

# Trileptal®

150mg or 600mg tablets  
oxcarbazepine

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## Consumer Medicine Information

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### What is in this leaflet

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This leaflet answers some common questions about Trileptal.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you or your child taking this medicine against the benefits they expect it will have.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.** You may need to read it again.

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### What Trileptal is used for

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Trileptal is used to control epilepsy, a condition in which there are repeated seizures (fits). There are many different types of seizures, ranging from mild to severe. Trileptal is able to reduce and sometimes to completely stop some types of seizures.

Seizures happen because of a temporary fault in the brain's electrical system. Normally, brain cells coordinate body movements by sending out signals through the nerves to the muscles in an 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.

Trileptal belongs to a group of medicines called anticonvulsants.

These medicines are thought to work by keeping the brain's cells under control.

Trileptal may be used alone or in combination with other medicines to treat your condition.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

Your doctor may have prescribed it for another purpose.

Trileptal is only available with a doctor's prescription. There is no evidence that this medicine is addictive.

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### Before you take Trileptal

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#### **When you must not take it**

**Do not take Trileptal if you have an allergy to:**

- oxcarbazepine (the active ingredient in Trileptal)
- any of the other ingredients of Trileptal listed at the end of this leaflet.

**Tell your doctor if you are allergic to carbamazepine, the active ingredient in Tegretol, another medicine used to treat epilepsy.**

About 25 to 30% of people who are allergic to Tegretol are also allergic to Trileptal.

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

**Do not take Trileptal after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

In that case, return it to your pharmacist.

**If you are not sure whether you should start taking Trileptal, talk to your doctor or pharmacist.**

#### **Before you start to take it**

**Tell your doctor if you have, or have had, any medical conditions, especially the following:**

- liver problems
- kidney problems
- a low level of sodium in your blood
- problems with your heart

**Tell your doctor if you are pregnant or intend to become pregnant.**

Trileptal may affect your unborn baby. But it is very important to control your epilepsy while you are pregnant, since seizures may also affect your baby. Your doctor can help you decide whether or not you should take Trileptal in this case.

**Tell your doctor if you are breastfeeding or plan to breastfeed.**

Trileptal passes into breast milk and may possibly affect your baby. Breast-feeding is not recommended while you are taking Trileptal.

**Tell your doctor 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.

#### **Taking other medicines**

**Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.** Some medicines and Trileptal may interfere with each other. These include:

- some of the other medicines used to treat seizures such as phenobarbitone, phenytoin, carbamazepine and valproic acid
- propranolol and calcium antagonists such as felodipine and verapamil, which are medicines used to treat heart problems and high blood pressure
- diuretic medicines, also called fluid or water tablets
- diazepam, a medicine used to help you sleep or calm you down
- some medicines used to treat depression, including imipramine, amitriptyline, clomipramine and citalopram
- progesterone, which is often used in hormone replacement therapy (HRT) for the menopause and in oral contraceptives (see below)
- cyclophosphamide, a medicine used to treat some types of cancer and to suppress the immune system
- cyclosporin, a medicine which controls your body's immune system.
- some medicines used to treat stomach ulcers, including omeprazole, lansoprazole and pantoprazole
- St John's wort, which is found in many medicines that you can buy without a prescription in a pharmacy, health food shop or supermarket
- proguanil, a medicine used to treat malaria

The above medicines may be affected by Trileptal or they may affect how well it works. You may need to take different amounts of your medicines or you may need to take different medicines. Your doctor will advise you.

**Tell your doctor if you are taking oral contraceptives (birth control pills).**

If you begin taking Trileptal while you are taking birth control pills, the pill may not work as well as it should. Unplanned pregnancies can happen. Your doctor can suggest

another form of birth control while you are taking Trileptal.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Trileptal.

**If you have not told your doctor about any of the above, tell him/her before you take Trileptal.**

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## How to take Trileptal

**Follow all directions given to you by your doctor and pharmacist carefully.**

These directions may differ from the information contained in this leaflet.

**If you do not understand the instructions on the label, ask your doctor or pharmacist for help.**

### How much to take

Adults: Your doctor will decide your starting dose. The dose can be gradually increased to the amount needed to control your seizures, usually between 600 mg and 2400 mg each day. Some people will need higher doses than other people.

Children: Your doctor will calculate the dose depending on the weight of the child.

### How to take it

**Take Trileptal twice each day, every day, at about the same time each day, unless your doctor tells you otherwise.**

The doses can be taken either with or without food.

**Tablets:** Take the tablets with a full glass of water.

If you have to divide any tablets, you can buy a tablet cutter from your pharmacist to make sure the dose is accurate.

### How long to take it

**Continue taking your medicine for as long as your doctor tells you.**

Trileptal helps to control your epilepsy but does not cure it. You must take this medicine every day, even if you feel well.

**Do not stop taking Trileptal or lower the dose without first checking with your doctor. Do not let yourself run out of medicine over the weekend or on holidays.** Stopping your medicine suddenly or lowering the dose may cause you to have seizures. Your doctor will usually reduce the dose slowly before you can stop taking it completely.

### If you forget to take it

**If it is almost time for your next dose of Trileptal, skip the missed dose. Take your next dose at the usual time and continue on with your normal schedule.**

**If your next dose of Trileptal is not due for quite a while, take a dose as soon as you remember. Then take your next dose at the usual time and continue on with your normal schedule.**

**Do not take a double dose to make up for the one that you missed.** This may increase the chance of you getting an unwanted side effect.

