

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

BIO-CARBAMAZEPINE 200 tablets

Carbamazepine

Sugar free.

Read all of this leaflet carefully before you start taking BIO-CARBAMAZEPINE 200.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- BIO-CARBAMAZEPINE 200 has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What BIO-CARBAMAZEPINE 200 is and what it is used for
2. What you need to know before you take BIO-CARBAMAZEPINE 200
3. How to take BIO-CARBAMAZEPINE 200
4. Possible side effects
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1. What BIO-CARBAMAZEPINE 200 is and what it is used for

Carbamazepine, the active ingredient in BIO-CARBAMAZEPINE 200, can affect the body in several different ways. It is an anti-convulsant medicine (prevents fits). It can also modify some types of pain.

BIO-CARBAMAZEPINE 200 is used:

- To treat some forms of epilepsy.
- To treat a painful condition of the face called trigeminal neuralgia.
- To treat a painful condition occurring in the back of the throat, tongue and ear called idiopathic glossopharyngeal neuralgia.

2. What you need to know before you take BIO-CARBAMAZEPINE 200

Do not take BIO-CARBAMAZEPINE 200:

- If you are allergic (hypersensitive) to carbamazepine, similar medicines such as tricyclic antidepressants (used to treat mood disorders) or to any of the other ingredients of BIO-CARBAMAZEPINE 200 (listed in section 6).
- If you have ever had problems with your bone marrow.
- If you have a heart problem called heart block.
- If you have taken medicines called monoamine oxidase inhibitors (MAOIs), used to treat depression, within the last 14 days.
- If you have a blood disorder called porphyria.
- If you are breastfeeding (see **Pregnancy and breastfeeding**).
- If you have a history of one of the following severe skin conditions:
 - Stevens-Johnson syndrome (SJS)
 - toxic epidermal necrolysis (TEN).

If you are not sure if any of the above applies to you, please talk to your doctor.

Warnings and precautions

Talk to your doctor or pharmacist or pharmacist before taking BIO-CARBAMAZEPINE 200

- A small number of people being treated with anti-epileptics such as BIO-CARBAMAZEPINE 200 have had thoughts of harming or killing themselves. If at any time you have these

thoughts, immediately contact your doctor.

- Serious skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported with the use of BIO-CARBAMAZEPINE 200 (see section 4). These serious skin reactions can be more common in people from some Asian countries. The risk of these reactions in patients of Han Chinese or Thai origin 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 BIO-CARBAMAZEPINE 200.
- If you develop a rash or these skin symptoms, stop taking BIO-CARBAMAZEPINE 200 and contact your doctor immediately.
- If you experience dizziness, drowsiness, decrease in blood pressure, confusion, due to BIO-CARBAMAZEPINE 200 treatment, this may lead to falls.
- Your doctor may want you to have a number of blood tests before you start taking BIO-CARBAMAZEPINE 200 and from time to time during your treatment. This is quite usual and nothing to worry about

Talk to your doctor before taking BIO-CARBAMAZEPINE if any of the following applies to you. BIO-CARBAMAZEPINE 200 might not be the right medicine for you.

- You pregnant or planning to become pregnant.
- You suffer from the sort of epilepsy where you get mixed seizures which include absences.
- You have any mental illness.
- You allergic to an epilepsy medicine called phenytoin, primidone or phenobarbital.
- You have liver problems.
- You have kidney problems associated with low sodium blood level or you have kidney problems and you are taking certain medicines called diuretics that lower sodium blood levels (such as hydrochlorothiazide, furosemide).
- You are an elderly person.
- You have eye problems such as glaucoma (increased pressure in the eye) or you have difficulty retaining your urine.

Other medicines and BIO-CARBAMAZEPINE 200

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell the doctor if you are taking:

- Hormone contraceptives, e.g. pills, patches, injections or implants.

BIO-CARBAMAZEPINE 200 affects the way the contraceptive works in your body, and you may get breakthrough bleeding or spotting. It may also make the contraceptive less effective and there will be a risk of getting pregnant.

Your doctor will be able to advise you about this, and you should think about using other contraceptives.

- Hormone replacement therapy (HRT). BIO-CARBAMAZEPINE 200 can make thyroid replacement therapy less effective.
- Medicines for depression or anxiety such as desipramine, fluoxetine, fluvoxamine, nefazodone, paroxetine, trazodone, bupropion, citalopram, mianserin, tricyclic antidepressants (e.g. imipramine, amitriptyline, nortriptyline, clomipramine).
- Corticosteroids ('steroids') such as prednisolone, dexamethasone. You might be taking these for inflammatory conditions such as asthma, inflammatory bowel disease, muscle and joint pains.
- Anticoagulants to stop your blood clotting (e.g. warfarin, acenocoumarol, rivaroxaban, dabigatran, apixaban and edoxaban).
- Antibiotics to treat infections including skin infections, TB (e.g. isoniazid, rifampicin) and other medicines such as erythromycin, clarithromycin, ciprofloxacin, doxycycline and rifabutin.
- Antifungals to treat fungal infections (e.g. itraconazole, ketoconazole, fluconazole, voriconazole).
- Painkillers containing paracetamol, tramadol, methadone or buprenorphine.
- Other medicines to treat epilepsy such as stiripentol, vigabatrin, felbamate, methsuximide,

oxcarbazepine, phenobarbital, phensuximide, phenytoin, primidone, clonazepam, clobazam, ethosuximide, lamotrigine, eslicarbazepine, tiagabine, topiramate, valproic acid, zonisamide.

