PART III: CONSUMER INFORMATION

PrTRILEPTAL®
(Oxcarbazepine)
Tablets and Oral Suspension

This leaflet is part III of a three-part "Product Monograph" published when TRILEPTAL® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about TRILEPTAL®. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

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

Epilepsy is a brain disorder that causes people to have recurring seizures and convulsions. 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 uncontrolled movements of muscles that we call an epileptic seizure.

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 (grand mal) seizure. There are two types of partial seizures: simple and complex. In simple partial seizures, the patient remains conscious, whereas in complex partial seizures, patients lose consciousness.

TRILEPTAL is used to treat partial seizures.

Usually, the doctor will attempt to find the one drug that works best but, with more severe epilepsy, a combination of two or more drugs may be needed to control seizures. TRILEPTAL can be used alone (i.e., monotherapy) or in combination with other antiepileptic drugs.

This medicine has been prescribed for you personally (or your child) and you should not give it to others.

What it does:

TRILEPTAL is thought to work by keeping the brain's "overexcitable" nerve cells under control, which may help to suppress or reduce the frequency of such seizures.

When it should not be used:

If you are allergic (hypersensitive) to oxcarbazepine or eslicarbazepine acetate (another active substance related to oxcarbazepine) or to any of the other substances listed in **'What the nonmedicinal ingredients are'**.

If you have fructose intolerance (severe abdominal pain, vomiting, and hypoglycemia following ingestion of fruit sugars), a rare hereditary problem, you should not take TRILEPTAL oral suspension.

What the medicinal ingredient is:

oxcarbazepine.

What the nonmedicinal ingredients are:

Each tablet also contains: silica, colloidal anhydrous; microcrystalline cellulose; hypromellose; crospovidone; magnesium stearate; macrogol 8000; talc; titanium dioxide; yellow and/or black and/or red iron oxides.

The suspension also contains: purified water, sorbitol, propylene glycol, microcrystalline cellulose and carboxymethylcellulose, ascorbic acid, yellow-plum-lemon aroma, methylparaben, polyethylene glycol-400 stearate, ethanol, sorbic acid, saccharin sodium, propylparaben **(see WARNINGS AND PRECAUTIONS/Important information about some of the ingredients of TRILEPTAL oral suspension).**

What dosage forms it comes in:

TRILEPTAL is available in tablets of 150 mg, 300 mg and 600 mg, and in oral suspension of 60 mg/mL.

The suspension is off-white to slightly red or slightly brown.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

- **Blood: Although infrequently reported, serious adverse effects affecting blood cell counts have been observed during the use of TRILEPTAL. Other side effects include: low white blood cell count, bone marrow depression and hepatitis. Close clinical and frequent laboratory supervision with your doctor should be maintained throughout treatment with TRILEPTAL in order to detect as early as possible any possible signs of a blood disorder. Your doctor should discontinue TRILEPTAL, if there is significant evidence of a bone marrow depression.**
- **Skin: Serious and sometimes fatal skin reactions known as Toxic Epidermal Necrolysis (TEN) and Stevens-Johnson Syndrome (SJS), have been reported with TRILEPTAL. Other serious skin reactions such as Drug Rash with Eosinophilia and Systemic Symptoms (DRESS), Acute Generalized Exanthematous Pustulosis (AGEP) and maculopapular rash have also been reported. Although very rare, serious forms of DRESS and**

AGEP may also lead to death. Since some cases of these skin reactions have been genetically linked, your doctor may recommend a blood test to determine whether you belong to an at-risk population.

- **Contact your doctor immediately if you are developing a rash or any serious skin reactions such as red skin, blistering of the lips, eyes or mouth, and skin peeling accompanied by fever. Your doctor will determine if it is indeed drug-related, and discontinue TRILEPTAL in this case.**

Important points you must tell your doctor before taking TRILEPTAL

- If you have ever shown unusual sensitivity (rash or any other signs of allergy) to carbamazepine or to any other drugs. If you have had an allergic reaction to carbamazepine you have a 25%-30% chance of being allergic to TRILEPTAL.
- If you have a kidney disease.
- If you have a serious liver 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 have a heart disease with shortness of breath and swelling of the feet or legs due to fluid retention.
- If you know that your blood level of sodium is low.
- If you are pregnant, breast-feeding or planning to become pregnant **(see 'What special precautions should pregnant or breast-feeding women take?').**
- If you are taking other medicines **(see INTERACTIONS WITH THIS MEDICATION: 'Can you use TRILEPTAL if you are taking other medicines?').**
- If you have a history, or family history, of bone disease.

You should also tell your doctor if any of these statements were applicable at any time in the past.

If you are a woman taking a hormonal contraceptive (such as "the pill"), TRILEPTAL may render this contraceptive ineffective. Therefore, you should use either a different method of contraception or an 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, check with your doctor or health professional.

