

Package leaflet: Information for the user

Levetiracetam 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 or nurse.
- 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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2. What you need to know before you take Levetiracetam oral solution
3. How to take Levetiracetam oral solution
4. Possible side effects
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1. What Levetiracetam oral solution is and what it is used for

Levetiracetam oral solution is an antiepileptic medicine (a medicine used to treat seizures in epilepsy).

Levetiracetam oral solution 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 Levetiracetam oral solution

Do not take Levetiracetam oral solution

- 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 or nurse before taking Levetiracetam oral solution

- 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 oral solution have had thoughts of harming or killing themselves. If you have any symptoms of depression and/or suicidal ideation, please contact your doctor.
- If you have a family or medical history of irregular heart rhythm (visible on an electrocardiogram), or if you have a disease and/or take a treatment that make(s) you prone to heartbeat irregularities or salt imbalances

Tell your doctor or pharmacist if any of the following side effects gets serious or last longer than a few days:

- Abnormal thoughts, feeling irritable or reacting more aggressively than usually, or if you or your family and friends notice important changes in mood or behaviour.

Other medicines and Levetiracetam oral solution

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

- Aggravation of epilepsy
- Your seizures may rarely become worse or happen more often, mainly during the first month after the start of the treatment or increase of the dose. If you experience any of these new symptoms while taking Levetiracetam Accord, see a doctor as soon as possible
- In a very rare form of early-onset epilepsy (epilepsy associated with SCN8A mutations) that causes multiple types of seizures and loss of skills you may notice that the seizures remain present or are becoming worse during your treatment.

Levetiracetam oral solution with food, drink and alcohol

You may take Levetiracetam oral solution with or without food. As a safety precaution, do not take Levetiracetam oral solution 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.

Levetiracetam oral solution 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

Levetiracetam oral solution may impair your ability to drive or operate any tools or machinery, as Levetiracetam oral solution 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.

Levetiracetam oral solution contains methyl parahydroxybenzoate, propyl parahydroxybenzoate and maltitol

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

Levetiracetam oral solution also contains maltitol (E965). 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 Levetiracetam oral solution

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

Levetiracetam oral solution 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 (from 16 years of age)

Adults (≥18 years) and adolescents from 16 years of age

Measure the appropriate dosage using the 10 ml syringe included in the package for patients 4 years and above.

Recommended dose:

Levetiracetam oral solution is taken twice daily, in two equally divided doses, each individual dose being measured between 5 ml (500mg) and 15 ml (1500mg). When you will first start taking Levetiracetam oral solution, your doctor will prescribe you a lower dose during 2 weeks before giving you the lowest daily dose.

Add-on therapy

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

Measure the appropriate dosage using the 10 ml syringe included in the package for patients of 4 years and above.

Recommended dose:

Levetiracetam oral solution is taken twice daily, in two equally divided doses, each individual dose being measured between 5 ml (500mg) and 15 ml (1500mg).

Dose in children 6 months and older

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

For children 6 months to 4 years, measure the appropriate dosage using the 3 ml syringe included in the package.

For children above 4 years, measure the appropriate dosage using the 10 ml syringe included in the package.

Recommended dose: Levetiracetam oral solution is taken twice daily, in two equally divided doses, each individual dose being measured between 0.1 ml (10mg) and 0.3 ml (30mg), per kg bodyweight of the child. (see table below for dose examples).

| 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)

For infants 1 month to less than 6 months, measure the appropriate dosage using the 1 ml syringe included in the package.

Recommended dose: Levetiracetam oral solution is taken twice daily, in two equally divided doses, each individual dose being measured between 0.07 ml (7mg) and 0.21 ml (21mg), per kg bodyweight of the infant. (see table below for dose examples).

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

| 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:

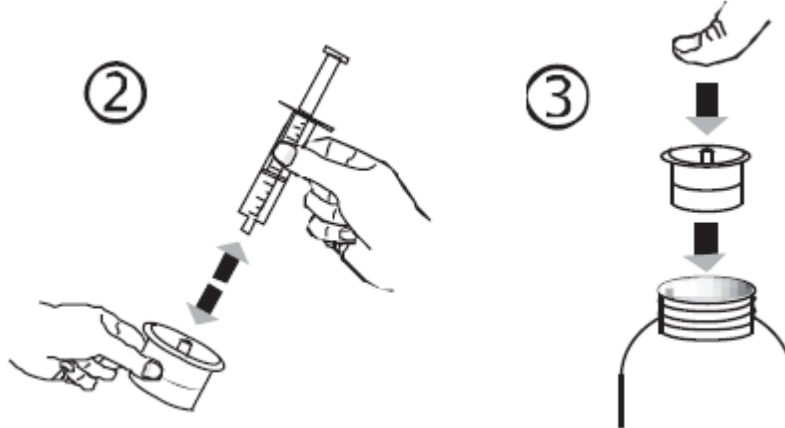
After measuring the correct dose with an appropriate syringe, Levetiracetam oral solution may be diluted in a glass of water or baby's bottle.

