

Teril

contains the active ingredient carbamazepine

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Teril.

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

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Teril against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What Teril is used for

Teril is used to:

- * control epilepsy, a condition where you have repeated seizures (fits)
- * treat trigeminal neuralgia, where there are sudden, repeated attacks of facial pain
- * control mania, a mental condition with episodes of overactivity, elation or irritability
- * prevent bipolar mood disorder where periods of mania alternate with periods of depression.

Teril belongs to a group of medicines called anticonvulsants. These medicines are thought to work by controlling brain chemicals which send signals to nerves so that

seizures do not happen. Teril also regulates other nerve functions in the body.

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

Ask your doctor if you have any questions about why Teril has been prescribed for you.

Your doctor may have prescribed Teril for another reason.

Teril is available only with a doctor's prescription.

There is no evidence that Teril is addictive.

Before you take Teril

When you must not take it

Do not take Teril if you are allergic to:

- * any other medicine containing carbamazepine (e.g., Tegretol)
- * phenytoin (Dilantin) and oxcarbazepine (Trileptal), which are other medicines for epilepsy.
- * tricyclic antidepressants, medicines used to treat depression
- * any of the ingredients listed at the end of this leaflet.

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 Teril if you are currently taking a medicine called a monoamine oxidase inhibitor (MAOI), or have taken one in the last 14 days.

Taking Teril with a MAOI or within 14 days of taking a MAOI may cause a serious reaction with a sudden increase in body temperature, extremely high blood pressure and severe convulsions.

Do not take Teril within 14 days of stopping a MAOI.

Ask your doctor or pharmacist if you are not sure whether you are taking, or have been taking a MAOI medicine.

MAOIs are used to treat depression and Parkinson's disease. Some examples of MAOIs include phenelzine, tranylcypromine, selegiline.

Do not take Teril if you have, or have had, any of the following:

- * severe liver disease
- * systemic lupus erythematosus (SLE)
- * acute intermittent porphyria, a rare blood pigment disorder
- * bone marrow depression, a blood disease with a low platelet, red blood cell or white blood cell count
- * an irregular heartbeat caused by a condition called A-V block
- * hepatic porphyria, a disturbance in the production of porphyrin, a pigment important for liver function and blood formation.

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

If it has expired or is damaged, return it to your pharmacist for disposal.

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

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

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

Teril may affect your unborn baby if you take it during pregnancy but it is still important that you control your fits while you are pregnant. Your doctor will discuss the risks and benefits of taking Teril during pregnancy and help you decide whether or not you should take Teril.

Tell your doctor if you are breastfeeding or wish to breastfeed.

Teril passes into breast milk but it is unlikely to affect your baby. You may breast-feed provided that you watch your baby for any signs of any unwanted side effect. If your baby develops a skin rash, becomes very sleepy or has other unusual symptoms, don't breast-feed again until you speak to your doctor. Your doctor will discuss the risks and benefits of taking Teril while breastfeeding.

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

- * heart problems
- * liver problems
- * kidney problems
- * increased pressure in the eye (glaucoma)
- * prostate problems
- * blood disorders caused by other medicines
- * any mental disorder such as depression or schizophrenia.

If you have not told your doctor about any of the above, tell them before you start taking Teril.

Taking other medicines

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

Some medicines may be affected by Teril, or may affect how well it works. These include:

- * other medicines used to treat fits or convulsions
- * MAOIs, medicines used to treat depression and Parkinson's disease e.g., phenelzine, tranylcypromine

Wait at least 14 days between stopping a MAOI and starting Teril.

- * other medicines used to treat depression such as fluvoxamine, fluoxetine, nefazodone, paroxetine, bupropion, citalopram, trazodone and tricyclic antidepressants
- * medicines used to treat mental disorders e.g., risperidone, clozapine, haloperidol, thioridazine, olanzapine, quetiapine, ziprasidone and lithium
- * medicines used to treat heart problems
- * medicines used to help you sleep or calm you down
- * other medicines used to treat seizures including phenytoin, levetiracetam and oxcarbazepine
- * diuretics (fluid tablets) which are medicines used to reduce water retention and high blood pressure, e.g., frusemide and hydrochlorothiazide
- * calcium channel blockers, medicines used to treat high blood pressure and heart problems e.g., verapamil, diltiazem, felodipine
- * warfarin, a medicine used to prevent blood clots
- * antibiotics e.g., erythromycin, rifampicin, clarithromycin, doxycycline

