LEVET® 250MG & 500MG FILM-COATED TABLET

Levetiracetam 250mg & 500mg

WHAT IS IN THIS LEAFLET:

WHAT LEVET IS USED FOR

LEVET 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). Levet 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 LEVET WORKS

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

BEFORE YOU USE LEVET

- *When you must not use it*

Do not take Levet

- 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.

Levet should not be used during pregnancy unless clearly necessary. A risk of birth defects for your unborn child cannot be completely excluded. Levet has shown unwanted reproductive effects in animal studies.

Breast-feeding is not recommended during treatment.

Children and adolescents

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

- *Before you start use it*

Talk to your doctor before taking Levet

- 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 Levet 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, or have recently taken or might take any other medicines.

HOW TO USE LEVET

- *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

Adults and adolescents (from 16 years of age):

The recommended starting dose is 250mg twice daily which should be increased to a dose of 500mg twice daily after two weeks. The dose can be further increased by 250mg twice daily every two weeks depending upon the response. Maximum dose: 1,500mg twice daily.

Add-on therapy

Adults (≥18 years) and Adolescents (12 to 17 years) of 50kg or more:

The initial therapeutic dose is 500mg twice daily. This dose can be started on the 1st day of treatment. Depending upon the response and tolerability, the daily dose can be increased up to 1,500mg twice daily. Dose changes can be made in 500mg twice daily increases or decreases every two to four weeks.

Children (4-11 years) and Adolescents (12-17 years) weighing less than 50 kg

The initial therapeutic dose is 10mg/kg twice daily.

Depending upon the response and tolerability, the dose can be increased up to 30 mg/kg twice daily. Dose changes should not exceed increases or decreases of 10mg/kg twice daily every 2 weeks. The lowest effective dose should be used.

- *When to use it*

Levet 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 Levet with or without food.

- *How long to use it*

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

- *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 Levet 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.

LEVET® 250MG & 500MG FILM-COATED TABLET

Levetiracetam 250mg & 500mg

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

- *Things to be careful of*

Driving and using machines

Levet may impair your ability to drive or operate any tools or machinery, as Levet 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 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 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 npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

STORAGE AND DISPOSAL OF LEVET

- *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 blister after EXP.
The expiry date refers to the last day of the month.

Do not store above 30°C.

- *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*

LEVET® 250MG & 500MG FILM-COATED TABLET

Levetiracetam 250mg & 500mg

LEVET 250 mg film-coated tablets: Light blue, oval, biconvex film-coated tablets, scored on both sides, debossed with LVT / 250 on one side.

LEVET 500 mg film-coated tablets: Yellow, oval, biconvex film-coated tablets, scored on both sides, debossed with LVT / 500 on one side.

The tablet can be divided into equal halves.

Ten Levet film-coated tablets are packed in Al/Al blisters. 3 blisters (3 x 10's), 6 blisters (6 x 10's) or 10 blisters (10x 10's) packed into an outer carton folding box. Not all pack sizes may be marketed.

Ingredients

Active ingredient:

What LEVET contains:
The active substance is called levetiracetam.

Each LEVET 250 mg Film-Coated Tablet contains 250 mg levetiracetam.

Each LEVET 500 mg Film-Coated Tablet contains 500 mg levetiracetam

Inactive ingredients

Tablet core: povidone K25, cellulose microcrystalline, croscarmellose sodium, crospovidone, silica colloidal anhydrous, talc, magnesium stearate.

LEVET 250 mg film-coated tablets
Film-coating: hydroxypropylcellulose, hypromellose, macrogol type 6000, titanium dioxide (E171), talc, indigo carmine (E132).

LEVET 500 mg film-coated tablets
Film-coating: hydroxypropylcellulose, hypromellose, macrogol type 6000, titanium dioxide (E171), talc, iron oxide yellow (E172).

- *MAL numbers*

LEVET 250 mg film-coated tablets
MAL18116063AZ

LEVET 500 mg film-coated tablets
MAL18116062AZ

MANUFACTURER

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PRODUCT REGISTRATION HOLDER

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