

Applicant: Ranbaxy Pharmaceuticals (Pty) Ltd
Product name: DIARAN MR 30
Dosage form: Modified Release Tablets
Strength: Each modified release tablet contains gliclazide 30 mg.

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S3**

DIARAN MR 30 Modified Release Tablets

Gliclazide

Sugar free

Read all of this leaflet carefully before you start taking DIARAN MR 30

- 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.
- **DIARAN MR 30** 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 **DIARAN MR 30** is and what it is used for
2. What you need to know before you take **DIARAN MR 30**
3. How to take **DIARAN MR 30**
4. Possible side effects
5. How to store **DIARAN MR 30**
6. Contents of the pack and other information

1. What **DIARAN MR 30** is and what it is used for

DIARAN MR 30 belongs to a group of medicines called sulphonylureas. Sulphonylureas are medicines, which cause blood sugar to decrease to normal levels in patients of diabetes where blood sugar is high and is not controlled by diet, physical exercise and weight loss alone.

2. What you need to know before you take **DIARAN MR 30**

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Do not take DIARAN MR 30 if:

- You have insulin dependent (type I) diabetes
- You have a known allergy to gliclazide, to any of the other ingredients or to other sulphonylureas and related medicines.
- You have had diabetic ketoacidosis (A rare but serious complication of high blood sugar levels that is rarely fatal. Deep rapid breathing and non-specific symptoms such as nausea, vomiting, stomach pain, a fruity breath odour, feeling faint or lightheaded. Insulin injections would be required to prevent further worsening of the condition)
- You have/had severe kidney or liver disease
- You are currently breast feeding
- You are pregnant or planning to become pregnant
- You are a child.
- You are taking medicines to treat fungal infections (miconazole).

Please consult your doctor, even if these statements were applicable to you at any time in the past.

Warnings and precautions

Take special care with **DIARAN MR 30**:

- In the first few weeks of treatment the risk of having reduced blood sugar levels (hypoglycaemia) may be increased, so close monitoring is necessary.
- Low blood sugar may occur:
 - If you are taking other medicines.
 - If you are under exceptional stress such as fever, trauma or any other surgical intervention which may affect your blood glucose control.
 - You are taking other hypoglycaemic medicines.
 - You skip meals, have periods of fasting or irregular mealtimes or change your diet
 - You do not balance physical exercise with your carbohydrate intake
 - You suffer from any endocrine disorder such as problems with your thyroid or glands that secrete hormones
 - Your kidney function is deteriorating

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- You drink alcohol, especially with skipped meals.

The use of oral hypoglycaemic agents (medicines to treat 'sugar' diabetes) may be associated with increased cardiac (heart) mortality as compared to treatment with diet alone or diet with insulin use.

If you have a family history of or known you have the hereditary condition glucose-6phosphate 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.

If you have the hereditary condition porphyria, acute porphyria can occur with the use of sulfonylurea medicines.

Other medicines and DIARAN MR 30

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

Care is needed if you are taking the following medicines along with **DIARAN MR 30**:

- Phenylbutazone, NSAIDS (medicines used for pain)
- Steroids (used to treat various conditions including rheumatism, arthritis, allergic conditions, certain skin diseases, asthma or certain blood disorders)
- Sulphonamides, chloramphenicol (medicines used for infections)
- Fluconazole, ketoconazole (medicines used for fungus infections)
- Beta blockers, captopril, enalapril (medicines to treat high blood pressure)
- Cimetidine (medicines to treat heart burn); ranitidine.
- Other antidiabetic agents (insulin, acarbose, biguanides; metformin, thiazolidinediones, dipeptidyl peptidase-4 inhibitors, GLP-1 receptor agonists)
- Monoamine oxidase inhibitors (medicines used for depression)
- Clofibrate (medicines used for cholesterol)
- Cyclophosphamide (medicines used for cancer)
- Dicoumarol (medicines used for blood clotting)
- Danazol (medicines used to treat breast disorders, heavy menstrual bleeding and endometriosis.
- Chlorpromazine (used to treat disorders of the nervous system)
- St Johns wort preparations

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- Fluoroquinolones used to treat bacterial infections.
- Warfarin used to reduce blood clotting
- Salbutamol, terbutaline and other beta-adrenergic agonists: Increased blood glucose levels due to beta-2 agonist effects
- Ephedrine, pseudoephedrine and common cold products.
- The hypoglycaemic action of **DIARAN MR 30** may be reduced with the concomitant administration of thiazide diuretics, oestrogen and adrenaline.

