

Package leaflet: Information for the patient

Lacosamide STADA 50 mg, filmomhulde tabletten
Lacosamide STADA 100 mg, filmomhulde tabletten
Lacosamide STADA 150 mg, filmomhulde tabletten
Lacosamide STADA 200 mg, filmomhulde tabletten 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 [Product Name] is and what it is used for
2. What you need to know before you take [Product Name]
3. How to take [Product Name]
4. Possible side effects
5. How to store [Product Name]
6. Contents of the pack and other information

1. What [Product Name] is and what it is used for

What [Product Name] is

[Product 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 [Product Name] is used for

- [Product Name] 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 take [Product Name]

DO NOT take [Product 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 heartbeat problem called second- or third-degree AV block.
- Do not take [Product 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 [Product 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. [Product 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 [Product Name].

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

[Product 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 [Product 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 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 [Product 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 [Product 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
- an 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 [Product Name].

[Product Name] with alcohol

As a safety precaution do not take [Product 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 planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

It is not recommended to take [Product Name] 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 [Product name], 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 take [Product 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 lacosamide may make you feel dizzy or cause blurred vision.

3. How to take [Product 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 [Product Name]

- Take [Product Name] twice each day - approximately 12 hours apart.
- Try to take it at about the same time each day.
- Swallow the [Product Name] tablet with a glass of water.
- You may take [Product Name] with or without food.

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. [Product Name] is used as a long term treatment. You should continue to take [Product Name] until your doctor tells you to stop.

How much to take

Listed below are the normal recommended doses of [Product 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 [Product Name] on its own

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

Your doctor may also prescribe a starting dose of 100 mg of [Product 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 [Product Name] with other antiepileptic medicines

The usual starting dose of [Product 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 [Product 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 [Product Name] is not recommended for children under 2 years of age.
- *In the treatment of primary generalised tonic-clonic seizures:* Observe that [Product Name] is not recommended for children under 4 years of age.
- The dose depends on their body weight. For dosages below 50 mg a syrup may be available. 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 [Product Name] than you should

If you have taken more [Product 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), heartbeat problems such a slow, fast or irregular heartbeat, coma or a fall in blood pressure with rapid heartbeat and sweating.

If you forget to take [Product 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 [Product 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 [Product Name]

Do not stop taking [Product 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 [Product Name], they will tell you how to 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
- Troubles 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 touch with reality
- Serious allergic reaction which causes swelling of the face, throat, hands, 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 listed in Appendix V. [To be completed nationally]. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store [Product 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 blister and the carton. The expiry date refers to the last day of that month.

This medicine 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 [Product Name] contains

- The active substance is lacosamide.
Each tablet of [Product Name] 50 mg contains 50 mg lacosamide.
Each tablet of [Product Name] 100 mg contains 100 mg lacosamide.
Each tablet of [Product Name] 150 mg contains 150 mg lacosamide.
Each tablet of [Product Name] 200 mg contains 200 mg lacosamide.

- The other ingredients are:

Tablet core

Cellulose, microcrystalline (E460)
Low-substituted hydroxypropylcellulose
Crospovidone (E1202)
Hydroxypropylcellulose (E463)
Silica colloidal anhydrous
Magnesium stearate

Coating

Poly(vinyl alcohol) (E1203)
Macrogol 3350 (E1521)
Titanium dioxide (E171)
Talc (E553b)

50 mg film-coated tablets

Red Iron Oxide (E172)
Black Iron Oxide (E172)
Indigo Carmine Aluminium Lake (E132)

100 mg film-coated tablets

Yellow Iron Oxide (E172)
Black Iron Oxide (E172)

150 mg film-coated tablets

Red Iron Oxide (E172)
Yellow Iron Oxide (E172)
Black Iron Oxide (E172)
Indigo Carmine Aluminium Lake (E132)

200 mg film-coated tablets

Indigo Carmine Aluminium Lake (E132)

What [Product Name] looks like and contents of the pack

[Product Name] is supplied as film-coated tablets.

[Product Name] 50 mg are pink film coated oblong biconvex tablets, embossed with '50' on one side, plain on the other with 10.3 mm length and 4.8 mm width approximately.

[Product Name] 100 mg are yellow, film coated oblong biconvex tablets, embossed with '100' on one side, plain on the other with 13.1 mm length and 6.1 mm width approximately.

[Product Name] 150 mg are beige, film coated oblong biconvex tablets, embossed with '150' on one side, plain on the other with 15.2 mm length and 7.1 mm width approximately.

[Product Name] 200 mg are blue, film coated oblong biconvex tablets, embossed with '200' on one side, plain on the other with 16.6 mm length and 7.7 mm width approximately.

