

Approved Patient Information Leaflet for Medicines for Human Use:

CARBAMAZEPINE 200 AUSTELL

SCHEDULING STATUS: S3

CARBAMAZEPINE 200 AUSTELL 200 mg tablets

Carbamazepine

Sugar Free

Read all of this leaflet carefully before you start taking CARBAMAZEPINE 200 AUSTELL

- 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.
- CARBAMAZEPINE 200 AUSTELL 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 CARBAMAZEPINE 200 AUSTELL is and what it is used for
2. What you need to know before you take CARBAMAZEPINE 200 AUSTELL
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1. What CARBAMAZEPINE 200 AUSTELL is and what it is used for

CARBAMAZEPINE 200 AUSTELL contains the active substance carbamazepine.

Carbamazepine is an anti-epileptic, neurotropic and psychotropic medicine. It is used as an anti-convulsant medicine (prevents fits), it can also modify some types of pain and can control mood disorders.

CARBAMAZEPINE 200 AUSTELL is used for the treatment of

- Some forms of epilepsy
- A painful condition of the face called trigeminal neuralgia
- To help control serious mood disorders when some other medicines do not work

2. What you need to know before you take CARBAMAZEPINE 200 AUSTELL

Do not take CARBAMAZEPINE 200 AUSTELL

- If you are hypersensitive (allergic) to carbamazepine or any of the other ingredients of CARBAMAZEPINE 200 AUSTELL (listed in section 6).
- If you have any heart problems
- If you ever had problems with your bone marrow
- If you have a blood disorder called porphyria
- If you have taken medicines called monoamine-oxidase inhibitors (MAOIs) within last 2 weeks.
- If you previously suffered from Stevens-Johnson syndrome (SJS) or toxic epidermal necrolysis (TEN).
- If you are breastfeeding or intend to breastfeed

Warnings and precautions

Take special care with CARBAMAZEPINE 200 AUSTELL:

- If you are pregnant or planning to have a baby
- If you suffer from epilepsy (fits)

- If you suffer from a mental illness
- If you have liver problems
- If you have kidney problems
- If you have any eye problems called glaucoma (increased pressure in the eye)
- If you have problems urinating

A small number of people being treated with anti-epileptics such as carbamazepine 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 carbamazepine. 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.

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 carbamazepine.

Other medicines and CARBAMAZEPINE 200 AUSTELL

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

Tell your doctor if you are taking any of the following medicines:

- Hormone contraceptives, e.g. pills, patches, injections or implants. Carbamazepine 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). CARBAMAZEPINE 200 AUSTELL can make HRT less effective.
- Any medicines for depression or anxiety.
- Corticosteroids ('steroids'). You might be taking these medicines for inflammatory conditions such as asthma, inflammatory bowel disease, muscle and joint pains.
- Anticoagulants to stop your blood clotting.
- Antibiotics to treat infections including skin infections and TB (e.g. ciprofloxacin).
- Antifungals to treat fungal infections.
- Painkillers containing paracetamol, dextropropoxyphene, tramadol, methadone or buprenorphine.
- Other medicines to treat epilepsy.
- Medicines for high blood pressure or heart problems.
- Antihistamines (medicines to treat allergy such as hayfever, itch, etc).
- Diuretics (water tablets).
- Cimetidine or omeprazole (medicines to treat gastric ulcers).
- Isotretinoin (a medicine for the treatment of acne).
- Metoclopramide or aprepitant (anti-sickness medications).
- Acetazolamide (a medicine to treat glaucoma - increased pressure in the eye).
- Danazol or gestrinone (treatments for endometriosis).
- Theophylline or aminophylline (used in the treatment of asthma).

- Ciclosporin, tacrolimus or sirolimus (immunosuppressants used after transplant operations but also sometimes in the treatment of arthritis or psoriasis).
- Medicines to treat schizophrenia (e.g. paliperidone, aripiprazole).
- Cancer medicines (e.g. temsirolimus, cyclophosphamide, lapatinib).
- The anti-malarial medicine, mefloquine.
- Medicines to treat HIV.
- Levothyroxine (used to treat hypothyroidism).
- Tadalafil (used to treat impotence).
- Albendazole (used to treat worms).
- Bupropion (used to help stop smoking).
- A herbal remedy called St John's Wort or Hypericum.
- Medicines or supplements containing Vitamin B (nicotinamide).

