

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrTRILEPTAL®

Oxcarbazepine Tablets and Oxcarbazepine Oral Suspension

Read this carefully before you start taking **TRILEPTAL®** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **TRILEPTAL**.

Serious Warnings and Precautions

- **Blood Disorders:** TRILEPTAL has been reported to cause serious adverse effects such as:
 - agranulocytosis (low white blood cell levels),
 - aplastic anemia (when cells meant to develop into mature blood cells are damaged),
 - leucopenia (low white blood cell levels),
 - thrombocytopenia (low blood platelet levels), and
 - hepatitis (inflammation of the liver).

Your healthcare professional will closely monitor your health for potential signs and symptoms of these blood disorders. If bone marrow depression appears, your healthcare professional may stop your treatment with TRILEPTAL.

- **Skin Reactions:** TRILEPTAL can also cause serious and sometimes fatal skin reactions such as:
 - Stevens-Johnson Syndrome (SJS),
 - Toxic Epidermal Necrolysis (TEN),
 - Drug Reaction with Eosinophilia And Systemic Symptoms (DRESS),
 - Acute Generalized Exanthematous Pustulosis (AGEP), and
 - maculopapular rash.

Some of these skin reactions are genetically linked, especially if you are of Asian descent. Your healthcare professional may perform a blood test to determine if TRILEPTAL is suitable for you.

- Tell your healthcare professional right away if you notice or develop a rash or any serious skin reactions. This can include red skin, blistering of the lips, eyes or mouth, and skin peeling accompanied by fever. Your healthcare professional may stop your treatment with TRILEPTAL.

See the **Serious side effects and what to do about them** table, below, for more information on these and other serious side effects.

What is TRILEPTAL used for?

TRILEPTAL is used alone or with other medicines to treat partial seizures in adults and children (6 to 16 years of age).

How does TRILEPTAL work?

TRILEPTAL is an anticonvulsant or antiepileptic drug used to treat epilepsy. It is thought to work by keeping the brain's "overexcitable" nerve cells under control. This may help to suppress or reduce the frequency of partial seizures.

What are the ingredients in TRILEPTAL?

Medicinal ingredient: oxcarbazepine

Non-medicinal ingredients:

- **Tablets:** colloidal anhydrous silica; croscopovidone; hypromellose; macrogol 4000 and 8000; magnesium stearate; microcrystalline cellulose; talc; titanium dioxide; yellow and/or black and/or red iron oxides.
- **Oral Suspension:** ascorbic acid, carboxymethylcellulose, ethanol, microcrystalline cellulose, methylparaben, polyethylene glycol-400 stearate, propylene glycol, propylparaben, purified water, saccharin sodium, sorbic acid, sorbitol, and yellow-plum-lemon aroma.

TRILEPTAL comes in the following dosage forms:

- Tablets: 300 mg and 600 mg
- Oral Suspension: 60 mg/mL

Do not use TRILEPTAL if:

- you are allergic to oxcarbazepine, eslicarbazepine acetate (an ingredient related to oxcarbazepine), or any of the other ingredients in TRILEPTAL.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take TRILEPTAL. Talk about any health conditions or problems you may have, including if you:

- have a history of allergic reactions to carbamazepine (such as a rash);
- are allergic to parabens (the oral suspension contains methylparaben);
- have problems of fructose intolerance (the oral suspension contains sorbitol);
- have or had kidney problems;
- have or had liver problems;
- have or had heart problems;
- are of an Asian descent;

- are taking other antiepileptic medicines (used to treat epilepsy);
- are pregnant or plan to become pregnant;
- are breastfeeding or plan to breastfeed;
- are taking diuretic medicines (used to get rid of salt and water by increasing the amount of urine produced);
- have low sodium levels in your blood level;
- have a history, or family history, of bone disease.

