

LACORESS

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 LACORESS?

LACORESS contains the active ingredient Lacosamide. LACORESS is used in patients over 4 years in combination with other medicines to control epilepsy and monotherapy in the treatment of partial-onset seizures with or without secondary generalisation in patients with epilepsy aged 16 years and older.

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

2. What should I know before I use LACORESS?

Do not use if you have ever had an allergic reaction to Lacosamide 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 LACORESS?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with LACORESS 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 LACORESS?

- The dose of LACORESS may depend on your condition, your body weight, and whether or not you are taking any other medicines. Your doctor will tell you how much LACORESS you will need to take each day.
- Swallow LACORESS tablets whole with a glass of water.

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

5. What should I know while using LACORESS?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using LACORESS.• Tell your doctor immediately if you notice an increase in seizures, if you have symptoms of depression or thoughts of harming yourself or if you feel LACORESS is not helping your condition.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly or change the dosage unless your doctor tells you to.• Do not take LACORESS to treat any other complaints unless your doctor tells you to.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how LACORESS affects you.• If you are feeling dizzy or drowsy, do not drive a car, operate machinery, or do anything else that could be dangerous.
Drinking alcohol	<ul style="list-style-type: none">• As a safety precaution, do not take LACORESS with alcohol.
Looking after your medicine	<ul style="list-style-type: none">• Store below 25°C. Keep your tablets in the pack until it is time to take them.• Do not store LACORESS or any other medicines in the bathroom or near a sink.• Do not leave your medicine on a window sill or in the car on hot days.• Keep LACORESS where children cannot reach it.

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

6. Are there any side effects?

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

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.

LACORESS

Active ingredient(s): *lacosamide* (la-KOE-sa-mide)

Consumer Medicine Information (CMI)

This leaflet provides important information about using LACORESS. **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 LACORESS.**

Where to find information in this leaflet:

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

1. Why am I using LACORESS?

LACORESS contains the active ingredient lacosamide.

LACORESS tablets 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.

LACORESS tablets is used in patients over 4 years in combination with other medicines to control epilepsy.

LACORESS tablets can only be used by itself in patients over 16 years. Epilepsy is a condition where you have repeated seizures. There are many different types of seizures, ranging from mild to severe.

Your doctor may have prescribed this medicine 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 LACORESS is addictive.

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

LACORESS 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.

2. What should I know before I use LACORESS?

Warnings

Do not use LACORESS 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.

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 LACORESS 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 to your pharmacist for disposal.

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

Check with your doctor if you:

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
- any mental health condition, such as depression.

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.

LACORESS 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 LACORESS 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 LACORESS if you are breastfeeding.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking LACORESS.

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 LACORESS and affect how it works.

These include:

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

LACORESS does not interact with the oral contraceptive pill.

However, you may be given LACORESS 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 LACORESS 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 LACORESS.

4. How do I use LACORESS?

How much to take / use

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

Your doctor will tell you how much LACORESS 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 LACORESS first of 50 mg or 100 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.

For use in children weighing less than 50kg, the doctor may start you on a low dose of 2 mg/kg/day. The doctor may slowly increase your dose 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.

When to take / use LACORESS

Take LACORESS twice a day, once in the morning and once at 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 to take LACORESS

- Swallow LACORESS tablets whole with a glass of water.

If you forget to use LACORESS

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.

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 to.

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

Stopping LACORESS 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 use too much LACORESS

If you think that you have used too much LACORESS, 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.

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

5. What should I know while using LACORESS?

Things you should 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 LACORESS.

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

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

Your doctor may need to change your medicine.

Call your doctor straight away if you:

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.

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

Things you should not do

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

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

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

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

Driving or using machines

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

As with other antiepileptic medicines LACORESS 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.

Drinking alcohol

Tell your doctor if you drink alcohol.

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

Looking after your medicine

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.

Store below 25°C.

Do not store LACORESS 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.

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

Keep LACORESS where children cannot reach it.

When to discard your medicine (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.

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.

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

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">dizziness or problems with balance or coordinationheadachenausea (feeling sick) or vomitingfeeling tired, drowsy or sleepyforgetfulnesstremorsitching	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> <p>Do not be alarmed by this list of side effects.</p> <p>The list includes the more</p>

	<p>common side effects of your medicine. They are mostly mild and short-lived.</p> <p>If you get any side effects, do not stop taking LACORESS without first talking to your doctor or pharmacist.</p>
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Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • 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 • feelings of depression • feeling aggressive or agitated • spinning sensations • double vision or blurred vision • having trouble sleeping 	<p>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.</p> <p>The list includes serious side effects that may require medical attention.</p> <p>You may need urgent medical attention or hospitalisation.</p>

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 LACORESS contains

Active ingredient (main ingredient)	Each LACORESS tablet contains either 50 mg, 100 mg, 150 mg or 200 mg of lacosamide as the active ingredient.
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • microcrystalline cellulose • crospovidone • hyprolose • colloidal anhydrous silica • magnesium stearate • Instacoat Universal A05G31016 Brown (PI 128223) (50 mg strength) • Instacoat Universal A05G11003 Yellow (PI 128221) (100 mg strength) • Instacoat Universal A05G11015 Brown (PI 128216) (150 mg strength) • Instacoat Universal A05G31013 Blue (PI 128217) (200 mg strength)
Potential allergens	LACORESS tablets do not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

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

What LACORESS looks like

LACORESS tablets are available in four strengths:

- 50 mg – pink, oval, film-coated tablets debossed with "423" on one side and plain on other side
- 100 mg – dark yellow, oval, film-coated tablets debossed with "L424" on one side and plain on other side
- 150 mg – salmon, oval, film-coated tablets debossed with "L425" on one side and plain on other side
- 200 mg – blue, oval, film-coated tablets debossed with "L426" on one side and plain on other side.

Who distributes LACORESS

Cipla Australia Pty Ltd.,
 Level 1, 132-136 Albert Road,
 South Melbourne, VIC 3205.
drugsafety@cipla.com
 Toll Free number: 1800 569 074

LACORESS 50 mg tablets - AUST R 337894
 LACORESS 100 mg tablets - AUST R 337933
 LACORESS 150 mg tablets - AUST R 337903
 LACORESS 200 mg tablets - AUST R 337917

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