CARBAMAZEPINE 200 AUSTELL with food and, drink and alcohol

You may take CARBAMAZEPINE 200 AUSTELL with or without food.

You should not drink alcohol while you are taking CARBAMAZEPINE 200 AUSTELL.

Pregnancy and breastfeeding and fertility

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.

Driving and using machines

CARBAMAZEPINE 200 AUSTELL can make you feel dizzy or drowsy, or may cause blurred vision, double 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 CARBAMAZEPINE 200 AUSTELL

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

Always take CARBAMAZEPINE 200 AUSTELL exactly as your doctor or pharmacist has instructed you. Check with your doctor or pharmacist if you are not sure.

Dose for Epilepsy

For Adults:

Take one (1) tablet once or twice a day.

Your doctor may tell you to increase your dose to two (2) tablets twice or three (3) times a day.

For some patients, your doctor may tell you to increase your dose to eight (8) tablets.

Dose for Trigeminal neuralgia

Take one (1) to two (2) tablets once or twice a day until you don't feel pain.

Your doctor may tell you to increase your dose to two (2) tablets twice or three (3) times a day.

For some patients, your doctor may tell you to increase your dose to eight (8) tablets.

Dose for Acute mania and maintenance treatment of (bipolar) affective disorders

Take two (2) to four (4) tablets once or twice a day.

Your doctor may tell you to increase your dose to two (2) tablets twice or three (3) times a day.

Method of administration

CARBAMAZEPINE 200 AUSTELL is for oral administration.

It may be taken with or without food.

Duration of administration

Your Health care provider will tell you how long your treatment with CARBAMAZEPINE 200 AUSTELL will last. If you have the impression that the effect of CARBAMAZEPINE 200 AUSTELL is too strong or too weak, tell your Health care provider.

If you take more CARBAMAZEPINE 200 AUSTELL than you should

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

If you forget to take CARBAMAZEPINE 200 AUSTELL

If you forget to take a dose, leave that dose out completely. Take your next dose at the right time and continue as before. Do not take a double dose to make up for forgotten individual doses.

If you stop taking CARBAMAZEPINE 200 AUSTELL

Suddenly stopping your treatment with CARBAMAZEPINE 200 AUSTELL may cause seizures. Do not stop taking your medicine unless your doctor tells you to.

4. Possible side effects

CARBAMAZEPINE 200 AUSTELL can have side effects.

Not all side effects reported for CARBAMAZEPINE 200 AUSTELL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while

taking CARBAMAZEPINE 200 AUSTELL, please consult your health care provider for advice.

If any of the following happens, stop taking CARBAMAZEPINE 200 AUSTELL 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
- Mouth ulcers or unexplained bruising or bleeding
- Sore throat or high temperature, or both
- Yellowing of your skin or the whites of your eyes
- Swollen ankles, feet or lower legs
- Any signs of nervous illness or confusion
- Pain in your joints and muscles, a rash across the bridge of the nose and cheeks and problems with breathing (these may be the signs of a rare reaction known as lupus erythematosus)
- Fever, skin rash, joint pain, and abnormalities in blood and liver function tests (these may be the signs of a multi-organ sensitivity disorder)
- Bronchospasm with wheezing and coughing, difficulty in breathing, feeling faint, rash, itching or facial swelling (these may be the signs of a severe allergic reaction)
- Pain in the area near the stomach
- You experience a fall due to dizziness, drowsiness, decrease in blood pressure, confusion.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- a low level of white blood cells which fight infections making it easier to get infections (leucopenia).
- a low number of cells (platelets) in the blood causing bruising or prolonged bleeding after injury (thrombocytopenia).
- skin rash accompanied with high number of a type of white blood cells called eosinophils (eosinophilia).
- dizziness and tiredness, feeling unsteady or finding it difficult to control movements, feeling or being sick.
- fluid retention and swelling, weight increase, low sodium in the blood which might result in confusion, headache, double or blurred vision, dry mouth.
- skin reactions which may be severe.
- changes in liver enzyme levels, feeling overtired and weak.

