

# TRILEPTAL<sup>®</sup> TABLET

Oxcarbazepine (300mg, 600mg)

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### What Trileptal is used for

Trileptal belongs to group of medicines called anticonvulsants or antiepileptics (medicines to treat epilepsy).

Trileptal is used to treat partial seizure (involves a limited area of the brain) and generalised tonic-clonic seizures (involves a wide area of the brain, cause loss of consciousness and can affect the whole body), in adults and children.

Trileptal can be used alone (i.e. monotherapy) or in combination with other antiepileptic medicines. It can replace other antiepileptic medicines when current therapy provides insufficient seizure control.

### How Trileptal works

Trileptal works by keeping the brain's "overexcitable" nerve cells under control, thereby suppressing or reducing the frequency of such seizures.

### Before you use Trileptal

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

The risk of serious skin reactions in patients of Han Chinese or Thai origin associated with oxcarbazepine, carbamazepine or chemically-related compounds may be predicted by testing a blood sample of these patients.

### Monitoring during your treatment with Trileptal

Before and during your treatment with Trileptal, your doctor may perform blood tests to determine the

dose for you. Your doctor will tell you when to have the tests.

### When you must not use Trileptal

- If you are allergic (hypersensitive) to oxcarbazepine (the active substance of Trileptal) or eslicarbazepine (another active substance related to oxcarbazepine) or any of the other ingredients of Trileptal listed at the end of this leaflet.

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

### **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 Trileptal.

Do not stop your treatment with Trileptal during pregnancy without first checking with your doctor. Ask your doctor or pharmacist for advice before taking any medicine during pregnancy.

### **Breast-feeding**

The active substance in Trileptal passes into breast milk. This could cause side effects for breast-fed babies. Therefore, you should not use Trileptal during breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine while you are breast-feeding.

### **Females of child-bearing potential**

If you are a woman taking a hormonal contraceptive (such as "the birth-control pill"), Trileptal may render this contraceptive ineffective. Therefore, you should use a different or additional non-hormonal method of contraception (e.g. intrauterine implants) while you are taking Trileptal.

### Before you start to use Trileptal

Tell your doctor:

- 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 (Trileptal).
- If you have a kidney disease.
- If you have a serious liver disease.
- If you have a heart disease, shortness of breath and/or swelling of the feet or legs due to fluid build-up.
- If you know that your blood level of sodium is low.

If any of the above applies to you, tell your doctor before you take Trileptal.

### **Taking Trileptal with alcoholic drink**

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

### **Older people (65 years or above)**

Trileptal can be used in people older than 65 years, keeping to the doctor's instructions.

### **Children and adolescents**

Trileptal can be used in children, keeping to the doctor's instructions. In children, your doctor may recommend thyroid function monitoring before therapy and during therapy.

### Taking other medicines

Tell your doctor or pharmacist about any other medicines you are taking or have recently taken, including any you have bought without a prescription because these might interact with Trileptal. This applies especially to:

- Hormonal contraceptives (such as the birth-control pill).
- Other antiepileptic drugs and enzyme inducing drugs (e.g. carbamazepine, phenobarbital, phenytoin and rifampicin).
- Felodipine (type of medicine used to treat high blood pressure).

- Medicines which reduce the level of sodium in your blood, e.g. diuretics (used to help the kidneys get rid of salt and water by increasing the amount of urine produced).
- Medicines which control your body's immune system (such as ciclosporin).

### **How to use Trileptal**

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

Do not exceed the recommended doses prescribed by your doctor. Swallow the tablets with a little water. If necessary, the tablets can be broken in half to help swallow them. Please ask your doctor or pharmacist for advice.

#### How much to use

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

Trileptal should be taken twice a day, every day, at about the same time of day, unless the doctor tells you otherwise. Taking the tablets at the same time each day will have the best effect on controlling epilepsy. It will also help you to remember when to take Trileptal.

##### ***Adults***

Initial dose: 600 mg per day. Take one 300 mg tablet twice daily.

Maintenance dose: Between 600 and 2400 mg per day. The maximum dose may reach, in exceptional cases, 4200 mg per day.

If you are taking another antiepileptic medicine, the dose is the same.

##### ***Elderly (65 years old and above)***

No special dose recommendations. Dose adjustments are recommended for elderly with kidney impairment.

##### ***Liver impairment***

No dosage adjustment is required in mild and moderate liver impairment.

##### ***Kidney impairment***

Initial dose: Half the usual starting dose (300mg/day) and increased slowly.

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

The dosage for children will be calculated by your doctor and depends on your child's weight. Initial dose: 8-10mg/kg per day given in 2 divided doses. Maintenance dose: 30-46mg/kg per day. The maximum dose is 46mg/kg per day.

#### When to use it

Trileptal can be taken with or without food. Take your medicine exactly as your doctor or pharmacist advises you.

#### How long to use Trileptal

Your doctor will tell you how long your/your child's treatment with Trileptal will last. The duration of treatment is based on your/your child's seizure type; ongoing treatment for many years may be necessary to control the seizures. Do not change the dose or stop treatment without talking to your doctor.

