Package leaflet: Information for the user
Levetiracetam Thame 100mg/ml Oral Solution

levetiracetam

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 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.

The name of your medicine is Levetiracetam Thame 100mg/ml Oral Solution but it will be referred to as Levetiracetam throughout this leaflet.

What is in this leaflet:

1. What Levetiracetam is and what it is used for

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

Do not take Levetiracetam

- 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

- 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 slowdown 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 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.
- Aggravation of epilepsy

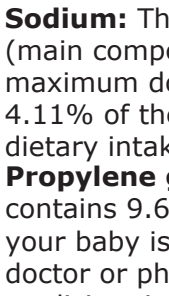
Your seizures may rarely become worse or happen more often, mainly during the first month after the start of the treatment or increase of the dose. If you experience any of these new symptoms while taking Levetiracetam, see a doctor as soon as possible.

Children and adolescents

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

Other medicines and Levetiracetam

Tell your doctor or pharmacist if you are taking or 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 results in a reduction of its effect.



Pregnancy and breast-feeding

If you are pregnant or breastfeeding, 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 this with your doctor. A risk of birth defects for your unborn child cannot be completely excluded. Breast-feeding is not recommended during treatment.

Driving and using machines

Levetiracetam 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 contains:
Methyl parahydroxybenzoate (E218):
May cause allergic reactions (possibly delayed).

Liquid Maltitol (E965): If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
Sodium: This medicine contains 82.2mg sodium (main component of cooking/table salt) per maximum dose of 30ml. This is equivalent to 4.11% of the recommended maximum daily dietary intake of sodium for an adult.
Propylene glycol (E1520): This medicine contains 9.61mg propylene glycol in each ml. If your baby is less than 4 weeks old, talk to your doctor or pharmacist before giving them this medicine, in particular if the baby is given other medicines that contain propylene glycol or alcohol.

3. How to take Levetiracetam

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 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 10ml syringe included in the package for patients 4 years and above.

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

When you will first start taking Levetiracetam, 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):
Measure the appropriate dosage using the 10ml syringe included in the package for patients of 4 years and above.
Recommended dose: Levetiracetam is taken twice daily, in two equally divided doses, each individual dose being measured between 5ml (500mg) and 15ml (1500mg).

Dose in children 6 months and older:
Your doctor will prescribe the most appropriate pharmaceutical form of Levetiracetam according to the age, weight and dose.

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

For children above 4 years, measure the appropriate dosage using the 10ml syringe included in the package.
Recommended dose: Levetiracetam is taken twice daily, in two equally divided doses, each individual dose being measured between 0.1ml (10mg) and 0.3ml (30mg), per kg bodyweight of the child. (see table below for dose examples).

Dose in children 6 months and older:

Weight	Starting dose: 0.1ml/kg twice daily	Maximum dose: 0.3ml/kg twice daily
6kg	0.6ml twice daily	1.8ml twice daily
8kg	0.8ml twice daily	2.4ml twice daily
10kg	1ml twice daily	3ml twice daily
15kg	1.5ml twice daily	4.5ml twice daily
20kg	2ml twice daily	6ml twice daily
25kg	2.5ml twice daily	7.5ml twice daily
From 50kg	5ml twice daily	15ml 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 **1ml** syringe included in the package.
Recommended dose: Levetiracetam is taken twice daily, in two equally divided doses, each individual dose being measured between 0.07ml (7mg) and 0.21ml (21mg), per kg bodyweight of the infant. (see table below for dose examples).

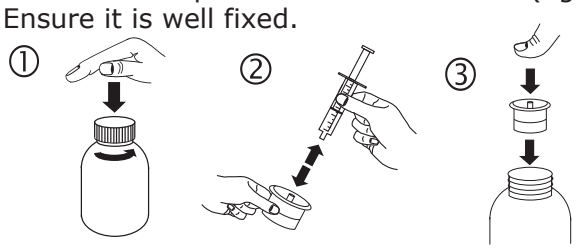
Dose in infants (1 month to less than 6 months):

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

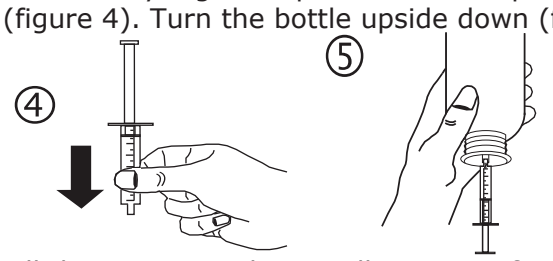
Method of administration:
After measuring the correct dosage with an appropriate syringe, Levetiracetam oral solution may be diluted in a glass of water or baby's bottle. You may take Levetiracetam with or without food. After oral administration the bitter taste of levetiracetam may be experienced.

