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Levetiracetam Actavis (*levetiracetam*)

An overview of Levetiracetam Actavis and why it is authorised in the EU

What is Levetiracetam Actavis and what is it used for?

Levetiracetam Actavis is an epilepsy medicine. It can be used on its own in patients from 16 years of age with newly diagnosed epilepsy, to treat partial-onset seizures (fits) with or without secondary generalisation. This is a type of epilepsy where too much electrical activity in one side of the brain causes symptoms such as sudden, jerky movements of one part of the body, distorted hearing, sense of smell or vision, numbness, or a sudden sense of fear. Secondary generalisation occurs when the overactivity later reaches the whole brain.

Levetiracetam Actavis can also be used as an add-on to other anti-epileptic medicines to treat:

- partial-onset seizures with or without generalisation in patients from one month of age;
- myoclonic seizures (short, shock-like jerks of a muscle or group of muscles) in patients from 12 years of age with juvenile myoclonic epilepsy;
- primary generalised tonic-clonic seizures (major fits, including loss of consciousness) in patients from 12 years of age with idiopathic generalised epilepsy (the type of epilepsy that is thought to have a genetic cause).

Levetiracetam Actavis contains the active substance levetiracetam and is a 'generic medicine'. This means that Levetiracetam Actavis contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU called Keppra. For more information on generic medicines, see the question-and-answer document here.

How is Levetiracetam Actavis used?

Levetiracetam Actavis is available as tablets to be swallowed with liquid. It can only be obtained with a prescription.

The usual starting dose in patients over 12 years weighing more than 50 kg is 500 mg twice a day. The daily dose can be increased up to 1,500 mg twice a day. For patients aged between one month and 17 years weighing less than 50 kg, the dose depends on body weight.

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

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How does Levetiracetam Actavis work?

The active substance in Levetiracetam Actavis, levetiracetam, is an anti-epileptic medicine. Epilepsy is caused by excessive electrical activity in the brain. The exact way in which levetiracetam works is still unclear but it seems to interfere with a protein called synaptic vesicle protein 2A, which is found in the spaces between nerves and is involved in the release of chemical messengers from nerve cells. This helps Levetiracetam Actavis to stabilise electrical activity in the brain and prevent seizures.

How has Levetiracetam Actavis been studied?

The company provided data from the published literature on levetiracetam. Studies on the benefits and risks of the active substance in the authorised uses have already been carried out with the reference medicine, Keppra, and do not need to be repeated for Levetiracetam Actavis. Because Levetiracetam Actavis is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Keppra. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the benefits and risks of Levetiracetam Actavis?

Because Levetiracetam Actavis is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why has Levetiracetam Actavis been approved?

The European Medicines Agency concluded that, in accordance with EU requirements, Levetiracetam Actavis has been shown to have comparable quality and to be bioequivalent to Keppra. Therefore, the Agency's view was that, as for Keppra, the benefits of Levetiracetam Actavis 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 Levetiracetam Actavis?

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

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

Other information about Levetiracetam Actavis

Levetiracetam Actavis received a marketing authorisation valid throughout the EU on 3 October 2011.

Further information on Levetiracetam Actavis can be found on the Agency's website: https://www.ema.europa.eu/en/medicines/human/EPAR/levetiracetam-actavis.

This overview was last updated in 06-2021.