

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Lacosamide Teva 50 mg Lacosamide Teva 100 mg Lacosamide Teva 150 mg Lacosamide Teva 200 mg

Film-coated tablets

Composition

Each Lacosamide Teva film-coated tablet contains 50 mg, 100 mg, 150 mg or 200 mg lacosamide.

For information about inactive ingredients and allergens, see section 2 "Important information about some of the ingredients of this medicine" and section 6 "Additional information".

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist. This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

Epilepsy is an illness characterized by recurrent fits (seizures). Lacosamide Teva is administered when the state of epilepsy in which the fits are initially partial (involving only one side of the brain), but may develop into generalized fits (involving extensive areas on both sides of the brain).

Treatment with Lacosamide Teva is long-term. Do not stop treatment without an explicit instruction from the doctor. Discontinuation of treatment may cause a recurrence or worsening of disease symptoms. See section "If you stop taking the medicine".

1. What is this medicine intended for?

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

Lacosamide Teva contains lacosamide, which belongs to a group of medicines called "antiepileptic medicines". These medicines are used to treat epilepsy.

Therapeutic group: Anticonvulsant.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients in this medicine (see "Important information about some of the ingredients of this medicine" in this section and "Additional information" in section 6).
- You have a certain type of heart beat problem called second- or third-degree AV block.

Do not take Lacosamide Teva if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

Special warnings about using this medicine

Do not use the medicine without consulting a doctor before starting treatment

- If you have thoughts of self-harm or suicidal thoughts. A small number of people treated with antiepileptic medicines such as lacosamide have had thoughts of self-harm or suicidal thoughts. If you have any of these thoughts at any time, tell your doctor immediately.
- If you have a heart problem that affects your heart beat and you often have a slow, fast or irregular heart beat (such as AV block, atrial fibrillation or atrial flutter).
- If you have a severe heart disease such as heart failure or have had a heart attack.
- If you are often dizzy or fall. Lacosamide Teva 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 this medicine.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Lacosamide Teva.

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

Children below the age of 4 years

Lacosamide Teva is not recommended for children aged under 4 years. This is because it is yet unknown whether Lacosamide Teva is effective and safe for children in this age group.

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.

It is especially important to inform the doctor or pharmacist if you are taking any of the following medicines that affect your heart, because Lacosamide Teva can also affect your heart:

- Medicines to treat heart problems.
- Medicines which 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 to treat various types of irregular heart beat or heart failure.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Lacosamide Teva.

It is also especially important to inform the doctor or pharmacist if you are taking any of the following medicines, because they may increase or decrease the effect of Lacosamide Teva 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 to treat mild anxiety and depression called St. John's wort.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Lacosamide Teva.

Using this medicine and food

The medicine may be taken with or without a meal.

Using this medicine and alcohol consumption

As a safety precaution do not take Lacosamide Teva with alcohol.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or planning to become pregnant, ask your doctor or pharmacist for advice before taking this medicine.

It is not recommended to take Lacosamide Teva if you are pregnant or breastfeeding, as the effects of Lacosamide Teva on pregnancy and the unborn baby or the newborn child are not known. It is also not known whether Lacosamide Teva passes into breast milk. Consult your doctor immediately if you get pregnant or are planning to become pregnant. The doctor will help you decide if you should take Lacosamide Teva or not.

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

Driving and using machines

Do not drive, cycle or use any tools or machines until you know how this medicine affects you. This is because Lacosamide Teva may make you feel dizzy or cause blurred vision.

Important information about some of the ingredients of this medicine

Lacosamide Teva 100 mg and 150 mg tablets contain the ingredient FD&C yellow #6/sunset yellow FCF aluminium lake (E110), which may cause allergic reactions.

Lacosamide Teva 200 mg tablets contain the ingredient Ponceau 4R aluminium lake (E124), which may cause allergic reactions.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are unsure about your dosage or treatment regimen.

