

## **Package leaflet: Information for the patient**

### **Oxcarbazepine Teva 150 mg, 300 mg and 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 Teva is and what it is used for
2. What you need to know before you take Oxcarbazepine Teva
3. How to take Oxcarbazepine Teva
4. Possible side effects
5. How to store Oxcarbazepine Teva
6. Contents of the pack and other information

#### **1. What Oxcarbazepine Teva is and what it is used for**

##### **What Oxcarbazepine Teva is**

The active ingredient of Oxcarbazepine Teva is oxcarbazepine.

Oxcarbazepine Teva belongs to a group of medicines called anticonvulsants or antiepileptics.

##### **What Oxcarbazepine Teva is used for**

Medicines such as Oxcarbazepine Teva are the standard treatment for epilepsy.

Epilepsy is a brain disorder that causes people to have recurring seizures and convulsions (also known as fits). 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 Teva 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 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 Teva works by keeping the brain's "overexcitable" nerve cells under control. This suppresses or reduces the frequency of such seizures.

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

#### **2. What you need to know before you take Oxcarbazepine Teva**

Follow all the doctor's instructions carefully. They may differ from the general information contained in this leaflet.

### **Monitoring during your treatment with Oxcarbazepine Teva**

Before and during your treatment with Oxcarbazepine Teva, 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 Teva:**

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

### **Warnings and precautions**

#### **Talk to your doctor or pharmacist before taking Oxcarbazepine Teva:**

- 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 Teva. 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 Teva tell your doctor immediately or go to the emergency department at your nearest hospital:**

- if you experience an **allergic reaction** after starting Oxcarbazepine Teva. 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 Teva 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 heart beat**.

### **Children and adolescents**

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

### **Other medicines and Oxcarbazepine Teva**

*Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.*

*This includes medicines bought without a prescription.*

This applies especially to:

- Hormonal contraceptives, such as the pill (see 'Warnings and precautions')
- Other antiepileptic medicines, such as carbamazepine, phenobarbital, phenytoin or lamotrigine
- 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 drugs, 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 Teva with food, drink and alcohol**

Oxcarbazepine Teva can be taken with or without food.

Alcohol may increase the sedative effects of Oxcarbazepine Teva. Avoid alcohol as much as possible and ask your doctor for advice.

### **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**

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

Do not stop your treatment with Oxcarbazepine Teva during pregnancy without first checking with your doctor.

Ask your doctor or pharmacist for advice before taking any medicine during pregnancy.

#### **Breast-feeding**

You should not breast-feed while taking Oxcarbazepine Teva. The active substance in Oxcarbazepine Teva passes into breast milk. This could cause side effects for breast-fed babies. Ask your doctor or pharmacist for advice before taking any medicine while you are breast-feeding.

#### **Driving and using machines**

Oxcarbazepine Teva 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

**Oxcarbazepine Teva contains lactose, sunset yellow (E110) and sodium**

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

This medicinal product contains sunset yellow (E110) and may cause allergic reactions.

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

### **3. How to take Oxcarbazepine Teva**

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

**How much to take**

**Dose for adults:**

- The recommended starting dose of Oxcarbazepine Teva 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**

Oxcarbazepine Teva can be taken by children aged 6 years or above.

The dosage for children depends on their weight.

- The recommended 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 Teva**

- 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 was not designed for dividing the tablet into equal doses.
- For small children who cannot swallow the tablets, or who cannot be given the necessary dose in tablet form, other pharmaceutical forms of oxcarbazepine are available.

**When and for how long to take Oxcarbazepine Teva**

Take Oxcarbazepine Teva 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 Teva 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 Teva 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 Teva may include: drowsiness, dizziness, feeling sick (nausea), being sick (vomiting), increased uncontrolled movements, lethargy, confusion, muscular twitching or significant worsening of convulsions, problems with coordination and/or involuntary movement of the eyes.

**If you forget to take Oxcarbazepine Teva**

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 tablet.

If you are unsure or have forgotten to take several doses, contact your doctor.

**If you stop taking Oxcarbazepine Teva**

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.

**Some side effects could be serious: get medical help immediately**

The following are signs of very rare (may affect up to 1 in 10,000 people), but potentially serious side effects that may require urgent medical treatment.

