Package Leaflet: Information for the user

Oxcarbazepine Amarox 150 mg film-coated tablets
Oxcarbazepine Amarox 300 mg film-coated tablets
Oxcarbazepine Amarox 600 mg film-coated tablets

Read all of this leaflet carefully before you 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 Oxcarbazepine Amarox is and what it is used for
2. What you need to know before you take Oxcarbazepine Amarox
3. How to take Oxcarbazepine Amarox
4. Possible side effects
5. How to store Oxcarbazepine Amarox
6. Contents of the pack and other information

1. What Oxcarbazepine Amarox is and what it is used for

What Oxcarbazepine Amarox is
Oxcarbazepine Amarox contains the active substance oxcarbazepine.
Oxcarbazepine Amarox belongs to a group of medicines called anticonvulsants or antiepileptics.

What Oxcarbazepine Amarox is used for
Medicines such as Oxcarbazepine Amarox are the standard treatment for epilepsy.
Epilepsy is a brain disorder that causes people to have recurring seizures and convulsions. Seizures happen because of a temporary fault in the brain's electrical activity. Normally brain cells coordinate body movements by sending out signals through the nerves to the muscles in an organised, orderly way. In epilepsy, brain cells send out too many signals in a disorderly fashion. The result can be uncoordinated muscular activity that is called an epileptic seizure.

Oxcarbazepine Amarox is used to treat partial seizures with or without secondarily generalised tonic-clonic seizures. Partial seizures involve a limited area of the brain, but may spread to the whole brain and may cause a generalised tonic-clonic seizure. There are two types of partial seizures: simple and complex. In simple partial seizures, the patient remains conscious, whereas in complex partial seizures, patients consciousness is altered.

Oxcarbazepine Amarox works by keeping the brain's "overexcitable" nerve cells under control. This suppresses or reduces the frequency of such seizures.

Oxcarbazepine Amarox can be used alone or in combination with other antiepileptic medicines.

Usually, the doctor will try to find the one medicine that works best for you or for your child. However, with more severe epilepsy, a combination of two or more medicines may be needed to control seizures.
Oxcarbazepine Amarox is for use in adults and in children of 6 years of age and above.

If you have any questions about how Oxcarbazepine Amarox works or why this medicine has been prescribed for you, ask your doctor.

2. What you need to know before you take Oxcarbazepine Amarox

Follow all your doctor's instructions carefully, even if they differ from the general information contained in this leaflet.

Monitoring during your treatment with Oxcarbazepine Amarox
Before and during your treatment with Oxcarbazepine Amarox, your doctor may perform blood tests to determine the dose for you. Your doctor will tell you when to have the tests.

Do not take Oxcarbazepine Amarox
- if you are allergic to oxcarbazepine or any of the other ingredients of this medicine (listed in section 6) or if you are allergic to eslicarbazepine.

If this applies to you, tell your doctor before taking Oxcarbazepine Amarox. If you think you may be allergic, ask your doctor for advice.

Warnings and precautions
Talk to your doctor or pharmacist before taking Oxcarbazepine Amarox:
- if you have ever shown **unusual sensitivity** (rash or any other signs of allergy) to carbamazepine or to any other medicines. If you are allergic to carbamazepine, the chances are approximately 1 in 4 (25 %) that you could also have an allergic reaction to oxcarbazepine.
- if you have **kidney disease**.
- if you have serious **liver disease**.
- if you are taking **diuretics** (medicines used to help the kidneys get rid of salt and water by increasing the amount of urine produced).
- if you have **heart disease**, shortness of breath and/or swelling of the feet or legs due to fluid build-up.
- if your **blood level of sodium is low** as shown by blood tests (see section 4 Possible side effects).
- if you are a woman **taking a hormonal contraceptive** (such as "the birth-control pill"). Oxcarbazepine may stop your contraceptive from working. Use a different or extra (non-hormonal) method of contraception while taking oxcarbazepine. This should help to prevent an unwanted pregnancy. Tell your doctor immediately if you get irregular vaginal bleeding or spotting. If you have any questions about this, ask your doctor or health professional.

The risk of serious skin reactions in patients of Han Chinese or Thai origin 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 oxcarbazepine.

