AMENDED PROPOSED PATIENT INFORMATION LEAFLET (CLEAN COPY)

SCHEDULING STATUS:

S3

ACCORD GLIMEPIRIDE 1 mg (tablets)

ACCORD GLIMEPIRIDE 2 mg (tablets)

ACCORD GLIMEPIRIDE 4 mg (tablets)

Glimepiride

Contains sugar (lactose monohydrate):

Each 1 mg tablet contains 78,4 mg lactose monohydrate.

Each 2 mg tablet contains 156,8 mg lactose monohydrate.

Each 4 mg tablet contains 154,8 mg lactose monohydrate.

Read all of this leaflet carefully before you start taking ACCORD GLIMEPIRIDE

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **ACCORD GLIMEPIRIDE** 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 **ACCORD GLIMEPIRIDE** is and what it is used for
2. What you need to know before you take **ACCORD GLIMEPIRIDE**
3. How to take **ACCORD GLIMEPIRIDE**
4. Possible side effects
5. How to store **ACCORD GLIMEPIRIDE**

6. Contents of the pack and other information

1. WHAT ACCORD GLIMEPIRIDE IS AND WHAT IT IS USED FOR

ACCORD GLIMEPIRIDE belongs to a group of medicines called sulphonylureas. It promotes the release of insulin from the pancreas, which consequently lowers blood sugar levels in your body.

This medicine is used:

- In combination with diet and exercise, to lower your blood sugar levels, if you have Type 2 diabetes mellitus (high blood sugar levels) and diet and exercise alone have failed to adequately reduce your blood sugar level.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ACCORD GLIMEPIRIDE

Do not take ACCORD GLIMEPIRIDE:

- if you are allergic (hypersensitive) to glimepiride, sulphonylureas, other sulphonamides or any of the other ingredients of **ACCORD GLIMEPIRIDE** (see section 6)
- if you are pregnant or if you are breastfeeding (see **Pregnancy and Breastfeeding**)
- if you have decreased liver function
- if you have moderate to severe decreased renal (kidney) function
- **ACCORD GLIMEPIRIDE** is not recommended for use in children.
- **ACCORD GLIMEPIRIDE** is not recommended for use in the treatment of insulin-dependent (Type1) diabetes mellitus.

Warnings and precautions

Take special care with ACCORD GLIMEPIRIDE:

Before you take this treatment, you should tell your doctor if you have or have had any medical problems such as:

- Type 1 diabetes mellitus (insulin dependent diabetes)
- Heart conditions
- Decreased liver function
- Decreased kidney function

- If you have a condition called G6PD deficiency (a genetic disorder which affects the red blood cells)

Hypoglycaemia

Hypoglycaemia (very low blood sugar levels) can occur. This can result due to an imbalance in the dosage, diet or physical exercise. It is common in the initial weeks of starting treatment; therefore, blood sugar levels need to be monitored regularly.

Avoid irregular meal times or skipping meals, as this may also result in your sugar levels dropping too low.

The symptoms of hypoglycaemia include headache, extreme hunger, nausea, vomiting, lack of energy, sleepiness, sleep disorders, restlessness, aggressiveness, impaired concentration, impaired alertness and reactions, depression, confusion, speech disorders, aphasia (difficulty speaking), visual disorders, tremor (shaking), paresis (difficulty in movement), sensory disturbances, dizziness, helplessness, loss of self-control, delirium, convulsions (seizures), drowsiness, loss of consciousness, coma, shallow breathing and slow heart rate.

Your body's natural response to hypoglycaemia (low blood sugar) includes symptoms such as sweating, clammy skin, anxiety, increased heart rate, high blood pressure, palpitations (awareness of your heartbeat), chest pain and irregular heart rate.
The symptoms of severe hypoglycaemia can resemble that of a stroke.

