

GLICLADA MODIFIED RELEASE TABLETS

Gliclazide (30 mg)

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What Gliclada is used for

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

Gliclada 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.

How Gliclada works

Gliclada reduces blood glucose levels by stimulating the secretion of a hormone, called insulin, from the pancreatic gland.

Before you use Gliclada

- When you must not use it

- if you are allergic to gliclazide or to any of the other ingredients of this medicine 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 the urine (this may mean you have diabetic ketoacidosis), a diabetic precoma or coma,
- if you have severe kidney or liver disease,
- if you are taking medicines to treat fungal infections (miconazole, see section "Taking with other medicines"),
- if you are breast feeding (see section 'Pregnancy and breast-feeding').

- Before you start use it

Talk to your doctor or pharmacist before taking Gliclada.

You should observe the treatment plan prescribed by your doctor to achieve proper blood sugar levels. This means, apart from regular tablet intake, to 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 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 have low blood sugar you may have the following symptoms: headache, intense hunger, nausea, vomiting, weariness, sleepiness, 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 your blood sugar levels continue to drop you may suffer from considerable confusion (delirium), develop cerebral 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 take 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 "Taking with other medicines"), or in special stress situations. These may include thirst, frequent urination, dry mouth, dry itchy skin, skin infections and diminished 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.

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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 hemoglobin level and breakdown of red blood cells (hemolytic anemia) can occur. Contact your doctor before taking this medicinal product.

Children and adolescents

Gliclada is not recommended for use in children due to a lack of data.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby while taking this medicine, inform your doctor so that he may prescribe a more suitable treatment for you. Gliclada is not recommended for use during pregnancy. You must not take Gliclada while you are breast-feeding.

- Taking other medicines

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. 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 (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:

- medicines to treat disorders of the central nervous system (chlorpromazine),
- medicines reducing inflammation (corticosteroids),
- medicine to treat asthma or used during labour (intravenous salbutamol, ritodrine and terbutaline),
- medicine 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 Gliclada, especially in elderly patients.

Gliclada may increase the effect 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 Gliclada.

Gliclada with food, drink and alcohol

Gliclada 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.

How to use Gliclada

Swallow your tablets whole.

Do not chew them.

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

- How much to use

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 starting dose is one tablet once daily.

The usual dose can vary from one to a maximum of four tablets in a single intake at breakfast. This depends on the response to treatment.

If a combination therapy of Gliclada with metformin, an alpha glucosidase 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.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Gliclada for as long as your doctor recommends.

- If you forget to use it

It is important that you take the medicine every day as regular treatment works better. However, if you forget to take a dose of Gliclada, 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 Gliclada

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 levels (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.

- If you use too much (overdose)

If you take too many tablets, contact your doctor or go to Emergency Department of nearest hospital immediately.

The signs of overdose are those of low blood sugar (hypoglycaemia) described in Section "Before you start use it". The symptoms can be helped by taking sugar (4 to 6 lumps) or sugary drinks straight away, followed by a substantial

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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.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists that are treating you that you are taking Gliclada.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Gliclada to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

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 symptoms of hypoglycaemia.

Gliclada 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.

Side effects

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

The assessment of side effects is based on their frequency.

The most commonly observed side effect is low blood sugar (hypoglycaemia).

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.

Digestive disorders

Abdominal pain, nausea, vomiting, indigestion, diarrhoea and constipation. These effects are reduced when Gliclada is taken with meals as recommended.

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.

Skin disorders

Skin reactions such as rash, redness, itching, hives, angioedema (rapid swelling of tissues such as eyelids, face lips, mouth, tongue or throat that may result in breathing difficulty) have been reported.

The rash may progress to widespread blistering or peeling of the skin. 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.

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.

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 very rarely 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 sulfonylureas, but may lead to life-threatening liver failure in isolated cases.

If you get any side effects, talk to your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Gliclada

- Storage

Keep out of the reach and sight of children.

Store below 30°C.

Do not store any medicine in the bathroom, or near a sink, or on a window sill.

Do not leave it in the car especially on hot days. Heat and dampness can destroy medicines.

Do not use your medicine after the expiry date which is stated on the pack after 'EXP'. The expiry date refers to the last day of that month.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

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Product Description

- What it looks like

The tablets are white, oval, biconvex.

- Ingredients

- Active ingredient: Gliclazide

- Inactive ingredients:

Lactose monohydrate

Hypromellose

Calcium carbonate

Colloidal anhydrous silica

Magnesium stearate

- MAL number:

MAL10110008AZ

Manufacturer

KRKA, d.d., Novo mesto,
Šmarješka cesta 6,
8501 Novo mesto, Slovenia

Product Registration Holder

Pahang Pharmacy Sdn. Bhd.
Lot 5979, Jalan Teratai,
5 ½ Mile Off Jalan Meru,
41050 Klang, Selangor, Malaysia

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