- Medicines for high blood pressure such as diltiazem, verapamil, calcium channel blockers (dihydropyridine group) e.g. felodipine, digoxin, simvastatin, atorvastatin, lovastatin, cerivastatin, ivabradine.
- Antihistamines (medicines to treat allergy such as hay fever, itch, etc) such as loratadine.
- Diuretics (water tablets) such as hydrochlorothiazide, furosemide.
- Medicines to treat gastric ulcers (cimetidine or omeprazole).
- A medicine for the treatment of acne (isotretinoin).
- Anti-sickness medicines (metoclopramide or aprepitant).
- A medicine to treat glaucoma - increased pressure in the eye (acetazolamide).
- Medicines for endometriosis (danazol).
- Medicines used in the treatment of asthma (theophylline or aminophylline).
- Immunosuppressants, used after transplant operations, but also sometimes in the treatment of arthritis or psoriasis (ciclosporin, tacrolimus or sirolimus).
- Medicines to treat schizophrenia (e.g. paliperidone, aripiprazole).
- Cancer medicines (e.g. temsirolimus, cyclophosphamide, lapatinib).
- Medicines to treat HIV (ritonavir, indinavir, saquinavir).
- Medicines used to treat hypothyroidism (levothyroxine).
- A medicine used to treat impotence (tadalafil).
- A medicine used to treat worms (praziquantel, albendazole).
- A medicine used to help stop smoking (bupropion).
- A herbal remedy called St John's wort (*Hypericum perforatum*).
- Medicines or supplements containing nicotinamide (vitamin B3).

BIO-CARBAMAZEPINE 200 with food and drink

- Drinking alcohol may affect you more than usual. It is recommended not to drink alcohol while taking BIO-CARBAMAZEPINE 200.

- Eating grapefruit, or drinking grapefruit juice, may increase your chance of experiencing side effects.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

You must discuss your epilepsy treatment with your doctor well before you become pregnant. If you do get pregnant while you're taking BIO-CARBAMAZEPINE 200 you must tell the doctor immediately. It is important that your epilepsy remains well controlled, but, as with other anti-epilepsy treatments, there is a risk of harm to the foetus. The risk will be weighed against the benefit by the doctor.

Women of childbearing potential should be advised to use alternative contraceptive methods while on treatment with carbamazepine and for 2 weeks following the last dose.

Do not take BIO-CARBAMAZEPINE 200 if you are breastfeeding.

Driving and using machines

BIO-CARBAMAZEPINE 200 can make you feel dizzy or drowsy, or may cause blurred vision, or you may have a lack of muscular coordination, especially at the start of treatment or when the dose is changed. If you are affected in this way, or if your eyesight is affected, you should not drive or operate machinery.

3. How to take BIO-CARBAMAZEPINE 200

Do not share medicines prescribed for you with any other person.

Always take BIO-CARBAMAZEPINE 200 exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

To treat epilepsy the usual doses are:

Adults: 800 – 1 200 mg a day, although higher doses may be necessary. If you are elderly, you might

require a lower dose.

Children:

Aged up to 1 year: 100 – 200 mg a day.

Aged 1 – 5 years: 200 – 400 mg a day.

Aged 5 – 10 years: 400 – 600 mg a day.

Aged 10 – 15 years: 600 – 1 000 mg a day.

To treat trigeminal neuralgia the usual dose is: 400 – 800 mg a day. The maximum dose is 1 600 mg a day. If you are elderly, you might require a lower dose.

Your doctor will tell you how long your treatment with BIO-CARBAMAZEPINE 200 will last. Do not stop treatment early because it may cause your condition to worsen.

If you have the impression that the effect of BIO-CARBAMAZEPINE 200 is too strong or too weak, talk to your doctor or pharmacist.

If you take more BIO-CARBAMAZEPINE 200 than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Take this leaflet and any remaining tablets with you, so that your doctor knows what you have taken.

If you forget to take BIO-CARBAMAZEPINE 200

If you forget to take a dose, take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose and then go on as before. Do not take two dosages at the same time.

4. Possible side effects

BIO-CARBAMAZEPINE 200 can have side effects.

Not all side effects reported for BIO-CARBAMAZEPINE 200 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BIO-CARBAMAZEPINE 200, please consult your health care provider for advice.

