

PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Lacomide 50 mg film-coated tablets

Lacomide 100 mg film-coated tablets

Lacomide 150 mg film-coated tablets

Lacomide 200 mg film-coated tablets

Each Lacomide film-coated tablet contains lacosamide 50 mg, 100 mg, 150 mg or 200 mg. For information regarding inactive ingredients see section 6 "Additional information".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any other questions, refer to the doctor or the pharmacist.

This medicine has been prescribed for treatment of your illness. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

Epilepsy is an illness characterized by recurring convulsion seizures. The medicine Lacomide is given when the state of epilepsy is such that the seizures are initially partial (involving only one side of the brain), but may develop into generalized seizures (that involve extensive areas on both sides of the brain).

Treatment with Lacomide is long-term. Do not stop the treatment without an explicit instruction from the doctor. Stopping the treatment may cause a recurrence or worsening of the disease symptoms. See section 3 in the subsection **"If you stop taking the medicine"**.

1. What is the medicine intended for?

- Lacomide is intended for use in adults, adolescents and children aged 4 years and older.
- Lacomide is indicated for the treatment of a certain type of epilepsy characterized by the occurrence of "partial-onset seizure with or without secondary generalization).
- Lacomide can be used alone or in combination with additional antiepileptic medicines.

Lacomide contains lacosamide, which belongs to the group of substances called "antiepileptic medicines". These medicines are used for treatment of epilepsy.

Therapeutic class: anticonvulsants.

2. Before using the medicine

ⓧ Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients this medicine contains (see section 6 "Additional information"). If you are uncertain whether you are allergic, please talk to your doctor.
- You have a certain type of heartbeat problem called second- or third-degree AV block. Do not take Lacomide if one of the conditions described above applies to you. If you are uncertain, talk to the doctor or pharmacist before taking the medicine.

ⓧ Special warnings regarding the use of the medicine:

The medicine should not be used without consulting a doctor before the beginning of treatment if:

- You have thoughts of self-harm or suicidal thoughts. A small number of people treated with anti-seizure medicines such as lacosamide, have had thoughts of self-harm or suicidal thoughts. If you have such thoughts at any time, tell your doctor immediately.
- You have a heart problem that affects your heartbeat and you often have a slow, rapid or irregular heartbeat (such as AV block, atrial fibrillation or atrial flutter).
- You have a severe heart disease such as heart failure or have had a heart attack.
- You are sometimes dizzy or sometimes fall. Lacomide may make you dizzy, which may increase the risk of accidental injury or fall. This means that you should take care until you get used to the effects of the medicine.

If one of the conditions described above applies to you (or if you are uncertain), talk to the doctor or pharmacist before taking Lacomide.

If you are taking Lacomide and you are experiencing symptoms of abnormal heartbeat (such as slow, rapid or irregular heartbeat, palpitations, shortness of breath, sensation of dizziness, fainting), seek medical advice immediately (see section 4).

ⓧ Children below 4 years of age:

Lacomide is not recommended for children under the age of 4 years, because it is still unknown whether Lacomide is effective and safe for children in this age group.

ⓧ Drug interactions:

If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist. It is especially important to inform the doctor or pharmacist if you are taking any of the following medicines that affect your heart, as Lacomide can also affect your heart:

- Medicines for treatment of heart problems.
- Medicines that can increase the PR interval on a heart scan (ECG or electrocardiogram), such as medicines for epilepsy or pain called carbamazepine, lamotrigine or pregabalin.
- Medicines used for the treatment of various types of irregular heartbeat or heart failure.

If one of the conditions described above applies to you (or if you are uncertain), talk to the doctor or pharmacist before taking Lacomide.

It is also especially important to inform the doctor or pharmacist if you are taking any of the following medicines, as they may increase or decrease the effect of Lacomide on your body:

- Medicines for fungal infections called fluconazole, itraconazole or ketoconazole.
- A medicine for HIV called ritonavir.
- Medicines for bacterial infections called clarithromycin or rifampicin.

• A herbal medicine used for the treatment of mild anxiety and depression called St. John's Wort. If one of the conditions described above applies to you (or if you are uncertain), talk to the doctor or pharmacist before taking Lacomide.

ⓧ Use of the medicine and food:

The medicine can be taken either with or without food.

ⓧ Use of the medicine and alcohol consumption:

As a safety precaution, do not take Lacomide with alcohol.

ⓧ Pregnancy, breastfeeding and fertility:

Women of childbearing age need to discuss the use of contraceptives with the doctor. Consult the doctor or pharmacist before starting treatment with the medicine if you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant.

It is not recommended to take Lacomide if you are pregnant as the effects of Lacomide on the pregnancy and the fetus are not known. It is not recommended to breastfeed your baby while taking Lacomide, as Lacomide passes into the breastmilk.

Consult the doctor immediately if you become pregnant or are planning to become pregnant. The doctor will help you decide whether you should take Lacomide or not.

