

diamicron[®]

**Gliclazide 80mg
scored tablets**

دایامائیکرون[®]

گلیکلازاید ۸۰ میلی گرام

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1. WHAT DIAMICRON 80 mg, scored tablet IS AND WHAT IT IS USED FOR

Pharmacotherapeutic group: Sulfonylurea – Oral antidiabetic (A: Alimentary tract and metabolism) - ATC code: A10BB09.
This medicine is intended for use in cases of non-insulin-dependent diabetes, when it is not controlled by diet.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DIAMICRON 80mg, scored tablet

Do not take DIAMICRON 80 mg, scored tablet:

- if you are allergic to gliclazide or any of the other ingredients of DIAMICRON 80 mg (listed in section 6), or to other medicines of the same group (sulphonylureas), or to other related medicines (hypoglycaemic sulphonamides);
- 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 suffer from severe liver or kidney disease,
- if you are taking medicines to treat fungal infections (miconazole, see section "Other medicines and DIAMICRON 80 mg, scored tablet");
- if you are breast-feeding (see section "Pregnancy, breast-feeding and fertility").

Warnings and precautions

Talk to your doctor or pharmacist before taking DIAMICRON 80 mg, scored tablet.

You should observe the treatment plan prescribed by your doctor to achieve proper blood sugar levels. This means, apart from regular tablet intake, you 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 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: Headaches, hunger, nausea, vomiting, 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 heart beat, 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, lose your 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, e.g. 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 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 (e.g. those acting on the central nervous system and beta-blockers).

If you are in stress situations (e.g. accident, 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 Diamicron 80 mg, scored tablet") 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 or high blood sugar) can occur when gliclazide is prescribed at the same time as 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.

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.

Cases of acute porphyria have been described with some other sulfonylurea drugs, in patients who have porphyria (inherited genetic disorders with accumulation in the body of porphyrins or porphyrin precursors).

Contact your doctor before taking this medicinal product.

Children and adolescents

DIAMICRON 80 mg is not recommended for use in children due to a lack of data.

Other medicines and DIAMICRON 80 mg, scored tablet

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other 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 agonists or insulin),
- antibiotics (e.g. sulphonamides, 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),
- medicines to treat 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 or high blood sugar) can occur when a medicine belonging to a class of antibiotics called fluoroquinolones is taken at the same time as DIAMICRON 80 mg, scored tablet, especially in elderly patients.

DIAMICRON 80 mg, scored tablet may increase the effects of medicines which reduce blood clotting (eg: warfarin).

Consult your doctor before you start taking another medicinal product. If you go into hospital, tell the medical staff that you are taking DIAMICRON 80 mg, scored tablet.

DIAMICRON 80 mg, scored tablet with food, drink and alcohol

DIAMICRON 80 mg 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, breast-feeding and fertility

DIAMICRON 80 mg, scored tablet is not recommended during pregnancy. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. You must not take DIAMICRON 80 mg, scored tablet while you are breastfeeding.

Package leaflet: Information for the patient

Athletes

Not applicable.

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 vehicle or using machines).

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

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

DIAMICRON 80 mg, scored tablet contains lactose

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

3. HOW TO TAKE DIAMICRON 80 mg, scored tablet

Always take this medicine exactly as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

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

Changes in external factors (e.g. weight reduction, change in lifestyle, stress) or improvements in the blood sugar control may require changed glyclazide doses.

The recommended dose is 2 tablets a day, as 2 separate doses each day. As with any medicine that lowers blood sugar, the dosage must be adjusted to the individual patient.

If a combination therapy of DIAMICRON 80 mg, scored tablet with metformin, an alpha-glucoside 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.

Oral route.

If you take more DIAMICRON 80 mg, scored tablet than you should:

Consult your doctor or pharmacist 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.

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 DIAMICRON 80 mg, scored tablet:

It is important to take your medicine every day as regular treatment works better.

However, if you forget to take a dose of DIAMICRON 80 mg, scored tablet 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 DIAMICRON 80 mg, scored tablet:

As the treatment for diabetes is usually life long, you should discuss with your doctor before stopping this medicinal product. Stopping could cause high blood sugar (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

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The most commonly observed side effect is low blood sugar (hypoglycaemia). For symptoms and signs see section "Warnings and precautions".

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.

Liver disorders

There have been isolated reports of 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.

Skin disorders

Skin reactions such as rash, redness, itching, blisters, hives, angioedema (rapid swelling of tissues such as eyelids, face, lips, mouth, tongue or throat that may result in breathing difficulty) have been reported. Rash may progress to widespread blistering or peeling of the skin. If you develop this, stop taking Diamicron 80 mg, seek urgent advice from a doctor and tell him that you are taking this

medicine.

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.

Blood disorders

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

Digestive disorders

Abdominal pain, nausea, vomiting, indigestion, diarrhoea and constipation. These effects are reduced when DIAMICRON 80 mg is taken with a meal, as recommended.

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 sulphonylureas, the following adverse events have been observed: cases of severe changes in the number of blood cells and allergic inflammation of the wall of blood vessel, reduction in blood sodium (hyponatraemia), symptoms of liver impairment (e.g. jaundice) which in most cases disappeared after withdrawal of the sulphonylureas, but may lead to life-threatening liver failure in isolated cases.

If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Reporting of side effects

If you get any 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 directly to Drug Regulatory Authority of Pakistan www.dra.gov.pk or to company website www.servier.com.pk

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE DIAMICRON 80 mg, scored tablet

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label after EXP

This medicine does not require any special storage conditions.

Do not use DIAMICRON 80 mg, scored tablet if you notice signs of deterioration in the packaging or the blisters.

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 DIAMICRON 80 mg, scored tablet contains

· The active substance is:

Gliclazide,80 mg
For one tablet

· The other ingredients are:

Lactose monohydrate, maize starch, talc and magnesium stearate.

What DIAMICRON 80 mg, scored tablet looks like and contents of the pack

Scored tablets.

Box of 20 tablets.

Marketing Authorisation Holder and Manufacturer

Servier Research and Pharmaceuticals [Pakistan] (Pvt.) Ltd.
Factory
9-KM Sheikhpura Road Lahore Pakistan.

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