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Lacosamide Injection

pronounced as (la koe' sa mide)

Why is this medication prescribed?

Lacosamide injection is used to control partial onset seizures (seizures that involve only one part of the brain) in adults and children 1 month of age and older who cannot take oral medications. Lacosamide injection is also used in combination with other medications to control primary generalized tonic-clonic seizures (formerly known as a grand mal seizure; seizure that involves the entire body) in adults and children 4 years of age and older who cannot take oral medications. Lacosamide injection is in a class of medications called anticonvulsants. It works by decreasing abnormal electrical activity in the brain.

How should this medicine be used?

Lacosamide injection comes as a solution (liquid) to be given intravenously (into a vein). It is usually injected slowly over a period of 30 to 60 minutes in children and adults, or over 15 minutes in adults if necessary. It is usually given twice a day in children or adults or 3 times daily for children weighing 6 kg (13 pounds) or less for as long as you are unable to take lacosamide tablets or oral solution by mouth.

You may receive lacosamide injection in a hospital or you may use the medication at home. If you will be using lacosamide injection at home, your health care provider will show you how to infuse the medication. Be sure that you understand these directions, and ask your health care provider if you have any questions. Ask your health care provider what to do if you have any problems infusing lacosamide injection.

Your doctor will probably start you on a low dose of lacosamide and gradually increase your dose, not more often than once a week.

Lacosamide may help control your condition but will not cure it. It may take a few weeks or longer before you feel the full benefit of lacosamide. Continue to use lacosamide even if you feel well. Do not stop using lacosamide without talking to your doctor, even if you experience side effects such as unusual changes in behavior or mood. If you suddenly stop using lacosamide, your seizures may happen more often. Your doctor will probably decrease your dose gradually.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before using lacosamide injection,

- tell your doctor and pharmacist if you are allergic to lacosamide, any other medications, or any of the ingredients in lacosamide injection. Ask your pharmacist or check the Medication Guide for a list of the ingredients.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention any of the following: beta blockers such as atenolol (Tenormin, in Tenoretic), labetalol (Trandate), metoprolol (Lopressor, Toprol XL), nadolol (Corgard), and propranolol (Hemangeol, Inderal); calcium channel blockers such as amlodipine (Norvasc, in Caduet, in Lotrel, in Exforge, others), diltiazem (Cardizem, Cartia, Tiazac, others), felodipine, isradipine, nicardipine, nifedipine (Procardia), nimodipine (Nymalize), nisoldipine (Sular), and verapamil (Calan, Verelan, in Tarka); and medications for irregular heartbeat such as amiodarone (Nexterone, Pacerone), digoxin (Lanoxin), dronedarone (Multaq), flecainide (Tambocor), propafenone (Rythmol), quinidine (in Nuedexta), and sotalol (Betapace, Sorine, Sotylize). Your doctor may need to change the doses of your medications or monitor you carefully for side effects. Many other medications may also interact with lacosamide, so be sure to tell your doctor about all the medications you are taking, even those that do not appear on this list.
- tell your doctor if you currently or have ever drunk large amounts of alcohol, used street drugs, or over-used prescription medications. Also tell your doctor if you have or have ever had depression, mood problems, suicidal thoughts or behavior; an irregular heartbeat; a heart attack; heart failure, or other heart problems; diabetic neuropathy (nerve damage caused by diabetes); or liver or kidney disease.
- tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. If you become pregnant while using lacosamide injection, call your doctor.
- you should know that lacosamide injection may make you dizzy or drowsy and may cause blurred vision or problems with coordination and balance. Do not drive a car, operate machinery, or participate in activities requiring alertness or coordination until you know how this medication affects you.
- you should know that your mental health may change in unexpected ways and you may become suicidal (thinking about harming or killing yourself or planning or trying to do so) while you are using lacosamide injection. A small number of adults and children 5 years of age and older (about 1 in 500 people) who took anticonvulsants like lacosamide injection to treat various conditions during clinical studies became suicidal during their treatment. Some of these people developed suicidal thoughts and behavior as early as 1 week after they started taking the medication. There is a risk that you may experience changes in your mental health if you take an anticonvulsant medication such as lacosamide injection, but there may also be a risk that you will experience changes in your mental health if your condition is not treated. You and your doctor will decide whether the risks of taking an anticonvulsant medication are greater than the risks of not taking the medication. You, your family, or your caregiver should call your doctor right away if you experience any of the following symptoms: panic attacks; agitation or restlessness; new or worsening irritability, anxiety, or depression; acting on dangerous impulses; difficulty falling asleep or staying asleep; aggressive, angry, or violent behavior; mania (frenzied, abnormally excited mood); talking or thinking about wanting to hurt yourself or end your life; or any other unusual changes in behavior or mood. Be sure that your family or caregiver knows which symptoms may be serious so they can call the doctor if you are unable to seek treatment on your own.
- you should know that lacosamide injection may cause dizziness, lightheadedness, fainting, or irregular heartbeat, especially when you get up too quickly from a lying position. If you develop these symptoms, lie down with your legs raised until you feel better, and call your doctor right away.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What should I do if I forget a dose?

Use the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not use a double dose to make up for a missed one.

What side effects can this medication cause?

Lacosamide injection may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- nausea
- vomiting
- diarrhea
- dry mouth
- numbness or tingling in the mouth
- blurred or double vision
- uncontrollable eye movements
- dizziness
- headache
- drowsiness
- uncontrollable shaking of a part of the body
- problems with coordination, balance, or walking
- weakness
- itching
- redness, irritation, pain, or discomfort at the injection spot

Some side effects can be serious. If you experience any of these symptoms, or those listed in the SPECIAL PRECAUTIONS section, call your doctor immediately:

- fast or pounding heartbeat or pulse
- shortness of breath
- slow heartbeat
- chest pain
- fainting
- swelling of the face, throat, tongue, lips, and eyes

- fever
- rash
- tiredness
- yellowing of the skin or eyes
- dark urine

Lacosamide injection may cause other side effects. Call your doctor if you have any unusual problems while using this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Your healthcare provider will tell you how to store your medication. Store your medication only as directed. Make sure you understand how to store your medication properly.

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

What other information should I know?

Keep all appointments with your doctor.

Do not let anyone else use your medication. Lacosamide injection is a controlled substance. Prescriptions may be refilled only a limited number of times; ask your pharmacist if you have any questions.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Vimpat[®] I.V.

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