

PART III: CONSUMER INFORMATION

PrTEGRETOL® Carbamazepine

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

ABOUT THIS MEDICATION

What the medication is used for:

TEGRETOL has been prescribed for you by your doctor:

- to reduce your number of seizures;
- to relieve the pain of trigeminal neuralgia;
- to treat your acute mania or bipolar disorder.

What it does:

TEGRETOL belongs to the family of medicines called anticonvulsants for treating epilepsy. TEGRETOL is also used for treating the pain of trigeminal neuralgia and for treating mania.

If you have any questions about how TEGRETOL works or why this medicine has been prescribed to you, ask your doctor.

When it should not be used:

You should not use TEGRETOL if:

- You are allergic (hypersensitive) to carbamazepine or to any of the other ingredients of TEGRETOL (See **What the non-medicinal ingredients are**) If you think you may be allergic, ask your doctor for advice. Do not take TEGRETOL if you are allergic to other tricyclic drugs such as amitriptyline, trimipramine, imipramine.
- You have severe heart disease (heart block).
- You have liver disease.
- You have a history of bone marrow depression.
- You have had serious blood illnesses in the past.
- You have a disturbance in the production of porphyrin, a pigment important for liver function and blood formation (also called hepatic porphyria).
- You are also taking medicines belonging to a special group of antidepressants called monoamine-oxidase inhibitors (MAOIs).
- You are also taking the drugs itraconazole or voriconazole (Vfend) for treatment of an infection.
- TEGRETOL should not be used to relieve trivial pain in the face or headaches.
- TEGRETOL suspension contains sorbitol which may cause stomach upset and diarrhea. Patients with rare hereditary problems of fructose intolerance should not take this medicine.

If any of the above applies to you, **tell your doctor before taking TEGRETOL.**

What the medicinal ingredient is:

Carbamazepine.

What the important nonmedicinal ingredients are:

TEGRETOL 200 mg Tablets: cellulose compounds, magnesium stearate, silicon dioxide.

TEGRETOL 100 mg and 200 mg CHEWTABS: cherry-mint flavour, cornstarch, erythrosine, gelatin, glycerin, magnesium stearate, silicon dioxide, sodium starch glycolate, stearic acid, sugar.

TEGRETOL CR 200 mg and 400 mg: acrylic esters, cellulose compounds, iron oxides, magnesium stearate, silicon dioxide, talc, titanium dioxide, castor oil derivative.

TEGRETOL 100 mg/tsp (5 mL) Suspension: citric acid, citrus-vanilla flavour, FD&C Yellow No. 6, pluronic polyol, potassium sorbate, propylene glycol, sucrose, sorbitol, water, xanthan gum.

What dosage forms it comes in:

TEGRETOL is available in the following forms:

- **Tablets** containing 200 mg carbamazepine.
- **CR tablets** (controlled-release tablets, which can be divided) containing 200 mg or 400 mg carbamazepine.
- **Chewable tablets** containing 100 mg or 200 mg carbamazepine.
- **Oral suspension:** 5 mL (1 measure) contain 100 mg carbamazepine.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

- **Blood:** Although infrequently reported and very rarely fatal, serious adverse effects affecting blood cell counts have been observed during the use of TEGRETOL. Other side effects include: low white blood cell count, bone marrow depression, hepatitis and signs of liver failure such as jaundice (yellowing of the skin or eyes). Contact your doctor immediately if you are experiencing any of these symptoms. Close clinical and frequent laboratory supervision with your doctor should be maintained throughout treatment with TEGRETOL in order to detect as early as possible any possible signs of a blood disorder. Your doctor should discontinue TEGRETOL, 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 TEGRETOL. 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. Some cases of these skin reactions have been genetically linked. Your doctor may recommend a blood test to determine if you belong to an at-risk population.

- Contact your doctor immediately if you are developing any combination of:
 - a rash or any serious skin reactions such as red skin, blistering of the lips, eyes or mouth, and skin peeling accompanied by fever
 - swollen lymph nodes
 - joint pain
 - enlargement of the liver and/or the spleen
 - problems related to the lungs, kidneys, pancreas, heart, bone marrow, thymus, and colon

Your doctor will determine if it is indeed drug-related, and discontinue TEGRETOL in this case.

- **Cancer:** Long-term toxicity studies in rats have indicated a possible cancer risk associated with carbamazepine. Before taking TEGRETOL, discuss with your doctor the potential benefits and possible risks of this treatment for you.

BEFORE you use TEGRETOL talk to your doctor or pharmacist:

- About your medical conditions, especially if you have or have had any liver, kidney, heart or thyroid disease or blood disorders (including those caused by other drugs).
- If you have a history, or family history, of bone disease or have taken antiepileptics (such as phenobarbital, phenytoin, primidone, oxcarbazepine, lamotrigine, sodium valproate and/or carbamazepine) for a prolonged period of time.
- If you are taking delavirdine, a medicine used to treat HIV-1 infection.
- About any allergies you may have, especially if you have ever shown any unusual sensitivity (rash or other signs of allergy) to oxcarbazepine or other drugs used to treat your condition. It is important to note that if you are allergic to TEGRETOL (carbamazepine), there is an approximately 1 in 4 (25%) chance that you could also have an allergic reaction to oxcarbazepine (TRILEPTAL®).
- If you are pregnant. Your doctor may recommend that you take folic acid before and during your pregnancy and vitamin K during the last weeks of pregnancy. Your doctor may also recommend that the newborn receive vitamin K and be observed for liver and gall bladder problems.
- If you are pregnant or planning on becoming pregnant to

discuss the potential risk of taking TEGRETOL during pregnancy since it may cause harm or abnormalities in the unborn child.

