



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Keppra (*levetiracetam*)

An overview of Keppra and why it is authorised in the EU

What is Keppra and what is it used for?

Keppra 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.

Keppra 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).

Keppra is a medicine that contains the active substance levetiracetam.

How is Keppra used?

Keppra is available as tablets, an oral solution and as a concentrate that is made up into a solution for infusion (drip into a vein).

The 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.

The medicine can only be obtained with a prescription. For more information about using Keppra, see the package leaflet or contact your doctor or pharmacist.

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How does Keppra work?

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

What benefits of Keppra have been shown in studies?

A study of Keppra used on its own in 576 patients with partial-onset seizures aged 16 years and over measured how many patients remained free of seizures for six months once they had reached their effective dose. In this study, Keppra was as effective as carbamazepine (another epilepsy medicine) in keeping patients free of seizures when taken on its own for partial onset seizures. In both groups, 73% of the patients experienced no seizures for six months once on an adequate dose.

Three studies involving over 1,000 patients looked at Keppra as an add-on treatment. The studies showed that:

- for partial onset seizures, placebo treatment reduced the weekly number of seizures by 6 to 7%, while the reduction with Keppra at a dose of 1,000 mg per day was between 18 and 33%, depending on the study. With Keppra at a dose of 2,000 mg, the reduction was 27%, and with 3,000 mg, it was around 39%. Keppra was also more effective than placebo in children;
- for myoclonic seizures, the number of seizure days per week was halved in 58% of the patients receiving Keppra and in 23% of the patients receiving placebo;
- for tonic-clonic seizures, the number of seizures fell by an average of 28% in the patients receiving placebo, compared with 57% in those receiving Keppra. However, there were too few patients aged below 12 years to support the use of Keppra for this type of seizure in this age group.

What are the risks associated with Keppra?

The most common side effects with Keppra (seen in more than 1 patient in 10) are nasopharyngitis (inflammation of the nose and throat), somnolence (sleepiness) and headache. For the full list of all side effects reported with Keppra, see the package leaflet.

Keppra must not be used in people who are hypersensitive (allergic) to levetiracetam, to other pyrrolidone derivatives (medicines with a similar structure to levetiracetam), or to any of the other ingredients.

Why is Keppra authorised in the EU?

Studies have shown that Keppra is effective when used on its own and as an add-on treatment for different seizures. The side effects of the medicine are considered manageable. The European Medicines Agency therefore decided that Keppra's benefits are greater than its risks and it can be authorised for use in the EU.

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

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

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

Other information about Keppra

Keppra received a marketing authorisation valid throughout the EU on 29 September 2000.

Further information on Keppra can be found on the Agency's website:

ema.europa.eu/medicines/human/EPAR/keppra

This overview was last updated in 04-2021.