NOVARTIS

TRILEPTAL®

300 mg and 600 mg Oxcarbazepine per film-coated tablet

Patient Information Leaflet

Document status: Final

Approval date: 18 September 2026

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SCHEDULING STATUS: S3

TRILEPTAL 300 and TRILEPTAL 600 Film-coated tablets

(Oxcarbazepine)

Sugar-free

Read all of this leaflet carefully before you start taking TRILEPTAL

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- TRILEPTAL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1 What TRILEPTAL is and what it is used for

2 What you need to know before and while you take TRILEPTAL

3 How to take TRILEPTAL

4 Possible side effects

5 How to store TRILEPTAL

6 Contents of the pack and other information

1. What TRILEPTAL is and what it is used for

What TRILEPTAL is

TRILEPTAL contains the active substance oxcarbazepine.

What TRILEPTAL is used for

TRILEPTAL is one of a group of medicines called anticonvulsants or antiepileptics (medicines to treat epilepsy).

TRILEPTAL is used to treat partial seizures and generalised tonic-clonic seizures in.

2. What you need to know before you take TRILEPTAL

Do not take TRILEPTAL:

- If you are hypersensitive (allergic) (experienced rash or any other sign of allergy) to oxcarbazepine (the active substance of TRILEPTAL), eslicarbazepine or to any other ingredients of TRILEPTAL listed in section 6.

Warnings and precautions

Talk to your doctor or pharmacist before taking TRILEPTAL:

- If you have ever shown unusual sensitivity (rash or any other signs of allergy) to carbamazepine, any other antiepileptic medicine or any other medicines. If you are allergic to carbamazepine, the chances are approximately 1 in 4 (25 %) that you may also develop an allergic reaction to oxcarbazepine (TRILEPTAL).
- If you have a serious liver or kidney disease.
- If you are taking diuretics (medicines used to help the kidneys get rid of salt and water by increasing the amount of urine produced).
- If you suffer from heart failure, shortness of breath and/or swelling of the feet or legs due to fluid build-up.
- If you know that your blood level of sodium is low.

- If you are taking other medicines (see 'Other medicines and TRILEPTAL').
- If you are a woman taking a hormonal contraceptive (e.g. "the pill"), TRILEPTAL may render this contraceptive ineffective. Therefore, you should use a different or additional non-hormonal method of contraception while you are taking TRILEPTAL. This should help to prevent an unwanted pregnancy. Tell your doctor at once if you get irregular vaginal bleeding or spotting. If you have any questions about this, ask your doctor or healthcare professional.

If any of the above applies to you, tell your doctor before you take TRILEPTAL.

Do not stop your treatment with TRILEPTAL without first checking with your doctor. To prevent sudden worsening of your seizure, do not discontinue your medicine abruptly.

If you develop any of the following symptoms after starting TRILEPTAL, tell your doctor immediately or go to the emergency department at your nearest hospital:

- If you experience an **allergic reaction** after starting TRILEPTAL. Symptoms include swelling of lips, eyelids, face, throat, mouth, or sudden breathing problems, fever with swollen glands, rash or skin blistering.
- If you notice symptoms of **hepatitis**, such as jaundice (yellowing of skin or the whites of the eyes).
- If you experience an increase in the frequency of seizures.
- If you notice possible symptoms of **blood disorders** such as tiredness, being short of breath when exercising, looking pale, headache, chills, dizziness, frequent infections leading to fever, sore throat, mouth ulcers, bleeding or bruising more easily than normal, nose bleeds, reddish or purplish patches, or unexplained blotches on the skin.
- A small number of people being treated with antiepileptics such as TRILEPTAL have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.
- If you have a **fast or unusually slow heartbeat.**

Other medicines and TRILEPTAL

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

This applies especially to:

- Hormonal contraceptives (e.g. the birth-control pill) (see 'TAKE SPECIAL CARE WITH TRILEPTAL').
- Other antiepileptic and enzyme-inducing medicines such as carbamazepine, phenobarbital, phenytoin or lamotrigine and rifampicin.
- Medicines which reduce the level of sodium in your blood, e.g. diuretics (used to help the kidneys get rid of salt and water by increasing the amount of urine produced).
- Medicines which control the body's immune system, e.g. ciclosporin and tacrolimus.