Do not stop treatment without consulting your doctor first, as this may increase your seizures. A worsening of your disease may also harm your baby.

ⓧ Driving and operating machinery:

Do not drive, ride a bicycle or use any tools or machinery until you know how this medicine affects you. This is because Lacomide may make you feel dizzy or cause blurred vision.

3. How should you use the medicine?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.

Dosage

The dosage and treatment regimen will be determined by the doctor only.

- Take Lacomide twice a day – once in the morning and once in the evening
- Try to take the medicine at about the same time each day
- Swallow the Lacomide tablet with a glass of water

Usually, the treatment starts by taking a low dose each day. The doctor will slowly increase your dose over a period of several weeks. After you reach the dose that is suitable for you, which is called "maintenance dose", you will take the same dose each day. Lacomide is used as a long-term treatment. Continue taking Lacomide until your doctor tells you to stop.

How much to take

Listed below are the normal recommended doses of Lacomide for different age groups and different weights.

Your doctor may prescribe a different dose if you have kidney or liver problems.

Adolescents and children weighing 50 kg or more and adults

Taking Lacomide as a monotherapy:

The starting dose of Lacomide is usually 50 mg, twice a day.

The doctor may prescribe a starting dose of 100 mg Lacomide, twice a day.

The doctor may increase your dose (which is taken

twice a day) by 50 mg each week. This will be until you reach a maintenance dose between 100 mg and 300 mg, twice a day.

Taking Lacomide with other antiepileptic medicines:

The starting dose of Lacomide is usually 50 mg, twice a day.

The doctor may increase your dose (which is taken twice a day) by 50 mg each week. This will be until you reach a maintenance dose between 100 mg and 200 mg, twice a day.

If you weigh 50 kg or more, the doctor may decide to start Lacomide treatment with a single loading dose of 200 mg. 12 hours later, you will start taking your maintenance dose for the long term.

Children and adolescents weighing less than 50 kg:

The dose will be determined according to the body weight of the child or adolescent. Children will receive treatment with tablets only if they are able to swallow tablets and receive the appropriate dosage with the different tablet strengths.

Alternatively, as stated below in the "Crushing/halving/chewing" section, if necessary, the tablet may be crushed and swallowed immediately with water. If a different dosage is needed, consult the doctor to determine the appropriate dosage and form of administration. In Israel, there is also a registered preparation that contains lacosamide in a dosage form of solution for intravenous injection.

Do not exceed the recommended dose.

Method of use

Crushing/halving/chewing

Do not halve the tablets; there is no score line, therefore you cannot guarantee that both halves will be the same. In order to make swallowing easier, if necessary, the tablet can be crushed and swallowed immediately with water. The crushed tablet may have a bitter taste.

Duration of treatment

Lacomide is intended for long-term treatment. You should complete the treatment recommended by the doctor. Do not stop the treatment without an instruction from the doctor.

If you accidentally took a higher dosage

If you took an overdose or a child accidentally swallowed this medicine, refer to the doctor or to a hospital emergency room immediately and take the package of the medicine with you. Do not try to drive.

You may suffer from:

- Dizziness
- Nausea or vomiting
- Convulsions, heartbeat problems such as slow, rapid or irregular heartbeat, coma or a decrease in blood pressure accompanied by rapid heartbeat and sweating

If you forgot to take the medicine

- If you forgot to take a dose, and remembered within the first 6 hours of the scheduled dose, take the dose as soon as you remember.
- If you forgot to take a dose, and remembered beyond the first 6 hours of the scheduled dose, do not take the missed dose. Instead, take Lacomide at the next scheduled time that you need to take it.
- Never take two doses together to compensate for a forgotten dose!

If you stop taking the medicine

- Do not stop taking Lacomide without talking to your doctor, as your epilepsy may return or worsen.
- If your doctor decides to stop your treatment with Lacomide, he will tell you how to gradually decrease the dosage step by step.

Follow the treatment as recommended by the doctor.

Even if there is an improvement in your health condition, do not stop treatment with the medicine without consulting the doctor.

Do not take medicines in the dark! Check the label and the dose every time you take a medicine. Wear glasses if you need them. If you have any other questions regarding the use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, using Lacomide may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Nervous system-related side effects, such as dizziness, may be higher after a loading dose. Talk to your doctor or pharmacist if you experience any of the following effects:

Very common side effects – side effects that occur in more than one user out of ten:

- Headache
 - Feeling of dizziness or nausea
 - Double vision (diplopia)
- Common side effects – side effects that occur in 1-10 users out of 100:**

- Balance problems, tremor, tingling (paresthesia) or muscle spasms, falling easily and getting bruises
- Problems with memory, thinking or expressing oneself, confusion
- Rapid and uncontrollable eye movements (nystagmus), blurred vision
- Sensation of dizziness (vertigo), feeling drunk
- Vomiting, dry mouth, constipation, digestive difficulties, excessive gas in the stomach or bowels, diarrhea
- A decrease in sensation threshold or sensitivity, difficulty pronouncing words, decrease in concentration
- Noise in the ear such as buzzing, ringing or beeping
- Nervousness, sleep disturbances, depression
- Sleepiness, tiredness or weakness (asthenia)
- Itch, rash

