LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Lacomed
(lacosamide)

SE/H/2420/01/DC

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lacosamide

syrup, 10 mg/ml

This is a summary of the public assessment report (PAR) for Lacomed. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Lacomed and what is it used for?

The product is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Vimpat.

The product is used in the treatment of epilepsy, for lowering the number of fits (seizures).
It belongs to a group of medicines called "antiepileptic medicines".

How does Lacomed work?

The precise mechanism by which lacosamide exerts its antiepileptic effect in humans remains to be fully investigated. Studies performed in cultured cells in laboratory environment have shown that lacosamide selectively increases slow inactivation of voltage-gated sodium channels on cells´ surface, resulting in stabilization of hyperexcitable membranes (surface) of the neurons (nerve cells).

The product can be used both on its own and in association with other antiepileptic medicines in adults, adolescents and children aged 2 years and older, in a type of epilepsy where fits first affect only one side of the patient´s brain. These may however spread to larger areas on both sides of the brain.

The product can also be used in association with other antiepileptic medicines in adults, adolescents and children aged 4 years and older to treat major fits, including loss of consciousness, in patients with epilepsy of unclear origin, so called "idiopathic" epilepsy (the type of epilepsy that is thought to have a genetic cause).

How is Lacomed used?

The pharmaceutical form is syrup 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 in Sweden.

What benefits of Lacomed have been shown in studies?

No additional studies were needed as the product is a generic medicine considered to be 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 from Lacomed?

Because the product is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Lacomed approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be similar to the reference medicine. Therefore, the Swedish Medical Products Agency 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 Lacomed?

A risk management plan has been developed to ensure that the product 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, 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 Lacomed

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

This summary was last updated in 2024-10.