

Medication Guide

Lacosamide (la-KOE-sa-mide) Oral Solution, CV

Read this Medication Guide before you start taking lacosamide oral solution and each time you get a refill. There may be new information. This Medication Guide describes important safety information about lacosamide oral solution. 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 oral solution?

Do not stop taking lacosamide oral solution without first talking to your healthcare provider.

Stopping lacosamide oral solution suddenly can cause serious problems.

Lacosamide oral solution can cause serious side effects, including:

- 1. Like other antiepileptic drugs, lacosamide oral solution 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.

- **Do not stop lacosamide oral solution without first talking to a healthcare provider.** Stopping lacosamide oral solution suddenly can cause serious problems. Stopping seizure medicine suddenly in a patient who has epilepsy can cause seizures that will not stop (status epilepticus).
2. Lacosamide oral solution 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 oral solution affects you.
 3. Lacosamide oral solution may cause you to have an irregular heartbeat or may cause you to faint. Call your healthcare provider if you have:
 - fast, slow, or pounding heartbeat
 - shortness of breath
 - feel lightheaded
 - fainted or if you feel like you are going to faint

If you have fainted or feel like you are going to faint you should lay down with your legs raised.

4. Lacosamide oral solution is a federally controlled substance (C-V) because it can be abused or lead to drug dependence. Keep your lacosamide oral solution in a safe place, to protect it from theft. Never give your lacosamide oral solution to anyone else, because it may harm them. Selling or giving away this medicine is against the law.

What is lacosamide oral solution?

Lacosamide oral solution is a prescription medicine that can be used with other medicines to treat partial-onset seizures in people 17 years of age and older.

It is not known if lacosamide oral solution is safe and effective in children under 17 years of age.

What should I tell my healthcare provider before taking lacosamide oral solution?

Before you take lacosamide oral solution, tell your healthcare provider, 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
 - have any other medical problems
 - are pregnant or plan to become pregnant. It is not known if lacosamide can harm your unborn baby. Tell your healthcare provider right away if you become pregnant while taking lacosamide oral solution. You and your healthcare provider will decide if you should take lacosamide oral solution while you are pregnant.
- If you become pregnant while taking lacosamide oral solution, 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. It is not known if lacosamide passes into your breast milk or if it can harm your baby. Talk to your healthcare provider about the best way to feed your baby if you take lacosamide oral solution.

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

Taking lacosamide oral solution 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 oral solution?

- Take lacosamide oral solution exactly as your healthcare provider tells you.
- Your healthcare provider will tell you how much lacosamide oral solution to take and when to take it.
- Your healthcare provider may change your dose if needed.
- Do not stop lacosamide oral solution without first talking to a healthcare provider. Stopping lacosamide oral solution suddenly in a patient who has epilepsy can cause seizures that will not stop (status epilepticus).
- Lacosamide oral solution may be taken with or without food.
- If your healthcare provider has prescribed lacosamide oral solution, be sure to ask your pharmacist for a medicine dropper or medicine cup to help you measure the correct amount of lacosamide oral solution. Do not use a household teaspoon. Ask your pharmacist for instructions on how to use the measuring device the right way.
- If you take too much lacosamide oral solution, call your healthcare provider or local Poison Control Center right away.

What should I avoid while taking lacosamide oral solution?

Do not drive, operate heavy machinery, or do other dangerous activities until you know how lacosamide oral solution affects you. Lacosamide oral solution 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 oral solution?

See “What is the most important information I should know about lacosamide oral solution?”.

Lacosamide oral solution may cause other serious side effects including:

Lacosamide oral solution may cause 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, swelling of the legs, yellowing of the skin or whites of the eyes, or dark urine.

The most common side effects of lacosamide oral solution include:

- double vision
- headache
- dizziness
- nausea

These are not all of the possible side effects of lacosamide oral solution. 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 healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store lacosamide oral solution?

- Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F).
- Do not freeze lacosamide oral solution.
- Throw away any lacosamide oral solution 7 weeks after you first open the bottle that has not been used.

Keep lacosamide oral solution and all medicines out of the reach of children

General Information about the safe and effective use of lacosamide oral solution.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use lacosamide oral solution for a condition for which it was not prescribed. Do not give lacosamide oral solution 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 oral solution. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about lacosamide oral solution that is written for health professionals.

For more information, go to www.amneal.com or call 1-877-835-5472.

What are the ingredients in lacosamide oral solution?

Active ingredient: lacosamide

Oral solution inactive ingredients: acesulfame potassium, anhydrous citric acid, flavor, glycerin, methylparaben, polyethylene glycol, purified water, sodium carboxymethylcellulose, sodium chloride and sorbitol solution.

Sodium hydroxide or hydrochloric acid may be added for adjustment of pH.

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Distributed by:

Anneal Pharmaceuticals
Bridgewater, NJ 08807

Rev. 03-2016-00

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