

1.3.1.3 Package leaflet: Information for the user

Oxcarbazepine Umedica 150 mg film-coated tablets
Oxcarbazepine Umedica 300 mg film-coated tablets
Oxcarbazepine Umedica 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 Umedica is and what it is used for
2. What you need to know before you take Oxcarbazepine Umedica
3. How to take Oxcarbazepine Umedica
4. Possible side effects
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1. What Oxcarbazepine Umedica is and what it is used for

What Oxcarbazepine Umedica is

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

What Oxcarbazepine Umedica is used for

Medicines such as oxcarbazepine 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 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, patient's consciousness is altered.

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

Oxcarbazepine 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 is for use in adults and in children of 6 years of age and above.

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

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

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 Umedica

Before and during your treatment with oxcarbazepine, 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:

- 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. If you think you may be allergic, ask your doctor for advice.

Warnings and precautions

Talk to your doctor or pharmacist before taking oxcarbazepine:

- 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, 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

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 indomethacin.
- 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 with food and alcohol

Oxcarbazepine can be taken with or without food.

Alcohol may increase the sedative effects of oxcarbazepine. 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 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.

Do not stop your treatment with oxcarbazepine 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 passes into breast milk. Although available data suggest that the amount of oxcarbazepine 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. If you are breastfeeding while taking oxcarbazepine 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 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 Umedica

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 for adults (including elderly patients) is 600mg per day.
- Take one 300mg tablet twice daily or two 150mg 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 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 150mg 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

- Swallow the tablets with a little water.
- The tablet can be divided into two equal doses.
- 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

Take oxcarbazepine 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 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 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 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 Umedica

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 Umedica

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 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. 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 this medicine.

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 the 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 Umedica

- 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.
- Do not use this medicine if you notice that the pack is damaged or shows signs of tampering.
- This medicine product does not require any special storage
- 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 Oxcarbazepine Umedica contains:

The active substance of Oxcarbazepine Umedica 150 mg, 300 mg, 600 mg film-coated tablets is Oxcarbazepine.

Oxcarbazepine Umedica 150 mg film-coated tablets

Each film-coated tablet contains 150 mg of Oxcarbazepine.

Oxcarbazepine Umedica 300 mg film-coated tablets

Each film-coated tablet contains 300 mg of Oxcarbazepine.

Oxcarbazepine Umedica 600 mg film-coated tablets

Each film-coated tablet contains 600 mg of Oxcarbazepine.

The other ingredients are:

Tablet core: Cellulose, Microcrystalline GR 101 (E460), Crospovidone (Type A) (E1202), Hydroxypropyl methyl cellulose 5cps (E464), Cellulose, Microcrystalline GR 102 (E460), Silicon, colloidal dioxide(E551), Magnesium Stearate (E470b).

Tablet coating:

- **150 mg tablet: Brownish light green**

Hypromellose 2910(E464), Polyethylene glycol(E1521), Talc(E553b), Titanium dioxide (E171), iron oxide yellow (E172), Red iron oxide (E172), Black iron oxide (E172).

- **300 mg tablet: Yellow**

Hypromellose 2910 (E464), Polyethylene glycol 8000(E1521), Talc(E553b), Titanium dioxide (E171), iron oxide yellow(E172)

- **600 mg tablet: Pink**

Hypromellose 2910 (E464), Polyethylene glycol 4000 (E1521), Talc(E553b), Titanium dioxide (E171), iron oxide red (E172), iron oxide black (E172).

What Oxcarbazepine Umedica looks like and contents of the pack

Oxcarbazepine Umedica 150 mg film-coated tablets are Pale yellow to brownish light green, oval shaped, film-coated tablets, scored on both sides and debossed with "OX150" on one side Dimension: approximately 11 × 6 mm.

Oxcarbazepine Umedica 300 mg film-coated tablets are Light yellow to yellow, oval shaped, film-coated tablets, scored on both sides and debossed with "OX300" on one side. Dimension: approximately 15 × 7 mm.

Oxcarbazepine Umedica 600 mg film-coated tablets are Light Pink to Pink, oval shaped, film-coated tablets, scored on both sides and debossed with 'OX600' on one side. Dimension: approximately 19 × 8 mm.

The tablets can be divided into two equal doses.

Oxcarbazepine Umedica 150 mg, 300 mg, 600 mg film-coated tablets are available in blister packs of 30, 50, 100, 200 and/or 500 tablets.

Not all pack sizes may be marketed.

Marketing Authorization Holder**Umedica Laboratories UK Ltd**

Office No. G42

The Panorama Park Street

Ashford, England

TN24 8DF

Manufacturer**Elara Pharmservices Limited**

5 Garden Court, Lockington Hall

Main Street, Lockington

Derby, DE74 2RH

United Kingdom

This medicinal product is authorized under the following names:

Oxcarbazepine Umedica 150 mg film-coated tablets - PL 60528/0042

Oxcarbazepine Umedica 300 mg film-coated tablets - PL 60528/0043

Oxcarbazepine Umedica 600 mg film-coated tablets - PL 60528/0044

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