**Package leaflet: Information for the patient**

# Leviphar 500 mg 100 Film-Coated Tablets
# Leviphar 1000 mg 100 Film-Coated Tablets

Levetiracetam

**Read all of this leaflet carefully before you start taking 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, ask your doctor, pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist. This includes any possible side effects not listed in this leaflet.

**What is in this leaflet**



## 1. What Leviphar is and what it is used for

Levetiracetam is an antiepileptic medicine (a medicine used to treat seizures in epilepsy).
Leviphar is used:
- On its own in adults and adolescents from 16 years of age with newly diagnosed epilepsy, to treat a certain form of 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 seizure with or without secondary generalization). Levetiracetam 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 generalization in adults, adolescents, children and infants from one month of age;
  - 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 adolescents from 12 years of age with idiopathic generalized epilepsy (the type of epilepsy that is thought to have a genetic cause).

## 2. What you need to know before you take Leviphar

**Do not take Leviphar**
- If you are allergic to levetiracetam, pyrrolidone derivatives or any of the other ingredients of this medicine (listed in Section 6).

**Warnings and precautions**

Talk to your doctor before taking Leviphar
- 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 Leviphar 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 heart rhythm (visible on an electrocardiogram), or if you have a disease and/or take a treatment that make(s) you prone to heartbeat irregularities or salt imbalances.

Tell your doctor or pharmacist if any of the following side effects gets serious or last longer than a few days:
- Abnormal thoughts, feeling irritable or reacting more aggressively than usually, or if you or your family and friends notice important changes in mood or behavior.
- Aggravation of epilepsy.

Your seizures may rarely become worse or happen more often, mainly during the first month after the start of the treatment or increase of the dose. If you experience any of these new symptoms while taking Leviphar, see a doctor as soon as possible.

**Children and adolescents**
- Leviphar is not indicated in children and adolescents below 16 years on its own (monotherapy).

**Other medicines and Leviphar**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Do not take macrogol (a drug used as laxative) for one hour before and one hour after taking levetiracetam as this may results in a loss of its effect.

**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. Levetiracetam 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.
A risk of birth defects for your unborn child cannot be completely excluded.
Breast-feeding is not recommended during treatment.

**Driving and using machines**

Leviphar 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 it is established that your ability to perform such activities is not affected.

**Leviphar contains sodium**

Leviphar (500 mg and 1000 mg) contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

## 3. How to take Leviphar

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. Leviphar must be taken twice a day, once in the morning and once in the evening, at about the same time each day.

**Adjunctive Therapy and monotherapy (from 16 years of age)**

**• Adults (≥18 years) and adolescents (12 to 17 years) weighing 50 kg or more:**

Recommended dose: between 1,000 mg and 3,000 mg each day.
When you will first start taking Leviphar, your doctor will prescribe you a lower dose during 2 weeks before giving you the lowest daily dose.
Example: if your daily dose is intended to be 1,000 mg, your reduced starting dose is 500 mg daily, and the dose will be gradually incremented to reach 1,000 mg daily after 2 weeks.

Method of administration

Swallow Leviphar tablets with a sufficient quantity of liquid (e.g. a glass of water). You may take Leviphar with or without food. After oral administration the bitter taste of levetiracetam may be experienced.

Duration of treatment
- Leviphar is used as a chronic treatment. You should continue Leviphar 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 you take more Leviphar than you should**

The possible side effects of an overdose of Leviphar 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.

**If you forget to take Leviphar:**

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 stop taking Leviphar:**

If stopping treatment, Leviphar should be discontinued gradually to avoid an increase of seizures. Should your doctor decide to stop your Leviphar treatment, he/she will instruct you about the gradual withdrawal of Leviphar.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Tell your doctor immediately, or go to your nearest emergency department, if you experience:**
- 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 behavior or other neurological signs including involuntary or uncontrolled movements. These could be symptoms of an encephalopathy.

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 in 10 people)*
- nasopharyngitis;
- somnolence (sleepiness), headache.

**Common:** *(may affect up to 1 in 10 people)*
- 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;
- abdominal pain, diarrhoea, dyspepsia (indigestion), vomiting, nausea;
- rash;
- asthenia/fatigue (tiredness).

**Uncommon:** *(may affect up to 1 in 100 people)*
- decreased number of blood platelets, decreased number of white blood cells;
- weight decrease, weight increase;
- suicide attempt and suicidal ideation, mental disorder, abnormal behaviour, hallucination, anger, confusion, panic attack, emotional instability/mood swings, agitation;
- amnesia (loss of memory), memory impairment (forgetfulness), abnormal coordination/ataxia (impaired coordinated 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 up to 1 in 1,000 people)*
- 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 (see sub-section "Tell your doctor immediately" for a detailed description of symptoms);
- seizures may become worse or happen more often;
- uncontrollable muscle spasms affecting the head, torso and limbs, difficulty in controlling movements, hyperkinesia (hyperactivity);
- change of the heart rhythm (Electrocardiogram);
- pancreatitis;
- liver failure, hepatitis;
- sudden decrease in kidney function;
- skin rash, which may form blisters and looks 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;
- limp or difficulty walking.

**Reporting side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Leviphar
- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the blister and the outer packaging. The expiry date refers to the last day of that month.
- Do not store above 30°C. Keep away from humidity.
- Do not use this medicine if you notice visible signs of deterioration.
- Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

**What Leviphar contains**
- The active substance is Levetiracetam
  Each tablet contains 500 mg/1000 mg of Levetiracetam.
- The other ingredients are:

**Tablet Core:** Croscarmellose sodium, povidone, colloidal anhydrous silica, magnesium stearate.
**Tablet coating:** Polyvinyl alcohol, polyethylene glycol, talc, titanium dioxide (for Leviphar 500 mg & 1000 mg) and iron oxide yellow (only for Leviphar 500 mg).

**What Leviphar looks like and contents of the pack**

Leviphar 500 mg film-coated tablets are yellow, oblong and plain.
Leviphar 1000 mg film-coated tablets are white, oblong and plain.
Leviphar 500 mg/ 1000 mg tablets are available in blister packs containing 100 film-coated tablets.

**Marketing Authorisation Holder and Manufacturer**

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Reg. N°. in Lebanon for Leviphar 500 mg, 100 film-coated tablets: 41123/1
Reg. N°. in Lebanon for Leviphar 1000 mg, 100 film-coated tablets: 41223/1

**This is a Medicament**
- Medicament is a product which affects your health and its consumption contrary to an instruction is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the Pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacist

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