

PACKAGE LEAFLET

ELEPSI[®] 200 mg film tablet

To be taken orally.

- **Active ingredient:** Each film tablet contains 200 mg Lacosamide
- **Excipients:** Microcrystalline cellulose, hydroxypropyl cellulose, hydroxypropyl cellulose (low substituted), crospovidone, magnesium stearate, prosolv HD30, colloidal silicon dioxide, polyvinyl alcohol-part hydrolyzed, talc, titanium dioxide, macragol, indigo carmine aluminum salt, lecithin (soya)

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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.*
- *Inform your doctor that you are taking this medicine if you seek medical attention from a doctor or health facility.*
- *Follow these instructions carefully. Do not take **lower or higher** doses than recommended.*

What is in this leaflet?

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- 2. What you need to know before you take ELEPSI[®]**
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1. What ELEPSI[®] is and what it is used for

- ELEPSI[®] contains lacosamide as the active ingredient and is used in the treatment of epilepsy (fits).
- ELEPSI[®] is a blue, biconvex, oval, film tablet.
- ELEPSI[®] is marketed in film-tablets in blister packs of 56.
- Lacosamide (ELEPSI[®]) is used to treat a certain form of epilepsy (see below) in patients aged 16 years and older. ELEPSI[®] is used in addition to other antiepileptic medicines.
- Epilepsy is a condition where the patients have repeated seizures. ELEPSI[®] 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 generalisation).

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

Do not take ELEPSI®

* If you are allergic to lacosamide or ELEPSI®, or any of the other ingredients of this medicine. If you are not sure whether you are allergic, please discuss with your doctor

* If you suffer from a certain type of heart rhythm disorder (second or third degree AV block)

CARE SHOULD BE EXERCISED when using ELEPSI® in the following conditions

A small number of people being treated with anti-epileptics such as ELEPSI® have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

Talk to your doctor before taking ELEPSI®

- If you suffer from a condition that is associated with impaired electric conduction across the heart (AV block, atrial fibrillation and atrial flutter) or from severe heart disease such as, heart failure or heart attack. Symptoms of AV block are slow or irregular pulse, feeling of lightheaded and fainting. In case of atrial fibrillation and flutter you may experience palpitations, rapid or irregular pulse and shortness of breath.
- ELEPSI® may cause dizziness, which could increase the risk of accidental injury or a fall. Therefore, you should be careful until you are used to the effects this medicine might have.
- Due to an increased risk of heart disease in the elderly, discuss this with your doctor if you have cardiac disease or are taking any other medicines that may be associated with prolonged heart rhythm.

If these warnings apply or have ever applied to you, please discuss with your doctor.

Use of ELEPSI® with food or drinks

ELEPSI® may be taken with or without food.

ELEPSI® with alcohol

As a safety precaution do not take ELEPSI® with alcohol, since ELEPSI® may cause dizziness or tiredness, which may worsen with alcohol.

Pregnancy

Please ask your doctor or pharmacist before taking this medicine.

It is not recommended to take ELEPSI® if you are pregnant, as the effects of ELEPSI® on pregnancy and the unborn baby are not known.

Tell your doctor immediately if you are pregnant or planning to become pregnant; he/she will decide if you should take ELEPSI®.

Breastfeeding

Please ask your doctor or pharmacist before taking this medicine.

It is not recommended to breast-feed your baby while taking ELEPSI®, as it is not known if ELEPSI® passes into the breast milk. If you are breast-feeding, please inform your doctor immediately; he/she will decide if you should take ELEPSI®.

Research has shown an increased risk of birth defects in children of women taking anti-epileptic medicines. On the other hand effective anti-epileptic therapy must not be interrupted since the worsening of the disease is harmful to both the mother and the unborn child.

Driving and using machines

ELEPSI[®] may cause dizziness or blurred vision. This may affect your ability to drive or operate any tools or machinery. You should not drive or use machines until you know whether this medicine affects your ability to perform these activities.

Important information about some of the ingredients of ELEPSI[®]

ELEPSI[®] contains lecithin (soya). If the patient is allergic to peanut or soya, do not take this medicinal product.

Other medicines and ELEPSI[®]

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is especially important if you take medicines to treat heart problems or if you are taking any medicine which can cause an abnormality on the ECG (electrocardiogram) called increased PR interval including carbamazepine, lamotrigine, pregabalin (medicines used to treat epilepsy) and medicines used to treat certain types of irregular heart beat or heart failure. If you are not sure if the medicines you are taking could have this effect, discuss this with your doctor.

Medicines such as fluconazole, itraconazole, ketoconazole (medicines used to treat fungal infections), ritonavir (a medicine used to treat HIV infection), clarithromycin, rifampicin (medicines used to treat bacterial infections) and St.John's wort (a medicine used to treat mild anxiety) could affect how the liver breaks down lacosamide.

If you are currently taking or have recently taken any prescription or non-prescription medicines, please inform your doctor or pharmacist.

3. How to take ELEPSI[®]?

• Instructions for appropriate use and dose/administration frequency:

Always take ELEPSI[®] exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Administration of a loading dose has not been studied in patients with status epilepticus.

ELEPSI[®] must be taken twice a day, once in the morning and once in the evening, at about the same time each day. ELEPSI[®] is used as a long term treatment.

The usual starting dose of ELEPSI[®] is 100 mg per day - taken twice a day – 50 mg in the morning and 50 mg in the evening. Your doctor may increase your daily dose every week by 100 mg, until you reach a so called maintenance dose between 200 mg and 400 mg per day, taken twice a day. You will use this maintenance dose for the long term treatment.

