LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Trelema
(lacosamide)

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Summary Public Assessment Report

Trelema

(lacosamide)

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

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

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

What is Trelema and what is it used for?

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

- Trelema 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.
- Trelema may be used on its own or with other antiepileptic medicines.

How does Trelema work?

Trelema 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 Trelema Trelema used?

The pharmaceutical form of Trelema 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 Trelema have been shown in studies?

Because Trelema 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 Trelema?

Because Trelema 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 Trelema approved?

It was concluded that, in accordance with EU requirements, Trelema 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 Trelema?

A risk management plan has been developed to ensure that Trelema 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 Trelema, 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 Trelema

The marketing authorisation for Trelema was granted on 2018-06-20 in Sweden.

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

This summary was last updated in 2018-06.