

Package leaflet: Information for the patient

Trelema 10 mg/ml solution for infusion lacosamide

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [Lacosamide] is and what it is used for
2. What you need to know before you use [Lacosamide]
3. How to use [Lacosamide]
4. Possible side effects
5. How to store [Lacosamide]
6. Contents of the pack and other information

1. What [Lacosamide] is and what it is used for

What [Lacosamide] is

[Lacosamide] contains lacosamide. This belongs to a group of medicines called 'antiepileptic medicines'. These medicines are used to treat epilepsy.

You have been given this medicine to lower the number of fits (seizures) you have.

What [Lacosamide] is used for

- [Lacosamide] is used:
 - on its own and in association with other antiepileptic medicines in adults, adolescents and children aged 2 years and older to treat a certain type of epilepsy characterised by the occurrence of partial-onset seizure with or without secondary generalisation. In this type of epilepsy, fits first affect only one side of your brain. However, these may then spread to larger areas on both sides of your brain;
 - in association with other antiepileptic medicines in adults, adolescents and children aged 4 years and older to treat primary generalised tonic-clonic seizures (major fits, including loss of consciousness) in patients with idiopathic generalised epilepsy (the type of epilepsy that is thought to have a genetic cause).

2. What you need to know before you use [Lacosamide]

Do not use [Lacosamide]

- if you are allergic to lacosamide or any of the other ingredients of this medicine (listed in section 6). If you are not sure whether you are allergic, please discuss with your doctor.
- if you have a certain type of heart beat problem called second or third degree AV block.

Do not use [Lacosamide] if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using this medicine.

Warnings and precautions

Talk to your doctor before using [Lacosamide] if

- you have thoughts of harming or killing yourself. A small number of people being treated

with antiepileptic medicinal products such as lacosamide have had thoughts of harming or killing themselves. If you have any of these thoughts at any time, tell your doctor straight away.

- you have a heart problem that affects the beat of your heart and you often have a particularly slow, fast or irregular heart beat (such as AV block, atrial fibrillation or atrial flutter).
- you have severe heart disease such as heart failure or have had a heart attack.
- you are often dizzy or fall over. [Lacosamide] may make you dizzy – this could increase the risk of accidental injury or a fall. This means that you should take care until you are used to the effects of this medicine.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before using [Lacosamide].

If you are taking [Lacosamide], talk to your doctor if you are experiencing a new type of seizure or worsening of existing seizures.

If you are using [Lacosamide] and you are experiencing symptoms of abnormal heartbeat (such as slow, rapid or irregular heartbeat, palpitations, shortness of breath, feeling lightheaded, fainting), seek medical advice immediately (see section 4).

Children

[Lacosamide] is not recommended for children aged under 2 years with epilepsy characterised by the occurrence of partial-onset seizure and not recommended for children aged under 4 years with primary generalised tonic-clonic seizures. This is because we do not yet know whether it will work and whether it is safe for children in this age group.

Other medicines and [Lacosamide]

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines that affect your heart. This is because [Lacosamide] can also affect your heart:

- medicines to treat heart problems
- medicines which can increase the 'PR interval' on a scan of the heart (ECG or electrocardiogram) such as medicines for epilepsy or pain called carbamazepine, lamotrigine or pregabalin
- medicines used to treat certain types of irregular heart beat or heart failure

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking [Lacosamide]

Also tell your doctor or pharmacist if you are taking any of the following medicines. This is because they may increase or decrease the effect of [Lacosamide] on your body:

- medicines for fungal infections such as fluconazole, itraconazole or ketoconazole
- a medicine for HIV such as ritonavir
- medicines used to treat bacterial infections such as clarithromycin or rifampicin
- a herbal medicine used to treat mild anxiety and depression called St. John's Wort

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before using [Lacosamide].

[Lacosamide] with alcohol

As a safety precaution do not use [Lacosamide] with alcohol.

Pregnancy and breast-feeding

Fertile women should discuss the use of contraceptives with the doctor.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

It is not recommended to use [Lacosamide] if you are pregnant, as the effects of [Lacosamide]

on pregnancy and the unborn baby are not known.

