

Teril® Tablets (Carbamazepine) Tablets USP

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Composition:

Teril Tablets 200 mg: Each tablet contains:
Carbamazepine USP 200 mg

Read all this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed for you only. Do not pass it onto 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.

What is in this leaflet?

- What is Teril Tablets?
- What are the indications for Teril Tablets?
- What should be the dose of Teril Tablets?
- What are the contraindications of Teril Tablets?
- What are special warning & precaution of Teril Tablet?
- What are the adverse effects of Teril Tablets?
- Other information for Teril Tablets?

What is Teril Tablets?

Each film coated tablets 200 mg Carbamazepine
Carbamazepine, the active ingredient in Teril Tablets, can affect the body in several different ways. It is an anti-convulsant medicine (prevents fits), it can also modify some types of pain and can control mood disorders.

What are the indications for Teril Tablets?

Teril is used: Epilepsy - generalized tonic-clonic and partial seizures.
Note: Teril is not usually effective in absences (petit mal) and myoclonic seizures. Moreover, anecdotal evidence suggests that seizure exacerbation may occur in patients with atypical absences.
The paroxysmal pain of trigeminal neuralgia.

For the prophylaxis of manic-depressive psychosis in patients unresponsive to lithium therapy.

What should be the dose of Teril Tablets?

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
Swallow the tablet whole, with a glass of water. Do not chew, crush or suck the tablet Take during, after or between meals.

Your doctor is likely to start treatment with a low dose and slowly increase it to suit your own needs. Ask your doctor or pharmacist if you are unsure about the correct dose but the recommended doses are as follows:

EPILEPSY

To treat epilepsy the usual doses are:

Adults: The recommended starting dose is 100 mg to 200 mg of Carbamazepine once or twice daily. Your doctor will slowly increase this dose to control your fits until the best response is obtained, often 800 to 1200 mg daily in divided doses, although higher doses may be necessary. Use in children and adolescents: Carbamazepine tablets should not be given to children under 5 years old. The recommended daily dose for children between 5 and 10 years old is 400 mg to 600 mg of

Carbamazepine, divided up throughout the day. Children over 10 years old may be given a total daily dose of between 600 mg and 1000 mg of Carbamazepine, divided up throughout the day.

TRIGEMINAL NEURALGIA

The starting dose is 200 to 400 mg daily (100 mg twice daily in elderly patients). Your doctor may increase the dose until you are free from pain. In most patients, a dosage of 200 mg three or four times a day is enough to treat the pain. In some cases, a dose of up to 1600 mg Carbamazepine daily may be needed. Once the pain goes away (remission), the doctor will slowly reduce your dose of Carbamazepine. The maximum recommended dose is 1200 mg a day. If possible, the doctor may gradually stop your treatment until another attack occurs.

TREATMENT OF MOOD SWINGS

The starting dose is 400 mg of Carbamazepine daily, divided up throughout the day. This dose may be increased slowly until your symptoms are controlled or until the maximum daily dose of 1600 mg of Carbamazepine is reached. The usual daily dose range is 400 – 600 mg in divided doses.

Elderly

Elderly patients may be more sensitive to the effects of Carbamazepine, so the doctor may prescribe smaller doses than those stated above.

Cardiac, hepatic or renal impairment

Patients who suffer from heart, liver or kidney problems may also be prescribed lower doses of Carbamazepine.

If you take more Teril than you should

If you take more Carbamazepine than you should, contact your doctor or local hospital emergency department immediately. Take the container and any remaining tablets with you. If you have trouble in breathing, a fast and irregular heartbeat, loss of consciousness, fainting, shakiness, sickness and/or vomiting, your dose may be too high. Stop taking your medicine and inform your doctor without delay.

If you forget to take a dose

If you forget to take a dose take it as soon as you remember unless it is nearly time for your next dose. Do not take double dose to make up for a forgotten dose.

If you stop taking Teril suddenly

If you stop taking Carbamazepine suddenly you may suffer unpleasant side effects. Always ask your doctor first.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

What are the contraindications of Teril Tablets?

A small number of people being treated with anti-epileptics such as carbamazepine have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor. Serious skin rashes (Stevens- Johnson syndrome, toxic epidermal necrolysis) have been reported with the use of carbamazepine appearing initially as reddish target-like spots or circular patches often with central blisters on the trunk.

Frequently, the rash can involve ulcers of the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes). These serious skin rashes are often preceded by influenza-like symptoms fever, headache, body ache (flu-like symptoms). The rash may progress to widespread blistering and peeling of the skin. The highest risk for occurrence of serious skin reactions is within the first months of treatment.

If you have developed Stevens-Johnson syndrome or toxic epidermal necrolysis with the use of carbamazepine, you must not be re-started on carbamazepine at any time.

These serious skin reactions can be more common in people from some Asian countries. The risk of these reactions in patients of Han Chinese or

Thai origin 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 carbamazepine.

If you develop a rash or these skin symptoms, stop taking carbamazepine and contact your doctor immediately.

