

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 VIMCOSA LACOSAMIDE?

VIMCOSA LACOSAMIDE film-coated tablets contains the active ingredient lacosamide. VIMCOSA LACOSAMIDE work by controlling brain chemicals which send signals to nerves so that seizures do not happen.

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

2. What should I know before I use VIMCOSA LACOSAMIDE?

Do not use if you have ever had an allergic reaction to VIMCOSA 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 VIMCOSA LACOSAMIDE?](#) In the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with VIMCOSA LACOSAMIDE 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 VIMCOSA LACOSAMIDE?

Your doctor will tell you how much VIMCOSA LACOSAMIDE 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.

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

5. What should I know while using VIMCOSA LACOSAMIDE?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using VIMCOSA LACOSAMIDE.• If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking LACOSAMIDE.• Stop taking VIMCOSA LACOSAMIDE and contact your doctor immediately if you become pregnant while you are taking VIMCOSA LACOSAMIDE.
Things you should not do	<ul style="list-style-type: none">• Do not give this medicine to anyone else, even if their condition seems similar to yours.• Do not use it to treat any other complaints unless your doctor tells you to.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how VIMCOSA LACOSAMIDE affects you.• VIMCOSA LACOSAMIDE cause problems with your ability to drive a car or operate machinery.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none">• Keep your medicine in the original container until it is time to take it.• Store it in a cool, dry place, below 25°C.

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

Are there any side effects?

- Less serious side effects: dizziness or problems with balance or coordination headache, nausea (feeling sick) or vomiting, feeling tired, drowsy or sleepy, forgetfulness, tremors.
- Serious side effects: feelings of depression , feeling aggressive or agitated , spinning sensations, double vision or blurred vision, having trouble sleeping
- Very serious side effects: 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.

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.

VIMCOSA LACOSAMIDE

Active ingredient(s): [*Lacosamide*]

Consumer Medicine Information (CMI)

This leaflet provides important information about using [VIMCOSA LACOSAMIDE]. **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 [VIMCOSA LACOSAMIDE].**

Where to find information in this leaflet:

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

1. Why am I using VIMCOSA LACOSAMIDE?

[VIMCOSA LACOSAMIDE] contains the active ingredient LACOSAMIDE

VIMCOSA LACOSAMIDE film-coated tablets are used in patients over 4 years in combination with other medicines to control epilepsy.

VIMCOSA LACOSAMIDE film-coated 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.

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 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 VIMCOSA LACOSAMIDE is addictive.

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

VIMCOSA LACOSAMIDE 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 VIMCOSA LACOSAMIDE?

When you must not take it

Do not take VIMCOSA LACOSAMIDE 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 VIMCOSA LACOSAMIDE 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.

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
- any mental health condition, such as depression.

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

VIMCOSA LACOSAMIDE 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 VIMCOSA LACOSAMIDE 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 VIMCOSA LACOSAMIDE if you are breastfeeding.

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

3. What if I am taking other medicines?

Taking other medicines

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

Some medicines and VIMCOSA LACOSAMIDE 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.

VIMCOSA LACOSAMIDE does not interact with the oral contraceptive pill.

However, you may be given VIMCOSA LACOSAMIDE 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 VIMCOSA LACOSAMIDE with other antiepileptic medicines.

4. How do I use VIMCOSA LACOSAMIDE?

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 VIMCOSA LACOSAMIDE 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 VIMCOSA LACOSAMIDE 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

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

How to take it

Swallow the tablets whole with a full glass of water.

Do not crush or chew the tablets.

When to take it

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

Stopping VIMCOSA LACOSAMIDE 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 in Australia 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

VIMCOSA LACOSAMIDE. 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.

5. What Should I Know While Using VIMCOSA LACOSAMIDE?

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 VIMCOSA LACOSAMIDE.

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

Tell your doctor if you feel VIMCOSA LACOSAMIDE is not helping your condition. Your doctor may need to change your medicine.

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

Otherwise, your doctor may think it is not working effectively and 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 should not do

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

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

Do not stop taking VIMCOSA LACOSAMIDE or change the dosage unless your doctor tells you to. Stopping VIMCOSA LACOSAMIDE suddenly may cause unwanted side effects or make your condition worse.

Things to be careful of

Driving or using machines

Be careful before you drive or use any machines or tools until you know how [VIMCOSA LACOSAMIDE] affects you.

As with other antiepileptic medicines VIMCOSA LACOSAMIDE 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 VIMCOSA LACOSAMIDE with alcohol.

Looking after your medicine

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 VIMCOSA LACOSAMIDE where young children cannot reach it.

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

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.

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. <p>The above list includes the more common side effects of your medicine. They are usually mild and short-lived.</p>	<p>Speak to your doctor if you have notice any of these less serious side effects and they worry you.</p>

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	<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>

More serious side effects

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

<ul style="list-style-type: none"> 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. <p>The above list includes more serious side effects. You may need urgent medical attention or hospitalisation.</p>	
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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.

Do not be alarmed by this list of side effects. You may not experience any of them.

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.

Product details

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

What [VIMCOSA LACOSAMIDE] contains

Active ingredient (main ingredient)	Each VIMCOSA LACOSAMIDE film-coated 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 Hypromellose Colloidal anhydrous silica. Magnesium Stearate Opadry II 85F20249 Purple (50 mg) Opadry 85F520062 Yellow

	<ul style="list-style-type: none"> (100 mg) Opadry II 85F27043 TAN (150 mg) Opadry II 85F505244 Blue (200 mg)
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Do not take this medicine if you are allergic to any of these ingredients.

What [VIMCOSA LACOSAMIDE] looks like

VIMCOSA LACOSAMIDE film-coated tablets are available in four strengths:

- 50 mg – Pink, oval shaped, film coated tablets debossed with "LAC" on one side and "50" on other side.
(Blister pack: Aust R 353576)
(Bottle pack: Aust R 353580)
- 100 mg – Dark yellow, oval shaped, film coated tablets debossed with "LAC" on one side and "100" on other side.
(Blister pack: Aust R 353583)
(Bottle pack: Aust R 353597)
- 150 mg – Peach, oval shaped, film coated tablets debossed with "LAC" on one side and "150" on other side.
(Blister pack: Aust R 353572)
(Bottle pack: Aust R 353588)
- 200 mg – Blue, oval shaped, film coated tablets debossed with "LAC" on one side and "200" on other side.
(Blister pack: Aust R 353578)
(Bottle pack: Aust R 353586)

The film-coated tablets are packed in

- PVC-Aclar Blister Carton: 14's, 56's, 168's Tablets
- HDPE Bottle: 56's Tablets

Who distributes VIMCOSA LACOSAMIDE

Pharmacor Pty Ltd.

Suite 803, Tower A, The Zenith,

821 Pacific Highway,

Chatswood NSW 2067

www.pharmacor.com.au

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