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EPAR summary for the public

Vimpat

lacosamide

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

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

What is Vimpat and what is it used for?

Vimpat is an epilepsy medicine used to treat partial-onset seizures (epileptic fits starting in one specific part of the brain) in patients with epilepsy aged 4 years and older. It can be used to treat partial-onset seizures with or without secondary generalisation (where the seizure subsequently spreads to other parts of the brain).

Vimpat is given on its own or combined with other medicines for epilepsy. It contains the active substance lacosamide.

How is Vimpat used?

Vimpat can only be obtained with a prescription and is available as tablets (50 mg; 100 mg; 150 mg; 200 mg), as a syrup (10 mg/ml) and as a solution for infusion (drip) into a vein. The usual starting dose in adults and older children (weighing at least 50 kg) is 50 mg twice a day which may be increased weekly to a maximum dose of 300 mg twice a day if used alone, or 200 mg twice a day if given with other epilepsy medicines. If the doctor decides that a faster effect is needed, treatment in some patients with Vimpat may be started with a higher first dose (called a loading dose). In younger patients weighing less than 50 kg, the dose is based on body weight, and treatment may be started with the syrup. For more details see the package leaflet.

Vimpat infusion can be used to begin treatment. It can also be used in patients who are temporarily unable to take the tablets or syrup.

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If treatment with Vimpat has to be stopped, the dose should be gradually reduced. Lower doses should be used in patients with severely reduced kidney function or reduced liver function.

How does Vimpat work?

The active substance in Vimpat, lacosamide, is an epilepsy medicine. Epilepsy is caused by excessive electrical activity in the brain. The exact way in which lacosamide works is still 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 spreading through the brain, reducing the chance of an epileptic fit.

What benefits of Vimpat have been shown in studies?

Vimpat was more effective than placebo (a dummy treatment) at reducing 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 by mouth at a dose of 200 mg, 400 mg or 600 mg a day, or placebo in addition to their existing treatment of up to three other epilepsy medicines. The main measure of effectiveness was the number of patients whose number of seizures was at least halved after 12 weeks of treatment with a stable dose. Taking the results of the three main studies together, 34% of the patients taking Vimpat 200 mg a day and 40% of the patients taking Vimpat 400 mg a day with their existing treatment had a reduction in their seizures by at least half. This compared with 23% of the patients taking 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 showed that Vimpat, used on its own by mouth at a dose of 200 mg to 600 mg a day, was at least as effective as carbamazepine, another medicine for epilepsy. The main measure of effectiveness was the proportion of patients who did not have a 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 4 years of age and supportive results from studies of the safety of Vimpat in this population.

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 loading 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 all side effects and restrictions with Vimpat, see the package leaflet.

Why is Vimpat approved?

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 seizures. Taking the known side effects into account, the Agency considered Vimpat's benefits to be greater than its risks and recommended that it be given marketing authorisation.

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.

Other information about Vimpat

The European Commission granted a marketing authorisation valid throughout the European Union for Vimpat on 29 August 2008.

The full EPAR for Vimpat 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 Vimpat read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 08-2017.