

PACKAGE LEAFLET

Package leaflet: Information for the user

Leosiggimed 100 mg/ml oral solution

Levetiracetam

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

1. What Leosiggimed is and what it is used for

Leosiggimed 100 mg/ml oral solution is an antiepileptic medicine (a medicine used to treat seizures in epilepsy).

Leosiggimed is used:

- on its own in adults and adolescents from 16 years of age with newly diagnosed epilepsy, to treat partial onset seizures with or without secondary generalisation
- as an add-on to other antiepileptic medicines to treat:
 - partial onset seizures with or without generalisation in adults, adolescents, children and infants from one month of age
 - myoclonic seizures in adults and adolescents from 12 years of age with juvenile myoclonic epilepsy
 - primary generalised tonic-clonic seizures in adults and adolescents from 12 years of age with idiopathic generalised epilepsy

2. What you need to know before you take Leosiggimed

Do not take Leosiggimed

- if you are allergic to levetiracetam or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Leosiggimed

- If you suffer from kidney problems, follow your doctor's instructions. He/she may decide if your dose should be adjusted.
- If you notice any slow down in the growth or unexpected puberty development of your child, please contact your doctor.
- If you notice an increase in seizure severity (e.g. increased number), please contact your doctor.
- A small number of people being treated with anti-epileptics such as levetiracetam have had

thoughts of harming or killing themselves. If you have any symptoms of depression and/or suicidal ideation, please contact your doctor.

Other medicines and Leosiggimed

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Leosiggimed with food, drink and alcohol

You may take Leosiggimed with or without food. As a safety precaution, do not take Leosiggimed with alcohol.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Leosiggimed should not be used during pregnancy unless clearly necessary. A risk of birth defects for your unborn child cannot be completely excluded. Levetiracetam has shown unwanted reproductive effects in animal studies at dose levels higher than you would need to control your seizures.

Breast-feeding is not recommended during treatment.

Driving and using machines

Leosiggimed may impair your ability to drive or operate any tools or machinery, as it may make you feel sleepy. This is more likely at the beginning of treatment or after an increase in the dose. You should not drive or use machines until it is established that your ability to perform such activities is not affected.

Leosiggimed contains methyl parahydroxybenzoate, propyl parahydroxybenzoate and maltitol.

Leosiggimed oral solution includes methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) which may cause allergic reactions (possibly delayed).

Leosiggimed oral solution also contains maltitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Leosiggimed

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

Leosiggimed must be taken twice a day, once in the morning and once in the evening, at about the same time each day.

Take the oral solution following your doctor's instructions.

Monotherapy

Dose in adults and adolescents (from 16 years of age):

General dose: between 10 ml (1000 mg) and 30 ml (3,000 mg) each day, divided in 2 intakes per day. When you will first start taking Leosiggimed, your doctor will prescribe you a **lower dose** during 2 weeks before giving you the lowest general dose.

Add-on therapy

Dose in adults and adolescents (12 to 17 years) weighing 50 kg or more:

General dose: between 10 ml (1,000 mg) and 30 ml (3,000 mg) each day, divided in 2 intakes per day.

Dose in infants (6 to 23 months), children (2 to 11 years) and adolescents (12 to 17 years) weighing less than 50 kg:

Your doctor will prescribe the most appropriate pharmaceutical form of Leosiggimed according to the age, weight and dose.

General dose: between 0.2 ml (20 mg) and 0.6 ml (60 mg) per kg bodyweight each day, divided in 2 intakes per day. The exact quantity of oral solution formulation should be delivered using the syringe provided in the cardboard box.

Weight	Starting dose: 0.1 ml/kg twice daily	Maximum dose: 0.3 ml/kg twice daily
6 kg	0.6 ml twice daily	1.8 ml twice daily
8 kg	0.8 ml twice daily	2.4 ml twice daily
10 kg	1 ml twice daily	3 ml twice daily
15 kg	1.5 ml twice daily	4.5 ml twice daily
20 kg	2 ml twice daily	6 ml twice daily
25 kg	2.5 ml twice daily	7.5 ml twice daily
From 50 kg	5 ml twice daily	15 ml twice daily

Dose in infants (1 month to less than 6 months):

General dose: between 0.14 ml (14 mg) and 0.42 ml (42 mg) per kg bodyweight each day, divided in 2 intakes per day. The exact quantity of oral solution formulation should be delivered using the syringe provided in the cardboard box.

Weight	Starting dose: 0.07 ml/kg twice daily	Maximum dose: 0.21 ml/kg twice daily
4 kg	0.3 ml twice daily	0.85 ml twice daily
5 kg	0.35 ml twice daily	1.05 ml twice daily
6 kg	0.45 ml twice daily	1.25 ml twice daily
7 kg	0.5 ml twice daily	1.5 ml twice daily

Method of administration:

Leosigimimed oral solution may be diluted in a glass of water or baby's bottle.

