

PATIENT INFORMATION LEAFLET

ELEPSI® 150 mg Film Coated Tablets

For oral use

Active substance: Each film-coated tablet contains 150 mg of lacosamide.

Excipients: Microcrystalline cellulose, hydroxypropyl cellulose (low-substituted), prosolv HD90, crospovidone, colloidal silicon dioxide, magnesium stearate, polyvinyl alcohol-partial hydrolysis, talc, titanium dioxide, polyethylene glycol, yellow iron oxide, lecithin (soya), red iron oxide.

Before starting to use this medicine, carefully read this PATIENT INFORMATION LEAFLET, 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.*
- *It may harm them, even if their symptoms are the same as yours.*
- *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 ELEPSI® is and what it is used for?**
- 2. What you need to know before you use ELEPSI®?**
- 3. How to use ELEPSI®?**
- 4. What are possible side effects?**
- 5. How to store ELEPSI®?**

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

ELEPSI® is a medication containing the active ingredient lacosamide and is used in the treatment of epilepsy (partial-onset seizures).

ELEPSI® is a salmon-colored, biconvex, oval, film-coated tablets.

It is presented in blister packaging containing 56 film-coated tablets.

ELEPSI® is used in patients aged 16 years and older either as monotherapy or as an adjunctive therapy with other epilepsy medications to treat a specific form of epilepsy (see below).

Epilepsy is a condition where patients experience recurrent seizures.

ELEPSI® is used alone or in addition to other epilepsy medications to treat a specific form of epilepsy in patients aged 16 years and older, where seizures initially affect only one side of the brain, but may later spread to larger areas on both sides (partial-onset seizures with or without secondary generalization).

2. What you need to know before you use ELEPSI®

DO NOT USE ELEPSI® if you have the following conditions:

Do not use ELEPSI® in the following cases:

- If you are allergic (hypersensitive) to lacosamide or any of the excipients in ELEPSI®. If you are unsure whether you are allergic, please consult your doctor.
- If 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 soy.

ELEPSI® should be used WITH CAUTION in following conditions:

If you have:

- If you have thoughts of harming yourself or committing suicide, talk to your doctor immediately. A small number of people treated with epilepsy medications like ELEPSI® have had thoughts of suicide or self-harm. If you ever have these thoughts, please consult your doctor right away.
- If you are experiencing complaints related to a condition involving electrical conduction in your heart (AV block, atrial fibrillation, and atrial flutter), severe heart disease such as heart failure or heart attack. Symptoms of AV block include slow or irregular pulse, dizziness, and fainting. In cases of atrial fibrillation and flutter, you may experience palpitations, rapid or irregular pulse, and shortness of breath.
- ELEPSI® may cause a feeling of dizziness, which increases the risk of accidental injury or falling. Therefore, you should be cautious until you are familiar with any effects caused by the medication.
- Elderly patients may have a higher risk of heart disease. If you have heart disease or are taking another medication that could prolong your heart rhythm, inform your doctor about this.

If any of these warnings apply to you, even if they occurred at any time in the past, please consult your doctor

Effects of food and drinks on ELEPSI®

ELEPSI® can be taken with or without food.

It is not recommended to consume alcohol while being treated with

ELEPSI® because ELEPSI® may cause you to feel tired or dizzy. Consuming alcohol could worsen these effects.

Pregnancy

Before using the medication, consult your doctor or pharmacist.

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

If you become pregnant during your treatment, consult your doctor or pharmacist immediately.

Breastfeeding

Before using the medication, consult your doctor or pharmacist.

It is not recommended to breastfeed 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® or not.

Studies have shown an increased risk of congenital defects (disorders) in children of women taking antiepileptic drugs. On the other hand, considering that worsening of the disease could be harmful to both the mother and the unborn child, treatment should not be discontinued.

Ability to drive and use machinery

ELEPSI® may cause dizziness or blurred vision. This can affect your ability to operate any machinery or drive. Until you know how ELEPSI® affects you, refrain from using machinery or vehicles.

Important information on some of the excipients of ELEPSI®

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

Concurrent use with other medicines

If you are currently using, have recently used, or are likely to use any medication, inform your doctor or pharmacist.

Especially, inform your doctor or pharmacist if you are using any of the following medications:

- Medications used for the treatment of heart conditions
- Medications such as carbamazepine, lamotrigine, pregabalin (used in epilepsy treatment) that may cause abnormalities on an ECG (electrocardiogram) known as prolongation of the PR interval
- Medications used for certain types of irregular heart rhythm or heart failure treatment

If you are unsure whether these medications will have these effects, consult your doctor or pharmacist.

