

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations)
- 1986

This medicine is dispensed with a doctor's prescription only

Teril 200 mg
Tablets
Active ingredient
Each tablet contains:
carbamazepine 200 mg

Inactive ingredients and allergens: See section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

1. What is this medicine intended for?

Anticonvulsant for the treatment of epilepsy, neurological pain in the trigeminal nerve in the face (trigeminal neuralgia), diabetes insipidus, to treat mania and for the preventative treatment of manic depression.

Therapeutic group:

Antiepileptic, neurotropic, psychotropic.

Teril belongs to a class of medicines called anticonvulsants.

These medicines apparently work by modulating the manner in which signals are conveyed in the brain by nerves so that attacks will not occur.

Teril also regulates other neural functions in the body.

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

There is no evidence that the medicine is addictive.

Do not use Teril to treat other effects unless instructed by the doctor.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient, carbamazepine, or to any other medicine containing carbamazepine or structurally similar medicines (such as tricyclic antidepressants) or to any of the other ingredients in this medicine (see section 6).
- You have or have had an irregular heartbeat due to a condition called atrioventricular block.
- You suffer or have suffered in the past from a blood disease with a reduced number of red or white blood cells or platelets.
- You have or have had a rare disorder in the production of porphyrin, which is a pigment that is important for liver function and for blood formation (also known as hepatic porphyria).

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| <ul style="list-style-type: none">• You are taking medicines belonging to a certain group of antidepressants called monoamine-oxidase inhibitors (MAOIs) or if you have taken them within the last 14 days. |
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Special warnings about using this medicine

Before treatment with Teril:

- Tell the doctor if you are allergic to oxcarbazepine (the active ingredient in Trileptin) or to phenytoin. These two medicines are also used to treat epilepsy. Some people who are allergic to oxcarbazepine or to phenytoin are also allergic to Teril.
- Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or breathing difficulties; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.
- Inform your doctor immediately if you develop severe skin reactions accompanied by fever. For example, rash; red skin; blistering of the lips, eyes or mouth; skin peeling. These reactions are more common in certain Asian countries (e.g., Taiwan, Malaysia and the Philippines). (See section 'Tests and follow-up').
- Taking Teril with medicines from the monoamine-oxidase inhibitor (MAOI) group, or within 14 days of taking MAOIs, could cause a serious reaction with a sudden elevation of body temperature, extremely high blood pressure and severe convulsions. (See section 'Do not use this medicine if').
- Do not take Teril if you have or have had systemic lupus erythematosus.
- Do not take Teril if you have or have had a severe heart or liver disease.

Ask your doctor in case you are unsure whether one of these conditions applies to you. If you are unsure whether you may take Teril, refer to the doctor or pharmacist.

Tell your doctor if you are allergic to any medicines, food, colors or preservatives. The doctor will want to know if you have a tendency to develop allergies.

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

- Heart, liver or kidney problems
- Increased pressure in the eye (glaucoma)
- Problems with the prostate gland or if you cannot retain your urine
- Past blood problems that were caused by medicines that you took
- Mental disorder such as depression or schizophrenia

Tell your doctor if at any time you have thoughts of harming or killing yourself. A small number of people treated with antiepileptics have had such thoughts and behaviors.

If you have not told your doctor about one of these conditions, tell them before you take Teril.

Tests and follow-up

The doctor may want to perform several tests before you begin taking Teril and from time to time during treatment, in order to help prevent undesirable side effects.

You must make sure to go to the visits to your doctor so that it will be possible to follow your progress.

The risk of severe skin reactions connected to carbamazepine or to similar chemical compounds in patients of Chinese or Thai origin may be predicted by testing a blood sample

of these patients. Your doctor will advise you whether a blood test is necessary before taking Teril.

