

OZICLIDE® MR

Gliclazide Modified Release Tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about OZICLIDE MR tablets (gliclazide).

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking OZICLIDE MR against the benefits it is expected to have for you.

If you have any concerns about using/taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with this medicine.

You may need to read it again.

What OZICLIDE MR is used for

OZICLIDE MR contains the active ingredient gliclazide, which is released progressively over 24 hours from the tablets. Gliclazide belongs to a group of sugar diabetes medicines called sulphonylureas (sometimes spelled "sulfonylureas").

Your doctor would have prescribed OZICLIDE MR for treatment of Type 2 diabetes. Your doctor would have advised you to continue dietary restrictions along with OZICLIDE MR. Type 2 diabetes usually develops in adulthood. OZICLIDE MR tablets are used when diet and exercise are not enough to control your blood glucose properly.

Glucose is used by the body as fuel, and all people have glucose circulating in their blood. In diabetes, levels of blood glucose are higher than is needed, a condition known as hyperglycaemia.

It is very important to control high blood glucose whether or not you feel unwell. This helps to avoid serious long-term health problems, which can involve the heart, eyes, nerves, and/or kidneys.

OZICLIDE MR lowers blood glucose by increasing the amount of insulin (a hormone that controls blood glucose levels) produced by your pancreas.

As with many medicines used for the treatment of diabetes, there is a possibility that blood glucose levels may become very low during treatment with OZICLIDE MR. This is known as hypoglycaemia.

Your doctor may prescribe OZICLIDE MR for another reason. Ask your doctor if you have any questions about why OZICLIDE MR has been prescribed for you.

There is no evidence that OZICLIDE MR tablets are addictive.

Gliclazide may affect your ability to drive a car or operate machinery.

Before you take OZICLIDE MR

When you must not take it

Do not take OZICLIDE MR if you are allergic to gliclazide, other sulphonylureas, or to other sulphonamides (possible cross-reaction) or to any of the tablet ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching, shortness of breath, swelling of the tongue or face.

Do not take if any of the following applies to you:

- **You have Type 1 diabetes mellitus (also known as insulin-dependent diabetes (NIDDM), or juvenile-onset diabetes)**
- **You are pregnant or planning to become pregnant. Your doctor will usually replace OZICLIDE MR with insulin while you are pregnant.**
- **You are breast-feeding**
- **You have diabetic ketoacidosis characterised by very high blood sugar levels (a problem which affects the acidity of your blood and can lead to coma and is mainly associated with Type 1 diabetes)**
- **You have severe liver and or kidney problems**
- **You are undergoing treatment with miconazole (antifungal medicine)**

Do not take OZICLIDE MR after the expiry date printed on the pack.

If you take it after the expiry date has passed, it may not work as well or may cause harm. Do not take OZICLIDE MR if the tablets do not look quite right.

Do not take OZICLIDE MR if the packaging is torn or shows signs of tampering.

Before you start to take it

Tell your doctor if you have allergies to:

- **any other medicines**
- **any other substances, such as foods, preservatives or dyes**

Tell your doctor if you are pregnant or planning to become pregnant.

Like many other medicines, OZICLIDE MR may affect your developing baby if you take it during pregnancy. Your baby may absorb this medicine in the womb or from breast milk and therefore there is a possibility of harm to the baby.

If it is necessary for you to take control of your blood glucose levels, your doctor can help you decide whether or not to take it during pregnancy.

Tell your doctor if you are breast-feeding or planning to breast-feed. Your doctor will discuss the possible risks and benefits of using OZICLIDE MR during breast-feeding.

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

- **You have a fever**
- **You have had an injury**
- **You have hormonal disorders of the adrenal or pituitary gland**
- **You do heavy exercise or work**
- **You have problems with your kidney(s) and/or liver**
- **You don't eat well**
- **You are in the habit of consuming alcoholic beverages**
- **You are an elderly person (more than 65 years of age)**
- **You are about to undergo surgery**

OZICLIDE MR tablets are not recommended for use in children.

Avoid alcoholic beverages until you have discussed their use with your doctor.

Tell your doctor if you plan to have blood/urine test.

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

You will need to undergo blood tests for monitoring your sugar levels at regular intervals.

If you have not told your doctor about any of the above, tell them before you take OZICLIDE MR.

Taking other medicines

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

- **Other sugar diabetes medicines (such as oral hypoglycaemic agents or insulin)**
- **Water tablets (e.g. thiazide diuretics like furosemide, bumetanide, hydrochlorothiazide, acetazolamide)**
- **MAO inhibitors (e.g. chlorpromazine, medicines used to treat certain mental illness)**
- **Antifungal medicines such as miconazole, fluconazole**
- **Antibiotics such as sulphonamides, chloramphenicol**
- **Antihypertensive medicines - ACE inhibitors (e.g. captopril, enalapril); beta blockers (e.g., propranolol, atenolol); reserpine; guanethidine, clonidine**
- **Pain relievers known as Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) e.g. ibuprofen, aspirin, phenylbutazone, azapropazone and oxyfenbutazone**
- **Medicines used to prevent blood from clotting normally (warfarin or coumarin drugs)**
- **Danazol (medicines used to treat certain menstrual disorders)**
- **Barbiturates (sedative drugs which may be used in the treatment of sleeplessness or epilepsy)**
- **Cimetidine (a medicine for a type of digestive disorder)**
- **Corticosteroids (used to treat various conditions including rheumatism, arthritis, allergic conditions, certain skin diseases, asthma or certain blood disorders)**
- **Anti-asthma medicines (salbutamol, terbutaline)**

These medicines may be affected by gliclazide, or may affect how well it works. You may need to use different amounts of your medicine or you may need to take different medicines. Your doctor or pharmacist will be able to tell you what to do when taking/being given OZICLIDE MR tablets with other medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking OZICLIDE MR tablets.

