Medication Guide

Lacosamide (la-KOE-sa-mide)
Tablets, for oral use, USP CV

Read this Medication Guide before you start taking lacosamide tablets and each time you get a refill. There may be new information. This Medication Guide describes important safety information about lacosamide tablets. This information does not take the place of talking to your healthcare provider about your medical condition or treatment.

What is the most important information I should know about lacosamide tablets?
Do not stop taking lacosamide tablets without first talking to your healthcare provider.
Stopping lacosamide tablets suddenly can cause serious problems. Stopping seizure medicine suddenly in a patient who has epilepsy can cause seizures that will not stop (status epilepticus).

Lacosamide tablets can cause serious side effects, including:

1. **Like other antiepileptic drugs, lacosamide tablets may cause suicidal thoughts or actions in a very small number of people, about 1 in 500.**

   Call a healthcare provider right away if you have any of these symptoms, especially if they are new, worse, or worry you:
   - thoughts about suicide or dying
   - attempt to commit suicide
   - new or worse depression
   - new or worse anxiety
   - feeling agitated or restless
   - panic attacks
   - trouble sleeping (insomnia)
   - new or worse irritability
   - acting aggressive, being angry, or violent
   - acting on dangerous impulses
   - an extreme increase in activity and talking (mania)
   - other unusual changes in behavior or mood

How can I watch for early symptoms of suicidal thoughts and actions?
- Pay attention to any changes, especially sudden changes, in mood, behaviors, thoughts, or feelings.
- Keep all follow-up visits with your healthcare provider as scheduled.
- Call your healthcare provider between visits as needed, especially if you are worried about symptoms.
- Suicidal thoughts or actions can be caused by things other than medicines. If you have suicidal thoughts or actions, your healthcare provider may check for other causes.

2. Lacosamide tablets may cause you to feel dizzy, have double vision, feel sleepy, or have problems with coordination and walking. Do not drive, operate heavy machinery, or do other dangerous activities until you know how lacosamide tablets affects you.
3. Lacosamide tablets may cause you to have an irregular heartbeat or may cause you to faint. In rare cases, cardiac arrest has been reported. Call your healthcare provider right away if you:
   - have a fast, slow, or pounding heartbeat or feel your heart skip a beat
   - feel lightheaded
   - fainted or if you feel like you are going to faint
   - have shortness of breath
   - have chest pain

   If you have fainted or feel like you are going to faint you should lay down with your legs raised.
4. Lacosamide tablets are a federally controlled substance (CV) because it can be abused or lead to drug dependence. Keep your lacosamide tablets in a safe place, to protect it from theft. Never give your lacosamide tablets to anyone else, because it may harm them. Selling or giving away this medicine is against the law.

What are lacosamide tablets?
Lacosamide tablets are a prescription medicine used:
- to treat partial-onset seizures in people 1 month of age and older.
- with other medicines to treat primary generalized tonic-clonic seizures in people 4 years of age and older.

It is not known if lacosamide tablets are safe and effective for partial-onset seizures in children under 1 month of age or for primary generalized tonic-clonic seizures in children under 4 years of age.

What should I tell my healthcare provider before taking lacosamide tablets?
Before you take lacosamide tablets, tell your healthcare provider about all of your medical conditions, including if you:
- have or have had depression, mood problems or suicidal thoughts or behavior.
- have heart problems.
- have kidney problems.
- have liver problems.
- have abused prescription medicines, street drugs or alcohol in the past.
- are pregnant or plan to become pregnant. It is not known if lacosamide tablets can harm your unborn baby. Tell your healthcare provider right away if you become pregnant while taking lacosamide tablets. You and your healthcare provider will decide if you should take lacosamide tablets while you are pregnant.
  - If you become pregnant while taking lacosamide tablets, talk to your healthcare provider about registering with the North American Antiepileptic Drug Pregnancy Registry. You can enroll in this registry by calling 1-888-233-2334. The purpose of this registry is to collect information about the safety of antiepileptic medicine during pregnancy.
- are breastfeeding or plan to breastfeed. lacosamide passes into breast milk.
  - Breastfeeding during treatment with lacosamide tablets may cause your baby to have more sleepiness than normal. If this happens, contact your baby's healthcare provider.
  - Talk to your healthcare provider about the best way to feed your baby if you take lacosamide tablets.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Taking lacosamide tablets with certain other medicines may cause side effects or affect how well they work. Do not start or stop other medicines without talking to your healthcare provider. Know the medicines you take. Keep a list of them and show it to your healthcare provider and pharmacist each time you get a new medicine.

How should I take lacosamide tablets?

- Take lacosamide tablets exactly as your healthcare provider tells you.
- Your healthcare provider will tell you how many lacosamide tablets to take and when to take it.
- Your healthcare provider may change your dose if needed.
- Do not stop lacosamide tablets without first talking to a healthcare provider. Stopping lacosamide tablets suddenly in a patient who has epilepsy can cause seizures that will not stop (status epilepticus).
- Lacosamide tablets may be taken with or without food.
- Swallow lacosamide tablets whole with liquid. Do not cut lacosamide tablets.
- If you take too much lacosamide tablets, call your healthcare provider or local Poison Control Center right away.

What should I avoid while taking lacosamide tablets?

Do not drive, operate heavy machinery, or do other dangerous activities until you know how lacosamide tablets affects you. Lacosamide tablets may cause you to feel dizzy, have double vision, feel sleepy, or have problems with coordination and walking.

What are the possible side effects of lacosamide tablets?

- See "**What is the most important information I should know about lacosamide tablets**?"

Lacosamide tablets may cause other serious side effects including:

- **A serious allergic reaction that may affect your skin or other parts of your body such as your liver or blood cells.** Call your healthcare provider right away if you have:
  - a skin rash, hives
  - fever or swollen glands that do not go away
  - shortness of breath
  - tiredness (fatigue)
  - swelling of the legs
  - yellowing of the skin or whites of the eyes
  - dark urine

The most common side effects of lacosamide tablets include:

- double vision
- headache
- dizziness
- nausea
- sleepiness

These are not all of the possible side effects of lacosamide tablets. For more information ask your healthcare provider or pharmacist. Tell your healthcare provider about any side effect that bothers you or that does not go away. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store lacosamide tablets?

- Store lacosamide tablets between 20°C to 25°C (68°F to 77°F).
- Lacosamide tablets come in child-resistant bottles of 30 tablets and 60 tablets.

Keep lacosamide tablets and all medicines out of the reach of children.

General Information about the safe and effective use of lacosamide tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use lacosamide tablets for a condition for which it was not prescribed. Do not give lacosamide tablets to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about lacosamide tablets. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about lacosamide tablets that is written for health professionals.

For more information, call Glenmark Pharmaceuticals Inc., USA at 1 (888) 721-7115.

What are the ingredients in lacosamide tablets?

Active ingredient: lacosamide

Tablet inactive ingredients: colloidal silicon dioxide, crospovidone, hydroxypropyl cellulose, hypromellose, low-substituted hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, talc, titanium dioxide and additional ingredients listed below:

- **50 mg tablets**: red iron oxide, black iron oxide, FD&C Blue #2/indigo carmine aluminum lake
- **100 mg tablets**: yellow iron oxide
- **150 mg tablets**: yellow iron oxide, red iron oxide, black iron oxide
- **200 mg tablets**: FD&C Blue #2/indigo carmine aluminum lake.

Distributed by:

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www.glenmarkpharma-us.com

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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