TRILEPTAL with food, drink and alcohol:

TRILEPTAL can be taken with or without food. Alcohol may increase the sedative effects of TRILEPTAL. Avoid alcohol as much as possible and ask your doctor for advice.

Pregnancy:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice.

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.

Birth defects

There may be an increased risk of birth defects associated with oxcarbazepine use during pregnancy; a risk of birth defects for your unborn child cannot be ruled out.

Neurodevelopmental disorders

Some studies have shown that exposure to oxcarbazepine in the womb negatively affects the development of brain function (neurodevelopment) in children.

Your doctor will tell you the benefits and potential risks involved and help you to decide whether you should take TRILEPTAL.

Do not stop your treatment with TRILEPTAL during pregnancy without first checking with your doctor. Ask your doctor, pharmacist or healthcare professional for advice before taking any medicine during pregnancy.

Breastfeeding:

Breastfeeding is not recommended during treatment with TRILEPTAL. If you are taking this medicine, ask your doctor for advice before starting breastfeeding.

The active substance in TRILEPTAL passes into breast milk. Although available data suggest that the amount of TRILEPTAL that passes to a breastfed baby is low, a risk of side effects for the baby cannot be ruled out.

Driving and using machines:

TRILEPTAL may make you feel sleepy or dizzy, or may cause blurred vision, double vision, lack of muscle coordination or a depressed level of consciousness, especially when starting treatment or increasing the dose. It is important to discuss with your doctor if you can drive a vehicle or operate machines while taking TRILEPTAL.

3. How to take TRILEPTAL

Do not share medicines prescribed for you with others.

Always take TRILEPTAL exactly as your doctor has told you. Check with your doctor if you are not sure.

The doctor will decide on the most suitable dosage according to the individual patient's medical need and response. Always take or give TRILEPTAL exactly as the doctor has instructed you.

How much to take

Dose for adults:

TRILEPTAL should be taken twice a day, every day, at about the same times of the day, unless the doctor tells you otherwise. Taking the medication 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 medication.

The usual starting dose of TRILEPTAL for adults (including elderly patients) is 600 mg per day. Take one 300 mg tablet twice daily. This dosage may be gradually increased if necessary until the best results are obtained. Maintenance doses are usually between 600 and 2 400 mg per day.

The dosage is the same if TRILEPTAL is being taken with another antiepileptic.

The starting dose in patients with kidney disease (with impaired renal function) is half the usual starting dose.

How to take TRILEPTAL tablets

Swallow the tablets with a little water. If necessary, the tablets can be broken in half to help you swallow them.

When and for how long to take TRILEPTAL:

Your doctor will tell you how long your/your child's treatment with TRILEPTAL will last. The duration of treatment is based on your/your child's seizure type; ongoing treatment for many years may be necessary to control the seizures. Do not change the dose or stop treatment without talking to your doctor.

If you take more TRILEPTAL than you should:

If you have taken many more TRILEPTAL tablets than your doctor prescribed, contact the nearest hospital or poison centre immediately.

If you forget to take TRILEPTAL

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. Do not double the dose at any time.

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

If you stop taking TRILEPTAL

Do not stop taking your medicine unless your doctor tells you to.

To prevent sudden worsening of your seizures, never discontinue your medicine abruptly.

If your treatment is stopped, it should be done gradually as instructed by your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

TRILEPTAL can have side effects.

Not all side effects reported for TRILEPTAL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TRILEPTAL, please consult your doctor, pharmacist or other healthcare professional for advice.

Some effects could be serious.

