

## Information for The Consumer

Please read this information carefully before you start to take your medicine, even if you have taken this drug before. Do not throw away this leaflet until you have finished your medicine as you may need to read it again. For further information or advice, please ask your doctor or pharmacist.

### What is <sup>Pr</sup>TEGRETOL\*

- TEGRETOL\* (carbamazepine) 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.
- TEGRETOL\* has been prescribed for you by your doctor to reduce your number of seizures; to relieve the pain of trigeminal neuralgia; or to treat your acute mania or bipolar disorder.

### Important Points you must tell your doctor before taking TEGRETOL\*

#### Tell your doctor:

- Tell about your medical conditions, especially if you have or have had any liver or kidney disease, heart disease or blood disorders.
- Inform your doctor of 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.
- If you are of Asian origin. Studies have shown that certain individuals of Asian origin may be at an increased risk of developing serious skin reactions during treatment with TEGRETOL\* (see Precautions When Taking TEGRETOL\*).
- If you are pregnant or thinking about becoming pregnant.
- If you are breast-feeding.
- If you have or have ever been diagnosed with mental problems, or have thought about suicide.
- Any other medicines (prescription and nonprescription) you are taking.
- Inform your doctor of your usual alcohol consumption.

**How to take TEGRETOL\***

- 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 (see **Precautions when taking TEGRETOL\***).
- 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.
- If you have accidentally taken too many tablets, **talk to your doctor straight away**. You may require medical attention.
- 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.

**When not to use TEGRETOL\***

You should not use TEGRETOL\* if:

- You are allergic (hypersensitive) to carbamazepine or to any of the other ingredients of TEGRETOL\* (See list of components at the end of this leaflet).
- You have severe heart disease
- 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 drugs belonging to a special group of antidepressants called monoamine-oxidase inhibitors (MAOIs).
- You are also taking the drug voriconazole (VFEND) for treatment of an infection.

If this applies to you, **tell your doctor before taking TEGRETOL\***. If you think you may be allergic, ask your doctor for advice.

**Precautions when taking TEGRETOL\***

- If you have blood illnesses (including those caused by other drugs).
- If you have ever shown unusual sensitivity (rash or any other signs of allergy) to oxcarbazepine or to any other medicines, especially other medicines used to treat your condition. It is important to note that if you are allergic to carbamazepine, there is an approximately 1 in 4 (25%) chance that you could also have an allergic reaction to oxcarbazepine (Trileptal<sup>®</sup>).
- If you have or have had heart, liver or kidney disease in the past.
- If you have increased pressure in the eye (glaucoma).
- If you were told by your physician that you suffer from a mental disorder called psychosis, that may be accompanied by confusion or agitation.
- Do not drive a car or operate dangerous machinery until you are sure that TEGRETOL\* does not affect your alertness.
- If you are a women 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. Tell your doctor at once if you get irregular vaginal bleeding or spotting. If you have any questions about this, ask your doctor or health professional.
- Avoid alcoholic drinks 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.

If any of these 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 **Possible side effects**).

- If you develop serious skin reactions such as rash, red skin, blistering of the lips, eyes or mouth, skin peeling and accompanied by fever, tell your doctor immediately. These reactions may be more frequent in patients of Asian origin. Reports of these reactions have been highest in patients from Taiwan, Malaysia and the Philippines.
- If you experience an increase in the number of seizures, tell your doctor immediately.
- If you notice symptoms suggestive of hepatitis, such as jaundice (yellowing of skin and eyes), 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.

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

**What to do in case of overdose**

- Contact your doctor or nearest hospital emergency ward, even though you may not feel sick.

**How to store TEGRETOL\***

- Store at room temperature (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 of children.

**What does TEGRETOL\* contain**

- TEGRETOL\* 200 mg Tablets: cellulose compounds, magnesium stearate, silicon dioxide
- TEGRETOL\* 100 mg and 200 mg CHEWTABS: cherry-mint flavour, corn starch, erythrosine, gelatin, glycerin, magnesium stearate, silicon dioxide, sodium starch glycolate, stearic acid, sugar
- TEGRETOL\* CR 200 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

TEGRETOL\* suspension contains sorbitol which may cause stomach upset and diarrhea. Patients with rare hereditary problems of fructose intolerance should not take this medicine.

### **Possible side effects**

TEGRETOL\*, can have some side effects in some people. These are often mild and occur more often early in treatment and usually wear off after a few days of treatment.

