

LEVERA (LEVETIRACETAM TABLETS)

Levetiracetam (250mg, 500mg, 1000mg)

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What Levera tablets are used for

Levera tablets are 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). Levera tablets have been given to you by your doctor to reduce the number of fits. Levera tablets are used 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 Levera tablets work

Levera tablets belong to a group called antiepileptic medicines. These medicines help reduce the occurrence of seizures in epilepsy.

Before you use Levera tablets

- When you must not take it

Do not take Levera tablets if: You are allergic (hypersensitive) to Levetiracetam or any of the other ingredients of this medicine (*see* 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.

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

Levera tablets 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.

Breast-feeding is not recommended during treatment.

Children and adolescents

Levera tablets is not indicated in children and adolescents before 16 years on its own (monotherapy).

- Before you start to take it

Talk to your doctor or pharmacist before taking Levera tablets:

- If you suffer from kidney problems, follow your doctor's instructions. Your doctor 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.

- Taking other medicines

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

How to use Levera tablets

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

- How much to use

Your doctor will tell you how much Levera tablets to take each day. The recommended dose is as follows:

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 Levera tablets, 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.

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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 Levetiracetam according to the age, weight and dose.

General dose: between 20 mg per kg bodyweight and 60 mg per kg bodyweight each day.

Levetiracetam 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 25kg and when tablets don't allow accurate dosage.

- When to use it

Levera tablets must be taken twice a day, once in the morning and once in the evening same as instructed by your doctor. It is always advisable to take doses at the same time each day. It will have the best effect and it will also help you to remember when to take Levera tablets.

Take the number of tablets following your doctor's instructions.

You can take this medicine with or without food. Swallow Levera tablets with a sufficient quantity of liquid (e.g. a glass of water).

- How long to use it

You should take Levera tablets regularly. This medicine is used as a chronic treatment. You should continue Levera 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 Levera tablets treatment, he/she will

instruct you about the gradual withdrawal of Levera tablets.

- If you forget to take it

Take it as soon as you remember and then go back to taking it as you would normally. If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not double a dose to make up for the one you have missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering your dose, ask your pharmacist for advice.

- If you take too much (overdose)

The possible side effects of an overdose of Levera tablets 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 Levera tablets

- 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 Levera tablets or change the dose without first checking with your doctor.

Do not let yourself run out of medicine over the weekend or on holidays.

Do not give Levera tablets to anyone else even if they have the same condition as you.

Do not use Levera tablets to treat other conditions unless your doctor says so.

Do not take any other medicines without first telling your doctor or consulting with a pharmacist.

- Things to be careful of

Driving and using machines:

Levera tablets may impair your ability to drive or operate any tools or machinery, as Levera tablets 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:

- nasopharyngitis (common cold),
- somnolence(sleepiness),
- headache.

Common:

- 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;

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-abdominal pain, diarrhoea, dyspepsia (indigestion), vomiting, nausea;
-rash; asthenia / fatigue (tiredness).

Uncommon:

-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:

-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),
-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.

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.

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 www.npra.gov.my [Consumers

→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and disposal of Levera tablets

- Storage

Store below 30°C.
Keep the Levera tablets out of the sight and reach of children.

- Disposal

If your doctor tells you to stop taking Levera tablets, or the products have passed their expiry date, ask your pharmacist what to do with any medicine that is left over.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

These measures will help to protect the environment.

Product description

- What it looks like

Levera tablets 250mg are white to off white, oval, biconvex, film coated tablets debossed 'L 64' and breakline on one side and plain on other side.
Levera tablets 500mg are yellow coloured, oval, biconvex, film coated tablets debossed 'L 65' and breakline on one side and plain on other side.

Levera tablets 1000mg are white to off white, oval, biconvex, film coated tablets debossed 'L 67' and breakline on one side and plain on other side.

- Ingredients

- Active Ingredient
Levetiracetam
- Inactive Ingredient
Tablet core

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Levetiracetam (250mg, 500mg, 1000mg)

Croscarmellose Sodium
Povidone K-30
Colloidal anhydrous silica
Magnesium Stearate
Film-coating
Polyvinyl alcohol
Titanium dioxide
Macrogol
Talc

500 mg
Iron oxide yellow

- MAL number:

Levera 250 : MAL20076038AZ
Levera 500 : MAL20076039AZ
Levera 1000 : MAL20076040AZ

Manufacturer

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Product Registration Holder

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