Do not take Teril:

- if you are allergic to carbamazepine or any of the ingredients of this medicine. Signs of a hypersensitivity reaction include swelling of the face or mouth (angioedema), breathing problems, runny nose, skin rash, blistering or peeling
- if you are allergic to similar drugs such as oxcarbazepine or phenytoin or a tricyclic antidepressant (e.g. amitriptyline)
- if you have a heart condition or had a problem with your bone marrow
- if you or a member of your family has the rare blood pigment disorder called porphyria
- if you are already taking medicine to treat a mental illness called a monoamine oxidase inhibitor (MAOI), such as phenelzine (or have taken an MAOI in the last two weeks).

What are special warning & precaution of Teril Tablet?

Talk to your doctor or pharmacist before taking Carbamazepine:

- if you have heart disease
 - if you have a history of liver or kidney disease
 - if you have kidney problems associated with low sodium blood level or if you have kidney problems and you are taking certain medicines that lower sodium blood levels (diuretics such as hydrochlorothiazide or furosemide)
 - if you have glaucoma (increased pressure in the eye)
 - if you have a difficulty to retain your urine
 - if you have suffered from a mental illness in the past
 - if you are elderly
 - if you suffer from the sort of epilepsy where you get mixed seizures, which include absences
 - if you have blood disorders (including those caused by other drugs) or if you have ever suffered a reaction to any other medicine, which has affected your blood, for example a low white blood cell count (leucopenia)
 - if you have had interrupted courses of treatment with carbamazepine. Your doctor may want to have regular blood and liver tests and, in some cases, urine tests, before you start taking Carbamazepine and from time to time during your treatment. This is quite usual and nothing to worry about.
- Children and adolescents Do not give this medicine to children less than 5 years old.

Other medicines and Carbamazepine

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines:

- other antiepileptics e.g. lamotrigine, phenytoin, fosphenytoin, primidone, sodium valproate, phenobarbitone, ethosuximide, oxcarbazepine, tiagabine, topiramate, vigabatrin, levetiracetam, progabide
- anticoagulants to thin the blood e.g. warfarin, acenocoumarol
- cimetidine or omeprazole, to treat heartburn or stomach ulcers
- medicine to treat mental illness e.g. lithium, haloperidol, thioridazine, olanzapine, risperidone, clozapine, quetiapine
- paliperidone or aripiprazole, to treat schizophrenia
- sedatives e.g. clobazam, clonazepam, alprazolam, valnoctamide
- antidepressants e.g. imipramine, fluoxetine, amitriptyline, clomipramine, nortriptyline, mianserin, sertraline, paroxetine, fluvoxamine, citalopram, trazodone
- the herbal remedy St John's wort (*Hypericum perforatum*) should not be taken while taking Carbamazepine. Consult your doctor before stopping the St John's wort preparation
- metoclopramide or aprepitant, often used to treat sickness
- antibiotics e.g. doxycycline, isoniazid, erythromycin, clarithromycin, ciprofloxacin
- isoniazid, rifampicin (used to treat tuberculosis)
- antifungals e.g. itraconazole, fluconazole, ketoconazole, voriconazole, albendazole

- corticosteroids e.g. prednisolone, dexamethasone
- ciclosporin, tacrolimus or sirolimus, immunosuppressants
- painkillers containing paracetamol, dextropropoxyphene, methadone, tramadol, buprenorphine
- medicine to treat heart conditions e.g. felodipine, isradipine, digoxin, verapamil, diltiazem
- diuretics ('water' tablets) e.g. furosemide, hydrochlorothiazide
- acetazolamide, to treat glaucoma
- muscle relaxants often used during operations e.g. alcuronium
- isotretinoin used to treat acne
- theophylline and aminophylline, for asthma
- danazol and gestrinone (used in the treatment of endometriosis)
- hormonal contraceptives e.g. pills, patches, injections or implants; as the effectiveness of these may be reduced and there will be a risk of getting pregnant. Your doctor can advise you about an alternative form of contraception.
- Hormone Replacement Therapy (HRT) e.g. tibolone
- tadalafil, used to treat impotence
- drugs to treat cancer e.g. imatinib, lapatinib, toremifene, cisplatin, doxorubicin, temsirolimus, cyclophosphamide
- mefloquine, used to treat malaria
- drugs to treat HIV known as protease inhibitors (e.g. indinavir, ritonavir, saquinavir)
- levothyroxine to treat hypothyroidism
- the anti-smoking aid, bupropion & antihistamines to treat allergies and hay fever, such as loratadine
- medicine or supplements containing Vitamin B (nicotinamide).

Teril with drink and alcohol

Carbamazepine with drink and alcohol Do not drink alcohol while taking Carbamazepine as this may increase the chance of side effects. The risk of side effects may also be increased if you eat grapefruit or drink grapefruit juice.

Pregnancy and breast-feeding

Pregnancy and breast-feeding If you are planning to become pregnant, talk to your doctor first. If you do get pregnant while taking Carbamazepine you must tell the doctor straightaway. With all anti-epileptic treatment, there is a risk of harm to the unborn baby, but it is important that your epilepsy remains well controlled. If you are pregnant and need to take an anticonvulsant, you are likely to be taking only one anticonvulsant. Your doctor will monitor you and your unborn child closely. It is important that you fully understand the risks and benefits, to both you and your baby, of taking Carbamazepine tablets.

