

PACKAGE LEAFLET

Package leaflet: Information for the patient

Diaclide MR 60 mg modified-release tablets gliclazide

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

1. What Diaclide MR is and what it is used for
2. What you need to know before you take Diaclide MR
3. How to take Diaclide MR
4. Possible side effects
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1. What Diaclide MR is and what it is used for

Diaclide MR contains the active substance gliclazide.

Gliclazide is a medicine that reduces blood sugar levels (oral antidiabetic medicine belonging to the sulfonylurea group).

Diaclide MR 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 Diaclide MR

Do not take Diaclide MR:

- if you are allergic to gliclazide or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to other medicines of the same group (sulfonylureas i.e. glipizide), or to other related medicines (sulfonamides i.e. hydrochlorothiazide)
- 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 miconazole to treat fungal infections (see section Other medicines and Diaclide MR")
- if you are breast-feeding (see section "Pregnancy and breast-feeding").

Warnings and precautions

Talk to your doctor or pharmacist before taking Diaclide MR.

This medicine should be used only if you are likely to have regular food intake (including breakfast). It is important to have a regular carbohydrate intake due to the increased risk of low blood sugar level (hypoglycaemia) if a meal is delayed or skipped, if an inadequate amount of food is consumed or if the food is low in carbohydrate.

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 including blood glucose self-monitoring if required.

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 (see section “Other medicines and Diaclide MR”)
- 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 a serious heart or circulation problem (affecting the circulation in the blood vessels like angina)

If you have low blood sugar (hypoglycaemia) you may have the following symptoms:

- headache
- intense hunger
- feeling sick (nausea)
- vomiting
- weariness
- sleep disorders
- restlessness
- aggressiveness
- poor concentration
- reduced alertness and reaction time
- depression
- confusion
- speech or visual disorders, which may include difficulty to read or write
- tremor
- sensory disturbances
- muscular weakness, partial paralysis
- dizziness
- 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).

Please contact your doctor or the nearest hospital if you develop the following symptoms:

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

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 or last for a long time.**

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. accidents, surgical operations, infection, fever) 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 Diaclide MR') 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.

If you have a family history, 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 medicinal product.

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).

Children and adolescents

Diaclide MR is not recommended for use in children and adolescents due to a lack of data.

Other medicines and Diaclide MR

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not take Diaclide MR if you are taking miconazole to treat fungal infections (see section "Do not take Diaclide MR")

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 (insulin or oral antidiabetics like acarbose, thiazolidinediones (e.g. pioglitazone), metformin, GLP-1 receptor agonists (e.g. exenatide, liraglutide, lixisenatide or albiglutide))
- antibiotics (e.g. sulfonamides, 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)
- painkillers or antirheumatics (phenylbutazone, anti-inflammatory agents)
- medicines containing alcohol
- medicines to treat high cholesterol (fibrates)
- medicines to treat fever or pain (salicylates)

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). It is important to self monitor your blood glucose level if taking this medicine, especially at the start of the treatment
- medicines to treat asthma or used during labour (intravenous salbutamol, ritodrine and terbutaline). It is important to self monitor your blood glucose level if taking this medicine
- medicines to treat breast disorders, heavy menstrual bleeding and endometriosis (danazol). It is important to monitor your blood and urine glucose level if taking this medicine.
- preparations containing St John's wort (*Hypericum perforatum*) used to treat mild depression.

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 as Diaclide MR, especially in elderly patients.

Diaclide MR may increase the effects of medicines which reduce blood clotting (e.g. warfarin).

Talk to your doctor before you start taking another medicine. If you go into hospital tell the medical staff you are taking Diaclide MR.

Diaclide MR with alcohol

Drinking alcohol while on the treatment Diaclide is not recommended as it can alter the control of your diabetes which can lead to diabetic coma.

Pregnancy and breast-feeding

Pregnancy

Diaclide MR is not recommended for use during pregnancy

Breast-feeding

Do not take Diaclide MR while you are breast-feeding.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Your doctor may prescribe a more suitable treatment for you.

Driving and using machines

Diaclide MR has no or negligible influence on the ability to drive and use 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. This can occur more often at the beginning of treatment with Diaclide MR.

