Package leaflet: Information for the user
Gliclazide MR 30mg prolonged-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.

What is in this leaflet
1. What this medicine is and what it is used for
2. What you need to know before you take this medicine
3. How to take this medicine
4. Possible side effects
5. How to store this medicine
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1. What this medicine is and what it is used for

The name of your medicine is Gliclazide MR 30mg prolonged-release tablets. The active ingredient is Gliclazide. It reduces blood sugar levels (oral antidiabetic medicine belonging to the sulfonylurea group).

This medicine 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 this medicine

Do NOT take this medicine
- if you are **allergic** to gliclazide or 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 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 medicines to treat **fungal infections** (miconazole, see "Taking other medicines");
- if you are **breastfeedin**g (see section "Pregnancy, breastfeeding and Fertility").

Warnings and precautions
Talk to your doctor or pharmacist before taking Gliclazide MR tablets .
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:
headache, intense 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 heartbeat, 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 self control, your breathing may be shallow and your heart beat 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. accidents, 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 **Gliclazide MR 30mg prolonged-release tablets**" 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 and high blood sugar) can occur when gliclazide is prescribed at the same time than 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. 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 on porphyrin precursors).

Children and adolescents
This medicine is not recommended for use in children due to a lack of data.

Other medicines and Gliclazide MR 30mg prolonged-release tablets

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 inhibitors or insulin),
- 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),
- 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 and high blood sugar) can occur when a medicine belonging to a class of antibiotics called fluoroquinolones is taken at the same time than , especially in elderly patients.

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

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

Taking this medicine with food, drink and alcohol
This medicine 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
This medicine is not recommended for use 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 this medicine while you are breastfeeding.

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 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).

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

3. How to take this medicine

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 recommened daily dose is one to four tablets (maximum 120 mg) in a single intake at breakfast time. This depends on the response to treatment.

If 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 (other medicines to treat high blood sugar) 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.

Methods and routes of administration
Oral use.
Swallow your tablets whole. Do not chew them.
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 tablets 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 this medicine
It is important to take your medicine every day as regular treatment works better.
However, if you forget to take a dose of this medicine, 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 this medicine
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 product, 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 "Warnings and Precautions" in Section 2 “What you need to know before you take”.

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.

Blood disorders:
Decrease in the number of cells in the blood has been reported (e.g. platelets, red and white blood cells).
This may cause:

- Paleness
- Prolonged bleeding
- Bruising
- Sore throat
- Fever

These symptoms usually vanish when the treatment is discontinued.

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 have been reported such as:

- Rash
- Redness
- Itching
- Hives
- Blisters
- Angioedema (rapid swelling of tissues such as eyelids, face, lips, mouth, tongue or throat that may result in breathing difficulty). The rash may progress to widespread blistering or peeling of the skin. If you develop this, stop taking this medicine, seek urgent advice from a doctor and tell him that you are taking this medicine.
- Exceptionally, signs of severe hypersensitivity reactions (DRESS): initially as flu-like symptoms and a rash on the face then an extended rash with a high temperature.

Digestive disorders:

- Abdominal pain
- Nausea, vomiting
- Indigestion
- Diarrhoea

- Constipation

These effects are reduced when this medicine is taken with a meal as recommended, See Section 3 "How to take"

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 sulfonylureas, 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 vessels, reduction in blood sodium (hyponatraemia), symptoms of liver impairment (e.g. jaundice) which in most cases disappeared after withdrawal of the sulfonylurea, but may lead to life threatening liver failure in isolated cases.

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 HPRA website: www.hpra.ie or email to: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store this medicine

- 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 and the blister strip after (EXP.). The expiry date refers to the last day of that month.
- Do not store above 25°C.
- 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 this medicine contains
- The active substance is gliclazide. One tablet contains 30 mg of gliclazide, in a prolonged-release formulation.

- The other ingredients are: Lactose monohydrate, Maize starch, Povidone, Hypromellose, Colloidal anhydrous silica and Magnesium stearate.

What these tablets look like

- The tablets are white to off white, capsule shaped, biconvex tablets debossed with 'C12' on one side and plain on the other side.

- The tablets are available in blisters packed in cartons of 7, 10, 14, 28, 20, 30, 56, 60, 84, 90, 100, 112, 120, 180 tablets. Not all pack sizes may be marketed.

Marketing Authorization Holder

Name and address:
Brillpharma (Ireland) Limited
Inniscarra, Main Street
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Email:info@brillpharma.co.uk

Manufacturer

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axcount Generika GmbH
Max-Planck-Straße 36d,
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This medicinal product is authorised in the Member States of the EEA under the following names:

UK: Zicron PR 30 mg prolonged-release tablets

IE: Gliclazide MR 30 mg prolonged-release tablets

DE: Gliclazid axcount 30 mg Tabletten mit veranderter Wirkstofffreisetzung

NL: Gliclazide Bristol 30 mg, tabletten met verlengde afgifte

MT: Zicron PR 30 mg prolonged-release tablets

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