Tell your doctor immediately or go to the emergency department at your nearest hospital or healthcare centre if any of the following side effects occur:

- 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 reactions 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 serious allergic reaction).
- Tiredness, shortness of breath when exercising, looking pale, headache, chills, dizziness, frequent infections leading to fever, sore throat, mouth ulcers, bleeding or bruising more easily than normal, nose bleeds, reddish or purplish 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).
- Red blotchy rash mainly on face which may be accompanied by fatigue, fever, nausea, loss of appetite (signs of systemic lupus erythematosus).
- Lethargy, confusion, muscular twitching or significant worsening of convulsions (symptoms that may be linked to low sodium levels in the blood).
- Flu-like symptoms with jaundice (yellowing of the skin or the whites of the eyes) (signs of hepatitis).
- Severe upper stomach (abdominal) pain, vomiting, loss of appetite (signs of pancreatitis).
- Weight gain, tiredness, hair loss, muscle weakness, feeling cold (signs of under active thyroid gland).

Other side effects:

If any of the following side effects occur, tell your doctor as soon as possible since they may require medical attention.

*Frequent***:**

Trembling; problems with coordination; involuntary movement of the eyes; feeling of anxiety and nervousness; feeling of depression.

Less frequent:

Irregular heartbeats or very fast or slow heart rate.

Tell your doctor if you have any of the following side effects and if they worry you:

Frequent:

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

Common:

Weakness; memory disturbances; impaired concentration; apathy; agitation; confusion; blurred vision; constipation; diarrhoea; stomach (abdominal) pain; acne; hair loss; disturbance of balance; weight increased.

Less frequently, TRILEPTAL has been associated with high blood pressure and vitamin B9 (folic acid) deficiency. Some of the signs of vitamin B9 deficiency are diarrhoea, feelings of depression and signs of a decrease in the number of blood cells (see subsection 'Some effects could be serious).

These are usually mild to moderate side effects of TRILEPTAL. Most of these effects are transient and usually diminish over time.

There have been reports of bone disorders, including osteopenia and osteoporosis (thinning of the bone), and fractures in patients on long-term treatment with TRILEPTAL.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of TRILEPTAL.

5. How to store TRILEPTAL

Tablets:

Blister packs: Store at or below 30 °C and protect from moisture. Keep out of the reach and sight of children.

Plastic containers: Store at or below 30 °C and protect from moisture. Keep well closed. Keep out of the reach and sight of children.

6. Contents of the pack and other information

What TRILEPTAL contains

The active substance in TRILEPTAL is oxcarbazepine.

- TRILEPTAL 300 mg film-coated tablets

  Each film-coated tablet contains 300 mg of oxcarbazepine.

- TRILEPTAL 600 mg film-coated tablets

  Each film-coated tablet contains 600 mg of oxcarbazepine.

The other ingredients are:

Tablet core: silica, anhydrous colloidal, microcrystalline cellulose, hypromellose, crospovidone, magnesium stearate.

Tablet coating:

• **300 mg** tablet: hypromellose, macrogol 8000, yellow iron oxide (E 172), talc, titanium dioxide (E 171);

• **600 mg** tablet: hypromellose, macrogol 4000, red iron oxide (E 172), black iron oxide (E 172), talc, titanium dioxide (E 171).

What TRILEPTAL looks like and contents of the pack

TRILEPTAL 300

Yellow, ovaloid, slightly biconvex, film-coated tablets, scored on both sides.

Embossed with “TE/TE” on one side and “CG/CG” on the other side.

Length: Approximately 15,2 mm

Width: Approximately 6,7 mm

Thickness: Approximately 4,9 mm

TRILEPTAL 600

Light pink, ovaloid, slightly biconvex, film-coated tablets, scored on both sides.

Embossed with “TF/TF” on one side and “CG/CG” on the other side.

Length: Approximately 18,7 mm

Width: Approximately 8,2 mm

Thickness: Approximately 6,4 mm

Contents of the pack

TRILEPTAL 300 and 600 film-coated tablets are supplied in blister packs of 50 or plastic containers of 60.

Holder of Certificate of Registration

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This leaflet was last revised on

18 September 2026

Registration number:

TRILEPTAL 300: X/2.5/205

TRILEPTAL 600: X/2.5/206

Note: The Professional Information has been made available to your healthcare provider.

2023-PSBGLC-1361-s