If any of the following happens, stop taking BIO-CARBAMAZEPINE 200 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to BIO-CARBAMAZEPINE 200. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Mouth ulcers or unexplained bruising or bleeding.
- Sore throat or fever-high temperature, or both.
- Jaundice (yellowing of the skin and eyes, dark urine, and tiredness), which may be symptoms of liver problems.
- Swollen ankles, feet or lower legs (oedema).
- Any signs of nervous illness (depression, restlessness, agitation, aggression) or confusion.
- Lupus erythematosus (pain in your joints and muscles, a rash across the bridge of the nose and cheeks and problems with breathing).
- multi-organ sensitivity disorder (fever, skin rash, joint pain, and abnormalities in blood and liver function tests).
- abdominal pain (pain in the area near the stomach).
- you experience a fall due to dizziness, drowsiness, decrease in blood pressure, confusion.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

The following side effects have been reported frequently:

- Leucopenia (a reduced number of the cells which fight infection making it easier to catch infections).
- Dizziness and tiredness.
- Feeling unsteady or finding it difficult to control movements.
- Feeling sick (nausea) or being sick (vomiting).
- Changes in liver enzyme levels (usually without any symptoms).
- Skin reactions which may be severe.
- Changes in the blood including an increased tendency to bruise or bleed.
- Fluid retention and swelling.
- Increase in body weight.
- Low sodium in the blood which might result in confusion.
- Headache.
- Blurred vision or other vision problems.
- Dry mouth and throat.

The following side effects have been reported less frequently:

- Abnormal involuntary movements including tremor or tics.
- Abnormal eye movements.
- Constipation or diarrhoea.
- Disease of the lymph glands.
- Folic acid deficiency.
- Hallucinations.
- Loss of appetite.
- Speech disorders.
- Numbness or tingling in the hands and feet.

- Muscle weakness.
- High blood pressure (which may make you feel dizzy, with a flushed face, headache, fatigue and nervousness).
- Low blood pressure (the symptoms of which are feeling faint, light-headed, dizzy, confused, having blurred vision).
- Changes to your heartbeat.
- Changes to the composition of the blood including anaemia.
- Porphyria (severe abdominal pain, red urine, severe constipation or hallucinations).
- Meningitis (an infection that causes inflammation in the brain).
- Swelling of the breasts and discharge of milk which may occur in both male and females.
- Abnormal thyroid function tests.
- Osteomalacia (softening of the bones).
- Osteoporosis (medical condition in which the bones become brittle and fragile).
- Increased blood fat levels (cholesterol).
- Taste disturbances.
- Conjunctivitis (pink eye).
- Eye disorders such as glaucoma.
- Hearing disorders.
- Heart and circulatory problems including deep vein thrombosis (DVT), the symptoms of which could include tenderness, pain, swelling, warmth, skin discoloration and prominent superficial veins.
- Lung or breathing problems.
- Severe skin reactions including Stevens-Johnson syndrome (these reactions may be more frequent in patients of Chinese or Thai origin). Frequently, the rash can involve ulcers of the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes).

These serious skin rashes are often preceded by influenza-like symptoms fever, headache, body ache (flu-like symptoms). The rash may progress to widespread blistering and peeling of the skin. The highest risk for occurrence of serious skin reactions is within the first months of

treatment.

- Sore tongue.
- Liver failure.
- Increased sensitivity of the skin to sunlight.
- Alterations in skin pigmentation.
- Acne.
- Excessive sweating.
- Hair loss.
- Increased hair growth on the body and face.
- Muscle weakness, pain or spasm.
- Sexual difficulties which may include reduced male fertility, loss of libido or impotence.
- Kidney failure.
- Blood spots in the urine.
- Increased or decreased desire to pass urine or difficulty in passing urine.

The following have also been reported, but the frequency cannot be estimated from the available information:

- Severe skin reactions, accompanied by feeling unwell and changes in blood results.
- Diarrhoea, abdominal pain, and fever (signs of inflammation of colon).
- Reactivation of herpes virus infection (can be serious when immune system is depressed).
- Complete loss of nails.
- Fracture.
- Decrease in the measure of the bone density.
- Slower reaction times and impaired performance in activities (sedation).
- Memory loss.
- Purple or reddish-purple bumps that may be itchy.

There have been reports of bone disorders including osteopenia and osteoporosis (thinning of the

bone) and fractures. Check with your doctor or pharmacist if you are on long-term antiepileptic medicines, have a history of osteoporosis, or take steroids.

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

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of BIO-CARBAMAZEPINE 200.

5. How to store BIO-CARBAMAZEPINE 200

- Store all medicines out of reach of children.
- Store at or below 25 °C. Keep well closed and protect from moisture.
- Do not store in your bathroom, to limit the contact with moisture in the surrounding air.
- Do not take your tablets after the expiry date stated on the container or outer carton.
- Please return all unused or expired medicines to your pharmacist and do not dispose of these medicines in drains or sewerage systems (via wastewater or household waste).

6. Contents of the pack and other information

What BIO-CARBAMAZEPINE 200 contains

Each tablet contains 200 mg carbamazepine.

The other ingredients are ammonium methacrylate copolymer (Eudragit RS 30D), croscarmellose sodium, diethyl phthalate, magnesium stearate, maize starch and microcrystalline cellulose.

What BIO-CARBAMAZEPINE 200 looks like and contents of the pack:

White, flat, round bevelled edge tablet. One side of the tablet is scored. The other side is engraved TARO 11.

BIO-CARBAMAZEPINE 200 is supplied in white, round plastic bottles in packs of 100.

Holder of the certificate of registration

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