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Levetiracetam Hospira (*levetiracetam*)

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

What is Levetiracetam Hospira and what is it used for?

Levetiracetam Hospira 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 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 used as an alternative for patients when oral treatment is temporarily not feasible.

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

Levetiracetam Hospira is given by infusion (drip into a vein) and 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 4 years and 17

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years weighing less than 50 kg, the dose depends on body weight.

The use of Levetiracetam Hospira infusion should be temporary.

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

How does Levetiracetam Hospira work?

The active substance in Levetiracetam Hospira, 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 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. 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 Hospira.

As for every medicine, the company provided data on the quality of Levetiracetam Hospira. There was no need for 'bioequivalence' studies to investigate whether Levetiracetam Hospira is absorbed similarly to the reference medicine to produce the same level of the active substance in the blood. This is because Levetiracetam Hospira is given by infusion into a vein, so the active substance is delivered straight into the bloodstream.

What are the benefits and risks of Levetiracetam Hospira?

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

Why is Levetiracetam Hospira authorised in the EU?

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

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

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

Other information about Levetiracetam Hospira

Levetiracetam Hospira received a marketing authorisation valid throughout the EU on 8 January 2014.

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

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

This overview was last updated in 06-2021.