Factors that can promote/cause hypoglycaemia include:

- Unwillingness (especially in the elderly) to co-operate
- Under-nourishment, irregular meal times or skipped meals
- Imbalance between physical exertion and carbohydrate intake
- Alteration of diet
- Consumption of alcohol, especially in combination with skipped meals
- Impaired kidney function

- Severe impairment of liver function
- Over-dosage with **ACCORD GLIMEPIRIDE**
- Thyroid disorders, pituitary (gland in the brain) disorders, corticoadrenal (gland on the kidney) disorders
- Using **ACCORD GLIMEPIRIDE** without having Type 2 diabetes mellitus

Hypoglycaemia can be quickly controlled by the immediate intake of glucose or sugar e.g. sugar lumps, sugar sweetened fruit juice or tea. It is therefore very important to always have a minimum of 20 g of glucose with you at all times. Artificial sweeteners will not be effective in treating hypoglycaemia.

If severe hypoglycaemia occurs, consult your physician or nearest hospital immediately.

Other medicines and ACCORD GLIMEPIRIDE

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

When **ACCORD GLIMEPIRIDE** is taken together with the medicines stated below, it may result in changes in blood sugar levels (see **POSSIBLE SIDE EFFECTS**). It is therefore important that you inform your doctor whether you are already being treated with the following medicines.

Medicines which could cause a decrease in blood sugar levels:

- medicines which lower blood sugar levels e.g. insulin (injections to reduce blood sugar levels), oral anti-diabetics (blood-sugar lowering medication taken by mouth)
- medicines used in the treatment of depression such as fluoxetine or a group of anti-depressants called monoamine oxidase inhibitors
- a class of medicines, used to treat high blood pressure, called ACE inhibitors
- medicines which treat~~s~~ fungal infections (~~an~~ antifungals called miconazole or fluconazole)
- male sex hormones (testosterone) or anabolic steroids (compounds used to promote body growth)
- a class of medicine which treats tuberculosis (TB) called para-aminosalicylic acid
- a medicine which treats infections caused by bacteria (antibiotics such as chloramphenicol, tetracyclines,

quinolones and sulphonamides)

- a medicine which aids in blood circulation called pentoxifylline (when injected in high doses)
- an antihistamine called tritoqualine
- medicines used to prevent blood clotting such as warfarin. If you are taking these together with **ACCORD GLIMEPIRIDE** then you need to have your blood tested
- medicines which treat pain, called phenylbutazone, azapropazone, oxyphenbutazone and salicylates
- medicines used in the treatment of cancer, called cyclophosphamide, trophosphamide or iphosphamides
- medicines which treat gout, called allopurinol, probenecid and sulphinpyrazone
- a medicine, which treats irregular heartbeats, called disopyramide
- a medicine, used to treat obesity, called fenfluramine
- medicines which lower the cholesterol levels in the blood, known as fibrates

Medicines which could cause an increase in blood sugar levels such as:

- a medicine, which treats glaucoma (eye disorder) and epilepsy (seizures), called acetazolamide
- prolonged use of laxatives (promotes bowel movements)
- medicines which treat epilepsy, depression and insomnia (difficulty sleeping), called barbiturates
- phenytoin which is also used to treat epilepsy
- a medicine, which lowers the cholesterol levels in the blood, called nicotinic acid (in high doses)
- medicines called corticosteroids (e.g prednisone), used to treat allergic reactions, asthma and pain
- hormones such as oestrogens and progestogens found in the oral contraceptive pill
- medicines which treat hypertension, such as diazoxide and diuretics
- medicines which treat nausea and mental disorders, called phenothiazines
- medicines which increase your blood pressure and heart rate, such as epinephrine (adrenalin) and other sympathomimetic agents
- a medicine used to treat tuberculosis (TB), called rifampicin
- a medicine used to treat low blood sugar levels, called glucagon
- medicines used to treat thyroid (gland in the neck) problems, called thyroid hormones

Other medicines such as:

- Antihistamines (allergy medication), heart medication (e.g. beta-blockers, clonidine and reserpine) can also affect the action of **ACCORD GLIMEPIRIDE**. When taking them, there is a possibility that you will be less aware of very low blood sugar levels in your body.

