Package leaflet: information for the patient

DIAMICRON MR 30 mg modified-release tablets
Gliclazide

Read the entire 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.
- Do you have any questions? Contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed for you only. It may harm others, even if their symptoms 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.

Contents of this leaflet:

1. What is DIAMICRON MR 30 mg and what is this medicine used for

DIAMICRON MR 30 mg is a medicine that lowers blood sugar levels (oral blood glucose-lowering medicine belonging to the sulfonylurea compounds).
DIAMICRON MR 30 mg is used for a certain type of diabetes (type 2 diabetes mellitus) in adults, when diet, exercise, and weight loss do not sufficiently control blood sugar levels.

2. When should you not use this medicine or be extra careful with it?

When should you not use this medicine?
- You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6 of this leaflet.
- You are allergic to other medicines in the same category (sulfonylurea derivatives), or to other related medicines (blood glucose-lowering sulfonamides).
- You have insulin-dependent diabetes (type 1).
- You have ketones and sugar in your urine (this could mean you have diabetic ketoacidosis), or a diabetic precoma or coma.
- You have a severe kidney or liver disease.
- You are using medications for yeast or fungal infections (miconazole, see section “Are you using any other medicines?”).
- You are breastfeeding (see section “Pregnancy and breastfeeding”).

When should you be extra careful with this medicine?
Contact your doctor before using this medicine.
It is wise to adhere to the treatment plan prescribed by your doctor to achieve good blood sugar levels. This obviously means taking your tablets regularly, but also adhering to your dietary guidelines, getting enough exercise, and if necessary, losing weight.

During your treatment with gliclazide, regular monitoring of your blood sugar levels (and possibly your urine) is necessary, as well as checks of your glycated hemoglobin (HbA1c).

During the first weeks of your treatment, you have a higher risk of low blood sugar levels (hypoglycemia). This means that monitoring is very important.

You may experience low blood sugar levels (hypoglycemia):
- if you eat your meals irregularly or skip meals,
- if you are fasting,
- if you are malnourished,
- if you change your diet,
- if you have more physical exertion but do not consume more carbohydrates,
- if you drink alcohol, especially if you also skip meals,
- if you are taking other medicines or herbal medicines at the same time,
- if you take too high doses of gliclazide,
- if you have a certain hormonal disorder (disorder of the thyroid, pituitary gland, or adrenal cortex),
- if your kidney or liver function is very poor.

If your blood sugar level is low, you may experience the following symptoms: Headache, a strong feeling of hunger, nausea, vomiting, fatigue, sleep disturbances, restlessness, aggressiveness, concentration disorders, decreased alertness and reaction time, depression, confusion, speech disorders or poor vision, trembling, sensory disturbances, dizziness, and helplessness. The following symptoms may also occur: sweating, clammy skin, anxiety, rapid or irregular heartbeat, high blood pressure, sudden severe chest pain that may radiate to nearby areas of the body (angina pectoris).

If your blood sugar levels continue to drop, you may become very confused (delirium), have seizures, lose self-control, breathe shallowly, and have a slow heartbeat, you may become unconscious.

In most cases, the symptoms disappear of low blood sugar very quickly if you take sugar in any form, for example, glucose tablets, sugar cubes, sweet juice, tea with sugar.
Therefore, you should always carry sugar in some form with you (glucose tablets, sugar cubes). Remember: sweeteners (artificial sweetener tablets) do not help.
Contact your doctor or the nearest hospital if sugar intake does not help or if the symptoms recur.

Symptoms of low blood sugar may be absent, less noticeable, or develop very slowly, or you may only realize too late that your blood sugar level is low. This can happen if you are an older patient taking certain medications (for example, medicines affecting the central nervous system or beta-blockers).
If you are in a stressful situation (an accident, surgical procedure, fever, etc.), your doctor may temporarily switch your medication to insulin therapy.

Symptoms of high blood sugar (hyperglycemia) may occur if gliclazide has not yet sufficiently lowered your blood sugar, if you have not adhered to the treatment plan prescribed by your doctor, if you are taking preparations with St. John's wort (Hypericum perforatum) (see section "Are you taking any other medicines?"), or in special stressful situations. Thirst, frequent urination, dry mouth, dry and itchy skin, skin infections, and decreased performance may occur, for example.

If these symptoms occur, you should contact your doctor or pharmacist.

Disturbances in blood sugar levels (too low or too high blood sugar levels) can occur when gliclazide is prescribed simultaneously with drugs belonging to the class of antibiotics called fluoroquinolones, especially in elderly patients. In this case, your doctor will remind you of the importance of monitoring your blood sugar levels.

If you have a family history of or know that you have a confirmed hereditary deficiency of glucose-6-phosphate dehydrogenase (G6PD) (abnormality of the red blood cells), a decrease in hemoglobin level and a breakdown of red blood cells (hemolytic anemia) may occur. Contact your doctor before taking this medicine.

