Package leaflet: Information for the user
Teglutik® 5mg/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 pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Teglutik 5mg/ml oral suspension but will be referred to Teglutik throughout the remainder of the leaflet.

What is in this leaflet:

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.

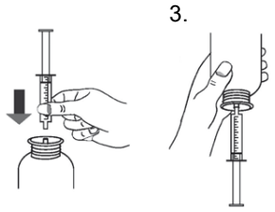
Method of administration:
Instructions for oral use:

Open the bottle: press the cap and turn it anticlockwise (figure 1)

1.

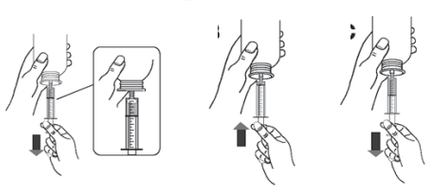
Take the syringe, remove the tip and insert the syringe in the adaptor opening (figure 2). Turn the bottle upside down (figure 3).

2. 3.



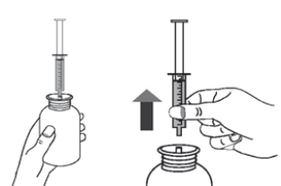
Fill the syringe with a small amount of suspension by pulling the plunger down (figure 3A), then push the piston upward in order to remove any possible bubble (figure 3B). Pull the piston down to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor (figure 3C).

3A. 3B. 3C.



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

4A. 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).

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**.
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.
This medicine does not require any special storage conditions.
Do not use this medicine after the expiry date which is stated on the pack and on the bottle, after 'EXP'. The expiry date refers to the last day of that month.
After opening, use within 15 days.

If your medicine shows any signs of deterioration or discolouration, consult your pharmacist for advice. If damaged, please tell your doctor or pharmacist.

Do not throw away medicines away via wastewater or household waste. Ask your pharmacist how to throw away any medicines that are no longer in use. This will help to protect the environment.

6. Contents of the pack and other information

What Teglutik contains
The active substance is riluzole. For every 1ml of oral suspension, there is 5mg of riluzole.
The other ingredients are: Liquid sorbitol (E420), aluminium and magnesium silicate, xanthan gum, saccharine sodium, 30% simethicone emulsion, sodium lauryl sulfate, macrogol cetostearyl ether and purified water.

What Teglutik is and contents of the pack
This medicine is presented as an opaque, homogeneous and slightly brown oral suspension after being gently shaken.

Teglutik is supplied in a 300ml glass bottle with a plastic graduated syringe for oral administration.

PL 20774/2441 - Teglutik 5mg/ml oral suspension

Manufactured by: Italfarmaco S.A, C/SAN Rafael 3, POL. IND. Alcobendas, 28108 Alcobendas, (Madrid) Spain. Procured from within the EU. Product Licence Holder: Quadrant Pharmaceuticals Limited, Lynstock House, Lynstock Way, Lostock, Bolton, BL6 4SA. Repackaged by: Maxearn Limited, Unit 29, Oakhill Trading Estate, Devonshire Rd, Worsley, Manchester, M28 3PT.

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Blind or partially sighted?
Is this leaflet hard to see or read?
Contact Quadrant Pharmaceuticals Ltd, Tel: 01204 471 269.