

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

The medicine is dispensed with a doctor's prescription only

TRILEPTIN® **TRILEPTIN®**
300 mg **600 mg**
Film-coated tablets Film-coated tablets

The active ingredient:

Each tablet contains:
Oxcarbazepine 300 mg

Each tablet contains:
Oxcarbazepine 600 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.

This medicine is not intended for infants and children under two years of age.

1. WHAT IS THE MEDICINE INTENDED FOR?

For treating epilepsy.

Therapeutic group:

Anti-epileptic.

Epilepsy is a condition in which repeated seizures and convulsions occur. Seizures happen because of a temporary fault in the brain's electrical activity. Normally brain cells coordinate body movements by sending out signals through the nerves to the muscles in an organised, orderly way. In epilepsy, brain cells send out too many signals in a disorderly fashion. The result can be uncoordinated muscular activity that is called an epileptic seizure. Trileptin works by keeping the brain's "overexcitable" nerve cells under control, thereby reducing the frequency of such seizures.

There are two main classes of epileptic seizures: generalized and partial.

Generalized seizures involve a wide area of the brain, cause loss of consciousness and can affect the whole body. There are two main types of generalized seizures: tonic-clonic seizures (grand mal) and absence seizures (petit mal).

Partial seizures involve a limited area of the brain (i.e. focal origin), but may spread to the whole brain and may cause a secondarily generalized tonic-clonic type seizure. There are two types of partial seizures: simple and complex. In simple partial seizures, the patient remains conscious, whereas in complex partial seizures, the patient's consciousness is altered.

Trileptin is used to treat partial seizures (simple, complex and secondarily generalized seizures) and generalized tonic-clonic seizures.

Usually, the doctor will attempt to find the one medicine that works best but, with more severe epilepsy, a combination of two or more medicines may be needed to control seizures. Trileptin can be used alone or in combination with other antiepileptic medicines.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

You are sensitive (allergic) to oxcarbazepine (the active substance of Trileptin) or to any of the other ingredients of the medicine listed in 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:

Before taking Trileptin, tell the doctor if:

You have suffered in the past from **unusual sensitivity** (rash or other signs of allergy) to carbamazepine or to other medicines. If you are allergic to carbamazepine, the chances are approximately 1 in 4 (25%) that you could also develop an allergic reaction to oxcarbazepine (Trileptin).

You have a **kidney disease**.

You have a **liver disease**.

You are taking **diuretics** (medicines used to help the kidneys get rid of salt and water by increasing the amount of urine).

You have a **heart disease**, shortness of breath and/or swelling of the feet or legs due to fluid build-up.

You know that your **blood levels of sodium are low**.

You are taking other medicines (see the detailed list regarding taking other medicines).

You are a woman taking a **hormonal contraceptive** (such as the birth-control pill), Trileptin may render this contraceptive ineffective. Therefore, you should use a different or additional non-hormonal contraceptive measure while you are taking Trileptin. This should help to prevent an unwanted pregnancy. Tell your doctor immediately if you experience irregular vaginal bleeding or spotting. If you have any questions about this, ask your doctor or health professional.

If you develop any of the following symptoms after starting treatment with Trileptin, refer to your doctor immediately

or go to the emergency room at your nearest hospital:

If an **allergic reaction** happens such as swelling of lips, eyelids, face, throat, mouth, or sudden breathing problems, fever with swollen glands (lymph node swelling), rash or skin blistering (see 'Some effects could be serious').

If you develop serious skin reactions such as rash, red skin, blistering of the lips, eyes or mouth, skin peeling accompanied by fever (see 'Side effects'). These reactions may be more frequent in patients in some Asian countries (e.g. Taiwan, Malaysia and The Philippines) and in patients with Chinese ancestry.

If you experience an **increase in the frequency of seizures**. This is **particularly important regarding children** but may occur in adults as well.

If you notice symptoms suggestive of **hepatitis**, such as jaundice (yellowing of skin and eyes).

If you notice symptoms suggestive of **blood disorders** such as tiredness, shortness of breath when exercising, looking pale, headache, chills, dizziness, frequent infections leading to fever, sore throat, ulcers in the mouth, bleeding or bruising more easily than normal, nose bleeds, reddish or purplish patches or unexplained blotches on the skin.

