

## 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.

### 1. Why am I using Rilutek?

Rilutek contains the active ingredient riluzole. Rilutek is used in the treatment of amyotrophic lateral sclerosis (ALS), a form of motor neurone disease which can cause muscle degeneration and muscle weakness.

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

### 2. What should I know before I use Rilutek?

Do not use if you have ever had an allergic reaction to riluzole or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. Talk to your doctor if you smoke cigarettes or consume caffeine.**

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

### 3. What if I am taking other medicines?

Some medicines may interfere with Rilutek and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use Rilutek?

- The recommended dose is usually one tablet two times a day.
- Rilutek may not work as well if it is taken at the same time as your meals. Rilutek should not be taken immediately before or after meals, especially meals which may contain food high in fat.
- Swallow Rilutek tablets whole with a full glass of water. Do not chew the tablets.

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

### 5. What should I know while using Rilutek?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are taking Rilutek.</li><li>• Tell your doctor straight away if you are pregnant, or become pregnant, while you are taking Rilutek.</li><li>• Tell your doctor or dentist that you are taking Rilutek if you plan to have surgery that needs a general anaesthetic.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop using this medicine or lower the dosage without checking with your doctor.</li><li>• Do not take more than the recommended dose unless your doctor tells you to.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Make sure you know how Rilutek affects you before you drive or use any machines or tools. Rilutek may cause drowsiness or dizziness in some people. If this occurs, do not drive or operate machinery.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Tell your doctor if you drink alcohol.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep Rilutek in the blister pack until it is time to take them.</li><li>• Keep Rilutek in a cool, dry place, protected from light, where the temperature stays below 25°C.</li></ul>

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

### 6. Are there any side effects?

All medicines can have side effects. Tell your doctor or pharmacist if you do not feel well whilst you are taking Rilutek. Most of the side effects from taking Rilutek are minor and temporary, such as headache, nausea and weakness. However, some serious side effects may need urgent medical attention. Examples of serious side effects include severe upper stomach pain and itching or yellowing of the skin.

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.

## Consumer Medicine Information (CMI)

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

**Where to find information in this leaflet:**

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

### 1. Why am I using Rilutek?

**Rilutek contains the active ingredient riluzole.** Rilutek works on how the nerve cells in your central nervous system communicate with each other.

**Rilutek is used in the treatment of amyotrophic lateral sclerosis (ALS), a form of motor neurone disease, which can cause muscle degeneration and muscle weakness.**

Your doctor may have prescribed this medicine for another reason. Ask your doctor if you have any questions about why this medicine has been prescribed for you.

It is important to remember that you may not feel any different when you take Rilutek. The benefits of using Rilutek may not be noticeable to you. You should not stop taking Rilutek without speaking to your doctor first.

### 2. What should I know before I use Rilutek?

#### Warnings

##### Do not use Rilutek if:

- you are allergic to riluzole, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you have liver disease
- you are pregnant or intend to become pregnant
- you are breastfeeding or intend to breastfeed
- the expiry date (EXP) printed on the pack has passed
- the packaging is damaged or shows signs of tampering.

##### Check with your doctor if you:

- have any other medical conditions especially liver disease, kidney disease or lung disease
- take any medicines for any other condition
- plan to have surgery

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.

This medicine should not be used during pregnancy.

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

This medicine should not be used if you are breastfeeding.

#### Use in children and adolescents

Do not use Rilutek in children or adolescents. There is no experience with the use of this medicine in this age group.

#### Cigarette smoke and caffeine

Tell your doctor if you smoke cigarettes or consume caffeine. Cigarette smoke and caffeine may affect the amount of Rilutek in your body.

If you have not told your doctor about any of the above, tell them before you take this medication.

### 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 interfere with Rilutek and affect how it works.** Some medicines may be affected by Rilutek.

You may need to use different amounts of your medicine or you may need to take different medicines. Your doctor will advise you.

**Medicines that may increase the effect of Rilutek include:**

- amitriptyline - a medicine used to treat depression
- clomipramine - a medicine used to treat depression
- diazepam - a medicine for sedation
- diclofenac - a medicine used to reduce pain and inflammation
- fluvoxamine - a medicine used to treat depression
- imipramine - a medicine used to treat depression
- quinolone antibiotics (e.g. ciprofloxacin, norfloxacin)
- theophylline - a medicine used to treat asthma

**Medicines that may reduce the effect of Rilutek include:**

- omeprazole - a medicine used to treat gastric ulcers and reflux
- rifampicin – an antibiotic medicine

Tell your doctor if you smoke cigarettes or consume caffeine. Cigarette smoke and caffeine may affect the amount of Rilutek in your body.

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

## 4. How do I use Rilutek?

### How much to take

- Your doctor will tell you how many tablets you should take, and when to take them.
- The recommended dose is usually one tablet two times a day.
- Do not take more than the dose your doctor has directed.
- Talk to your doctor if you are unsure what dose to take.
- You should not change the dosage without speaking to your doctor first.
- Follow the instructions provided and take Rilutek until your doctor tells you to stop.

