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Lacosamide UCB (*lacosamide*)

An overview of Lacosamide UCB and why it is authorised in the EU

What is Lacosamide UCB and what is it used for?

Lacosamide UCB 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 or 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).

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

This medicine is the same as Vimpat, which is already authorised in the EU. The company that makes Vimpat has agreed that its scientific data can be used for Lacosamide UCB ('informed consent').

How is Lacosamide UCB used?

The medicine 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 with Lacosamide UCB 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 bodyweight, and treatment may be started with the syrup.

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

If treatment with Lacosamide UCB 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.

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

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How does Lacosamide UCB work?

The active substance in Lacosamide UCB, 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 in the brain, reducing the chance of an epileptic fit.

What benefits of Lacosamide UCB have been shown in studies?

Lacosamide UCB 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 Lacosamide UCB 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 Lacosamide UCB 200 mg a day and 40% of the patients taking Lacosamide UCB 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 Lacosamide UCB, 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 Lacosamide UCB and 91% in those taking carbamazepine. Around 78% of Lacosamide UCB-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 Lacosamide UCB 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 Lacosamide UCB 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 Lacosamide UCB in children from 4 years of age and supportive results from studies of the safety of Lacosamide UCB in this population.

What are the risks associated with Lacosamide UCB?

The most common side effects with Lacosamide UCB (which may affect more than 1 in 10 people) are dizziness, headache, diplopia (double vision) and nausea (feeling sick). The risk of 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.

Lacosamide UCB must not be used in people who have second or third degree atrioventricular (AV) block (a type of heart rhythm disorder).

For the full list of side effects and restrictions of Lacosamide UCB, see the package leaflet.

Why is Lacosamide UCB authorised in the EU?

The European Medicines Agency decided that Lacosamide UCB, 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 Lacosamide UCB'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 Lacosamide UCB?

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

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

Other information about Lacosamide UCB

Lacosamide UCB received a marketing authorisation valid throughout the EU on 26 August 2019

Further information on Lacosamide UCB can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/lacosamide-ucb.

This overview was last updated in Sep 2019.