### **Some effects could be serious:**

**Check with your doctor immediately or make sure that someone else can do this for you if any of the following (less common or rare) side effects occur. They may be early signs of serious damage to your blood, liver, kidneys or other organs and may urgently need medical treatment.**

- If you have fever, sore throat, rash, ulcers in the mouth, swollen glands or more easily getting infections (signs of lack of white blood cells).
- If you have 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 (lack of all blood cells).
- If you have red blotchy rash mainly on the face which may be accompanied by fatigue, fever, nausea, loss of appetite (signs of systemic lupus erythematosus).
- If you have any yellowing of the white of your eyes or your skin (signs of hepatitis).
- If you have darkening of urine (signs of porphyria or hepatitis)
- If you have severe decreased urine output due to kidney disorders, blood in the urine.
- If you have severe upper abdominal pain, vomiting, loss of appetite (signs of pancreatitis).

- If you have skin rash, redness of the skin, blistering of the lips, eyes or mouth, skin peeling, accompanied by fever, chills, headache, cough, body aches (signs of serious skin reactions)
- If you have 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 (signs of angioedema and severe allergic reactions).
- If you have lethargy, confusion, muscular twitching or significant worsening of convulsions (symptoms that may be linked to low sodium levels in the blood).
- If you have fever, nausea, vomiting, headache, stiff neck and extreme sensitivity to bright light (signs of meningitis).
- If you have muscular stiffness, high fever, altered consciousness, high blood pressure, excessive salivation (signs of neuroleptic malignant syndrome)
- If you have irregular heartbeat, chest pain.
- If you have disturbed consciousness, fainting.

If you experience any of these, **tell your doctor straight away.**

**Other side effects:**

**Check with your doctor as soon as possible if any of the following side effects occur, since they may need medical attention:**

More common: loss of muscle coordination, allergic skin reactions, swelling of the ankles, feet or lower legs (oedema), increase in seizures (fits), blurred vision, double vision.

Less common: trembling, uncontrolled body movements.

Rare: changes in behavior, confusion, weakness, itching with redness and swelling of the eye (conjunctivitis), feeling pressure/pain in the eye (signs of increased pressure in the eye), muscle spasms, uncontrolled eye movements, itching, swollen glands, agitation or hostility (especially in the elderly), fainting, difficulty in speaking or slurred speech,

depression with restlessness, nervousness or other mood or mental changes, hallucinations, ringing or other unexplained sounds in the ears, decreased hearing, troubled breathing, chest pain, fast or unusually slow heartbeat, numbness, tingling in hands and feet, frequent urination, sudden decrease in amount of urine, taste disturbances, unusual secretion of breast milk, breast enlargement in men, swelling and redness along a vein which is extremely tender when touched, often experienced as painful (thrombophlebitis), increased sensitivity of the skin to sun, softening or thinning or weakening of bones causing an increased risk of broken bones (lack of vitamin D, osteoporosis).

**Usually the following side effects do not need medical attention. However, if they last for more than a few days or cause real distress, check with your doctor.**

More common: vomiting, nausea, dizziness, sleepiness, unsteadiness, weight gain, headache, dry mouth.

Less common: constipation, diarrhea.

Rare: abdominal pain, aching joints or muscles, increased sweating, loss of appetite, loss of hair, excessive body and facial hair, sexual disturbances, male infertility, red and sore tongue, mouth sores, alterations in skin pigmentation, acne.

If any of these affects you severely, **tell your doctor.**

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

#### REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada through the Canada Vigilance Program collects information on serious and unexpected side effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Canada Vigilance:

By toll-free telephone: 866-234-2345

By toll-free fax: 866-678-6789

Online: [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)

By email: [CanadaVigilance@hc-sc.gc.ca](mailto:CanadaVigilance@hc-sc.gc.ca)

By regular mail:

Canada Vigilance National Office  
Marketed Health Products Safety and  
Effectiveness Information Division  
Marketed Health Products Directorate  
Health Products and Food Branch  
Health Canada  
Tunney's Pasture, AL 0701C  
Ottawa ON K1A 0K9

*NOTE: Before contacting Canada Vigilance, you should contact your physician or pharmacist.*

**Who manufactures TEGRETOL\***

**TEGRETOL\* Tablets, CHEWTABS, TEGRETOL\* CR and TEGRETOL\*  
Suspension are manufactured by:**

Novartis Pharmaceuticals Canada Inc.  
385 Bouchard  
Dorval, Quebec H9S 1A9

REMINDER: This medicine has been prescribed only for you. Do not give it to anybody else!

IF YOU REQUIRE ANY FURTHER INFORMATION OR ADVICE, PLEASE CONSULT YOUR DOCTOR OR PHARMACIST.

TEGRETOL\* is a registered trademark