There have been cases of acute porphyria (this is a metabolic disease. The disease can cause problems throughout your body, but especially in your liver, intestines, brain, and skin. In acute porphyria, this disease occurs suddenly) described in patients who have porphyria and use other medications containing a substance called 'sulfonylurea'.

Children and adolescents up to 18 years
Use of DIAMICRON MR 30 mg in children is not recommended due to insufficient data.

Are you using any other medications?
Are you using any other medications besides DIAMICRON MR 30 mg, have you done so recently, or is there a possibility that you will use other medications in the near future? Then tell your doctor or pharmacist. The blood sugar-lowering effect of gliclazide can be enhanced and symptoms of low blood sugar may occur if one of the following medicines is used:

- other medicines for the treatment of high blood sugar (oral antidiabetics, GLP-1 receptor agonists, or insulin),
- antibiotics (sulfonamides, clarithromycin),
- medicines for the treatment of high blood pressure or heart failure (beta-blockers, ACE inhibitors such as captopril or enalapril),

- medicines for the treatment of fungal infections (miconazole, fluconazole),
- medicines for the treatment of stomach or duodenal ulcers (H_2receptor antagonists),
- antidepressants (monoamine oxidase inhibitors),
- painkillers or anti-rheumatics(phenylbutazone, ibuprofen),
- medicines containing alcohol.

The blood glucose-lowering effect of gliclazide can be weakened, resulting in increased blood sugar levels, when using one of the following medicines:

- medicines for the treatment of central nervous system disorders (chlorpromazine),
- medicines that reduce inflammation (corticosteroids),
- medicines for the treatment of asthma or used during childbirth (intravenous salbutamol, ritodrine, and terbutaline),
- medicines for the treatment of breast disorders, heavy menstrual bleeding, and endometriosis (danazol),
- preparations containing St. John's wort (Hypericum perforatum).

Disturbances in blood sugar levels (too low or too high blood sugar) can occur when a medicine belonging to the class of antibiotics called fluoroquinolones is taken simultaneously with Diamicron MR 30 mg, especially in elderly patients.

DIAMICRON MR 30 mg can enhance the effects of medicines that inhibit blood clotting (warfarin).

Consult your doctor before taking any other medication. If you go to a hospital, inform the medical staff that you are using this medication.

What should you be aware of with food, drink, and alcohol?
This medicine can be taken during meals and with non-alcoholic drinks. Drinking alcohol is not recommended as it can have an unpredictable effect on the treatment of your diabetes.

Pregnancy and breastfeeding
Use of this medicine during pregnancy is not recommended. Are you pregnant, do you think you might be pregnant, or do you want to become pregnant? Then contact your doctor before using this medicine. You should not use this medicine if you are breastfeeding.

Driving and using machines
Your concentration or reaction ability may be impaired if your blood sugar is too low
(hypoglycemia), or too high (hyperglycemia), or if you have vision problems due to hypo- or hyperglycemia. Keep in mind that you could endanger yourself and/or others (for example, when driving or using machines). Ask your doctor if you are allowed to drive if you:

- often have periods of low blood sugar (hypoglycemia),
- experience few or no warning signs that you have low blood sugar (hypoglycemia).

3. How to use this medicine?

Dosage
Always use this medicine exactly as your doctor or pharmacist has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

The dosage is determined by your doctor, depending on your blood sugar level and possibly the sugar levels in your urine.
Changes in other factors (weight loss, a different lifestyle, stress) or improved control of blood sugar levels may necessitate a change in the dosage of gliclazide.
The recommended daily dosage is one to four tablets (maximum 120 mg) to be taken at once during breakfast. The exact dosage depends on the effect of the treatment. This medicine is for oral use. Take your tablet(s) with breakfast with a glass of water (preferably at the same time each day). Swallow the tablets whole. Do not chew them. After taking your tablet(s), you should always have a meal.

If your doctor starts a combination therapy of this medicine with metformin, an alpha-glucosidase inhibitor, a thiazolidinedione, a dipeptidyl peptidase-4 inhibitor, a GLP-1 receptor agonist, or insulin, your doctor will determine the correct dosage of each of these medicines individually for you.

If you notice that your blood sugar levels are high despite taking the medicine as prescribed, you should contact your doctor or pharmacist.

Have you used too much of this medicine?
If you have taken too many tablets, you must contact your doctor or the emergency department of the nearest hospital immediately. The symptoms of overdose are the same as those of low blood sugar (hypoglycemia) as described in section 2. You can counteract these symptoms by immediately taking sugar (4 to 6 lumps) or a sugary drink, and then a substantial snack or meal. If the patient is unconscious, you must immediately alert a doctor and call emergency services. Even if a person, such as a child, has accidentally taken this product, you should act in this way. Unconscious patients should not be given food or drink.
There should always be someone available who knows how to act in an emergency as described above.

Have you forgotten to use this medicine?
It is important that you take your medicine every day because you will benefit more from the treatment.
However, if you have forgotten to take a dose of this medicine, you should take the next dose at the usual time.
Do not take a double dose to make up for a forgotten dose.