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:

- Medicines from the monoamine-oxidase inhibitor (MAOI) group: do not take Teril with MAOIs or within 14 days of having taken MAOIs.
- Other medicines to treat depression, such as fluoxetine, fluvoxamine, paroxetine, nefazodone and tricyclic antidepressants.
- Other medicines to treat seizures, including levetiracetam, phenytoin, valproic acid, lamotrigine, topiramate and oxcarbazepine.
- Certain medicines to treat mental disorders, such as clozapine, haloperidol, thioridazine, lithium, olanzapine, quetiapine, loxapine, risperidone and ziprasidone.
- Certain medicines to treat heart problems or high cholesterol.
- Certain medicines that help you sleep or calm you down.
- Painkillers such as paracetamol, ibuprofen, dextropropoxyphene, tramadol.
- Warfarin, for the prevention of blood clots.
- Ticagrelor, a medicine used to prevent blood clots.
- Diuretics, medicines used to reduce retention of fluids and high blood pressure.
- Antibiotics and anti-fungal medicines to treat infections such as erythromycin, clarithromycin, ciprofloxacin, doxycycline, itraconazole, voriconazole, ketoconazole, fluconazole.
- Medicines to treat tuberculosis such as isoniazid, rifampicin, rifabutin.
- Corticosteroids such as prednisolone, dexamethasone.
- St. John's wort, an ingredient of herbal medicines.
- Antihistamines such as terfenadine and loratadine, medicines used to prevent or relieve symptoms of allergy such as hay fever.
- Acetazolamide, a medicine to reduce fluid retention and treat glaucoma and several types of seizures.
- Cimetidine, to treat stomach ulcers or duodenal ulcers.
- Theophylline, to treat asthma.
- Ciclosporin and other medicines to prevent transplant rejection or to treat severe rheumatoid arthritis and several skin diseases.
- Certain medicines to treat cancer such as cisplatin, doxorubicin.
- Methadone, to control acute pain and treat heroin addiction.
- Metoclopramide, to treat nausea and vomiting.
- Isotretinoin, to treat acne.
- Danazol, to treat endometriosis.
- A vitamin called nicotinamide.
- Muscle relaxants such as oxybutynin, or those used during surgery.
- Medicines to treat Human Immunodeficiency Virus (HIV) such as indinavir, ritonavir, saquinavir.
- Levothyroxine, to treat an underactive thyroid gland.
- Albendazole, praziquantel, to treat worm infestations.

- Medicines containing estrogen and progesterone, including hormone replacement therapy and contraception.
- Tadalafil, to treat difficulty in achieving or keeping an erection.
- Felodipine, to treat high blood pressure.

The above medicines could be affected by Teril or could affect the action of Teril. It may be necessary to change the dosage of the medicines or to take other medicines.

Tell your doctor if you are using hormonal contraceptives (e.g., contraceptive pills or injections).

If you are of childbearing age, you must use an effective form of contraception throughout your treatment and for two weeks after taking the last dose.

If you are beginning to take Teril while using hormonal contraceptives, they may be less effective, and unplanned pregnancies are possible.

Your doctor can suggest additional (non-hormonal) forms of contraception while using Teril.

Your doctor and pharmacist have additional information about medicines that need to be used cautiously or avoided while using Teril.

Using Teril and food

Do not drink grapefruit juice or eat grapefruits, as this could increase the effect of Teril. Other juices, such as orange juice or apple juice, do not have this effect.

Using this medicine and alcohol consumption

Be cautious with drinking alcohol during treatment with Teril. This combination could cause you to be more sleepy or dizzy than usual.

Your doctor may suggest that you abstain from alcohol while being treated with Teril.

Pregnancy and breastfeeding

Pregnancy

Inform your doctor if you are pregnant or are planning to become pregnant.

Your doctor will discuss the possible risk of taking Teril during pregnancy with you, as it could harm or lead to defects in the baby during pregnancy or immediately after birth.

However, it is very important to control your seizures during pregnancy if you have epilepsy. Your doctor will help you decide whether or not to take Teril in this case.

If you get pregnant during treatment with Teril, refer to the doctor immediately.

The doctor can discuss with you the risks involved with taking Teril during pregnancy.

Breastfeeding

Inform the doctor if you are breastfeeding or are planning to breastfeed.

Teril passes into breast milk, but is not likely to affect your baby. You may breastfeed, provided that you are alert to any signs of undesirable side effects in your baby. If your baby develops a skin rash, if the baby is very sleepy or has other unusual symptoms, stop breastfeeding, and refer to the doctor.