Consumption of alcohol is not recommended.

Please tell your doctor or pharmacist if you are using or have recently used other medicines, including medicines obtained without a prescription.

Taking ACCORD GLIMEPIRIDE with food and drink and alcohol

This treatment can be taken immediately before a substantial breakfast or, if not after breakfast, then immediately before the first main meal of the day.

It is very important not to skip meals after taking **ACCORD GLIMEPIRIDE**.

The consumption of alcohol is not recommended.

Pregnancy and Breastfeeding

Do not take **ACCORD GLIMEPIRIDE** if you are pregnant, planning to become pregnant or breastfeeding.

Ask your doctor or pharmacist for advice before taking any medicine, if you are pregnant or breastfeeding.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby please consult your doctor, pharmacist or other healthcare professional for advice before taking ACCORD GLIMEPIRIDE.

Driving and using machinery:

Alertness and responsiveness may be impaired (reduced) during treatment with **ACCORD GLIMEPIRIDE** due to very high or very low blood sugar levels, especially at the start of treatment or during a change in dose or a missed dose. This can affect the ability to drive or to operate machinery.

It is not always possible to predict to what extent [PRODUCT NAME] may interfere with your daily activities. You

should ensure that you do not engage in the above activities until you are aware of the measure to which [PRODUCT NAME] affects you.

ACCORD GLIMEPIRIDE CONTAINS LACTOSE MONOHYDRATE

ACCORD GLIMEPIRIDE contains lactose which is a type of sugar. If you have been told by your doctor that you cannot tolerate or digest some sugars (have intolerance to some sugars e.g. lactose intolerant), talk to your doctor before taking **ACCORD GLIMEPIRIDE**.

3. HOW TO TAKE ACCORD GLIMEPIRIDE:

Always take ACCORD GLIMEPIRIDE as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Your doctor will advise you on a diet and exercise program which you should continue over the full treatment period. Always take this treatment exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

ACCORD GLIMEPIRIDE must be taken immediately before a substantial breakfast or alternatively immediately before the first main meal of the day. It is very important not to skip meals after the tablets are taken. The tablets must be swallowed whole with approximately half a glass of water.

Dosage

Adults:

- The starting dose is 1 mg once daily.
- The tablets must be taken at the times and in the doses prescribed by the physician, normally at the same time every day.
- Sugar levels in the blood and urine need to be monitored carefully.
- A gradual dose increase is allowed on the advice of your physician.
- Consult your ~~physician~~ doctor of your weight changes or any lifestyle changes which could require an adjustment of your dosage.

The maximum daily dose of 8 mg of glimepiride should not be exceeded. Your doctor will tell you which dose suits

you.

Duration of treatment

Your doctor will indicate the duration of your treatment with **ACCORD GLIMEPIRIDE**. **ACCORD GLIMEPIRIDE** must be used very regularly and for as long as your doctor advises, even if it is for a very long time. Do not stop your treatment by yourself.

Do not share medicines prescribed for you with others.

If you have the impression that the effect of ACCORD GLIMEPIRIDE is too strong or too weak, talk to your doctor or pharmacist.

If you take more ACCORD GLIMEPIRIDE than you should:

If you have taken too many tablets, or if someone accidentally swallows some, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison centre.

If you forget to take ACCORD GLIMEPIRIDE:

If you miss a dose, simply take your usual dose when it is next due.

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

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS:

ACCORD GLIMEPIRIDE can cause side effects.

Not all side effects reported for ACCORD GLIMEPIRIDE are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while taking ACCORD GLIMEPIRIDE, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking [PRODUCT NAME] and tell your doctor immediately or go to the casualty department at your nearest hospital.

- Rash or itching skin
- Difficulty breathing
- Low blood pressure
- Sensitivity of skin to light

These are all very serious side effects. If you have them, you may have had a serious reaction to [PRODUCT NAME]. You may need urgent medical attention or hospitilisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Sweating, feeling tired, dizziness, feeling hungry, tingling lips, feeling shaky or trembling, a fast or pounding heartbeat (palpitations). These may be signs of hypoglycaemia, which means your blood sugar levels have dropped too low.
- Changes in your vision

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Nausea, vomiting, feeling of fullness in the stomach, stomach pain, diarrhoea, metallic taste, anorexia (eating disorder), increase appetite and weight gain.

