

LACOSAM

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using LACOSAM?

LACOSAM contains the active ingredient lacosamide. LACOSAM is used by itself (in patients over 16 years) or in combination with other medicines (in patients over 4 years) to control epilepsy.

For more information, see Section [1. Why am I using LACOSAM?](#) in the full CMI.

2. What should I know before I use LACOSAM?

Do not use if you have ever had an allergic reaction to LACOSAM or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use LACOSAM?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with LACOSAM and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use LACOSAM?

- Swallow LACOSAM tablets whole with a glass of water.

More instructions can be found in Section [4. How do I use LACOSAM?](#) in the full CMI.

5. What should I know while using LACOSAM?

| | |
|------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Things you should do | <ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using LACOSAM.• If you are pregnant or become pregnant while taking LACOSAM. |
| Things you should not do | <ul style="list-style-type: none">• Do not stop using this medicine suddenly.• Do not take LACOSAM to treat any other complaints unless your doctor tells you to.• Do not drink alcohol before or after taking this medicine. |
| Driving or using machines | <ul style="list-style-type: none">• Be careful driving or operating machinery until you know how this medicine affects you. |
| Drinking alcohol | <ul style="list-style-type: none">• Do not drink alcohol before or after taking this medicine. |
| Looking after your medicine | <ul style="list-style-type: none">• Keep your tablets in the pack until it is time to take them.• Keep the medicine in a cool dry place where the temperature stays below 25°C |

For more information, see Section [5. What should I know while using LACOSAM?](#) in the full CMI.

6. Are there any side effects?

LACOSAM helps most people with epilepsy but 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. Common side effects include: dizziness or problems with balance or coordination, headache, nausea, feeling tired, drowsy or sleepy, forgetfulness, tremors or itching.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

LACOSAM

Active ingredient(s): *lacosamide*

Consumer Medicine Information (CMI)

This leaflet provides important information about using LACOSAM. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using LACOSAM.**

Where to find information in this leaflet:

- [1. Why am I using LACOSAM?](#)
- [2. What should I know before I use LACOSAM?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use LACOSAM?](#)
- [5. What should I know while using LACOSAM?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using LACOSAM?

LACOSAM contains the active ingredient lacosamide. LACOSAM 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.

LACOSAM is used to by itself (in patients over 16 years) or in combination with other medicines (in patients over 4 years) to control epilepsy. Epilepsy is a condition where you have repeated seizures. There are many different types of seizures, ranging from mild to severe.

2. What should I know before I use LACOSAM?

Warnings

Do not use LACOSAM if:

- you are allergic to lacosamide, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- you have, or have had, a heart condition causing an uneven heart beat.

Check with your doctor or pharmacist if you:

- have any other medical conditions:
 - heart problems
 - kidney problems
 - liver problems
 - Any mental health condition, such as depression.
- take any medicines for any other condition especially barbiturates (such as phenobarbitone) or any other

antiepileptic medicines (such as carbamazepine, lamotrigine or levetiracetam)

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with 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.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

3. What if I am taking other medicines?

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

Some medicines may interfere with LACOSAM and affect how it works.

- medicines to treat heart problems
- medicine which may have an effect on your heartbeat 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect LACOSAM.

4. How do I use LACOSAM?

How much to take / use

- 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.
- Swallow LACOSAM tablets whole with a glass of water.
- Follow the instructions provided and use LACOSAM until your doctor tells you to stop.

When to take / use LACOSAM

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

If you forget to use LACOSAM

LACOSAM should be used regularly at the same time each day.

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 use too much LACOSAM

If you think that you have used too much LACOSAM, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling **13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using LACOSAM?

Things you should do

Call your doctor straight away if you:

- Notice an increase in seizures

- Have symptoms of depression or thoughts of harming yourself.
- Become pregnant while taking this medicine, tell your doctor.
- 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.
- For any reason, you have not taken this medicine exactly as prescribed.

Remind any doctor, dentist or pharmacist you visit that you are using LACOSAM.

Things you should not do

- Do not stop using this medicine suddenly.
- 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.

Driving or using machines

Be careful before you drive or use any machines or tools 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.

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

Drinking alcohol

Tell your doctor if you drink alcohol.

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

Looking after your medicine

- 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.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

| Less serious side effects | What to do |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none">• dizziness or problems with balance or coordination• Headache• Nausea (feeling sick) or vomiting• Feeling tired, drowsy or sleepy• Forgetfulness• Tremors• Itching. | Speak to your doctor if you have any of these less serious side effects and they worry you. |

Serious side effects

| Serious side effects | What to do |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none">• Feelings of depression• Feeling aggressive or agitated• Spinning sensations• Double vision or blurred vision• Having trouble sleeping.• 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. | Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects. |

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What LACOSAM contains

| | |
|-------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Active ingredient (main ingredient) | 50 mg, 100mg, 150 mg or 200 mg of lacosamide |
| Other ingredients (inactive ingredients) | <ul style="list-style-type: none">• microcrystalline cellulose• hypromellose• colloidal anhydrous silica,• magnesium stearate The following strengths also contain: <ul style="list-style-type: none">• 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 |

Do not take this medicine if you are allergic to any of these ingredients.

What LACOSAM looks like

LACOSAM are available in four strengths:

- 50 mg –Pink, oval, coated tablets, debossed “L” on one side and “50” on other side (Aust R 296765).
- 100 mg – Dark yellow, oval, coated tablets, debossed “L” on one side and “100” on other side (Aust R 296757).
- 150 mg –Salmon, oval, coated tablets, debossed “L” on one side and “150” on other side (Aust R 296755).
- 200 mg –Blue, oval, coated tablets, debossed “L” on one side and “200” on other side (Aust R 296763).

Who sponsors LACOSAM

Accord Healthcare Pty Ltd
Level 24, 570 Bourke St
Melbourne
VIC 3000

Distributor

Viatrix Pty Ltd
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30-34 Hickson Road
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