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Zebinix (*eslicarbazepine acetate*)

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

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 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.

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

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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 Zebinix with 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 and did not prematurely withdraw from the study (276 out of 388 patients) 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 halved the number of seizures 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. Severe skin reactions, including Stevens-Johnson syndrome, have also been reported with Zebinix.

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).

For the full list of side effects and restrictions with Zebinix, see the package leaflet.

Why is Zebinix authorised?

The European Medicines Agency decided that Zebinix's benefits are greater than its risks and that it be authorised for use in the EU.

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.

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

Other information about Zebinix

Zebinix received a marketing authorisation valid throughout the EU on 21 April 2009.

Further information on Zebinix can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports.

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