SCHEDULING STATUS S3

DIAGEN MR 30 Modified release tablet
DIAGEN MR 60 Modified release tablet
Gliclazide

Sugar free

Read all of this leaflet carefully before you start taking DIAGEN MR

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

What DIAGEN MR is and what it is used for

DIAGEN MR is a medicine that reduces blood sugar levels in certain forms of diabetes (Type 2 diabetes mellitus) in adults, when diet, exercise and weight loss alone do not have an adequate effect on keeping blood sugar at the correct level.

What you need to know before you take DIAGEN MR

Do not take DIAGEN MR:

- if you are allergic (hypersensitive) to glimepiride or other sulfonylureas (medicines used to lower your blood sugar such as gliclazide) or sulfonamides (medicines for bacterial infections such as sulfamethoxazole) or any of the other ingredients of **DIAGEN MR** (listed in section 6).
- if you have insulin-dependent diabetes (Type 1).

- if you have ketone bodies and sugar in your urine (this may mean you have diabetic keto-acidosis), a diabetic pre-coma or coma.
- if you have severe kidney or liver disease.
- if you are taking medicines to treat fungal infections (miconazole).
- if you are pregnant and breastfeeding your baby.

Warnings and precautions

Talk to your doctor before taking DIAGEN MR

- Low blood sugar (Hypoglycaemia) may occur: Take special precaution:
- if you take meals irregularly or skip meals altogether,
- if you are fasting,
- if you are malnourished,
- if you change your diet,
- if you increase your physical activity and carbohydrate intake does not match this increase,
- if you drink alcohol, especially in combination with skipped meals,
- if you take other medicines or natural remedies at the same time,
- if you take too high doses of gliclazide,
- if you suffer from particular hormone-induced disorders (functional disorders of the thyroid gland, of the pituitary gland or adrenal cortex),
- if your kidney function or liver function is severely decreased.
- If you have low blood sugar you may have the following symptoms:

Headache, intense hunger, nausea, vomiting, weariness, sleep disorders, restlessness, aggressiveness, poor concentration, reduced alertness and reaction time, depression, confusion, visual and speech disorders, tremor, paresis, sensory disorders, dizziness and helplessness.

- The following signs and symptoms may also occur:

sweating, clammy skin, anxiety, fast or irregular heartbeat, high blood pressure, sudden strong pain in the chest that may radiate into nearby areas (angina pectoris).

Other medicines and DIAGEN MR

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

The following products are likely to increase the risk of lowering the blood sugar levels (hypoglycaemia):

Contraindicated combination:

- Medicines to treat fungal infections (miconazole, fluconazole, ketoconazole

Combinations which are not recommended:

- painkiller or antirheumatics (phenylbutazone, ibuprofen)

It is preferable to use a different anti-inflammatory medicine.

- Alcohol, avoid alcohol or medicines containing alcohol.

Combinations requiring precautions for use:

- Anti-diabetic medicines (insulins, acarbose, metformin, thiazoidinediones, dipeptidyl peptidas-4 inhibitors, GLP-1 receptor agonists).
- Fluconazole
- medicines to treat high blood pressure or heart failure (beta blockers, ACE-inhibitors such as captopril, or enalapril)
- H_2-receptor antagonists
- antibiotics (e.g. sulphonamides, clarithromycin)

The Following products may cause an increase in blood sugar levels

Combination which is not recommended:

- medicines to treat breast disorders, heavy menstrual bleeding and endometriosis (danazol: diabetogenic effect of danazol)

Combinations requiring precautions during use:

- medicines to treat disorders of the central nervous system (chlorpromazine)
- Medicines reducing inflammation (glucocorticoids)
- Medicines to reduce asthma or used during labour (intravenous ritodrine, salbutamol, terbutaline).
- St Johns Wort (*Hypericum perforatum*) preparations
- Ephedrine, pseudoephedrine and common cold medicines

The following products may cause abnormalities in the blood sugar stability (dysglycaemia)

Combinations requiring precautions during use:

- Antibiotic: Fluoroquinolones: Blood glucose disturbance (low blood sugar and high

blood sugar) can occur when taken at the same time, especially in elderly patients.

Combination which must be taken into account:

- **DIAGEN MR** may increase the effects of medicines which reduce blood clotting (warfarin: anticoagulant therapy used for depression
- Sulfonylureas

DIAGEN MR with food and drink

DIAGEN MR can be taken with food and non-alcoholic drinks.

Drinking alcohol is not recommended as it can change the control of your diabetes in an unpredictable manner.

Pregnancy, breast-feeding and fertility

If you are pregnant or breastfeeding your baby while taking **DIAGEN MR**, please consult your doctor, pharmacist or other healthcare professional for advice before taking **DIAGEN MR**.

DIAGEN MR is not recommended for use during pregnancy. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby while taking **DIAGEN MR**, inform your doctor so that he may prescribe a more suitable treatment for you.

You must not take **DIAGEN MR** while you are pregnant or breast-feeding.

Driving and using machines

Your ability to concentrate or react may be impaired if your blood sugar is too low (hypoglycaemia), or too high (hyperglycaemia) or if you develop visual problems as a result of such conditions. Bear in mind that you could endanger yourself or others (e.g. when driving a car or using machines).

Please ask your doctor whether you can drive a car if you:

- have frequent episodes of low blood sugar (hypoglycaemia),
- have few or no warning signals of low blood sugar (hypoglycaemia).

