

Lacosamide Te Arai

Lacosamide

10mg/mL oral solution

What is in this leaflet

Please read this leaflet carefully before you start using lacosamide.

This leaflet answers some common questions about lacosamide. 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 using lacosamide against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine. You may need to read it again.

What lacosamide is used for

Lacosamide is used in patients over 4 years in combination with other medicines to control epilepsy. Lacosamide 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 lacosamide for another reason.

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

There is no evidence that lacosamide is addictive.

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

Before you use lacosamide

When you must not use it

Do not use lacosamide if:

- Lacosamide or 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 lacosamide if you have, or have had, a heart condition causing an uneven heartbeat.

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 using lacosamide, talk to your doctor or pharmacist.

Before you start to use it

Tell your doctor if:

- 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.

If you have not told your doctor about any of the above, tell them before you start using lacosamide.

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.

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 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 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 lacosamide.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking lacosamide.

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

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

Lacosamide does not interact with the oral contraceptive pill.

However, you may be given 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 lacosamide with other antiepileptic medicines.

How to take lacosamide

How much to take

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 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 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.

For use in children weighing less than 50kg, the doctor may start you on a low dose of lacosamide oral solution first of 0.1 mL/kg twice a day. The doctor may slowly increase your dose up to a maximum of 0.6 mL/kg 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

It is important that you use the correct device to measure your dose. Your doctor or pharmacist will let you know which device to use depending on the dose that has been prescribed.

If the required dose is between 1 mL and 10 mL, you should use the 10 mL oral syringe and the adaptor.

If the required dose is between 10 mL and 20 mL, you will need to use the 10 mL syringe two times.

If the required dose is above 20 mL, you should use the 25 mL measuring cup.

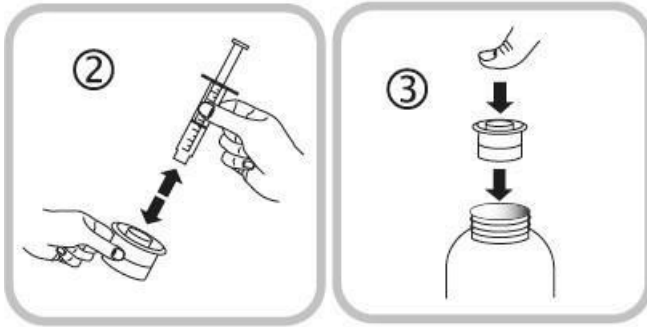
To use the syringe with adaptor

Open the bottle by pressing the cap while turning it anti-clockwise (1).



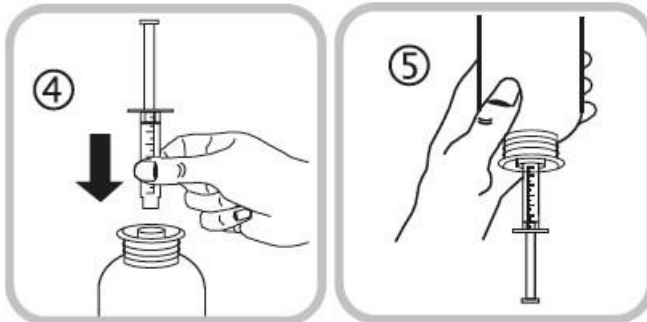
Follow these steps the first time you take lacosamide:

- Take off the adaptor from the oral syringe (2).
- Put the adaptor into the top of the bottle (3). Make sure it is fixed well in place. You do not need to remove the adaptor after use.

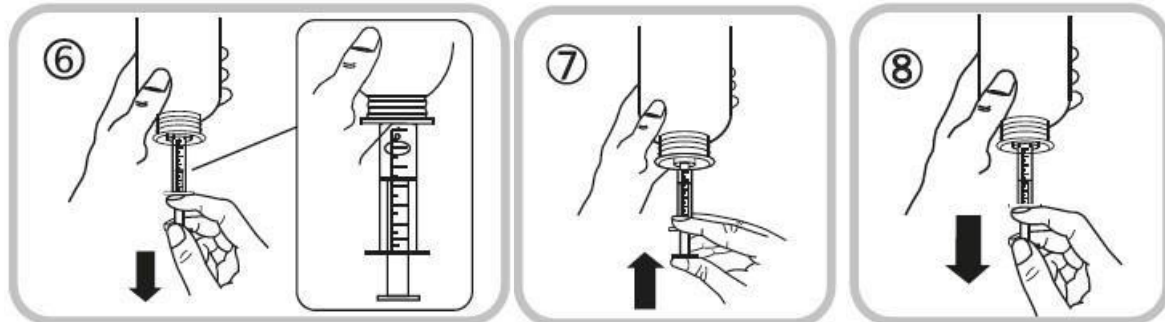


Follow these steps each time you take Lacosamide:

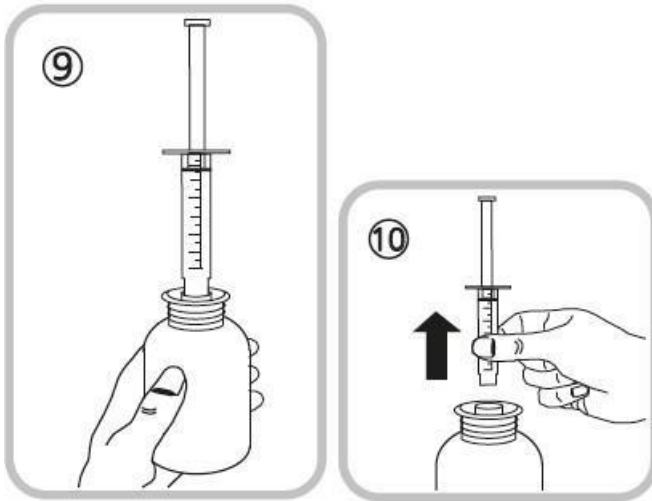
- Put the oral syringe into the adaptor opening (4).
- Turn the bottle upside down (5).