Less frequent side effects:

- disease of the lymph glands, changes to the levels of white and red blood cells and the composition of blood including anaemia. These changes may lead to getting infections, headache, tiredness and weakness.
- generalised allergic reaction including rash, swelling, joint pain, fever, problems with the kidneys, liver, lungs and other organs.
- swelling of the breasts and discharge of milk which may occur in both male and females.
- folic acid deficiency, porphyria, hallucinations, depression, loss of appetite, restlessness, aggression, agitation, confusion and slurred speech.
- abnormal involuntary movements including tremor or tics, abnormal eye movements, numbness or tingling in the hands and feet, muscle weakness, meningitis and altered taste.

- inflammation or infection of the eye, cataracts.
- hearing disorders, e.g. ringing in the ears.
- 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.
- changes in heart beat; 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).
- lung problems that may cause fever or difficulty breathing.
- diarrhoea, constipation, stomach pain, pancreas problems (which may cause feeling bloated, fat in the stool, pain in the back and vomiting.)
- liver problems including jaundice (yellowing of the skin and the whites of the eyes.)
- symptoms of lupus (an inflammation disease caused when the immune system attacks itself) which may include fever, muscle pain and rash.
- severe skin reactions such as Stevens-Johnson syndrome which includes fever, sore mouth, tongue and throat with a rash, that develops quickly, and possibly blistering of the skin, mouth, genitals and anal regions.
- increased sensitivity of the skin to sunlight, alterations in skin pigmentation (darkened patches or spots on the skin), acne, excessive sweating, hair loss, increased hair growth on the body and face.
- osteomalacia (which may be noticed as pain on walking and bowing of the bones in the legs), osteoporosis (bones become weak and brittle), joint pain, muscle pain or spasm.
- kidney failure which may cause blood spots in the urine, increased or decreased need to pass urine or difficulty in passing urine.

- sexual difficulties which may include reduced male fertility, loss of libido or impotence.
- abnormal thyroid function tests, increased levels of fat in the blood.

Side effects with frequency unknown:

- reactivation of herpes virus infection (can be serious when immune system is depressed).
- Drug Rash with Eosinophilia and Systemic Symptoms (DRESS) which is characterised by a rash with purple or reddish-purple bumps that may be itchy accompanied by feeling unwell and changes in blood results.
- Acute Generalized Exanthematous Pustulosis (AGEP) which is a skin eruption that is characterised by the rapid appearance of areas of red skin studded with small blisters filled with white/yellow fluid.
- shedding of the nails, scaly spots or patches on the skin.
- falling down, drowsiness, memory loss.
- diarrhoea, abdominal pain, and fever (signs of inflammation of the colon)
- fracture, decrease in the measure of the bone density.

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 or nurse. 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 CARBAMAZEPINE 200 AUSTELL.

5. How to store CARBAMAZEPINE 200 AUSTELL

- Store all medicines out of reach of children
- Store at or below 25 °C.
- Store in the original package.
- Keep the blisters in the outer carton
- There are no special storage instructions for CARBAMAZEPINE 200 AUSTELL.
- Do not use after the expiry date stated on the label / carton

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What CARBAMAZEPINE 200 AUSTELL contains

- The active substance is carbamazepine. Each tablet contains 200 mg of carbamazepine.
- The other ingredients are Partially Pregelatinized Maize Starch, FD & C Red 40, Crosscarmellose Sodium, Colloidal Silicon dioxide, Magnesium Stearate

What CARBAMAZEPINE 200 AUSTELL looks like and contents of the pack

CARBAMAZEPINE 200 AUSTELL is supplied in PVDC coated rigid PVC/PE laminate and Aluminum lid foil blisters strips.

Blisters are packed into a cardboard cartons of 28, 56, 84 or 100 tablets.

CARBAMAZEPINE 200 AUSTELL is a pink colored capsule shaped, 13,60 mm X 5,5 mm biconvex, uncoated tablets, debossed 'CAR' on one side and '200' on the partially scored side.

Holder of Certificate of Registration

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