

PATIENT INFORMATION LEAFLET

LEV-END® 1000 mg film-coated tablet For oral use.

- **Active substance(s):** Each film-coated tablet contains 1000 mg levetiracetam.
- **Excipient(s):** Polyethylene glycol 6000, colloidal anhydrous silica, magnesium stearate, croscarmellose sodium, hydroxypropyl methylcellulose, talc, titanium dioxide.

Read this PATIENT INFORMATION LEAFLET carefully before you start using this medicine, because it contains important information for you.

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, please ask your doctor or pharmacist.*
- *This medicine has been prescribed for you only. Do not pass it on to others.*
- *If you go to a doctor or hospital during the use of this medicine, inform your doctor about this*
- *Follow the instructions in this leaflet exactly. Do not use **higher or lower doses** than the dose which was recommended for you.*

In this Patient Information Leaflet:

1. ***What LEV-END® is and what it is used for?***
2. ***Before you use LEV-END®***
3. ***How to use LEV-END®?***
4. ***Possible side effects***
5. ***How to store LEV-END®?***

1 – What LEV-END® is and what it is used for?

LEV-END® is presented in blister packaging of 50 film-coated tablets. Tablets are white, biconvex, oval film coated tablet debossed with “L1000” on one side and score line on the other side.

LEV-END® is an antiepileptic drug used in the treatment of epileptic seizures.

LEV-END® is used alone in partial onset seizures with or without secondary generalization in patients from 16 years of age.

LEV-END® is used as an add-on to other antiepileptic medicines to treat:

- partial onset seizures with or without generalization in adults and children from 4 years of age;
- myoclonic seizures (shock-like jerks) in adults and adolescents from 12 years of age
- primary generalized tonic-clonic seizures in adults and adolescents from 12 years of age.

2 – Before you use LEV-END®

DO NOT USE LEV-END® in the following conditions

- If you are allergic (hypersensitive) to levetiracetam, the active substance of LEV-END®, or any of its excipients.

TAKE SPECIAL CARE WITH LEV-END® in the following conditions:

- 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 levetiracetam 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 have a family or medical history of irregular heartbeat (visible on electrocardiogram), if you have a disease that predisposes you to heartbeat irregularities or salt imbalances and/or if you are receiving treatment

If any of the following side effects become serious or last longer than a few days, consult your doctor or pharmacist

- Abnormal thoughts, feeling irritable or reacting more aggressively than usual, or mood you, your family and/or friends notice significant changes in your condition or behaviour
- Exacerbation of epilepsy

Your seizures may rarely get worse or occur more frequently, especially in the first month after starting treatment or increasing the dose.

In a very rare form of early onset epilepsy causing multiple seizure types and loss of ability (epilepsy associated with SCN8A mutations), you may find that your seizures persist or worsen during your treatment.

If you experience any of these new symptoms while taking LEV-END®, you should contact your doctor as soon as possible.

consult your doctor at the same time. If these warnings apply to you at any time in the past, please consult your doctor.

Using LEV-END® with food and drink:

You can take LEV-END® with or without food. As a safety precaution, do not take LEV-END® with alcohol.

Pregnancy:

Ask your doctor or pharmacist for advice before using the medicine.

If you are pregnant or think you may be pregnant, please inform your doctor.

LEV-END® should not be used during pregnancy unless clearly necessary. A risk of birth defects with LEV-END® for your unborn child cannot be completely ruled out. Levetiracetam has shown unwanted reproductive effects in animal studies at dose levels higher than you would need to control your seizures.

If you notice that you are pregnant during treatment, please consult your doctor or pharmacist immediately.

Breastfeeding:

Ask your doctor or pharmacist for advice before using the medicine.

Breast-feeding is not recommended during treatment.

Effects on ability to drive and use machines:

LEV-END® may impair your ability to drive or operate any tools or machinery, as it may make you feel 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 your doctor evaluate your response to treatment and allows it.

Important information about some of the ingredients of LEV-END®

LEV-END® contains less than 1 mmol (23 mg) of sodium per dose; i.e. it is actually "sodium free".

If you do not have a hypersensitivity to the excipients contained in LEV-END[®], no adverse effect is observed due to these substances.

Using with other medicines

Do not take macrogol (a drug used as laxative) for one hour before and one hour after taking levetiracetam as this may result in a loss of its effect.

Please tell your doctor if you are taking methotrexate (a medicine used in diseases such as immune system disorders or cancer) together with LEV-END[®].

Please tell your doctor or pharmacist if you are taking or have recently taken any other prescription or nonprescription medicine.

