

PATIENT INFORMATION LEAFLET

ELEPSÍ® 50 mg film-coated tablets

For oral administration.

- **Active ingredient:** 50 mg lacosamide per film-coated tablet
- **Excipients:** Microcrystalline cellulose, hydroxypropyl cellulose, hydroxypropyl cellulose (low-substituted), crospovidone, magnesium stearate, prosolv HD90, colloidal silicon dioxide, polyvinyl alcohol-part. hydrolyzed, talc, titanium dioxide, polyethylene glycol, indigo carmine aluminum lake, red iron oxide, black iron oxide, lecithin (soy).

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 or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *Please tell your doctor that you are taking this medicine if you seek medical assistance during the use of this medicine.*
- *Follow these instructions carefully. Do not take **higher or lower** doses than recommended.*

What is in this leaflet:

1. *What is ELEPSÍ® and what is it used for?*
2. *Before using ELEPSÍ®, what should be considered*
3. *How to use ELEPSÍ®*
4. *What are the possible side effects of ELEPSÍ®.*
5. *Storage of ELEPSÍ®*

Titles are included.

1. What is ELEPSÍ® and what is it used for?

- ELEPSÍ® is a medication containing the active ingredient lacosamide, used in the treatment of a condition called epilepsy (seizures).
- ELEPSÍ® is a pink-colored, biconvex, oval film-coated tablet.
- It is presented in blister packaging containing 14 film-coated tablets.
- ELEPSÍ® is used in patients aged 16 and older either alone or in addition to other epilepsy medications to treat a specific form of epilepsy (see below).
- Epilepsy is a condition where patients experience recurring seizures.
- ELEPSÍ® is used in patients aged 16 and older either alone or in addition to other epilepsy medications to treat a form of epilepsy where seizures initially affect only one side of the brain, but may later spread to larger areas on both sides of the brain or may not spread at all (partial-onset seizures with or without secondary generalization).

2. Before using ELEPSI®, please pay attention to the following:

DO NOT USE ELEPSI® if:

- You are allergic (hypersensitive) to lacosamide or any of the other ingredients of ELEPSI®.
- You have a significant type of heart rhythm disorder (second or third degree AV block).
- ELEPSI® contains lecithin (soya). Do not use this medicinal product if you are allergic to peanuts or soya. If you are unsure whether you are allergic, please consult your doctor.

USE ELEPSI® WITH CAUTION if:

- If you have thoughts of harming yourself or committing suicide, talk to your doctor immediately. A small number of people being treated with epilepsy medicines like ELEPSI® have had thoughts of harming themselves (suicidal thoughts) or taking their own lives. If at any time you have these thoughts, please consult your doctor immediately.
- If you have a condition related to electrical conduction in your heart (AV block, atrial fibrillation, and atrial flutter), congestive heart failure, or severe heart disease such as a heart attack. Symptoms of AV block include slow or irregular heartbeat, feeling dizzy, and fainting. In cases of atrial fibrillation and flutter, you may experience palpitations, fast or irregular heartbeat, and shortness of breath.
- ELEPSI® may cause dizziness, which increases the risk of accidental injury or falls. Therefore, you should be cautious until you know how the medication affects you.
- If you are elderly, you may have a higher risk of heart disease. If you have heart disease or are taking another medication that may prolong your heart rhythm, inform your doctor about this.

If any of these warnings apply to you, even if they have applied in the past, please consult your doctor.

Use of ELEPSI® with food and drinks:

You can take ELEPSI® with or without food.

Avoid alcohol while being treated with ELEPSI® as it may make you feel tired or dizzy. Drinking alcohol may worsen these effects.

Pregnancy:

Consult your doctor or pharmacist before using the medicine.

It is not recommended to use ELEPSI® during pregnancy because the effects of ELEPSI® on pregnancy and the unborn baby are unknown. If you are pregnant or planning to become pregnant, inform your doctor immediately. Your doctor will decide whether you should take ELEPSI®.

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

Breastfeeding:

Consult your doctor or pharmacist before using the medicine.

Breastfeeding is not recommended while using ELEPSI® because it is not known whether ELEPSI® passes into breast milk. If you are breastfeeding, inform your doctor immediately. Your doctor will decide whether you should use ELEPSI®.

Research has shown an increased risk of congenital defects (abnormalities) in children of women taking antiepileptic drugs. However, considering the harm to both the mother and the unborn child if the disease worsens, treatment should not be discontinued.