Other warnings you should know about:

TRILEPTAL can cause the following:

- **Bone disorders:** Treatment with antiepileptic drugs, such as oxcarbazepine, for long periods can decrease bone mineral density. This may lead to weakened or brittle bones.
- **Hyponatremia** (low sodium levels in the blood): Treatment with TRILEPTAL can cause hyponatremia. Your healthcare professional will monitor you/your child closely for signs and symptoms of hyponatremia. They may decide to reduce or stop your treatment with TRILEPTAL.
- **Hypothyroidism** (underactive/low thyroid): Treatment with TRILEPTAL can cause hypothyroidism. Your healthcare professional will monitor the status of your thyroid hormone levels, especially in children. They may decide to reduce or stop your treatment with TRILEPTAL.
- **Mental and motor impairment:** Treatment with TRILEPTAL can affect your mental and motor performance. This can cause difficulty with concentration, speech problems, language problems, drowsiness, fatigue, coordination abnormalities, ataxia, and walking problems. Tell your healthcare professional if you experience any of these symptoms.
- **Seizure aggravation:** Treatment with TRILEPTAL has been associated with seizure aggravation, especially in children. If you notice you are having more seizures or changes in the pattern of your seizures, tell your healthcare professional right away. They will determine if your dose should be reduced or stopped.
- **Suicidal thoughts or behaviour:** Antiepileptic drugs, such as TRILEPTAL, can increase the risk of suicidal thoughts and behaviours (harming or killing themselves). If at any time you have these thoughts, contact your healthcare professional right away.

See the **Serious side effects and what to do about them** table, below, for more information on these and other serious side effects.

Pregnancy:

If you are able to get pregnant, plan to become pregnant, are pregnant, or are taking hormonal birth control, there are specific risks you should discuss with your healthcare professional.

- TRILEPTAL can affect hormonal birth control drugs such as “the pill”. Therefore, you should use either a different method of birth control or an additional non-hormonal method while you are taking TRILEPTAL. This should help to prevent an unwanted pregnancy. Tell your healthcare professional right away, if you get irregular vaginal bleeding or spotting. If you have any questions about this, talk to your healthcare professional.
- There may be a risk to your baby if you take antiepileptic drugs during pregnancy. Tell your healthcare professional if you are pregnant or plan to become pregnant. They will discuss the benefits and potential risks with you, and help you to decide whether you should take TRILEPTAL.
- Taking TRILEPTAL during pregnancy can also affect the amount of oxcarbazepine in your blood. Your healthcare professional may recommend regular blood testing during your pregnancy to check that TRILEPTAL is appropriately controlling your seizures.
- Antiepileptic drugs, such as TRILEPTAL, can decrease your levels of folic acid. This can lead to fetal abnormality. Your healthcare professional may recommend taking folic acid supplements before and during pregnancy.
- Stopping TRILEPTAL abruptly can worsen your seizures. **Do not stop your treatment with TRILEPTAL during pregnancy without first checking with your healthcare professional.**

Breastfeeding:

- The active ingredient in TRILEPTAL can pass into breast milk. This could cause side effects for breastfed babies. Talk with your health care professional about the risks and benefits of breastfeeding while taking TRILEPTAL.

Tests and Monitoring: Your healthcare professional may assess your health before and during your treatment with TRILEPTAL. This can include blood tests to identify your genetics, assess your sodium levels, assess thyroid hormone levels, and monitor the levels of the drug.

Driving and using machines: TRILEPTAL can cause dizziness, drowsiness, visual disturbances, blurred visions, and hyponatremia (low sodium levels in the blood), especially at the beginning of your treatment. Before you drive or do tasks that require special attention, wait until you know how you respond to TRILEPTAL.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with TRILEPTAL:

- hormonal contraceptives that contain ethinylestradiol and levonorgestrel such as the birth-control pill.
- other antiepileptic medicines such as carbamazepine, phenobarbital, phenytoin, valproic acid, lamotrigine, and phenytoin.
- medicines that are used to treat bacterial infections such as rifampicin.
- medicines known as calcium antagonists that decrease blood pressure such as felodipine and verapamil.
- medicines that reduce the level of sodium in your blood such as diuretics (increases the amount of urine produced to help the kidneys get rid of salt and water).
- medicines that can affect your body's immune system such as cyclosporine.
- alcohol which may increase the sedative effects (making you more sleepy). Avoid alcohol as much as possible and ask your healthcare professional for advice.

How to take TRILEPTAL:

- TRILEPTAL should be taken twice a day at about the same time of every day.
- TRILEPTAL can be taken with or without food.
- Do not stop your treatment with TRILEPTAL without first checking with your healthcare professional. To prevent sudden worsening of your seizure, your healthcare professional will not discontinue your medicine abruptly.

Usual dose:

Your healthcare professional will determine the right dose for you/your child depending on your unique situation. Take TRILEPTAL exactly as prescribed by your healthcare professional. Your healthcare professional may start with a low dose and slowly adjust the dose as needed. If you are taking the oral suspension, see the detailed instructions for use below.

