TEGRETOL TABLETS/CR TABLETS/ SYRUP ®

carbamazepine (200mg, 400mg, 100mg/5mL)

What is in this leaflet

What Tegretol is used for

Tegretol belongs to a group of medicines called antiepileptics (medicine for seizures). Due to its mode of action it can be used for other diseases too.

Tegretol is used to treat certain types of seizures (epilepsy). It is also used to treat some neurological diseases (such as a painful condition of the face called 'trigeminal neuralgia'), certain psychiatric conditions (such as a disorder known as mania, episodes of bipolar mood disorders and a certain type of depression) as well as alcohol-withdrawal syndrome. It must not be used for common aches or pains.

How Tegretol works

Epilepsy is a disorder characterized by two or more seizures (fits). Seizures occur when messages from the brain to the muscles are not properly passed on by the nerve pathways in the body. Tegretol helps to control the passing-on of these messages. Tegretol also regulates nerve functions for the other diseases mentioned above.

Before you use Tegretol

You may only take Tegretol after a full medical examination.

The risk of serious skin reactions in patients of Han Chinese or Thai origin associated with carbamazepine or chemically related compounds may be predicted by testing a blood sample of these patients. Your doctor should be able to advise if a blood test is necessary before taking Tegretol.

- When you must not use it

- If you are allergic (hypersensitive) to carbamazepine or to any of the other ingredients of Tegretol listed at the end of this leaflet.
- If you have severe heart disease.
- If you have had a serious blood illness in the past.
- If you have a disturbance in the production of porphyrin, a pigment important for liver function and blood formation (also called 'hepatic porphyria').
- If you are also taking medicines belonging to a special group of antidepressants called monoamine-oxidase inhibitors (MAOIs).
- If baby is less than 4 weeks of age.

If any of these apply to you, do not take Tegretol and tell your doctor.

Pregnancy and breast-feeding

Tell your doctor if you are pregnant or plan to become pregnant.

It is important to control epileptic seizures during pregnancy. However, there is a possible risk of physical birth abnormalities (major congenital malformations) to your baby if you take antiepileptic medication (medicine for seizures) during pregnancy.

Risk of neurodevelopmental disorders cannot be excluded among children born to women with epilepsy treated with carbamazepine alone or in combination with other antiepileptic drugs during pregnancy.

Findings from a large, published epidemiology study have shown that the use of carbamazepine may affect the growth of your unborn baby during pregnancy.

Your doctor will discuss with you the potential risk of taking Tegretol during pregnancy.

Do not stop your treatment with Tegretol during without first checking with your doctor.

Breast-feeding

Tell your doctor if you are breast-feeding. The active ingredient in Tegretol passes into the breast milk. As long as your doctor agrees in your special case, and your child is closely watched for side effects, you may breast-feed your child. However, if side effects appear, e.g. if your baby gets very sleepy, stop breast-feeding and tell your doctor.

- Before you start to use it

If any of these apply to you, tell your doctor or pharmacist, or health care provider before 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.
- If you have or have had heart, liver or kidney disease in the past.
- If you have increased pressure in the eye (glaucoma) or if you have difficulty or pain when passing urine.
- If you were told by your physician that you suffer from a mental disorder called psychosis that may be accompanied by confusion or agitation.
- If you are a female of child-bearing age, you should use an effective method of contraception throughout your treatment and for 2 weeks after your last dose. If you are taking a 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 while you are taking Tegretol. If you have any questions about this, ask your doctor or health professional.

Taking Tegretol with food or drink
Do not drink alcohol when you are on 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.

Children (4 weeks of age or above) and adolescents (below 18 years) and older people (65 years of age or above)
Tegretol may be safely used in children 4 weeks of age or above and in elderly patients, keeping to the doctor's instructions. If necessary, special information will be given, such as on the need for careful dosage and close observation (see also sections "How to use Tegretol" and "Side Effects").

Important information about some of the ingredients of Tegretol
One mL of Tegretol oral suspension contains 175 mg of sorbitol. When taken according to the dosage recommendations, the maximum daily dose contains 17.5 g of sorbitol. Sorbitol may cause stomach upset and diarrhoea. Patients with rare hereditary problems of fructose intolerance should not take this medicine.
Tegretol oral suspension contains parahydroxybenzoates which may cause allergic reactions (possibly delayed).
One mL of Tegretol oral suspension contains 25 mg of propylene glycol. Tegretol oral suspension should not be used for babies less than 4 weeks of age, as the liver and kidney are not completely developed in these patients, thereby affecting the elimination of propylene glycol from the body.

