

Package leaflet: Information for the patient
Levetiracetam Wockhardt 100 mg/ml Oral Solution

Read all of this leaflet carefully before you or your child 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. 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 effect please tell your doctor or pharmacist. This includes possible side effects not listed in this leaflet. See section 4

Levetiracetam Wockhardt 100 mg/ml Oral Solution is referred to as Levetiracetam Oral Solution throughout this leaflet.

What is in this leaflet:

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

1. What Levetiracetam Oral Solution is and what it is used for

Levetiracetam 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 a certain form of epilepsy. Epilepsy is a condition where the patients have repeated fits (seizures). Levetiracetam is used for the epilepsy form in which the fits initially affect only one side of the brain, but could thereafter extend to larger areas on both sides of the brain (partial onset seizure with or without secondary generalisation). Levetiracetam has been given to you by your doctor to reduce the number of fits.
- 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 (short, shock-like jerks of a muscle or group of muscles) in adults and adolescents from 12 years of age with juvenile myoclonic epilepsy
 - primary generalised tonic-clonic seizures (major fits, including loss of consciousness) in adults and adolescents from 12 years of age with idiopathic generalised epilepsy (the type of epilepsy that is thought to have a genetic cause).

2. What you need to know before you take Levetiracetam Oral Solution

Do not take Levetiracetam Oral Solution

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

Warnings and precautions

Talk to your doctor 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.

- 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.

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.

Children and adolescents

- Levetiracetam Oral Solution is not indicated in children and adolescents below 16 years on its own (monotherapy)

Other medicines and Levetiracetam Oral Solution:

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

Do not take macrogol (a drug used as laxative) for one hour before and one hour after taking levetiracetam as this may result in a reduction of its effect.

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 for advice before taking this medicine. Levetiracetam can be used during pregnancy, only if after careful assessment it is considered necessary by your doctor. You should not stop your treatment without discussing it with your doctor.

A risk of birth defects to your unborn child cannot be completely excluded.

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 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.

Levetiracetam Oral Solution contains methyl parahydroxybenzoate, propyl parahydroxybenzoate and maltitol.

Levetiracetam Oral Solution includes methylparahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) which may cause allergic reactions (possibly delayed). Levetiracetam 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 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

Dose in adults 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.

General 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 general 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.

General 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.

General 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).

Dose in children 6 months and older:

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.

General 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
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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. You may take Levetiracetam Oral Solution with or without food. After oral administration the bitter taste of levetiracetam may be experienced.

Instructions for use:

- Open the bottle: press the cap and turn it anticlockwise
- Separate the adaptor from the syringe. Insert the adaptor into the bottle neck. Ensure it is well fixed.
- Take the syringe and put it in the adaptor opening. Turn the bottle upside down
- Fill the syringe with a small amount of solution by pulling the piston down, then push the piston upward in order to remove any possible bubble. Pull the piston down to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor. Turn the bottle the right way up. Remove the syringe from the adaptor.
- 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.
- Drink the whole contents of the glass/baby's bottle.
- Close the bottle with the plastic screw cap.
- Wash the syringe with water only.

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.

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, Levetiracetam Oral Solution should be discontinued gradually to avoid an increase of 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 have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

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

Tell your doctor immediately, or go to your nearest emergency department, if you experience:

- weakness, feel light-headed or dizzy or have difficulty breathing, as these may be signs of a serious allergic (anaphylactic) reaction
- swelling of the face, lips, tongue and throat (Quincke's oedema)
- flu-like symptoms and a rash on the face followed by an extended rash with a high temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes (Drug Reaction with Eosinophilia and Systemic Symptoms [DRESS])
- symptoms such as low urine volume, tiredness, nausea, vomiting, confusion and swelling in the legs, ankles or feet, as this may be a sign of sudden decrease of kidney function
- a skin rash which may form blisters and look 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)
- a more severe form of rash causing skin peeling in more than 30% of the body surface (toxic epidermal necrolysis)
- signs of serious mental changes or if someone around you notices signs of confusion, somnolence (sleepiness), amnesia (loss of memory), memory impairment (forgetfulness), abnormal behaviour or other neurological signs including involuntary or uncontrolled movements. These could be symptoms of an encephalopathy.

The most frequently reported adverse reactions were nasopharyngitis, somnolence (sleepiness), headache, fatigue and dizziness. At the beginning of the treatment or at dose increase side effects like sleepiness, tiredness and dizziness may be more common. These effects should however decrease over time.

Very common: (may affect more than 1 user in 10 people)

- nasopharyngitis;
- somnolence (sleepiness), headache.

Common: (may affect 1 to 10 users in 100 people)

- anorexia (loss of appetite);
- depression, hostility or aggression, anxiety, insomnia, nervousness or irritability;
- convulsion, balance disorder (equilibrium disorder), dizziness (sensation of unsteadiness), lethargy (lack of energy and enthusiasm), 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 1,000 people)

- 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;
- elevated/abnormal values in a liver function test;
- hair loss, eczema, pruritus;
- muscle weakness, myalgia (muscle pain);

- injury.

Rare: (may affect 1 to 10 users in 10,000 people)

- infection;
- decreased number of all blood cell types;
- severe allergic reactions (DRESS, anaphylactic reaction [severe and important allergic reaction], Quincke's oedema [swelling of the face, lips, tongue and throat]);
- decreased blood sodium concentration;
- suicide, personality disorders (behavioural problems), thinking abnormal (slow thinking, unable to concentrate);
- 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);
- pancreatitis;
- liver failure, hepatitis;
- sudden decrease in kidney function
- 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*).
- rhabdomyolysis (breakdown of muscle tissue) and associated blood creatine phosphokinase increase. Prevalence is significantly higher in Japanese patients when compared to non-Japanese patients
- limp or difficulty walking.

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 the leaflet. You can also report side effects directly via the national reporting systems listed below:

Ireland:

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; e-mail: medsafety@hpra.ie

Malta:

ADR Reporting, Website: www.medicinesauthority.gov.mt/adrportal

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 stated on the carton and bottle after EXP.

The expiry date refers to the last day of the month. Do not use after 1 month of first opening the bottle. Store below 25°C.

Store in the original bottle to protect from light.

Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away any 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 called levetiracetam. Each 1 ml contains 100 mg of levetiracetam.

The other ingredients are: Sodium citrate, Citric acid, Methyl parahydroxybenzoate (E218), Propyl parahydroxybenzoate (E216), Ammonium glycyrrhizate, Glycerol (E422), Maltitol (E965), Acesulfame potassium (E950), Grape flavour, Purified water.

What Levetiracetam Oral Solution looks like and contents of the pack

Levetiracetam Oral Solution is a clear 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 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 syringe (graduated every 0.05 ml) and an adaptor for the syringe.

Marketing Authorisation Holder in Ireland & Malta: Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, Ireland

Manufacturer: CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

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