Instructions for use:

1. Open the bottle: press the cap and turn it anticlockwise (figure 1)
2. Separate the adaptor from the syringe (figure 2). Insert the adaptor into the bottle neck (figure 3). Ensure it is well fixed.

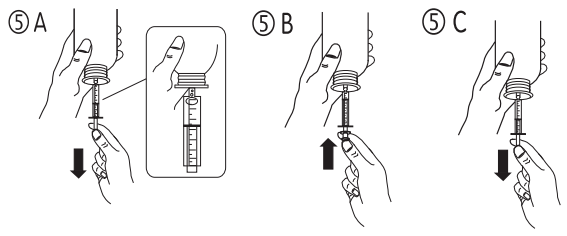


Take the syringe and put it in the adaptor opening (figure 4). Turn the bottle upside down (figure 5).

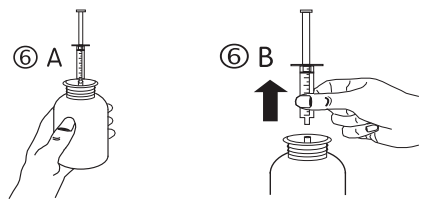


3. Fill the syringe with a small amount of solution by pulling the piston down (figure 5A), then push the piston upward in order to remove any possible bubble (figure 5B). Pull the piston down to the graduation mark corresponding to the quantity in milliliters (ml) prescribed by your doctor (figure 5C).

TURN OVER



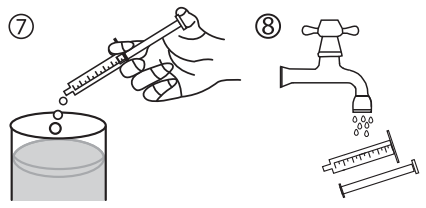
4. Turn the bottle the right way up (figure 6A). Remove the syringe from the adaptor (figure 6B).



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).

5. Drink the whole contents of the glass/baby's bottle.

6. Close the bottle with the plastic screw cap. Wash the syringe with water only (figure 8).



Duration of treatment:

- Levetiracetam is used as a chronic treatment. You should continue Levetiracetam 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 than you should

The possible side effects of an overdose of Levetiracetam are sleepiness, agitation, aggression, decrease of alertness, inhibition of breathing and coma.
Contact your doctor if you took more Levetiracetam than you should. Your doctor will establish the best possible treatment of overdose.

If you forget to take Levetiracetam:

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:

If stopping treatment, Levetiracetam should be discontinued gradually to avoid an increase of seizures. Should your doctor decide to stop your Levetiracetam treatment, he/she will instruct you about the gradual withdrawal of Levetiracetam.

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.

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 in 10 people

- nasopharyngitis;
- somnolence (sleepiness), headache.

Common: may affect up to 1 in 10 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 up to 1 in 100 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 up to 1 in 1000 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);
- seizures may become worse or happen more often;
- uncontrollable muscle spasms affecting the head, torso and limbs, difficulty in controlling movements, hyperkinesia (hyperactivity);
- change of the heart rhythm (Electrocardiogram);
- 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;
- 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.

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 Yellow Card Scheme Website at: 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

- 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 the month.
- This medicinal product does not require any special storage conditions.
- Discard 7 months after first opening.
- Store in the original bottle, 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 protect the environment.

6. Contents of the pack and other information

What Levetiracetam contains

The active substance is levetiracetam.
Each ml of oral solution contains 100mg levetiracetam.

The other ingredients are: sodium citrate (E331) (for pH-adjustment), citric acid monohydrate (for pH-adjustment), methyl parahydroxybenzoate (E218), ammonium glycyrrhizate, glycerol (E422), maltitol liquid (E965), grape flavour (contains propylene glycol (E1520)) and purified water.

What Levetiracetam looks like and contents of the pack

Levetiracetam oral solution is a clear, colourless or pale yellow to pale brown colour solution with grape flavour supplied in amber glass bottles with tamper evident child resistant plastic cap.

The 300ml glass bottle is packed in a cardboard box containing a 10ml oral syringe with 0.25ml graduation mark and an adaptor for the syringe.

The 150ml glass bottle is packed in a cardboard box containing a 3ml oral syringe with 0.1ml graduation mark and an adaptor for the syringe.

The 150ml glass bottle is packed in a cardboard box containing a 1ml oral syringe with 0.05ml graduation mark and an adaptor for the syringe.

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer:

Thame Laboratories
Unit 4, Bradfield Road,
Ruislip, Middlesex,
HA4 0NU, UK

If this leaflet is hard to see or read, please call +44 (0) 208 515 3700 for help.

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:
UK (NI) and IE: Levetiracetam Thame 100mg/ml Oral Solution

This leaflet was last revised in 04/2022.