

Package leaflet: Information for the patient
Oxcarbazepine Mylan 150/300/600 mg Film-coated tablets
oxcarbazepine

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

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

Oxcarbazepine Mylan contains the active ingredient oxcarbazepine. Oxcarbazepine Mylan belongs to a group of medicines called anticonvulsants or antiepileptics which are used in the treatment of epilepsy.

Oxcarbazepine Mylan is used to help control seizures or fits in patients that have epilepsy. People with epilepsy are prone to having periods of uncontrolled electrical activity in the brain. These periods of uncontrolled electrical activity may lead to seizures. Oxcarbazepine helps to control electrical activity in the brain. This reduces the chances of having seizures.

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

Oxcarbazepine Mylan can be used alone or along with other antiepileptic medicines.

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

Follow all instructions given to you by your doctor carefully, even if they differ from the information contained in this leaflet.

Do not take Oxcarbazepine Mylan:

- if you are allergic to oxcarbazepine, eslicarbazepine or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Oxcarbazepine Mylan:

- if you are **allergic** (e.g. have ever developed a rash or other allergic reactions) to carbamazepine, a similar anticonvulsant, as there is approximately a 1 in 4 (25%) chance you may be allergic to oxcarbazepine too
- if you have liver problems or develop liver problems during treatment (see under **Possible side effects**)
- if you have kidney problems, especially kidney problems associated with a low level of sodium (salt) in your blood. Oxcarbazepine Mylan can lower the sodium levels in your blood further which may lead to symptoms of sodium shortage (see under **Possible side effects**). If you have a kidney disease your doctor may examine your blood before and at regular intervals after starting treatment with Oxcarbazepine Mylan
- if you are taking other medicines that can lower sodium levels in the blood (e.g. diuretics, desmopressin and non-steroid anti-inflammatory drugs (NSAIDs) such as indometacin and ibuprofen). See under **Other medicines and Oxcarbazepine Mylan**
- if you have heart problems such as heart failure (breathlessness and swollen ankles). Your doctor will measure your weight regularly to make sure that you do not retain water
- if you have a heart rhythm disorder
- if you are using hormonal contraceptives (see under **Other medicines and Oxcarbazepine Mylan**)

During treatment

If you have possible signs of a blood disorder such as tiredness, breathlessness when exercising, looking pale, headache, chills, dizziness, infections leading to fever, sore throat, mouth ulcer, bleeding or bruising more easily than normal, nose bleeding, reddish or purplish patches, unexplained blotches on skin, talk to your doctor.

A small number of people being treated with anti-epileptics such as Oxcarbazepine Mylan have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported with the use of oxcarbazepine, appearing initially as reddish target-like spots or circular patches often with central blisters on the trunk.

Additional signs to look for include ulcers in the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes). These potentially life-threatening skin rashes are often accompanied by flu-like symptoms. The rash may progress to widespread blistering or peeling of the skin.

The highest risk for occurrence of serious skin reactions is within the first weeks of treatment. There is an increased risk of these reactions occurring in patients of Han Chinese, Thai or other Asian origin (see below, "Patients of Han Chinese or Thai origin").

If you have developed Stevens-Johnson syndrome or toxic epidermal necrolysis with the use of oxcarbazepine, you must not be re-started on oxcarbazepine at any time.

If you develop a rash or these skin symptoms, seek immediate advice from a doctor and tell them that you are taking this medicine.

This medicine can lead to a condition called hypothyroidism (low levels of thyroid hormone). If you are a child, your doctor may examine your blood at regular intervals after starting treatment with Oxcarbazepine.

If you experience an increase in the frequency of seizures, speak to your doctor as he/she may decide to stop your treatment with Oxcarbazepine. This is particularly important for children but may also occur in adults.

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.

Patients of Han Chinese or Thai origin

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 are of other Asian origin, (e.g. Phillipino or Malaysian) your doctor may also consider testing a blood sample before treatment.

Children and adolescents

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

Other medicines and Oxcarbazepine Mylan

Tell your doctor if you are taking, have recently taken or might take any other medicines, particularly any of the following medicines as they may interact with Oxcarbazepine Mylan:

- other anticonvulsant medicines such as phenobarbitone, phenytoin, carbamazepine, lamotrigine and valproic acid. Your doctor may need to adjust the dosage of these medicines when they are given in combination with Oxcarbazepine Mylan. In combination with lamotrigine there is an increased possibility of side effects like nausea, drowsiness, dizziness and headache occurring
- hormonal contraceptives (like the “pill”). Oxcarbazepine Mylan can stop these medicines working properly. Another form of contraception should also be used
- medicines to treat mental illness such as lithium and MAOIs (Monoamine Oxidase Inhibitors), like phenelzine and moclobemide. Combination with lithium might increase the occurrence of side effects
- medicines that can lower sodium levels in the blood (e.g. diuretics, desmopressin and non-steroid anti-inflammatory drugs such as indometacin and ibuprofen). Oxcarbazepine Mylan can lower the sodium levels in your blood further which may lead to symptoms of sodium shortage (see **Possible side effects**). Your doctor should examine your blood before and at regular intervals after starting treatment with Oxcarbazepine Mylan
- medicines used to control the body’s immune system (immunosuppressants) such as ciclosporin, tacrolimus.
- rifampicin (an antibiotic used to treat bacterial infection)