- * anti-fungal medicines e.g., ketoconazole, fluconazole, voriconazole and itraconazole
- * pain relievers e.g., paracetamol, dextropropoxyphene, ibuprofen and tramadol
- * corticosteroids e.g., cortisone, prednisone, and dexamethasone
- * antihistamines, medicines used to prevent or relieve the symptoms of allergy or hayfever e.g., loratadine and terfenadine
- * medicines used to prevent organ transplant rejection or to treat immune diseases and some skin diseases such as cyclosporine and everolimus
- * medicines used to treat stomach or duodenal ulcers, such as cimetidine and omeprazole
- * isoniazid, a medicine used to treat tuberculosis (TB)
- * isotretinoin, a medicine used to treat acne
- * metoclopramide, a medicine used to treat nausea and vomiting
- * theophylline and aminophylline, medicines used to treat asthma
- * danazol, a medicine commonly used to treat endometriosis
- * ticlopidine, a medicine used to prevent blood clotting
- * cisplatin, imatinib and doxorubicin, medicines used to treat some cancers
- * acetazolamide, a medicine used to treat glaucoma, fluid retention and seizures
- * methadone, a medicine used to control severe pain and to treat heroin addiction
- * muscle relaxants used during surgery, such as dantrolene and oxybutynin
- * St John's Wort (*Hypericum perforatum*), a herbal medicine used in the treatment of depression, anxiety and sleep disorders
- * Levothyroxine, a medicine used to treat underactive thyroids
- * praziquantel, a medicine used to treat worm infections of the blood

- * a vitamin called nicotinamide
- * medicines containing oestrogen and progesterone, including hormone replacement therapy and contraceptives
- * medicines to treat HIV e.g., ritonavir, indinavir and saquinavir.

Your doctor can tell you what to do if you are taking any of these medicines.

While you are taking Teril tell your doctor if you are using hormonal contraceptive (birth control pill or injections) and use a barrier type of contraception, such as a condom or a diaphragm.

Teril may reduce the effectiveness of hormonal contraceptives. Unplanned pregnancies can happen. Your doctor can suggest another form of birth control while you are taking Teril.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

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

How to take Teril

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

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist.

How much to take

Your doctor will tell you how much Teril you need to take each day. The dose varies from patient to patient and may depend on your age, medical condition and whether or not you are taking other medicines.

Your doctor will usually start you on

a low dose and then gradually increase it depending on your condition and how you respond to this medicine.

How to take it

Swallow the tablets with a glass of water.

Teril tablets can be divided in half along the breakline, if advised by your doctor or pharmacist.

When to take it

Take Teril during or immediately after food.

This will lessen the chance of a stomach upset.

Take your medicine at about the same time each day, spaced evenly apart.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take it for

Keep taking Teril for as long as your doctor recommends.

Teril helps to control your condition but does not cure it. You must take it regularly every day, even if you feel well.

Do not stop taking Teril 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 unwanted side effects or make your condition worse. If you are taking this medicine to treat epilepsy, you could develop seizures (fits). 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, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

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

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

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 Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Teril. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Keep the telephone numbers of these places handy.

Some of the symptoms of an overdose may include agitation, disorientation, drowsiness, fainting, vomiting, difficulty breathing, fast and irregular heartbeat, blurred vision and slurred speech.

While you are taking Teril

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking Teril.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Teril.

Tell your doctor, if for any reason, you have not taken your medicine exactly as prescribed.

Otherwise your doctor may change your treatment unnecessarily.

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

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

Tell your doctor immediately if you have any suicidal thoughts or other mental/mood changes.

Teril may cause suicidal thoughts or actions in a very small number of people, about 1 in 500.

Patients and caregivers should be alert and monitor for these effects.

If you or someone you know is showing any of the following warning signs of suicide while taking Teril, contact your doctor or a mental health professional right away or go to the nearest hospital for treatment:

- * thoughts or talk of death or suicide
- * thoughts or talk of self-harm or harm to others
- * any recent attempts of self-harm
- * increase in aggressive behaviour, irritability, or any other unusual changes in behaviour or mood.

All mentions of suicide or violence must be taken seriously.

If you plan to have surgery, including dental surgery, tell your doctor or dentist that you are taking Teril.

This medicine may interfere with some of the medicines used during surgery.

Visit your doctor regularly so they can check on your progress.

To help prevent unwanted side effects from happening, your doctor may want to do some tests before you start taking Teril and from time to time during the course of your treatment. You may need to have tests to check your eyes, liver, kidneys or blood.

Things you must not do

Do not stop taking Teril, or lower the dose, without 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 unwanted side effects or make your condition worse. Your doctor will usually reduce the dose slowly before you can stop taking it completely.

Do not use Teril to treat any other conditions unless your doctor tells you to.

Do not give Teril to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how Teril affects you.

Teril may cause drowsiness or dizziness in some people. If either of these occur, do not drive, operate machinery or do anything else that could be dangerous.

Be careful drinking alcohol while taking Teril.

Combining Teril and alcohol can make you more drowsy or dizzy. Your doctor may suggest you avoid alcohol while you are being treated with Teril.

Be careful drinking grapefruit juice while taking Teril.

