

Patient Information Leaflet

SCHEDULING STATUS

S3

DIARAN MR 60 tablets

Gliclazide 60 mg

Read all of this leaflet carefully before you start taking DIARAN MR 60 TABLETS

- **Keep this leaflet. You may need to read it again.**
- If you have further questions, please ask your doctor or your pharmacist.
- **DIARAN MR 60 tablets** 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 you need to know before you take **DIARAN MR 60 tablets**
2. What you need to know before you take **DIARAN MR 60 tablets**
3. How to take **DIARAN MR 60 tablets**
4. Possible side effects
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6. Contents of the pack and other information

1. What DIARAN MR 60 is and what is it used for

DIARAN MR 60 Tablets contains the active substance gliclazide an oral antidiabetic medicine belonging to the sulfonylurea group. Gliclazide reduces blood sugar levels.

Gliclazide is used in a certain form 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.

2. What you need to know before you take DIARAN MR 60 Tablets

Do not take gliclazide

- If you are allergic to gliclazide or any of the other ingredients of **DIARAN MR 60**

Tablets (listed in section 6), or to other hypoglycaemic medicines of the same group (sulfonylureas), or to other related medicines (sulfonamides)

- 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 currently breast feeding
- If you are pregnant or planning to become pregnant
- If you are a child and suffering from diabetes
- If you are taking medicines to treat fungal infections (miconazole) (see section "**Other medicines and DIARAN MR 60**"),

Warnings and precautions

Symptoms of low blood sugar (hypoglycaemia) usually disappear after absorption of carbohydrates (sugar). However, despite initial effective measures, low blood sugar (hypoglycaemia) may occur. Artificial sweeteners have no effect on low blood sugar (hypoglycaemia). In the case of severe prolonged low blood sugar (hypoglycaemia), immediate medical treatment and even hospitalisation is necessary. In an exceptional stress situation e.g. trauma, fever, infection or surgical intervention, blood glucose regulation may deteriorate and a temporary change to Insulin may be necessary to maintain good metabolic control. Gastro-intestinal side-effects can be avoided or minimised if DIARAN MR 60 MR 60 mg is taken with breakfast. Hepato-biliary (liver and the gallbladder) symptoms usually disappear after discontinuation of treatment.

Discontinue treatment if cholestatic (obstructive) jaundice (yellow discoloration of the skin) appears.

Beta-blockers (medicines to treat high blood pressure) may decrease the efficacy of DIARAN MR 60(a sulphonylurea) by impairing the release of insulin. Beta-blockers may mask the typical sympathomimetic warning signs and symptoms of low blood sugar

(hypoglycaemia) and may inhibit the normal physiological response to low blood sugar (hypoglycaemia).

Talk to your doctor before taking gliclazide. You should observe the treatment plan prescribed by your doctor to achieve proper blood sugar levels. This means, apart from regular tablet intake, to observe the dietary regimen, have physical exercise and, where necessary, reduce weight.

During gliclazide treatment regular monitoring of your blood (and possibly urine) sugar level and also your glycated haemoglobin (HbA1c) is necessary. In the first few weeks of treatment the risk of having reduced blood sugar levels (hypoglycaemia) may be increased. So particularly close medical monitoring is necessary.

Low blood sugar (hypoglycaemia) may occur:

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
- 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.

Symptoms of low blood sugar (hypoglycaemia)

If you have low blood sugar you may have the following symptoms:

headache, intense hunger, nausea (feeling sick), vomiting (being sick), weariness, sleep disorders, restlessness, aggressiveness, poor concentration, reduced alertness and reaction

time, depression, confusion, speech or visual disorders, tremor, sensory disturbances, 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).

If blood sugar levels continue to drop you may suffer from considerable confusion (delirium), develop convulsions (fits), lose self-control, your breathing may be shallow and your heartbeat slowed down, you may become unconscious.

In most cases the symptoms of low blood sugar vanish very quickly when you consume some form of sugar, for instance glucose tablets, sugar cubes, sweet juice, sweetened tea. You should therefore always carry some form of sugar with you (glucose tablets, sugar cubes). Remember that artificial sweeteners or products containing only artificial sweeteners are not effective. Please contact your doctor or the nearest hospital if taking sugar does not help or if the symptoms recur.

Symptoms of low blood sugar may be absent, less obvious or develop very slowly or you are not aware in time that your blood sugar level has dropped. This may happen if you are an elderly patient taking certain medicines (for instance those acting on the central nervous system and beta blockers). If you are in stress-situations (accidents, surgical operations, fever etc.) your doctor may temporarily switch you to insulin therapy.

