

LECETAM FILM COATED TABLET

Levetiracetam (250mg, 500mg)

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What LECETAM is used for

LECETAM 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 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 works

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

Before you use LECETAM

- When you must not use it

Do not take LECETAM

- If you are allergic to levetiracetam, pyrrolidone derivatives or any of the other ingredients of this medicine (see section **Product Description**).

Pregnancy and breastfeeding:

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 should not be used during pregnancy unless clearly necessary. A risk of birth defects for your unborn child cannot be completely excluded.

LECETAM has shown unwanted reproductive effects in animal studies.

Breast-feeding is not recommended during treatment.

Children and adolescents

LECETAM 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

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

- 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

- 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 number of tablets following your doctor's instructions.

Monotherapy:

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

General dose: between 1000 mg and 3,000 mg each day.

When you will first start taking LECETAM, 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 1,000 mg and 3,000 mg each day.

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

Swallow LECETAM tablets with a sufficient quantity of liquid (e.g. a glass of water).

- When to use it

LECETAM 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 with or without food.

- How long to use it

LECETAM is used as a chronic treatment. You should continue LECETAM 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 should be discontinued gradually to avoid an increase of seizures.

Should your doctor decide to stop your LECETAM treatment, he/she will instruct you about the gradual withdrawal of LECETAM.

- 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 tablet.

- If you use too much (overdose)

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

Contact your doctor if you took more tablets 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.

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 to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

LECETAM may impair your ability to drive or operate any tools or machinery, as LECETAM 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.

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;

- 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 (behavioural problems), thinking abnormal (slow thinking, unable to concentrate);
- uncontrollable muscle spasms affecting the head, torso and limbs, difficulty in controlling movements, hyperkinesias (hyperactivity);
- 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*).

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 muscleache, 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 behaviour 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 npa.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of LECETAM

- Storage

Do not store above 30°C. Keep all medicines out of reach of children.

- 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 250 Tablet:

Light blue, oblong, biconvex, film coated tablet with engraved L-250 on one side and plain on the other.

Lecetam 500 Tablet:

Yellow, oblong, biconvex, film coated tablet with engraved L-500 on one side and plain on the other.

- Ingredients

- Active ingredient:

Levetiracetam (250 mg, *500 mg)

- Inactive ingredients:

Croscarmellose sodium, Povidone (PVP K-30), Purified water, Isopropyl alcohol, Silicified microcrystalline cellulose (PROSOLV SMCC 90), Sodium starch glycolate (Explotab), Magnesium stearate, Hypromellose (HPMC 2910), Propylene glycol, Methylene chloride, Titanium dioxide, Talc, Lake brilliant blue (C.I. No. 42090), Lake carmoisine (C.I. No. 14720), *Yellow iron oxide (C.I. No. 77492), Butylated hydroxytoluene and Polyethylene glycol (PEG 400)

- MAL number(s):

Manufacturer

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

Product Registration Holder

Medispec (M) Sdn Bhd
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