It is not recommended to breast-feed your baby while taking [Lacosamide], as [Lacosamide] passes into breast milk.

Seek advice immediately from your doctor if you get pregnant or are planning to become pregnant. They will help you decide if you should use [Lacosamide] or not.

Do not stop treatment without talking to your doctor first as this could increase your fits (seizures). A worsening of your disease can also harm your baby.

Driving and using machines

Do not drive, cycle or use any tools or machines until you know how this medicine affects you. This is because [Lacosamide] may make you feel dizzy or cause blurred vision.

This medicine contains 30 mg sodium (main component of cooking/table salt) in each vial or 60 mg sodium in each ampoule. This is equivalent to 1.5% or 3% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

3. How to use [Lacosamide]

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Using [Lacosamide]

- [Lacosamide] can be started by:
 - o taking the medicine by mouth or
 - o by being given as an intravenous infusion (sometimes called an 'i.v. infusion') where the medicine is given into your vein by a doctor or nurse. It is given over 15 to 60 minutes.
- The i.v. infusion is usually used for a short time when you cannot take the medicine by mouth.
- Your doctor will decide for how many days you will have infusions. There is experience with twice daily infusions of [Lacosamide] for up to 5 days. For longer term treatment [Lacosamide] tablets and syrup are available.

When you change from the infusion to taking the medicine by mouth (or the other way around) the total amount you take each day and how often you take it stays the same.

Use [Lacosamide] twice each day (approximately 12 hours apart).

Try to use it at about the same time each day.

How much to use

Listed below are the normal recommended doses of [Lacosamide] for different age groups and weights. Your doctor may prescribe a different dose if you have problems with your kidneys or with your liver.

Adolescents and children weighing 50 kg or more and adults

When you use [Lacosamide] on its own

The usual starting dose of [Lacosamide] is 50 mg twice a day.

The treatment with [Lacosamide] may also start with a dose of 100 mg of [Lacosamide] twice a day.

Your doctor may increase your twice daily dose every week by 50 mg. This will be until you reach a maintenance dose between 100 mg and 300 mg twice a day.

When you use [Lacosamide] with other antiepileptic medicines

The usual starting dose of [Lacosamide] is 50 mg twice a day.

Your doctor may increase your twice daily dose every week by 50 mg. This will be until you reach a maintenance dose between 100 mg and 200 mg twice a day.

If you weigh 50 kg or more, your doctor may decide to start [Lacosamide] treatment with a single 'loading' dose of 200 mg. You would then start your ongoing maintenance dose 12 hours later.

Children and adolescents weighing less than 50 kg

- In the treatment of partial-onset seizure: Observe that [Lacosamide] is not recommended for children under 2 years of age.
- In the treatment of primary generalised tonic-clonic seizures: Observe that [Lacosamide] is not recommended for children under 4 years of age.

When you use [Lacosamide] on its own

Your doctor will decide the dose of [Lacosamide] based on your body weight.

The usual starting dose is 1 mg (0.1 ml), for each kilogram (kg) of body weight, twice a day.

Your doctor may then increase your twice daily dose every week by 1 mg (0.1 ml), for each kg of your body weight. This will be until you reach a maintenance dose.

Dosing charts including the maximum recommended dose are provided below. This is for information only. Your doctor will work out the right dose for you.

To be used twice daily for children from 2 years of age weighing from 10 kg to less than 40 kg

Weight	Week 1 Starting dose: 0.1 ml/kg	Week 2 0.2 ml/kg	Week 3 0.3 ml/kg	Week 4 0.4 ml/kg	Week 5 0.5 ml/kg	Week 6 Maximum recommended dose: 0.6 ml/kg
10 kg	1 ml	2 ml	3 ml	4 ml	5 ml	6 ml
15 kg	1.5 ml	3 ml	4.5 ml	6 ml	7.5 ml	9 ml
20 kg	2 ml	4 ml	6 ml	8 ml	10 ml	12 ml
25 kg	2.5 ml	5 ml	7.5 ml	10 ml	12.5 ml	15 ml
30 kg	3 ml	6 ml	9 ml	12 ml	15 ml	18 ml
35 kg	3.5 ml	7 ml	10.5 ml	14 ml	17.5 ml	21 ml

