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Levetiracetam ratiopharm (*levetiracetam*)

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

What is Levetiracetam ratiopharm and what is it used for?

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

Levetiracetam ratiopharm is available as tablets to be swallowed with liquid and an oral solution to be drunk. 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 infants and children under the age of 6 years or weighing less than 25 kg, the oral solution is recommended.

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

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How does Levetiracetam ratiopharm work?

The active substance in Levetiracetam ratiopharm, levetiracetam, is an epilepsy medicine. Epilepsy is caused by excessive 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 ratiopharm to stabilise electrical activity in the brain and prevent seizures.

How has Levetiracetam ratiopharm 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 ratiopharm.

Because Levetiracetam ratiopharm is a generic medicine, studies in patients have been limited to tests to determine that the tablets are bioequivalent to the reference medicine, Keppra. Two medicines are bioequivalent when they produce the same levels of the active substance in the body. The company provided data to show that a bioequivalence study was not needed for the oral solution as the composition was sufficiently similar to the reference medicine.

What are the benefits and risks of Levetiracetam ratiopharm?

Because Levetiracetam ratiopharm 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 is Levetiracetam ratiopharm authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Levetiracetam ratiopharm 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 ratiopharm 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 ratiopharm?

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

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

Other information about Levetiracetam ratiopharm

Levetiracetam ratiopharm received a marketing authorisation valid throughout the EU on 26 August 2011.

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

Information on the the reference medicine can also be found on the Agency's website.

This overview was last updated in 06-2021.