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Applicant: AUROGEN SA (PTY) LTD
Proprietary name: CARBAMAZEPINE 200 /400 mg AURO
Carbamazepine 200/400 PH.EUR and Prolonged released tablet

1.3.2.2
Application no.: 59420.418/
59421.419
Date: 14 JULY 2026

PATIENT INFORMATION LEAFLET SCHEDULING STATUS

S4

PATIENT INFORMATION LEAFLET

CARBAMAZEPINE 200 mg AURO Film-coated tablets

CARBAMAZEPINE 400 mg AURO Film-coated tablets

Carbamazepine

Sugar Free

Read all of this leaflet carefully before you start taking CARBAMAZEPINE AURO

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse or other healthcare provider.
- **CARBAMAZEPINE AURO** 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 AURO** is and what it is used for.
2. What you need to know before you use **CARBAMAZEPINE AURO**.
3. How to use **CARBAMAZEPINE AURO**.
4. Possible side effects.
5. How to store **CARBAMAZEPINE AURO**.
6. Contents of the pack and other information.



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1. What CARBAMAZEPINE AURO is and what it is used for

The active substance of **CARBAMAZEPINE AURO** is carbamazepine.

CARBAMAZEPINE AURO belongs to a group of medicines called antiepileptics (medicine for seizures).

CARBAMAZEPINE AURO 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') as well as certain psychiatric conditions (mania episodes of bipolar mood disorders and a certain type of depression).

2. What you need to know before you take CARBAMAZEPINE AURO

Do not take CARBAMAZEPINE AURO:

- If you are hypersensitive (allergic) to carbamazepine or any of the other ingredients of **CARBAMAZEPINE AURO**: (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

Special care should be taken with **CARBAMAZEPINE AURO**:

- If you are pregnant or planning to have a baby



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- If you have or have had heart, liver or kidney disease in the past.
- If you develop any blood cell related problems (e.g. decrease in white blood cells that fight off infection or low platelets that cause easy bruising). These may also result in sore throat, rash, mouth sores and/or fever and you must see your doctor immediately.
- If you were told by your doctor that you suffer from any mental disorders such as psychosis, in the past, which may cause you to become confused and anxious.
- If you have increased eye pressure (glaucoma) or if you have difficulty or pain passing urine.
- If you have any problems with your thyroid.
- If you are a female of childbearing age, you should use an effective method of contraception throughout your treatment and for at least two weeks after your last dose. Birth control pills/tablets may not be as effective method of contraception while taking **CARBAMAZEPINE AURO**, therefore different or additional contraception methods need to be used such as condoms.
- Use of **CARBAMAZEPINE AURO** can make you feel dizzy, drowsy and confused and possibly lead to increased risk of falling.
- If you have any thoughts of harming or killing yourself, contact your doctor immediately as a small number of people taking **CARBAMAZEPINE AURO** may experience this.
- Do not stop taking **CARBAMAZEPINE AURO** without first asking your doctor. As this may cause your condition (seizures) to become worse.
- If you develop a rash or skin problems, stop taking **CARBAMAZEPINE AURO** and contact your doctor immediately or go to the nearest casualty/hospital.
- These reactions may be more frequent in patients from some Asian countries (e.g. Taiwan, Malaysia and the Philippines) and in patients with Chinese ancestry due to genetic factors.
- If you are a patient with a genetically at-risk population (populations for example, patients of the Japanese and Caucasian populations, patients who belong to the indigenous populations



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of the Americas, Hispanic populations, people of southern India, and people of Arabic descent), consider testing for the presence of HLA-A*3101.

Before starting you on [PRODUCT NAME] your doctor should consider testing for the presence of HLA-B*1502 allele if you have ancestry in genetically at-risk populations.

- If you experience more seizures (fits)

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 AURO**.

Taking other medicines with CARBAMAZEPINE AURO:

Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines). See

Do not take **CARBAMAZEPINE AURO**.

- 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.



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- Hormone Replacement Therapy (HRT) – oestrogens and progesterones.

CARBAMAZEPINE AURO can make HRT less effective.

- Medicines for depression or anxiety e.g. olanzapine.
- Corticosteroids ('steroids') e.g. prednisolone, dexamethasone. 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 e.g. warfarin, acenocoumarol, rivaroxaban, dabigatran, apixaban and edoxaban.
- Antibiotics to treat infections including skin infections and TB (e.g. ciprofloxacin).
- Antifungals to treat fungal infections e.g. itraconazole, voriconazole.
- Painkillers containing paracetamol, dextropropoxyphene, tramadol, methadone or buprenorphine.
- Other medicines to treat epilepsy e.g. stiripentol, vigabatrin .
- Medicines for high blood pressure or heart problems e.g. felodipine, digoxin, simvastatin, atorvastatin, lovastatin, cerivastatin, ivabradine.
- Antihistamines (medicines to treat allergy such as hayfever, itch, etc) e.g. loratadine
- Diuretics (water tablets) e.g. hydrochlorothiazide, furosemide.
- 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).



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- Cancer medicines (e.g. temsirolimus, cyclophosphamide, lapatinib).
- Medicines to treat HIV e.g. ritonavir
- 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).
- Muscle relaxants such as oxybutynin, dantrolene
- When you take **CARBAMAZEPINE AURO** and isoniazid (used to treat tuberculosis) there can be an increase in isoniazid in the blood which may lead to liver problems.
- Medicines called platelet aggregation inhibitors – used to prevent platelets from clumping together as they may cause increase in blood clots. E.g. ticlopidine
- Taking lithium (for treatment of mental conditions) and [PRODUCT NAME] can cause more problems nervous system related side effects such as confusion, anxiety etc.
- **CARBAMAZEPINE AURO** use may decrease the effects of muscle relaxants (e.g. pancuronium) so the dosage may need to be adjusted/increased at the advice of your doctor.