Driving and using machines:

ELEPSI® may cause dizziness or blurred vision, which can affect your ability to operate any tools or machinery. Until you know how ELEPSI® affects you, do not drive or operate machinery.

Important information about the excipients in ELEPSI®:

ELEPSI® contains lecithin (soya). Do not use this medicinal product if you are allergic to peanuts or soya.

Interaction with other medicines:

Inform your doctor or pharmacist if you are currently using, have recently used, or may use any other medicine.

- Medications used to treat heart conditions
- Medications such as carbamazepine, lamotrigine, pregabalin (used in epilepsy treatment) that may cause abnormalities in the EKG (electrocardiogram) known as PR interval prolongation
- Medications used to treat specific types of irregular heart rhythms or heart failure as they may cause abnormalities in EKG (electrocardiogram) PR interval prolongation or may be used to treat irregular heart rhythms or heart failure.

If you are unsure whether your medications will have this effect, consult your doctor or pharmacist.

Especially inform your doctor or pharmacist if you are using any of the following medications, as they may increase or decrease the effect of ELEPSI® in your body:

- Fluconazole, itraconazole, ketoconazole (used in the treatment of fungal infections)
- Ritonavir (used in the treatment of HIV infection)
- Clarithromycin or rifampicin (used in the treatment of bacterial infections)
- St. John's Wort (also known as hypericum, used in the treatment of mild anxiety)

If you are currently using any prescription or non-prescription medications or have used them recently, please inform your doctor or pharmacist about them.

3. How to use ELEPSI®?

Instructions for appropriate use and dosage/application frequency:

Always use ELEPSI® exactly as your doctor has told you. If you are unsure, consult your doctor or pharmacist.

Your doctor will typically start treatment with a low dose and gradually increase it over a few weeks. The dose that is suitable for you will be determined as the "maintenance dose," which you will take every day in the specified amount. ELEPSI® should be taken twice daily, approximately at the same time each day—once in the morning and once in the evening. ELEPSI® is used for long-term treatment. You should continue the treatment until your doctor advises otherwise.

If you have kidney or liver problems, your doctor may prescribe a different dose for you.

Monotherapy (Treatment with ELEPSI® alone):

The recommended starting dose for ELEPSI® is 50 mg twice daily. Your doctor may also start your treatment with a dose of 100 mg twice daily.

Your doctor may adjust your maintenance dose weekly, increasing it by 100 mg twice daily, up to a total daily dose of 200 mg to 600 mg.

Adjunctive therapy (Treatment with other antiepileptic drugs):

The starting dose of ELEPSI® for adjunctive therapy is 100 mg daily (50 mg in the morning and 50 mg in the evening).

Your doctor may adjust your maintenance dose weekly, increasing it by 100 mg twice daily, up to a total daily dose of 200 mg to 400 mg.

Your doctor may initiate ELEPSI® treatment with a single loading dose of 200 mg, followed by an maintenance dose regimen approximately 12 hours later.

- **Method and route of administration:**

ELEPSI® is a film-coated tablet for oral use only.

Swallow the film-coated tablet with a glass of water. It can be taken on an empty stomach or with food.

- **Different age groups:**

Use in children:

The use of ELEPSI® in children and adolescents under 16 years of age is not recommended.

Use in elderly patients:

In elderly patients, if there is decreased kidney function, your doctor will adjust the ELEPSI® dose accordingly.

- **Special usage conditions:**

Kidney impairment:

There is no need for dose adjustment in patients with mild to moderate kidney impairment (CLCR > 30 ml/min). A maximum dose of 250 mg/day is recommended for patients with severe kidney impairment (CLCR ≤ 30 ml/min) and end-stage kidney failure.

For patients requiring hemodialysis, an additional dose of up to 50% of the divided daily dose is recommended immediately after hemodialysis.

Treatment of patients with end-stage kidney failure should be approached with caution due to limited clinical experience and accumulation of a metabolite with no known pharmacological activity.

Dose adjustment should be carefully considered in all patients with kidney impairment.

Liver impairment:

The recommended maximum dose for patients with mild to moderate liver impairment is 300 mg/day. Dose titration should be done carefully, taking into account the presence of accompanying kidney impairment.

ELEPSI® is used for long-term treatment. You should continue using ELEPSI® until your doctor tells you to stop.

If you feel that the effect of ELEPSI® is too strong or too weak, talk to your doctor or pharmacist.

If you have taken more ELEPSI® than you should:

If you have taken more ELEPSI® than prescribed, speak to a doctor or pharmacist.

