

**PATIENT PACKAGE INSERT IN ACCORDANCE
WITH THE PHARMACISTS' REGULATIONS
(PREPARATIONS) - 1986**

**The medicine is dispensed with
a doctor's prescription only**

**TRILEPTIN®
300 mg**

Film-coated tablets

The active ingredient:

Each tablet contains:
Oxcarbazepine 300 mg

Inactive ingredients:

See section 6 'Further Information'.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

For treating epilepsy.

Therapeutic group:

Anti-epileptic.

Epilepsy is a disease characterized by repeated seizures and convulsions.

Trileptin is intended for the treatment of primary generalized tonic-clonic seizures and partial seizures, with or without secondary generalized spread.

**TRILEPTIN®
600 mg**

Film-coated tablets

Each tablet contains:
Oxcarbazepine 600 mg

2. BEFORE USING THE MEDICINE

⚠ Do not use the medicine if:

You have a known hypersensitivity (allergy) to oxcarbazepine (the active ingredient of Trileptin), eslicarbazepine (an active ingredient similar to oxcarbazepine) or to any of the other ingredients contained in the medicine (see section 6 'Further Information').

If this applies to you, inform the doctor before taking Trileptin.

If you think that you may be allergic, consult the doctor.

Special warnings regarding use of the medicine:

Refer to your doctor immediately if you experience side effects that suggest a hypersensitivity reaction. These may manifest by swelling of the lips, face or neck, accompanied by difficulty breathing, speaking or swallowing, skin rash, fever and joint pain.

If you take Trileptin when using oral contraceptives (birth-control pills), your periods may become irregular. The pill may no longer work and you should talk to your doctor about which other additional contraceptive methods [e.g. intrauterine device (coil)] may be suitable for you.

⚠ Before treatment with Trileptin, tell the doctor if:

You have ever developed an unusual skin rash or other signs of allergy during previous treatment with oxcarbazepine (Trileptin), eslicarbazepine (an active substance similar to oxcarbazepine), carbamazepine or to any other medicine

You have a heart disease

You have a kidney or liver disease

Results of blood tests you have undergone were abnormal
You are taking any medicines that increase urine output (diuretics)

You are being treated with other antiepileptics or calcium channel blockers

It is very important that your doctor checks you at regular intervals

Inform your doctor if you experience an increase in the frequency of seizures. This is particularly important for children, but may also occur in adults. Depending on the state of your health, you may have to undergo blood tests to ensure that you are receiving the best possible treatment.

Before any emergency medical treatment or any type of surgery or dental treatment, you must inform the doctor responsible for you that you are taking Trileptin.

Inform your doctor or pharmacist if you are suffering from any other illnesses or if you have any allergies.

A small number of patients treated with antiepileptics, such as Trileptin, have had thoughts of harming or killing themselves. If you ever have such thoughts, refer to your doctor immediately.

⚠ Tests and follow-up

Before and during treatment with Trileptin, your doctor may perform blood tests to determine the dosage for you. Your doctor will tell you when to do the tests.

⚠ Drug interactions

If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

In particular, if you are taking:

Hormonal contraceptives (such as birth-control pills)

Other antiepileptic medicines (such as: carbamazepine, phenobarbital or phenytoin)

Rifampicin

Felodipine (to treat high blood pressure)

Medicines which reduce the level of sodium in your blood, e.g., diuretics (medicines that help the kidneys eliminate salt and water from the body by increasing the amount of urine)

Medicines that regulate the immune system (such as ciclosporin)

⚠ Using Trileptin and food

The medicine can be taken during or after a meal.

⚠ Using Trileptin and alcohol consumption

Do not drink alcohol during the course of treatment with Trileptin.

⚠ Elderly people

Trileptin can be used in adults older than 65, while carefully following the doctor's instructions.

⚠ Children and adolescents

Trileptin can be used in children aged 2 and over, while carefully following the doctor's instructions.

In children, the doctor may recommend monitoring thyroid function before and during treatment.

⚠ Pregnancy

Inform the doctor if you are pregnant, breastfeeding or planning to become pregnant.

It is important to avoid epileptic seizures during pregnancy. However, taking Trileptin (or other antiepileptic medicines) during pregnancy may also endanger your baby.

Your doctor will tell you the benefits and potential risks and will decide if you can continue taking Trileptin.

⚠ Women of childbearing age

If you are taking a hormonal contraceptive (such as a birth-control pill), Trileptin may render it ineffective. Therefore, you must use a different or an additional non-hormonal contraceptive [e.g., intrauterine device (coil)] during treatment with Trileptin.

⚠ Breastfeeding

The active ingredient in Trileptin passes into the breast milk and could cause side effects in breastfed babies. For further information, refer to your doctor. Breastfeeding is not recommended during treatment with Trileptin.

⚠ Driving and using machines

This medicine may affect your responsiveness and your ability to drive or use tools or machinery. Trileptin may cause you to feel drowsy or dizzy or may cause blurred vision, double vision, reduced muscle coordination or depressed level of consciousness, especially at the beginning of treatment or when increasing the dosage. Children should be cautioned against riding a bicycle or playing near the road and the like.