To be used twice daily for children and adolescents weighing from 40 kg to less than 50 kg

Weight	Week 1 Starting dose: 0.1 ml/kg	Week 2 0.2 ml/kg	Week 3 0.3 ml/kg	Week 4 0.4 ml/kg	Week 5 Maximum recommended dose: 0.5 ml/kg
40 kg	4 ml	8 ml	12 ml	16 ml	20 ml
45 kg	4.5 ml	9 ml	13.5 ml	18 ml	22.5 ml

When you use [Lacosamide] with other antiepileptic medicines

Your doctor will decide the dose of [Lacosamide] based on your body weight.

For children and adolescents weighing from 10 kg to less than 50 kg, the usual starting dose is 1 mg (0.1 ml), for each kilogram (kg) of body weight, twice a day.

Your doctor may then increase your twice daily dose every week by 1 mg (0.1 ml) for each kg

of body weight. This will be until you reach a maintenance dose.

Dosing charts including the maximum recommended dose are provided below. This is for information only. Your doctor will work out the right dose for you.

To be used twice daily for children from 2 years of age **weighing from 10 kg to less than 20 kg**

Weight	Week 1 Starting dose: 0.1 ml/kg	Week 2 0.2 ml/kg	Week 3 0.3 ml/kg	Week 4 0.4 ml/kg	Week 5 0.5 ml/kg	Week 6 Maximum recommended dose: 0.6 ml/kg
10 kg	1 ml	2 ml	3 ml	4 ml	5 ml	6 ml
15 kg	1.5 ml	3 ml	4.5 ml	6 ml	7.5 ml	9 ml

To be used twice daily for children and adolescents **weighing 20 kg to less than 30 kg**

Weight	Week 1 Starting dose: 0.1 ml/kg	Week 2 0.2 ml/kg	Week 3 0.3 ml/kg	Week 4 0.4 ml/kg	Week 5 Maximum recommended dose: 0.5 ml/kg
20 kg	2 ml	4 ml	6 ml	8 ml	10 ml
25 kg	2.5 ml	5 ml	7.5 ml	10 ml	12.5 ml

To be used twice daily for children and adolescents **weighing 30 kg to less than 50 kg**

Weight	Week 1 Starting dose: 0.1 ml/kg	Week 2 0.2 ml/kg	Week 3 0.3 ml/kg	Week 4 Maximum recommended dose: 0.4 ml/kg
30 kg	3 ml	6 ml	9 ml	12 ml
35 kg	3.5 ml	7 ml	10.5 ml	14 ml
40 kg	4 ml	8 ml	12 ml	16 ml
45 kg	4.5 ml	9 ml	13.5 ml	18 ml

If you stop using [Lacosamide]

If your doctor decides to stop your treatment with [Lacosamide], they will decrease the dose step by step. This is to prevent your epilepsy from coming back again or becoming worse.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Nervous system side effects such as dizziness may be higher after a loading dose.

Talk to your doctor or pharmacist if you get any of the following:

Very common (may affect more than 1 in 10 people)

- Headache
- Feeling dizzy or sick (nausea)
- Double vision (diplopia)

Common (may affect up to 1 in 10 people)

- Short jerks of a muscle or group of muscles (myoclonic seizures)
- Difficulties in coordinating your movements or walking
- Problems in keeping your balance, shaking (tremor), tingling (paresthesia) or muscle spasms, falling easily and getting bruises

- Trouble with your memory, thinking or finding words, confusion
- Rapid and uncontrollable movements of the eyes (nystagmus), blurred vision
- A spinning sensation (vertigo), feeling drunk
- Being sick (vomiting), dry mouth, constipation, indigestion, excessive gas in the stomach or bowel, diarrhoea
- Decreased feeling or sensitivity, difficulty in articulating words, disturbance in attention
- Noise in the ear such as buzzing, ringing or whistling
- Irritability, trouble sleeping
- Sleepiness, tiredness or weakness (asthenia)
- Itching, rash

