

LACOSAM

lacosamide

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about LACOSAM. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking LACOSAM against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What LACOSAM is used for

LACOSAM are used by itself (in patients over 16 years) or in combination with other medicines to control epilepsy. Epilepsy is a condition where you have repeated seizures. There are many different types of seizures, ranging from mild to severe.

This medicine belongs to a group of medicines called antiepileptics. These medicines are thought to work by controlling brain chemicals which send signals to nerves so that seizures do not happen.

Your doctor may have prescribed it for another reason.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

There is no evidence that LACOSAM is addictive.

This medicine is available only with a doctor's prescription.

LACOSAM is not recommended for use in children under the age of 4 years as its safety and effectiveness has not been established in this age group.

Before you take LACOSAM

When you must not take it

Do not take LACOSAM if you have an allergy to:

- **any of the ingredients listed at the end of this leaflet.**

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not take LACOSAM if you have, or have had, a heart condition causing an uneven heart beat.

If you are not sure whether any of the above conditions apply to you, ask your doctor.

Do not take this medicine after the expiry date printed on the pack.

Do not take this medicine if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor or pharmacist if you:

- are taking any other medicines, especially barbiturates (such as phenobarbitone) or any other antiepileptic medicines (such as carbamazepine, lamotrigine or levetiracetam)
- have allergies to any other substances, such as foods, preservatives or dyes.

Tell your doctor if you have, or have had, any medical conditions, especially the following:

- heart problems
- kidney problems
- liver problems.

Tell your doctor if you are pregnant or intend to become pregnant.

LACOSAM may affect your developing baby if you take it during pregnancy. However, it is very important to control your seizures while you are pregnant. Your doctor will outline and weigh up all the risks and benefits of taking LACOSAM during pregnancy to help decide whether or not you should take it.

Tell your doctor if you are breastfeeding or plan to breastfeed.

Your doctor will discuss the risks and benefits of using LACOSAM if you are breastfeeding.

If you have not told your doctor about any of the above, tell them

before you start taking LACOSAM.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and LACOSAM may interfere with each other. These include:

- medicines to treat heart problems
- medicine which may have an affect on your heart beat such as carbamazepine, lamotrigine or pregabalin.

LACOSAM does not interact with the oral contraceptive pill.

However, you may be given LACOSAM together with other antiepileptic medicines that do interact and may affect the effectiveness of your contraceptive. Your doctor may advise you to use an additional method of contraception if you take LACOSAM with other antiepileptic medicines.

How to take LACOSAM

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

Your doctor will tell you how much LACOSAM you will need to take each day. This may depend on your condition, your body weight, and whether or not you are taking any other medicines.

Your doctor may start you on a low dose of LACOSAM first of 50 mg twice a day. Your doctor may slowly increase your dose up to a maximum of 300 mg twice a day, until you are taking enough to control your epilepsy and you are not having any seizures.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

How to take it

Swallow LACOSAM tablets whole with a glass of water.

When to take it

Take LACOSAM twice a day, once in morning and once in night.

Take it at about the same time each day.

Taking your medicine at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take this medicine before or after food.

How long to take it

Most antiepileptic medicines take time to work, so do not be discouraged if you do not feel better straight away.

Continue taking your medicine for as long as your doctor tells you.

This medicine helps control your condition, but does not cure it. Therefore you must take your medicine every day, even if you feel well.

Do not stop taking LACOSAM, or change the dosage, without checking with your doctor. Do not let yourself run out of medicine over the weekend or on holidays.

Stopping LACOSAM suddenly may cause unwanted side effects or make your condition worse. Your doctor will slowly reduce your dose before you can stop taking it completely.

If you forget to take it

Contact your doctor if you have missed one or more doses.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much LACOSAM. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of overdose may include feeling dizzy, drowsy or having an upset stomach.

While you are using LACOSAM

Things you must do

Tell your doctor immediately if you notice an increase in seizures.

Tell your doctor immediately if you have symptoms of depression or thoughts of harming yourself.

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking this medicine.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking LACOSAM.

Before you have any surgery or emergency treatment, tell your doctor or dentist that you are taking LACOSAM.

Tell your doctor if you feel LACOSAM is not helping your condition.

Your doctor may need to change your medicine.

Tell your doctor if, for any reason, you have not taken this medicine exactly as prescribed.

Otherwise, your doctor may change your treatment unnecessarily.

If you become pregnant while taking this medicine, tell your doctor.

Be sure to keep all of your doctor's appointments so that your progress can be checked.

Your doctor will check your progress and may want to take some tests from time to time. This helps to prevent unwanted side effects.

Things you must not do

Do not give LACOSAM to anyone else, even if their symptoms seem similar to yours or they have the same condition as you.

Do not take LACOSAM to treat any other complaints unless your doctor tells you to.

Do not stop taking LACOSAM or change the dosage unless your doctor tells you to.

Stopping LACOSAM suddenly may cause unwanted side effects or make your condition worse.

Things to be careful of

Be careful driving or operating machinery until you know how LACOSAM affects you.

As with other antiepileptic medicines LACOSAM may cause dizziness or drowsiness. This is more frequent at the beginning of treatment or after an increase in the dose.

If you are feeling dizzy or drowsy, do not drive a car, operate machinery, or do anything else that could be dangerous.

As a safety precaution, do not take LACOSAM with alcohol.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking LACOSAM.

This medicine helps most people with epilepsy but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by the following lists of side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

If you get any side effects, do not stop taking LACOSAM without first talking to your doctor or pharmacist.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- dizziness or problems with balance or coordination
- headache
- nausea (feeling sick) or vomiting
- feeling tired, drowsy or sleepy
- forgetfulness
- tremors
- itching.

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- feelings of depression
- feeling aggressive or agitated
- spinning sensations
- double vision or blurred vision
- having trouble sleeping.

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- thoughts of harming yourself
- more frequent or more severe seizures

- fainting or feeling lightheaded
- heart palpitations or a rapid or irregular pulse
- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using LACOSAM

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they will not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store LACOSAM or any other medicine in the bathroom or near a sink.

Do not leave your medicine on a window sill or in the car on hot days.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

LACOSAM tablets are available in four strengths:

- 50 mg –Pink, oval, coated tablets, debossed “L” on one side and “50” on other side.
- 100 mg – Dark yellow, oval, coated tablets, debossed “L” on one side and “100” on other side.
- 150 mg –Salmon, oval, coated tablets, debossed “L” on one side and “150” on other side.
- 200 mg –Blue, oval, coated tablets, debossed “L” on one side and “200” on other side.

Ingredients

Each LACOSAM tablet contains either 50 mg, 100mg, 150 mg or 200 mg of lacosamide as the active ingredient.

Other ingredients in LACOSAM tablets include:

- microcrystalline cellulose
- hypolose
- colloidal anhydrous silica,
- magnesium stearate

The following strengths also contain:

- 50 mg - Opadry II complete film-coating system 85G500007 purple
- 100 mg - Opadry II complete film-coating system 85G52072 yellow
- 150 mg - Opadry II complete film-coating system 85G565024 brown
- 200 mg - Opadry II complete film-coating system 85G505009 blue

LACOSAM tablets do not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

Accord Healthcare Pty Ltd
Level 24, 570 Bourke St
Melbourne

VIC 3000

Australian registration numbers:

LACOSAM 50 mg tablets

- AUST R 296765

LACOSAM 100 mg tablets

- AUST R 296757

LACOSAM 150 mg tablets

- AUST R 296755

LACOSAM 200 mg tablets

- AUST R 296763