Package leaflet: Information for the patient

DACADIS® MR 30 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.

In this leaflet:

1. What Dacadis MR is and what it is used for

Dacadis MR is a medicine to reduce blood sugar levels (oral antidiabetic medicine belonging to the sulfonylurea group of medicines).
Dacadis 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.

2. What you need to know before you take Dacadis MR

Do not take Dacadis MR
- if you are allergic to gliclazide or to any of the other ingredients of this medicine (listed in section 6), or to other medicines of the same group (sulfonylureas), or to other related medicines (hypoglycaemic sulfonamides),
- if you have insulin-dependent (type 1) diabetes,
- if you have ketone bodies and sugar in the urine (this may mean you have diabetic keto-acidosis), diabetic pre-coma or coma,
- if you have severe kidney or liver disease,
- if you are taking medicines to treat fungal infections (miconazole – see section 'Other medicines and Dacadis MR'),
- if you are breast feeding.

If you think any of the above situations applies to you, tell your doctor or pharmacist.

Warnings and precautions
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.

During gliclazide treatment regular monitoring of your blood (and possibly urine) sugar level is necessary. Your doctor may also take blood tests to monitor your glycated haemoglobin (HbA_{1c}).

You should observe the treatment plan prescribed by your doctor in order to achieve the recommended blood sugar levels. This means regular tablet intake in addition to a dietary regimen and physical exercise and, where necessary, reduced weight.

In the first few weeks of treatment the risk of having reduced blood sugar levels (hypoglycaemia) may be increased. Therefore it is vital that you are carefully monitored by your doctor.

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 without an appropriate increase in carbohydrate intake,
- 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 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 suffer from low blood sugar you may have the following symptoms: headache, intense hunger, paleness, weakness, exhaustion, nausea, vomiting, weariness, sleepiness, sleep disorders, restlessness, aggressiveness, impaired concentration, reduced alertness and reaction time, depression, confusion, speech or visual disorders, tremor, sensory disturbances, dizziness, helplessness. The following signs and symptoms may also occur: sweating, clammy skin, anxiety, fast or irregular heartbeat, high blood pressure, and sudden strong pain in the chest that may radiate into nearby areas (angina pectoris).

If your blood sugar levels continue to drop you may suffer from considerable confusion (delirium), develop convulsions, lose self-control, breathing may be shallow and your heart beat slowed down, you may fall into unconsciousness possibly resulting in coma.

In most cases the symptoms of low blood sugar vanish very quickly when you consume some form of sugar, e.g. sugar cubes, sweet juice, sweetened tea. You should therefore always take some form of sugar with you (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.

It is possible that symptoms of low blood sugar may be absent, that they develop slowly or that you do not realise 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). It may also happen when you suffer from certain disorders of the endocrine system (e.g. certain disorders of thyroid function and anterior pituitary or adrenocortical insufficiency).

If you are in stress-situations (e.g. accidents, surgical operations, infections with 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 taken the medicine in the way your doctor has told you, if you take St. John's wort (*Hypericum perforatum*) preparations (see section 'Other medicines and Dacadis MR') or in special stress situations. Signs of high blood sugar may include thirst, frequent urination, dry mouth, dry itchy skin, skin infections and diminished performance. Contact your doctor or pharmacist if you experience any of these.

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

If you have a family history of or know that 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 prophyria (inherited genetic disorders with accumulation in the body of porphyrins or porphyrin precursors).

Children and adolescents
Dacadis MR is not to be used for the treatment of diabetes in children and adolescents under 18 years of age.

Other medicines and Dacadis MR
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

The effectiveness and safety of Dacadis MR may be affected if this medicine is taken at the same time as certain other medicines. Conversely, other medicines may be affected if they are taken at the same time as Dacadis 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 (oral antidiabetics, GLP-1 receptor agonists or insulin),
- antibacterial medicines (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 indigestion and ulcers in the stomach or duodenum (H_2 receptor antagonists such as ranitidine),

- medicines to treat depression (monoamine oxidase inhibitors such as selegiline, phenelzine),
- painkillers or antirheumatics (ibuprofen, phenylbutazone),
- 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:
- medicine to treat disorders of the central nervous system (chlorpromazine),
- medicines reducing inflammation (glucocorticoids such as hydrocortisone, prednisolone),
- medicine to treat asthma (salbutamol when given by injection),
- medicines used during labour (ritodrine and terbutaline given by injection),
- medicine to treat breast disorders, heavy menstrual bleeding and endometriosis (danazol),
- herbal preparations of St. John's wort (*Hypericum perforatum*) sometimes used to treat depression.

Blood glucose disturbance (low blood sugar and high blood sugar) can occur when medicines belonging to a class of antibiotics called fluoroquinolones are taken at the same time with gliclazide and so it is important to have your blood glucose monitored.

Gliclazide may increase the effect of warfarin (a medicine that inhibits blood clotting).

Consult your doctor before you start taking another medicinal product. If you go into hospital tell the medical staff you are taking Dacadis MR.

Dacadis MR with food, drink and alcohol
Dacadis MR 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 and can even lead to coma.

