LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Lacosamide G.L.
(lacosamide)

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Summary Public Assessment Report

Lacosamide G.L.

(lacosamide)

Film-coated tablet 50 mg, 100 mg, 150 mg, 200 mg

This is a summary of the public assessment report (PAR) for Lacosamide G.L. It explains how Lacosamide G.L. was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Lacosamide G.L.

For practical information about using Lacosamide G.L., patients should read the package leaflet or contact their doctor or pharmacist.

What is Lacosamide G.L. and what is it used for?

Lacosamide G.L. is a 'generic medicine'. This means that Lacosamide G.L. is similar to a 'reference medicine' already authorised in the European Union (EU) called Vimpat.

- Lacosamide G.L. is used in adults, adolescents and children aged 4 years and older.
- It is used to treat a certain type of epilepsy called '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.
- Lacosamide G.L. may be used on its own or with other antiepileptic medicines.

How does Lacosamide G.L. work?

Lacosamide G.L. 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.

How is Lacosamide G.L. used?

The pharmaceutical form of Lacosamide G.L. is film-coated tablet for oral use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

What benefits of Lacosamide G.L. have been shown in studies?

Because Lacosamide G.L. is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Vimpat. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of Lacosamide G.L.?

Because Lacosamide G.L. is a generic medicine and is bioequivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine. For the full list of restrictions, see the package leaflet.

Why is Lacosamide G.L. approved?

It was concluded that, in accordance with EU requirements, Lacosamide G.L. has been shown to have comparable quality and to be bioequivalent to the reference medicine Vimpat. Therefore, the Medical Products Agency in Sweden decided that, as for Vimpat, the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Lacosamide G.L.?

A risk management plan has been developed to ensure that Lacosamide G.L. is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Lacosamide G.L., including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Lacosamide G.L.

The marketing authorisation for Lacosamide G.L. was granted on 2018-06-20 in Sweden.

The full PAR for Lacosamide G.L. can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Lacosamide G.L., please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2018-06.