3 – How to use LEV-END[®]?

Instructions for appropriate method and dose/frequency of administration:

Take the number of tablets following your doctor's instructions. LEV-END[®] tablets must be taken twice a day, once in the morning and once in the evening, at about the same time each day.

Monotherapy (treatment with LEV-END[®] alone)

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

- General dose: between 1,000 (1 tablet) mg and 3,000 (3 tablets) mg each day.
- When you will first start taking LEV-END[®], your doctor will prescribe you a lower dose during 2 weeks before, giving you the lowest general dose.

For example: if your daily dose is 2,000 mg, you should take 1 tablet in the morning and in the evening.

Add-on Therapy (concomitant treatment with other antiepileptic drugs)

Dose in adults (≥18 years) and adolescents (12 to 17 years) weighing 50 kg or more:

- General dose: between 1,000 mg and 3,000 mg each day.
- If you are starting treatment with LEV-END[®] for the first time, your doctor will prescribe a low dose of LEV-END[®] for 2 weeks before giving you the lowest daily dose.

For example: if your daily dose is 2000 mg, you should take 1 tablet in the morning and in the evening.

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

- General dose: between 20 mg / kg body weight and 60 mg / kg body weight each day.
- Your doctor will prescribe the most appropriate pharmaceutical form of LEV-END[®] according to the age, weight and dose.

For example, for a general dose of 20 mg / kg per day, you should give your 25 kg child one LEV-END[®] 250 mg tablet in the morning and in the evening.

Route and method of administration:

LEV-END[®] tablets are for oral use.

Swallow LEV-END[®] tablets with a sufficient quantity of liquid (e.g a glass of water). After oral administration the bitter taste of LEV-END[®] may be experienced.

Duration of use:

- Treatment with LEV-END® is long-term. You should continue treatment with LEV-END® for as long as your doctor has prescribed.
- Do not stop treatment without telling your doctor because your seizures may increase.

•Different age groups:**Use in children:**

LEV-END® may be used in adults and children from 4 years of age.

Use in elderly:

In elderly patients (over 65 years), if the renal function is reduced, LEV-END® dose will be adjusted by your doctor.

•Special populations:**Kidney/Liver failure:**

If you have kidney failure, LEV-END® dose will be adjusted by your doctor according to your kidney function. If you have severe hepatic insufficiency, your doctor will reduce the dose.

If you have the impression that the effect of LEV-END® is too strong or too weak, talk to your doctor or pharmacist.

If you have used more LEV-END® than you should:

The possible side effects of an overdose of LEV-END® are sleepiness, extreme restlessness, hostility/aggression, confusion, inhibition of breathing and coma. Your doctor will establish the best possible treatment of overdose.

If you may have taken more LEV-END® than you should, talk to a doctor or pharmacist.

If you forget to use LEV-END®:

Contact your doctor if you have missed one or more doses.

Do not use a double dose to make up for a forgotten dose.

If you stop using LEV-END®:

•LEV-END® is used as a chronic (long-term) treatment. As long as your doctor tells you, you should continue with LEV-END® treatment.

•Do not interrupt treatment without your doctor's recommendation, because this can increase your seizures.

Your doctor should decide to discontinue LEV-END® treatment. Your doctor will instruct you about a gradual withdrawal.

Consult your doctor or pharmacist if you have any questions about the use of this medicine.

4 - Possible side effects

Like all medicines, side effects can occur in people sensitive to the contents of LEV-END®.

If you experience one of following, stop using LEV-END®, tell your doctor immediately and contact the emergency department of nearest hospital.

- weakness, feel light-headed or dizzy or have difficulty breathing, as these may be signs of a serious allergic (anaphylactic) reaction
- swelling of the face, lips, tongue and throat (Quincke's oedema)
- flu-like symptoms and a rash on the face followed by an extended rash with a high temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes (Drug Reaction with Eosinophilia and Systemic Symptoms [DRESS])
- symptoms such as low urine volume, tiredness, nausea, vomiting, confusion and swelling in the legs, ankles or feet, as this may be a sign of sudden decrease of kidney function
- a 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)
- a more severe form of rash causing skin peeling in more than 30% of the body surface (toxic epidermal necrolysis)
- signs of serious mental changes or 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 (brain disease, injury or dysfunction).

These are very serious side effects. If you have any of these, you may need urgent medical attention or hospitalisation.