Instruction for use:

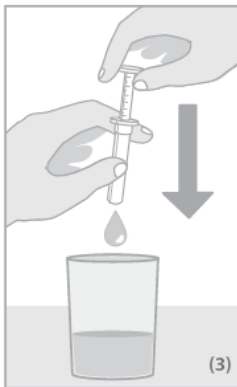
<Instruction for use for 10 ml syringes>



Open the bottle. Before starting the measuring procedure make sure that the transparent dosing body of the syringe as well as the white plunger are in the bottom most position. To measure the dosing quantity, use one hand to hold the dosing body and the other hand to pull up the plunger until you reach the graduation mark corresponding to the quantity in milliliters (ml) prescribed by your doctor (Figure 1).



Pull the syringe by the dosing body out of the bottle (Figure 2).



Empty the contents of the syringe in a glass of water by pushing down the plunger. Be sure to drink the whole contents of the glass. The contents of the syringe can also be given directly from the syringe into the mouth or emptied onto a spoon (Figure 3).

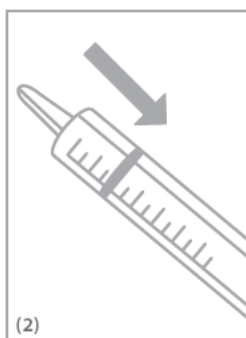


Wash the syringe with water after use and close the bottle with the plastic screw cap (Figure 4).

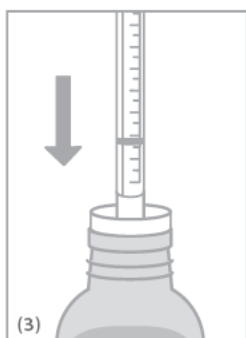
<Instruction for use for 1 ml and 3 ml syringes with an adaptor>



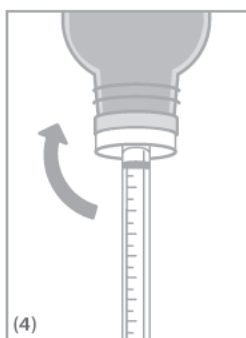
Open the bottle and push the syringe adaptor firmly into the bottle neck (Figure 1).



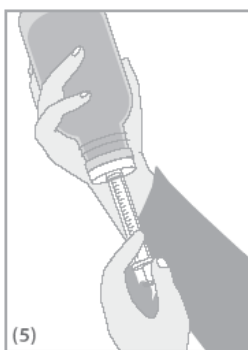
Take the syringe and pull back the plunger a little way (Figure 2).



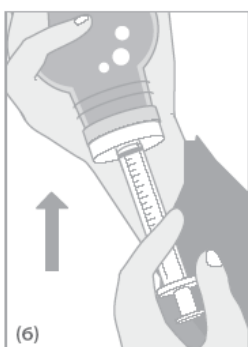
Push the tip of the syringe into the adaptor opening. Push the plunger down slowly to introduce air inside the bottle (Figure 3).



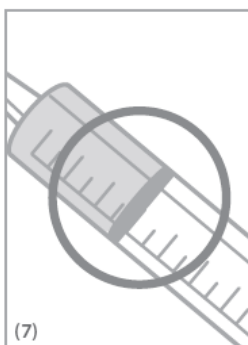
Turn the bottle upside down with the syringe still in place (Figure 4).



Pull the plunger down and fill the syringe with a quantity of solution slightly beyond the prescribed dose (Figure 5).



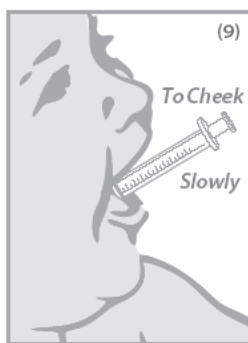
If any bubbles appear in the syringe keep the bottle upside down and slightly push in the plunger and pull it back again. Repeat until there are no bubbles in the syringe (Figure 6).



Push the plunger in slowly to the graduation mark corresponding to the quantity in milliliters (ml) prescribed by your doctor (Figure 7).



Turn the bottle the right way up and remove the syringe (Figure 8).



For young children gently put the tip of the syringe into the child's mouth to the inside of the cheek. Push the plunger in slowly and allow the child to swallow the content of the syringe. The content of the syringe can also be emptied in a glass of water or baby's bottle. Be sure to drink the whole contents of the glass (Figure 9).



Wash the syringe with water after use and close the bottle with the plastic screw cap (Figure 10).

Duration of treatment:

- Leosiggimed is used as a chronic treatment. You should continue Leosiggimed treatment for as long as your doctor has told you.
- Do not stop your treatment without your doctor's advice as this could increase your seizures. Should your doctor decide to stop your Leosiggimed treatment, he/she will instruct you about the gradual withdrawal of Leosiggimed.