If you stop using this medicine
Since diabetes treatment usually needs to be continued for life, you should always discuss any intention to stop this treatment with your doctor first. Stopping the treatment can cause high blood sugar (hyperglycemia). This increases the risk of developing additional diabetes-related complaints.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

Like any medicine, this medicine can cause side effects, although not everyone gets them.

The most common side effect is low blood sugar (hypoglycemia). (See section "When should you be extra careful with this medicine?".)
If these symptoms or signs are not treated, drowsiness, loss of consciousness, or even coma may occur. If your blood sugar is very low or remains low for a long time, you should seek medical help immediately, even if this hypoglycemia is temporarily relieved by taking sugar.

Liver disorders
There have been some rare reports of abnormal liver function, where the skin and eyes may turn yellow. If you experience this side effect, you should immediately see your doctor. These symptoms usually disappear when the medication is stopped. Your doctor will then decide whether you should stop taking this medicine.

Skin disorders
Skin reactions such as rash, redness, itching, hives, blisters, angioedema (rapid swelling of tissues such as eyelids, face, lips, mouth, tongue, or throat that can result in breathing problems) have been reported. Rash may spread to widespread blistering or peeling of the skin.
If you experience this, stop taking DIAMICRON MR 30 mg, urgently contact a doctor and inform them that you are taking this medicine.
In rare cases, signs of severe hypersensitivity reactions (DRESS) have been reported: initially as flu-like symptoms and a rash on the face, followed by widespread skin rash with fever.

Blood disorders
A decrease in the number of blood cells (e.g., platelets, red and white blood cells) which can lead to pale skin and mucous membranes, prolonged bleeding time, bruising, sore throat, and fever have been reported. These symptoms usually disappear when the treatment is stopped.

Digestive disorders
Abdominal pain, nausea, vomiting, indigestion, diarrhea, and constipation. These effects decrease when the medicine is taken with a meal, as recommended.

Eye disorders
You may experience a short-term deterioration in your vision, especially at the start of treatment. This effect is related to changes in your blood sugar levels.

As with other sulfonylureas, the following side effects were observed:

cases of severe changes in the number of blood cells and allergic inflammation of the blood vessel walls, decrease in sodium in the blood (hyponatremia), symptoms of liver failure (e.g., jaundice), which usually disappeared after discontinuation of the sulfonylurea, but in isolated cases could lead to life-threatening liver failure.

Reporting side effects
If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb (website: www.lareb.nl). By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How should you store this medicine?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. It can be found on the box and the blister pack after EXP. It includes a month and a year. The last day of that month is the expiry date.

There are no special storage conditions for this medicine.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will then be destroyed responsibly and will not enter the environment.

6. Contents of the package and other information

What substances are in this medicine?
- The active substance in this medicine is gliclazide. Each modified-release tablet contains 30 mg of gliclazide.
- The other substances in this medicine are calcium hydrogen phosphate dihydrate, maltodextrin, hypromellose, magnesium stearate, anhydrous colloidal silicon dioxide.

What does DIAMICRON MR 30 mg look like and what is in a package?
DIAMICRON MR 30 mg is a white, oblong modified-release tablet, engraved on both sides, 'DIA 30' on one side and  on the other side. The tablets are supplied in
a blister pack in boxes of 7, 10, 14, 20, 28, 30, 56, 60, 84, 90, 100, 100 (unit dose blister pack), 112, 120, 180, or 500 tablets.
Not all pack sizes may be marketed.

Marketing authorization holder and manufacturer

Marketing authorization holder
Les Laboratoires Servier

50, rue Carnot
92284 Suresnes cedex- France

Manufacturers
Les Laboratoires Servier Industrie
905 route de Saran
45520 Gidy - France

or

Servier (Ireland) Industries Ltd.,
Gorey Road,
Arklow - Co. Wicklow - Ireland.

or

Anpharm Pharmaceutical Enterprise S.A.03-236 Warsaw, ul.
Annopol 6B - Poland
or

SERVIER S.L.

Avd. de los Madroños, 33
28043 Madrid - Spain
Registered under RVG 25617

Registered under RVG 25617

This medicine is registered in EEA member states under the following names:

Belgium	UNI DIAMICRON®
Cyprus	DIAMICRON® MR 30 mg
Czech Republic	DIAPREL® MR
Denmark	DIAMICRON UNO® 30mg
Estonia	DIAPREL® MR
France (RMS)	DIAMICRON® 30mg
Greece	DIAMICRON® MR
Hungary	DIAPREL® MR
Iceland	DIAMICRON UNO® 30mg
Ireland	DIAMICRON® MR 30mg
Italy	DIAMICRON® 30mg
Lithuania	DIAPREL® MR
Luxembourg	DIAMICRON® 30mg
Netherlands	DIAMICRON MR ® 30 mg
Austria	DIAMICRON® MR 30 mg
Poland	DIAMICRON® 30 mg
Portugal	DIAMICRON® LM 30mg
Slovenia	DIAPREL® MR
Slovakia	DIAPREL® MR

Spain	DIAMICRON 30 mg
United Kingdom	DIAMICRON® 30 mg MR

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