# PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS:** S3

**PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:**

GLIMEPIRIDE 1 OETHMAAN tablets (each tablet contains 1 mg glimepiride)

GLIMEPIRIDE 2 OETHMAAN tablets (each tablet contains 2 mg glimepiride)

GLIMEPIRIDE 4 OETHMAAN tablets (each tablet contains 4 mg glimepiride)

**Please read this leaflet carefully before taking GLIMEPIRIDE 1, 2, AND 4 OETHMAAN tablets**.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- GLIMEPIRIDE 1, 2, AND 4 OETHMAAN 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.

## 1. WHAT GLIMEPIRIDE 1, 2, AND 4 OETHMAAN CONTAINS:

Active ingredient: Glimepiride

Inactive ingredients: Iron oxide, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone and sodium starch glycollate.

## 2. WHAT GLIMEPIRIDE 1, 2, AND 4 OETHMAAN IS USED FOR:

Glimepiride act by stimulating your pancreas to increase the insulin secretion, resulting in reduced plasma glucose levels.

GLIMEPIRIDE 1, 2, AND 4 OETHMAAN is indicated as adjunctive therapy to diet and exercise in the treatment and control of type 2 diabetes (previously known as non-insulin-dependent diabetes mellitus, or NIDDM).

Remember that you and your health care professional must always try to first control your diabetes through changes in diet and level of physical activity before using any medication.

## 3. BEFORE YOU TAKE GLIMEPIRIDE 1, 2, AND 4 OETHMAAN

### Do not take GLIMEPIRIDE 1, 2, AND 4 OETHMAAN:

- If you are hypersensitive (allergic) to glimepiride or any of the other ingredients of GLIMEPIRIDE 1, 2, AND 4 OETHMAAN.
- If you are pregnant or breast-feeding.
- If you suffer from Type 1 diabetes (previously known as insulin-dependent diabetes mellitus, or IDDM).
- If you suffer from liver problems.
- GLIMEPIRIDE 1, 2, AND 4 OETHMAAN must not be given to children.
- If you have ketoacidosis.
- If you suffer from severe infection or trauma.

### Take special care with GLIMEPIRIDE 1, 2, AND 4 OETHMAAN: Do not take GLIMEPIRIDE 1, 2, AND 4 OETHMAAN:

- Tell your doctor if you suffer from heart disease, congestive heart failure or angina pectoris. Your doctor will decide whether you may use GLIMEPIRIDE 1, 2, AND 4 OETHMAAN.
- Tell your doctor if you suffer from kidney function impairment.
- Tell your doctor if you suffer from thyroid problems.
- This type of medicine may cause hypoglycaemia (very low blood glucose levels). Symptoms of hypoglycaemia are anxiety, behavioural change similar to drunkenness, blurred vision, cold sweats,

cool pale skin, difficulty in concentrating, drowsiness, excessive hunger, fast heartbeat, headache, nausea, nervousness, nightmares, restless sleep, slurred speech, and unusual tiredness or weakness.

*Hypoglycaemia is more likely to occur if you are an elderly person, if you have irregular or missed mealtimes, if you have intense and prolonged exercise or if you use alcohol.* If symptoms of hypoglycaemia occur, try to eat glucose tablets, corn syrup, honey or sugar cubes or drink fruit juice, non-diet soft drink, or sugar dissolved in water. Eat a small snack, such as crackers or a half sandwich when scheduled meal is longer than one hour away. Do not eat foods high in fat, such as chocolate.

**Pregnancy and breast-feeding:**

If you are pregnant or breast feeding your baby while taking GLIMEPIRIDE 1, 2, AND 4 OETHMAAN, please consult your doctor, pharmacist or other health care professional for advice. The safety of GLIMEPIRIDE 1, 2, AND 4 OETHMAAN in pregnant and breast-feeding women has not yet been established.

**Driving and using machinery:**

Your ability to concentrate and react may be reduced as a result of visual problems. Do not drive or operate machines after taking GLIMEPIRIDE 1, 2, AND 4 OETHMAAN.

**Important information about some of the ingredients of GLIMEPIRIDE 1, 2, AND 4 OETHMAAN:**

GLIMEPIRIDE 1, 2, AND 4 OETHMAAN tablets contain lactose (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking

GLIMEPIRIDE 1, 2, AND 4 OETHMAAN.

**Using other medicines with GLIMEPIRIDE 1, 2, AND 4 OETHMAAN:**

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of GLIMEPIRIDE 1, 2, AND 4 OETHMAAN 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.

Numerous interactions have been reported with GLIMEPIRIDE 1, 2, AND 4 OETHMAAN

Concurrent use of certain medication, such as corticosteroids, oral contraceptives, and thiazide diuretics may cause GLIMEPIRIDE 1, 2, AND 4 OETHMAAN to be less effective.

The hypoglycaemic effect of GLIMEPIRIDE 1, 2, AND 4 OETHMAAN may be increased when the following medicines are simultaneously administered: ACE inhibitors (prescribed for high blood pressure), allopurinol (treatment for gout), certain analgesics, medicines used to treat fungal infections, certain antibiotics, cimetidine, coumarin anticoagulants, heparin, certain antidepressants (MAOI's and tricyclic antidepressants), ranitidine and thyroid hormones.

