Trileptal®

Film-coated tablet and oral suspension

Oxcarbazepine

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Trileptal?

Trileptal contains the active ingredient oxcarbazepine. Trileptal is used to treat some types of Epilepsy in adults and children.

For more information, see Section 1. Why am I using Trileptal? in the full CMI.

2. What should I know before I use Trileptal?

Do not use if you have ever had an allergic reaction to Trileptal or any of the ingredients listed at the end of the CMI.
Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use Trileptal? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Trileptal and affect how it works. A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Trileptal?

- Initial dose of Trileptal in adults is 600 mg/day (8-10 mg/kg/day) given in 2 divided doses.
- Initial dose of Trileptal in children is 8-10 mg/kg/day given in 2 divided doses.
- Follow all directions given to you by your doctor and pharmacist regarding your dose carefully.

More instructions can be found in Section 4. How do I use Trileptal? in the full CMI.

5. What should I know while using Trileptal?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using Trileptal. • If you become pregnant while taking Trileptal, tell your doctor immediately.

	• Call your doctor immediately if at any time you have thoughts of harming or killing yourself.
Things you should not do	• Do not stop using this medicine suddenly. • Do not lower the dose without first checking with your doctor.
Driving or using machines	• Trileptal may cause dizziness, sleepiness, clumsiness, lack of coordination, double vision or blurred vision in some people. • Be careful before you drive or use any machines or tools until you know how Trileptal affects you.
Drinking alcohol	• Alcohol may increase the sedative effects of this medicine and may make you feel dizzy, sleepy or more lightheaded than usual. • Be careful when drinking alcohol while you are on Trileptal.

Looking after your medicine	• Store below 30°C. Keep the medicine away from children. • Keep your capsules in the pack until it is time to take them.

For more information, see Section 5. What should I know while using Trileptal? in the full CMI.

6. Are there any side effects?

Common side effects include headache, sleepiness, lack of energy, skin rash, double vision, blurred vision, agitation, suicidal thoughts and behaviour, muscle cramps, weakness, feeling sick, clumsiness and lack of coordination.
For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

Trileptal®

Film-coated tablet and oral suspension

Active ingredient: *Oxcarbazepine*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Trileptal. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Trileptal.**

Where to find information in this leaflet:

1. Why am I taking Trileptal?
2. What should I know before I take Trileptal?
3. What if I am taking other medicines?
4. How do I take Trileptal?
5. What should I know while taking Trileptal?
6. Are there any side effects?
7. Product details

1. Why am I taking Trileptal?

Trileptal contains the active ingredient oxcarbazepine. Trileptal belongs to group of medicines that are used in the treatment of seizures (fits) and are called anticonvulsants or antiepileptics.

Trileptal is used in adults and children to control some types of epilepsy. Epilepsy is a condition in which there are repeated convulsions or 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 an unorganised way. The result can be uncoordinated muscular activity that is called an epileptic seizure.

Trileptal works by keeping the brain's overexcitable nerve cells under control and so reduces the frequency of seizures.

2. What should I know before I take Trileptal?

Warnings

Do not use Trileptal if:

- you are allergic to oxcarbazepine, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you are allergic to eslicarbazepine (active ingredient related to oxcarbazepine).

- you develop any hypersensitivity reactions such as itchy rash or hives on skin, fever, swelling of lips, eyelids, tongue.
- you develop any skin reactions such as Stevens-Johnson Syndrome (SJS) (skin disease with symptoms such as blisters and sores on skin, eyes, nose, genitals, mouth, skin pain, rash, fever).
- you develop Toxic Epidermal Necrolysis (TEN) or Lyell's syndrome (severe form of SJS with symptoms such as peeling and blistering of skin, including mouth, eyes and genitals).
- you develop erythema multiforme (skin disorder with symptoms such as red colour patches which turn into sores).

Check with your doctor if you:

- are of Han Chinese or Thai origin. There is a risk of serious skin reactions [SJS, TEN] which can be predicted by testing your blood. Your doctor should be able to advise if you need a blood test before starting this medicine.
- have any other medical conditions such as liver, kidney, heart diseases.
- take any medicines for any other condition.
- are allergic to carbamazepine, the active ingredient in Teril® and Tegretol® tablets, which are other medicines used to treat epilepsy.
- have a positive blood test to Human Leukocyte Antigen (HLA)-A*3101. Serious skin reactions can occur.

- have an intolerance to sorbitol, fructose or parabens. Do not take Trileptal oral suspension as it may cause allergic reactions. You can take Trileptal tablets.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Women of childbearing age who are taking Trileptal should use highly effective contraception (preferably non-hormonal, e.g. intrauterine implants (IUD)) as there may be chances of failure of the effectiveness of oral contraceptive drugs.

It is important to control epileptic seizures during pregnancy, however, there may be a risk of brain or growth problems to your unborn baby if you take Trileptal or other 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 during pregnancy.