Symptoms of high blood sugar (hyperglycaemia) may occur when gliclazide has not yet sufficiently reduced the blood sugar, when you have not complied with the treatment plan prescribed by your doctor, if you take St John's Wort (*Hypericum perforatum*) preparations (see section "**Other medicines and gliclazide**"), or in special stress situations. These may include thirst, frequent urination, dry mouth, dry itchy skin, skin infections and reduced performance. If these symptoms occur, you must contact your doctor or pharmacist.

Blood glucose disturbance (low blood sugar and high blood sugar) can occur when gliclazide is prescribed at the same time than medicines belonging to a class of antibiotics called fluoroquinolones, especially in elderly patients. In this case, your doctor will remind you the importance of monitoring your blood glucose.

Glucose-6-phosphate dehydrogenase (G6DP)

If you have a family history of or know you have the hereditary condition glucose-6-phosphate dehydrogenase (G6PD) deficiency (abnormality of red blood cells), lowering of the haemoglobin level and breakdown of red blood cells (haemolytic anaemia) can occur. Contact your doctor before taking this medicine.

Children

Gliclazide modified release tablet is not recommended for use in children due to a lack of data.

Other medicines and gliclazide

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

The blood sugar lowering effect of gliclazide may be strengthened and signs of low blood sugar levels may occur when one of the following medicines is taken:

- other medicines used to treat high blood sugar (oral antidiabetics, GLP-1 receptor inhibitors or insulin),
- antibiotics (sulphonamides, chloramphenicol, clarithromycin)
- medicines to treat high blood pressure or heart failure (beta blockers, ACE-inhibitors such as captopril, or enalapril),
- medicines to treat fungal infections (miconazole, fluconazole),
- medicines to treat ulcers in the stomach or duodenum (H₂ receptor antagonists- cimetidine, ranitidine),
- medicines used for depression (monoamine oxidase inhibitors),
- painkiller or antirheumatics (phenylbutazone, ibuprofen),

- medicines containing alcohol.

The blood glucose lowering effect of gliclazide may be weakened and raised blood sugar levels may occur when one of the following medicines is taken:

- medicines to treat disorders of the central nervous system (chlorpromazine),
- medicines reducing inflammation (corticosteroids),
- medicines to treat asthma or used during labour (intravenous salbutamol, ritodrine and terbutaline),
- medicines to treat breast disorders, heavy menstrual bleeding and endometriosis (danazol),
- St John's Wort -*Hypericum perforatum*- preparations.

Blood glucose disturbance (low blood sugar and high blood sugar) can occur when a medicine belonging to a class of antibiotics called fluoroquinolones is taken at the same time than gliclazide, especially in elderly patients. Gliclazide may increase the effects of medicines which reduce blood clotting (warfarin). Consult your doctor before you start taking another medicine. If you go into hospital tell the medical staff you are taking gliclazide.

DIARAN MR 60 Tablets with food, drink and alcohol

DIARAN MR 60 Tablets can be taken with food and non-alcoholic drinks.

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

Pregnancy and breastfeeding

Gliclazide is not recommended for use during pregnancy. 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 health care provider. You must not take gliclazide while you are breastfeeding.

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 (for instance 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).

DIARAN MR 60 tablets contain lactose.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take DIARAN MR 60

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

Always take DIARAN MR 60 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.

Change in external factors (weight reduction, change in life style, stress) or improvements in the blood sugar control may require changed gliclazide doses. The usual starting dose is 30 mg as a single intake at breakfast time. The dosage depends on the response to treatment.

The maximum dosage is 120 mg daily.

DIARAN MR 60 is for oral use. Take your tablet(s) with a glass of water at breakfast time (and preferably at the same time each day). Swallow your tablets whole. Do not chew them.

You must always eat a meal after taking your tablet(s).

If a combination therapy of gliclazide with metformin, an alpha glucosidase inhibitor, a thiazolidinedione, a dipeptidyl peptidase-4 inhibitor, a GLP-1 receptor agonist or insulin is initiated your doctor will determine the proper dose of each medicine individually for you.

If you notice that your blood sugar levels are high although you are taking the medicine as

prescribed, you should contact your doctor or pharmacist.