3. How to take DIAGEN MR

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

Always take **DIAGEN MR** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The dose is determined by the doctor, depending on your blood and possibly urine sugar levels.

The usual dose is one to four **DIAGEN MR 30** tablets every day as a single daily dose taken with breakfast. This depends on the response to treatment.

The tablet, or half tablet should be swallowed whole (in one piece). Do not chew or crush the tablet.

Your doctor will tell you how long your treatment with **DIAGEN MR** will last. If you have the impression that the effect of **DIAGEN MR** is too strong or too weak, tell your doctor or pharmacist.

If you take more DIAGEN MR than you should

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

The signs of overdose are those of low blood sugar (hypoglycaemia). The symptoms can be helped by taking sugar (4 to 6 lumps) or sugary drinks straight away, followed by a substantial snack or meal. If the patient is unconscious immediately inform a doctor and call the emergency services. The same should be done if somebody, e.g. a child, has taken the product unintentionally. Unconscious patients must not be given food or drink.

It should be ensured that there is always a pre-informed person that can call a doctor in case of emergency.

If you forget to take DIAGEN MR

If you forget to take your tablet you should take it as soon as you remember on the same day. If you do not remember on the same day, take your normal dose (one tablet) on the next day. Do not take a double dose to make up for a forgotten individual dose.

Effects when treatment with DIAGEN MR is stopped

As the treatment for diabetes is usually life long, you should discuss with your doctor before stopping **DIAGEN MR**. Stopping could cause high blood sugar (hyperglycaemia) which increases the risk of developing complications of diabetes.

4. Possible side effects

DIAGEN MR can have side effects.

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

If any of the following happens, stop taking **DIAGEN MR** and tell your doctor immediately or go to the casualty department at your nearest hospital:

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

These are all very serious side effects. If you have them, you may have had a serious reaction to **DIAGEN MR**. You may need urgent medical attention or hospitalisation.

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

Frequent:

- low blood sugar (hypoglycaemia),
- sweating, clammy skin, anxiety,
- chest pain, changes in heartbeat, high blood pressure,

Less frequent:

- abnormal liver function, which can cause yellow skin and eyes.

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

Tell your doctor if you notice any of the following:

Less frequent:

Blood disorders

Decrease in the number of cells in the blood has been reported less frequently (e.g. platelets, red and white blood cells). This may cause paleness, prolonged bleeding, bruising, sore throat, fever. These symptoms usually vanish when the treatment is discontinued.

Skin disorders

Skin reactions have been reported such as rash, redness, itching, hives, angioedema (rapid swelling of tissues such as eyelids, face, lips, mouth, tongue or throat that may result in breathing difficulty). The rash may progress to widespread blistering or peeling of the skin.

Digestive disorders

Stomach pain or discomfort, feeling or being sick, indigestion, diarrhoea, constipation.

Eye disorders

Your vision may be affected for a short time especially at the start of treatment. This effect is due to changes in blood sugar levels.

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 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 **DIAGEN MR**.

5. How to store DIAGEN MR

Store all medicines out of reach of children.

- Store at or below 25 °C in a dry place.
- Store in original container.
- Do not use after the expiry date stated on the carton / label.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What DIAGEN MR contains

The active substance is gliclazide.

Each **DIAGEN MR 30** tablet contains gliclazide 30 mg.

Each **DIAGEN MR 60** tablet contains gliclazide 60 mg.

The other ingredients are: hypromellose, magnesium stearate, microcrystalline cellulose.

What DIAGEN MR looks like and contents of the pack

DIAGEN MR 30: A white to off-white, oblong, biconvex tablet debossed with "M" on one side of the tablet and "GL30" on the other side.

DIAGEN MR 60: A white to off-white, oblong, biconvex tablet debossed with" M" on the left side of the breakline on one side and GL on the left side of the breakline and 60 on the right side of the breakline on the other side.

Contents of the pack:

DIAGEN MR 30:

PVC blister pack comprises of clear, transparent, PVC film on one side and hard tempered aluminium foil coated with heat seal lacquer on other side. Ten tablets per strip. 30/60/90 tablets per carton.

PVC/PVDC blister pack comprises of clear, transparent, PVC film coated with PVdC on one side and hard tempered aluminium foil coated with heat seal lacquer on other side. Ten tablets per strip. 30/60/90 tablets per carton.

HDPE bottle pack comprises of round wide mouth white high-density polyethylene bottle with white opaque polypropylene child resistant closure with wad containing aluminium induction sealing liner with absorbent cotton.
60 / 100 tablets per bottle.

DIAGEN MR 60:
HDPE bottle pack comprises of round wide mouth white high-density polyethylene (HDPE) bottle with white opaque polypropylene child resistant closure (CR) with wad containing aluminium induction sealing liner with desiccant (silica gel sachet/canister).
60 / 100 tablets per bottle.

HDPE bottle pack (marketable pack) comprises of round wide mouth white high density polyethylene (HDPE) bottle with white opaque polypropylene screw cap with aluminium induction sealing liner wad with desiccant (silica gel canister). 30 tablets per bottle.

Holder of Certificate of Registration
MYLAN (PTY) LTD
4 Brewery Street
Isando
Johannesburg, 1609
Republic of South Africa

This leaflet was last revised in 07 Septermber 2022

Registration numbers
DIAGEN MR 30 mg: 52/21.2/1025
DIAGEN MR 60 mg: 52/21.2/1026

Access to the corresponding Professional Information
To follow