- Taking other medicines
Tell your doctor or pharmacist or healthcare provider if you are taking, have recently taken any other medicines, including medicines obtained without a prescription because these might interact with Tegretol (carbamazepine). It is particularly important for Tegretol since many other medicines interact with it. For example:

- Anti-inflammatory drugs (ibuprofen)
- Antibiotics (erythromycin, clarithromycin, doxycycline)
- Anticoagulants (oral anticoagulants: warfarin, rivaroxaban, dabigatran)
- Antidrepressants (bupropion, fluoxetine, sertraline)
- Antiepileptics (stiripentol, valproic acid, vigabatrin, phenobarbital, phenytoin)
- Antifungals (azoles: itraconazole, ketoconazole, fluconazole, voriconazole)
- Antihistamines (terfenadine)
- Antipsychotics (olanzapine)
- Antituberculosis (isoniazid, rifampicin)
- Antivirals (ritonavir)
- Cardiovascular drugs (diltiazem, verapamil, statins)
- Corticosteroids (prednisolone)
- Dermatological drugs (isotretinoin)
- Diuretics (hydrochlorothiazide, furosemide)

You may need a change in your dose or, sometimes, to stop one of the medicines.
Hormonal contraceptives (birth control medicines) may become less effective during treatment with Tegretol, and you should consider using other effective contraceptive methods (non-hormonal).

How to use Tegretol
Always take this medicine exactly as your doctor has told you. Check with your doctor, or pharmacist, or healthcare provider if you are not sure. Do not exceed the recommended dose prescribed by your doctor. This will help you to get the best results and reduce the chance of serious side effects. Do not take extra unprescribed doses of Tegretol, do not take it more often, and do not take it for a longer time than your doctor tells you.
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.

- How much to use
Treatment of *epilepsy* with all forms of tablets and oral suspension is usually started at 100 to 200 mg once or twice a day in adults. The dosage is then gradually raised until – generally at 400mg 2 to 3 times daily. In some patients 1,600 mg or even 2,000 mg daily may be appropriate. The maximum dose of oral suspension is 1,200 mg (60 mL) a day.
For children's dose, please refer to the product insert for full information.

For *trigeminal neuralgia and glossopharyngeal neuralgia,* the starting dosage of 200 to 400 mg a day is slowly raised until there is no pain (usually 200 mg 3 to 4 times a day). The maximal dose is 1,200 mg a day. For elderly patients a lower starting dose, 100 mg twice a day, is recommended.

For *acute mania and maintenance treatment of bipolar affective disorders* the usual dosage is 400 to 600 mg a day (dosage range: about 400 to 1,600 mg a day). The maximum dose of oral suspension is 1,200 mg (60 mL) a day.
Your doctor will tell you exactly how many doses of Tegretol to take.

For *Alcohol-withdrawal syndrome*, the average dose is 200mg 3 times daily. In severe cases, it can be raised during the first few days (e.g. to 400 mg 3 times daily).

- When and how to use Tegretol
Tegretol is always (except possibly on the first day) given in divided daily doses, i.e. 2 to 4 times a day, depending on your medical condition. The dose prescribed by your doctor may be different from those listed above. In this case follow your doctor's instructions.
Take Tegretol during or after a meal. Swallow the tablets with some liquid; if necessary, the tablets may be broken in half along the line.

- How long to use Tegretol
Continue taking *Tegretol* for as long as your doctor recommends.

- If you forget to use Tegretol
If you forget to take a dose, take it as soon as possible. However, if it is almost time for your next dose, do not take the missed one; just go back to your regular dosing timetable. Do not

double the dose to make up for the forgotten dose.

- If you use more Tegretol than you should (overdose)

If you have accidentally taken too many tablets, talk to your doctor straight away. You may require medical attention.
If you experience difficulty in breathing, a fast and irregular heartbeat, loss of consciousness, fainting, shakiness, sickness and/or vomiting, your dose may be too high. Stop taking your medicine and inform your doctor without delay.

While you are using Tegretol

- Things you must do

It is very important that your doctor checks your progress at regular visits. He or she may want to take periodic blood tests, especially when you start taking Tegretol. This is quite usual and nothing to worry about.
Before having any kind of surgery, including dental or emergency treatment, tell the doctor in charge that you are taking Tegretol.

Tell your doctor or pharmacist, or healthcare provider immediately if you get any of these symptoms during treatment with Tegretol:

- If an allergic reaction happens, such as swelling of lips, eyelids, face, throat, mouth, or sudden breathing problems, fever with lymph nodes swelling, rash or skin blistering, tell your doctor immediately or go to the emergency department at your nearest hospital.
- If you experience an increase in the number of seizures.
- If you notice symptoms suggestive of hepatitis, such as jaundice (yellowing of skin and eyes).
- If at any time you have thoughts of harming or killing yourself. A small number of people being treated with antiepileptics have had such thoughts or behaviour.
- If you have kidney problems associated with low sodium blood level or if you have kidney problems and you are taking also certain medicines that lower sodium blood level (diuretics such as hydrochlorothiazide, furosemide).