Driving and using machines

Exercise caution while driving, operating machines or performing work that requires you to be alert until you know how Teril affects you.

As regards to children, they should be cautioned against riding a bicycle, playing near the road, climbing trees and the like.

Teril may cause sleepiness, dizziness, blurred vision, double vision or lack of muscular coordination, mainly when starting treatment or when increasing the dosage.

Exposure to the sun

When outdoors, wear protective clothing and use a sunscreen with a protection factor higher than 15. Do not use tanning lamps, tanning beds or tanning booths.

This medicine causes the skin to be sensitive to sunlight, much more so than usual.

Exposure to sunlight could cause skin rash, itchiness, redness or severe sunburn. Tell your doctor if your skin does appear burnt.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine.

The doctor will tell you what dose to take every day. This depends on your age, your medical condition, and on whether you are taking additional medicines.

The doctor will usually start your treatment on a low dose, and increase it gradually to the lowest amount required to control your condition. Some patients will need higher doses.

Do not exceed the recommended dose.

Method of administration

The tablet may be split.

Do not chew! Swallow the tablets with a full glass of water.

When should Teril be taken

Take the medicine during or after a meal. This will help prevent abdominal discomfort.

Teril is usually taken in 2 or 3 doses during the day, but your doctor may tell you to take more or less, depending on your condition.

If you forget to take Teril

If the time until your next dose is more than two or three hours, take the forgotten dose as soon as you remember. Take the next dose at the regular time, and continue with the regular schedule.

If the time until your next dose is less than two or three hours, skip the forgotten dose. Take the next dose at the regular time, and continue with the regular schedule.

Do not take a double dose to make up for the forgotten dose. This could increase the risk of an undesirable side effect.

If you are unsure about what to do, refer to the doctor or pharmacist.

If you have difficulty remembering when to take the medicine, ask the pharmacist for help.

For how long should Teril be taken

Adhere to the treatment as recommended by the doctor.

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

Stopping treatment

Do not stop treatment with Teril and do not reduce the dose without consulting the doctor. Ensure in advance that you have a sufficient amount so that you are not left without medicine on weekends or holidays.

Stopping treatment suddenly or reducing the dose could cause undesirable side effects or worsen your condition.

If you are taking this medicine to treat epilepsy, you could develop seizures (attacks).

Your doctor will usually reduce the dose gradually until you can stop taking the medicine altogether.

If you took more Teril than needed (an overdose)

If you have taken an overdose or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you. Do this even if you do not experience any signs of toxicity or discomfort.

Some of the symptoms of an overdose may include agitation, instability, disorientation, fainting, vomiting, breathing difficulty, rapid and irregular pulse, blurred vision and slurred speech.

While using Teril

Tell your doctor if, for any reason, you did not take the medicine exactly as prescribed. Otherwise, the doctor may think that the medicine is not effective and will unnecessarily change the treatment.

Before any operation or emergency treatment, tell the attending doctor or dentist that you are taking Teril. This medicine could clash with some of the medicines used during surgery.

If you are about to begin treatment with a new medicine, remind your doctor and pharmacist that you are being treated with Teril.

Tell every doctor, dentist or pharmacist who treats you that you are being treated with Teril.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Teril may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

If you feel unwell during treatment with Teril, tell your doctor or pharmacist as soon as possible.

All medicines may have side effects. They are sometimes severe, but most of the time are not. For some of the side effects, you may need medical treatment. The risk of side effects is greater if you are over the age of 65.

Most of the side effects are mild to moderate and usually disappear after a few days of treatment.