Less frequent side effects include:

- Visual impairment (impaired eyesight)
- impairment of liver function e.g. jaundice (yellowish skin), hepatitis (swelling of the liver)
- blood disorders such as low numbers of white blood cells giving a higher risk of infections (*leucopenia, agranulocytosis*); low numbers of platelets with the risk of bruising (*thrombocytopaenia*), breakdown of red blood cells (haemolytic anaemia), breakdown of red and white blood cells (*pancytopenia*)
- allergic reactions such as itching, hives and rashes. These can develop into shortness of breath

(dyspnoea), decrease in blood pressure and shock. Hypersensitivity of the skin to light can also occur. If any of these symptoms occur, consult a physician immediately

- dizziness and drowsiness
- skin rash with irregular red patches (*erythema multiforme*); serious allergic reaction with fever, red patches, joint pain and/or eye problems (*Stevens-Johnson syndrome*); extreme redness and scaling of the skin (*exfoliative dermatitis*); reddish, painful lumps on the skin particularly below the knees (*erythema nodosum*)

If your blood sugar levels are not sufficiently lowered, then hyperglycaemia (very high blood sugar levels) can occur. The symptoms include increased urinary frequency (polyuria), intense thirst, dryness of the mouth and dry skin. If these symptoms persist, then consult your physician for an adjustment of your dose.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction 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 **ACCORD GLIMEPIRIDE**.

5. HOW TO STORE ACCORD GLIMEPIRIDE:

Store all medicines out of reach of children.

Store at or below 25 ˚C. Protect from moisture and light.

Do not use after the expiry date on the carton. Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewage system (e.g. toilets).

Keep the blisters in the carton until required for use.

6. CONTENT OF THE PACK AND OTHER INFORMATION

What ACCORD GLIMEPIRIDE contains

The active substance is glimepiride.

Each tablet contains 1 mg, 2 mg or 4 mg glimepiride.

The other ingredients are lactose monohydrate, sodium starch glycolate, iron oxide red (1 mg & 2 mg only), povidone and magnesium stearate.

What ACCORD GLIMEPIRIDE looks like and contents of the pack

ACCORD GLIMEPIRIDE 1 mg: Pink coloured, round, flat, uncoated tablets with bevelled edges and a score line on one side and plain on the other side.

ACCORD GLIMEPIRIDE 2 mg: Light pink coloured, oval shaped, uncoated tablets, with a score line on one side and plain on the other side.

ACCORD GLIMEPIRIDE 4 mg: White, oval shaped, uncoated tablets, with a score line on one side and plain on the other side.

ACCORD GLIMEPIRIDE is packed as follows:

ACCORD GLIMEPIRIDE 1 mg: Blister Strips of clear PVC/PVDC Aluminium foil with 10 tablets per blister.

Marketed in packs of 30's.

ACCORD GLIMEPIRIDE 2 mg: Blister Strips of clear PVC/PVDC Aluminium foil with 10 tablets per blister.

Marketed in packs of 30's.

ACCORD GLIMEPIRIDE 4 mg: Blister Strips of clear PVC/PVDC Aluminium foil with 10 tablets per blister.

Marketed in packs of 30's.

HOLDER OF CERTIICATE OF REGISTRATION

Accord Healthcare (Pty) Ltd

Tuscany Office Park

6 Coombe Place

Rivonia

Gauteng

SOUTH AFRICA

This leaflet was last revised in

05 August 2011

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REGISTRATION NUMBER

ACCORD GLIMEPIRIDE 1 mg: 41/21.2/0656

ACCORD GLIMEPIRIDE 2 mg: 41/21.2/0657

ACCORD GLIMEPIRIDE 4 mg: 41/21.2/0658