

# LECETAM ORAL SOLUTION

Levetiracetam (100 mg/mL)

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## What LECETAM ORAL SOLUTION is used for

LECETAM ORAL SOLUTION is used:  
 ⇒ on its own in adults and adolescents from 16 years of age with a certain type of newly diagnosed 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 seizures with or without secondary generalization). LECETAM ORAL SOLUTION 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 secondary generalization in adults and children from 4 years of age with epilepsy
- 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 generalized tonic-clonic seizures (major fits, including loss of consciousness) in adults and children from 12 years of age with Idiopathic Generalized Epilepsy

## How LECETAM ORAL SOLUTION works

LECETAM ORAL SOLUTION is an antiepileptic medicine (a medicine used to treat seizures in epilepsy).

## Before you use LECETAM ORAL SOLUTION

### - When you must not use it

- ⊗ Do not take LECETAM ORAL SOLUTION if you are allergic to Levetiracetam, pyrrolidone derivatives or any of the other ingredients of this medicine (see section **Product Description**).

### ⇒ **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.
- LECETAM ORAL SOLUTION 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. LECETAM ORAL SOLUTION has shown unwanted reproductive effects in animal studies.
- Breastfeeding is not recommended during treatment.

### ⇒ Children and adolescents

- LECETAM ORAL SOLUTION is not indicated in children and adolescents before 16 years on its own (monotherapy).

### - Before you start to use it

Talk to your doctor before taking LECETAM 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 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 LECETAM 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 notice any abnormal and aggressive behaviors, or if you or your family and friends notice important changes in mood or behavior, immediately contact your doctor.

⇒ If you have a family or medical history of heart problems, for example disturbance in heart rhythm (visible on an electrocardiogram) or if you are taking any other medicine that makes you prone to have disturbance in heart rhythm or unusual amount of salt in the body.

### - Taking other medicines

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

## How to use LECETAM ORAL SOLUTION

### - How much to use

⇒ Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Take the oral solution following your doctor's instruction.

### Monotherapy:

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

- General dose: between 1000 mg and 3000 mg each day.
- When you will first start taking LECETAM 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:

- General dose: between 1000 mg and 3000 mg each day.

Dose in children (4 to 11 years) and adolescents (12 to 17 years) weighing less than 50 Kg.

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

LECETAM ORAL SOLUTION is a presentation more appropriate to children under the age of 6 years and to children and adolescent (from 6 to 17 years) weighing less than 25 Kg and when tablets don't allow accurate dosage.

# LECETAM ORAL SOLUTION

Levetiracetam (100 mg/mL)

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
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

## - Method of administration

⇒ LECETAM ORAL SOLUTION may be diluted in a glass of water. You may take LECETAM ORAL SOLUTION with or without food. After oral administration the bitter taste of Levetiracetam may be experienced.

## - When to use it

⇒ LECETAM ORAL SOLUTION must be taken twice a day, once in the morning and once in the evening, at about the same time each day. You may take LECETAM ORAL SOLUTION with or without food.

## - How long to use it

LECETAM ORAL SOLUTION is used as a chronic treatment. You should continue LECETAM 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 stopping treatment, LECETAM ORAL SOLUTION should be discontinued gradually to avoid an increase of seizures. Should your doctor decide to stop your LECETAM ORAL SOLUTION treatment, he/she will instruct you about the gradual withdrawal of LECETAM ORAL SOLUTION.

## - If you forget to use it

⇒ 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 use too much (overdose)

⇒ The possible side effects of an overdose of LECETAM ORAL SOLUTION are sleepiness, agitation, aggression, decrease of alertness, inhibition of breathing and coma.

**Contact your doctor if you took more LECETAM ORAL SOLUTION than you should. Your doctor will establish the best possible treatment of overdose.**

## While you are using it

### - Things you must do

⇒ Take your medicine exactly as your doctor has told you.

⇒ LECETAM ORAL SOLUTION may be diluted in a glass of water or baby's bottle.