- Swelling of the lips, eyelids, face, throat or mouth, accompanied by difficulty in breathing, speaking or swallowing (signs of anaphylactic reactions and angioedema) or other 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 a serious allergic reaction including Lyell's syndrome, Stevens-Johnson syndrome and erythema multiforme)
- 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)
- 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)
- Lethargy, confusion, muscle twitching or significant worsening of convulsions (possible symptoms of low sodium levels in the blood) (see 'Special warnings and precautions')
- 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)
- Weight gain, tiredness, hair loss, muscle weakness, feeling cold (signs of under active

thyroid gland)

**Tell your doctor immediately or go to the emergency department at your nearest hospital if you get any of the above side effects.** The doctor will also decide whether Oxcarbazepine Teva has to be stopped immediately and how to continue further medical care.

**Other side effects: tell a doctor as soon as possible**

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

- Low sodium levels in the blood, trembling, coordination problems; involuntary movement of the eyes; anxiety and nervousness; depression, mood swing; rash
- Weakness; memory disturbances; impaired concentration; apathy; agitation; confusion; blurred vision; visual disturbance; constipation; diarrhoea; stomach (abdominal) pain; acne; hair loss; balance disturbances

Uncommon: may affect up to 1 in 100 people

- *Low number of white blood cells*
- Hives. You may also have raised levels of liver enzymes while taking Oxcarbazepine Teva

Very rare: may affect up to 1 in 10,000 people

- Irregular heart beat or a very fast or slow heart rate

Not known: frequency cannot be estimated from the available data

- Speech disorder
- High blood pressure, fall

**Tell your doctor as soon as possible if you get any of the above side effects.** They may require medical attention.

These are usually mild to moderate side effects of Oxcarbazepine Teva. Most of these effects are transient and usually diminish over time.

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 at: [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 Oxcarbazepine Teva**

- 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 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 Oxcarbazepine Teva contains

- The active substance is oxcarbazepine. Each film-coated tablet contains 150, 300, 600 mg oxcarbazepine.
- The other ingredients are:  
*Tablet core:* lactose monohydrate, maize starch, crospovidone, povidone (K-30), cellulose microcrystalline, sodium starch glycolate (type A), silica colloidal anhydrous and magnesium stearate.  
*Film-coating:* hypromellose, macrogol 6000, macrogol 400, titanium dioxide (E171), iron oxide yellow (E172), sunset yellow aluminium lake (E110).

### What Oxcarbazepine Teva looks like and contents of the pack

#### Film-coated tablet

Oxcarbazepine Teva 150 mg Film-coated Tablets are yellow to dark yellow, film coated capsule shaped tablets. One side of the tablet is scored in half and debossed with "9" on one side of the score and "3" on the other. The other side of the tablet is scored in half and debossed with "72" on one side of the score and "81" on the other. *The score line is only there to help you break the tablet if you have difficulty swallowing it whole.*

Oxcarbazepine Teva 300 mg Film-coated Tablets are yellow to dark yellow, film coated capsule shaped tablets. One side of the tablet is scored in half and debossed with "9" on one side of the score and "3" on the other. The other side of the tablet is scored in half and debossed with "72" on one side of the score and "82" on the other. *The score line is only there to help you break the tablet if you have difficulty swallowing it whole.*

Oxcarbazepine Teva 600 mg Film-coated Tablets are yellow to dark yellow, film coated capsule shaped tablets. One side of the tablet is scored in half and debossed with "9" on one side of the score and "3" on the other. The other side of the tablet is scored in half and debossed with "72" on one side of the score and "83" on the other. *The score line is only there to help you break the tablet if you have difficulty swallowing it whole.*

Oxcarbazepine Teva 150 mg Film-coated Tablets are available in pack sizes of 1, 30, 50, 56, 100, 200 & 500 film-coated tablets. Hospital pack: 500 film-coated tablets.

Oxcarbazepine Teva 300 mg Film-coated Tablets are available in pack sizes of 1, 30, 50, 56, 100, 200 & 500 film-coated tablets. Hospital packs: 50 & 500 film-coated tablets.

Oxcarbazepine Teva 600 mg Film-coated Tablets are available in pack sizes of 1, 30, 50, 56, 100, 200 & 500 film-coated tablets. Hospital packs: 50 & 500 film-coated tablets.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**  
**TEVA UK Limited, Eastbourne, BN22 9AG.**

**\*OR\***

**Marketing Authorisation Holder: TEVA UK Limited, Eastbourne, BN22 9AG.**

**Manufacturer: Merckle GmbH, Ludwig-Merckle-Strasse 3, 89143 Blaubeuren, Germany**

**\*OR\***

**Marketing Authorisation Holder: TEVA UK Limited, Eastbourne, BN22 9AG.**

**Manufacturer: Balkanpharma Dupnitsa AD., 3 Samokovsko shosse str., Dupnitsa 2600, Bulgaria**

**This leaflet was last revised in August 2018.**

PL 00289/1084, 1085 and 1086