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 have any further questions on the use of this medicine, ask your doctor.

Will TRILEPTAL affect your ability to drive or use machines?

It is important to discuss with your doctor if you can drive a vehicle or operate 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 at the beginning of treatment, and may affect your ability to operate machinery, including a vehicle.

Important information about some of the ingredients of TRILEPTAL oral suspension

One mL of TRILEPTAL oral suspension contains 175 mg of sorbitol (an inactive ingredient). When taken according to the dosage recommendations, the maximum daily dose contains 7 g of sorbitol. Sorbitol may cause stomach upset and diarrhea. Patients with rare hereditary problems of fructose intolerance should not take this medicine.

TRILEPTAL oral suspension contains ethanol (alcohol), less than 100 mg per dose.

TRILEPTAL oral suspension contains parahydroxybenzoates which may cause allergic reactions (possibly delayed).

What special precautions should pregnant or breast-feeding women take?
Tell your doctor if you are pregnant, breast-feeding, 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 drugs during pregnancy. 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.

During pregnancy there can be a gradual decrease in the amount of the active ingredient in TRILEPTAL in your blood. As a precaution to check that the blood levels of the active ingredient are adequate for controlling your seizures, your doctor may recommend periodic blood testing throughout your pregnancy.

The active ingredient in TRILEPTAL passes into breast milk. This could cause side effects for breast-fed babies. Therefore, you should not use TRILEPTAL during breast-feeding.

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

INTERACTIONS WITH THIS MEDICATION

Can you use TRILEPTAL if you are taking other medicines?

Before taking any medicine at the same time as TRILEPTAL talk to your doctor or pharmacist. This applies to both prescription and non-prescription (over-the-counter) medicines because these might interact with TRILEPTAL, and especially to:

- Hormonal contraceptives (such as the birth-control pill). **(see WARNINGS AND PRECAUTIONS)**
- Other antiepileptic drug (e.g. carbamazepine, phenobarbital, phenytoin).
- rifampicin

- Calcium antagonists (such as felodipine) (type of medicine used to treat high blood pressure).
- 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 your body's immune system (such as cyclosporine).

What foods and drinks should be avoided?

Alcohol may increase the sedative effects (making you more sleepy) of TRILEPTAL. Avoid alcohol as much as possible and ask your doctor for advice.

PROPER USE OF THIS MEDICATION

TRILEPTAL can be taken with or without food.

Usual dose:
(if you are taking the oral suspension, see 'TRILEPTAL Oral Suspension - Instructions For Use')

Take your medicine exactly as your doctor or pharmacist tells you.

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

The usual starting dose of TRILEPTAL for adults (including elderly patients) is 600 mg per day. Take one 300 mg tablet twice daily or two 150 mg tablets twice daily or 5 ml of oral suspension twice daily. This dosage may be gradually increased if necessary until the best results are obtained. This is usually achieved at a dose between 600 and 2400 mg per day.

If TRILEPTAL is being taken with another antiepileptic, best results may be obtained with a dose between 600 and 1200 mg per day. Your doctor will decide the best dose of TRILEPTAL if you are taking another antiepileptic.

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

The dosage for children will be calculated by your doctor and depends on your child's weight. The starting dose is 8-10 mg/kg bodyweight per day given in two divided doses.

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; and 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.**

TRILEPTAL Oral Suspension - Instructions For Use

Please read these instructions carefully so that you know how to use the medicine dispensing system correctly.

The oral dosing syringe which is used to withdraw the correct dose from the bottle is graduated in mL. If your dosing instructions are in mg, contact your doctor or pharmacist for advice.

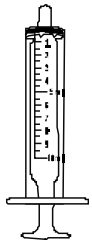
About the Medicine Dispensing System

There are three parts to the dispensing system:

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

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

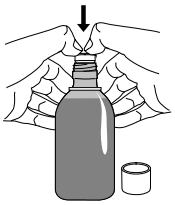
3. A 10 mL oral dosing syringe that fits into the plastic adapter to withdraw the prescribed dose of medicine from the bottle.



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 safe to close the bottle after each use.



3. Hold the open bottle upright on a table and push the plastic adapter **firmly** into the neck of the bottle as far as you can.

4. Replace the cap to be sure that the adapter has been fully forced into the neck of the bottle.

Note: you may not be able to push the adapter fully down but it will be forced into 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 the instructions for **Taking the Medicine**.

Taking the Medicine.

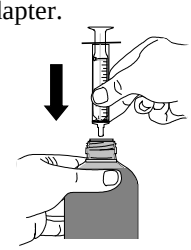
The medicine can be swallowed directly from the oral syringe, or mixed in a small glass of water.

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).