[Product Name] is available in packs of 14, 56 and 168 film-coated tablets in transparent PVC/PVDC blisters sealed with an aluminium foil and packed into cardboard boxes.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

STADA Arzneimittel AG
Stadastr.2-18
61118 Bad Vilbel
Duitsland

Manufacturer

STADA Arzneimittel AG
Stadastr.2-18
61118 Bad Vilbel
Duitsland

STADA Arzneimittel GmbH
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1190 Wenen,
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18 km Marathon Avenue
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Griekenland

THORNTON & ROSS LIMITED
Manchester Road
Linthwaite, Huddersfield, West Yorkshire,
HD7 5QH,
Verenigd Koninkrijk

This medicinal product is authorised in the Member States of the EEA under the following names:

RVG 120362 Lacosamide STADA 50 mg, filmomhulde tabletten
RVG 120364 Lacosamide STADA 100 mg, filmomhulde tabletten
RVG 120365 Lacosamide STADA 150 mg, filmomhulde tabletten
RVG 120366 Lacosamide STADA 200 mg, filmomhulde tabletten

Dit geneesmiddel is geregistreerd in lidstaten van de EEA onder de volgende namen:

{ Oostenrijk	Lacosamid STADA 50 mg Filmtabletten
	Lacosamid STADA 100 mg Filmtabletten
	Lacosamid STADA 150 mg Filmtabletten
	Lacosamid STADA 200 mg Filmtabletten
Duitsland	Lacosamid AL 50 mg Filmtabletten
	Lacosamid AL 100 mg Filmtabletten
	Lacosamid AL 150 mg Filmtabletten

	Lacosamid AL 200 mg Filmtabletten
Denemarken	Lacosamid STADA
Spanje	Lacosamida STADA 50 mg comprimidos recubiertos con película EFG Lacosamida STADA 100 mg comprimidos recubiertos con película EFG Lacosamida STADA 150 mg comprimidos recubiertos con película EFG Lacosamida STADA 200 mg comprimidos recubiertos con película EFG
Italië	Lacosamide EG 50 compresse rivestite con film Lacosamide 100 compresse rivestite con film Lacosamide 150 compresse rivestite con film Lacosamide 200 compresse rivestite con film
Zweden	Lacosamide STADA 50 mg filmdragerade tabletter Lacosamide STADA 100 mg filmdragerade tabletter Lacosamide STADA 150 mg filmdragerade tabletter Lacosamide STADA 200 mg filmdragerade tabletter
Nederland	Lacosamide STADA 50 mg, filmomhulde tabletten Lacosamide STADA 100 mg, filmomhulde tabletten Lacosamide STADA 150 mg, filmomhulde tabletten Lacosamide STADA 200 mg, filmomhulde tabletten
Slowakije	Lacosamide Stada 50 mg filmom obalené tablety Lacosamide Stada 100 mg filmom obalené tablety Lacosamide Stada 150 mg filmom obalené tablety Lacosamide Stada 200 mg filmom obalené tablety
België	Lacosamide EG 50 mg filmomhulde tabletten Lacosamide EG 100 mg filmomhulde tabletten Lacosamide STADA 150 mg filmomhulde tabletten Lacosamide STADA 200 mg filmomhulde tabletten
Finland	Lacosamide STADA 50 mg tabletti, kalvopäällysteinen Lacosamide STADA 100 mg tabletti, kalvopäällysteinen Lacosamide STADA 150 mg tabletti, kalvopäällysteinen Lacosamide STADA 200 mg tabletti, kalvopäällysteinen
Frankrijk	LACOSAMIDE EG 50 mg, comprimé pelliculé LACOSAMIDE EG 100 mg, comprimé pelliculé LACOSAMIDE EG 150 mg, comprimé pelliculé LACOSAMIDE EG 200 mg, comprimé pelliculé
IJsland	Lacosamide STADA 50 mg filmuhúðuð tafla Lacosamide STADA 100 mg filmuhúðuð tafla Lacosamide STADA 150 mg filmuhúðuð tafla Lacosamide STADA 200 mg filmuhúðuð tafla
Luxemburg	Lacosamide EG 50 mg comprimés pelliculés Lacosamide EG 100 mg comprimés pelliculés Lacosamide EG 150 mg comprimés pelliculés Lacosamide EG 200 mg comprimés pelliculés
Verenigd Koninkrijk	Lacosamide STADA 50 mg film-coated tablets Lacosamide STADA 100 mg film-coated tablets Lacosamide STADA 150 mg film-coated tablets Lacosamide STADA 200 mg film-coated tablets

Deze bijsluiter is voor de laatste keer goedgekeurd in juni 2023.

This leaflet was last revised in June 2023.