If you develop any of the following symptoms after starting Oxcarbazepine Amarox, tell your doctor immediately or go to the emergency department at your nearest hospital:
- if you experience an **allergic reaction** after starting oxcarbazepine. Symptoms include swelling of lips, eyelids, face, throat, mouth, or sudden breathing problems, fever with swollen glands, rash or skin blistering.
- if you notice symptoms of **hepatitis**, such as jaundice (yellowing of skin or the whites of the eyes).
- if you experience an increase in the frequency of seizures. This is particularly important for children but may also occur in adults.
- if you notice possible symptoms of **blood disorders** such as, tiredness, being short of breath when exercising, looking pale, headache, chills, dizziness, frequent infections leading to fever, sore throat, mouth ulcers, bleeding or bruising more easily than normal, nose bleeds, reddish or purplish patches, or unexplained blotches on the skin.

- a small number of people being treated with antiepileptics such as oxcarbazepine have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.
- if you have a **fast or unusually slow heartbeat**.

Children and adolescents
In children, your doctor may recommend thyroid function monitoring before therapy and during therapy.

Other medicines and Oxcarbazepine Amarox
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
This applies especially to:
- Hormonal contraceptives, such as the pill (see Warnings and precautions).
- Other antiepileptic and enzyme inducing medicines, such as carbamazepine, phenobarbital, phenytoin or lamotrigine and rifampicin.
- Medicines that reduce the level of sodium in your blood, such as diuretics (used to help the kidneys get rid of salt and water by increasing the amount of urine produced), desmopressin and non-steroidal anti-inflammatory medicines, such as indometacin.
- Lithium and monoamine oxidase inhibitors (medicines used to treat mood swings and some types of depression).
- Medicines that control the body's immune system, such as ciclosporin and tacrolimus.

Oxcarbazepine Amarox with food and alcohol
Oxcarbazepine Amarox can be taken with or without food.
Alcohol may increase the sedative effects of Oxcarbazepine Amarox. Avoid alcohol as much as possible and ask your doctor for advice.

Pregnancy and breast-feeding
Pregnancy
If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
It is important to control epileptic seizures during pregnancy. However, there may be a risk to your baby if you take antiepileptic medicines during pregnancy.

Birth defects
Studies have not shown an increased risk of birth defects associated with oxcarbazepine use during pregnancy, however, a risk of birth defects for your unborn child cannot be completely ruled out.

Neurodevelopmental disorders
Some studies have shown that exposure to oxcarbazepine in the womb negatively affects the development of brain function (neurodevelopment) in children, while other studies have not found such an effect. The possibility of an effect on neurodevelopment cannot be ruled out.

Birth weight
If you use Oxcarbazepine Amarox during pregnancy, your child may be smaller and weigh less than expected at birth [born small for gestational age (SGA)]. Among women with epilepsy, in one study, around 15 out of every 100 children born to mothers who had taken oxcarbazepine during pregnancy were smaller and weighed less than expected at birth, compared to around 11 out of every 100 children born to women not taking anti-seizure medication during pregnancy.

Your doctor will tell you the benefits and potential risks involved and help you to decide whether you should take Oxcarbazepine Amarox.
Do not stop your treatment with Oxcarbazepine Amarox during pregnancy without first checking with your doctor.

Breast-feeding

If you are taking this medicine, ask your doctor for advice before starting breastfeeding. The active substance in Oxcarbazepine Amarox passes into breast milk. Although available data suggest that the amount of Oxcarbazepine Amarox that passes to a breastfed baby is low, a risk of side effects for the baby cannot be ruled out. Your doctor will discuss with you the benefits and potential risks of breastfeeding while taking Oxcarbazepine Amarox. If you are breastfeeding while taking Oxcarbazepine Amarox and you think your baby is having side effects such as excessive sleepiness or poor weight gain, tell your doctor immediately.

Driving and using machines
Oxcarbazepine Amarox may make you feel sleepy or dizzy, or may cause blurred vision, double vision, lack of muscle coordination or a depressed level of consciousness especially when starting treatment or increasing the dose.
It is important to discuss with your doctor whether you can drive a vehicle or operate machines while taking this medicine.

3. How to take Oxcarbazepine Amarox

Always take this medicine exactly as your doctor or pharmacist has told you, even if this differs from the information given in this leaflet. Check with your doctor or pharmacist if you are not sure.

