

MEDICATION GUIDE

Lacosamide (la koe´ sa mide) Injection, USP, CV for intravenous use

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

Do not stop taking lacosamide injection without first talking to your healthcare provider. Stopping lacosamide injection 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 injection can cause serious side effects, including:

1. **Like other antiepileptic drugs, lacosamide injection 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 injection 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 affects you.
 3. Lacosamide 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
 - have shortness of breath
 - have chest pain
 - feel lightheaded
 - fainted or if you feel like you are going to faintIf you have fainted or feel like you are going to faint you should lay down with your legs raised.
 4. Lacosamide injection is a federally controlled substance (CV) because it can be abused or lead to drug dependence. Keep your lacosamide injection in a safe place, to protect it from theft. Never give your lacosamide injection to anyone else, because it may harm them. Selling or giving away this medicine is against the law.

What is lacosamide injection?

Lacosamide injection is a prescription medicine used:

- to treat partial-onset seizures in people 17 years of age and older.

It is not known if lacosamide injection is safe and effective for partial-onset seizures in children under 1 month of age.

What should I tell my healthcare provider before taking lacosamide injection?

Before you take lacosamide injection, 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 injection can harm your unborn baby. Tell your healthcare provider right away if you become pregnant while taking lacosamide injection. You and your healthcare provider will decide if you should take lacosamide injection while you are pregnant.
 - If you become pregnant while taking lacosamide injection, 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 injection 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 injection.

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

- Taking lacosamide 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 injection?

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

What should I avoid while taking lacosamide injection?

Do not drive, operate heavy machinery, or do other dangerous activities until you know how lacosamide injection affects you.

Lacosamide injection 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 injection?

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

Lacosamide injection 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 injection include:

- double vision
- headache
- dizziness
- nausea
- sleepiness

These are not all of the possible side effects of lacosamide. 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 injection?

- Store lacosamide injection at room temperature between 68°F to 77°F (20°C to 25°C).
- Do not freeze lacosamide injection.

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

General Information about the safe and effective use of lacosamide injection

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

What are the ingredients in lacosamide injection? Active ingredient: lacosamide

Injection inactive ingredients: sodium chloride (7.6 mg/mL), water for injection, hydrochloric acid (for pH adjustment).

Pediatric use information is approved for UCB, Inc.'s VIMPAT® (lacosamide) injection. However, due to UCB, Inc.'s marketing exclusivity rights, this drug product is not labeled with that information.

Rx Only

**APOTEX INC.
LACOSAMIDE INJECTION, USP
200 mg/ 20mL**

Manufactured by:

Maiva Pharma Pvt. Ltd.
No 32, Sipcot Industrial
Complex, Phase I, Hosur,
Tamilnadu 635126,
India (IND)

Manufactured for:

Apotex Corp.
Weston, Florida
USA 33326

Revised: October 2023

Revision: 6

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