If at any time you have **thoughts of harming or killing yourself**. A small number of people being treated with antiepileptics have had such thoughts or behavior.

If **your heartbeat is fast or unusually slow**.

Do not stop treatment with Trileptin without consulting the doctor. In order to prevent sudden worsening of the seizures, do not stop taking the medicine abruptly.

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) (see section 'Special warnings regarding use of the medicine').

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

Calcium blockers such as: felodipine (medicine used to treat high blood pressure and heart problems).

Medicines which reduce the level of sodium in your blood, e.g., diuretics (medicines used to help the kidneys get rid of salt and water by increasing the amount of urine); desmopressin and anti-inflammatory non-steroidal medicines.

Medicines which control the immune system (such as ciclosporin and tacrolimus).

Lithium and monoamine oxidase inhibitors (medicines used for treating mood swings and certain types of depression).

Using Trileptin and food

The medicine can be taken with or without food.

Using Trileptin and consumption of alcohol

Alcohol may increase the sedative effects of Trileptin. Avoid alcohol as much as possible and ask your doctor for advice.

Elderly people

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

Children and adolescents

This medicine is not intended for infants and children under the age of two.

In children, it is possible that the doctor will recommend monitoring thyroid function before and during treatment.

Pregnancy

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

It is important to control epileptic seizures during pregnancy. However, there may be a risk to your baby if you take antiepileptic medicines during pregnancy. Your doctor will tell you the benefits and potential risks involved and help you to decide whether you should take Trileptin.

Do not stop your treatment with Trileptin during pregnancy without consulting your doctor.

Ask your doctor or pharmacist for advice before taking any medicine during pregnancy.

Breast-feeding

The active substance in Trileptin passes into the breast milk and could cause side effects in breast-fed babies. Therefore, you should not use Trileptin during breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine while you are breast-feeding.

Women of childbearing age

If you are taking a hormonal contraceptive (such as a birth-control pill), Trileptin may render this contraceptive ineffective. Therefore, you must use a different or an additional non-hormonal contraceptive during treatment with Trileptin.

Driving and using machines

It is important to consult your doctor regarding your ability to drive a vehicle or operate machines, as Trileptin may cause sleepiness or dizziness or may cause blurred vision, double vision, lack of muscle coordination or depressed level of consciousness, especially at the beginning of treatment or when increasing the dose. Children should be cautioned against riding a bicycle or playing near the road and the like.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain.

The dosage and manner of treatment will be determined by the doctor only. The usual dosage is generally:

Trileptin should be taken twice a day, every day, at about the same time of day, unless the doctor tells you otherwise. Taking the tablets at the same time each day will have the best effect on controlling epilepsy. It will also help you to remember when to take the tablet(s).

Do not exceed the recommended dose.

How to take the medicine

Do not chew! Swallow the tablets with a little water. If necessary, the tablets can be broken in half to help swallow them.

Duration of treatment

Your doctor will tell you how long your or your child's treatment with Trileptin will last. The duration of treatment is based on the seizure type. On-going treatment for many years may be necessary to control the seizures.

Do not change the dosage and do not stop treatment without talking to your doctor.

Tests and follow-up

Before and during treatment with Trileptin, your doctor may perform blood tests to determine the dose for you. The doctor will tell you when to undergo these tests.

The blood sodium concentration may decrease during treatment with Trileptin; therefore, it is advisable to monitor blood sodium levels before starting treatment and during treatment, especially if your blood sodium levels are usually low. If you are taking diuretics, your blood sodium levels should be closely monitored.

The risk of serious skin reactions in patients of Chinese or Thai origin, associated with oxcarbazepine, carbamazepine or chemically-related compounds, 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 Trileptin.

If you take more Trileptin than you should

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. Symptoms of an overdose may include: sleepiness, dizziness, nausea, vomiting, increase in uncontrolled movements, lethargy, confusion, muscle twitches or significant worsening of seizures, coordination problems and/or uncontrolled eye movements.

If you forget to take Trileptin

If you have only forgotten one dose, take it as soon as you remember. However, if it is time for your next dose, do not take the missed dose. Just go back to your regular dosing timetable. Never take two doses together!