How much to take

Use in adults
- The **usual starting dose** of Oxcarbazepine Amarox for adults (including elderly patients) is 600 mg per day.
- Take one 300 mg tablet twice daily or two 150 mg tablets twice daily.
- Your doctor may increase the dose gradually to find the best dose for you. The best results are usually with doses between 600 and 2,400 mg per day.
- If you take another antiepileptic medicine, the dose is the same.
- If you have kidney disease (with impaired kidney function), the starting dose is half the usual starting dose.
- If you have severe liver disease, your doctor may adjust your dose.

Use in children and adolescents
Oxcarbazepine Amarox can be taken by children aged 6 years or above.
The dosage for children depends on their weight.
- The starting dose is 8 to 10 milligrams per kilogram of bodyweight per day given in two divided doses. For example, a 30-kg child would start treatment with one 150 mg tablet twice daily.
- Your doctor may increase the dose gradually to find the best dose for your child. The best results are usually with a dose of 30 milligrams per kilogram of bodyweight per day. The maximum dose for a child is 46 milligrams per kilogram of bodyweight per day.

How to take Oxcarbazepine Amarox
- Swallow the tablets with a little water.
- If necessary, the tablets can be broken in half to help swallow them. Do not break the tablets to take only half of the dose. The score line is only there to help you break the tablet if you have difficulty swallowing it whole.
- For small children who cannot swallow tablets, or who cannot be given the necessary dose in tablet form, oxcarbazepine is also available as an oral suspension.

When and for how long to take Oxcarbazepine Amarox
Take Oxcarbazepine Amarox twice a day, every day, at about the same time of day, unless the doctor tells you otherwise. This will have the best effect on controlling epilepsy. It will also help you to remember when to take the tablet(s).

Your doctor will tell you how long your or your child's treatment with Oxcarbazepine Amarox will last. The length of treatment will depend on your or your child's seizure type. Treatment may be needed for many years to control the seizures. Do not change the dose or stop treatment without talking to your doctor.

If you take more Oxcarbazepine Amarox than you should
If you have taken more tablets than your doctor prescribed, contact the nearest hospital or your doctor immediately. Symptoms of overdose with Oxcarbazepine Amarox may include:
- drowsiness, dizziness, problems with coordination and/or involuntary movement of the eyes, muscular twitching or significant worsening of convulsions, headache, loss of consciousness, coma,
- feeling sick (nausea), being sick (vomiting), increased uncontrolled movements,
- lethargy, double vision, narrowing of black part of the eye, blurred vision,
- tiredness,
- short and shallow breathing (respiratory rate depression),
- irregular heart beat (QTc prolonged interval),
- trembling, headache, coma, decreased consciousness, uncontrollable movements of mouth, tongue and limbs,
- aggression, agitation, confusion
- low blood pressure
- breathlessness

If you forget to take Oxcarbazepine Amarox
If you have forgotten one dose, take it as soon as you remember. However, if it is time for your next dose, do not take the missed dose. Go back to your regular dosing timetable. Do not take a double dose to make up for a forgotten dose.
If you are unsure or have forgotten to take several doses, contact your doctor.

If you stop taking Oxcarbazepine Amarox
Do not stop taking your medicine unless your doctor tells you to.
To prevent sudden worsening of your seizures, never discontinue your medicine abruptly.
If your treatment is stopped, it should be done gradually as instructed by your doctor.

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.

Tell your doctor immediately or go to the emergency department at your nearest hospital if you get any of the following side effects:
The following are signs of potentially serious side effects that may require urgent medical treatment. The doctor will also decide whether Oxcarbazepine Amarox has to be stopped immediately and how to continue further medical care.
Uncommon (may affect up to 1 in 100 people):
- Weight gain, tiredness, hair loss, muscle weakness, feeling cold (signs of under active thyroid gland).
- Fall

Rare (may affect up to 1 in 1,000 people):
- Swelling of the lips, eyelids, face, throat or mouth, accompanied by difficulty in breathing, speaking or swallowing (signs of anaphylactic reactions and angioedema)..
- Skin rash and/or fever which may be manifestations of DRESS (Drug Rash with Eosinophilia and Systemic Symptoms), AGEP (Acute Generalized Exanthematous Pustulosis).
- Tiredness, shortness of breath when exercising, looking pale, headache, chills, dizziness, frequent infections leading to fever, sore throat, mouth ulcers, bleeding or bruising more easily

than normal, nose bleeds, reddish or purplish patches, or unexplained blotches on the skin (signs of a decrease in the number of blood platelets or decrease in the number of blood cells).
- Lethargy, confusion, muscle twitching or significant worsening of convulsions (possible symptoms of low sodium levels in the blood due to inappropriate ADH secretion). (see warnings and precautions).

