

Summary Public Assessment Report

Lacosamide Medical Valley (lacosamide)

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(lacosamide)

Syrup, Film-coated tablet, 150 mg, 10 mg/ml, 200 mg, 50 mg, 100 mg

This is a summary of the public assessment report (PAR) for Lacosamide Medical Valley. It explains how Lacosamide Medical Valley 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 Medical Valley.

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

What is Lacosamide Medical Valley and what is it used for?

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

Lacosamide Medical Valley is used in adults, adolescents and children aged 4 years and older in the treatment of epilepsy.

How does Lacosamide Medical Valley work?

Lacosamide Medical Valley 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 the brain. However, these may then spread to larger areas on both sides of the brain. The medicine may be used on its own or with other antiepileptic medicines.

How is Lacosamide Medical Valley used?

The pharmaceutical form of Lacosamide Medical Valley is film-coated tablets and 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 Lacosamide Medical Valley have been shown in studies?

No additional studies were needed as Lacosamide Medical Valley 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 of Lacosamide Medical Valley?

Because Lacosamide Medical Valley 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 restrictions, see the package leaflet.

Why is Lacosamide Medical Valley approved?

It was concluded that, in accordance with EU requirements, Lacosamide Medical Valley has been shown to have comparable quality and is considered to be similar 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 Medical Valley?

A risk management plan has been developed to ensure that Lacosamide Medical Valley 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 Medical Valley, 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 Medical Valley

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

This summary was last updated in YYYY-MM.

Infoga datum enligt när sPAR blir klar för publicering.