If you have taken more DIARAN MR 60 Tablets than you should

If you take too many tablets, contact your doctor or the nearest hospital Accident & Emergency department immediately. The signs of overdose are those of low blood sugar (hypoglycaemia) described in Section 2. 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. 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 DIARAN MR 60 Tablets

It is important to take your medicine every day as regular treatment works better. However, if you forget to take a dose of gliclazide, take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

If you stop taking DIARAN MR 60

As the treatment for diabetes is usually life long, you should discuss with your doctor before stopping this medicine. Stopping could cause high blood sugar levels (hyperglycaemia) which increases the risk of developing complications of diabetes. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

DIARAN MR 60 Tablets can have side effects.

Not all side effects reported for gliclazide are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while taking gliclazide, please consult your doctor, pharmacist or healthcare professional for advice. Side effects are most likely to happen at the start of treatment.

If any of the following happens, stop taking DIARAN MR 60 Tablets and tell your doctor immediately or go to the casualty department at your nearest hospital:

Skin diseases

Skin reactions have been reported such as:

- rash,
- redness,
- itching,
- hives,
- blisters,
- 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,
- exceptionally, signs of severe hypersensitivity reactions (DRESS) have been reported: initially as flu-like symptoms and a rash on the face then an extended rash with a high temperature.

These are all very serious side effects. If you have them, you may have had a serious reaction to gliclazide. 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:

- Abnormal liver function, which can cause yellow skin and eyes. If you get this, see your doctor immediately. The symptoms generally disappear if the medicine is stopped. Your doctor will decide whether to stop your treatment;

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:

- Low blood sugar (hypoglycaemia). For symptoms and signs see Section “**Warnings and precautions**” in Section 2 “**What you need to know before you take**”. If left untreated, these symptoms could progress to drowsiness, loss of consciousness or possibly coma. If an episode of low blood sugar is severe or prolonged, even if it is temporarily controlled by eating sugar, you should seek immediate medical attention.

Less frequent side effects:

- Blood disorders

Decrease in the number of cells in the blood has been reported (for instance 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.

- Digestive disorders

- stomach pain or discomfort,
- feeling or being sick,
- indigestion,
- diarrhoea,
- constipation

These effects are reduced when gliclazide is taken with a meal as recommended, See Section 3 "How to take **DIARAN MR 60 TABLETS**".

- 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.

As for other sulfonylureas, the following adverse events have been observed:

- Cases of severe changes in the number of blood cells,
- Allergic inflammation of the wall of blood vessels,
- Reduction in blood sodium (hyponatraemia),
- Symptoms of liver impairment (for instance jaundice) which in most cases disappeared after withdrawal of the sulfonylureas, but may lead to life-threatening

liver failure in isolated cases.

- Liver disease

There have been isolated reports of abnormal liver function tests, which can cause yellow skin and eyes. If you get this, see your doctor immediately. The symptoms generally disappear if the medicine is stopped. Your doctor will decide whether to stop your treatment.

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 Med Safety APP (Medsafety XSAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of DIARAN MR 60 Tablets.

Suspected adverse reactions can also be reported directly to the Holder of certificate of registration via email or telephonically: pharmacovigilance.africasme@sunpharma.com or tel:+27(0) 12 643 2000

5. How to store DIARAN MR 60

KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN.

Do not use this medicine after the expiry date which is stated on the carton and blister.

The expiry date refers to the last day of that month.

Keep the blisters in the outer carton in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What DIARAN MR 60 Tablets contains

The active substance is gliclazide.

Each tablet contains 60 mg of gliclazide.

The other ingredients are pregelatinised starch (maize), lactose monohydrate, sodium

citrate, purified water, hypromellose, magnesium stearate.

What DIARAN MR 60 looks like and contents of the pack

White to off white oval-shaped tablets, scored on both sides, engraved with 'Z' and 'I' on one side and plain on the other side.

Cold form blister pack

Cold form blister pack comprises of cold form blister laminate composed of oriented polyamide, aluminium foil and PVC with backing of aluminium foil coated with heat seal lacquer on the inner side in packs of 30's.

Triplex blister pack

Triplex blister pack comprises of clear transparent PVC film laminated with polyethylene and coated with PVdC on inner side with the backing of hard tempered, aluminium foil coated with heat seal lacquer on inner side, in packs of 30's.

HDPE bottle pack:

HDPE bottle pack comprises of white opaque HDPE bottle with child resistant closure with induction seal liner and absorbent cotton in packs of 30's and 100's.

Holder of Certificate of Registration

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Access to the corresponding PIL translation: The PIL is available in one other language (Afrikaans), a copy is accessible on the company website: <https://sunpharma.com/south-africa-products/>