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.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.
Do not take any new medicines without consulting your doctor.
Do not give product name to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

Tegretol may make you feel sleepy or dizzy or may cause blurred vision, double vision, or you may have a lack of muscular coordination especially when starting treatment or increasing the dose. You should therefore be careful when driving a vehicle, operating a machine or doing other activities requiring careful attention.

Side effects

As with all medicines, patients treated with Tegretol may experience side effects, although not everybody gets them.
Most of the side effects are mild to moderate and will generally disappear after a few days of treatment.

Some effects could be serious
and may affect up to 1 in every 1,000 people)

Check with your doctor immediately or make sure that someone else can do this for you if any of the following 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 salvation (signs of neuroleptic malignant syndrome).
- If you have irregular heartbeat, chest pain.
- If you have disturbed consciousness, fainting.
- If you have diarrhea, abdominal pain, and fever (signs of an inflammation of the colon). The frequency of this side effect is not known.
- If you experience a fall due to dizziness, drowsiness, decrease in blood pressure, confusion.

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:
Very common: *may affect more than 1 in 10 people*
- loss of muscle coordination, inflammation of the skin with itchy rash and redness, itchy rash.

Common: *may affect up to 1 in every 10 people*
- swelling of the ankles, feet or lower legs (oedema), changes in behavior, confusion, weakness, increase in seizures (fits, due to insufficient amount of sodium in your body).

Uncommon: *may affect up to 1 in every 100 people*
- trembling, uncontrolled body movements, muscle spasms,

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.

Very common: *may affect more than 1 in 10 people*
- vomiting, nausea, dizziness, sleepiness, unsteadiness, weight gain.

Common: *may affect up to 1 in every 10 people*
- headache, dry mouth.

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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my
[Public→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Tegretol
- *Storage*
- Keep out of the reach and sight of children.
- Do not use after the expiry date shown on the label of the package.
- Tegretol 200mg Tablet: Do not store above 30°C. Protect from moisture.
- Tegretol CR 200mg and 400mg: Store below 30°C. Protect from moisture
- Tegretol Syrup: Store below 30 °C and protect from light.
- Remember to take back any unused medicine to your pharmacist.

- *Disposal*
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description
- What it looks like
Tegretol 200mg Tablet:
White, round, flat, with bevelled edges. One side bears the imprint "CG", the other "GK" and a score.

Tegretol CR 200mg Tablets:
Beige-orange, oval, slightly biconvex coated tablets with a score on each side. One side bears the imprint "H/C", the other "C/G".

Tegretol CR 400mg Tablets:
Brownish-orange, oval, slightly biconvex coated tablets with a score on each side. One side bears the imprint "ENE/ENE", the other "CG/CG".

Tegretol 100MG/5ML Syrup:
Viscous suspension, white, caramel flavored.

- Ingredients:
- *Active ingredients*
- The active substance of Tegretol is carbamazepine.

- *Inactive ingredients*
- The other ingredients are:

Tablets
cellulose microcrystalline, magnesium stearate, silica, colloidal anhydrous, carmellose sodium, low substituted

CR tablets
silica, colloidal anhydrous/colloidal silicon dioxide; ethylcellulose aqueous dispersion; cellulose microcrystalline/microcrystalline cellulose; polyacrylate dispersion 30%; magnesium stearate; croscarmellose sodium; talc; water purified. Film coating: Hypromellose; talc; macrogolglycerol hydroxystearate/castor oil, polyoxyl 40 hydrogenated; pigment suspension yellow; pigment suspension red; pigment suspension white; water purified

Oral suspension
Microcrystalline cellulose and carmellose sodium/microcrystalline cellulose and carboxymethylcellulose sodium; caramel aroma 52929 A; methyl parahydoxybenzoate/methylparaben; hydroxyethylcellulose; propylene glycol; macrogol stearate; propyl parahydroxybenzoate/propylparaben; saccharin sodium; sorbic acid; sorbitol, liquid (noncrystallizing)/noncrystallizing sorbitol solution; water, purified.

- MAL Number:
Tegretol 200mg Tablet:
MAL20000032ARZ

Tegretol CR 200mg Tablets:
MAL20000749ARZ

Tegretol CR 400mg Tablets:
MAL20000269ARZ

Tegretol 100MG/5ML Syrup:
MAL20001250ACRZ

Manufacturer
Tegretol 200mg, CR 200mg & CR 400mg
Novartis Farma S.P.A., Via Provinciale Schito 131, 80058 Torre Annunziata, Italy

Tegretol 100mg/5ml Syrup
Delpharm Huningue S.A.S,
26 Rue De La Chapelle,
68330, France

Product Registration Holder
Novartis Corporation (Malaysia) Sdn. Bhd.
Level 18, Imazium,
No. 8, Jalan SS21/37,

Damansara Uptown,
47400 Petaling Jaya,
Selangor

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