### When to take Rilutek

- Take your prescribed dose at about the same time each day.
- Rilutek should not be taken immediately before or after meals, especially meals which may contain food high in fat.
- Rilutek may not work as well if it is taken at the same time as your meals.
- Swallow Rilutek tablets whole with a full glass of water.
- Do not chew the tablets.

### If you forget to take Rilutek

Rilutek should be taken regularly at the same time each day.

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking your tablets as you would normally.**

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

If you are not sure what to do, ask your doctor.

### If you take too much Rilutek

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

#### You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26 in Australia or 0800 764 766 in New Zealand), 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 using Rilutek?

### Things you should do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Rilutek.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking Rilutek.

### Call your doctor straight away if you:

- become pregnant while you are taking this medicine.

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

### Things you should not do

- Do not stop taking this medicine or lower the dosage without checking with your doctor.
- Do not take more than the recommended dose unless your doctor tells you to.
- Do not give this medicine to anyone else, even if they have the same condition as you.
- Do not use this medicine to treat any other complaints unless your doctor tells you to.

### Monitoring during treatment

During your treatment with Rilutek, your doctor will do some blood tests from time to time to check for any possible signs of liver damage.

### Driving or using machines

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

Rilutek may cause drowsiness or dizziness in some people. Make sure you know how you react to it before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy.

### Drinking alcohol

**Tell your doctor if you drink alcohol.**

### Looking after your medicine

- Keep your tablets in the blister pack until it is time to take them. If you take the tablets out of the box or blister pack, they may not keep well.
- Keep your tablets in a cool, dry place, protected from light, where the temperature stays below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Heat and dampness can destroy some medicines.

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
- in the car or on window sills.

**Keep it where young children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### 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.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are 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
<b>General:</b> <ul style="list-style-type: none"><li>weakness or loss of strength</li></ul> <b>Gut-related:</b> <ul style="list-style-type: none"><li>stomach ache</li><li>nausea</li><li>vomiting</li></ul> <b>Skin-related:</b> <ul style="list-style-type: none"><li>rash</li><li>flaking skin</li></ul> <b>Joint-related:</b> <ul style="list-style-type: none"><li>joint stiffness</li></ul> <b>Nervous system-related:</b> <ul style="list-style-type: none"><li>headache</li><li>dizziness</li><li>sleepiness</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>  <b>These are the most common side effects if this medicine.</b>

### Serious side effects

Serious side effects	What to do
<b>Gut-related:</b> <ul style="list-style-type: none"><li>severe upper stomach pain, often with nausea and vomiting</li></ul> <b>Skin-related:</b> <ul style="list-style-type: none"><li>swelling of the hands, feet or legs</li><li>itching or yellowing of the skin</li></ul> <b>Blood-related:</b> <ul style="list-style-type: none"><li>bruising more easily</li></ul> <b>Breathing-related:</b> <ul style="list-style-type: none"><li>shortness of breath</li><li>difficulty breathing</li></ul> <b>Heart-related:</b> <ul style="list-style-type: none"><li>irregular or fast heartbeat</li></ul> <b>Immune system-related:</b> <ul style="list-style-type: none"><li>frequent infections, such as fever, severe chills, sore throat or mouth ulcers</li></ul> <b>Nervous system-related:</b> <ul style="list-style-type: none"><li>tingling sensations around the mouth</li></ul>	<b>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.</b>  <b>You may need urgent medical attention or hospitalization. Serious side effects are rare.</b>

**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.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

### 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](http://www.tga.gov.au/reporting-problems) in Australia or in New Zealand at <https://pophealth.my.site.com/carmreportnz/s/>. 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 Rilutek contains

<b>Active ingredient (main ingredient)</b>	riluzole 50mg
<b>Other ingredients (inactive ingredients)</b>	calcium hydrogen phosphate microcrystalline cellulose

	colloidal anhydrous silica magnesium stearate croscarmellose sodium hypromellose macrogol 6000 titanium dioxide
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**Do not take this medicine if you are allergic to any of these ingredients.**

### **What Rilutek looks like**

Rilutek tablets are white and capsule-shaped. Each tablet is engraved with the text RPR 202 (AUST R 79744).

Each pack contains 56 tablets.

### **Who distributes Rilutek**

Distributed in Australia by:

sanofi-aventis australia pty ltd

12-24 Talavera Road

Macquarie Park NSW 2113

Freecall: 1800 818 806

Email: [medinfo.australia@sanofi.com](mailto:medinfo.australia@sanofi.com)

Distributed in New Zealand by:

Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics

PO Box 62027

Sylvia Park Auckland 1644

Freecall: 0800 283 684

Email: [medinfo.australia@sanofi.com](mailto:medinfo.australia@sanofi.com)

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