LEVEVITAE® 500mg

Levetiracetam (500mg) film-coated tablets

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What Levevitae is used for

Levevitae 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). Levevitae 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 Levevitae works

- Alone (without another anti-epileptic drug) in patients from 16 years of age with newly diagnosed epilepsy, to treat partial onset seizures with or without secondary generalization.
- Together with other anti-epileptic medicines to treat:
  - The partial onset seizures with or without generalization in patients from 4 years of age.
  - Myoclonic seizures in patients 12 years and older with juvenile myoclonic epilepsy.
  - Primary generalised tonic-clonic seizures in patients from 12 years of age with generalized idiopathic epilepsy.

Before you use Levevitae

- *When you must not use it*

If you are allergic (hypersensitive) to levetiracetam or any of the other ingredients of Levevitae.

Pregnancy and lactation

Consult your doctor or pharmacist before taking any medication. If you are pregnant or think you may be pregnant, tell your doctor. Levevitae should not be used during pregnancy unless clearly necessary. The risk to the baby during pregnancy is unknown. In animal studies, Levevitae has shown unwanted effects on reproduction, at greater doses than you may need to control your seizures. Breastfeeding is not recommended during treatment.

- *Before you start use it*

Take special care with Levevitae:

- If you have kidney problems, follow the instructions of your doctor who will decide whether to adjust the dose to be taken.
- If you notice any decrease in your child's growth or unexpected puberty development, contact your doctor.
- A small number of people being treated with anti-epileptics such as Levevitae have had thoughts of harming or killing themselves. If you have any symptoms of depression and/or suicidal thoughts, contact your doctor.

- *Taking other medicines*

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

How to use Levevitae

- *How much to use*

Monotherapy

Dose in adults and adolescents (from 16 years old)

General dose: 1000 mg (2 tablets) and 3000 mg (6 tablets) per day.

When you start taking Levevitae, your doctor will prescribe a lower dose for two weeks before giving the lowest general dose.

For example: for a daily dose of 2000 mg, you must take 2 tablets in the morning and 2 tablets in the evening.

Concomitant treatment

Dose in adults and adolescents (12 to 17 years) weighing 50 kg or more:

General dose: 1000 mg (2 tablets) and 3000 mg (6 tablets) per 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 levetiracetam according to age, weight and dose.

Form of administration:

Swallow the Levevitae with enough liquids (e.g. A glass of water).

- *When to use it*

Levevitae should be taken twice daily, once in the morning and once in the evening, at about the same time each day.

Take the number of tablets prescribed by your doctor.

- *How long to use it*

- Levevitae is used as a chronic treatment. You should continue Levevitae treatment for the time indicated by your doctor.
- Do not stop your treatment without your doctor's recommendation since it could increase seizures. If your doctor decides to stop your treatment with Levevitae, he/she will give you instructions for the gradual withdrawal of Levevitae.

- *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)*

Possible side effects of an overdose of Levevitae are drowsiness, agitation, aggressiveness, decreased alertness, breathing inhibition and coma.

Contact your doctor if you have taken more tablets than you should. Your

doctor will prescribe the best possible overdose treatment.

While you are using it

- *Things you must do*

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Levevitae.

Tell your doctor immediately if you become pregnant while taking this medication.

- *Things you must not do*

Levevitae may be taken with or without meals. As a security measure does not take Levevitae with alcohol.
Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.
Do not give Levevitae to anyone else, even if they have the same symptoms or condition as you.

- *Things to be careful of*

Driving and using machines
Levevitae may impair your ability to drive or operate any tools or machinery, as it can make you feel drowsy. This is more likely at the beginning of treatment or when the dose is increased. You should not to drive or use machinery until it is established that your ability to perform these activities is not affected.

Side effects

Like all medicines, Levevitae can cause side effects, although not everybody gets them.
Tell your doctor if you have any of the following side effects and you're concerned.
Some of the side effects like drowsiness, weakness and dizziness may be more common when treatment is started or the dose is increased. However, these side effects should diminish over time.
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.

Very common

• Nasopharyngitis (common cold)
• Somnolence (sleepiness), headache.

Common

• Anorexia (loss appetite)
• Depression, hostility/aggression, anxiety, insomnia, nervousness/irritability
• Convulsion, balance disorder (equilibrium disorder), dizziness (sensation of unsteadiness), lethargy (lack if energy and enthusiasm), tremor (involuntary trembling)
• Vertigo (sensation of rotation)
• Cough
• Abdominal pain, diarrhoea, dyspepsia (indigestion), vomiting, nausea
• Rash
• Asthernia/fatigue (tiredness)

Uncommon

• Thrombocytopenia (decreased number of blood platelets), leukopenia (decreased number of white blood cells)
• Weight decreased, weight increase
• Suicide attempt, suicidal ideation, psychotic disorder, abnormal behaviour, hallucination anger, confusional state, panic attack, affect liability/mood swings, agitation
• Amnesia (loss of memory), memory impairment (forgetfulness), abnormal coordination, abnormal/ataxia (impaired coordination movements), paraesthesia (tingling), disturbance in attention (loss of concentration)
• Diplopia (double vision), vision blurred
• Liver function test abnormal
• Alopecia (hair loss), eczema, pruritus
• Muscular weakness myalgia (muscle pain)
• Injury

Rare

• Infection
• Decreased number of all blood cell types (Pancytopenia, neutropenia, agranulocytosis)
• Drug reaction with eosinophilia and systemic symptoms (DRESS), Hypersensitivity (including angioedema and anaphylaxis)
• Hyponatremia (decreased blood sodium concentration)
• Completed suicide, personality disorder (behavioural problems), thinking abnormal (slow thinking, unable to concentrate)
• Choreoathetosis (uncontrollable muscle spasms affecting the head, torso and limbs), dyskinesia (difficulty in controlling movements), hyperkinesia (hyperactivity)
• Pancreatitits (pancreas inflammation)
• Hepatic failure (liver failure), hepatitis
• Acute Kidney injury
• Toxic epidermal necrolysis (a more severe form causing skin peeling in more than 30% of the body surface), Stevens-Johnson syndrome (a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals), erythema multiforme [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)]
• Rhabdomyolysis (breakdown of muscle tissue) and blood creatinine phosphokinase increased

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.moh.gov.my [Public→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Levevitae

- *Storage*

Keep out of reach and sight of children.
This medication does not require any special storage conditions.
Do not use this medicine after the expiry date which appears in the box after EXP and blister after EXP.
The expiry date is the last day of that month.

- *Disposal*

Medication should not be disposed of via drainage or household waste. If in doubt ask your pharmacist how to dispose of medicines and recipients no longer needed. This will help protect the environment.

Product Description

- *What it looks like*

The film-coated tablets are yellow, oblong, biconvex. The cardboard box have 30 or 100 film-coated tablets.
The Levevitae tablets are packaged in blister packs and come in cardboard boxes.

- *Ingredients*

- Active ingredient:

The active ingredient is levetiracetam. Each tablet contains 500 mg of levetiracetam.

- Inactive ingredients:

Tablet core: calcium hydrogen phosphate dihydrate, cellulose microcrystalline, crospovidone type A, hydroxypropylcellulose,
Film coating: Opadry 20J22730 (Yellow)(Hypromellose, titantium dioxide, hydroxypropylcellulose, propylene glycol, sorbitan monooleate, sorbic acid FCC, vanillin, quinoline yellow aluminium lake)

- *MAL number*

MAL20076020ACZ

Manufacturer

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Greece

Product Registration Holder

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