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Levetiracetam Teva (*levetiracetam*)

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

What is Levetiracetam Teva and what is it used for?

Levetiracetam Teva 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 Teva can also be used as an add-on to other epilepsy medicines to treat:

- partial-onset seizures with or without generalisation in patients from 1 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 be inherited).

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

Levetiracetam Teva 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 Sun, see the package leaflet or contact your doctor or pharmacist.

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How does Levetiracetam Teva work?

The active substance in Levetiracetam Teva, 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 Teva to stabilise electrical activity in the brain and prevent seizures.

How has Levetiracetam Teva 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 Teva.

As for every medicine, the company provided data on the quality of Levetiracetam Teva. The company also carried out studies that showed that it is 'bioequivalent' to the reference medicine. 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 are the benefits and risks of Levetiracetam Teva?

Because Levetiracetam Teva 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 Teva authorised in the EU?

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

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

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

Other information about Levetiracetam Teva

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

Further information on Levetiracetam Teva can be found on the Agency's website: https://www.ema.europa.eu/en/medicines/human/EPAR/levetiracetam-teva. Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 06-2021.