Dosage

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

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

You will usually start by taking a low dose each day and your doctor will slowly increase it over a number of weeks. When you reach the dose that is suitable for you, this is called the "maintenance dose", you then take the same amount each day. Lacosamide Teva is used as a long term treatment. You should continue to take Lacosamide Teva until your doctor tells you to stop.

How much to take

Listed below are the normal recommended doses of Lacosamide Teva for different age groups and weights. Your doctor may prescribe a different dose if you have problems with your kidneys or with your liver.

Adolescents and children weighing 50 kg or more and adults

When you take Lacosamide Teva as monotherapy:

The usual starting dose of Lacosamide Teva is 50 mg twice a day. Your doctor may prescribe a starting dose of 100 mg Lacosamide Teva twice a day.

Your doctor may increase your dose (administered twice daily) every week by 50 mg until you reach a maintenance dose between 100 mg and 300 mg twice a day.

When you take Lacosamide Teva with other antiepileptic medicines:

The usual starting dose of Lacosamide Teva is 50 mg twice a day.

Your doctor may increase your dose (administered twice daily) every week by 50 mg until you reach a maintenance dose between 100 mg and 200 mg twice a day.

If you weigh 50 kg or more, your doctor may decide to start Lacosamide Teva treatment with a single loading dose of 200 mg. You will then start taking your ongoing maintenance dose 50 mg later.

Children and adolescents weighing less than 50 kg

The dose depends on their body weight. 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, and as appears later in the "crushing/splitting/chewing" section, if necessary, the tablet may be crushed and immediately swallowed with water. If a different dosage is required, consult with your doctor to determine the appropriate dosage and form of administration. The medicine is also registered in Israel as a solution for intravenous injection.

Do not exceed the recommended dose.

Manner of use

Crushing/splitting/chewing

Do not split the tablets. There is no score line, therefore you cannot guarantee uniformity of both the parts. To make swallowing easier, if necessary, the tablet may be crushed and immediately swallowed with water. The crushed tablet may have a bitter taste.

Duration of treatment

Lacosamide Teva is intended for long-term treatment.

You should complete the treatment recommended by the doctor. Do not stop the treatment without the doctor's instruction.

If you have accidentally taken a higher dose

If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately contact a doctor or go to a hospital emergency room and bring the medicine package with you. Do not try to drive.

You may experience:

- Dizziness.
- Nausea or vomiting.
- Seizures, heart beat problems such as slow, fast or irregular heart beat, coma or a decrease in blood pressure with rapid heartbeats and sweating.

If you forget to take the medicine

- If you forgot to take a dose within the first 6 hours of the scheduled dose time, take it as soon as you remember.
- If you forgot to take a dose beyond the first 6 hours of the scheduled dose time, do not take the missed dose anymore. Instead take Lacosamide Teva at the next time that you would normally take it.
- Never take a double dose to make up for a forgotten dose!

If you stop taking the medicine

- Do not stop taking Lacosamide Teva without talking to your doctor, since your epilepsy may return again or worsen.
- If your doctor decides to stop your treatment with Lacosamide Teva, he will tell you how to decrease the dose step by step.

Adhere to the treatment as recommended by your doctor.

Even if your health improves, do not stop taking this medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and dose every time you take a medicine. Wear glasses if you need them. If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Lacosamide Teva may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Nervous system 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:

Very common side effects (affect more than 1 in 10 patients):

- Headache.
- Feeling of dizziness or nausea.
- Double vision (diplopia).

Common side effects (affect up to 1 in 10 patients):

- Problems in keeping balance, tremor, tingling (paresthesia) or muscle spasms, falling easily and getting bruises.
- Problems with memory, thinking or wording, confusion.
- Rapid and uncontrollable movements of the eyes (nystagmus), blurred vision.
- A spinning sensation (vertigo), feeling drunk.
- Vomiting, dry mouth, constipation, indigestion, excessive gas in the abdomen or bowels, diarrhea.
- Decreased threshold of sensation or sensitivity, difficulty in articulating words, decrease in concentration.
- Noise in the ear such as buzzing, ringing or wheezing.
- Irritability, sleep disorders, depression.
- Sleepiness, tiredness or weakness (asthenia).
- Itching, rash.

