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 if you feel lightheaded, have chest pain, have shortness of breath, feel lightheaded, or feel like you are going to faint.

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 affect 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
   - have shortness of breath
   - have chest pain
   - feel lightheaded
   - 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 is 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 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 should be taken exactly as prescribed. Your healthcare provider will tell you how many lacosamide tablets to take and when to take it. It is important to take lacosamide tablets at the same time each day.

Tell your healthcare provider if you have heart problems.

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 liver problems.
- have kidney problems.
- have abused prescription medicines, street drugs or alcohol in the past.
- have had a stroke.
- have liver disease.
- have kidney disease.
- have or have had a high blood pressure.
- have or have had a low blood pressure.
- have or have had high cholesterol.
- have or have had any condition that can affect your heart or blood vessels.
- have or have had a heart attack, heart failure, or other serious heart condition.
- have or have had a seizure.
- have or have had a mental health condition.
- have or have had any unusual or不良的 change in behavior or mood.
- are pregnant or plan to become pregnant. It is not known if lacosamide tablets can harm your unborn baby. Tell your healthcare provider 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.
- 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 tablets.
- are taking any other prescription or nonprescription medicines, vitamins, or herbal supplements.

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

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 many 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 at 20°C to 25°C (68°F to 77°F).

Lacosamide tablets come in a child-resistant package.

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.

What are the ingredients in lacosamide tablets?

Active ingredient: lacosamide

Inactive ingredients: Microcrystalline cellulose, low substituted hydroxypropyl cellulose, crospovidone, hydroxypropyl cellulose, colloidal silicon dioxide, magnesium stearate, polyvinyl alcohol, talc, titanium dioxide, polyethylene glycol, soya lecithin and additional ingredients listed below:

- 50 mg tablets: red iron oxide, FD&C Blue #2 and black iron oxide
- 100 mg tablets: yellow iron oxide
- 150 mg tablets: yellow iron oxide, red iron oxide and black iron oxide
- 200 mg tablets: FD&C Blue #2

Additional pediatric use information is approved for UCB, Inc.’s VIMPAT™ (lacosamide) tablets. However, due to UCB, Inc.’s marketing exclusivity rights, this drug product is not labeled with that pediatric information

Distributed by:
Sun Pharmaceutical Industries, Inc.
Cranbury, NJ 08512

Manufactured by:
Sun Pharmaceutical Industries Ltd.

For more information, call 1-800-818-4555.

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