DIARAN MR 30 with food or drink

DIARAN MR 30 can be taken with food and non-alcoholic drinks.

Pregnancy and breastfeeding

The safety of this medicine for use during pregnancy and lactation has not been established. Do not take this medicine if you are pregnant, planning to become pregnant or are breast feeding your baby.

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby , please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Driving and using machines

DIARAN MR 30 has no or negligible influence on the ability to drive and use machines. However, patients should be made aware of the symptoms of hypoglycaemia and should be careful if driving or operating machinery, especially at the beginning of treatment.

3. How to take DIARAN MR 30

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

Always take **DIARAN MR 30** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor may prescribe some blood tests before starting treatment with this medicine and during the course of your treatment to check your blood sugar and liver function.

Swallow your tablet whole with a glass of water. Do not chew them.

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The usual dose is:

The total daily dose can vary from one tablet to four tablets taken as a single daily dose. This depends on the response to treatment. All treatments for diabetes are lifelong.

You should take your tablet(s) with breakfast and preferably at the same time each day.

If you are currently using another medicine your doctor will decide on the dose of **DIARAN MR 30** to take and whether you need to stop taking the other medicine.

*If you have the impression that the effect of **DIARAN MR 30** tablet is too strong or too weak, talk to your doctor or pharmacist.*

If you have taken more DIARAN MR 30 than you should

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Take this leaflet or some tablets with you so your doctor will know what you have taken.

If you forget to take DIARAN MR 30

If you forget to take a tablet, take them as soon as you remember, do not increase your dose the next day. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

If you stop taking DIARAN MR 30

Do not stop taking **DIARAN MR 30** without talking to your doctor.

4. Possible side effects

DIARAN MR 30 can have side effects.

Not all side effects reported for **DIARAN MR 30** are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while taking **DIARAN MR 30**, please consult your health care provider for advice.

Side effects are most likely to happen at the start of treatment. If any of the following happens, stop taking **DIARAN MR 30** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Rashes, hives, itching, chest constriction, shortness of breath or swelling of the face, lips, hands or feet, fainting, high temperature.

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These are all very serious side effects. If you have them, you may have had a serious reaction to **DIARAN MR 30**. 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:

- Hypoglycemia characterized by tiredness, uncontrolled shaking, cold sweats, fast heart beat, feeling faint or lightheaded, hunger pangs, anxiety, inability to concentrate, blurred vision, or nervousness. If not treated promptly, may progress to confusion, or coma.

If you experience any of these symptoms, you should immediately take sugar (glucose) tablets or sweetened juices.

To avoid hypoglycemia do not miss or delay meals or change your diet, take more **DIARAN MR 30** than needed, do a more intense, rigorous physical exercise or more work than normal.

- Yellowing of skin and whites of the eyes with decreased appetite and abdominal pain. These generally disappear if the medicine is stopped.

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

Tell your doctor if you notice any of the following:

- Nausea, vomiting, heartburn, loss of appetite, constipation, diarrhoea and a metallic taste. These side-effects are reduced when **DIARAN MR 30** is taken with a meal as recommended.
- Skin rashes and itching
- Visual disturbances (may occur especially on initiation of treatment, due to changes in blood glucose levels).

If you are unclear about any of the side-effects mentioned, you should discuss them with your doctor or pharmacist.

There may be changes in the results of certain laboratory tests such as

-Elevated liver enzymes

-Decreased number of blood cells called leucocytes, platelets and low haemoglobin.

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:

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<https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of **DIARAN MR 30**.

5. How to store DIARAN MR 30

Store all medicines out of reach of children.

- Store at or below 25 °C.in the original package, protected from moisture.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the 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 DIARAN MR 30 contains

. The active substance is gliclazide.

The other ingredients are calcium hydrogen phosphate dihydrate, colloidal anhydrous silica, hypromellose, magnesium stearate, povidone.

What DIARAN MR 30 looks like and contents of the pack

White to off-white biconvex, uncoated caplet with '**G30**' debossed on one side and plain on the other.

Carton contains 30 tablets packed in cold form blister strips or PVdC coated PVC blister strips of 10 tablets each.

Holder of Certificate of Registration

RANBAXY PHARMACEUTICALS (PTY) LTD

a Sun Pharma company

14 Lautre Road, Stormill Ext 1

Roodepoort, 1724

South Africa

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