Taking Teril with grapefruit juice may increase the chances of side effects. Your doctor may suggest you avoid grapefruit juice while you are being treated with Teril.

If outdoors, wear protective clothing and use at least a SPF 30+ sunscreen. Do not use a sunlamp or tanning bed or booth.

Teril may cause your skin to be much more sensitive to sunlight than it normally is. Exposure to sunlight may cause a skin rash, itching, redness or severe sunburn.

If your skin does appear to be burning, tell your doctor.

Side effects

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

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

Like all other medicines, Teril may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

If you are over 65 years of age, you may have an increased chance of getting side effects.

Do not be alarmed by this 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 if you notice any of the following and they worry you:

- * dizziness or lightheadedness
- * feeling tired or drowsy
- * eye pain
- * restlessness, agitation or confusion
- * difficulty in speaking or slurred speech
- * numbness or tingling in hands or feet
- * muscle pain or cramps
- * unsteadiness when walking, reduced coordination
- * headache
- * stomach pain or discomfort
- * diarrhoea
- * constipation
- * swollen, red, sore tongue
- * mouth ulcers or cold sores
- * change in sense of taste
- * blurred or double vision, swollen runny eyes, difficulty seeing
- * ringing or buzzing in the ears or other changes in hearing
- * frequent need to urinate (pass water)

- * sweating
- * hair loss
- * acne
- * change in skin colour
- * excessive hairiness, especially in women
- * sexual disturbances such as impotence
- * breast enlargement in men
- * unusual secretion of breast milk
- * nausea, vomiting
- * dry mouth
- * weight gain.

The above list includes the more common side effects of Teril. They tend to be mild and short-lived.

Tell your doctor as soon immediately if you notice the following side effects:

- * signs of frequent infections such as fever, chills, sore throat or mouth ulcers
- * bleeding or bruising more easily than normal.

The above serious side effects occur commonly and require urgent medical attention. They are due to Teril affecting your blood count.

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

- * signs of allergy such as swelling of the face, lips, tongue or other parts of the body; wheezing or troubled breathing; skin rash, itching, hives, blisters or peeling skin
- * sudden increase in body temperature, together with sweating, fast heart beat and muscle stiffness
- * more frequent or more severe fits
- * constant "flu-like" symptoms (chills, fever, sore throat, swollen glands, aching joints, lack of energy)
- * depression, aggressive behaviour, recurrence of a previous mental illness, hallucinations (hearing or seeing things that are not there)

- * tiredness, headache, shortness of breath when exercising and looking pale
- * persistent nausea or vomiting, loss of appetite and feeling generally unwell, which may be accompanied by pain in the abdomen, fever, itching, a yellow colour to skin or eyes (jaundice), dark coloured urine or light coloured bowel motions
- * blood in the urine
- * passing less urine than normal, which may occur with lack of energy, vomiting, headache or confusion
- * painful swelling of the arms and legs
- * sudden onset of uncontrollable muscle spasms affecting the eyes, head, neck and body
- * change in heartbeat (slow, fast or irregular)
- * symptoms of sunburn such as redness, itching, swelling or blistering that may happen more quickly than normal
- * swelling or redness along a vein or nerve, which is extremely tender when touched
- * sudden severe headache, sudden loss of co-ordination or vision, pain in the calves, thighs or chest
- * signs that blood clots may have formed, such as sudden severe headache, sudden loss of coordination or vision, pain in calves, thighs or chest
- * severe headache together with stiffness of the neck, muscle spasms and extreme sensitivity to bright light.

The above side effects are serious and require medical attention or even hospitalisation. These serious side effects are very rare.

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

Other side effects not listed above may also occur in some patients. Some of these side effects (e.g., changes in thyroid function or liver function, increased cholesterol level)

can only be found when your doctor does tests from time to time to check your progress.

After taking Teril

Storage

Keep Teril 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.

Keep your medicine in the original container until it is time to take it.

Keep your tablets in a cool dry place where the temperature stays below 30 degrees C.

Do not store Teril or any other medicine in the bathroom or near a sink.

Do not leave Teril in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking Teril, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Teril is a round, white, scored tablet marked "CB" over "200" on one side and "G" on the reverse.

Each bottle contains 200 tablets.

Ingredients

The active ingredient in Teril is carbamazepine. Each Teril tablet contains 200 mg of carbamazepine.

The tablets also contain the following inactive ingredients:

- * microcrystalline cellulose
- * pregelatinised maize starch
- * sodium starch glycollate
- * purified talc
- * colloidal anhydrous silica
- * magnesium stearate.

The tablets are gluten free.

Manufacturer

Teril is made in Australia by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Chase Building 2

Wentworth Park Road

Glebe NSW 2037

Phone: (02) 9298 3999

www.alphapharm.com.au

Medical Information

Phone: 1800 028 365

Australian registration number:

Teril - AUST R 17674

This leaflet was prepared on

4 February 2009.