If you notice any of the following side effects, tell your doctor immediately or proceed to the nearest emergency room:

- Signs of allergy, such as swelling of the face, lips, tongue or other parts of the body; wheezing or difficulty breathing; skin rash, itching, hives, unconsciousness
- Blisters or peeling of the skin
- Sudden increase in body temperature accompanied by sweating, rapid pulse, altered consciousness, increased secretion of saliva and muscle rigidity
- Persistent “flu-like” symptoms (chills, fever, sore throat, swollen glands, joint pain, lack of energy, frequent infections), bleeding or bruising more easily than usual, nosebleeds
- Shortness of breath and dizziness during physical activity
- Prolonged nausea or vomiting, loss of appetite and generally feeling unwell, which may be accompanied by abdominal pain, fever, itching, yellow skin or eyes, dark urine or light feces
- Severe pain in the upper abdomen, often with nausea, vomiting and loss of appetite
- More frequent or more severe seizures (attacks)
- Sudden onset of uncontrollable muscle spasms affecting the eyes, head, neck and body
- Depression, aggressive behavior, recurrence of previous mental illness, hallucinations (seeing or hearing things that do not exist)
- Swelling of the feet and legs or weight gain due to accumulation of fluids
- Change in pulse (rapid, slow, irregular), sometimes with chest pain
- Urinating less than usual, which may be accompanied by lack of energy, vomiting, headache, muscle spasms and confusion
- Blood in the urine
- Symptoms of sunburn such as redness, itching, swelling or being covered with blisters that occur more rapidly than usual
- Swelling and redness along the length of a vein or nerve, which is very sensitive to touch
- Signs of the formation of blood clots, such as sudden severe headache, sudden loss of coordination or vision, pain in the lower part of the leg, thighs or chest
- Severe headache accompanied by a stiff neck, muscle spasms and extreme sensitivity to bright light
- Diarrhea, abdominal pain and fever (signs of a possible disorder of the large intestine)
- Red blotchy rash, mainly on the face, which may be accompanied by fatigue, fever, nausea, loss of appetite
- Pressure or pain in the eye
- Falling due to dizziness, sleepiness, decreased blood pressure or confusion

If you notice any of the following side effects and they bother you, tell your doctor:

Very common side effects – effects that occur in more than 1 in 10 users

- Instability while walking
- Dizziness
- Tiredness or drowsiness
- Nausea or vomiting

Common side effects – effects that occur in 1-10 in 100 users

- Headache
- Blurred or double vision, difficulty seeing
- Dry mouth
- Weight gain

Uncommon side effects – effects that occur in 1-10 in 1,000 users

- Diarrhea
- Constipation

Rare side effects – effects that occur in 1-10 in 10,000 users

- Restlessness, agitation or confusion
- Difficulty speaking or slurred speech
- Numbness or a tingling sensation in the hands or feet
- Abdominal pain or discomfort
- Loss of appetite
- Weakness

Very rare side effects – effects that occur in less than one in 10,000 users

- Altered sense of taste
- Swollen, teary eyes
- Ringing or buzzing in the ears or other changes in hearing
- Muscle pain or spasms
- Change in skin color
- Acne
- Sweating
- Hair loss
- Excessive hair, especially in women
- Frequent need to urinate
- Sexual disorders such as impotence
- Breast enlargement in men
- Unusual secretion of milk from the breast
- Mouth ulcers and cold sores
- Swollen, red, painful tongue
- Excessive salivation

Tell your doctor if you notice any other effect that makes you feel unwell.

Additional side effects (not listed above) may occur in some patients.

Some of them (e.g., changes in sodium levels, thyroid gland function, bone structure, cholesterol level or blood pressure) will be found only in tests that the doctor will perform periodically in order to check your progress.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.

- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

Storage conditions

- Store below 25°C.
- Store in the original package.

6. Additional information

In addition to the active ingredient, this medicine also contains:

Teril 200 mg:

microcrystalline cellulose, dibasic calcium phosphate, hydroxypropyl methylcellulose, magnesium stearate, colloidal silicon dioxide.

What the medicine looks like and contents of the pack:

Teril 200 mg

A round, white to off-white tablet. There is a score line on one side of the tablet, with the letter "T" engraved above it and the number "76" below it. The other side of the tablet is plain.

The tablets are available in blisters in packages of 28 or 50 tablets.

Not all pack sizes may be marketed.

Manufacturer and registration holder:

Taro Pharmaceutical Industries Ltd., 14 Hakitor St., Haifa Bay 2624761

Revised in August 2021 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry:

Teril 200 mg: 12963.30784