

PLECAZ MR TABLET 60MG

Gliclazide 60mg

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What Plecaz MR 60mg is used for

Plecaz MR is a tablet that contains gliclazide as the active ingredient.

Plecaz MR is used for 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 Plecaz MR 60mg works

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

Before you use Plecaz MR 60mg

-When you must not use it

Do not take *Plecaz MR* if you:

- if you are allergic to gliclazide or any of the other ingredients of *Plecaz MR*, or to other medicines of the same group (sulfonylurea), 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.

- if you are breastfeeding.

-Before you start to use it

If you are not sure if any of these apply to you, talk to your doctor or pharmacist before taking *Plecaz MR*.

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 refuse to co-operate especially in elderly patient.
- 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.

During gliclazide treatment, it is important to follow dietary advice, take regular exercise and regular monitoring of blood glucose levels to avoid the risk of hypoglycaemia.

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.

Plecaz MR should not be given to patients with rare inherited condition i.e., galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption.

-Taking other medicines

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

The following medicines are likely to increase the risk of hypoglycaemia when one of the following medicines is taken:

- medicines to treat fungal infections (miconazole)
- 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 to treat breast disorders, heavy menstrual bleeding and endometriosis (danazol).
- medicines to treat asthma or used during labour (intravenous salbutamol, ritodrine and terbutaline),
- medicines which reduce blood clotting (e.g. warfarin).

Use of fluoroquinolone with *Plecaz MR* may cause dysglycaemia (abnormality in blood sugar).

If you are not sure, please talk to your doctor or pharmacist before use *Plecaz MR*.

How to use Plecaz MR 60mg

-How much to use

Always take *Plecaz MR* exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Plecaz MR is not able to deliver all approved dose regimes of gliclazide, other approved dosage forms and strengths of gliclazide should be used in such cases.

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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 daily dose is one half to 2 tablets per day i.e., 30 to 120mg orally in single intake at breakfast time.

If a combination therapy of *Plecaz MR* 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.

-When to use it

You should take your medicine at breakfast time each day with a drink of water.

You must always eat a meal after taking *Plecaz MR*.

-How long to use it

Continue taking *Plecaz MR* 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.

If you forget to take a dose of *Plecaz MR*, take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

-If you take 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. The signs of overdose are those of low blood sugar

(hypoglycaemia) in Section 'Side Effect'.

While you are using Plecaz MR 60mg

-Things you must do

Taking Plecaz MR 60mg with food, drink and alcohol.

Plecaz 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.

-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 *Plecaz MR* to anyone else, even if they have the same symptoms or condition as you.

-Things to be careful of

Pregnancy and breast-feeding

The use of *Plecaz MR* is not recommended for use during pregnancy and it is recommended to change to insulin during pregnancy.

You must not take *Plecaz MR* while you are breastfeeding.

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).

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).

In most cases the symptoms of low blood sugar vanish very quickly when you consume some form of sugar, (for instance glucose tablets, sugar cubes, sweet juice, sweetened tea). However, please remember that artificial sweeteners are not effective.

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.

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.

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 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.

Blood disorders

Decrease in the number of cells in the blood (for instance platelets, red and white blood cells) which may cause

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paleness, prolonged bleeding, bruising, sore throat and fever have been reported. These symptoms usually vanish when the treatment is discontinued.

Digestive disorders

Abdominal pain, nausea, vomiting, indigestion, diarrhoea, and constipation. These effects are reduced when *Plecaz MR* is taken with a meal as recommended.

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 (for instance jaundice) which in most cases disappeared after withdrawal of the sulfonylureas, but may lead to life-threatening liver failure in isolated cases.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell 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 npa.moh.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Plecaz MR 60mg

-Storage

Keep out of the reach and sight of children.

Do not store above 30°C.

Do not take the tablet after the expiry date shown on the pack and blisters.

-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

15mm length, white to off white uncoated oblong-shaped tablets with plain on one side and Pharmaniaga logo on the other side.

-Ingredients

-Active ingredient:

Gliclazide 60mg

-Inactive ingredients:

Lactose Monohydrate, Hydroxypropyl Methylcellulose, Colloidal Silicon Dioxide, Maltodextrin and Magnesium Stearate.

-MAL number

MAL22036017AZ

Manufacturer

Pharmaniaga Manufacturing Berhad (198001006232),
11A, Jalan P/1, Kawasan Perusahaan Bangi, 43650 Bandar Baru Bangi, Selangor Darul Ehsan, Malaysia.

Product Registration Holder

Pharmaniaga Manufacturing Berhad (198001006232),
11A, Jalan P/1, Kawasan Perusahaan Bangi, 43650 Bandar Baru Bangi, Selangor Darul Ehsan, Malaysia.

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