Uncommon side effects (affect up to 1 in 100 patients):

- Slow heart rate, palpitations, irregular pulse or other changes in the electrical activity of your heart (conduction disorder).
- Exaggerated feeling of physical and mental wellbeing, seeing and/or hearing things which do not exist.
- Allergic reaction to medicine intake, hives.
- Blood tests may show abnormal liver function, liver injury.
- Thoughts of self-harm or suicidal thoughts or attempting 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 lower legs.
- Fainting.
- Abnormal involuntary movements (dyskinesia).
- Difficulty in coordinating movement or walking.

Side effects of unknown frequency (the frequency of these effects cannot be determined from the available data):

- Abnormal heartbeat (ventricular tachycardia).
- Sore throat, high fever and a higher risk of developing infections. Blood tests may show a severe decrease in a specific type of white blood cells (agranulocytosis).
- A serious skin reaction which may include: high fever and other flu-like symptoms, a rash on the face, widespread rash, swollen glands (enlarged lymph nodes). Blood tests may show increased levels of liver enzymes, increased level of a type of white blood cells (eosinophilia).
- A widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome), and a more severe form of skin peeling in more than 30% of the body surface (Toxic epidermal necrolysis).
- Seizure.

Additional side effects in children

Common side effects (affect up to 1 in 10 children):

- Runny nose (nasopharyngitis).
- Fever.
- Sore throat (pharyngitis).
- Eating less than usual.

Uncommon side effects (affect up to 1 in 100 children):

- Feeling sleepy or lack of energy (lethargy).

Side effects of unknown frequency (the frequency of these effects cannot be determined from the available data):

- Changes in behavior, not behaving normally.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link:

<https://sideeffects.health.gov.il>

5. How to store the medicine?

Avoid poisoning! To avoid poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use the medicine after the expiry date (exp. date) which is stated on the package and blister. The expiry date refers to the last day of that month.

Storage conditions:

Store below 25°C.

Do not throw away any medicine via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, this medicine also contains: Cellulose microcrystalline, crospovidone, hydroxypropylcellulose - low substituted, hydroxypropylcellulose, silica colloidal anhydrous, magnesium stearate

The film-coating contains: Polivinyl alcohol, titanium dioxide, polyethylene glycol, talc

In addition, the film-coating contains:

Lacosamide Teva 50 mg:

Red iron oxide, black iron oxide, yellow iron oxide

Lacosamide Teva 100 mg:

Yellow iron oxide, Quinoline yellow, FD&C yellow #6/sunset yellow FCF aluminium lake (E110)

Lacosamide Teva 150 mg:

Yellow iron oxide, FD&C yellow #6/sunset yellow FCF aluminium lake (E110)

Lacosamide Teva 200 mg:

FD&C blue/brilliant blue FCF aluminium lake, Ponceau 4R aluminium lake (E124)

What the medicine looks like and contents of the pack

Lacosamide Teva 50 mg: pink oval tablet, debossed "50" on one side and plain on the other side.

Lacosamide Teva 100 mg: yellow oval tablet, debossed "100" on one side and plain on the other side.

Lacosamide Teva 150 mg: orange oval tablet, debossed "150" on one side and plain on the other side.

Lacosamide Teva 200 mg: blue oval tablet, debossed "200" on one side and plain on the other side.

Blister packs: Each pack contains 14, 56, 60, 98, 112, 168, 200 or 210 tablets

Bottle packs: Each pack contains 60 tablets

Not all pack sizes may be marketed.

Manufacturer and registration holder's name and address

Teva Ltd.,
124 Dvora HaNevi'a St.,
Tel Aviv 6944020.

This leaflet was revised in May 2022 according to MOH guidelines.

Registration numbers of the medicines in the National Drug Registry of the Ministry of Health:

Lacosamide Teva 50 mg: 163-96-35487

Lacosamide Teva 100 mg: 163-97-35488

Lacosamide Teva 150 mg: 163-98-35489

Lacosamide Teva 200 mg: 163-99-35490