Uncommon side effects – side effects that occur in 1-10 users out of 1,000:

- Slow heartbeat, palpitations, irregular heartbeat or other changes in the electrical activity of the heart (conduction disorder)
- Exaggerated feeling of physical and mental wellbeing, seeing and/or hearing non-existing things
- Allergic reaction to medicine intake, hives
- Blood tests may show abnormal liver function, hepatic impairment
- Thoughts of self-harm, suicidal thoughts or attempting to self-harm: tell your doctor immediately
- Feeling angry or agitated
- Abnormal thinking or losing touch with reality

- Serious allergic reaction accompanied by swelling of the face, throat, hands, feet, ankles or shins
- Fainting
- Abnormal involuntary movements (dyskinesia)
- Difficulties in coordinating movements or walking

Side effects with unknown frequency (effects whose frequency has not yet been determined):

- Anabnormal rapid heartbeat (ventricular tachycardia)
- Sore throat, high fever and higher risk of suffering from infections. Blood tests may show a severe decrease in a specific type of white blood cells (agranulocytosis)

- A severe skin reaction which may include: high fever and other flu-like symptoms, facial rash, widespread rash, swollen glands (enlarged lymph nodes). Blood tests may show increased levels of liver enzymes, increase in certain white blood cells (eosinophilia)
- An extensive rash with blisters and peeling of the skin, especially around the mouth, nose, eyes and genitalia (Stevens-Johnson syndrome), and a more severe form of skin peeling in more than 30% of the body surface (toxic epidermal necrolysis)

- Convulsions

Additional side effects in children:

- Fever, runny nose (nasopharyngitis), sore throat (pharyngitis), eating less than usual, changes in behavior, not behaving as normal, lack of energy (lethargy).
- Feeling sleepy is a very common side effect in children and may affect more than 1 out of 10 children.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not indicated in the leaflet, consult with the doctor. Reporting side effects

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: <https://sideeffects.health.gov.il>.

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (EXP.) appearing on the package and blister. The expiry date refers to the last day of that month.
- Store at a temperature below 30°C.
- Do not discard medicines via wastewater or the trash. Ask the pharmacist how to dispose of medicines that are not in use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient the medicine also contains:

Silicified Microcrystalline Cellulose, Microcrystalline Cellulose, Low-substituted Hydroxypropyl Cellulose, Crospovidone, Magnesium Stearate, Hydroxypropyl Cellulose.

In addition, the coating contains:

Lacomide 50 mg:

Opadry II White Ready-to-use blend (Qualitative composition: Polyvinyl Alcohol - partially hydrolyzed, Titanium Dioxide, Macrogol, Talc), Opadry II Purple Ready-to-use blend (Qualitative composition: Polyvinyl Alcohol - partially hydrolyzed, Titanium Dioxide, Macrogol, Talc, Red iron oxide, Black iron oxide).

Lacomide 100 mg:

Opadry II White Ready-to-use blend (Qualitative composition: Polyvinyl Alcohol - partially hydrolyzed, Titanium Dioxide, Macrogol, Talc).

Lacomide 150 mg:

Opadry II Purple Ready-to-use blend (Qualitative composition: Polyvinyl Alcohol - partially hydrolyzed, Titanium Dioxide, Macrogol, Talc, Red iron oxide, Black iron oxide).

Lacomide 200 mg:

Opadry II Yellow Ready-to-use blend (Qualitative composition: Polyvinyl Alcohol - partially hydrolyzed, Titanium Dioxide, Macrogol, Talc, Iron oxide Yellow).

What does the medicine look like and what are the contents of the package?

Lacomide 50 mg tablets are light-pinkish purple, elliptical, film-coated tablets, debossed with "L50" on one side.

Lacomide 100 mg tablets are white, elliptical, film-coated tablets, debossed with "L100" on one side. Lacomide 150 mg tablets are purple, elliptical, film-coated tablets, debossed with "L150" on one side. Lacomide 200 mg tablets are yellow, elliptical, film-coated tablets, debossed with "L200" on one side.

The medicine is marketed in a blister package containing 10, 14, 20, 50, 56 or 60 film-coated tablets. Not all package sizes may be marketed.

Name and address of the manufacturer/ marketing authorization holder: CTS Chemical Industries Ltd., 3 Hakidma St., Kiryat Malachi. **Registration numbers of the medicines in the National Drug Registry of the Ministry of Health:**

Lacomide 50 mg: 171-63-36265-00

Lacomide 100 mg: 171-64-36266-00

Lacomide 150 mg: 171-65-36267-00

Lacomide 200 mg: 171-66-36268-00

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