

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Zebinix 200 mg

Zebinix 800 mg

Tablets

Active ingredient:

Each Zebinix 200 mg tablet contains 200 mg eslicarbazepine acetate.

Each Zebinix 800 mg tablet contains 800 mg eslicarbazepine acetate.

For inactive ingredients and allergens in the medicine, see section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist. This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

1. What is this medicine intended for?

Zebinix is used:

- as a single medicine (monotherapy) for treatment of partial seizures with or without secondary generalisation in adult patients with newly diagnosed epilepsy.
- with other antiepileptic medicines (adjunctive therapy), for treatment of adult, adolescent and pediatric patients above 6 years of age experiencing partial seizures with or without secondary generalisation.

Therapeutic group: antiepileptic medicines, carboxamide derivatives.

2. Before using this medicine

Do not use this medicine if:

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| <ul style="list-style-type: none">• You are sensitive (allergic) to the active ingredient eslicarbazepine acetate, to other carboxamide derivatives (e.g. carbamazepine or oxcarbazepine, medicines used to treat epilepsy) or to any of the other ingredients in this medicine (see section 6 'Additional information').• You suffer from a certain type of heart rhythm disorder (second or third degree atrioventricular (AV) block). |
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Special warnings about using this medicine

Contact your doctor immediately:

- If you have blistering or peeling of the skin and/or mucous membranes, rash, swallowing or breathing problems, swelling of your lips, face, eyelids, throat or tongue. These could be signs of an allergic reaction.
- If you suffer from confusion, worsening of seizures or decreased consciousness, which can be signs of low blood salt levels.
- A small number of people treated with antiepileptic medicines have experienced thoughts of self-harm or suicide. If you have such thoughts at any time during treatment with Zebinix, contact your doctor immediately.
- Serious and potentially life-threatening skin reactions, including Stevens-Johnson syndrome/toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in post-marketing experience in patients treated with Zebinix.

If you develop a serious rash or other skin symptoms (see section 4 'Side effects'), stop taking Zebinix and contact your doctor or seek medical attention immediately.

Before treatment with Zebinix, tell your doctor:

- If you have kidney problems. Your doctor may need to adjust your dose. Zebinix is not recommended for patients with severe renal disease.
- If you have liver problems. Zebinix is not recommended for patients with severe liver problems.
- If you are taking any medicine which may cause an ECG (electrocardiogram) abnormality called prolonged PR interval. If you are not sure if the medicines you are taking could have such effect, talk to your doctor.
- If you suffer from a heart disease such as heart failure or heart attack, or have any heart rhythm disorder.
- If you suffer from seizures that begin with a widespread electric discharge that involves both sides of the brain.

Additional warnings:

- Zebinix may make you feel dizzy and/or drowsy, particularly at the beginning of treatment. Take special care during treatment with Zebinix to avoid accidental injury, such as fall.
- In patients of Han Chinese or Thai origin, the risk of serious skin reactions associated with carbamazepine or chemically related compounds may be predicted by testing a blood sample of these patients. Your doctor will be able to recommend a blood test before taking Zebinix, if necessary.

Children

Zebinix is not intended for children aged 6 years and below.

Safety and efficacy of Zebinix

The safety and efficacy of this medicine in children aged 6 years and below were not proved.

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. The reason for this is that some of them may interfere with how Zebinix works or Zebinix may interfere with their effect. Particularly if you are taking:

- phenytoin (to treat epilepsy), since your dose may need to be adjusted.
- carbamazepine (to treat epilepsy) - since your dose may have to be adjusted and the following side effects of Zebinix may occur at higher frequency: double vision, abnormal coordination and dizziness.
- hormonal contraceptives (such as contraceptive pills), since Zebinix may make them less effective.
- simvastatin (to lower cholesterol levels), since your dose may have to be adjusted.
- rosuvastatin, a medicine used to lower cholesterol levels.
- warfarin – an anticoagulant.
- monoamine oxidase inhibitor (MAOIs) antidepressants.
- Do not take oxcarbazepine (a medicine for treatment of epilepsy) with Zebinix, as it is not known whether it is safe to take these medicines together.

See 'Pregnancy and breastfeeding' section below for information about contraception.

Pregnancy and breastfeeding

The effects of Zebinix on pregnancy and the unborn baby are not known, therefore it is not recommended to use Zebinix during pregnancy. If you are planning a pregnancy, talk to your doctor before you stop using contraception and before you become pregnant. Your doctor may decide to change your treatment.

There are limited data from the use of eslicarbazepine acetate in pregnant women. Research has shown an increased risk of birth defects and problems with neurodevelopment (development of the brain) in

children of women taking antiepileptic medicines, particularly when more than one antiepileptic medicine is taken at the same time.

If you are pregnant or think you might be pregnant, contact your doctor straight away. You should not stop taking the medicine until you have discussed this with your doctor. Stopping the medication without consulting your doctor could cause seizures, which could be dangerous to you and your unborn child. Your doctor may decide to change your treatment.