Pregnancy and breast-feeding
Dacadis MR is not recommended for use during pregnancy.
You must not take Dacadis MR while you are breastfeeding.
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
Dacadis MR has no known influence on the ability to drive and use machines. However, 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 Dacadis 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 hypoglycaemia,
- have fewer or no warning symptoms of hypoglycaemia.

Dacadis MR contains lactose.
If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Dacadis MR

Dose
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 of Dacadis MR is determined by the doctor, depending on your blood and possibly urine sugar levels. Changes 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 starting dose is one tablet (30 mg) once daily. The usual dose can vary from one to a maximum of four tablets (30 to 120 mg) taken at the same time, with breakfast. This depends on the response to treatment.

If 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 Dacadis MR with metformin, an alpha glucosidase inhibitor, a thiazolidinedione, a 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 still high or have become too low although you are taking the medicine as instructed, contact your doctor or pharmacist.

Route and method of administration
Oral use.
Swallow your tablets whole with a glass of water while having your breakfast, preferably at the same time each day. You must always eat a meal after or while taking your tablets. It is also important not to skip a meal when you are on Dacadis MR.

Do not crush or chew your tablets. If you do, there is a danger you could overdose because the medicine will be absorbed into your body too quickly.

Use in children and adolescents
Dacadis MR is not recommended for use in children and adolescents as there is no data available.

If you take more Dacadis MR 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. 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 Dacadis MR
If you forget to take a dose take the next dose at the usual time.

Do not take a double dose to make up for a forgotten tablet.

If you stop taking Dacadis MR If you interrupt or stop the treatment you should be aware that your blood sugar control will deteriorate. Stopping could lead to high blood sugar (hyperglycaemia), which increases the risk of developing complications of diabetes. If any change is necessary it is important to contact your doctor first.

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

4. Possible side effects

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

Tell your doctor immediately if you experience any of the following side effects, which can be serious:

Rare (may affect up to 1 in 1,000 people):
- Decrease in the number of red or white blood cells, or platelets in the blood, which may cause tiredness, shortness of breath or pale skin, fever, severe chills, sore throat or mouth ulcers (reduced white blood cells), bleeding or bruising more easily than usual or nose bleeds
- Inflammation of the liver (hepatitis) which may cause nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin or whites of the eyes (jaundice), light coloured bowel motions, dark coloured urine
- Severe skin reactions including red skin, blistering of the lips, eyes or mouth, peeling of the skin, fever (Stevens-Johnson syndrome and toxic epidermal necrolysis); exceptionally, signs of severe allergic reactions (DRESS (Drug reaction with eosinophilia and systemic symptoms)) have been reported: initially as flu-like symptoms and a rash on the face then an extended rash with a high temperature
- Angioedema, which causes rapid swelling of the eyelids, face, lips, mouth, tongue or throat and may result in difficulty breathing.

Not known (frequency cannot be estimated from the available data):
- Signs of a serious allergic reaction, which may include an itchy skin rash, difficulty breathing, wheezing.

Your medicine will need to be stopped. Your doctor will tell you how to do this.

Other side effects:

Common (may affect up to 1 in 10 people):
- Hypoglycaemia (low blood sugar). For symptoms and signs see section 2, 'Warnings and precautions'. If left untreated these symptoms could progress to drowsiness, loss of consciousness and 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.

Uncommon (may affect up to 1 in 100 people):
- Abdominal pain
- Nausea

- Vomiting
- Indigestion
- Diarrhoea
- Constipation.

These effects are reduced when Dacadis MR is taken with a meal as recommended.

Rare (may affect up to 1 in 1,000 people)*:*
- Decrease in the number of cells in the blood(e.g. platelets and red blood cells), which may cause paleness, prolonged bleeding, bruising, tiredness, headaches, shortness of breath or dizziness. These symptoms usually vanish when the treatment is stopped
- Skin reactions such as rash, redness, itching, hives and blisters
- Abnormal liver function tests
- 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.

These generally disappear if the medicine is stopped.

Not known (frequency cannot be estimated from the available data):
- Allergic inflammation of the walls of blood vessels
- Low sodium levels in the blood, which may cause confusion, tiredness, loss of appetite, restlessness or irritability, muscle weakness, cramps or uncontrollable movement.

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 via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Dacadis MR

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

Expiry date
Do not use this medicine after the expiry date which is stated on the blister, the tablet container and the carton. The expiry date refers to the last day of that month.

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 thrown away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Dacadis MR contains
- The active substance is gliclazide. Each modified-release tablet contains 30 mg gliclazide.

- The other ingredients are lactose monohydrate (see section 2, 'Dacadis MR contains lactose'), hypromellose, calcium carbonate, colloidal anhydrous silica, magnesium stearate.

What Dacadis MR looks like and contents of the pack
The modified-release tablets are white, oval, biconvex tablets.
Dacadis MR is available in blisters in boxes of 10, 14, 20, 28, 30, 56, 60, 84, 90, 100, 120 or 180 tablets and in tablet containers of 90, 120 or 180 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
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