

Eslicarbazepine  
Amarox 200 mg tablets  
eslicarbazepine acetate  
2072097

#### Package leaflet: Information for the user

#### Eslicarbazepine Amarox 200 mg tablets eslicarbazepine acetate

**Read all of this leaflet carefully before you or your child start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet

1. What Eslicarbazepine Amarox is and what it is used for
2. What you need to know before you take Eslicarbazepine Amarox
3. How to take Eslicarbazepine Amarox
4. Possible side effects
5. How to store Eslicarbazepine Amarox
6. Contents of the pack and other information

#### 1. What Eslicarbazepine Amarox is and what it is used for

Eslicarbazepine Amarox contains the active substance eslicarbazepine acetate. Eslicarbazepine Acetate belongs to a group of medicines called antiepileptics used to treat epilepsy, a condition where someone has repeated seizures or fits.

Eslicarbazepine Amarox is used:

- on its own (monotherapy) in adult patients with newly diagnosed epilepsy
- with other antiepileptic medicines (adjunctive therapy), in adult, adolescents and children patients above 6 years of age who are experiencing seizures that affect one part of the brain (partial seizure). These seizures may or may not be followed by a seizure affecting all of the brain (secondary generalisation)

Eslicarbazepine Amarox has been given to you by your doctor to reduce your number of seizures.

#### 2. What you need to know before you take Eslicarbazepine Amarox

##### Do not take Eslicarbazepine Amarox:

- if you are allergic to eslicarbazepine acetate, to other carboxamide derivatives (e.g. carbamazepine or oxcarbazepine, medicines used to treat epilepsy) or to any of the other ingredients of this medicine (listed in section 6);
- if you suffer from a certain type of heart rhythm disorder (second or third degree atrioventricular (AV) block).

#### Warnings and precautions

Talk to your doctor or pharmacist before taking Eslicarbazepine Amarox.

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.

Please tell your doctor:

- if you have kidney problems. Your doctor may need to adjust the dose. Eslicarbazepine Amarox is not recommended in patients with severe renal disease.
- if you have liver problems. Eslicarbazepine Amarox is not recommended in patients with severe liver problems.
- if you are taking any medicine which can cause an abnormality on the ECG (electrocardiogram) called increased PR interval. If you are not sure if the medicines you are taking could have this effect, discuss with 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.

A small number of people being treated with antiepileptics have had thoughts of harming or killing themselves. If at any time you have these thoughts, when taking Eslicarbazepine Amarox, contact your doctor immediately.

Eslicarbazepine Amarox may make you feel dizzy and/or drowsy, particularly at the beginning of treatment. Take special care when taking Eslicarbazepine Amarox to avoid accidental injury, such as fall.

#### Take special care with Eslicarbazepine Amarox:

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 Eslicarbazepine Amarox.

If you develop a serious rash or another skin symptoms (see section 4), stop taking Eslicarbazepine Amarox and contact your doctor or seek medical attention immediately.

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 should be able to advise if a blood test is necessary before taking Eslicarbazepine Amarox.

#### Children

Eslicarbazepine Amarox is not to be given to children aged 6 years and below.

#### Other medicines and Eslicarbazepine Amarox

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is just in case any of them interfere with how Eslicarbazepine Amarox works or how Eslicarbazepine Amarox interferes with their effect.

Tell your doctor if you are taking:

- phenytoin (a medicine used to treat epilepsy) since your dose may need to be adjusted;
- carbamazepine (a medicine used to treat epilepsy) since your dose may have to be adjusted and the following side effects of Eslicarbazepine Amarox may occur in higher frequency: seeing double, abnormal coordination and dizziness;

- hormonal contraceptives (such as the contraceptive pill) since Eslicarbazepine Amarox may make these less effective;
- simvastatin (a medicine used to lower cholesterol levels) since your dose may have to be adjusted;
- rosuvastatin, a medicine used to lower cholesterol level;
- the blood thinner - warfarin;
- monoamino oxidase inhibitors (MAOIs) antidepressants;
- do not take oxcarbazepine (a medicine used to treat epilepsy) with Eslicarbazepine Amarox, as it is not known whether it is safe to take these medicines together.

See 'Pregnancy and breast-feeding' section for advice about contraception.

#### Pregnancy and breast-feeding

It is not recommended to take Eslicarbazepine Amarox if you are pregnant, as the effects of Eslicarbazepine Amarox on pregnancy and the unborn baby are not known.

If you are planning a pregnancy, talk to your doctor before you stop 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 or think you might be pregnant, tell your doctor straight away. You should not stop taking your medicine until you have discussed this with your doctor. Stopping your 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 Eslicarbazepine Amarox. Eslicarbazepine Amarox may affect how hormonal contraceptives, such as the contraceptive (birth control) pill, work and make them less effective at preventing pregnancy.

Therefore, it is recommended that you use other forms of safe and effective contraception, when taking Eslicarbazepine Amarox. Talk to your doctor, who will discuss with you the most suitable type of contraception to use while you are taking Eslicarbazepine Amarox. If treatment with Eslicarbazepine Amarox is discontinued you should continue using effective contraception up to the end of the current menstrual cycle.

If you take Eslicarbazepine Amarox during pregnancy, your baby is also at risk for bleeding problems right after birth.

Your doctor may give you and your baby a medicine to prevent this.

Do not breast-feed while you are taking Eslicarbazepine Amarox. It is not known whether it passes into breast milk.

#### Driving and using machines

Eslicarbazepine Amarox may make you feel dizzy, drowsy and affect your vision, particularly at the beginning of treatment. If this happens to you, do not drive or use any tools or machines.