CARBAMAZEPINE AURO with alcohol

Do not drink alcohol when you are on **CARBAMAZEPINE AURO**.

Do not drink grapefruit juice or eat grapefruit since this can increase the effect of

CARBAMAZEPINE AURO. Other juices, like orange juice or apple juice, do not have this effect.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby,



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please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

It is important to control epileptic seizures during pregnancy. However, there is a possible risk to your baby if you take antiepileptic medication (medicine for seizures) including

CARBAMAZEPINE AURO 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 medicines during pregnancy.

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

Do not stop your treatment with **CARBAMAZEPINE AURO** during pregnancy without first checking with your doctor.

Breastfeeding

Tell your doctor if you are breastfeeding. The active ingredient in **CARBAMAZEPINE AURO** passes into the breast milk. Mothers on **CARBAMAZEPINE AURO** should not breastfeed their infants.

Women of child-bearing potential

You should use an effective method of contraception throughout your treatment with **CARBAMAZEPINE AURO** and for 2 weeks after the last dose. Irregularity of the menstrual period may occur in women taking hormonal contraceptives (birth control medicines) and **CARBAMAZEPINE AURO**.

The hormonal contraceptive may become less effective, and you should consider using a different or additional non-hormonal contraceptive method.



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Driving and using machines

CARBAMAZEPINE AURO 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 AURO

For Adults:

Treatment is usually started at 100 mg of **CARBAMAZEPINE AURO** (which is half of the 200 mg tablet)) to 200 mg once or twice a day, this can be slowly increased to 400 mg twice or three times a day.

In some cases, 1600 mg (4 tablets of 400 mg or 8 tablets of 200 mg) in 3 to 4 divided doses may be needed.

Dose for Trigeminal neuralgia

Treatment is usually started at 200 mg to 400 mg of **CARBAMAZEPINE AURO** and is slowly increased until there is no more pain (usually 200 mg tablets taken 3 to 4 times a day). For older patients, a lower starting dose is needed, 100 mg (half of 200 mg tablet) taken twice a day.

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

Treatment is usually started at 400 mg to 600 mg and can be increased up to 1600 mg (4 tablets of 400 mg or 8 tablets of 200 mg) taken over the course of 2 - 3 times a day.

Method of administration

CARBAMAZEPINE AURO is for oral administration. It may be taken with or without food.

Duration of administration



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Your healthcare provider will tell you how long your treatment with **CARBAMAZEPINE AURO** will last. If you have the impression that the effect of **CARBAMAZEPINE AURO** is too strong or too weak, tell your doctor or pharmacist.

If you take more CARBAMAZEPINE AURO 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 AURO

Take the tablet as soon as you remember. Take the next tablet of **CARBAMAZEPINE AURO** at the usual time and then continue as normal.

Do not take a double dose to make up for forgotten individual doses.

If you are not sure what to do or have missed more than one dose, ask your doctor, pharmacist or other healthcare provider.

4. Possible side effects

CARBAMAZEPINE AURO can have side effects:

Not all side effects reported for **CARBAMAZEPINE AURO** are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking **CARBAMAZEPINE AURO**, please consult your health care provider for advice.

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

- 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.



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- 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.
- 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 all very serious side effects. If you have them, you may have had a serious allergic reaction to **CARBAMAZEPINE AURO**. 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:

Frequent side effects



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- 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, sleepiness, 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.



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- 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.)
- increased sensitivity of the skin to sunlight, alterations in skin pigmentation (darkened patches or spot 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
- Neuroleptic malignant syndrome (high fever, muscle stiffness, confusion)
- Inflammation and soreness of the mouth, tongue and/or lips

Side effects with frequency unknown:

- reactivation of herpes virus infection (can be serious when immune system is depressed).
- 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.



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- 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, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of this

CARBAMAZEPINE AURO.

5. How to store CARBAMAZEPINE AURO

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 25 °C. Keep it in a dry place.

Do not use after expiry date stated on the label.

Keep the blisters in the carton until required for use.

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 AURO contains

The active substance is carbamazepine.



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The content of the capsules is Cellulose Microcrystalline

Magnesium stearate, Silica Colloidal Anhydrous Ethyl Cellulose

Croscarmellose Sodium Silica Colloidal Anhydrous

Talc and magnesium Stearate

WHAT CARBAMAZEPINE AURO LOOKS LIKE AND CONTENTS OF THE PACK

CARBAMAZEPINE AURO capsules are available in the following containers:

Blister strips (PVC/foil) containing, 30 capsules.

Not all pack sizes may be marketed.

CARBAMAZEPINE 200 mg AURO: White to off white film coated approximately 12.5 X 5.8 mm oval shaped biconvex tablets, debossed with "C and 2" separated by score line on both sides.

CARBAMAZEPINE 400 mg AURO: White to off white film coated approximately 17.5 X 7.0 mm oval shaped biconvex tablets, debossed with "C and 4" separated by score line on both sides.

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

AUROGEN SA (Pty) Ltd

Woodhill Office Park, Building 1, First Floor

53 Phillip Engelbrecht Avenue

Meyersdal, Ext. 12, 1448

Johannesburg

South Africa



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REGISTRATION NUMBERS:

CARBAMAZEPINE 200 mg AURO: 59/2.5/420.418

CARBAMAZEPINE 400 mg AURO: 59/2.5/421.419

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14 July 2026

