GLICLADA MODIFIED RELEASE TABLETS

Gliclazide 60 mg *Consumer Medication Information Leaflet (RiMUP)*

What is in this leaflet

1. What *Gliclada* is used for
2. How *Gliclada* works
3. Before you use *Gliclada*
4. How to use *Gliclada*
5. While you are using it
6. Side effects
7. Storage and Disposal of *Gliclada* Product Description
8. Manufacturer and Product Registration Holder
9. Date of revision

What *Gliclada* is used for

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 is a medicine that reduces blood sugar levels (antidiabetic medicine taken orally) by stimulating insulin secretion.

Before you use *Gliclada*

- *When you must not use it*

Do not take *Gliclada:*

- if you are allergic (hypersensitive) to gliclazide, to other sulphonylureas, to sulphonamides or to any of the other ingredients of this medicine,
- 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),
- if you are breast feeding

Pregnancy and lactation

Do not take *Gliclada* if you are pregnant, trying to get pregnant or think you may be pregnant. If you get pregnant while taking *Gliclada* stop taking it immediately and contact your doctor so he may prescribe you a more suitable treatment for you.

Do not take *Gliclada* if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- *Before you start use it*

This medicine should be used only if you are likely to have a 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 (HbA1c).

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.

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 renal 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, and 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 breast that may radiate into neighboring areas (angina pectoris).

If your blood sugar levels continue to drop you may suffer from considerable confusion (delirium), develop cerebral convulsions, lose self-control, breathing may be shallow and your heart beat slowed down, you may fall into unconsciousness possibly resulting in coma. The clinical picture of a severe reduced blood sugar level may resemble that of a stroke.

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, and sweetened tea. You should therefore always take some form of sugar with you (sugar cubes).

Remember that 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 symptom 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, fever, trauma, surgical interventions.) 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 or in

special stress situations. Symptoms 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.

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 to be used for the treatment of diabetes in children and adolescents under 18 years of age.

- *Taking other medicines*
Tell your doctor if you are taking any other medicines, including any that you buy from a pharmacy, supermarket or health food shop without a prescription.

The effectiveness and safety of *Gliclada* 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 *Gliclada*.

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. sulphonamides, clarithromycin),
- medicines to treat high blood pressure or heart failure (beta blockers, ACE-inhibitors such as captopril, or enalapril),
- medicines to treat fungal infections (miconazol, fluconazole),
- medicines to treat indigestion and ulcers in the stomach or duodenum (H2 receptor antagonists such as ranitidine),
- 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:
- medicine to treat disorders of the central nervous system (chlorpromazine),
- medicines reducing inflammation (glucocorticoids),
- 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).

Gliclazide may potentiate anticoagulation during concurrent treatment with warfarin (a medicine that inhibits blood clotting).

How to use *Gliclada*

- *How much to use*
Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

The dose of *Gliclada* 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 30 mg once daily. The usual dose can vary from 30 mg to a maximum of 120 mg tablets in a single intake at breakfast. This depends on the response to treatment.

If blood glucose is not adequately controlled, your doctor may increase it in successive steps usually not less than 1 month apart. 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.

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

Special populations

Elderly
Gliclada should be prescribed using the same dosing regimen recommended for patients under 65 years of age.

Patients with renal impairment
In patients with mild to moderate renal impairment the same dosing regimen can be used as in patients with normal renal function with careful patient monitoring.

Paediatric population
The safety and efficacy of *Gliclada* in children and adolescents have not been established.
No data are available in children.

- *When to use it*
Use as directed by your doctor or pharmacist.

Gliclada is to be taken as a single dose at breakfast time, preferably at the same time each day. It is recommended that the tablet(s) is swallowed whole with a glass of water whilst having your breakfast. Do not chew the tablets. You must always eat a meal after taking your tablet(s). It is important not to skip a meal when you are on *Gliclada*. *Gliclada* can be taken with food and non-alcoholic drinks. Avoid alcohol as it can alter the control of your diabetes in an unpredictable manner and can even lead to coma.

- *How long to use it*
Continue taking *Gliclada* for as long as your doctor recommends.

- *If you forget to use it*
Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- *If you use too much (overdose)*
Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

The signs of overdose are those of low blood sugar (hypoglycaemia).

Moderate symptoms of hypoglycaemia without any loss of consciousness or neurological signs, must be corrected by carbohydrate intake, dose adjustment and/or change of diet. Strict monitoring should be continued until the doctor is sure that the patient is out of danger.
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.

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
Gliclada has no known 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. 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.

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, *Gliclada* can cause side effects, although not everybody gets them.
Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

As with other sulphonylureas, treatment with *Gliclada* modified release tablets can commonly cause hypoglycaemia (low blood sugar) if meals are taken irregularly,and, in particular, if they are skipped. Possible symptoms of hypoglycaemia are listed in section *"Before you start use it"*

If a hypoglycaemic episode is severe or prolonged, and even if it is temporarily controlled by intake of sugar, immediate medical treatment or even hospitalization is required.

Gastrointestinal disorders
Gastrointestinal disturbances, including abdominal pain, nausea, vomiting, dyspepsia, diarrhoea and constipation are uncommon; if these should occur, they can be avoided or minimized if gliclazide is taken with breakfast.

Cases of severe changes in the number of blood cells and allergic inflammation of the wall of blood vessels, reduction in blood sodium (hyponatraemia), signs and symptoms of liver impairment (e.g. jaundice) which in most cases disappeared after withdrawal of the sulphonylureas, but may led to life threatening liver failure in isolated cases.

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 this medicine out of the reach and sight of children. Do not store above 30°C. Store in the original package in order to protect from moisture.
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.

Product Description
- *What it looks like*
White to almost white, oval, biconvex tablets.

- *Ingredients*
Active ingredient:
Each modified-release tablet contains 60 mg gliclazide.

Inactive ingredients:
Hypromellose, lactose monohydrate, colloidal anhydrous silica and magnesium stearate.

- *Registration No.:*
MAL19021006AZ

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

Product Registration Holder
Pahang Pharmacy Sdn. Bhd.
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