Oxcarbazepine Mylan with alcohol

Take special care if drinking alcohol while taking Oxcarbazepine Mylan as it may make you feel very drowsy.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Oxcarbazepine affects the way hormonal contraceptives work and there is a risk of getting pregnant. You should use other contraceptives if you are of a child-bearing age.

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.

Your doctor will tell you the benefits and potential risks involved and help you to decide whether you should take Oxcarbazepine Mylan.

Do not stop your treatment with Oxcarbazepine Mylan 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 Mylan 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 Mylan. If you are breastfeeding while taking Oxcarbazepine Mylan 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 has a moderate influence on the ability to drive and use machines. You should be aware that Oxcarbazepine Mylan can cause side effects like dizziness, drowsiness, balance or co-ordination problems, eye problems including double or blurred vision, low levels of sodium in the blood which can cause muscle weakness, reduced levels of consciousness, especially when starting treatment or increasing the dose which can influence your ability to drive or operate machines. Do not drive or operate machines if you experience such side effects.

Oxcarbazepine Mylan contains lactose

If you have been told by your doctor that you have an **intolerance to some sugars**, contact your doctor before taking this medicine.

3. How to take Oxcarbazepine Mylan

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

Where the required dose cannot be administered using whole tablets, other oxcarbazepine containing preparations are available.

Your doctor will probably start treatment with a low dose and, if necessary gradually increase it to suit your own needs. The recommended doses are as follows:

Adults

The starting dose is 300 mg twice daily. If needed your doctor may slowly increase the dose every week by a maximum of 600 mg daily. The maintenance dose is between 600 mg and 2400 mg daily.

If you are also taking other anticonvulsant medicines, your doctor may need to reduce their dose or increase the dose of Oxcarbazepine Mylan more slowly.

If other anticonvulsive medicines are replaced by Oxcarbazepine Mylan their dose will be decreased gradually.

Use in children and adolescents of 6 years and older

The starting dose is 8-10 mg/kg of body weight daily, divided into two doses. If needed your doctor may increase the dose approximately every week by 10 mg/kg of body weight daily up to a maximum daily dose of 46 mg/kg of body weight per day. The maintenance dose in combination with other anticonvulsive medicines is normally 30 mg/kg body weight daily.

For children who cannot swallow tablets or where the required dose cannot be administered using tablets, other oxcarbazepine containing pharmaceutical forms are available.

Use in children under 6 years of age

Oxcarbazepine Mylan is not recommended for children under 6 years old since it has not been shown to be a safe and effective treatment in this age group.

Patients with kidney problems

If you have kidney problems your doctor may start treatment with half the normal starting dose and increase the dose of Oxcarbazepine Mylan more slowly than that stated above.

Patients with severe liver problems

If you have severe liver problems, your doctor may need to alter the amount you take. Always follow your doctor's instructions.

Where the required dose cannot be administered using tablets, other oxcarbazepine containing pharmaceutical forms are available.

Method of administration:

Swallow the film-coated tablet with a glass of water with or without food. **Do not** crush or chew them. The score line is only there to help you break the tablet if you have difficulty swallowing it whole but cannot divide the tablet in equal half doses.

If you take more Oxcarbazepine Mylan than you should:

If you have taken more Oxcarbazepine Mylan than you should contact your doctor or pharmacist straight away. Symptoms of overdose are low levels of sodium in the blood, anger, agitation, being confused, drowsiness or sleepiness, dizziness, feeling sick (nausea), being sick (vomiting), tiredness, changes to your heart rhythm (fast, irregular heartbeat), shaking, seizures/convulsions, headache, coma, loss of consciousness, uncontrolled twitching or jerking, double or blurred vision, narrowing of the pupil, low blood pressure, shortness of breath, an abnormal degree of muscular or bodily activity, lack of co-ordination of movements and uncontrolled eye movements.

If you forget to take Oxcarbazepine Mylan:

Take it as soon as you remember. However, if it is almost time for your next dose, do not take the missed dose, take the next dose on time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Oxcarbazepine Mylan

Do not stop taking Oxcarbazepine Mylan suddenly without consulting your doctor since this could lead to a sudden increase in seizures/convulsions. If your treatment with Oxcarbazepine Mylan is stopped your doctor will do this slowly.

