PATIENT INFORMATION LEAFLET

Read the entire leaflet carefully before you start using Gulf Carbamazepine 200

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

SCHEDULING STATUS: S3

NAME OF MEDICINE:

GULF CARBAMAZEPINE 200

WHAT GULF CARBAMAZEPINE 200 CONTAINS:

Active ingredient: Each tablet contains 200 mg carbamazepine

Inactive ingredients: Starch, sodium starch glycollate, gelatin, silicon dioxide, magnesium stearate

WHAT GULF CARBAMAZEPINE 200 IS USED FOR:

Gulf Carbamazepine 200 tablets are used for the treatment of various types of epilepsy (fits).

BEFORE YOU TAKE GULF CARBAMAZEPINE 200:

Do not take Gulf Carbamazepine 200 if:

- you are hypersensitive/allergic or ever had a harmful reaction to carbamazepine, tricyclic anti-depressants or any of the inactive ingredients of **Gulf Carbamazepine 200**
- you suffer from heart rhythm problems
- you have ever had problems with your bone marrow
- you have a disorder called porphyria
- you are currently using monoamine oxidase inhibitors (a type of anti-depressant) or have stopped using them over the last 14 days
- you are pregnant or breastfeeding

Take special care with Gulf Carbamazepine 200:

- If you suffer from any blood disorders

- if you suffer from any liver or kidney impairment
- if you consume alcohol
- Gulf Carbamazepine 200 may cause you to experience confusion, especially if you are elderly
- If you have an eye condition called glaucoma (raised pressure in the eye)
- If you develop any skin reactions while taking Gulf Carbamazepine 200 you should contact your doctor immediately.
- If you are using oral contraceptives (see "Pregnancy and breastfeeding" below)

Using Gulf Carbamazepine 200 with food and drink:

Gulf Carbamazepine 200 should be taken during or after meals with a little liquid. The tablets should not be chewed.

Pregnancy and Breastfeeding:

Gulf Carbamazepine 200 should not be taken if you are pregnant or breastfeeding.

If you become pregnant or breastfeeding your baby while taking Gulf Carbamazepine 200 consult your doctor, pharmacist or other health care professional for advice.

If Gulf Carbamazepine 200 is taken by a pregnant mother then there is a possibility of the infant suffering from developmental disorders and malformations of the body.

Driving and using machinery:

You may feel dizzy while using Gulf Carbamazepine 200. This is more likely when you start treatment or if your treatment is changed and when you drink alcohol. If this happens to you then do not drive or use any tools or machinery.

USING OTHER MEDICINES WITH GULF CARBAMAZEPINE 200:

Tell your doctor if you are using:

- Hormone contraceptives, e.g. pills, patches, injections or implants. Gulf 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 forms of contraception.
- Any medicines for depression or anxiety

- Corticosteroids ('steroids'). You might be taking these for inflammatory conditions such as asthma, inflammatory bowel disease, muscle and joint pains.
- Anticoagulants (warfarin) to stop your blood clotting
- Antibiotics to treat infections including skin infections and TB
- Antifungals to treat fungal infections
- Painkillers containing paracetamol, tramadol, or methadone
- 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 (medication for nausea)
- Acetazolamide (a medicine to treat glaucoma - increased pressure in the eye)
- Theophylline or aminophylline (used in the treatment of asthma)
- Ciclosporin (an immunosuppressant, used after transplant operations, but also sometimes in the treatment of arthritis or psoriasis)
- Medicines to treat schizophrenia
- Cancer medication
- Medicines to treat HIV
- Levothyroxine (used to treat hypothyroidism)
- Muscle relaxants
- A herbal remedy called St John's Wort or hypericum
- Medicines or supplements containing Vitamin B (nicotinamide)

If you are taking medicines on a regular basis, including complementary or traditional medicines and other medicines bought over the counter, the use of Gulf Carbamazepine 200 with another medicine may cause undesirable interactions. Please consult your doctor,

pharmacist or other health care professional for advice.

HOW TO USE GULF CARBAMAZEPINE 200:

Your doctor will tell you how many tablets to take and when to take them. Always follow his/her instructions carefully. The dose will be on the label of the container given to you. Check the label carefully. It is important to take the tablets at the right times. If you are not sure, ask your doctor or pharmacist. Keep taking your tablets for as long as you have been told, unless you have any problems. In that case, check with your doctor.

Your doctor will usually start Gulf Carbamazepine 200 at a fairly low dose which can then be increased to suit you individually. The dose needed varies between patients. You can take Gulf Carbamazepine 200 during, after or between meals. Swallow the tablets with a drink. You are usually told to take a dose two or three times a day. If necessary you may break the tablets in half along the scored line.

Do not share medicines prescribed for you with others.

IF YOU TAKE MORE GULF CARBAMAZEPINE 200 THAN YOU SHOULD:

Overdosage could cause disorientation, agitation, hallucination, difficulty in breathing, vomiting, fluid retention, faster heart beat

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

If you forget to take Gulf Carbamazepine 200:

Take it as soon as you remember. However if it is nearly time to take your next dose, skip the missed dose and go back to your normal dosing schedule.

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

Effects when treatment with Gulf Carbamazepine 200 is stopped:

Do not stop your treatment with **Gulf Carbamazepine 200** suddenly, as it may cause withdrawal symptoms.

POSSIBLE SIDE-EFFECTS:

Tell your doctor straight away if you notice the following:

- Skin rash or peeling, mouth ulcers or unexplained bruising or bleeding
- Sore throat or high temperature, or both
- Yellowing of your skin or the whites of your eyes (jaundice)
- Swollen ankles, feet or lower legs (oedema)
- 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)
- Stomach ache

The following side-effects occur frequently with use of Gulf Carbamazepine 200:

Drowsiness and sleepiness. Speak to your doctor if you notice more or extreme drowsiness/sleepiness during the course of the day.

Dizziness, blurred vision, headaches, hallucination, confusion (more likely in elderly patients)

Trouble with sleeping, tiredness, fatigue, restlessness or difficulty in moving

If they carry on, are severe or bother you, speak to you doctor or pharmacist. Do not stop treatment.

Not all side-effects reported for Gulf Carbamazepine 200 are included in this leaflet. Should your general health worsen while taking Gulf Carbamazepine 200, please consult your doctor, pharmacist or other health care professional for advice.

STORAGE AND DISPOSAL INFORMATION:

Store at or below 25 °C in a cool, dry place. Do not remove blisters from unit carton until required for use. Protect from light and moisture. Keep the HDPE containers tightly closed.

Keep all medicines in a safe place, out of reach of children.

Return all unused or expired medicines to your pharmacist.

PRESENTATION:

Push through clear PVC/silver Al blister strips in a pack of 28, 30 or 100 tablets in a printed unit carton.

White HDPE containers of 30, 100, 500 or 1000 tablets

IDENTIFICATION OF THE MEDICINE:

White, round flat tablet with a central break-line on one side

REGISTRATION NUMBER:

43/2.5/0840

THE NAME AND THE BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Gulf Drug Company (Pty) Ltd

22 Burnside Drive

Old Mill Industrial Park

Mount Edgecombe, 4300

DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:

27/07/2012