Your ability to drive and use tools or machinery may also be affected by your disease. Refer to your doctor for further information.

Only start Trileptin treatment after a comprehensive medical examination. Trileptin is suitable for many patients with epilepsy, but not for everyone.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

Dosage

The dosage and manner of treatment will be determined by the doctor only.

Do not change the dosage prescribed for you. If you think the effect of the medicine is too weak or too strong, refer to your doctor or pharmacist.

Do not exceed the recommended dose.

How to take

The film-coated tablets have a score line so that they can be split into two halves to ease swallowing. Swallow the film-coated tablets with a small amount of liquid.

Do not crush or chew the tablets since they are coated.

If you accidentally took a higher dosage

If you have taken an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forget to take Trileptin

If you forgot to take one dose at the designated time, take a dose as soon as you remember. However, if it is time to take the next dose, do not take the forgotten dose, but rather return to your normal dosing routine. Never take a double dose.

If you have forgotten more than one dose, consult your doctor. Adhere to the treatment as recommended by the doctor. This is important to achieve the best results and to reduce the risk of side effects.

If you stop taking Trileptin

Do not stop the treatment abruptly without consulting your doctor. The doctor will tell you when and how to stop the treatment. Abrupt discontinuation of Trileptin treatment may worsen your condition.

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

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Trileptin may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them. These usually occur at the start of treatment and pass after a few days.

If you experience one or more of the following side effects, refer to a doctor immediately or make sure that someone else does this for you immediately. These symptoms may be the first signs of a serious side effect requiring urgent treatment:

Swelling of the lips, face or neck, accompanied by breathing difficulties, speaking or swallowing, or other reactions, such as: skin rash, fever, and joint pains.

Severe skin reactions such as skin rash, skin redness, blistering of the lips, eyes or mouth and skin peeling accompanied by fever. These effects are more frequent in patients from certain Asian countries (e.g., Thailand, Malaysia, Philippines) and in patients of Chinese origin.

Swelling of the ankles, feet or lower leg.

Increasing confusion, drowsiness, headaches or difficulties moving the arms or legs.

Signs of severe symptoms affecting the skin or mucous membranes such as blistering, skin peeling and severe allergic reactions.

Fever, sore throat, ulcers in the mouth, inexplicable bruises, reddish or purplish coloring of the skin.

Flu-like symptoms with jaundice (signs of hepatitis).

Severe upper abdominal pain, vomiting, loss of appetite (signs of pancreatitis).

In children under 4 years of age: lethargy, trembling, decreased appetite and irritability, swollen and painful joints.

Refer to your doctor as soon as possible if you experience one or more of the following side effects:

Headache, trembling, tingling sensation in the hands and feet, vomiting, skin rash, irregular periods, inexplicable ringing in the ears, coordination disturbances, frequent mood swings, anxiety, depression, speech disturbances.

Bone diseases such as osteopenia (low bone density) and osteoporosis (bone depletion) have been reported in patients receiving prolonged treatment, as well as bone fractures.

The following side effects may occur when taking Trileptin:

Very common side effects (occur in more than one in 10 users):
tiredness, headache, drowsiness, dizziness, nausea, vomiting, double vision.

Common side effects (occur in 1 to 10 in 100 users):
weight gain, diarrhoea, constipation, abdominal pain, visual disturbances, blurred vision, acne, hair loss, weakness, memory disturbances, physical restlessness (agitation).

Very rare side effects (occur in fewer than one in 10,000 users):
increased blood pressure, folic acid deficiency.

Additional side effects:

sleep disturbances, weight loss, decreased blood pressure. Generally, these side effects do not require medical care. However, if they last more than a few days or cause you certain problems, consult your doctor.

If a side effects occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
<https://sideeffects.health.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

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

Storage conditions

Do not store above 30°C.

6. FURTHER INFORMATION

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

Trileptin 300 mg

Tablet:

Cellulose, microcrystalline; crospovidone; hypromellose; magnesium stearate; silica, colloidal anhydrous.

Tablet coating:

Hypromellose; talc; titanium dioxide (C.I. no. 77891, E171); macrogol 8000; iron oxide, yellow (C.I. no. 77492, E 172).

Trileptin 600 mg

Tablet:

Cellulose; microcrystalline; crospovidone; hypromellose; magnesium stearate; silica, colloidal anhydrous.

Tablet coating:

Hypromellose; titanium dioxide; macrogol 4000; talc; iron oxide, red; iron oxide, black.

What the medicine looks like and the contents of the package

Trileptin 300 mg:

A film coated, oval, yellow, slightly biconvex tablet, with a score line and the imprint TE/TE on one side, with a score line and the imprint CG/CG on the other side.

Trileptin 600 mg:

A film coated, oval, pale pink, slightly biconvex tablet, with a score line and the imprint TF/TF on one side, with a score line and the imprint CG/CG on the other side.

Both dosages are marketed in packages of 50 tablets.

Registration Holder and Importer and its address:
Novartis Israel Ltd., P.O.B 7126, Tel Aviv.

Revised in October 2020

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

300 mg Tablets - 106 80 28707

600 mg Tablets - 106 81 28708