TRILEPTAL Oral Suspension - Instructions for Use

- Please read these instructions carefully before you take TRILEPTAL oral suspension. This will tell you how to properly use the medicine dispensing system.
- An oral dosing syringe is provided to withdraw the correct dose from the bottle. This syringe is graduated in millilitres (mL). If your dosing instructions are in milligrams (mg), do not take your medicine and immediately contact your healthcare professional for advice.

About the Medicine Dispensing System

There are three parts to the dispensing system:

1. A plastic adapter that you push onto the neck of the bottle the first time you open the bottle. The adapter must always remain on the bottle.



2. A bottle containing 250 mL of the medicine, with a child resistant cap. Always replace the cap after use.



3. A 10 mL oral dosing syringe that fits into the plastic adapter. This is used to withdraw the prescribed dose of medicine from the bottle.

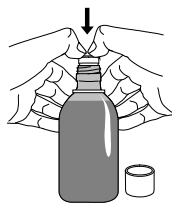


Preparing the Bottle

1. Shake the bottle of medicine for **at least 10 seconds**.



2. Remove the child resistant cap by pushing it **firmly** down and turning it anti-clockwise (as shown on the top of the cap). **Note:** Keep the cap to close the bottle after each use.



3. Hold the open bottle upright on a table and push the plastic adapter **firmly** onto the neck of the bottle as far as you can.
4. Replace the cap to be sure that the adapter has been fully forced onto the neck of the bottle. **Note:** You may not be able to push the adapter fully down but it will be forced onto the bottle when you screw the cap back on.

Now the bottle is ready to use with the syringe. The adapter must always stay in the bottle. To dispense a dose, please follow all of the instructions for **Taking the Medicine** below.

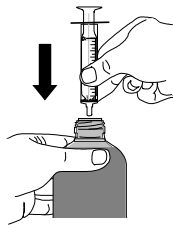
Taking the Medicine

The medicine can be swallowed directly from the oral syringe, or mixed in a small glass of water.

1. Shake the bottle well. Prepare the dose right away.

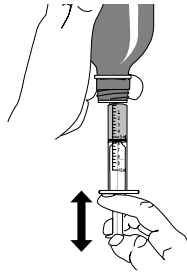


2. Push and turn the child resistant cap to open the bottle. **Note:** Always replace the cap after use.
3. Check the plunger is fully down inside the barrel of the oral syringe.
4. Keep the bottle upright and insert the oral syringe **firmly** into the plastic adapter.

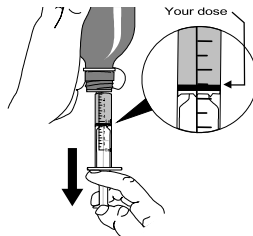


5. Hold the oral syringe in place and carefully turn the bottle upside down.
6. Slowly pull the plunger fully down so that the syringe fills with medicine. Push the plunger back up completely to expel any large air bubbles that may be trapped inside

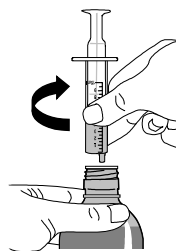
the oral syringe.



7. Withdraw the prescribed dose by slowly pulling the plunger down. Ensure that the top edge of the black ring is exactly level with the marker on the oral syringe barrel that indicates the prescribed dose.

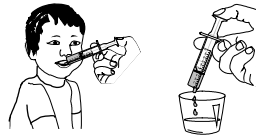


8. Carefully turn the bottle upright. Take out the oral syringe by gently twisting it out of the plastic adapter. The plastic adapter should stay in the bottle. **Note:** If the prescribed dose is more than 10 mL, you will need to reload the oral syringe to make up the full dose.



9. The dose of medicine can be swallowed directly from the oral syringe. You/your child must sit upright and the plunger must be pushed **slowly** into you/your child's mouth to swallow. Alternatively, the dose can be mixed in a small glass of water just prior to

administration. Stir and drink the entire mixture right away.



10. Replace the child resistant cap after use.

Cleaning:

- After use, rinse the syringe with water, shake out the excess liquid, and leave out to dry.

Overdose:

If you think you, or a person you are caring for, have taken too much TRILEPTAL, contact a healthcare professional, hospital emergency department, or regional Poison Control Center immediately, even if there are no symptoms.