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

If you have any conditions affecting your kidneys your doctor may prescribe different doses.

- **Route and method of administration**

ELEPSI[®] tablet is for oral use only.

You should swallow the tablet with a glass of water. You may take it with or without food.

- **Age groups:**

Use in children:

Since the efficacy and safety of ELEPSI[®] in children and adolescents under 16 years of age have not been tested, treatment with ELEPSI[®] is not recommended in this age group.

Use in elderly

In older patients with impaired kidney functions, the prescribing physician may adjust ELEPSI[®] dose.

- **Special precautions for use:**

Renal impairment

No dose adjustment is necessary in patients with mild or moderate renal impairment (creatinine clearance >30 ml/min). In patients with severe renal impairment (creatinine clearance ≤ 30 ml/min) and in patients with end-stage renal disease, a maximum maintenance dose of 250 mg/day is recommended.

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

Treatment of patients with end-stage renal disease should be made with caution, since there is limited clinical experience and accumulation of a metabolite (with no known pharmacological activity).

In all patients with renal failure, dose titration should be made with caution

Hepatic impairment:

No dose adjustment is needed for patients with mild to moderate hepatic impairment. The dose titration in these patients should be performed with caution considering co-existing renal impairment.

ELEPSI[®] is prescribed for long-term treatment. You should continue taking ELEPSI[®] until your doctor decides to stop the treatment.

If you have an impression that the effect of ELEPSI[®] is too weak or too strong, talk to your doctor or pharmacist.

If you have taken more ELEPSI[®] than you should:

Talk to your doctor or pharmacist if you have taken more ELEPSI[®] than you should.

You may experience dizziness, sickness, vomiting, seizures, or heart symptoms. Do not drive.

If you forget to take ELEPSI®

If you miss a dose of ELEPSI® by a few hours, take it as soon as you remember. If it is close (less than 6 hours) to your next dose, don't take the missed tablet anymore. Just take ELEPSI® at the next time that you would normally take it.

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

Side effects that may occur when ELEPSI® treatment is stopped

- Do not stop taking ELEPSI® without talking to your doctor, as your symptoms may come back again or become worse.
- If your doctor decides to stop your treatment with ELEPSI®, he/she will instruct you about how you should decrease the dose step by step.
- If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. What are possible side effects?

Like all medicines, ELEPSI® may cause side effects in subjects who have hyper-sensitivity to its ingredients.

Nervous system side effects such as dizziness may be higher after a loading dose.

Side effects are categorized as follows according to their frequency of occurrence:

Very common : may affect more than 1 user in 10

Common : may affect 1 to 10 users in 100

Uncommon : may occur in less than 1 patient in 100 but more than 1 patient in 1000

Rare : may occur in less than 1 patient in 1000 but more than 1 patient in 10000

Very rare : may occur in less than 1 patient in 10000

Not known : frequency cannot be estimated from available data

Very common

- Dizziness
- Headache
- Nausea
- Double vision (diplopia)

Common:

- Depression
- Insomnia
- Mental confusion
- Decrease or absence of the sense of touch (hypoesthesia)
- Difficulty in articulation (dysarthria)
- Disturbed attention
- Difficulty in the coordination of movements
- Memory disturbance

- Sleepiness
- Shakiness
- Difficulty in thinking or finding the words
- Rapid and uncontrolled movements of the eyes (nystagmus)
- Tingling sensation (paresthesia)
- Balance disorder
- Blurred vision
- A feeling of spinning (vertigo)
- Buzzing, ringing or other noises in the ear (tinnitus)
- Vomiting
- Constipation
- Bloating
- Diarrhea
- Dyspepsia
- Dry mouth
- Itching
- Fall
- Bruise
- Skin wounds
- Rash
- Difficulty in sleeping
- Walking disorder
- Tiredness
- Unusual tiredness and weakness
- Feeling drunk
- Irritability
- Muscle spasms

Uncommon:

- Slow heart rate
- Heart conduction disorder
- Exaggerated feeling of wellbeing
- Allergic reaction to drug intake
- Liver function test abnormal
- Attempt to commit suicide
- Thoughts about suicide or hurting yourself
- Palpitations and/or rapid or irregular pulse
- Aggression
- Agitation
- Abnormal thinking and/or loss of touch with reality
- Serious allergic reaction which causes swelling of the face, throat, hand, feet, ankles, or lower legs
- Hives
- Hallucinations (Seeing and/or hearing things that are not real)

Not known

- Decrease in blood granulocyte count (agranülositoz)

- Severe hypersensitivity reactions (DRESS) (Redness and rash in the skin, facial swelling, disturbed blood counts, enlarged lymph nodes etc.)
- 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).

If get any side effects, talk to your doctor or pharmacist.

You should also inform your doctor or pharmacist if you get any side effects not listed in these instructions.

Reporting of side effects

If you experience any side effects listed or not listed in this leaflet, talk to your doctor, pharmacist, or nurse. Also, you can report the side effects to TUFAM (Turkish Pharmacovigilance Center) by calling at 0 800 314 00 08 or by clicking the “Drug Side Effect Reporting” icon at www.titck.gov.tr. By reporting these side effects, you will help collecting more information on the safety of this medicine.

5. How to store ELEPSI®

ELEPSI® should be kept in its original packing out of the reach and sight of children.
Store at room temperature below 25°C

Please use this product in accordance with the expiry date.

Keep it in its original package.

Do not use ELEPSI® after the expiry date on the packing.

If you notice any compromise in the product and/or its packing, do not use ELEPSI®.

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