If you have any further questions on the use of this product, 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 or go to your nearest hospital casualty department straight away if you have any of the following serious side effects; you may need medical attention:

Uncommon (may affect up to 1 in 100 people):

- an increase in the number of infections you get which may cause fever, severe chills, sore throat, or mouth ulcers (this may indicate you have a low number of white blood cells in your body)
- weight gain, tiredness, hair loss, muscle weakness, feeling cold (signs of under active thyroid gland).
- Fall

Rare (may affect upto 1 in 1,000 people)

- swollen face, lips, eyelids, tongue, throat or mouth, difficulty in speaking, swallowing and sudden signs of nettle rash with difficulty in breathing, shortness of breath, wheezing (signs of angioedema and anaphylactic reactions)
- 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)

- potentially life-threatening skin rashes such as severe blistering of the skin and/or mucous membranes of the lips, eyes, mouth, nasal passages or genitals and skin peeling on much of the body surface (signs of serious allergic reaction including Lyell's syndrome, Stevens-Johnson syndrome, toxic epidermal necrolysis) (see section 2, "Warnings and precautions")
- red (moist), itchy and irregular spots similar to the rash of measles, which starts on the limbs and sometimes on the face and the rest of the body. The spots may blister or may progress to form raised, red, pale-centred marks. Those affected may have fever, sore throat, headache and/or diarrhoea (erythema multiforme).
If such skin reactions have occurred during use of oxcarbazepine, you must not use Oxcarbazepine Mylan. Your doctor may decide to withdraw treatment with Oxcarbazepine Mylan
- hypersensitivity reactions can also affect other parts of the body and may cause problems with your lungs (such as breathing difficulties or coughing, which may produce phlegm or blood), kidneys (producing little or no urine, or blood in the urine) or liver (signs of liver problems are described below, however this may also lead to swelling of the brain, causing changes in the way you think or act, or make you very sleepy). Other effects you may see include changes to your blood (described separately in this leaflet), an enlarged spleen (causing swelling and pain/tenderness in the belly) or swollen and painful glands in the neck, armpit or groin
- red blotchy rash mainly on face which may be accompanied by fatigue, fever, feeling sick (nausea) or loss of appetite (systemic lupus erythematosus)
- bleeding or bruising more easily than normal (thrombocytopenia)

- signs of inflammation of the liver (nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin or whites of the eyes (jaundice), light coloured bowel motions, dark coloured urine). Your liver function may need to be checked
- inflammation of the pancreas which includes the following signs: severe upper stomach pain that spreads to the back, often with feeling or being sick (pancreatitis).
- heart condition which can cause light-headedness, fainting and irregular heart rhythm (atrioventricular block).

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 Mylan. Most of these effects are transient and usually diminish over time.

Very common (may affect more than 1 in 10 people)

- tiredness, headache, feeling dizzy, tired or drowsy/sleepy, feeling sick (nausea), being sick (vomiting), double vision.

Common (may affect up to 1 in 10 people):

- feeling weak; memory loss/disturbances; difficulty concentrating; lack of emotion or motivation (apathy); agitated or other mood changes; confusion; blurred vision; disturbance in vision; diarrhoea or constipation, stomach (abdominal) pain; acne; hair loss; loss of co-ordination; weight increase; speech disorder.

Uncommon (may affect up to 1 in 100 people):

- high blood pressure; hives
- you may also have raised level of liver enzymes while taking Oxcarbazepine Mylan.

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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme via the 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 Mylan

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 container or blister and the carton. The expiry date refers to the last day of that month.

Do not store above 30°C.

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 Mylan contains

- The active substance is oxcarbazepine. Each film-coated tablet contains 150 mg, 300 mg or 600 mg of oxcarbazepine.
- The other ingredients (excipients) are:
Tablet core: crospovidone; hypromellose; microcrystalline cellulose; silica, colloidal anhydrous and magnesium stearate.
Tablet coating: black iron oxide (E172); red iron oxide (E172); yellow iron oxide (E172); hypromellose; lactose monohydrate (see section 2 'Oxcarbazepine Mylan contains lactose'); macrogol 4000 and titanium dioxide (E171).

What Oxcarbazepine Mylan looks like and contents of the pack

Film-coated tablet.

The film-coated tablets are oblong, buff-coloured and have a scoreline on each side. The scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

The 150 mg/ 300 mg/ 600 mg film-coated tablets are marked 'OX/150'/'OX /300'/'OX/600' on one side and 'G/G' on the other side.

Oxcarbazepine Mylan film-coated tablets are available in plastic tablet containers of 100, 200 and 500 tablets and blister packs of 10, 20, 30, 50, 60, 100 and 200 tablets.*

*Not all pack sizes may be marketed.

Oxcarbazepine Mylan film-coated tablets are available as Oxcarbazepine Mylan 150 mg, 300 mg and 600 mg film-coated tablets.

Marketing Authorisation Holder:

Mylan, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom.

Manufacturers:

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Mylan Hungary Kft., Mylan utca 1., Komárom, 2900, Hungary.

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