#### If you forget to use Trileptal

If you have only 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. Just 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 use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Some of the symptoms of an overdose may include sleepiness, dizziness, nausea and vomiting, loss of coordination, loss of consciousness, headache, tremor and involuntary eye movement.

### **While using Trileptal**

#### Things you must do

- If you develop any of the following symptoms after

starting Trileptal, tell your doctor immediately or go to the emergency department at your nearest hospital: If an allergic reaction happens such as swelling of lips, eyelids, face, throat, mouth, or sudden breathing problems, fever with swollen glands (lymph node swelling), rash or skin blistering.

- If you develop serious skin reactions such as rash, red skin, blistering of the lips, eyes or mouth, skin peeling and accompanied by fever. These reactions may be more frequent in patients in some Asian countries and in patients with Chinese ancestry.
- 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 symptoms suggestive of hepatitis, such as jaundice (yellowing of skin and eyes).
- If at any time you have thoughts of harming or killing yourself. A small number of people being treated with antiepileptics have had such thoughts or behaviour.

#### Things you must not do

Do not stop your treatment with Trileptal without first checking with your doctor. To prevent sudden worsening of your seizure, do not discontinue your medicine abruptly.

#### Things to be careful of

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

This medicine may affect your ability to drive or use machines. If the tablets make you feel sleepy, dizzy or may cause blurred vision, double vision, lack of muscle coordination or a depressed level of consciousness, especially when starting treatment or increasing dose, please discuss with your doctor.

### **Side effects**

As with all medicines, patients treated with Trileptal may experience side effects, although not everybody gets them.

#### Some effects could be serious

- 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).
- 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, nausea, loss of appetite (signs of systemic lupus erythematosus).
- Lethargy, confusion, muscular twitching or significant worsening of convulsions (symptoms that may be linked to low sodium levels in the blood) (see Before you start to use Trileptal).
- Flu-like symptoms with jaundice (signs of hepatitis).
- Severe upper stomach abdominal pain, vomiting, loss of appetite (signs of pancreatitis).
- Weight gain, tiredness, hair loss, muscle weakness, feeling cold (signs of under active thyroid gland).

If you experience any of these, tell your doctor straight away.

#### **Some side effects are very common**

*These side effects may affect more than 1 in every 10 patients:* tiredness; headache; dizziness; drowsiness; nausea; vomiting; double vision.

#### **Some side effects are common**

*These side effects may affect between 1 and 10 in every 100 patients:* trembling; problems with coordination; involuntary movement of the eyes; feeling of anxiety and nervousness; feeling of depression; mood swings; weakness; memory disturbances; impaired concentration; apathy (lack of emotion); agitation; confusion; blurred vision; constipation; diarrhoea; stomach (abdominal) pain; acne; hair loss; disturbance of balance; weight increased.

#### **Some side effects are very rare**

*These side effects may affect less than 1 in every 10,000 patients:* irregular heartbeats or very fast or slow heart rate; high blood pressure; vitamin B9 (folic acid) deficiency. Some of the signs of vitamin B9 deficiency are: diarrhoea, feeling of depression and signs of decrease in the number of blood cells (see subsection "Some effects could be serious").

#### **Other side effects**

*Unknown frequency:* Speech disorders; bone disorders including osteopenia and osteoporosis (thinning of the bone) and fractures in patients on long term-treatment with Trileptal.

If any of these affects you severely, tell your doctor.

If you notice any side effects not mentioned in this leaflet, inform your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website [npra.moh.gov.my](http://npra.moh.gov.my) (Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI))

#### **Storage and disposal of Trileptal**

##### **- Storage**

- Keep this medicine out of the sight and reach of children.
- Do not use Trileptal after the expiry date which is printed on the box.
- Store Trileptal in the original package.
- Do not store Trileptal above 30°C. Do not use any Trileptal pack that is damaged or shows signs of tampering.

##### **- Disposal**

- Return any unused tablets to your pharmacy for safe disposal.
- Medicines should not be disposed of via wastewater or household waste. These measures will help to protect the environment.

#### **Product description**

##### **What it looks like**

Trileptal is supplied as film-coated tablets. Each tablet contains 300 mg or 600 mg of the active substance oxcarbazepine.

The 300 mg tablet is yellow, ovaloid slightly biconvex, scored on both sides, and embossed with TE/TE on one side and CG/CG on the other side.

The 600 mg tablet is light pink, ovaloid slightly biconvex, scored on both sides, and embossed with TF/TF on one side and CG/CG on the other side.

##### **Ingredients**

- Active substance of Trileptal is oxcarbazepine.
- Inactive ingredients are:
  - tablet core: silica, colloidal anhydrous; microcrystalline cellulose; hypromellose; crospovidone; magnesium stearate;
  - tablet coating:
    - For the 300 mg tablet: hypromellose, macrogol 8000, yellow iron oxide (E 172), talc, titanium dioxide (E 171);
    - For the 600 mg tablet: hypromellose, macrogol 4000, red iron oxide (E 172), black iron oxide (E 172), talc, titanium dioxide (E 171).

##### **MAL Numbers**

Trileptal 300mg film-coated tablet:  
MAL20021155ARZ  
Trileptal 600mg film-coated tablet:  
MAL07050038ARSZ

**Manufacturer**

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**Product Registration Holder**

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