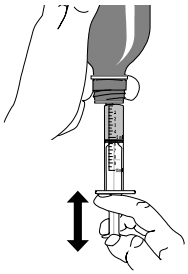
3. Check the plunger is fully down inside the barrel of the oral syringe.

4. Keep the bottle upright and insert the oral syringe **firmly** into the plastic adapter.

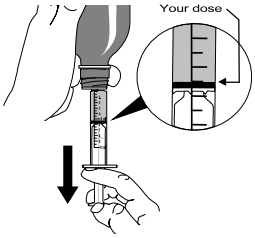


5. Hold the oral syringe in place and carefully turn the bottle upside down.

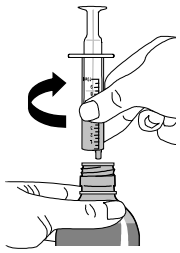
6. Slowly pull the plunger fully down so that the syringe fills with medicine. Push the plunger back up completely to expel any large air bubbles that may be trapped inside the oral syringe.



7. Withdraw the prescribed dose: slowly pull the plunger down until 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 (the patient must be sitting upright and the plunger must be pushed **slowly** to allow the patient 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.

11. **Cleaning:** After use, rinse the syringe with water and shake out as much residual liquid as possible and leave out to dry.

<u>Overdose</u>:

If you have taken many more tablets or much more oral suspension than your doctor prescribed, contact your doctor, the nearest hospital or regional Poison Control Center immediately, even though you may not feel sick. You may require medical attention.

<u>Missed Dose:</u>

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 have forgotten to take several doses, contact your doctor.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

The most common side-effects may include:

- Fatigue, sleepiness, dizziness, unsteadiness,
- Headache
- Nausea, vomiting, abdominal pain, diarrhea, constipation
- Double vision, uncontrolled eye movement, blurred vision

- Anxiety, nervousness, feeling of depression, mood swing, memory problems, difficulty concentrating, apathy (feeling indifferent/loss of interest), agitation, confusion
- Trembling, problems with muscle coordination, weakness
- Acne, hair loss.
- 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.

If any of the side effects affects you severely, or if you notice any side effect not listed in this leaflet, please tell you doctor or pharmacist.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist right away		Seek immediate emergency medical treatment
		Only if severe	In all cases	
Uncommon	**Decreased White Blood Cells:** frequent infections, fever, sore throat, 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			√
	Hypersensitivity reactions: skin rash, fever, swollen glands (swelling of the lymph nodes), and pain in the muscles and joints			√
	Serious skin reaction: blistering of the skin and/or mucous membranes of the lips, eyes, mouth, nasal passages or genitals			√

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist right away		Seek immediate emergency medical treatment
		Only if severe	In all cases	
	Systemic lupus erythematosus: red blotchy rash mainly on the face which may be accompanied by fatigue, fever, nausea, loss of appetite			√
	Decrease blood cells: tiredness, shortness of breath when exercising, looking pale, headache, chills, dizziness, frequent infections leading to fever, sore throat, mouth ulcers		√	
	Decrease blood platelets: bleeding or bruising more easily than normal, nose bleeds, reddish or purplish patches, or unexplained blotches on the skin		√	
	Low sodium level in blood: Lack of energy, confusion, muscular twitching or significant worsening of convulsions		√	
	Hepatitis: nausea, loss of appetite, vomiting combined with itching, upper stomach (abdominal) pain, yellowing of the skin or eyes		√	
	Flu-like symptoms accompanied with liver disorders		√	
	Underactive thyroid gland: weight gain, tiredness, hair loss, muscle weakness, feeling cold		√	

This is not a complete list of side effects. For any unexpected effects while taking TRILEPTAL, contact your doctor or pharmacist.

HOW TO STORE IT

The tablets should be stored at room temperature (15-30° C). Do not use TRILEPTAL after the expiry date which is printed on the label.

The oral suspension should be stored at room temperature (15-30° C). Do not use TRILEPTAL after the expiry date which is printed on the box. Store TRILEPTAL in the original package. Use within 7 weeks after first opening the bottle.

Do not use any TRILEPTAL pack that is damaged or show signs of tampering.

Keep TRILEPTAL out of the reach and sight of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- **Report online at www.healthcanada.gc.ca/medeffect**
- **Call toll-free at 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
  - **Fax toll-free to 1-866-678-6789, or**
  - **Mail to:**

    Canada Vigilance Program
    Health Canada
    Postal Locator 1908C
    Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:

www.novartis.ca

or by contacting the sponsor, Novartis Pharmaceuticals Canada Inc., at:

1-800-363-8883

Please consult your doctor or pharmacist with any questions or concerns you may have regarding your individual condition.

This leaflet was prepared by Novartis Pharmaceuticals Canada Inc., 385 Bouchard Blvd., Dorval, Quebec, H9S 1A9

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