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Vimpat (*lacosamide*)

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

What is Vimpat and what is it used for?

Vimpat is a medicine used on its own or as an add-on to other epilepsy medicines in the treatment of partial-onset seizures (epileptic fits starting in one specific part of the brain) with or without secondary generalisation (where the abnormal electrical activity spreads through the brain) in patients with epilepsy aged 24 years and older

Vimpat can also be used as add-on to other epilepsy medicines in the treatment of primary generalised tonic-clonic seizures (major fits, including loss of consciousness) in patients from 4 years of age with idiopathic generalised epilepsy (the type of epilepsy that is thought to have a genetic cause).

Vimpat contains the active substance lacosamide.

How is Vimpat used?

Vimpat can only be obtained with a prescription and is available as tablets, as a syrup and as a solution for infusion (drip) into a vein. Vimpat should be taken twice a day; the dosage depends on the patient's weight and age, as well as whether Vimpat is used alone or with other epilepsy medicines.

Vimpat infusion can be used to begin treatment. It can also be used in patients who are temporarily unable to take the medicine by mouth.

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

How does Vimpat work?

The active substance in Vimpat, lacosamide, is an epilepsy medicine. Epilepsy is caused by abnormal electrical activity in the brain. The exact way in which lacosamide works is unclear but it seems to reduce the activity of sodium channels (pores on the surface of nerve cells) that allow electrical impulses to be transmitted between nerve cells. This action may prevent abnormal electrical activity in the brain, reducing the chance of an epileptic fit.

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What benefits of Vimpat have been shown in studies?

Partial-onset seizures

Vimpat was effective at reducing partial-onset seizures in three main studies involving a total of 1,308 patients aged 16 years and above also taking other epilepsy medicines. Patients were given Vimpat at a dose of 200 mg, 400 mg or 600 mg a day, or placebo (a dummy treatment) in addition to their existing epilepsy medicines. Taking the results of the three studies together, 34% of the patients taking Vimpat 200 mg a day and 40% of those taking 400 mg a day had a reduction in their seizures by at least half after 12 weeks of treatment. This compared with 23% of the patients receiving placebo. The 600-mg dose was as effective as the 400-mg dose but it had more side effects.

A fourth study involving 888 recently diagnosed patients found that Vimpat, used on its own at a dose of 200 to 600 mg a day, was at least as effective as carbamazepine, another epilepsy medicine. The main measure of effectiveness was the proportion of patients who did not have a partial-onset seizure for at least 6 months after reaching a stable dose. This was found to be 90% in those taking Vimpat and 91% in those taking carbamazepine. Around 78% of Vimpat-treated and 83% of carbamazepine-treated patients did not have a seizure for 12 months.

Two additional studies looked at the appropriate duration of the infusion for Vimpat solution and compared its safety with that of placebo infusions in a total of 199 patients. An additional study in 118 patients was carried out to test that starting treatment with doses of 200 mg Vimpat by infusion, followed by regular doses taken by mouth, can be applied safely and that adequate levels in the body are achieved. The company also provided data to support dosing of Vimpat in children from 2 years of age and supportive results from studies of the safety of Vimpat in this population.

Tonic-clonic seizures

A further study involving 242 patients aged from 4 years with idiopathic generalised epilepsy compared Vimpat with placebo, both used with other epilepsy medicines. The study showed that Vimpat lowered the risk of having a tonic-clonic seizure: after 24 weeks of treatment, around 31% of patients taking Vimpat were free from seizures compared with around 17% of patients receiving placebo.

What are the risks associated with Vimpat?

The most common side effects with Vimpat (seen in more than 1 patient in 10) are dizziness, headache, diplopia (double vision) and nausea (feeling sick). Side effects affecting the nervous system such as dizziness may be higher after a high first dose and dizziness was the most common reason for stopping treatment.

Vimpat must not be used in people who have second- or third-degree AV block (a type of heart rhythm disorder). For the full list of side effects and restrictions with Vimpat, see the package leaflet.

Why is Vimpat authorised in the EU?

The European Medicines Agency decided that Vimpat, used alone or added to other epilepsy medicines, had been shown to be effective in the treatment of partial-onset and tonic-clonic seizures. Taking its side effects into account, the Agency decided that Vimpat'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 Vimpat?

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

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

Other information about Vimpat

Vimpat received a marketing authorisation valid throughout the EU on 29 August 2008.

Further information on Vimpat can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/vimpat.

This overview was last updated in 03-2022.