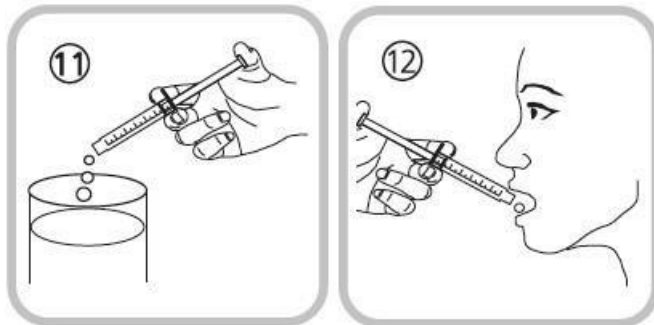
- Hold the bottle upside down in one hand and use the other hand to fill the oral syringe.
- Pull the piston down to fill the oral syringe with a small amount of solution (6).
- Push the piston up to get rid of any bubbles (7).
- Pull the piston down to the millilitre (mL) dose marker prescribed by your doctor (8).



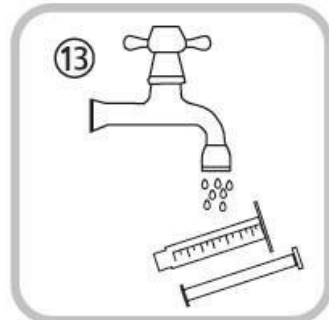
- Turn the bottle the right way up (9).
- Take the oral syringe out of the adaptor (10).



- Empty the contents of the oral syringe into a little water by pushing the piston to the bottom of the oral syringe (11) – you will then need to drink all of the water (add just enough to make it easy to drink) or
- Drink the solution directly from the oral syringe without water (12) – drink the whole contents of the oral syringe.



- Close the bottle with the plastic screw cap (you do not need to remove the adaptor).
- Wash the oral syringe with water only (13).



When to take it

Take 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.

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.

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 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 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.

While you are using lacosamide

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 lacosamide.

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

Tell your doctor if you feel 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 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 lacosamide to anyone else, even if their symptoms seem similar to yours or they have the same condition as you.

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

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

Stopping lacosamide 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 lacosamide affects you.

As with other antiepileptic medicines 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 lacosamide with alcohol.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much lacosamide.

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.

Side Effects

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

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 this list 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 lacosamide 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 mostly 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 more serious side effects. You may need urgent medical attention or hospitalisation.

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

Other side effects not listed above may happen in some people.

After using lacosamide

Storage

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and bottle after EXP. The expiry date refers to the last day of that month.

Once you have opened the bottle, you must not use it longer than 2 months. Do

not freeze. Do not refrigerate.

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

Lacosamide Te Arai 10 mg/mL oral solution is a slightly viscous clear, colourless liquid in a bottle of 200 mL.

The carton boxes of Lacosamide Te Arai oral solution contain a 25 mL measuring cup with graduation marks and a 10 mL oral syringe with an adaptor.

The measuring cup is suitable for doses above 20 mL.

The measuring cup shows three different, non-linear scales on three different sides to allow a fine graduation of different doses. Each graduation mark is accompanied by the respective volume statement in mL. The minimum extractable volume is 2 mL, which is 20 mg of lacosamide. The maximum extractable volume is 25 mL, which is 250 mg of lacosamide.

The 10 mL oral syringe is suitable for doses between 1 mL and 20 mL. One full 10 mL oral syringe corresponds to 100 mg of lacosamide. The minimum extractable volume is 1 mL, which is 10 mg of lacosamide. After this, each graduation mark (0.25 mL) corresponds to 2.5 mg of lacosamide (for example, 4 graduation marks corresponds to 10 mg).

Ingredients

Active ingredient(s):

- The active substance is lacosamide. 1 mL oral solution contains 10 mg lacosamide.

Inactive ingredients:

The other ingredients are sorbitol liquid 70 % (not crystallising) (E 420), glycerol, propylene glycol (E 1520), macrogol 4000, sodium chloride, carmellose sodium, acesulfame potassium (E 950), citric acid, sodium methyl para-hydroxybenzoate (E 219), strawberry flavour (contains propylene glycol (E 1520)), aspartame (E 951), purified water.

Sponsor Details

Lacosamide Te Arai is supplied in New Zealand by:

Te Arai BioFarma Ltd

PO Box 46205
Herne Bay, 1147
Auckland
NEW ZEALAND

0800 832 724

Date of Preparation

This leaflet was prepared on 9 August 2023.