If you take more Leosiggimed than you should:

The possible side effects of an overdose of Leosiggimed are sleepiness, agitation, aggression, decrease of alertness, inhibition of breathing and coma.

Contact your doctor if you took more Leosiggimed than you should. Your doctor will establish the best possible treatment of overdose.

If you forget to take Leosiggimed:

Contact your doctor if you have missed one or more doses.

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

If you stop taking Leosiggimed:

If stopping treatment, as with other antiepileptic medicines, Leosiggimed should be discontinued gradually to avoid an increase of seizures.

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

4. Possible side effects

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

Some of the side effects like sleepiness, tiredness and dizziness may be more common at the beginning of the treatment or at dose increase. These effects should however decrease over time.

Very common: may affect more than 1 user in 10

- nasopharyngitis;
- somnolence (sleepiness), headache.

Common: may affect 1 to 10 users in 100

- anorexia (loss of appetite);
- depression, hostility or aggression, anxiety, insomnia, nervousness or irritability;
- convulsion, balance disorder (equilibrium disorder), dizziness (sensation of unsteadiness), lethargy, tremor (involuntary trembling);
- vertigo (sensation of rotation);
- cough;
- abdominal pain, diarrhoea, dyspepsia (indigestion), vomiting, nausea;
- rash;
- asthenia/fatigue (tiredness).

Uncommon: may affect 1 to 10 users in 1000

- decreased number of blood platelets, decreased number of white blood cells;
- weight decrease, weight increase;
- suicide attempt and suicidal ideation, mental disorder, abnormal behaviour, hallucination, anger, confusion, panic attack, emotional instability/mood swings, agitation;
- amnesia (loss of memory), memory impairment (forgetfulness), abnormal coordination/ataxia (impaired coordinated movements), paraesthesia (tingling), disturbance in attention (loss of concentration);
- diplopia (double vision), vision blurred;
- liver function test abnormal;
- hair loss, eczema, pruritus;
- muscle weakness, myalgia (muscle pain);
- injury.

Rare: may affect 1 to 10 users in 10,000

- infection;
- decreased number of all blood cell types;
- severe hypersensitivity reactions (DRESS);
- decreased blood sodium concentration;
- suicide, personality disorders (behavioural problems), thinking abnormal (slow thinking, unable to concentrate);
- uncontrollable muscle spasms affecting the head, torso and limbs, difficulty in controlling movements, hyperkinesia (hyperactivity);
- pancreatitis;
- hepatic failure, hepatitis;
- skin rash, which may form blisters and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge) (*erythema multiforme*), a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (*Stevens-Johnson syndrome*), and a more severe form causing skin peeling in more than 30% of the body surface (*toxic epidermal necrolysis*).

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. You can also report side effects directly via [the national reporting system listed in Appendix V*](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Leosiggimed

Keep this medicine out of the sight and reach of children.

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the cardboard box and bottle after EXP:.

The expiry date refers to the last day of that month.

Do not use after 4 months of first opening the bottle.

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 Leosiggimed contains

- The active substance is called levetiracetam. Each ml contains 100 mg of levetiracetam.
- The other ingredients are: sodium citrate, citric acid monohydrate, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), ammonium glycyrrhizate, glycerol (E422), maltitol liquid (E965), acesulfame potassium (E950), grape flavour, purified water.

What Leosiggimed looks like and contents of the pack

Leosiggimed 100 mg/ml oral solution is a clear, faint coloured solution.

The 300 ml glass bottle of Leosiggimed (for children aged 4 years and older, adolescents and adults) is packed in a cardboard box containing a 10 ml oral syringe (graduated every 0.25 ml).

The 300 ml glass bottle of Leosiggimed (for infants and young children aged from 6 months to less than 4 years) is packed in a cardboard box containing a 3 ml oral syringe (graduated every 0.1 ml) and an adaptor for the syringe.

The 300 ml glass bottle of Leosiggimed (for infants aged 1 month to less than 6 months) is packed in a cardboard box containing a 1 ml oral syringe (graduated every 0.05 ml) and an adaptor for the syringe.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

<[To be completed nationally]>

{Name and address}

<{tel}>

<{fax}>

<{e-mail}>

Manufacturer

Balkanpharma-Troyan AD
Troyan 5600
Bulgaria

<This medicinal product is authorised in the Member States of the EEA under the following names:>

<{Name of the Member State}> <{Name of the medicinal product}>

<{Name of the Member State}> <{Name of the medicinal product}>

This leaflet was last revised in 2014-06-11.

<[To be completed nationally]>

<Detailed information on this medicine is available on the web site of {MS/Agency}>