**If you have forgotten to take several doses, contact your doctor.**

**If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.**

### If you take too much (overdose)

**Immediately telephone your doctor or the National Poisons and Hazardous Chemicals Information Centre, Dunedin (Phone 0800 POISON or 080 764 766) for advice or go to the Accident and Emergency Department at your nearest hospital, if you think you or anyone else may have taken too much Trileptal. Do this even if there are no signs of discomfort or poisoning.**

**Keep the telephone numbers for these places handy.**

Some of the symptoms of an overdose may include sleepiness, dizziness, nausea and vomiting, loss of coordination, hyperactivity and rolling of the eyes.

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## While you are taking Trileptal

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### *Things you must do*

**Tell your doctor immediately if you become pregnant while taking Trileptal.**

Your doctor can discuss with you the risks of taking Trileptal while you are pregnant.

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

**Be sure to keep all of your doctor's appointments so that your progress can be checked.**

This helps to provide you with the best treatment and to prevent unwanted side effects from happening.

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Trileptal.**

**Tell any doctor, dentist or pharmacist who treats you that you are taking Trileptal.**

### *Things you must not do*

**Do not stop taking Trileptal or lower the dose without first checking with your doctor.**

**Do not use Trileptal to treat any other complaints unless your doctor tells you to.**

**Do not give this medicine to anyone else, even if their symptoms seem similar to yours or they have the same condition as you do.**

### *Things to be careful of*

**Be careful driving, operating machinery or doing jobs that require you to be alert, until you know how Trileptal affects you.**

**Children should avoid doing things like riding bicycles or climbing trees.**

This medicine may cause dizziness, drowsiness or blurred vision in some people, especially when you first start to use it or when the dose is increased.

**Be careful when drinking alcohol while you are taking Trileptal.**

The combination could make you sleepier, dizzier or more light headed than usual.

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## Side effects

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Trileptal.**

All medicines can have unwanted side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

**Do not be alarmed by the following list of possible side effects.**

You may not experience any of them.

**Ask your doctor or pharmacist to answer any questions you may have.**

**Tell your doctor or pharmacist if you notice any of the following and they worry you:**

- tiredness or drowsiness
- dizziness or spinning sensation
- headache
- weakness, lack of energy
- shakiness, clumsiness, lack of coordination
- agitation, nervousness, depression
- difficulty in concentrating, forgetfulness, confusion
- blurred or double vision
- nausea (feeling sick) or vomiting
- constipation
- diarrhoea
- pain in the abdomen
- hair loss
- acne

The above side effects are usually mild. They tend to happen at the start of treatment and usually lessen after awhile.

**Tell your doctor immediately or go to the Accident and Emergency Department at your nearest hospital if you notice any of the following:**

- signs of allergy such as swelling of the face, lips, tongue or neck; difficulty in breathing, speaking or swallowing; severe itching, rash, or hives
- signs of a serious skin reaction, such as painful red areas, large blisters, peeling of layers of skin, bleeding in the lips, eyes, mouth, nose or genitals. These signs may be accompanied by fever and chills, aching muscles and feeling generally unwell
- constant "flu-like" symptoms such as chills, fever, sore throat, swollen glands, mouth ulcers, aching joints, lack of energy
- unusual bleeding or bruising, reddish/purplish patches under the skin
- irregular heart beat
- signs of possible pancreatitis or a serious liver problem, which may include persistent nausea, vomiting, severe abdominal pain, loss of appetite, unusual tiredness, yellowing of the skin and/or eyes, dark urine or pale bowel motions
- a low level of sodium in the blood, which very rarely leads to symptoms such as decreased alertness, confusion, nausea, vomiting, blurred vision and increased seizures
- shortness of breath when exercising
- high blood pressure
- vitamin B9 (folic acid) deficiency. Signs of vitamin B9 deficiency are: diarrhoea, feeling of depression and decrease in the number of blood cells.

The above are signs of very rare but serious side effects that may require urgent medical attention.

**Tell your doctor if you notice anything else that is making you feel unwell.**

Some people may have other side effects not yet known or mentioned in this leaflet. Some of the side effects (for example, low sodium levels, changes in liver function) can only be found when your doctor does tests from time to time to check your progress.

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## **After taking Trileptal**

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### **Storage**

- Keep your medicine in the original container until it is time to take a dose.
- Store the medicine in a cool dry place where the temperature stays below 30°C.
- Do not store Trileptal or any other medicine in the bathroom or near a sink.
- Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

### **Keep Trileptal where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### **Disposal**

**If your doctor tells you to stop taking Trileptal or you find that it has passed the expiry date, ask your pharmacist what to do with any medicine you have left over.**

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## **Product description**

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### **What it looks like**

Trileptal tablets: available in packs of 100 tablets.

- Trileptal 150 mg: Pale grey/green marked with a break line on both

sides, coded TD on one side and CG on the other

- Trileptal 600 mg: light pink marked with a break line on both sides, coded TF/TF on one side and CG/CG on the other.

### **Ingredients**

Trileptal tablets: Contain 150 or 600 mg of oxcarbazepine as the active ingredient. They also contain:

- silica - colloidal anhydrous
- cellulose - microcrystalline
- hypromellose
- crospovidone
- magnesium stearate
- macrogol 4000
- talc – purified
- titanium dioxide (E171)
- iron oxide yellow CI 77492 (E172)
- iron oxide black
- iron oxide red

Trileptal tablets do not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

### **Sponsor**

Trileptal is supplied in New Zealand by:

Novartis New Zealand Limited  
Private Bag 65904  
Mairangi Bay  
Auckland  
Building G, 5 Orbit Drive  
Rosedale  
Auckland 0632  
Telephone 0800 652 422

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