

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### EXMAL

300 mg tablets, 600 mg tablets

#### OXCARBAZEPINE

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*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.*

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*• 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 •*

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#### What is in this leaflet?

1. What Exmal is and what it is used for
2. What you need to know before you take Exmal
3. How to take Exmal
4. Possible side effects
5. How to store Exmal

#### *1. WHAT EXMAL IS AND WHAT IT IS USED FOR What Exmal is*

The active ingredient of Exmal is oxcarbazepine.

Exmal belongs to a group of medicines called anticonvulsants or antiepileptics.

#### **What Exmal is used for**

Medicines such as Exmal 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.

Exmal 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.

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

Exmal 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.

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

## 2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE EXMAL

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

Monitoring during your treatment with Exmal

Before and during your treatment with Exmal, 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 Exmal**

- if you are allergic (hypersensitive) to oxcarbazepine or any other ingredients of Exmal tablets.

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

### **Warnings and precautions**

If any of the following apply to you, tell your doctor before you take Exmal:

- 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 (Exmal).
- 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") Exmal may stop your contraceptive from working. Use a different or extra (non-hormonal) method of contraception while taking Exmal. 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 Exmal, tell your doctor immediately or go to the emergency department at your nearest hospital:

- if you experience an allergic reaction after starting Exmal. 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 Exmal 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 Exmal***

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines bought without a prescription.

This applies especially to:

- Hormonal contraceptives, such as the pill (see Take special care with Exmal).
- 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.

### ***Exmal with food and drink***

Exmal can be taken with or without food.

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

### ***Pregnancy, breast-feeding and fertility***

**Pregnancy**

Tell your doctor if you are pregnant or planning to become pregnant.

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 Exmal.

Do not stop your treatment with Exmal 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 Exmal. The active substance in Exmal 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***

Exmal 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 EXMAL**

Always take Exmal 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**

##### **Dose for adults**

- The usual starting dose of Exmal for adults (including elderly patients) is 600 mg per day.
- Take one 300 mg tablet 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.

##### **Dose for children**

Exmal 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 Exmal**

- 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 tablets, or who cannot be given the necessary dose in tablet form, Exmal is available as an oral suspension.

#### **When and for how long to take Exmal**

Take Exmal 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 Exmal 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 Exmal 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 Exmal 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 Exmal**

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 double the dose at any time.

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

### ***If you stop taking Exmal***

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 product, ask your doctor or pharmacist.

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, Exmal can cause side effects, although not everybody gets them. These side effects may occur with certain frequencies, which are defined as follows:

- **Very common:** affects more than 1 patient in 10
- **Common:** affects 1 to 10 patients in 100
- **Uncommon:** affects 1 to 10 patients in 1,000
- **Very rare:** affects less than 1 patient in 10,000
- **Not known:** frequency cannot be estimated from the available data

Some side effects could be serious: get medical help immediately

The following are signs of very rare, 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 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 Take special care with Exmal).
  - 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 Exmal has to be stopped immediately and how to continue further medical care.

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

**Common:**

- trembling; coordination problems; involuntary movement of the eyes; anxiety and nervousness; depression, mood swing; rash.

**Very rare:**

- irregular heart beat or a very fast or slow heart rate.

**Unknown:**

- Speech disorder

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

**Other side effects:** tell a doctor if they worry you

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

**Very common:**

- tiredness; headache; dizziness; drowsiness; feeling sick (nausea); being sick (vomiting); double vision.

**Common:**

- weakness; memory disturbances; impaired concentration; apathy; agitation; confusion; blurred vision; visual disturbance; constipation; diarrhoea; stomach (abdominal) pain; acne; hair loss, balance disturbances.

**Uncommon:**

- hives. You may also have raised levels of liver enzymes while taking Exmal.

**Not known:**

- high blood pressure, fall.

Tell your doctor if any of the above side effects gets severe.

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

### ***5. HOW TO STORE EXMAL***

- Keep out of the reach and sight of children.
- Do not use 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 Exmal if you notice that the pack is damaged or shows signs of tampering.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

This leaflet was last approved in 09/2014.