Missed Dose:

If you/your child miss/misses one dose, take it as soon as you remember. However, if it is almost time for your next dose, do not take the missed dose. Instead, take the next scheduled regular dose. Do not double the dose at any time.

If you have forgotten to take several doses, contact your healthcare professional.

What are possible side effects from using TRILEPTAL?

These are not all the possible side effects you may have when taking TRILEPTAL. If you experience any side effects not listed here, tell your healthcare professional.

The most common side-effects may include:

- sleepiness
- unsteadiness
- diarrhea
- double vision
- abnormal vision
- uncontrolled eye movement
- blurred vision
- abnormal gait (unable to walk normally)
- anxiety
- nervousness

- feeling of depression
- mood swing
- memory problems
- difficulty concentrating
- apathy (feeling indifferent/loss of interest)
- agitation
- trembling
- problems with muscle coordination
- acne
- weight increase

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.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNCOMMON			
Decreased white blood cells: frequent infections with fever, chills, sore throat, or mouth ulcers		√	
RARE			
Suicidal thoughts or actions: thoughts, plans and actions taken for the purpose of killing or harming yourself		√	
VERY RARE			
Allergic reactions: swelling of the lips, eyelids, face, throat, or mouth, difficulty in breathing, speaking or swallowing, wheezing, drop in blood pressure, feeling sick to your stomach and throwing up, hives, or rash			√
Hypersensitivity reactions: skin rash, hives, itching, shortness of breath, wheezing, runny nose, watery eyes, fever, swollen glands (swelling of the lymph nodes), and pain in the muscles and joints			√
Serious skin reactions (including Stevens-Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN), Drug Rash With Eosinophilia And Systemic Symptoms (DRESS), Acute Generalized Exanthematous Pustulosis (AGEP), and maculopapular rash): blistering of the skin and/or mucous membranes of the lips, eyes, mouth, nasal			√

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
passages or genitals, rash, hives, itching, dermatitis, redness, blistering, or peeling of skin,			
Systemic lupus erythematosus (an autoimmune disease that occurs when your body's immune system attacks your own tissues and organs, including your joints, skin, kidneys, blood cells, heart and lungs): fatigue, fever, joint pain, stiffness, swelling, rash on the face that covers the cheeks and the bridge of the nose or rashes elsewhere on the body, skin lesions, shortness of breath, chest pain, dry eyes, headaches, confusion, or memory loss			√
Decrease blood cells: tiredness, shortness of breath when exercising, looking pale, headache, chills, dizziness, frequent infections leading to fever, sore throat, mouth ulcers		√	
Thrombocytopenia (low blood platelets): bleeding or bruising more easily and/or longer than usual if you hurt yourself, nose bleeds, reddish or purplish patches, unexplained blotches on the skin, skin that is red or warm, coldness, tingling, numbness, pale skin, muscle pain, muscle spasms, or weakness		√	
Hyponatremia (low sodium in the blood): lack of energy,		√	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
confusion, muscular twitching, achy, stiff, uncoordinated muscles, coma, or significant worsening of convulsions			
Hepatitis (inflammation of the liver): nausea, loss of appetite, vomiting combined with itching, upper stomach (abdominal) pain, yellowing of the skin or eyes, fatigue, fever, light coloured stool, trouble thinking clearly, or yellowing of the skin		✓	
Flu-like symptoms accompanied with liver disorders		✓	
Hypothyroidism (underactive/low thyroid): weight gain, tiredness, hair loss, muscle weakness, feeling cold, dry skin, constipation, puffy face, heavier than normal or irregular menstrual periods, or enlarged thyroid gland		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- **TRILEPTAL tablets:** Store between 15°C to 30°C. Do not use TRILEPTAL after the expiry date which is printed on the label.
- **TRILEPTAL oral suspension:** Store between 15°C to 25°C in the original package. Do not use TRILEPTAL after the expiry date which is printed on the box. Use within 7 weeks after first opening the bottle.
- Do not use any TRILEPTAL pack that is damaged or show signs of tampering.
- Keep out of the reach and sight of children.

If you want more information about TRILEPTAL:

- Talk to your healthcare professional
- Find the full Product Monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.novartis.ca, or by calling 1-800-363-8883.

This leaflet was prepared by Novartis Pharmaceuticals Canada Inc.

Last Revised: SEP 24, 2024

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