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

### - Things you must not do

⊗ **Do not stop taking the medicine unless advised by your doctor.**

⊗ **Do not give Lecetam Oral Solution to anyone else, even if they have the same symptoms or condition as you.**

### - Things to be careful of

#### Driving and using machines

- LECETAM ORAL SOLUTION may impair your ability to drive or operate any tools or machinery, as Lecetam oral solution may make you 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.

LECETAM ORAL SOLUTION includes Methylparaben and Propylparaben which may cause allergic reactions (possibly delayed).

LECETAM ORAL SOLUTION also contains Maltitol solution. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Your seizures may rarely become worse or happen more often, mainly during the first month after starting the treatment or increase of the dose of

LECETAM ORAL SOLUTION. If you notice any of these symptoms while taking LECETAM ORAL SOLUTION, immediately contact your doctor. 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.

## Side effects

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

- The most frequently reported side effects are 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 (common cold);
- Somnolence (sleepiness), headache

*Common: may affect 1 to 10 users in 100 people*

- Anorexia (loss 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, diarrhea, dyspepsia (indigestion), vomiting, nausea;
- Rash;
- Asthenia/fatigue (tiredness)

*Uncommon: may affect 1 to 10 users in 1000 people*

- Decreased number of blood platelets, decreased number of white blood cells;
- Weight decrease, weight increase
- Suicide attempt and suicidal ideation, mental disorder, abnormal behavior, hallucination, anger, confusion, panic attack, emotional instability/mood swings, agitation;

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- Amnesia (loss of memory), memory impairment (forgetfulness), abnormal coordination/ataxia (impaired coordination 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]);
- Decreased blood sodium concentration;
- Suicide, personality disorders (behavioral problems), thinking abnormal (slow thinking, unable to concentrate); severe confusion (delirium);
- Uncontrollable muscle spasms affecting the head, torso and limbs, difficulty in controlling movements, hyperkinesias (hyperactivity);
- Encephalopathy (degenerative disease of the brain);
- Seizures may become worse or happen more often;
- Disturbance in heart rhythm (electrocardiogram);
- Pancreatitis (pancreas inflammation);
- Liver failure, hepatitis;
- 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*), 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.*)
- Acute kidney injury
- 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.

*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)

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known. Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you do not understand anything in this list.

Tell your doctor immediately if you notice any of the following:

- Symptoms such as low urine volume, tiredness, nausea, vomiting, confusion and swelling in the legs, ankles or feet, may be a sign of sudden decrease of kidney function
- Signs or symptoms including muscle ache, feeling of weakness and dark urine may indicate the side effect of rhabdomyolysis (breakdown of muscle tissue).
- If someone around you notices signs of confusion, somnolence (sleepiness), amnesia (loss of memory), memory impairment (forgetfulness), abnormal behavior or other neurological signs including involuntary or uncontrolled movements, these could be symptoms of an encephalopathy.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) [Consumer Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

### Storage and Disposal of LECETAM ORAL SOLUTION

#### Storage

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

- Do not use this medicine after the expiry date stated on the carton box and label after EXP.
- The expiry date refers to the last day of the month.
- Store at temperature of not more than 30°C. Once opened, the contents of the bottle should be used within 12 weeks.

#### Disposal

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.

### Product Description

#### - What it looks like?

LECETAM ORAL SOLUTION is clear, colorless solution with grape flavor

#### - Ingredients

- Active ingredient:  
*Levetiracetam (100 mg/ml)*
- Inactive ingredients:  
*Maltitol solution, Glycerin, Methylparaben, Propylparaben, Sodium citrate dihydrate, Anhydrous citric acid, Acesulfame potassium, Sucralose, Grape concord (Adinop), Purified water*

#### - MAL Number: -

### Manufacturer

UNISON LABORATORIES CO., LTD.  
39 Moo 4, Klong Udomcholjorn, Muang Chachoengsao, Chachoengsao 24000 Thailand

### Product Registration Holder/Importer

Medispec (M) Sdn Bhd  
B-1-07, Jalan SS 25/22, Taman Mayang, 47301 Petaling Jaya, Selangor, Malaysia

### Date of Revision

11/11/2025

### Serial number

NPRA (R2) 25/057