If you are a woman of childbearing age and are not planning a pregnancy, you should use effective contraception during treatment with Zebinix. Zebinix may affect how hormonal contraceptives, such as the contraceptive pill, work and make them less effective in preventing pregnancy. Therefore, it is recommended that you use other forms of safe and effective contraception when taking Zebinix. Talk to your doctor about the most suitable type of contraception to use while you are taking Zebinix. If treatment with Zebinix is discontinued, you should continue using effective contraception up to the end of the current menstrual cycle.

If you take Zebinix during pregnancy, your baby is also at risk of bleeding problems right after birth. Your doctor may give you and your baby a medicine to prevent this.

Do not breastfeed while you are taking Zebinix. It is not known whether it passes into breast milk.

Driving and using machines

Zebinix may make you feel dizzy, drowsy and affect your vision, particularly at the beginning of the treatment. If you experience any of these effects, do not drive or use any tools or machines.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dosage or about how to take this medicine.

Only your doctor will determine your dosage and how you should take this medicine. The recommended dosage is usually:

Adults

Dose at the start of treatment

400 mg once daily for one or two weeks, before increasing to the maintenance dose. Your doctor will decide whether you will be given this dose for one or two weeks.

Maintenance dose

The usual maintenance dose is 800 mg once daily.

Depending on how you respond to Zebinix, your dose may be increased to 1,200 mg once daily. If you are taking Zebinix as a single medicine, your doctor may consider if you can benefit from a dose of 1,600 mg once daily.

Patients with kidney problems

If you have kidney problems, you will usually be given a lower dose of Zebinix. Your doctor will determine the correct dose for you. Zebinix is not recommended if you have severe kidney problems.

Elderly (over 65 years of age)

If you are elderly and taking Zebinix as a single medicine, the dose of 1,600 mg is not suitable for you.

Children above 6 years of age

Dose at the start of treatment

The starting dose is 10 mg/kg body weight taken once a day for one or two weeks, before increasing to the maintenance dose.

Maintenance dose

Depending on the response to Zebinix, the dose may be increased by 10 mg/kg body weight, at intervals of one or two weeks, up to 30 mg/kg body weight. The maximum dose is 1,200 mg taken once daily.

Children with weight \geq 60 kg

Children with 60 kg or more body weight should take the same dose as adults.

Do not exceed the recommended dose.

Method of administration

Zebinix is intended for oral administration. Swallow the tablet with a glass of water.

Zebinix tablets may be taken with or without food.

If you have difficulty swallowing the whole tablet, you may crush the tablet and add it to a small amount of water or apple sauce and take all the dose immediately.

The tablet can be divided into equal doses.

If you have accidentally taken a higher dose

If you have accidentally taken more Zebinix than you should, you are potentially at risk of having more seizures; or you may feel like your heart beat is irregular or faster. Contact a doctor or go to a hospital immediately if you experience any of the above symptoms. Bring the medicine package with you. If a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine

If you forget to take a tablet, take it as soon as you remember and carry on as usual. Do not take a double dose to make up for a forgotten dose.

Adhere to the treatment as recommended by your doctor. Even if your health improves, do not stop treatment with this medicine without consulting your doctor.

If you stop taking this medicine

Do not stop taking the tablets suddenly. If you do, you are at risk of having more seizures. Your doctor will decide how long you should take Zebinix. Should your doctor decide to stop the treatment with Zebinix, your dose will usually be reduced gradually. It is important that your treatment is completed as advised by your doctor; otherwise, your symptoms may get worse.

Do not take medicines in the dark! Check the label and dose each time you take a medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

As with any medicine, using Zebinix may cause side effects in some users. Do not be alarmed by this list of side effects, you may not experience any of them.

The following side effects can be very serious. If they happen to you, **stop taking Zebinix and tell a doctor or go to a hospital immediately**, as you may need urgent medical treatment:

blistering or peeling of the skin and/or mucous membranes, rash, swallowing or breathing problems, swelling of your lips, face, eyelids, throat or tongue. These could be signs of an allergic reaction.

Very common side effects (affect more than 1 in 10 users)

- Feeling dizzy or sleepy.

Common side effects (affect 1-10 in 100 users)

- Feeling unsteady or having a sensation of spinning or floating;
- Nausea or vomiting;

- Headache;
- Diarrhea;
- Double vision or blurred vision;
- Difficulty in concentration;
- Feeling lack of energy or tiredness;
- Shaking;
- Skin rash;
- Blood tests showing low levels of sodium in the blood;
- Decrease of appetite;
- Difficulty in sleeping;
- Difficulty in coordinating movements (ataxia);
- Weight increase.