Side effects are classified in categories as shown below:

Very common	: in at least 1 patient of 10.
Common	: in less than 1 of 10 patients and more than 1 of 100 patients.
Uncommon	: in less than 1 of 100 patients but, more than 1 of 1000 patients.
Rare	: in less than 1 of 1000 patients but more than 1 of 10.000 patients. Very
rare	: in less than 1 of 10.000 patients.
Unknown	: Cannot be estimated based on available data

Very common:

- Nasopharyngitis (inflammation of the nose and pharynx)
- Drowsiness (somnolence)
- Headache

Common:

- Anorexia (loss of appetite)
- Depression
- Hostility or aggression
- Anxiety
- Insomnia
- Nervousness or irritability
- Convulsion
- Balance disorder (equilibrium disorder)
- Dizziness (sensation of unsteadiness)
- Tremor (involuntary trembling)
- Lethargy (lack of energy and enthusiasm)

- Vertigo (sensation of rotation)
- Cough
- Abdominal pain
- Diarrhea
- Dyspepsia (indigestion)
- Nausea
- Vomiting
- Rash
- Asthenia/fatigue (tiredness)

Uncommon:

- Decrease in the number of blood clotting cells
- Decreased white blood cell count
- Weight decrease
- Weight increase
- Suicide attempt and suicidal ideation
- Mental disorder
- Abnormal behavior
- Hallucination
- Anger
- Confusion
- Panic attack
- Emotional instability/mood swings
- Agitation (state of extreme uneasiness)
- Amnesia (loss of memory)
- Memory impairment (forgetfulness)
- Abnormal coordination/ ataxia (impaired coordinated movements)
- Paraesthesia (tingling)
- Disturbance in attention (loss of concentration)
- Diplopia (double vision)
- Blurred vision
- Elevated/abnormal liver function test
- Hair loss
- Eczema (skin inflammation)
- Pruritus
- Muscle weakness
- Myalgia (muscle pain)
- Injuries

Rare:

- Infection
- Decreased number of all blood cell types
- Severe allergic reactions (DRESS, anaphylactic reaction [severe and important allergic reaction], Quincke's oedema [swelling of the face, lips, tongue and throat])
- Decreased blood sodium concentration
- Suicide
- Personality disorders (behavioral problems)
- Thinking abnormal (slow thinking, unable to concentrate)
- Delirium

- Encephalopathy (For a detailed description of the symptoms, see the subheading ‘If any of the following occurs, stop taking LEV-END® and tell your doctor immediately’)
- Seizures worsen or occur more frequently
- Uncontrollable muscle spasms (Choreathetosis)
- Difficulty in controlling movements (Dyskinesia)
- Hyperactivity (hyperkinesia)
- Pancreatitis
- Liver failure
- Inflammation of liver (hepatitis)
- Sudden decrease in kidney function
- A condition characterized by various types of bubbles (Papules, vesicles, bulls, etc.) present at the same time in skin and mucous membranes (erythema multiform)
- A widespread rash with blisters in the skin, mouth, eyes and genitals (Stevens-Johnson syndrome)
- Peeling skin (a more severe form 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.
- limp or difficulty walking.
- a combination of fever, muscle stiffness, unstable blood pressure and heart rate, confusion and low level of consciousness (may be symptoms of a disorder known as neuroleptic malignant syndrome). The incidence is significantly higher in Japanese patients than in non-Japanese patients.

Very rare:

- recurring unwanted thoughts or sensations or the urge to do something over and over again (Obsessive Compulsive Disorder).

The most frequently reported side effects are nasopharyngitis, somnolence (sleepiness), headache, fatigue and dizziness.

At the beginning of treatment or at dose increase, side effects like sleepiness, tiredness and dizziness may be more common. These effects should however decrease over time.

If you notice any side effects not mentioned in this leaflet, inform your doctor or pharmacist.

Reporting of side effects

If you get any side effects, stated or not stated in the Patient Information Leaflet, talk to your doctor or pharmacist. Also, please report the side effects you have to Turkish Pharmacovigilance Center (TÜFAM) by either clicking to “Reporting Drug Side Effect” icon on www.titck.gov.tr or calling side effect reporting line via 0 800 314 00 08. By reporting the side effects you can help provide more information on the safety of this medicine.

TÜFAM	Turkish Pharmacovigilance Center www.titck.gov.tr
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5 – How to store LEV-END®

Keep out of the sight and reach of children and in its packaging.

Store at room temperatures below 25°C.

Use in accordance with the expiry date.

Do not use LEV END® after the expiry date indicated on the package.

Do not use LEV-END® if you notice any defects in the product and/or its packaging.

Do not throw away expired or unused medicines! Give it to the collection system determined by the Ministry of Environment, Urbanisation and Climate Change.

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