PATIENT INFORMATION LEAFLET

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **PARTID-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.
- This leaflet provides a summary about **PARTID-200** and does not include everything there is to know about your medicine. This information does not take the place of talking with your healthcare provider about your medical condition or treatment.

SCHEDULING STATUS: S3

PROPRIETARY NAME (and dosage form):

PARTID-200 (tablets)

1. WHAT PARTID-200 CONTAINS:

- The active substance is carbamazepine 200 mg per tablet.
- The other ingredients are microcrystalline cellulose, carmellose sodium, colloidal silicon dioxide, purified talc, magnesium stearate and sodium starch glycollate.

2. WHAT IS PARTID-200 USED FOR:

PARTID-200 is used to treat some forms of epilepsy (psychomotor or temporal-lobe epilepsy, generalized tonic-clonic seizures, mixed forms of seizures and simple or complex partial seizures), trigeminal neuralgia (a painful condition of the face), mania and bipolar

affective disorders. It is not effective in atypical or generalized absence seizures (petit mal) or myoclonic seizures.

3. BEFORE YOU TAKE PARTID-200:

Do not take PARTID-200:

- If you know you are allergic to carbamazepine, or tricyclic antidepressants, or any of the ingredients.
- You have abnormal conduction of heart.
- You have a history of not producing normal blood cells.
- You have Porphyria (a disorder of blood pigments)
- You are or have taken medicines used to treat depression, within the last 14 days.

Take special care with PARTID-200 if:

- You think you might be pregnant, are planning to become pregnant or become pregnant while taking Partid-200. It is important that your epilepsy remains well controlled, but there is a risk of harm to the foetus.
- You have or have ever had problems with your bone marrow. You must contact your doctor immediately should you get a fever, sore throat, mouth ulcers, rash, or unexplained or easy bruising of the skin.
- You have or have had liver problems. You must contact your doctor if you develop jaundice.
- You get an allergic reaction or severe skin reaction (i.e. widespread rash with blisters and peeling skin; particularly around the eyes, nose, mouth and genitals or extensive peeling of the skin) which may develop into more serious problems if not treated. You must contact your doctor immediately if you get a skin rash.
- You are of Asian ancestry and have been tested previously for carrying the genetic variant HLA-B*1502, discuss this with your doctor before taking **PARTID-200**.
- You have or have had any heart or kidney problems.

- You suffer from the sort of epilepsy where you get mixed seizures which include absences.
- You have any mental illness.
- You have any eye problems such as glaucoma (increased pressure in the eye).
- You are taking hormone contraceptives. **PARTID-200** affects the way contraceptives work in the body, and you may get breakthrough bleeding and 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. You should think about using alternative birth control.

Pregnancy and Breast-feeding:

You must discuss your epilepsy treatment with your doctor well before you become pregnant. If you do get pregnant while you're taking **PARTID-200** you must tell the doctor straightaway. It is important that your epilepsy remains well controlled, but as with other anti-epilepsy treatments, there is a risk of harm to your baby. Make sure you are very clear about the risks and the benefits of taking **PARTID-200**.

If you are pregnant or breast feeding your baby while taking PARTID-200, please consult your doctor, pharmacist or other health care professional for advice.

Driving and using machinery:

PARTID-200 can make you feel dizzy or drowsy, 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.

Taking other medicines with PARTID-200:

Be aware that if you are taking the following medicines they may increase the amount of **PARTID-200** in your body and cause side effects to occur:

- Isoniazid (used to treat tuberculosis).

- Verapamil and diltiazem medicines (used to treat chest pain and abnormal heart rhythms).
- Dextropropoxyphene (used to treat pain).
- Viloxazine, fluoxetine, fluvoxamine, desipramine and nefazodone,(used to treat depression).
- Cimetidine (used to treat gastric ulcers).
- Acetazolamide (used to treat glaucoma).
- Danazol (used to treat endometriosis).
- Nicotinamide (Vitamin B containing supplements).
- Macrolide antibiotics e.g. erythromycin, troleandomycin, josamycin, clarithromycin (used to treat various infections).
- Azoles, e.g. itraconazole, miconazole, ketoconazole, fluconazole (used to treat fungal infections).
- Antihistamines e.g. loratadine (used to treat itching).
- Valproic acid and valpromide used for seizures.
- Clobazam (used to treat anxiety disorders).
- Isotretinoin (used to treat acne).

There are medicines that may decrease the amount of **PARTID-200** in your body and will not treat your seizures appropriately:

- Phenobarbitone, clonazepam, felbamate, clonazepam, ethosuximide, primidone, methosuximide, phensuximide, lamotrigine, zonisamide, tiagabine, topiramate and phenytoin medicines (used to treat seizures).
- Theophylline (used to relief airway narrowing in asthma).
- Rifampicin (used to treat tuberculosis).
- Cisplatin, cyclosporine and doxorubicin medicines (used to treat cancer).

- Alprazolam (used to treat anxiety).
- Corticosteroids (used to treat inflammatory conditions such as asthma, inflammatory bowel disease).
- Prednisolone, dexamethasone (used for muscle and joint pains).
- Doxycycline (used to treat different types of infections).
- Felodipine (used to treat high blood pressure).
- Imipramine, methadone (used to relieve severe pain).
- Oral contraceptives.
- Oral anticoagulants e.g. warfarin, phenprocoumon, dicoumarol (to stop blood clotting).
- Imipramine, amitryptiline, nortriptyline, clomipramine and clozapine, medicines (used to treat depression)
- A herbal remedy called *St. John's Wort* (used to treat depression).
- Phenytoin (used to treat fits / seizures).It may alter the amount of **PARTID-200** in your body.

