

Lacosamide Sandoz®

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 Lacosamide Sandoz?

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

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

2. What should I know before I use Lacosamide Sandoz?

Do not use Lacosamide Sandoz 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 Lacosamide Sandoz?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Lacosamide Sandoz 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 Lacosamide Sandoz?

- Your doctor will tell you how much Lacosamide Sandoz 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 Lacosamide Sandoz 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.

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

5. What should I know while using Lacosamide Sandoz?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are using Lacosamide Sandoz.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.
Things you should not do	<ul style="list-style-type: none">Do not stop taking your medicine or change the dosage without checking with your doctor.Do not give your medicine to anyone else, even if they have the same condition as you.
Driving or using machines	<ul style="list-style-type: none">As with other antiepileptic medicines Lacosamide Sandoz may cause dizziness or drowsiness. This is more frequent at the beginning of treatment or after an increase in the dose. If you have any of these symptoms, do not drive, 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 Lacosamide Sandoz with alcohol.
Looking after your medicine	<ul style="list-style-type: none">Store below 30°C

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

6. Are there any side effects?

Common side effects: dizziness or problems with balance or coordination, headache, nausea (feeling sick) or vomiting, feeling tired, drowsy or sleepy. **Serious side effects:** feeling of depression, aggressive or agitated, spinning sensation, double vision or blurred vision.

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.

Lacosamide Sandoz®

Active ingredient(s): *lacosamide*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Lacosamide Sandoz. **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 Lacosamide Sandoz.**

Where to find information in this leaflet:

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

1. Why am I using Lacosamide Sandoz?

Lacosamide Sandoz contains the active ingredient **lacosamide**. Lacosamide Sandoz belong 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.

Lacosamide Sandoz is used in patients over 4 years in combination with other medicines to control epilepsy. Lacosamide Sandoz tablets are used by itself (in patients over 16 years) to control epilepsy.

2. What should I know before I use Lacosamide Sandoz?

Warnings

Do not use Lacosamide Sandoz 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
 - any other specific reactions listed in the PI
- you have, or have had, a heart condition causing an uneven heartbeat.
- It is after the expiry printed on the pack or if the packaging is torn or shows signs of tampering. If it has

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

Check with your doctor if you:

- have allergies to any other medicines, especially barbiturates (such as phenobarbitone) or any other antiepileptic medicines (such as carbamazepine, lamotrigine or levetiracetam) or any other medicines, foods, preservatives or dyes.
- have any other medical conditions:
 - heart problems
 - kidney problems
 - liver problems

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.

Lacosamide Sandoz 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 Lacosamide Sandoz 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 Lacosamide Sandoz if you are breastfeeding.

Use in Children

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

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 Lacosamide Sandoz 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.

You may need different amounts of your medicines, or you may need to take different medicines.

Lacosamide Sandoz does not interact with the oral contraceptive pill.

However, you may be given Lacosamide Sandoz 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 Lacosamide Sandoz 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 Lacosamide Sandoz.

4. How do I use Lacosamide Sandoz?

How much to take

- Your doctor will tell you how much Lacosamide Sandoz 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 Lacosamide Sandoz 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.

When to take Lacosamide Sandoz

- **Take Lacosamide Sandoz twice a day, once in the morning and once at night. Take it at about the same time each day.**

Taking it 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 Lacosamide Sandoz

Swallow the tablets whole with a full glass of water.

How to long to take Lacosamide Sandoz

- 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 to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.
- **Do not stop taking Lacosamide Sandoz, or change the dosage, without checking with your doctor. Do not let yourself run out of medicine over the weekend or on holidays.**
Stopping Lacosamide Sandoz 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 use Lacosamide Sandoz

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

Do not take a double dose to make up for the dose 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 use too much Lacosamide Sandoz

If you think that you have used too much Lacosamide Sandoz, you may need urgent medical attention. Symptoms of overdose may include feeling dizzy, drowsy or having an upset stomach.

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 Lacosamide Sandoz?

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
- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Lacosamide Sandoz.
- **If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.** It may affect other medicines used during surgery.
- **Tell your doctor if you feel Lacosamide Sandoz 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 immediately.
- **If you are about to have any blood tests, tell your doctor that you are taking this medicine.** It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor will check your progress and may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

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

Things you should not do

- **Do not stop using this medicine suddenly or change the dosage without checking with your doctor.** If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects.
- **Do not take Lacosamide Sandoz to treat any other complaints unless your doctor tells you to.**
- **Do not give your medicine to anyone else, even if they have the same condition as you.**

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Lacosamide Sandoz affects you.

As with other antiepileptic medicines Lacosamide Sandoz may cause dizziness or drowsiness. This is more frequent at the beginning of treatment or after an increase in the dose. If you have any of these symptoms, do not drive, 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 Lacosamide Sandoz 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 below 30°C 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.

A locked cupboard at least one-and-a-half metres 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.

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. Do not be alarmed by the following lists of side effects. You may not experience any of them.

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>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> <p>They are generally mild and do not cause patients to stop taking Lacosamide Sandoz.</p>

Serious side effects

Serious side effects	What to do
<p>Head and neurology related:</p> <ul style="list-style-type: none"> • feelings of depression • feeling aggressive or agitated • spinning sensations • having trouble sleeping • thoughts of harming yourself • more frequent or more severe seizures <p>Eye related:</p> <ul style="list-style-type: none"> • double vision or blurred vision <p>Heart related:</p> <ul style="list-style-type: none"> • fainting or feeling lightheaded • heart palpitations or a rapid or irregular pulse <p>Allergy related:</p> <ul style="list-style-type: none"> • 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>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>

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.

This leaflet was prepared in January 2025.

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7. Product details

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

What Lacosamide Sandoz contains

Active ingredient (main ingredient)	lacosamide
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• microcrystalline cellulose• hypolose• crospovidone• isopropyl alcohol• colloidal anhydrous silica• magnesium stearate• purified water <p>The following strengths also contain:</p> <p>50 mg – Opadry II Purple 85F500018</p> <p>100 mg – Opadry II Yellow 85F520118</p> <p>150 mg – Opadry II TAN 85F570032</p> <p>200 mg – Opadry II Blue 85F505070</p>

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

What Lacosamide Sandoz looks like

Lacosamide Sandoz 50 mg – Pink coloured, oval shaped tablets debossed with “173” on one side and plain on other side (Aust R 309010)

Lacosamide Sandoz 100 mg – Dark yellow coloured, oval shaped tablets debossed with “174” on one side and plain on other side (Aust R 309009)

Lacosamide Sandoz 150 mg – Peach coloured, oval shaped tablets debossed with “175” on one side and plain on other side (Aust R 309011)

Lacosamide 200 mg – Blue coloured, oval shaped tablets debossed with “176” on one side and plain on other side (Aust R 309008)

Not all presentations may be marketed.

Who distributes Lacosamide Sandoz

Sandoz Pty Ltd
100 Pacific Highway
North Sydney, NSW 2060
Australia
Tel 1800 726 369