- If you are a female of childbearing age you should use an effective method of contraception throughout your treatment and for 2 weeks after your last dose. If you are taking hormonal contraceptive (birth control medicine), TEGRETOL may render this contraceptive ineffective. Therefore, you should use a different or additional non-hormonal method of contraception while you are taking TEGRETOL. This should help to prevent an unwanted pregnancy.
- If you get irregular vaginal bleeding or spotting.
- If you are breast-feeding, TEGRETOL is known to pass into breast milk. You must discuss with your doctor the benefits of breastfeeding against any possible risks to the infant. If you decide to breastfeed, the baby must be observed for liver and gall bladder problems, drowsiness, and allergic skin reactions.
- About any other medicines (prescription and non-prescription) you are taking.
- About your usual alcohol consumption.
- If you have increased pressure in the eye (glaucoma).
- If you have difficulty passing urine (urinary retention).
- If you were told by your physician that you suffer from mental problems, a mental disorder called psychosis that may be accompanied by confusion or agitation, or have thoughts about suicide.

If any of the following apply to you, **tell your doctor.**

- If an allergic reaction happens such as fever with lymph nodes swelling, rash or skin blistering, tell your doctor immediately or go to the emergency department at your nearest hospital. (see **Side effects and what to do about them**).
- If you experience an increase in the number of seizures, tell your doctor immediately.
- If you experience any side effects such as drowsiness, headache, unsteadiness on the feet, double vision, dizziness, nausea or vomiting, consult your doctor.
- If, at any time, you have thoughts of harming or killing yourself. A small number of people being treated with antiepileptic drugs have reported having such thoughts or behavior. Should this happen to you, or to those in your care if you are a caregiver or guardian, talk to your doctor immediately. Close observation by a doctor is necessary in this situation. **Do not discontinue your medication on your own.**
- If you have kidney problems associated with low sodium blood level or if you have kidney problems and you are also taking certain medicines that lower sodium blood level (diuretics such as hydrochlorothiazide, furosemide).
- If you experience dizziness, drowsiness, decrease in blood pressure, confusion, due to TEGRETOL treatment, which may lead to falls.

TEGRETOL may affect male fertility or cause abnormal sperm.

Periodic eye examinations are recommended while taking TEGRETOL.

Do not drive a car or operate dangerous machinery until you are sure that TEGRETOL does not cause dizziness, drowsiness, sleepiness, blurred or double vision, affect your muscular coordination or affect your alertness.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor or pharmacist if you are taking or have recently taken any prescription, non-prescription medicines or natural health products. It is particularly important for TEGRETOL, since many other medicines interact with it.

You may need a change in your dose or, sometimes, to stop one of these other medicines.

Irregularity of the menstrual period may occur in women taking hormonal contraceptives (birth control medicines) and TEGRETOL. The hormonal contraceptive may become less effective and you should use another different or additional non-hormonal contraceptive method.

- Avoid alcohol consumption when taking TEGRETOL.
- Do not drink grapefruit juice or eat grapefruit since this can increase the effect of TEGRETOL. Other juices, like orange juice or apple juice, do not have this effect.

PROPER USE OF THIS MEDICATION

Usual dose:

Dosage should be individualised. It is very important that you take TEGRETOL exactly as your doctor instructed.

- Never increase or decrease the recommended dose of TEGRETOL you are taking unless your doctor tells you to.
- If you are taking TEGRETOL, **do not suddenly stop taking it** without first checking with your doctor. Your doctor will tell you if and when you can stop taking this medicine
- TEGRETOL Tablets, CHEWTABS and Suspension should be taken in 2-4 divided doses daily, with meals whenever possible.
- TEGRETOL CR tablets should be swallowed unchewed with a little liquid during or after a meal.
- Shake TEGRETOL Suspension well before you take it or else you may not receive the correct dose.

Adults and Children Over 12 Years of Age

Initial dose 100 to 200 mg once or twice a day. Your doctor will decide the best dosage for you. Always follow your doctor's instructions.

For the treatment of trigeminal neuralgia, the maximum dose is 1200 mg a day.