Beta blockers may mask the typical sympathetic warning signs of hypoglycaemia.

Do not take alcohol and GLIMEPIRIDE 1, 2, AND 4 OETHMAAN simultaneously. You may experience side effects such as facial flushing.

## 4. HOW TO TAKE GLIMEPIRIDE 1, 2, AND 4 OETHMAAN

Always take GLIMEPIRIDE 1, 2, AND 4 OETHMAAN Exactly as your doctor has instructed you. You should check with your doctor if you are unsure. If you have the impression that the effect of

GLIMEPIRIDE 1, 2, AND 4 OETHMAAN is too strong or too weak, talk to your doctor or pharmacist.

**Initial dose:** The usual initial dose is 1 mg GLIMEPIRIDE 1 OETHMAAN once a day with breakfast or the first main meal.

**Maintenance dose:** Your doctor will decide what is the optimum maintenance dose based on your blood glucose response. The usual maintenance dose is 1 to 4 mg once daily.

Do not take more than 8 mg once a day.

If you are an elderly person or suffer from kidney impairment, you must take an initial dose of 1 mg once a day.

Your doctor may combine GLIMEPIRIDE 1, 2, AND 4 OETHMAAN with other medicines to control your blood glucose levels.

**If you take more GLIMEPIRIDE 1, 2, AND 4 OETHMAAN 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 GLIMEPIRIDE 1, 2, AND 4 OETHMAAN:**

Do not take a double or larger dose to make up for the forgotten individual doses. Continue to take the next tablet at the usual time.

If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.

## 5. POSSIBLE SIDE EFFECTS

GLIMEPIRIDE 1, 2, AND 4 OETHMAAN can have side effects. Not all side effects reported for GLIMEPIRIDE 1, 2, AND 4 OETHMAAN are included in this leaflet. Should your general health worsen while taking GLIMEPIRIDE 1, 2, AND 4 OETHMAAN, please consult your doctor, pharmacist or other health care professional for advice.

Less frequently, GLIMEPIRIDE 1, 2, AND 4 OETHMAAN may cause the following side effects: diarrhoea, dizziness, stomach pain, headache, nausea, unusual tiredness or weakness, or vomiting.

Contact your doctor if you experience the following:

- Hypoglycaemia. Symptoms are anxiety, behavioural change similar to drunkenness, blurred vision, cold sweats, cool pale skin, difficulty in concentrating, drowsiness, excessive hunger, fast heartbeat, headache, nausea, nervousness, nightmares, restless sleep, slurred speech, unusual tiredness or weakness.
- Allergic skin reactions including itchiness, redness of skin and hives.
- Changes in your vision.

## 6. STORING AND DISPOSING OF GLIMEPIRIDE 1, 2, AND 4 OETHMAAN

- Keep well closed and store in a dry place below 30 °C.
- KEEP ALL MEDICINES OUT OF REACH OF CHILDREN
- Do not use the tablets after the expiry date printed on the carton and blister.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

## 7. PRESENTATION OF GLIMEPIRIDE 1, 2, AND 4 OETHMAAN

GLIMEPIRIDE 1 OETHMAAN: Transparent or white opaque PVC/Aluminium foil blisters containing 10 tablets each.

3 (10) blister strips to be packed into a carton i.e. 30 tablets per carton or 10 (10) blister strips to be packed into a carton i.e. 100 tablets per carton or 28 tablets packed in a blister to be packed in a carton.

GLIMEPIRIDE 2 OETHMAAN: Transparent or white opaque PVC/Aluminium foil blisters containing 10 tablets each.

3 (10) blister strips to be packed into a carton i.e. 30 tablets per carton or 10 (10) blister strips to be packed into a carton i.e. 100 tablets per carton or 28 tablets packed in a blister to be packed in a carton.

GLIMEPIRIDE 4 OETHMAAN: Transparent or white opaque PVC/Aluminium foil blisters containing 10 tablets each.

3 (10) blister strips to be packed into a carton i.e. 30 tablets per carton or 10 (10) blister strips to be packed into a carton i.e. 100 tablets per carton or 28 tablets packed in a blister to be packed in a carton.

## 8. IDENTIFICATION OF GLIMEPIRIDE 1, 2, AND 4 OETHMAAN

GLIMEPIRIDE 1 OETHMAAN: Light red, flat, modified oblong, scored tablet, encoded G/1 on one side.

GLIMEPIRIDE 2 OETHMAAN: Light green, flat, modified oblong, scored tablet, encoded G/2 on one side.

GLIMEPIRIDE 4 OETHMAAN: Light blue, flat, modified oblong, scored tablet, encoded G/4 on one side.

**9. REGISTRATION NUMBER:**

GLIMEPIRIDE 1 OETHMAAN: 39/21.2/0023

GLIMEPIRIDE 2 OETHMAAN: 39/21.2/0024

GLIMEPIRIDE 4 OETHMAAN: 39/21.2/0025

**10. NAME AND ADDRESS OF REGISTRATION HOLDER:**

**Oethmaan Biosims (Pty) Ltd.**

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**11. DATE OF PUBLICATION:**

21 June 2013