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EPAR summary for the public

Levetiracetam Hospira

levetiracetam

This is a summary of the European public assessment report (EPAR) for Levetiracetam Hospira. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Levetiracetam Hospira.

For practical information about using Levetiracetam Hospira, patients should read the package leaflet or contact their doctor or pharmacist.

What is Levetiracetam Hospira and what is it used for?

Levetiracetam Hospira is an anti-epileptic medicine that contains the active substance levetiracetam. 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 side 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 Hospira 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 four years of age;
- myoclonic seizures (short, shock-like jerks of a muscle or a 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 Hospira is a 'generic medicine'. This means that Levetiracetam Hospira is similar to a 'reference medicine' already authorised in the European Union (EU) called Keppra. For more information on generic medicines, see the question-and-answer document here.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

How is Levetiracetam Hospira used?

Levetiracetam Hospira can only be obtained with a prescription and is available as a concentrate (100 mg/ml) that is made up into a solution for infusion (drip) into a vein.

When Levetiracetam Hospira is used on its own, the starting dose is 250 mg twice a day, increasing two weeks later to 500 mg twice a day. The dose can be further increased at two-week intervals according to the patient's response, to a maximum dose of 1,500 mg twice a day.

When Levetiracetam Hospira is added to another anti-epileptic treatment, the starting dose in patients over 12 years weighing 50 kg or more is 500 mg twice a day. The daily dose can be increased up to 1,500 mg twice a day. In patients aged between four and 17 years weighing less than 50 kg, the starting dose is 10 mg per kilogram body weight twice a day, which can be increased up to 30 mg/kg twice a day.

Lower doses are used in patients who have reduced kidney function.

Levetiracetam Hospira infusion should only be used temporarily, while treatment by mouth is not feasible.

How does Levetiracetam Hospira work?

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

How has Levetiracetam Hospira been studied?

The company provided data from the published literature on levetiracetam. No additional studies were needed as Levetiracetam Hospira is a generic medicine that is given by infusion and contains the same active substance as the reference medicine, Keppra.

What are the benefits and risks of Levetiracetam Hospira?

Because Levetiracetam Hospira 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 Hospira approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Levetiracetam Hospira has been shown to have comparable quality and to be bioequivalent to Keppra. Therefore, the CHMP's view was that, as for Keppra, the benefit outweighs the identified risk. The Committee recommended that Levetiracetam Hospira be approved for use in the EU.

What measures are being taken to ensure the safe and effective use of Levetiracetam Hospira?

A risk management plan has been developed to ensure that Levetiracetam Hospira is used as safely as possible. Based on this plan, safety information has been included in the summary of product

characteristics and the package leaflet for Levetiracetam Hospira, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Levetiracetam Hospira

The European Commission granted a marketing authorisation valid throughout the European Union for Levetiracetam Hospira on the 08 January 2014.

The full EPAR for Levetiracetam Hospira can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Levetiracetam Hospira, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The full EPAR for the reference medicine can also be found on the Agency's website.

This summary was last updated in 01-2014.