You may experience symptoms such as dizziness, nausea, vomiting, seizures, or irregular heartbeat, which can lead to a drop in blood pressure, rapid heartbeat, sweating, or coma.

Avoid driving a car.

If you forget to take ELEPSI®:

If you forget to take ELEPSI® for a few hours, take it as soon as you remember. If it's almost time for your next dose (less than 6 hours away), skip the missed dose and take the next dose at the usual time.

Do not take a double dose to make up for forgotten doses.

Effects when stopping treatment with ELEPSI®:

- Do not stop using ELEPSI® without consulting your doctor, as your symptoms may return or worsen.
- If your doctor decides to discontinue ELEPSI® treatment, follow your doctor's instructions on how to gradually reduce the dose.
- If you have any further questions about using the medicine, consult your doctor or pharmacist.

4. Potential side effects

Like all medications, ELEPSI® may cause side effects in individuals who are sensitive to its ingredients.

Nervous system side effects, such as dizziness, may be more commonly observed after the loading dose.

Stop using ELEPSI® and IMMEDIATELY inform your doctor or go to the nearest emergency department if any of the following occur:

- Severe allergic reaction causing swelling of the face, neck, hands, feet, joints, or lower legs.
- Severe hypersensitivity reactions (DRESS syndrome) including skin redness and rash, swelling of the face, abnormalities in blood counts, enlargement of lymph nodes, liver enzyme elevations, and increase in a certain type of white blood cell count (eosinophilia).
- Formation of blisters on the skin, mouth, eyes, and genital area (Stevens-Johnson syndrome) and peeling of the skin (toxic epidermal necrolysis affecting more than 30% of the body surface area).

If any of these symptoms occur, you may need urgent medical intervention or hospitalization.

Side effects are categorized as follows:

Very common	: Can occur in at least 1 out of 10 patients.
Common	: Can occur in less than 1 out of 10, but more than 1 out of 100 patients.
Uncommon	: Can occur in less than 1 out of 100, but more than 1 out of 1000 patients.
Rare	: Can occur in less than 1 out of 1000, but more than 1 out of 10000 patients.
Very rare	: Can occur in less than 1 out of 10000 patients.
Not known	: Frequency cannot be estimated from the available data.

Very common:

- Headache
- Feeling dizzy or nauseous
- Double vision

Common:

- Problems with balance
- Difficulty coordinating movements or walking
- Tremors
- Tingling sensation (paresthesia) or muscle spasms
- Easy falling and bruising on the skin
- Memory impairment
- Difficulty thinking of or finding words
- Confusion
- Rapid and uncontrolled eye movements (nystagmus)
- Blurred vision
- Dizziness (vertigo)
- Feeling drunk
- Vomiting
- Dry mouth
- Constipation
- Indigestion
- Excessive gas in the stomach or intestines
- Diarrhea
- Decreased sensation or touch perception
- Difficulty speaking
- Attention disturbance
- Ringing, buzzing, roaring, or whistling sounds in the ear
- State of excessive sensitivity to stimuli (irritability)
- Difficulty sleeping
- Depression
- Drowsiness
- Fatigue and weakness (asthenia)
- Itching
- Rash

Uncommon:

- Slowing of heart rate, palpitations, irregular heartbeat, or other changes in heart electrical activity (heart conduction disorder)
- Feeling excessively good
- Seeing or hearing things that are not real
- Allergic reaction to the medication
- Rash (urticaria)
- Abnormal liver function tests, liver disorder
- Suicidal thoughts and self-harm thoughts, suicide attempt: Seek medical help immediately
- Feeling angry or excessively restless (agitation)
- Abnormal thoughts or loss of reality perception
- Fainting

Unknown frequency:

- Swelling of the throat, high fever, and more frequent infections. Severe decrease in specific class of white blood cells in blood tests (agranulocytosis)
- Convulsions

If any of these side effects affect you severely, inform your doctor immediately.

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

Reporting of side effects

Talk to your doctor, pharmacist or nurse if you experience any side effects listed or not listed in this leaflet. Also reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

5. Storage of ELEPSİ®

Store ELEPSİ® in a place where children cannot see or reach it, and keep it in its original packaging.

Store below 30°C.

Use ELEPSİ® in accordance with the expiration date.

Store in the original packaging.

Do not use ELEPSİ® after the expiration date printed on the packaging.

Do not use ELEPSİ® if you notice any defects in the product or packaging.

Do not dispose of expired or unused medication in the trash! Dispose of them according to the collection system established by the Ministry of Environment and Urbanization.

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This leaflet has been approved <{DD month YYYY}>. [To be completed nationally]