Especially inform your doctor or pharmacist if you are using any of the following medications because these medications may increase or decrease the effects 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 perforatum, used in mild anxiety treatment)

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

If you are currently using or have recently used any prescription or over-the-counter medication, please inform your doctor or pharmacist about them.

3. How to use ELEPSI® ?

• Instructions for appropriate use and dose/frequency of administration:

Here are the instructions for appropriate use and dosage frequency of ELEPSI®:

- Always use ELEPSI® exactly as your doctor has instructed. If you are unsure, consult your doctor or pharmacist.
- Your doctor will typically start the 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 amount specified.
- ELEPSI® should be taken twice daily, approximately at the same times each day, once in the morning and once in the evening.
- ELEPSI® is used as a long-term treatment. You should continue the treatment until your doctor advises to stop.
- If you have kidney or liver problems, your doctor may prescribe a different dose for you.

For Monotherapy (Treatment with ELEPSI® alone):

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

Your doctor can adjust your maintenance dose weekly with increases of 100 mg per day, up to a total of 300 mg twice daily (total dose: 200 mg/day to 600 mg/day).

For Adjunctive Therapy (Treatment with ELEPSI® alongside other antiepileptic drugs):

The starting dose for ELEPSI® in adjunctive therapy is 100 mg/day [50 mg in the morning and 50 mg in the evening].

Your doctor can adjust your maintenance dose weekly with increases of 100 mg per day, up to a total of 200 mg twice daily (total dose: 200 mg/day to 400 mg/day).

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

• **Administration route and method:** ELEPSI® film-coated tablets are 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 epilepsy is not recommended for children and adolescents under 16 years old.
- **Use in elderly:** In elderly patients with reduced kidney function, the dose of ELEPSI® will be adjusted by your doctor taking this into consideration.

• **Special usage conditions:**

Renal Impairment:

In patients with mild to moderate renal impairment ($CL_{CR} > 30$ mL/min), no dose adjustment is necessary.

For patients with severe renal impairment ($CL_{CR} \leq 30$ mL/min) and end-stage renal disease, a maximum daily dose of 250 mg is recommended.

In 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 renal failure should be approached cautiously due to limited clinical experience and the potential accumulation of a metabolite (which has no known pharmacological activity).

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

Hepatic Impairment:

In patients with mild to moderate hepatic impairment, the recommended maximum dose is 300 mg per day. Dose titration should be done carefully, taking into account concomitant renal 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:

Speak to a doctor or pharmacist if you have taken more ELEPSI® than prescribed.

You may experience heart-related symptoms such as dizziness, nausea, vomiting, seizures, or irregular heartbeat (slow, fast, or irregular), as well as low blood pressure accompanied by rapid heartbeat and sweating.

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 is close to the time of your next scheduled dose (less than 6 hours), do not take the missed dose. Take the next dose at the normal time.

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

Effects when discontinuing treatment with ELEPSI®:

- Do not stop treatment with ELEPSI® without consulting your doctor, as your symptoms may return or worsen.
- If your doctor decides to discontinue treatment with ELEPSI®, follow your doctor's instructions on how to gradually reduce the dose of the medication.
- If you have any other questions regarding the use of the medication, consult your doctor or pharmacist.

4.Possible side effects of ELEPSI®:

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).

Side effects are categorized as follows:

Very common: Can occur in at least 1 out of 10 patients.

Common: Can occur in fewer than 1 out of 10 patients, but more than 1 out of 100 patients.

Uncommon: Can occur in fewer than 1 out of 100 patients, but more than 1 out of 1000 patients.

Rare: Can occur in fewer than 1 out of 1000 patients, but more than 1 out of 10,000 patients.

Very rare: Can occur in fewer than 1 out of 10,000 patients.

Unknown: Cannot be estimated from available data.

Very common (may affect more than 1 in 10 people):

- Headache
- Feeling dizzy or nauseous
- Double vision

Common (may affect up to 1 in 10 people):

- 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 (may affect up to 1 in 100 people):

- 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 ELEPSI®

Store ELEPSI® in a place where children cannot see or reach, in its original packaging.

Store below 25°C.

Use in accordance with the expiry date.

Store in the original packaging.

Do not use ELEPSI® after the expiration date printed on the packaging. The expiration date indicates the last day of the specified month.

Do not dispose of expired or unused medications in the trash! Dispose of them according to the collection system established by the Ministry of Environment, Urbanization, and Climate Change

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This leaflet has been approved <{DD month YYYY}>.

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