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

Do not take Trileptal during breast-feeding as the main ingredient in Trileptal passes into breast milk and may affect your baby.

Ask your doctor or pharmacist for advice before taking any medicine during pregnancy and breast-feeding.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Trileptal and affect how it works. Tell your doctor if you are taking:

- Any sodium-lowering medicines (diuretics, desmopressin)
- Certain medicines which are used to treat inflammation, NSAIDs (e.g. indomethacin)
- Other medicines that are used to treat seizures such as phenobarbitone, phenytoin, carbamazepine, lamotrigine, rifampicin and valproic acid
- Hormonal Contraceptives
- High blood pressure or heart problem medicines such as felodipine and verapamil
- St John's wort (medicinal herb)
- Diazepam, a medicine used to help you sleep or calm you down

- Depression medicines, including imipramine, amitriptyline, clomipramine and citalopram
- Progesterone, which is often used in hormone replacement therapy (HRT) for menopause and in oral contraceptives (refer to Pregnancy and breastfeeding)
- Cyclophosphamide, a medicine used to treat some types of cancer and to suppress the immune system
- Some medicines used to treat stomach ulcers, including omeprazole, lansoprazole and pantoprazole
- Proguanil, a medicine used to treat malaria
- Medicines (such as cyclosporin) used to help prevent organ transplant rejection or to treat certain problems with the immune system.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Trileptal.

4. How do I take Trileptal?

How much to take

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

Before starting your treatment or during treatment your doctor may perform blood tests to determine the dose for you.

Your doctor will decide on your starting dose.

For adults:

Initial dose of Trileptal is 600 mg/day (8-10 mg/kg/day) given in 2 divided doses.

If required, your doctor might increase your dose gradually to control your seizures.

Maintenance doses are usually between 600 mg/day and 2400 mg/day.

The maximum daily dose is 2400 mg/day. Do not exceed the recommended dose.

If you do not understand what dose to take, ask your doctor or pharmacist for help.

Follow the instructions provided and use Trileptal until your doctor tells you to stop.

For Paediatric patients (below 18 years):

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

Initial dose of Trileptal is 8-10 mg/kg/day given in 2 divided doses.

The dose can gradually be increased if necessary and your doctor will guide you.

For Patients with Kidney disease:

Usually, the starting dose is half the initial starting dose. Your doctor will advise you about the dose.

When to take Trileptal

Take Trileptal twice each day.

Trileptal can be taken with or without food.

How to take Trileptal

The tablets are scored and can be broken into two halves if required to make it easier to swallow. If you want to divide any tablets, you can buy a tablet cutter from your pharmacist to make sure the dose is accurate.

Oral suspension:

The oral suspension is suitable for young children and other patients who cannot swallow tablets.

Diagrams and instructions on how to use the dispensing system can be found in the carton.

Shake the bottle well before taking Trileptal oral suspension and prepare the dose immediately afterwards.

Withdraw the prescribed amount of oral suspension from the bottle using the oral syringe supplied.

Swallow the Trileptal oral suspension directly from the syringe or mix in a small glass of water just prior to taking/giving.

After each use, close the bottle and wipe the outside of the syringe with a dry, clean tissue.

The prescribed dose should be given in millilitres (mL) and not in milligrams (mg). This is important because the oral dosing syringe which is used to withdraw the correct dose from the bottle is marked in mL.

If your prescription is in mg or if you do not understand the dose, contact your doctor or pharmacist for advice.

If you forget to take Trileptal

Trileptal should be taken regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you take too much Trileptal

If you think that you have taken too much Trileptal, you may need urgent medical attention.

Symptoms of overdose:

- Double vision, excessive constriction (shrinking) of your pupils, blurred vision, rapid, uncontrollable movements of the eyes.
- Feeling sick, vomiting, excessive restlessness, tiredness.
- Drowsiness, sleepiness, dizziness, clumsiness and lack of coordination, unintentional shaking movements in one or more parts of the body.

- Convulsion, headache, coma, loss of consciousness, uncontrollable twitching, jerking or writhing movements.
- Aggression, agitation, confusional state.
- Low blood pressure, difficulty in breathing.
- Low level of sodium in blood (symptoms such as loss of energy, headache, feeling sick, vomiting).

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking Trileptal?

Things you should do

If you become pregnant while taking Trileptal, tell your doctor immediately.

Keep all your doctor's appointments so that your progress can be checked.

Call your doctor straight away if you:

- **have thoughts of harming or killing yourself.**

Remind any doctor, dentist or pharmacist you visit that you are using Trileptal.

Things you should not do

- Do not stop using this medicine suddenly.
- Do not give this medicine to anyone else, even if their symptoms seem like yours or they have the same condition as you do.

Withdrawal effect of Trileptal:

Do not lower the dose without first checking with your doctor.

