

OZICLIDE MR

Gliclazide Modified Release (60 mg)

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What **OZICLIDE MR** is used for

OZICLIDE MR is used to control blood sugar level 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.

Follow all directions given to you by your doctor carefully.

How **OZICLIDE MR** works

OZICLIDE MR contains gliclazide which belongs to a group of medicines called sulphonylureas. Sulphonylureas work by reducing blood sugar levels.

Gliclazide in **OZICLIDE MR** is in a "modified release" form. This means the tablet releases active ingredient gradually and therefore you only have to take the tablet once a day

Before you use **OZICLIDE MR** S

- *When you must not use it*

Do not use **OZICLIDE MR** :

- If you are allergic to gliclazide or any of the other ingredients of **OZICLIDE MR** , or to other medicines of the same group (sulphonylureas) or to other related medicines (sulphonamides).
- 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)
- If you are breastfeeding

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

- *Before you start to use it*

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

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.

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 suffer from serious blood vessels problems such as coronary heart disease, severe carotid disease, diffuse vascular disease,
- If you are taken off from prolonged and/or high dose steroid treatment.

If you have low blood sugar you may have the following symptoms:

Headache, intense hunger, being sick, feeling sick, weariness, sleep disorders, agitation, 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, changes in the rhythm or rate of the 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), fits, 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 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), or in special stress situations (e.g. accidents, surgical operations, fever, infections etc.) your doctor may temporarily switch you to insulin therapy. 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 (a rare blood pigment disorder) have been described with some other sulfonylurea drugs, in patients who have porphyria.

There is no or limited experience with the use of gliclazide during pregnancy in humans. **OZICLIDE MR** are not recommended for use during pregnancy. Tell your doctor if you are pregnant or plan to become pregnant.

Important information of some of the ingredients of OZICLIDE MR

Your medicine also contains an inactive ingredient called lactose, which is a type of sugar. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine.

- Taking other medicines

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

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 (insulin or oral antidiabetics such as metformin,
- Antibiotics (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 (miconazole, fluconazole),
- Medicines to treat ulcers in the stomach or duodenum (H₂ receptor antagonists),
- Medicines to treat depression (monoamine oxidase inhibitors),
- Painkiller (phenylbutazone),
- Non-steroidal anti-inflammatory drugs
- 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 or high blood sugar) can occur when a medicine belonging to a class of antibiotics called fluoroquinolones is taken at the same time than **OZICLIDE MR** .

OZICLIDE MR 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 **OZICLIDE MR** .

If you need a laboratory investigation such as blood test or urine test, do inform your doctor about the medicine you are taking.

How to use OZICLIDE MR

Follow all directions given to you by your doctor or pharmacist carefully.

How much to use

The dose is determined by the doctor, depending on your blood and possibly urine sugar levels.

The usual starting dose is 30 mg daily.

The daily dose may vary from 30 mg to 120 mg, in a single intake at breakfast time.

This depends on the response to treatment. The maximum daily dose is 120 mg (2 tablets of **OZICLIDE MR 60 mg**).

Combination treatment with other antidiabetic agents

If combination therapy of **OZICLIDE MR** with metformin, an alpha glucosidase inhibitor or insulin is initiated your doctor will determine the proper dose of each medicine individually for you.

In the elderly (over 65)

OZICLIDE MR are prescribed using the same dosing regimen recommended for patients under 65 years of age.

Children

This medicine is not recommended in children.

- How to take it

Swallow the tablets with a glass of water. **OZICLIDE MR** should be taken as whole without breaking.

- When to use it

Your doctor will advise you on the best time of the day to take your medicine.

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).

- How long to use it

Your doctor will advise you on how long you should continue to take your medicine.

- If you forget to use it

It is important to take your medicine every day as regular treatment works better.

However, if you forget to take a dose of OZICLIDE MR S, take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

- If you use too much (overdose)

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 “**Before you use OZICLIDE MR S**”. 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.

Immediately telephone your doctor or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much **OZICLIDE MR S**. Do this even if there are no signs of discomfort or poisoning.

While you are using it

- Things you must do

Always follow dietary advice given by doctor, take regular exercise, and regularly monitor blood glucose levels.

Tell your doctor or pharmacist that you are taking **OZICLIDE MR** if you are about to be started on any new medicines.

Tell your doctor if you become pregnant or are trying to become pregnant or intend to breastfeed while you are taking **OZICLIDE MR**.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Make sure you check your blood glucose levels regularly. This is the best way to tell if your diabetes is being controlled properly. Your doctor or diabetes educator will show you how and when to do this.

Visit your doctor regularly so that they can check on your progress.

Carefully follow your doctor's and dietician's advice on diet and exercise.

Tell your doctor immediately if you notice the return of any symptoms of hyperglycaemia that you had before starting **OZICLIDE MR**

- Things you must not do

Do not stop taking **OZICLIDE MR** or alter the dose, without first checking with your doctor.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use **OZICLIDE MR** to treat any other complaints unless your doctor says to.

Do not skip meals while taking **OZICLIDE MR**.

- Things to be careful of

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).

Side effects

Like other medicines, **OZICLIDE MR** may cause some unwanted side effects.

Tell your doctor as soon as possible if you do not feel well while you are taking **OZICLIDE MR S**. Your doctor may decide to adjust the dose of **OZICLIDE MR** or may change to a different medicine.

If any of the following happens, stop taking **OZICLIDE MR S**, tell your doctor immediately, or go to Accident and Emergency at the nearest hospital:

Rash, redness, itching, hives; swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing; severe blisters and bleeding in the lips, eyes, mouth, nose and genitals.

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.

Hypoglycaemia

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.

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.

Digestive disorders

Stomach pain or discomfort, feeling or being sick, indigestion, diarrhoea, constipation.

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.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

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

Storage and Disposal

Storage

Store below 30°C, protected from moisture
KEEP MEDICINE OUT OF THE REACH OF CHILDREN.

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

OZICLIDE MR 60 MG White to off white oblong tablets, engraved with 'Z' and 'I' on one side and plain on the other side.

Ingredients

- **Active ingredient:** Gliclazide 60mg

Inactive ingredients:

Magnesium Stearate, Hypromellose, Pregelatinized starch, Sodium citrate, Lactose, Purified Water.

MAL number:

MAL18026187AZ

Manufacturer & Product registration holder

RANBAXY (MALAYSIA) SDN. BHD.

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