Uncommon side effects (affect 1-10 in 1,000 users)

- Clumsiness;
- Allergy;
- Constipation;
- Seizures;
- Underactive thyroid gland. Symptoms include decreased level of thyroid hormone (seen in blood tests), cold intolerance, large tongue, thin and brittle fingernails or hair and low body temperature;
- Liver problems (such as increased liver enzymes);
- High blood pressure or severe increase in blood pressure;
- Low blood pressure or a fall in blood pressure on standing up;
- Blood tests showing low levels of salts (including chloride) in the blood or a reduction in red blood cell count;
- Dehydration;
- Eye movement changes, blurred vision or red eyes;
- Falls;
- Thermal burn;
- Poor memory or forgetfulness;
- Crying, feeling depressed, nervous or confused, lack of interest or emotion;
- Inability to speak, write or understand written or spoken language;
- Agitation;
- Attention deficit/hyperactivity disorder;
- Irritability;
- Mood changes or hallucinations;
- Difficulty in speaking;
- Nosebleed;
- Chest pain;
- Tingling and/or feeling numb in any part of your body;
- Migraine;
- Burning sensation;
- Abnormal sense of touch;
- Disturbances in the sense of smell;
- Ringing in the ears;
- Hearing difficulty;
- Swelling in your legs and arms;
- Heartburn, upset stomach, abdominal pain, abdominal bloating and discomfort or dry mouth;
- Charcoal (dark) stool;
- Inflamed gums or toothache;
- Sweating or dry skin;
- Itching;

- Skin changes (e.g. red skin);
- Hair loss;
- Urinary tract infection;
- Feeling generally weak, unwell or having chills;
- Weight loss;
- Muscle pain, pain in limbs, muscular weakness;
- Bone metabolism disorder;
- Increased level of bone proteins;
- Flushing, cold limbs;
- Slower or irregular heart beat;
- Feeling extremely sleepy;
- Sedation;
- Neurological movement disorder in which muscle contraction causes twisting and repetitive movements or abnormal posture;
- Medicine toxicity;
- Anxiety.

Side effects of unknown frequency (the frequency cannot be estimated from available data)

- Reduction in blood platelet count, which increases the risk of bleeding or bruising;
- Acute pain in the back or stomach (caused by inflammation of the pancreas);
- Reduction in white blood cell count, which makes infections more likely;
- Reddish target-like macules or circular patches, often with central blisters on the trunk, skin peeling, ulcers in the mouth, throat, nose, genitals and eyes, red and swollen eyes, and these effects may be preceded by fever and/or flu-like symptoms (Stevens-Johnson syndrome/toxic epidermal necrolysis);
- Initially flu-like symptoms, rash on the face and then widespread rash, high body temperature, liver enzyme elevation, blood abnormalities (eosinophilia), enlarged lymph nodes and involvement of other body organs (Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS or drug hypersensitivity syndrome);
- Serious allergic reaction which causes swelling of the face, throat, hands, feet, ankles, or lower legs;
- Urticaria (skin rash with itching);
- Lethargy, confusion, muscle twitching or significant worsening of convulsions (possible symptoms of low sodium levels in the blood due to inappropriate antidiuretic hormone [ADH] secretion).

The use of Zebinix is associated with an ECG (electrocardiogram) abnormality called prolonged PR interval. Side effects associated with this ECG abnormality (e.g. fainting and slowing of heart beat) may occur.

There have been reports of bone disorders, including osteopenia and osteoporosis (thinning of the bone) and fractures associated with structurally related antiepileptic medicines like carbamazepine and oxcarbazepine. Consult your doctor or pharmacist if you receive long-term antiepileptic treatment, have a history of osteoporosis or take steroids.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects or by entering the link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

Storage conditions:

No special storage conditions. It is recommended to store at room temperature.

6. Additional information

In addition to the active ingredient, this medicine also contains:

Povidone K29/32, croscarmellose sodium, magnesium stearate

What the medicine looks like and contents of the pack:

Zebinix 200 mg

Zebinix 200 mg tablets are white and oblong. The tablets have 'ESL 200' engraved on one side and are scored on the other side, with a length of 11 mm. The tablet can be divided into equal doses.

Carton packs of 20 or 60 tablets contain tablets packaged in blisters.

Zebinix 800 mg

Zebinix 800 mg tablets are white and oblong. The tablets have 'ESL 800' engraved on one side and are scored on the other side, with a length of 19 mm. The tablet can be divided into equal doses.

Carton packs of 20, 30, 60, 90 or 180 tablets contain tablets packaged in blisters.

Not all pack sizes may be marketed.

Registration holder's name and address:

Truemed Ltd., 10 Beni Gaon St., Poleg Industrial Park P.O.B. 8105, Netanya 4250499

Manufacturer's name and address:

BIAL - Portela & C^a, S.A., À Av. da Siderurgia Nacional 4745-457 S. Mamede do Coronado, Portugal

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Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Zebinix 200 mg - 170-76-37082

Zebinix 800 mg - 170-77-37083

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