Trileptal should be withdrawn gradually to minimize the potential risk of increased seizure frequency.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Trileptal affects you.

Trileptal may cause dizziness, sleepiness, clumsiness and lack of coordination, double vision or blurred vision, visual disturbances, depressed level of consciousness and low sodium levels in blood in some people.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may increase the sedative effects of this medicine and may make you feel dizzy, sleepy or more lightheaded than usual.

Be careful when drinking alcohol while you are on Trileptal.

Looking after your medicine

- Store below 30°C
- Keep your tablets in the pack until it is time to take them.
- Use the oral suspension within 7 weeks of first opening the bottle.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
General problems: • Sleepiness • Headache • Dizziness • Tiredness, drowsiness • Weight gain • Dizziness, spinning sensation • Unusual weakness • Lack of energy • Unusual hair loss or thinning **Tummy Problems:** • Feeling sick • Vomiting	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Less serious side effects	What to do
• Diarrhoea, • Pain in tummy. • Constipation • Decreased appetite **Skin issues:** • Rash • Acne **Eye problems:** • Double vision • Blurred vision • Visual disturbance	

Serious side effects

Serious side effects	What to do
Hypersensitivity reactions: • Fever • Rash • Swelling or pain in joints • Swelling of the lips, eyelids, throat, face or mouth • Difficulty breathing or swallowing	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
• Muscle pain **Skin problems:** • Severe blistering of skin, lips, eyes, mouth, nose. **Gut problems:** • Severe gut pain, vomiting, loss of appetite **Hormone problems:** • Weight gain, tiredness, hair loss, muscle weakness, feeling cold **Heart problems:** • Fast, unusually slow, or an irregular heart-beat **General problems:** • Low sodium in your blood (symptoms such as extreme tiredness, confusion, muscle twitching, or significant worsening of fits) • Flu-like symptoms with yellowing of skin or whites of the eyes **Nervous system problems:**	

Serious side effects	What to do
• Speech disorders including difficulty in speaking • Clumsiness and lack of coordination, affecting balance and walking, limb or eye movements and/or speech • Unintentional shaking movements in one or more parts of the body. • Rapid, uncontrollable movements of the eyes • Disturbance in attention • Loss of memory • Increased fits • Balance problems **Bone-related disorders:** • Back pain, stooped posture or loss of height, broken bone from minor fall (symptoms of Osteopenia or Osteoporosis: diseases that weaken bones. **Psychiatric problems:** • Agitation • Anxiety	

Serious side effects	What to do
• Suicidal thoughts and behaviour • Nervousness • Mood swings • Being confused • Difficulty concentrating • Being forgetful • Depression • Lack of feeling or emotion that can affect your motivation and wellbeing (Apathy) **Blood problems:** • Tiredness, looking pale, headache, chills, dizziness, frequent infection (sore throat, fever, mouth ulcers, bleeding or bruising more easily), nose bleeds, reddish or purplish patches or blotches on the skin • Red blotchy rash mainly on the face, with fatigue, fever, nausea, loss of appetite	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Trileptal contains

Active ingredient **(main ingredient)**	oxcarbazepine
Other ingredients **(inactive ingredients)**	Trileptal tablets: colloidal anhydrous silica, microcrystalline cellulose, hypromellose,

	crospovidone, magnesium stearate, macrogol 8000 (300 mg tablet only), macrogol 4000 (150 and 600 mg tablets only), purified talc, titanium dioxide, iron oxide yellow (150 and 300 mg tablets only), iron oxide red (150 and 600 mg tablets only), iron oxide black (150 and 600 mg tablets only). Oral suspension: purified water, sorbitol solution (70 percent) (non-crystallising), propylene glycol, dispersible cellulose, ascorbic acid, yellow-plum-lemon aroma, methyl hydroxybenzoate, PEG-8 stearate, sorbic acid, saccharin sodium and propyl hydroxybenzoate, sugar, sorbates, Ethanol is a component of the flavour.

Do not take this medicine if you are allergic to any of these ingredients.

What Trileptal looks like

Tablets

Trileptal 150 mg: oval, scored, pale grey green tablets coded TD on one side and CG on the other.

Trileptal 300 mg: oval, scored, yellow tablets coded TE/ TE on one side and CG/CG on the other.

Trileptal 600 mg: oval, scored, light pink tablets coded TF/TF on one side and CG/CG on the other.

Oral suspension

Trileptal 60 mg/mL: off-white to slightly reddish-brown oral suspension supplied with an oral dosing syringe and a press-in bottle adaptor

Australian Registration Numbers.

Tablets:

Trileptal 150 mg AUST R 76200

Trileptal 300 mg AUST R 76201

Trileptal 600 mg AUST R 76202

Oral suspension:

60 mg/mL: AUST R 81195.

Who distributes Trileptal

NOVARTIS Pharmaceuticals Australia Pty Limited

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® = Registered trademark

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