If you are unsure or have forgotten to take several doses, contact your attending doctor.

Adhere to the treatment as recommended by the doctor.

Stopping treatment

Stopping treatment with Trileptin may cause your seizures to worsen.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor or pharmacist.

In the event that the doctor has determined that you should stop treatment with Trileptin, stop treatment in a gradual manner, in order to reduce the possibility of increased frequency of epileptic seizures to a minimum.

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.

Some effects could be serious and may require urgent medical treatment:

Swelling of the lips, eyelids, face, throat or mouth, accompanied by difficulty in breathing, speaking or swallowing (signs of anaphylactic reactions and angioedema), or other signs of hypersensitivity such as: skin rash, fever, and pain in the muscles and joints.

Severe blistering of the skin and/or mucous membranes of the lips, eyes, mouth, nasal passages or genitals (signs of a serious allergic reaction).

Tiredness, feeling of shortness of breath when exercising, paleness, headache, chills, dizziness, recurring infections leading to fever, sore throat, mouth ulcers, bleeding or bruising more easily than normal, nose bleeds, reddish or purplish skin patches or unexplained blotches on the skin (signs of a decrease in the number of blood platelets or decrease in the number of blood cells).

Rash, manifested by red blotches, mainly on the face, which may be accompanied by fatigue, fever, nausea and loss of appetite (signs of systemic lupus erythematosus).

Lethargy, confusion, muscular twitching or significant worsening of convulsions (signs that may be linked to low sodium levels in the blood) (see section 'Special warnings regarding use of the medicine').

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

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

Weight gain, tiredness, hair loss, muscle weakness, feeling cold (signs of an under active thyroid gland).

In children under 4 years of age: somnolence, lethargy, decreased appetite and irritability, swollen and painful joints, loss of muscle control following disturbances to the nervous system (ataxia), vomiting, involuntary eye movements, tremor.

Refer immediately to the attending doctor or to an emergency room of the nearest hospital if you have any of the side effects detailed above.

The doctor will decide whether there is a need to immediately stop Trileptin treatment and how treatment should be continued.

Other side effects:

Very common side effects (affecting more than 1 in every 10 patients):

tiredness; headache; dizziness; drowsiness; nausea; vomiting; double vision.

If any of these side effects affects you severely, **contact the doctor.**

Common side effects (affecting between 1-10 in every 100 patients):

trembling; problems with coordination; involuntary movement of the eyes; feeling of anxiety and nervousness; feeling of depression; mood swings; weakness; memory disturbances; impaired concentration; apathy; agitation; confusion; blurred vision; constipation; diarrhea; abdominal pain; acne; hair loss; disturbance of balance.

If any of these side effects affects you severely, contact the doctor.

Very rare side effects (affecting less than 1 in every 10,000 patients):

irregular heartbeat or very fast or very slow heart rate, high blood pressure, vitamin B9 (folic acid) deficiency. Some of the signs of vitamin B9 deficiency are: diarrhea, feeling of depression and signs of decrease in the number of blood cells (see section 'Some effects could be serious').

Side effects of unknown frequency

Speech impairments, bone disorders including osteopenia and osteoporosis (thinning of the bone) and fractures in patients on long term-treatment with Trileptin.

If any of the side effects affects you severely, **contact the doctor.**

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

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. Store in the original package. Do not store above 30°C.

Do not use the medicine if the pack is damaged or shows signs of tampering.

Return any unused tablets to the pharmacy for safe disposal.

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 does the medicine look like and what are the contents of the package

Trileptin 300 mg:

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

Trileptin 600 mg:

Ovaloid, light pink colored, slightly biconvex film-coated tablet, with a score and the imprint TF/TF on one side, with a score and the imprint CG/CG on the other side.

Both dosages are marketed in packages of 50 tablets.

Registration Holder and address: Novartis Israel Ltd., 36 Shacham St., Petach-Tikva.

Name of manufacturer and address: Novartis Farma S.p.A., Torre Annunziata, Italy for: Novartis Pharma AG, Basel, Switzerland.

This leaflet was checked and approved by the Ministry of Health in August 2014.

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

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