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EPAR summary for the public

Lacosamide Accord

lacosamide

This is a summary of the European public assessment report (EPAR) for Lacosamide Accord. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Lacosamide Accord.

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

What is Lacosamide Accord and what is it used for?

Lacosamide Accord is an epilepsy medicine used to treat partial-onset seizures (epileptic fits starting in one specific part of the brain) in patients with epilepsy aged 16 years or older. It can be used to treat partial-onset seizures with or without secondary generalisation (where the seizure subsequently spreads to other parts of the brain).

Lacosamide Accord is given on its own or combined with other medicines for epilepsy.

Lacosamide Accord contains the active substance lacosamide. It is a 'generic medicine'. This means that Lacosamide Accord contains the same active substance and works in the same way as a 'reference medicine' already authorised in the European Union (EU) called Vimpat. For more information on generic medicines, see the question-and-answer document here.

How is Lacosamide Accord used?

The medicine can only be obtained with a prescription and is available as tablets (50 mg; 100 mg; 150 mg; 200 mg). The usual starting dose is 50 mg twice a day which may be increased weekly to a maximum dose of 300 mg twice a day if used alone, or 200 mg twice a day if given with other epilepsy medicines. If the doctor decides that a faster effect is needed, treatment with Lacosamide Accord may be started with a higher first dose (called a loading dose).

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If treatment with Lacosamide Accord has to be stopped, the dose should be gradually reduced. For further information, see the package leaflet.

How does Lacosamide Accord work?

The active substance in Lacosamide Accord, lacosamide, is an epilepsy medicine. Epilepsy is caused by excessive electrical activity in the brain. The exact way in which lacosamide works is still unclear but it seems to reduce the activity of sodium channels (pores on the surface of nerve cells) that allow electrical impulses to be transmitted between nerve cells. It is also thought that lacosamide might help protect nerve cells from damage. Together, these actions may prevent abnormal electrical activity spreading through the brain, reducing the chance of an epileptic fit.

How has Lacosamide Accord been studied?

Studies on the benefits and risks of the active substance in the approved uses have already been carried out with the reference medicine, Vimpat, and do not need to be repeated for Lacosamide Accord.

As for every medicine, the company provided studies on the quality of Lacosamide Accord. There was no need for 'bioequivalence' studies to investigate whether Lacosamide Accord is absorbed similarly to the reference medicine to produce the same level of the active substance in the blood. This is because the active substance, lacosamide, has been shown to be highly soluble and completely absorbed, meaning that almost 100% of the substance reaches the blood when taken by mouth.

What are the benefits and risks of Lacosamide Accord?

Because Lacosamide Accord is a generic medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Lacosamide Accord approved?

The European Medicines Agency concluded that, in accordance with EU requirements, Lacosamide Accord has been shown to be comparable to Vimpat. Therefore, the Agency's view was that, as for Vimpat, the benefit outweighs the identified risk. The Agency recommended that Lacosamide Accord be approved for use in the EU.

What measures are being taken to ensure the safe and effective use of Lacosamide Accord?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Lacosamide Accord have been included in the summary of product characteristics and the package leaflet.

Other information about Lacosamide Accord

The European Commission granted a marketing authorisation valid throughout the European Union for Lacosamide Accord on 18 September 2017.

The full EPAR for Lacosamide Accord can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Lacosamide Accord, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The full EPAR for the reference medicine can also be found on the Agency's website.

This summary was last updated in 09-2017.