#### Eslicarbazepine Amarox contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

#### 3. How to take Eslicarbazepine Amarox

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

##### Adults

##### Dose when you start 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 Eslicarbazepine Amarox, your dose may be increased to 1,200 mg once daily. If you are taking Eslicarbazepine Amarox on its own your doctor may consider you can benefit of 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 Eslicarbazepine Amarox. Your doctor will work out the correct dose for you. Eslicarbazepine Amarox is not recommended if you have severe kidney problems.

##### Elderly (over 65 years of age)

If you are elderly and taking Eslicarbazepine Amarox on its own the dose of 1,600 mg is not a suitable dose for you.

##### Children above 6 years of age

##### Dose when you start treatment

The starting dose is 10 mg per 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 Eslicarbazepine Amarox, the dose may be increased by 10 mg per kg body weight, at intervals of one or two weeks, up to 30 mg per kg body weight. The maximum dose is 1,200 mg once daily.

##### Children with >60 kg

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

Other form of this medicine, like oral suspension, maybe more suitable for children. Ask your doctor or pharmacist.

##### Method and route of administration

Eslicarbazepine Amarox is for oral use. Swallow the tablet with a glass of water. Eslicarbazepine Amarox 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 take more Eslicarbazepine Amarox than you should

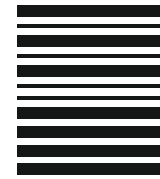
If you accidentally take more Eslicarbazepine Amarox than you should, you are potentially at risk of having more seizures; or you may feel like your heart beat is irregular or faster. Contact a doctor or go to a hospital immediately if you experience any of the above symptoms. Take the medicine pack with you. This is so the doctor knows what you have taken.



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**If you forget to take Eslicarbazepine AmaroX**

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.

**If you stop taking Eslicarbazepine AmaroX**

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

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

**4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects can be very serious. If they happen to you stop taking Eslicarbazepine AmaroX 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** (may affect more than 1 in 10 people) side effects are:

- Feeling dizzy or sleepy.

**Common** (may affect up to 1 in 10 people) side effects are:

- Feeling unsteady or having a sensation of spinning or floating;
- Feeling sick or vomiting;
- Headache;
- Diarrhoea;
- Seeing double or blurred vision;
- Difficulty in concentration;
- Feeling low in energy or tired;
- Shaking;
- Skin rash;
- Blood tests showing that you have low levels of sodium in your blood;
- Decrease of appetite;
- Difficulty in sleeping;
- Difficulty in coordinating movements (ataxia);
- Weight increase.

**Uncommon** (may affect up to 1 in 100 people) side effects are:

- Clumsiness;
- Allergy;
- Constipation;
- Seizures;
- Underactive thyroid gland. Symptoms include decreased level of thyroid hormone levels (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 that you have low levels of salts (including chloride) in your blood or a reduction in red blood cells;
- Dehydration;
- Eye movement changes, fuzzy vision or red eye;
- Having falls;
- Thermal burn;
- Poor memory or forgetfulness;
- Crying, feeling depressed, nervous or confused, lack of interest or emotion;
- Inability to speak or write or understand spoken or written 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;
- Heart burn, stomach upset, abdominal pain, abdominal bloating and discomfort or dry mouth;
- Charcoal (dark) stool;
- Inflamed gums or toothache;
- Sweating or having 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 bone proteins;
- Flushing, cold limbs;
- Slower or irregular heart beat;
- Feeling extremely sleepy;
- Sedation;
- Neurological movement disorder where your muscles contract causing twisting and repetitive movements or abnormal postures. Symptoms include tremors, pain, cramping;
- Medicine toxicity;
- Anxiety.

**Not known** (frequency cannot be estimated from available data) side effects are:

- Reduction in blood platelets which increases risk of bleeding or bruising;
- Severe pain in the back and stomach (caused by inflammation of the pancreas);
- Reduction in white blood cells which makes infections more likely;
- Reddish target-like macules or circular patches often with central blisters on the trunk, skin peeling, ulcers of mouth, throat, nose, genitals and eyes, red and swollen eyes and can be preceded by fever and/or flu-like symptoms (Stevens-Johnson syndrome/toxic epidermal necrolysis);
- Initially flu-like symptoms, rash on the face then widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement (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, hand, 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 ADH secretion).

The use of Eslicarbazepine AmaroX is associated with an abnormality in ECG (electrocardiogram) called increase in 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 with structurally related antiepileptics medicines like carbamazepine and oxcarbazepine. Check with your doctor or pharmacist, if you are on long-term antiepileptic treatment, have a history of osteoporosis, or take steroids.

**Reporting of side effects**

If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme website [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Eslicarbazepine AmaroX**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date, which is stated on the blister, bottle and the carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

**6. Contents of the pack and other information****What Eslicarbazepine AmaroX contains**

The active substance is eslicarbazepine acetate. Each tablet contains 200 mg of eslicarbazepine acetate.

The other ingredients are:

Povidone, croscarmellose sodium, glycerol monostearate, sodium stearyl fumarate.

**What Eslicarbazepine AmaroX looks like and contents of the pack**

Eslicarbazepine AmaroX 200 mg tablets are White to off-white, oblong tablets, with functional scoring on both the side and engraved with 'E31' on one side and 'H' on the other side. The tablets may be mottled and should be free from physical defects. The tablet can be divided into equal doses.

Blisters pack containing 60 tablets.

HDPE bottle containing 30 tablets.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

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