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Levetiracetam Actavis Group (*levetiracetam*)

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

What is Levetiracetam Actavis Group and what is it used for?

Levetiracetam Actavis Group 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 Group 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 Group contains the active substance levetiracetam and is a 'generic medicine'. This means that Levetiracetam Actavis Group 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 Group used?

Levetiracetam Actavis Group is available as a solution to be drunk (100 mg/ml).

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 Group, see the package leaflet or contact your doctor or pharmacist.

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How does Levetiracetam Actavis Group work?

The active substance in Levetiracetam Actavis Group, levetiracetam, is an epilepsy medicine. Epilepsy is caused by too much electrical activity in the brain. The exact way in which levetiracetam works is still unclear but it attaches to a protein called synaptic vesicle protein 2A, which is involved in the release of chemical messengers from nerve cells. This helps levetiracetam to stabilise electrical activity in the brain and prevent seizures.

How has Levetiracetam Actavis Group 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 Group.

As for every medicine, the company provided data on the quality of Levetiracetam Actavis Group. The company also provided information to show that there was no need for a study to show that the medicine was bioequivalent to the reference medicine, since the composition of the two medicines was comparable. Two medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect.

What benefit has Levetiracetam Actavis Group shown during the studies?

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

Why is Levetiracetam Actavis Group authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Levetiracetam Actavis Group 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 Group outweigh the identified risks and it can be authorised for use in the EU.

Other information about Levetiracetam Actavis Group

Levetiracetam Actavis Group received a marketing authorisation valid throughout the EU on 5 December 2011.

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

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