Patient Information Leaflet

SCHEDULING STATUS **S3**

ZECARB 200 TABLETS

Carbamazepine 200 mg per tablet

Sugar free

Read this full leaflet carefully before you start taking ZECARB 200.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other health care provider.
- ZECARB 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 ZECARB 200 is and what it is used for.
2. What you need to know before you take ZECARB 200.
3. How to take ZECARB 200
4. Possible side effects that you may experience.
5. How to store ZECARB 200 .
6. Contents of the pack and other information.

1. What ZECARB 200 is and what it is used for.

ZECARB 200 is indicated for use in patients with generalised tonic-clonic and both simple and complex partial seizures.

ZECARB 200 is also used in the treatment of trigeminal neuralglia.

Epilepsy with motor and psychic manifestations:

- psychomotor or temporal-lobe epilepsy
- generalised tonic-clonic seizure
- mixed forms of seizures complex or simple partial seizures (with or without loss of consciousness) with or without secondary generalisation
- complex or simple partial seizures (with or without loss of consciousness) with or without secondary generalisation.

Acute mania and maintenance treatment of bipolar affective disorders to prevent or attenuate recurrence. Idiopathic trigeminal neuralgia. Idiopathic glossopharyngeal neuralgia. It is suitable for both monotherapy and combination therapy. It is usually not effective in absences (petit mal) and myoclonic seizures.

2. What you need to know before you take ZECARB 200.

Do not take ZECARB 200

- If you are hypersensitivity(allergic) to carbamazepine or any of the ingredients of ZECARB 200 (listed in section 6)
- Patients with atrioventricular conduction abnormalities unless paced.
- Should not be given to patients with liver damage.

Warnings and precautions

Tell your doctor or health care provider before being given the tablets:

Special care should be taken with ZECARB 200 if you suffer from the following

- with raised intra-ocular pressure
- patients with a history of blood disorders or of cardiac, hepatic or renal disease.

Children and adolescents

Suggested daily doses for children:

Up to 1 year of age: 100 to 200 mg

1 to 5 years: 200 to 400 mg

5 to 10 years: 400 to 600 mg

10 to 15 years: 600 mg to 1 g

Since carbamazepine has no long plasma half-life, a twice daily dosage regimen is usually adequate to maintain an effective plasma concentration.

Other medicines and ZECARB 200

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

Carbamazepine should not be given to patients taking a monoamine oxidase inhibitor or within 14 days of stopping such treatment.

Carbamazepine is extensively bound to plasma proteins and is therefore susceptible to interactions with medicines liable to compete for similar binding sites.

Carbamazepine is an enzyme inducer and induces its own metabolism as well as that of a number of other medicines, including some antibiotics, anticoagulants, and sex hormones (notably, oral contraceptives).

Carbamazepine and phenytoin may also mutually enhance one another’s metabolism. The metabolism of Carbamazepine is similarly enhanced by enzyme inducers such as phenobarbitone.

Pregnancy, breastfeeding and fertility

Pregnancy and lactation

In woman of childbearing age, anticonvulsant therapy should wherever possible prescribed as monotherapy. If pregnancy occurs in a woman receiving carbamazepine,

the potential benefits if therapy must be carefully weighed against its possible hazards, particularly in the first three months of pregnancy.

Driving and using machines

Drowsiness and dizziness, especially at initiation of therapy. Patients must be warned against driving or performing tasks where loss of concentration may lead to accidents.

3. How to take ZECARB 200

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

ZECARB 200 is for oral administration. It may be taken with or without food.

Your health care provider will tell you how long your treatment with ZECARB 200 will last.
If you have the impression that the effect of ZECARB 200 is too strong or too weak, tell your health care provider.
If you take more ZECARB 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.

If you forget to use ZECARB 200

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 ZECARB 200

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

Possible side effects

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

If any of the following happens, stop receiving ZECARB 200 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth, or throat which may cause difficulty in swallowing or breathing, rash or itching

These are all very serious side effects. If you have them, you may have had a serious reaction to ZECARB 200. 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 heartbeat; 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, lightheaded, 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 include fever, sore mouth, tongue and throat with a rash, that develop 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 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.

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, pharmacist or nurse. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reactions 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 ZECARB 200

4. How to store ZECARB 200

- Store all medicines out of reach of children.
- Store at or below 25 °C
- Protect from light

- Store in the original package in order to protect from moisture

Return all unused medicine to your pharmacist.

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

5. Contents of the pack and other information

What ZECARB 200 contains

- The active substance is carbamazepine 200 mg per tablet.
- The other ingredients are nitrogen, sodium chloride, sodium metabisulphite 0,1 % *m/v* as anti-oxidant, water for injection.

What ZECARB 200 looks like and contents of the pack

White to off-white, round, biconvex, uncoated tablets plain on both the sides.

ZECARB 200 tablets are available in unit cartons containing 9 x 10 (90's), 6 x 14 (84’s), 4 x 14 (56’s) or 2 x 14 (28's) aluminium foil strip packs

Holder of Certificate of Registration

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Access to the corresponding Professional Information

To follow