

# Teglutik® Oral Suspension

## 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 Teglutik®?

Teglutik® contains the active ingredient riluzole. Teglutik® is used to treat people with amyotrophic lateral sclerosis (ALS), a form of motor neurone disease, which can cause muscle degeneration leading to muscle weakness.

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

### 2. What should I know before I use Teglutik®?

Do not use if you have ever had an allergic reaction to Teglutik® 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.**

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

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

Some medicines may interfere with Teglutik® 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 Teglutik®?

- The recommended daily dose is 20mL (10mL every 12 hours).

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

### 5. What should I know while using Teglutik®?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Tell any doctor, dentist or pharmacist you visit that you are using Teglutik®</li><li>• Tell your doctor or dentist that you are taking Teglutik® if you plan to have surgery that needs a general anesthetic.</li><li>• Contact your Doctor immediately if you become pregnant while you are taking Teglutik®.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop taking Teglutik®, 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><li>• Do not give Teglutik® to anyone else, even if they have the same condition as you.</li><li>• Do not use Teglutik® to treat any other complaints unless your doctor tells you to.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful driving or operating machinery until you know how Teglutik® affects you.</li><li>• Teglutik® 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.</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 Teglutik® in the bottle, inside the box, until it is time to take it.</li><li>• Keep Teglutik® in a cool dry place where the temperature stays below 25°C.</li></ul>

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

### 6. Are there any side effects?

The most common side effects are stomachache, nausea or vomiting, headache, joint stiffness, skin problems eg. rash, flaking skin, dizziness, sleepiness, and weakness or loss of strength. Serious side effects which may require urgent medical attention may include irregular or fast heartbeat, frequent infections such as fever, severe chills, sore throat or mouth ulcers, swelling of the hands, feet or legs, tingling sensations around the mouth, shortness of breath or difficulty breathing, severe upper stomach pain (often with nausea and vomiting), itchy skin or yellow skin, or if you start to bleed or bruise easily.

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.

# Teglutik® Oral Suspension (Tee-gloo-tick)

Active ingredient(s): riluzole (Ril-you-zol)

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Teglutik®. **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 Teglutik®.**

Where to find information in this leaflet:

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

### 1. Why am I using Teglutik®?

Teglutik® contains the active ingredient riluzole. Teglutik® is Schedule 4 (S4): Prescription Only Medicine.

Teglutik® is used to treat people with amyotrophic lateral sclerosis (ALS), a form of motor neurone disease, which can cause muscle degeneration leading to muscle weakness.

### 2. What should I know before I use Teglutik®?

#### Warnings

Do not use Teglutik® if:

- you are allergic to riluzole or any of the ingredients listed at the end of this leaflet.
- you have liver disease
- you are pregnant or intend to become pregnant
- you are breastfeeding or intend to breastfeed
- Always check the ingredients to make sure you can use this medicine.

#### Children and adolescents

This medicine should not be given to children and adolescents under 18 years of age because there is no experience with the use of this medicine in children.

Check with your doctor if you:

- have any other medical conditions such as:
  - liver disease;
  - kidney disease;
  - lung disease
- take any medicines for any other condition

#### Pregnancy and breastfeeding

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

This medicine is not recommended to be used during pregnancy.

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

It is not known whether it passes into breast milk. Your doctor will discuss the risks and benefits of taking Teglutik® if you are breastfeeding or planning to breastfeed.

#### Intolerance to sugars

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

**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?](#)**

### 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 Teglutik® and affect how it works. These include:**

- theophylline - a medicine used to treat asthma
- amitriptyline - a medicine used to treat depression
- tacrine - a medicine used in patients with Alzheimer's Disease
- some types of antibiotics eg. rifampicin and quinolones
- omeprazole - a medicine used to treat gastric ulcers.
- some medicines used to treat depression eg. Clomipramine and fluvoxamine
- diazepam - a medicine for sedation.
- diclofenac - a medicine used to reduce pain and inflammation.

These medicines may be affected by Teglutik® or may affect how well it works. You may need to use different amounts of your medicine, or you may need to take different medicines. Your doctor or pharmacist will advise you.

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

## 4. How do I use Teglutik®?

### How much to take

- The recommended daily dose is 20mL (10mL every 12 hours).
- Follow the instructions provided and use Teglutik® until your doctor tells you to stop.

### When to take Teglutik®

- Teglutik® should be taken by mouth every 12 hours, at the same time of the day each day (for example, in the morning and evening).
- Teglutik® should not be taken immediately before or after meals, especially meals which may contain food high in fat.
- Teglutik® may not work as well if it is taken at the same time as your meals.

### How to take Teglutik®

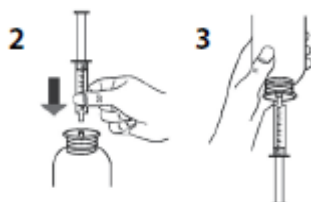
- Follow all directions given to you by your doctor or pharmacist carefully.
- If you do not understand the instructions in this leaflet, ask your doctor or pharmacist for help.
- Teglutik® should be taken by mouth or via a Percutaneous Endoscopic Gastrostomy (PEG)
- Teglutik® is administered by means of graduated dosing syringe.

### Method of administration:

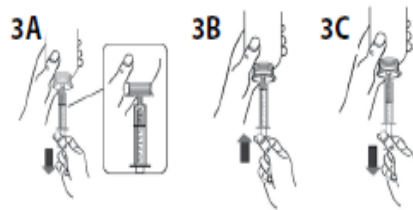
- The bottle of Teglutik® should be gently shaken for at least 30 seconds by rotating the bottle by 180°. You will know when the liquid turns slightly brown.
- Open the bottle: press the cap and turn it anticlockwise (figure 1).