Very rare (may affect up to 1 in 10,000 people):
- Signs of hypersensitivity reactions such as skin rash, fever and pain in the muscles and joints.
- Severe blistering of the skin and/or mucous membranes of the lips, eyes, mouth, nasal passages or genitals (signs of serious allergic reaction including Lyell´s syndrome, Stevens-Johnson syndrome and erythema multiforme).
- Red blotchy rash mainly on face which may be accompanied by fatigue, fever, feeling sick (nausea) or loss of appetite (signs of systemic lupus erythematosus).
- Flu-like symptoms with jaundice (yellowing of the skin or the whites of the eyes) (signs of hepatitis).
- Severe upper stomach (abdominal) pain, being sick (vomiting), loss of appetite (signs of inflammation of the pancreas).

Tell your doctor as soon as possible if you get any of the following side effects, they may require medical attention:
Common (may affect up to 1 in 10 people):
- trembling; coordination problems; involuntary movement of the eyes; anxiety and nervousness; depression, mood swing; rash.

Very rare (may affect up to 1 in 10,000 people):
- irregular heart beat or a very fast or slow heart rate.

Other side effects that may occur:
These are usually mild to moderate side effects of Oxcarbazepine Amarox. Most of these effects are transient and usually diminish over time.

Very common (may affect more than 1 in 10 people)**:**
- tiredness; headache; dizziness; drowsiness; feeling sick (nausea); being sick (vomiting); double vision.

Common (may affect up to 1 in 10 people):
- weakness; memory disturbances; impaired concentration; apathy; agitation; confusion; blurred vision; visual disturbance; constipation; diarrhoea; stomach (abdominal) pain; acne; hair loss, balance disturbances; weight increased; speech disorder.

Uncommon (may affect up to 1 in 100 people):
- High blood pressure; hives.
- You may also have raised levels of liver enzymes while taking Oxcarbazepine Amarox.

Rare (may affect up to 1 in 1,000 people):
- there have been reports of bone disorders including osteopenia and osteoporosis (thinning of the bone) and fractures. Check with your doctor or pharmacist if you are on long-term antiepileptic medication, 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 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 Oxcarbazepine 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 and the outer carton. 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 to protect the environment.

6. Contents of the pack and other information

What Oxcarbazepine Amarox contains
The active substance is oxcarbazepine.
Each film-coated tablet contains 150 mg of oxcarbazepine.
Each film-coated tablet contains 300 mg of oxcarbazepine.
Each film-coated tablet contains 600 mg of oxcarbazepine.

The other ingredients are:
Tablet core: Cellulose microcrystalline, hypromellose, silica colloidal anhydrous, crospovidone and magnesium stearate

Tablet coating: Polyvinyl alcohol-part. hydrolyzed, macrogol, talc, titanium dioxide, iron oxide yellow, iron oxide red and ferrosoferric oxide

What Oxcarbazepine Amarox looks like and contents of the pack
Oxcarbazepine Amarox 150 mg film-coated tablets
Brown colored, Oval shaped, biconvex, film coated tablets, approximately 11.0 x 5.5 mm diameter, de-bossed with ‘V’ on one side and ‘7’ and ‘6’ on another side separated by a score line on both sides.

Oxcarbazepine Amarox 300 mg film-coated tablets
Brown colored, Oval shaped, biconvex, film coated tablets, approximately 15.0 x 6.5 mm diameter, de-bossed with ‘V’ on one side and ‘7’ and ‘7’ on another side separated by a score line on both sides.

Oxcarbazepine Amarox 600 mg film-coated tablets
Brown colored, Oval shaped, biconvex, film coated tablets, approximately 18.5 x 8.0 mm diameter, de-bossed with ‘V’ on one side and ‘7’ and ‘8’ on another side separated by a score line on both sides.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Oxcarbazepine is available in blister pack containing 50 film-coated tablets.

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