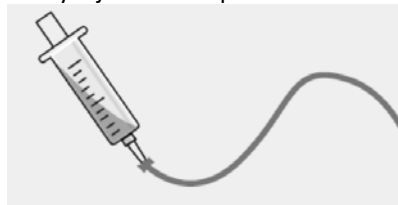
You can get all these supplies from your local pharmacy.

Follow the steps below to make up the suspension:

- Follow one of the procedures above for preparing a 1 mg per 1 mL oral suspension of RUZURGI for, 10 mg or less per dose, or 10 mg or more per dose.
- Using the syringe **with the catheter tip** withdraw the prescribed dose from the bottle.



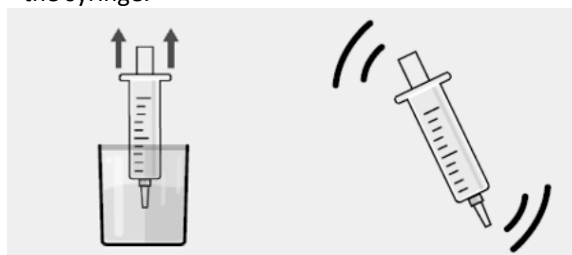
- Connect the syringe to the feeding tube and immediately inject the suspension into the stomach.



- If the prescribed dose is more than 10 mg, repeat steps 2 and 3 until you have taken the prescribed dose.

Flush the feeding tube

- Disconnect the syringe from the feeding tube.
- Refill the syringe with 10 mL of sterile water and shake the syringe.



- Connect the syringe to the feeding tube and flush any remaining suspension into the stomach.
- Refrigerate the suspension between doses and discard any unused suspension after 24 hours.

If you forget to take RUZURGI

RUZURGI should be taken according to the directions provided by your doctor. **If you miss your dose at the usual time, and it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

Do not take a double dose to make up for the dose you missed.

If you take too much RUZURGI

If you think that you have taken too much RUZURGI, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking RUZURGI?

Things you should do

Take RUZURGI exactly as prescribed by your doctor.

Remind any doctor, dentist, or pharmacist you visit that you are taking RUZURGI.

Call your doctor straight away if you:

- are pregnant or planning to become pregnant.

Things you should not do

- Do not stop taking this medicine or change the dose without first checking with your doctor.
- Do not give RUZURGI to anyone else even if they have the same condition as you.
- Do not take RUZURGI for any other conditions unless your doctor tells you to.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how RUZURGI affects you.

RUZURGI may cause dizziness in some people.

Looking after your medicine

RUZURGI tablets

- Store below 25°C for up to 3 months. Do not refrigerate.
- Keep your tablets in the bottle and tightly closed until you are ready to take them.

Store it in a cool dry place away from moisture, heat or sunlight; for example:

- do not store it in the bathroom or near a sink, or
- do not store it in the car or on windowsills.

Keep it where young children cannot reach it.

Oral suspension of RUZURGI tablets

- Refrigerate the oral suspension between doses.

Keep it where young children cannot reach it.

When to discard your medicine

RUZURGI tablets have a 3 month expiry from the date of first use.

The oral suspension has an expiry of 24 hours from when it is prepared. Discard any unused suspension.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them should be minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• Numbness, burning, prickling, or tingling sensation in the arms, hands, legs, feet, mouth, or other parts of the body.• Muscle spasms• Back pain• Stomach or gut pain• Indigestion• Dizziness• Nausea (feeling sick)	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• Seizures, fits or convulsions Allergy-related: <ul style="list-style-type: none">• Shortness of breath• Wheezing or difficulty breathing• Swelling of the face, lips, tongue, or other parts of the body• Rash, itching, hives on the skin	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What RUZURGI tablets contain

Active ingredient (main ingredient)	Each tablet contains 10 mg of amifampridine
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• colloidal anhydrous silica• calcium hydrogen phosphate dihydrate

	<ul style="list-style-type: none">• magnesium stearate• microcrystalline cellulose• sodium starch glycollate
Potential allergens	Not applicable

Do not take this medicine if you are allergic to any of these ingredients.

RUZURGI does not contain gluten.

What RUZURGI looks like

RUZURGI is a white to off-white oval-shaped tablet. On one side it is scored and debossed with “10” on the left of the score line and “110” on the right of the score line. On the other side it is debossed with “LACUNA” (Aust R 352630).

RUZURGI is available in bottles of 100 tablets.

Who distributes RUZURGI

Lacuna Pharma Pty Ltd
21/21 Kangoo Road,
Somersby
NSW 2250

This leaflet was updated in September 2024.

RUZURGI® v3.0