

Package leaflet: Information for the patient

[Lacosamide Medical Valley] 50 mg film-coated tablets
[Lacosamide Medical Valley] 100 mg film-coated tablets
Lacosamide Medical Valley 150 mg film-coated tablets
Lacosamide Medical Valley 200 mg film-coated tablets

lacosamide

Read all of this leaflet carefully before you start taking 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.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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 [invented name] is and what it is used for
2. What you need to know before you take [invented name]
3. How to take [invented name]
4. Possible side effects
5. How to store [invented name]
6. Contents of the pack and other information

1. What [invented name] is and what it is used for

What [invented name] is

[invented name] 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 [invented name] is used for

- [invented name] is used:
 - o 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;
 - o 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 take [invented name]

Do not take [invented name]

- 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 take [invented name] if any of the above applies to you. If you are not sure, talk to your doctor or

pharmacist before taking this medicine

Warnings and precautions

Talk to your doctor before taking [invented name] 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 and atrial flutter).
- you have severe heart disease such as heart failure or have had a heart attack.
- you are often dizzy or fall over. [invented name] 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 taking [invented name].

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

If you are taking [invented name] 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

[invented name] 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 [invented name]

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 [invented name] 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 [invented name].

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 [invented name] on your body:

- medicines for fungal infections such as fluconazole, itraconazole or ketoconazole
- medicines 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 taking [invented name].

[invented name] with alcohol

As a safety precaution do not take [invented name] 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 taking this medicine.

It is not recommended to take [invented name] if you are pregnant, as the effects of [invented name] on pregnancy and the unborn baby are not known. It is not recommended to breast-feed your baby while taking [invented name] as [invented name] 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 take [invented name] 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 [invented name] may make you feel dizzy or cause blurred vision.

3. How to take [invented name]

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Other form(s) of this medicine may be more suitable for children; ask your doctor or pharmacist.

Taking [invented name]

Take [invented name] twice each day - approximately 12 hours apart..

- Try to take it at about the same time each day.
- Swallow the [invented name] tablet with a glass of water.
- You may take [invented name] with or without food.
- The tablet can be divided into equal doses.

You will usually start by taking a low dose each day and your doctor will slowly increase this over a number of weeks. When you reach the dose that works for you, this is called the 'maintenance dose', you then take the same amount each day. [invented name] is used as a long term treatment. You should continue to take [invented name] until your doctor tells you to stop.

How much to take

Listed below are the normal recommended doses of [invented name] 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 take [invented name] on its own

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

Your doctor may also prescribe a starting dose of 100 mg of [invented name] 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 take [invented name] with other antiepileptic medicines

The usual starting dose of [invented name] 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 [invented name] 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 [invented name] is not recommended for children under 2 years of age.

- *In the treatment of primary generalised tonic-clonic seizures:* Observe that [invented name] is not recommended for children under 4 years of age.

The dose depends on their body weight. They usually start treatment with the syrup and only change to tablets if they are able to take tablets and get the correct dose with the different tablet strengths. The doctor will prescribe the formulation that is best suited to them.

If you take more [invented name] than you should

If you have taken more [invented name] than you should, contact your doctor immediately. Do not try to drive.

You may experience:

- Dizziness
- Feeling sick (nausea) or being sick (vomiting)
- Fits (seizures), heart beat problems such as a slow, fast or irregular heart beat, coma or a fall in blood pressure with rapid heartbeat and sweating.

If you forget to take [invented name]

- If you have missed a dose within the first 6 hours of the scheduled dose, take it as soon as you remember.
- If you have missed a dose beyond the first 6 hours of the scheduled dose, do not take the missed tablet anymore. Instead take [invented name] at the next time that you would normally take it.
- Do not take a double dose to make up for a forgotten dose.

If you stop taking [invented name]

- Do not stop taking [invented name] without talking to your doctor, as your epilepsy may come back again or become worse.
- If your doctor decides to stop your treatment with [invented name], he/she will instruct you about how you should decrease the dose step by step.

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 single 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 depression
- 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 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 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 behavior) 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 [invented name]

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 blister after EXP. The

expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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.
Each tablet of [invented name] 50 mg contains 50 mg lacosamide.
Each tablet of [invented name] 100 mg contains 100 mg lacosamide.
Each tablet of [invented name] 150 mg contains 150 mg lacosamide.
Each tablet of [invented name] 200 mg contains 200 mg lacosamide.
- The other ingredients are:
Tablet core: microcrystalline cellulose, hydroxypropylcellulose - low substituted, hydroxylpropyl-cellulose, crospovidone, colloidal anhydrous silica, magnesium stearate

Film-coat: poly(vinyl alcohol), macrogol, titanium dioxide (E 171), talc, colourants*

* The colourants are:

50 mg tablet: red iron oxide (E 172), black iron oxide (E 172), indigo carmine aluminium lake (E 132)

100 mg tablet: yellow iron oxide (E 172)

150 mg tablet: yellow iron oxide (E 172), red iron oxide (E 172), black iron oxide (E 172)

200 mg tablet: indigo carmine aluminium lake (E 132)

What [invented name] looks like and contents of the pack

[invented name] 50 mg are pink, oval film-coated tablets with a break-score on both sides. The tablet can be divided into equal doses.

[invented name] 100 mg are yellow, oval film-coated tablets with a break-score on both sides. The tablet can be divided into equal doses.

[invented name] 150 mg are brown, oval film-coated tablets with a break-score on both sides. The tablet can be divided into equal doses.

[invented name] 200 mg are blue, oval film-coated tablets with a break-score on both sides. The tablet can be divided into equal doses.

[invented name] is available in packs of 14, 56, and 168 film-coated tablets. The packs are available with PVC/Al blister or PVC/PVdC/Al blister.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

[To be completed nationally].

Manufacturer

G.L. Pharma GmbH
Schlossplatz 1, A-8502 Lannach
Austria

Delorbis Pharmaceuticals Ltd.
17 Athinon str.
Ergates Industrial Area
2643 Ergates, Lefkosia
Cyprus

This medicine is authorised in the Member States of the European Economic Area under the following names:

Sweden	Lacosamide Medical Valley 50/100/150/200 mg filmdragerade tabletter Lacosamide Medical Valley, 10 mg/ml, Sirap
Germany	Lacosamid AXiromed 50/100/150/200 mg Filmtabletten Lacosamid AXiromed 10 mg/ml, Sirup
Denmark	Lacosamide Medical Valley
Finland	Lacosamide Medical Valley 50/100/150/200 mg tabletti, kalvopäällysteinen Lacosamide Medical Valley 10 mg/ml siirappi
Iceland	Lacosamide Medical Valley 50/100/150/200 mg filmuhúðaðar töflur
Netherlands	Lacosamide Xiromed 50 mg, 150 mg filmomhulde tabletten Lacosamide Xiromed 10 mg/ml, stroop
Norway	Lacosamide Medical Valley

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