Instructions for use:

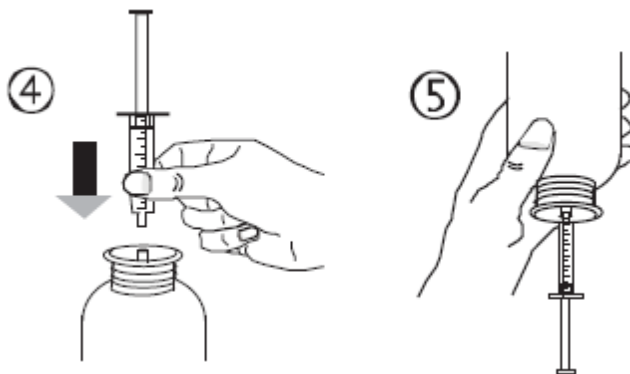
- Open the bottle: press the cap and turn it anticlockwise (figure 1)



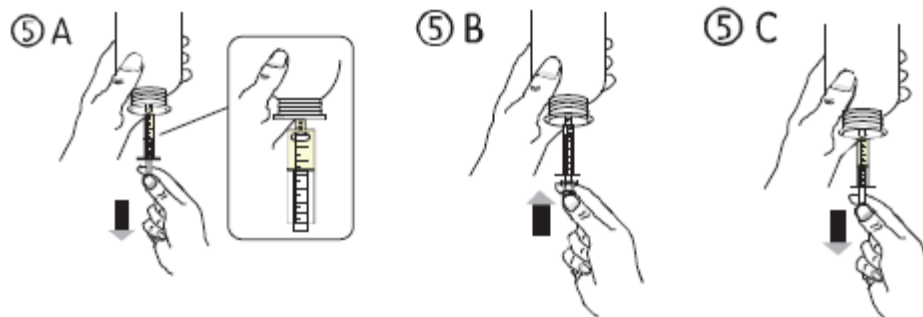
- Separate the adaptor from the syringe (figure 2). Insert the adaptor into the bottle neck (figure 3). Ensure it is well fixed.



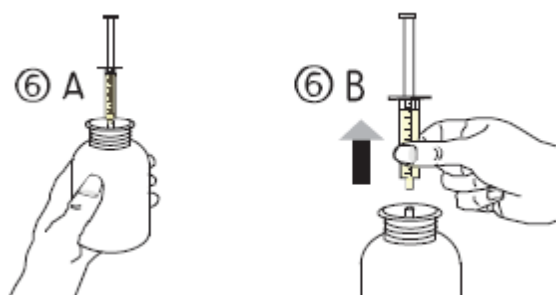
- Take the syringe and put it in the adaptor opening (figure 4). Turn the bottle upside down (figure 5).



- Fill the syringe with a small amount of solution by pulling the piston down (figure 5A), then push the piston upward in order to remove any possible bubble (figure 5B). Pull the piston down to the graduation mark corresponding to the quantity in milliliters (ml) prescribed by your doctor (figure 5C).



- Turn the bottle the right way up (figure 6A). Remove the syringe from the adaptor (figure 6B).



- Empty the contents of the syringe in a glass of water or baby's bottle by pushing the piston to the bottom of the syringe (figure 7).



- Drink the whole contents of the glass/baby's bottle.
- Close the bottle with the plastic screw cap.
- Wash the syringe with water only (figure 8).



Duration of treatment:

- Levetiracetam oral solution is used as a chronic treatment. You should continue Levetiracetam oral solution 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 Levetiracetam oral solution treatment, he/she will instruct you about the gradual withdrawal of Levetiracetam oral solution.

If you take more Levetiracetam oral solution than you should

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

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

If you forget to take Levetiracetam oral solution

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 Levetiracetam oral solution

If stopping treatment, as with other antiepileptic medicines, Levetiracetam oral solution 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 or nurse.

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);
- seizures may become worse or happen more often;
- delirium;
- encephalopathy (see sub-section “Tell your doctor immediately” for a detailed description of symptoms);
- uncontrollable muscle spasms affecting the head, torso and limbs, difficulty in controlling movements, hyperkinesia (hyperactivity);
- change of the heart rhythm (Electrocardiogram);
- 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*).

- combination of fever, muscle stiffness, unstable blood pressure and heart rate, confusion, low level of consciousness (may be signs of a disorder called *neuroleptic malignant syndrome*). Prevalence is significantly higher in Japanese patients when compared to non-Japanese patients.

Very rare: may affect up to 1 in 10000 people

- repeated unwanted thoughts or sensations or the urge to do something over and over again (Obsessive Compulsive Disorder).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

Yellow Card Scheme

Website: 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 Levetiracetam oral solution

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

Do not use this medicine after the expiry date which is stated on the carton 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.

This medicinal product does not require any special temperature storage conditions. Store in the original container in order to protect from light.

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 to protect the environment.

6. Contents of the pack and other information

What Levetiracetam oral solution contains

- The active substance is 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 containing propylene glycol, purified water.

What Levetiracetam oral solution looks like and contents of the pack

Levetiracetam oral solution is clear, colourless grape flavoured liquid.

The 300 ml glass bottle of Levetiracetam oral solution (for children aged 4 years and above, adolescents and adults) is packed in a cardboard box containing a 10 ml oral syringe (graduated every 0.25 ml) and an adaptor for the syringe.

The 150 ml glass bottle of Levetiracetam oral solution (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 150 ml glass bottle of Levetiracetam oral solution (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.

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This leaflet was last revised in 05/2023