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 Diaclide MR

Always take this medicine 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 (e.g. weight reduction, change in life style, stress) or improvements in the blood sugar control may require changed gliclazide doses.

The recommended dose is half of one to two tablets (from 30 mg to a maximum of 120 mg) in a single intake at breakfast time. This depends on the response to treatment.

The starting dose is usually 30 mg once a day. If your blood glucose is not adequately controlled, your doctor may increase your dose in successive steps usually not less than 1 month apart.

If a combination therapy of Diaclide MR with metformin, an alpha glucosidase inhibitor or insulin is initiated your doctor will determine the proper dose of each medicine individually for you.

Please talk to your doctor or pharmacist if you have the impression that Diaclide MR is acting too strongly or not strongly enough.

The tablet can be divided into equal doses.

Swallow your half-tablet or whole tablets in one piece. Do not chew or crush.

Take your tablet(s) with a glass of water at breakfast time (and preferably at the same time each day). You must always eat a meal after taking your tablet(s).

If you take more Diaclide MR than you should

If you take too many tablets, you may suffer from low blood sugar (hypolycaemia), 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. 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 Diaclide MR

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

However, if you forget to take a dose of Diaclide MR 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 Diaclide MR

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).

If you have any further questions on the use of this medicine, ask your doctor, or pharmacist or nurse.

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.**

Stop taking the tablets and tell your doctor immediately if you get any of the following side effects:

- a reduction in the number of red and white blood cells and platelets (may cause tiredness, easy bruising, fever, frequent nose bleeds and increased risk of infections, e.g. sore throat and mouth ulcers)
- liver disorders like hepatitis which may cause nausea (feeling sick), vomiting, loss of appetite, fever, itching, yellowing of the skin and eyes, dark urine, pale stools, which could lead to liver failure
- purple-coloured spots and patches on the skin; skin sores mostly located on the legs, buttocks, or trunk; blisters on the skin; hives which may last longer than 24 hours and open sores with dead tissue
- serious skin reactions such as Stevens-Johnson syndrome with severe blistering and bleeding in the lips, eyes, mouth, nose and genitals and toxic epidermal necrolysis which can cause rash, blistering or peeling of the skin
- a reaction to the medicine which may include a red rash with raised bumps, raised temperature, swollen glands (e.g. in the armpits) and general feeling of being unwell. Blood tests may show changes in how the liver is working or changes in the number or type of certain blood cells
- swelling of the face, lips, tongue or throat, difficulty breathing or swallowing

Other side effects

Very rare: may affect up to 1 in 10,000 people

- a reduction in the number of red blood cells which may cause paleness, tiredness, headache, dizziness
- skin reactions such as rash, redness, itching, hives, red raised rash, blisters
- increase levels of liver enzymes which may be seen in blood tests

Not known: frequency cannot be estimated from the available data

- impaired vision due to changes in blood sugar level
- reduction in blood sodium (hyponatraemia)

These symptoms usually vanish when the treatment is discontinued.

Digestive disorders

Abdominal pain, nausea (feeling sick), vomiting, indigestion, diarrhoea, and constipation have been reported. These effects are reduced when Diaclide MR is taken with breakfast as recommended.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA

Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Diaclide MR

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 carton, bottle and blister after EXP.

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

In use for bottles: Use within 100 days of opening.

This medicinal product does not require any special storage conditions.

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 Diaclide MR contains

The active substance is gliclazide. Each modified-release tablet contains 60 mg of gliclazide.

The other ingredients are hypromellose, cellulose microcrystalline and magnesium stearate

What Diaclide MR looks like and contents of the pack

Diaclide MR is 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, 60 on the right side of the breakline on the other side. The tablet can be divided in equal doses.

Diaclide MR is available in blister packs containing 10, 30, 60 or 90 tablets, unit dose blisters of 30 x 1 or 90 x 1 tablets and in bottles of 30, 60, 90 or 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Viatrix Limited, Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland

Manufacturer

Mylan Hungary Kft., H-2900, Komárom, Mylan utca 1, Hungary

This medicinal product is authorised in the Member States of the EEA under the following names:

France:	Gliclazide Viartis 60 mg, comprimé sécable à libération modifiée
Ireland:	Diaclide MR 60 mg modified-release tablets
Poland:	Diagen
Portugal:	Gliclazida Mylan

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