Carbamazepine can pass into breast milk. Talk to your doctor before you decide to breast-feed. If you do breast feed and you take Carbamazepine, tell your doctor straight away if your child becomes very drowsy or suffers from skin reactions or yellow skin and eyes, dark urine or pale stools. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this any medicine.

Driving and operating machines

Driving and operating machines Carbamazepine tablets can make you feel dizzy or drowsy especially at the start of treatment or when the dose is changed. If you are affected in this way, or if your eyesight is affected or you have a lack of muscular coordination, you should not drive or operate machinery.

What are the adverse effects of Teril Tablets?

Like all medicines, this medicine can cause side effects, although not everybody gets them. Side effects are more common at the start of treatment, but usually disappear after a few days or when the dose is adjusted to be right for you.

Tell your doctor or go to your nearest hospital emergency department immediately if you suffer from the following serious side effects:

Very common: may affect more than 1 in 10 people

- a low white cell count (leucopenia) causing more infections than usual.

Uncommon: may affect up to 1 in 100 people

- severe peeling of the skin which can affect a large area of your body

Rare: may affect up to 1 in 1,000 people

- have difficulty breathing, experience chest pain, wheezing and coughing, a rash, itching, facial swelling or feel faint, all symptoms of a severe allergic reaction

- fever, skin rash, joint pain, and abnormalities in blood and liver function tests (these may be the signs of a multi-organ sensitivity disorder)

- suffer from pain in your joints and muscles, have a rash across the bridge of your nose and cheeks, and have problems breathing (symptoms of the rare reaction, systemic lupus erythematosus)

- experience yellowing of your skin or the whites of your eyes, which may in some cases indicate inflammation of the liver.

Very rare: may affect up to 1 in 10,000 people

- notice any unusual signs of mental illness or confusion

- potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported. Symptoms include worsening of a skin rash, blistering of the lips, eyes or mouth or a severe skin reaction accompanied by fever. These reactions may be more frequent in those of Chinese and Thai origin.

- suffer from a sore throat, high temperature or both

- a sudden increase in body temperature, extremely high blood pressure and severe convulsions (neuroleptic malignant syndrome)

- have severe or persistent pain in the stomach region that spreads to the lower back, often with nausea and vomiting (pancreatitis)

- meningitis (signs and symptoms include fever, feeling sick, being sick, headache, stiff neck, extreme sensitivity to sunlight, twitching of muscles, abnormal blood test results)

- feel feverish or notice unexplained bruising or bleeding of your skin which could show you have anemia (a change in your blood)

- heart and circulatory problems including a blood clot (thrombosis), which can cause tenderness, swelling, pain chest, shortness of breath; heart failure (symptoms include shortness of breath, swelling of feet or legs due to fluid build-up, getting tired easily after light physical activity)

- blood changes including: o decreases in white blood cells (agranulocytosis) causing more infections than usual with symptoms like fever, severe chills, sore throat or mouth ulcers o conditions in which red blood cells, white blood cells and platelets are all reduced in number

- liver failure (symptoms include yellowing of your skin or the white of your eyes, dark urine, light colored bowel motions, nausea, vomiting, and feeling generally unwell)

- severe allergic reactions (signs include wheezing, coughing, difficulty in breathing, feeling faint, rash, itching, swelling of the face, lips, mouth, tongue or throat).

Not known:

frequency cannot be estimated from the available data

- severe skin reactions, accompanied by feeling unwell, fever and changes in blood results.

Other side effects that can occur:

Very common (may affect more than 1 in 10 people):

- feeling dizzy, tired or drowsy

- difficulty controlling movements and feeling unsteady

- feeling or being sick

- skin reactions, including hives (urticaria) which may be severe

- changes in liver enzyme levels (usually without any symptoms).

Common (may affect up to 1 in 10 people):

- swollen ankles or lower legs, fluid retention weight gain

- low sodium levels in the blood causing headache, confusion, being sick, lethargy, muscular twitching, convulsions

- double vision, eyesight changes e.g. blurred vision

- dry mouth

- headache

- changes in the blood including an increased tendency to bruise or bleed

- eosinophilia (increase in some white blood cells)

- increase in alkaline phosphatase (an enzyme found in body tissues such

as liver and bone).

Rare (may affect up to 1 in 1000 people):

- folic acid deficiency

- increased levels of white blood cells in the body (seen in a blood test), fever

- disease of the lymph glands

- hallucinations (seeing or hearing things that are not there)

- depression or mood changes

- feeling restless, aggressive or agitated

- feeling confused

- numbness or tingling in the hands or feet, weakness of the arms or legs

- muscle weakness, loss of muscle control, speech problems, uncontrolled movements of the face and tongue

- loss of appetite

- raised or low blood pressure

- changes in heart rhythm

- stomach pain

- itching (pruritus).

Other important information for Teril Tablet?

Presentation

Teril Tablets 200 mg: Available pack of 5 x 10's tablets

Storage

Store below 30 °C.

Protect from light, heat and moisture.

Keep all medicines out of the reach of children.

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