Children 6-12 Years of Age

Initial dose 100 mg in divided doses on the first day. Your doctor will decide the best dosage for you. Always follow your doctor's instructions.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose, take your TEGRETOL as soon as possible. However, if the time is close to the next dose, do not take the missed dose and return to your regular dosing schedule. Do not double the dose to make up for the forgotten dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects may include:

- purple or reddish-purple bumps that may be itchy
- trembling, uncontrolled body movements, muscle spasm, loss of muscle coordination, weakness
- agitation or hostility (especially in the elderly), depression with restlessness, nervousness or other mood or mental changes, changes in behaviour, confusion, headache, memory loss
- blurred vision, double vision, itching with redness and swelling of the eye (conjunctivitis), uncontrolled eye movements
- difficulty speaking or slurred speech, taste disturbances, dry mouth, red and sore tongue, mouth sores
- ringing or other unexplained sounds in the ears, decreased hearing
- numbness, tingling in hands and feet
- unusual secretion of breast milk, breast enlargement in men, sexual disturbances (erectile dysfunction), male infertility
- increased sensitivity of the skin to sun, alterations in skin pigmentation, acne, increased sweating
- reactivation of herpes virus infection (can be serious when the immune system is depressed)
- complete loss of the nails, loss of hair, excessive body and facial hair

- vomiting, nausea, loss of appetite, constipation, diarrhea, abdominal pain
- dizziness, sleepiness, unsteadiness, drowsiness, fatigue
- weight gain
- aching joints or muscles
- experience a fall due to dizziness, drowsiness, decrease in blood pressure, confusion

Long-term use of antiepileptics such as carbamazepine, phenobarbital, phenytoin, primidone, oxcarbazepine, lamotrigine and sodium valproate is associated with a risk of decreased bone mineral density that may lead to weakened or brittle bones, or fracture.

If any of these affects you severely, contact your doctor

TEGRETOL can cause abnormal blood test results. Your doctor will decide when to perform blood tests and will interpret the results.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical treatment
		Only if severe	In all cases	
Very common	Decreased White Blood Cells: fever, sore throat, rash, ulcers in the mouth, swollen glands, or more easily getting infections.	√		
	Suicidal Thoughts or Actions: thoughts, plans and actions taken for the purpose of killing or harming yourself.		√	
Common	Edema: swelling of the ankles, feet or lower legs.	√		
Rare	Systemic Lupus Erythematosus: red blotchy rash mainly on the face which may be accompanied by fatigue, fever,	√		

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Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical treatment
		Only if severe	In all cases	
	nausea, loss of appetite.			
	Hallucination: see or hear things that are not there.	√		
	High Blood Pressure Low Blood Pressure: dizziness, fainting, light-headedness.	√		
Very rare	Glaucoma: pressure/pain in the eye.			√
	Thrombophlebitis : swelling and redness along a vein which is extremely tender or painful when touched.		√	
	Angioedema and Severe Allergic Reactions: swelling of the face, eyes, or tongue, difficulty swallowing, wheezing, hives and generalized itching, rash, fever, abdominal cramps, chest discomfort or tightness, difficulty breathing, unconsciousness.			
	Serious Skin Reactions: any combination of itchy skin rash, redness, blistering of the lips, eyes or mouth, skin peeling, accompanied by fever, chills, headache, cough, body aches or swollen lymph nodes, joint pain, enlargement of the liver and/or the spleen. Any			√

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

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical treatment
	Only if severe	In all cases	
problems related to the lungs, kidneys, pancreas, heart, bone marrow, thymus, and colon.			
Hepatitis: yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite.		√	
Meningitis: fever, nausea, vomiting, headache, stiff neck and extreme sensitivity to bright light.			√
Pancreatitis: severe upper abdominal pain, vomiting, loss of appetite.	√		
Severe decreased urine output due to kidney disorders, blood in the urine. Frequent urination.	√		
Porphyria: darkening of urine, severe abdominal pain, excessive sweating, vomiting, and anxiety.		√	
Lack of All Blood Cells: tiredness, headache, being short of breath when exercising, dizziness; looking pale, frequent infections leading to fever, chills, sore throat or mouth ulcers; bleeding or bruising more easily than normal, nose bleeds.	√		
Neuroleptic Malignant Syndrome: muscular stiffness, high fever, altered			√

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

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical treatment
	Only if severe	In all cases	
consciousness, high blood pressure, excessive salivation.			
Irregular heartbeat, chest pain, fast or unusually slow heartbeat, trouble breathing.	√		
Thromboembolism (blood clot): swelling, pain and redness in an arm or a leg that can be warm to touch. You may develop sudden chest pain, difficulty breathing and heart palpitations.			√
Circulatory Collapse: the body is unable to circulate blood to the organs. This is very serious and can lead to death.			√
Disturbed consciousness, fainting.		√	
Hyponatremia (low sodium in the blood): lethargy, confusion, muscular twitching or significant worsening of convulsions.	√		
Unknown			
Inflammation of the colon: diarrhea, abdominal pain and fever.		√	

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

HOW TO STORE IT

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Store at room temperature (TEGRETOL tablets store at 15-25°C and TEGRETOL CR store below 25°C, TEGRETOL CHEWTABS and TEGRETOL Suspension store below 30°C).

- Protect from humidity, such as in bathrooms where you shower often.
- Protect TEGRETOL CHEWTABS and TEGRETOL Suspension from light.
- Keep out of 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, Ontario
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

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

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

<http://www.novartis.ca>

or by contacting the sponsor, Novartis Pharmaceuticals Canada Inc., at:
1-800-363-8883

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