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Lacosamide Adroiq (*lacosamide*)

An overview of Lacosamide Adroiq and why it is authorised in the EU

What is Lacosamide Adroiq and what is it used for?

Lacosamide Adroiq is a medicine used on its own or as an add-on to other epilepsy medicines in the treatment of partial-onset seizures (epileptic fits starting in one specific part of the brain) with or without secondary generalisation (where the abnormal electrical activity spreads through the brain) in patients with epilepsy aged 2 years and older.

Lacosamide Adroiq can also be used as add-on to other epilepsy medicines in the treatment of primary generalised tonic-clonic seizures (major fits, including loss of consciousness) in patients from 4 years of age with idiopathic generalised epilepsy (the type of epilepsy that is thought to have a genetic cause).

Lacosamide Adroiq is a 'generic medicine'. This means that Lacosamide Adroiq contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU. The reference medicine for Lacosamide Adroiq is Vimpat. For more information on generic medicines, see the question-and-answer document here.

Lacosamide Adroiq contains the active substance lacosamide.

How is Lacosamide Adroiq used?

Lacosamide Adroiq is available as a solution for infusion (drip) into a vein and is given twice a day.

The medicine can only be obtained with a prescription.

For more information about using Lacosamide Adroiq, see the package leaflet or contact your doctor or pharmacist.

How does Lacosamide Adroiq work?

The active substance in Lacosamide Adroiq, lacosamide, is an epilepsy medicine. Epilepsy is caused by abnormal electrical activity in the brain. The exact way in which lacosamide works is 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. This action may prevent abnormal electrical activity in the brain, reducing the chance of an epileptic fit.

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How has Lacosamide Adroiq been studied?

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

As for every medicine, the company provided studies on the quality of Lacosamide Adroiq. There was no need for 'bioequivalence' studies to investigate whether Lacosamide Adroiq is absorbed similarly to the reference medicine to produce the same level of the active substance in the blood. This is because Lacosamide Adroiq is given by infusion into a vein, so the active substance is delivered straight into the bloodstream.

What are the benefits and risks of Lacosamide Adroiq?

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

For the list of side effects and restrictions with Lacosamide Adroiq, see the package leaflet.

Why is Lacosamide Adroiq authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Lacosamide Adroiq has been shown to be comparable to Vimpat. Therefore, the Agency's view was that, as for Vimpat, the benefits of Lacosamide Adroiq outweigh the identified risks and it can be authorised for use in the EU.

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

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

As for all medicines, data on the use of Lacosamide Adroiq are continuously monitored. Suspected side effects reported with Lacosamide Adroiq are carefully evaluated and any necessary action taken to protect patients.

Other information about Lacosamide Adroiq

Lacosamide Adroiq received a marketing authorisation valid throughout the EU on 31 May 2023.

Further information on Lacosamide Adroiq can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/lacosamide-adroiq. Information on the reference medicine can also be found on the Agency's website

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