PARTID-200 may increase or decrease the effects of other medicines that are used concurrently e.g.:

- Folic acid. Your body will require more folic acid.
- Paracetamol (used as a pain killer). The effect of the paracetamol will be less than it should.
- Isoniazid (used to treat tuberculosis). It may cause the isoniazid to have liver problems.
- Lithium (used to treat depression), metoclopramide (used to treat heartburn), or neuroleptics - haloperidol, thioridazine (used to treat psychotic disorders). It may cause central nervous system effects.

- Hydrochlorothiazide or furosemide, diuretics (water tablets). It may cause low levels of sodium in the blood.
- Pancuronium, (used as muscle relaxants). It may cause neuromuscular blockage.
- Alcohol. It may worsen the central nervous system effects caused by the **PARTID-200**.

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of PARTID-200 with these medicines may cause undesirable interactions. Tell your doctor or pharmacist if you are taking any other medicines, including any you have bought at your pharmacy, supermarket or health food shop. Please consult your doctor, pharmacist or other healthcare professional for advice.

4. HOW TO TAKE PARTID-200:

Always take **PARTID-200** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

- The usual dose for adults is an initial dose of 100 mg to 200 mg once or twice daily is recommended which may be gradually increased to a usual maintenance dose of 800 mg to 1200 mg daily in divided doses. Doses up to 1600 mg daily in divided doses may occasionally be necessary.
- For patients with epilepsy, a low initial dose is recommended, which should be adjusted until the optimum dosage to achieve adequate control of seizures.
- For children 5 years and older, therapy may begin with 100 mg daily, increasing at weekly intervals by 100 mg. A maintenance dosage of 10 to 20 mg/kg bodyweight daily in divided doses is recommended.
  - Children aged 5 years should be given 200 to 400 mg daily.
  - Children aged 6 to 10 years should be given 400 to 600 mg daily.
  - Children aged 11 to 15 years should be given 600 to 1000 mg daily.

- For patients with Trigeminal neuralgia, an initial dose of 200 to 400 mg should be given and gradually increased as necessary until pain is relieved. Doses up to 1600 mg daily in divided doses may be required. When pain relief has been achieved, then dosage should be gradually reduced to the minimum effective dose.
- For the elderly and particularly sensitive patients, an initial dosage of 100 mg twice daily is recommended.
- When the patient is transferred from another anticonvulsant to **PARTID-200**, the dosage of the first should be reduced gradually.
- If you have the impression that the effect of **PARTID-200** is too strong or too weak, talk to your doctor or pharmacist.
- Do not chew the tablets.
- Always take **PARTID-200** during or after meals with a little liquid.

If you take more PARTID-200 than you should:

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 PARTID-200:

If you miss a dose of **PARTID-200**, take it as soon as you remember. Wait and take the next dose at the regular time. Do not take double dose to make up for forgotten individual doses.

5. POSSIBLE SIDE EFFECTS:

PARTID-200 can have side effects. The following list of

side effects is not complete. Report any new or continuing symptoms to your healthcare provider. If you have questions about side effects, ask your healthcare provider. Your healthcare provider may be able to help you manage these side effects.

PARTID-200 may cause the following side effects:

- *Frequent*: Dizziness; drowsiness; tiredness; headache; double or blurred vision; allergic skin reactions where itching may be severe; leucopenia (a reduced number of the cells which fight infection making it easier to catch infections); nausea; vomiting; dryness of the mouth; fluid retention; weight increase; low levels of sodium in the blood and changes in liver enzyme levels.
- *Less frequent*: feeling unsteady or finding it difficult to control movements; abnormal involuntary movements including tremor or tics abnormal eye movements; speech disorders (e.g. slurred speech); disease of the lymph glands; folic acid deficiency; a generalised allergic reaction including rash, joint pain, fever, problems with the kidneys and other organs; hallucinations; depression; loss of appetite; restlessness; aggression; agitation; confusion; 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 heart beat; stomach pain; liver problems including jaundice; symptoms of lupus; changes to the composition of the blood including anaemia; porphyria; meningitis; osteomalacia (which may be noticed as pain on walking and bowing of the long bones in the legs); swelling of the breasts and discharge of milk which may occur in both male and females; abnormal thyroid function tests; taste disturbances; conjunctivitis; glaucoma; hearing disorders; heart and circulatory problems; 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, sore mouth or 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 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.

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

6. STORING AND DISPOSING OF PARTID-200:

- Store below 25 ºC.
- Protect from light.
- Keep all medicines out of the reach and sight of children.
- Do not use **PARTID-200** after the expiry date printed on the label or carton.
- Do not store **PARTID-200** in a damp place such as a bathroom medicine cabinet or near the kitchen sink.
- Store in the original strip or container.
- Keep the container tightly closed.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused **PARTID-200** in drains or toilets.

General information about PARTID-200.

PARTID-200 was prescribed for your particular condition. Do not use **PARTID-200** for another condition. Do not give **PARTID-200** to other people, even if they have the same symptoms you have. It may harm them.

Keep PARTID-200 and all medicines out of the reach of children and pets.

This summary does not include everything there is to know about **PARTID-200**

7. PRESENTATION:

PARTID-200 comes in silver bioxilary oriented polypropylene patient ready packs containing 15 or 84 tablets.

PARTID-200 also comes in clear transparent PVC/aluminium foil blister strips containing 28, 50, 56, 84 or 100 tablets, and finally in milky-white high-density polyethylene containers containing 100 tablets.

8. IDENTIFICATION:

White to off white, biconvex, circular, uncoated tablet.

9. REGISTRATION NUMBER:

PARTID-200: 37/2.5/0482

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Oethmaan Biosims (Pty) Ltd

Office 207A, 1st floor, Sherwood House,

Greenacres Office Park,

Cnr Victory & Rustenburg Roads,

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11. DATE OF PUBLICATION:

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