Uncommon (may affect up to 1 in 100 people)

- Slow heart rate, palpitations, irregular pulse or other changes in the electrical activity of your heart (conduction disorder)
- Exaggerated feeling of wellbeing, seeing and/or hearing things which are not there
- Allergic reaction to medicine intake, hives
- Blood tests may show abnormal liver function, liver injury
- Thoughts of harming or killing yourself or attempting suicide: tell your doctor straight away
- Feeling angry or agitated
- Abnormal thinking or losing of touch with reality
- Serious allergic reaction which causes swelling of the face, throat, hand, feet, ankles, or lower legs
- Fainting
- Abnormal involuntary movements (dyskinesia)

Not known (frequency cannot be estimated from the available data)

- Abnormal rapid heartbeat (ventricular tachyarrhythmia)
- A sore throat, high temperature and getting more infections than usual. Blood tests may show a severe decrease in a specific class of white blood cells (agranulocytosis).
- A serious skin reaction which may include a high temperature and other flu-like symptoms, a rash on the face, extended rash, swollen glands (enlarged lymph nodes). Blood tests may show increased levels of liver enzymes and a type of white blood cell (eosinophilia).
- A widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome), and a more severe form causing skin peeling in more than 30% of the body surface (toxic epidermal necrolysis).
- Convulsion

Additional side effects when given as an intravenous infusion

There may be local side effects.

Common (may affect up to 1 in 10 people)

- Injection site pain or discomfort or irritation

Uncommon (may affect up to 1 in 100 people)

- Injection site redness

Additional side effects in children

The additional side effects in children were fever (pyrexia), runny nose (nasopharyngitis), sore throat (pharyngitis), eating less than usual (decreased appetite), changes in behaviour, not acting like themselves (abnormal behaviour) and lacking in energy (lethargy). Feeling sleepy (somnolence) is a very common side effect in children and may affect more than 1 in 10 children.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system. By reporting side effects you can help provide more information on the safety of this

medicine.

5. How to store [Lacosamide]

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 vial/ampoule after EXP. The expiry date refers to the last day of that month.

Do not freeze.

Each vial/ampoule of [Lacosamide] solution for infusion must be used only once (single use). Any unused solution should be discarded.

Only clear solution free from particles and discoloration should be used.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What [Lacosamide] contains

- The active substance is lacosamide.
1 ml [Lacosamide] solution for infusion contains 10 mg lacosamide.
1 vial contains 10 ml [Lacosamide] solution for infusion equivalent to 100 mg lacosamide.
1 ampoule contains 20 ml [Lacosamide] solution for infusion equivalent to 200 mg lacosamide.
- The other ingredients are: sodium chloride, hydrochloric acid (for pH adjustment), sodium hydroxide (for pH adjustment), water for injection.

What [Lacosamide] looks like and contents of the pack

[Lacosamide] 10 mg/ml solution for infusion is a clear, colourless solution.

[Lacosamide] solution for infusion is available in packages of 1 vial/ampoule and 5 vials/ampoules. Each vial contains 10 ml. Each ampoule contains 20 ml.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

G.L. Pharma GmbH, Schlossplatz 1, 8502 Lannach

This leaflet was last revised in April 2023.

The following information is intended for medical or healthcare professionals only.

This medicinal product is for single use only, any unused solution should be discarded.

[Lacosamide] solution for infusion was found to be physically compatible and chemically stable when mixed with the following diluents for at least 48 hours and stored in glass bottles or PVC bags at temperatures up to 25°C.

Diluents:

- Sodium chloride 9 mg/mL (0.9%) solution for injection

- Glucose 50 mg/mL (5%) solution for injection
- Ringer's solution for injection
- Sodium chloride and Dextrose solution for injection (Sodium chloride 0.18% w/v and Dextrose 4% w/v)
- Lactated Ringer's solution for injection

Product with particulate matter or discolouration should not be used.

After dilution:

Chemical and physical in-use stability has been demonstrated for 48 hours at temperatures up to 25°C for product mixed with the diluents mentioned in 6.6 and stored in glass or PVC bags. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would not be longer than 24 hours at 2 to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.