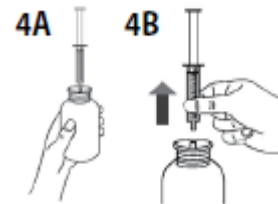
- Take the syringe, remove the tip and insert the syringe in the adaptor opening (figure 2). Turn the bottle upside down (figure 3).



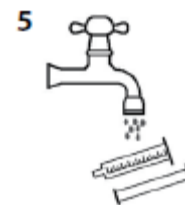
- Fill the syringe with a small amount of Teglutik® by pulling the plunger down (figure 3A), then push the piston upward in order to remove any possible bubble (figure 3B). Pull the piston down to the graduation mark corresponding to the quantity in milliliters (mL) prescribed by your doctor (figure 3C).



- Turn the bottle the right way up (figure 4A). Remove the syringe from the adaptor (figure 4B).



- Administer orally the whole content of the syringe. Dilution in water is not necessary.
- Close the bottle with the plastic screw cap.
- Wash the syringe with water only and re-assemble it with its tip cap once dried (figure 5).



- For PEG administration, the tubing should be washed with 10 mL of water before and after administration of Teglutik®.

### If you forget to use Teglutik®

Teglutik® should be used regularly at the same time each day. If you miss or forget your dose at the usual time, take it as soon as you remember, and then go back to taking your medicine as you would normally.

**If 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 are not sure what to do, ask your doctor or pharmacist.

### If you use too much Teglutik®

If you think that you have used too much Teglutik®, 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 using Teglutik®?

### Things you should do

- Tell any doctor, dentist or pharmacist you visit that you are using Teglutik®
- Tell your doctor or pharmacist if you are about to be started on any new medicine that you are taking Teglutik®.
- Tell your doctor or dentist that you are taking Teglutik® if you plan to have surgery that needs a general anesthetic.
- Tell your doctor if you smoke and how much coffee you drink. Nicotine and caffeine may affect the amount of Teglutik® in your body.
- During your treatment with Teglutik® your doctor will do some blood tests from time to time to check for any possible signs of liver damage.

### Call your doctor straight away if you:

- become pregnant while you are taking Teglutik®

### 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 your 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.
- Do not use this medicine if the bottle shows signs of tampering.

### Driving or using machines

#### Be careful before you drive or use any machines or tools until you know how Teglutik® affects you.

Teglutik® 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

- Store Teglutik® inside the box, until it is time to take it.
- If you take Teglutik® out of the box or bottle it may not keep well.
- Store in a cool, dry place where the temperature stays below 25°C.
- Do not store Teglutik® in the bathroom or near a sink.
- Do not leave it in the car or on window sills.
- Heat and dampness can destroy some medicines.

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

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

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

### When to discard your medicine

- If your doctor tells you to stop taking Teglutik®
- If the expiry date on the carton or Teglutik® bottle has passed.
- If 15 days has passed after first opening Teglutik®.

### 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
<p><b>Stomach related:</b></p> <ul style="list-style-type: none"> <li>• stomachache</li> <li>• feeling sick (nausea)</li> <li>• vomiting</li> </ul> <p><b>Other side effects</b></p> <ul style="list-style-type: none"> <li>• headache</li> <li>• joint stiffness</li> <li>• skin problems eg. rash, flaking skin</li> <li>• dizziness</li> <li>• sleepiness</li> <li>• weakness or loss of strength</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

### Serious side effects

Serious side effects	What to do
<p><b>General complaints:</b></p> <ul style="list-style-type: none"> <li>• irregular or fast heartbeat</li> <li>• frequent infections such as fever, severe chills, sore throat or mouth ulcers</li> <li>• swelling of the hands, feet or legs</li> <li>• tingling sensations around the mouth</li> <li>• shortness of breath or difficulty breathing</li> </ul>	<p><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></p>

Serious side effects	What to do
<b>Liver complaints:</b> <ul style="list-style-type: none"> <li>• Severe upper stomach pain, often with nausea and vomiting</li> <li>• If your skin becomes itchy or yellow or if you start to bleed or bruise easily. You may be developing a liver problem.</li> </ul>	<b>If any of the following happen, stop taking this medicine and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:</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.

### 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). 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 Teglutik® contains

<b>Active ingredient (main ingredient)</b>	The active substance is riluzole. 1 mL of Teglutik® contains 5 mg of riluzole.
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>• sorbitol solution (70% w/w) (non-crystallising)</li> <li>• aluminium magnesium silicate</li> <li>• xanthan gum</li> <li>• saccharin sodium</li> <li>• antifoam AF emulsion Q7-2587</li> <li>• sodium lauryl sulfate</li> <li>• cetareth-25</li> <li>• purified water</li> </ul>
<b>Potential allergens</b>	<ul style="list-style-type: none"> <li>• sorbitol : 1 mL of Teglutik® contains 400 mg of sorbitol (equivalent to 571.43 mg of sorbitol solution (70% w/w)). Products containing sorbitol may have a laxative effect or cause diarrhoea.</li> </ul>

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

### What Teglutik® looks like

Teglutik® is presented as a slightly brown, opaque homogeneous oral suspension after being manually gently shaken.

Teglutik® is available in a carton containing a bottle of 250 mL or 300 mL, or in a multipack consisting of 2 single cartons each with one bottle of 250 mL. Each carton is supplied with a plastic graduated oral dosing syringe. The syringe barrel is graduated in millilitres up to 10 mL. Not all pack sizes may be marketed.

### Who distributes Teglutik®

Asteri Pharma Pty Ltd  
6 Lux Way  
Brunswick, Victoria 3056  
Australia

Telephone: 1800 175 659

Website: <https://www.asteripharma.com/>

This leaflet was prepared in January 2026.