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EPAR summary for the public

Zebinix

eslicarbazepine acetate

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

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

What is Zebinix and what is it used for?

Zebinix is an epilepsy medicine used to treat adults with partial-onset seizures (epileptic 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. Zebinix can be taken on its own, in newly diagnosed epilepsy, or can be added to existing antiepileptic medicines.

Zebinix can also be used in adolescents and children above 6 years of age, in combination with existing therapies, to treat partial-onset seizures with or without secondary generalisation.

Zebinix contains the active substance eslicarbazepine acetate.

How is Zebinix used?

Zebinix can only be obtained with a prescription. It is available as tablets (200 mg, 400 mg, 600 mg and 800 mg) and as a suspension to be taken by mouth.

For adults and children weighing 60 kg or more, treatment is started at a dose of 400 mg once a day, before increasing it to the standard dose of 800 mg once a day after one or two weeks. In children weighing less than 60 kg, the starting dose is 10 mg per kg body weight once a day. The dose is then increased after one or two weeks to 20 mg/kg per day and then to 30 mg/kg per day, based on the patient's response. For adults who take Zebinix on its own, a dose up to 1,600 mg may be used. For

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

children and adults who use Zebinix in combination with other medicines the maximum dose is 1,200 mg once a day.

Zebinix should not be used in patients with severe kidney problems and the dose should be adjusted in moderately impaired kidney function.

How does Zebinix work?

The active substance in Zebinix, eslicarbazepine acetate, is converted into eslicarbazepine in the body. Epilepsy is caused by excessive electrical activity in the brain. For electrical impulses to travel along nerves there needs to be a rapid movement of sodium into the nerve cells. Eslicarbazepine is thought to work by blocking 'voltage-gated sodium channels', which stops sodium entering the nerve cells. This reduces the activity of the nerve cells in the brain, reducing the intensity and the number of seizures.

What benefit of Zebinix have been shown in studies?

Three main studies compared the effects of Zebinix with those of placebo (a dummy treatment) in 1,050 adults with partial-onset seizures that were not controlled by other medicines. All of the patients also received other epilepsy medicines. Looking at the results of the three studies taken together, Zebinix 800 mg and 1,200 mg were more effective than placebo at reducing the number of seizures, when used as add-on to other epilepsy medicines. At the start of the study, patients had around 13 seizures per month. Over the 12 weeks of treatment, this fell to 9.8 and 9.0 seizures per month in patients taking Zebinix 800 mg and Zebinix 1,200 mg respectively, compared with 11.7 per month in those taking placebo.

Another study compared Zebinix taken on its own with another epilepsy medicine, carbamazepine, in 815 newly diagnosed adults. Zebinix was effective, although slightly less than carbamazepine, at reducing seizures after 6 months of treatment: 71% of patients who took Zebinix (276 out of 388 patients) and did not prematurely withdraw from the study were seizure-free after 6 months compared with 76% of patients taking carbamazepine (300 out of 397 patients).

The effects of Zebinix were also studied in children with partial-onset seizures. In these studies, all the children also received other epilepsy medicines. In one study involving 123 children aged 6 to 16 years, Zebinix over 12 weeks reduced the number of seizures by half in 51% of patients (42 out of 83). This compared with 25% of patients (10 out of 40) on placebo. A second study in children aged 2 to 18 years did not find a difference between Zebinix and placebo, this was explained by the fact that lower doses were used.

What are the risks associated with Zebinix?

In clinical trials, around half of the patients treated with Zebinix experienced side effects. Side effects were usually mild to moderate in intensity and occurred mostly in the first week of treatment. For adults, the most common side effects with Zebinix (seen in more than 1 patient in 10) are dizziness, somnolence (sleepiness), headache and nausea. For the full list of all side effects reported with Zebinix, see the package leaflet.

Zebinix must not be used in people who are hypersensitive (allergic) to eslicarbazepine acetate, any of the other ingredients or other carboxamide derivatives (medicines with a similar structure to eslicarbazepine acetate, such as carbamazepine or oxcarbazepine). It must not be used in people with second or third degree atrioventricular block (a problem with electrical transmission in the heart).

Why is Zebinix approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Zebinix's benefits are 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 Zebinix?

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

Other information about Zebinix

The European Commission granted a marketing authorisation valid throughout the European Union for Zebinix on 21 April 2009.

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

This summary was last updated in 04-2017.