

Package leaflet: Information for the user
TEGLUTIK 5 mg/ml oral suspension
riluzole

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What TEGLUTIK is and what it is used for
2. What you need to know before you take TEGLUTIK
3. How to take TEGLUTIK
4. Possible side effects
5. How to store TEGLUTIK
6. Contents of the pack and other information

1. What TEGLUTIK is and what it is used for

What TEGLUTIK is

The active substance in TEGLUTIK is riluzole which acts on the nervous system.

What TEGLUTIK is used for

TEGLUTIK is used in patients with amyotrophic lateral sclerosis (ALS). ALS is a form of motor neurone disease where attacks of the nerve cells responsible for sending instructions to the muscles lead to weakness, muscle waste and paralysis. The destruction of nerve cells in **motor neurone** disease may be caused by too much glutamate (a chemical messenger) in the brain and spinal cord. TEGLUTIK stops the release of glutamate and this may help in preventing the nerve cells being damaged. Please consult your doctor for more information about ALS and the reason why this medicine has been prescribed for you.

2. What you need to know before you take TEGLUTIK

Do not take TEGLUTIK

- if you are **allergic** to riluzole or any of the other ingredients of this medicine (listed in section 6),
- if you have any **liver disease** or increased blood levels of some enzymes of the liver (**transaminases**),
- if you are **pregnant or breast-feeding**.

Warnings and precautions

Talk to your doctor or pharmacist before taking TEGLUTIK:

- if you have any **liver problems**: yellowing of your skin or the white of your eyes (jaundice), itching all over, feeling sick, being sick;
- if your **kidneys** are not working very well;
- if you have any **fever**: it may be due to a low number of white blood cells which can cause an increased risk of infection;

If any of the above applies to you, or if you are not sure, tell your doctor who will decide what to do.

Children and Adolescents

If you are less than 18 years of age, the use of TEGLUTIK is not recommended because there is no information available in this population.

Other medicines and TEGLUTIK

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Pregnancy, breast-feeding and fertility

You **must not** take TEGLUTIK if you are pregnant, think you may be pregnant, or if you are breast feeding.

If you think you may be pregnant or if you intend to breast-feed, ask your doctor for advice before taking this medicine.

Driving and using machines

You can drive or use any tools or machines, unless you feel dizzy or light headed after taking this medicine.

TEGLUTIK contains liquid sorbitol (E420) and sodium.

This medicine contains 4000 mg sorbitol (E420) in 10 ml of oral suspension. Sorbitol is a source of fructose. If your doctor has told you that you have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you take this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per 10 ml of oral suspension, that is to say essentially 'sodium-free'

3. How to take TEGLUTIK

The suspension can be given per oral administration and alternatively it is also suitable for administration via enteral feeding tubes.

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

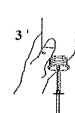
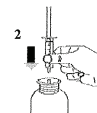
The recommended dose is 100 mg a day (50 mg every 12 hours). 10 ml of the oral suspension, containing 50 mg of riluzole, should be taken by mouth every 12 hours, at the same time of the day each day (for example, in the morning and evening). The suspension is administered by means of graduated dosing syringe.

The oral suspension must be manually gently shaken for at least 30 seconds by continuously turning the bottle up and down until the TEGLUTIK suspension is mixed well and you do not see any clear liquid at the top of the suspension or any particles at the bottom of the bottle.

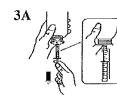
Method of administration:



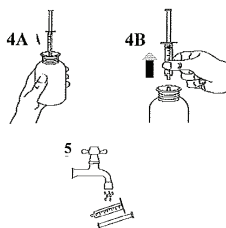
Instructions for oral use:
Open the bottle: press the cap and turn it anticlockwise (figure 1)



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 suspension 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.
- 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).

Instructions for use via enteral feeding tubes:

Ensure that the enteral feeding tube is free from obstruction before administration.

1. Flush the enteral tube with 30 ml of water
2. Administer the required dose of Teglutik oral suspension with a graduated dosing syringe
3. Flush the enteral tube with 30 ml of water

If you take more TEGLUTIK than you should

If you take too much suspension, contact your doctor or the nearest hospital emergency department immediately.

If you forget to take TEGLUTIK

If you forget to take your dose, leave out that dose completely and take the next dose at the usual time.

Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, TEGLUTIK can cause side effects, although not everybody gets them.

Important

Tell your doctor immediately

- if you experience any **fever** (increase in temperature) because TEGLUTIK may cause a decrease in the number of white blood cells. Your doctor may want to take a blood sample to check the number of white blood cells, which are important in fighting infections.
- if you experience any of the following symptoms: yellowing of your skin or the white of your eyes (jaundice), itching all over, feeling sick, being sick, as these may be signs of **liver disease** (hepatitis). Your doctor may do regular blood tests while you are taking TEGLUTIK to make sure that this does not occur.
- if you experience cough or difficulties in breathing, as this may be a sign of **lung disease** (called interstitial lung disease).

Other side effects

Very common side effects (may affect more than 1 in 10 people)

- tiredness
- feeling sick
- increased blood levels of some enzymes of the liver (transaminases).

Common side effects (may affect up to 1 in 10 people):

- dizziness
- numbness or tingling of the mouth
- vomiting
- sleepiness

- increase in heart beat
- diarrhoea
- headache
- abdominal pain
- pain

Uncommon side effects (may affect up to 1 in 100 people)

- anaemia
- allergic reactions
- inflammation of the pancreas (pancreatitis).

Not known (frequency cannot be estimated from the available data)

- rash

As riluzole oral suspension is more rapidly absorbed than riluzole tablets, a slight increase in tiredness, dizziness, diarrhoea and transaminases cannot be excluded.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store TEGLUTIK

Keep out of the sight and reach of children.

Do not use TEGLUTIK after the expiry date which is stated on the carton and the bottle, after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Once opened, use within 15 days.

Do not throw away any medicines via wastewater or household waste.

Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What TEGLUTIK contains

- The active substance is riluzole. 1 ml of oral suspension contains 5 mg of riluzole.
- The other ingredients are: Liquid Sorbitol (E420), Aluminum magnesium Silicate, Xanthan Gum (E415), Saccharin Sodium (E954), Simethicone emulsion 30%, Sodium Laurilsulphate, Macrogol Cetostearyl Ether, Water.

What TEGLUTIK looks like and content of the pack

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

TEGLUTIK is available in a bottle of 250 and 300 ml with a plastic graduated oral dosing syringe. Not all pack sizes are marketed.

Pack sizes are:

- cartoon box containing one or two bottles of 250 ml of riluzole 5 mg/mL Oral Suspension
- cartoon box containing one bottle of 300 mL of riluzole 5 mg/mL Oral Suspension.

The syringe barrel is graduated in milliliters up to 10 ml.

Marketing Authorisation Holder

ITALFARMACO S.A.
San Rafael, 3
28108 Alcobendas,
Madrid, Spain

Manufacturer

ITALFARMACO S.A.
San Rafael, 3
28108 Alcobendas,
Madrid, Spain

Licensee

Versalya Pharma
(Italfarmaco Group)
C/San Rafael, 3
28108 Alcobendas.
Madrid, Spain

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