How OZICLIDE MR is given

How much to take

Your doctor will tell you how many tablets you will need to take each day. This may depend on your age, your blood sugar levels, condition and whether or not you are taking any other sugar diabetes medicines.

Take your medicine as instructed by your doctor. Do not take more than the doctor told you to. Check the label carefully for how much to take and how often to take. Your pharmacist or doctor can help if you are not sure.

How to take it

It is important to take your OZICLIDE MR at the same time each day, usually with breakfast. Taking OZICLIDE MR with food can help to minimize the risk of hypoglycaemia.

Swallow your tablet(s) with a glass of water. Do not crush the tablets or break them.

Adults

Your doctor will select a dose when they prescribe OZICLIDE MR for you, and may adjust this later. The usual dose of OZICLIDE MR is between one and four tablets once daily. OZICLIDE MR tablets can be used to replace other sugar diabetes medicines or can be used with other sugar diabetes medicines.

When to take it

Take your OZICLIDE MR tablets at about the same time everyday. Taking your tablets at the same time will have the best effect. It will also help you to remember when to take the tablets.

How long to take it

Continue taking OZICLIDE MR tablets until your doctor tells you to stop. OZICLIDE MR helps to control your blood sugar level but does not cure your condition (Type II diabetes). Therefore you must continue taking OZICLIDE MR every day for as long as your doctor tells you.

Do not stop taking OZICLIDE MR tablets because your blood sugar levels are controlled.

Do not stop taking OZICLIDE MR, or lower the dosage, without checking with your doctor.

Do not let yourself run out of medicine over the weekend or on holidays.

Stopping OZICLIDE MR without doctor's advice may make your blood sugar levels rise. Your doctor will decide when you should stop taking it.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, then go back to taking it as you would normally.

Do not double a dose to make up for the dose you have missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (Overdose)

Immediately telephone your doctor or the Poisons Information Centre, or go to Emergency department at your nearest hospital, if you think that you or anyone else has taken too much of OZICLIDE MR tablets. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention. Keep these telephone numbers handy.

While you are using OZICLIDE MR

Things you must remember

Take OZICLIDE MR tablets exactly as your doctor tells you to.

Try not to miss any doses and take the medicine even if your blood sugar levels are better.

Visit your doctor regularly for check-ups.

Tell all doctors, dentists and pharmacists who are treating you that you are taking OZICLIDE MR tablets.

If you are about to be started on any new medicine, tell your doctor or pharmacist that you are taking OZICLIDE MR tablets.

Tell your doctor if you are to undergo any blood or urine test.

If you become pregnant while taking OZICLIDE MR tablets, tell your doctor immediately.

Things you must do

Take OZICLIDE MR exactly as your doctor has prescribed.

Otherwise you may not get the full benefits from treatment.

Tell all doctors, dentists, pharmacists and diabetes educators who are involved with your treatment that you are taking OZICLIDE MR.

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.

Make sure that you, your friends, family and work colleagues can recognise the symptoms of hypoglycaemia and hyperglycaemia and know what to do.

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

Carefully follow your doctor's and dietitian's advice on diet, drinking alcohol and exercise.

Tell your doctor immediately if you notice the return of any symptoms of hyperglycaemia that you had before starting OZICLIDE MR, or if your blood sugar levels are high.

These may be signs that OZICLIDE MR is no longer working, even though you may have been taking it successfully for some time.

Things you must not do

Do not give OZICLIDE MR to anyone else, even if they have the same condition as you.

Do not use OZICLIDE MR to treat other complaints unless your doctor tells you to.

Do not stop taking OZICLIDE MR, or change the dosage, without checking with your doctor.

Do not skip meals while taking OZICLIDE MR.

Things to be careful of

If you drink alcohol while taking OZICLIDE MR, you may get flushing, headache, breathing difficulties, rapid heart beat, stomach pains or feel sick and vomit.

Be careful driving or operating machinery until you know how OZICLIDE MR affects you.

OZICLIDE MR may cause dizziness and drowsiness in some people. Drinking alcohol can make this worse. If either of these occurs, do not drive, operate machinery or do anything else that could be dangerous. Be careful not to let your blood glucose levels fall too low. Low blood glucose levels may slow your reaction time and affect your ability to drive or operate machinery.

Things that would be helpful for you in recognizing and treating symptoms of high or low blood sugar levels:

Recognising and treating hypoglycaemia (very low blood sugar levels) Hypoglycaemia may occur during OZICLIDE MR treatment.

- **The first signs of hypoglycaemia are usually weakness, trembling or shaking, sweating, light-headedness, dizziness, headache or lack of concentration, irritability, tearfulness, hunger, and/ or numbness around the lips and tongue.**
- **At the first signs of hypoglycaemia take some sugar to raise your blood sugar level quickly.**
- **Do this by eating 5 to 7 jelly beans, 3 teaspoons of sugar or honey, drinking half a can of non-diet soft drink, taking 2-3 glucose tablets or a tube of glucose gel.**
- **Then take some extra carbohydrates such as plain biscuits, fruit or milk unless you are within 10-15 minutes of your next meal. Taking this extra carbohydrate will help to prevent a second drop in your blood glucose level.**
- **If not treated quickly, hypoglycaemia symptoms may progress to loss of co-ordination, slurred speech, confusion, fits or loss of consciousness.**

If hypoglycaemia symptoms do not get better straight away after taking sugar then go to the Accident and Emergency department at your nearest hospital - if necessary by calling an ambulance.

Contact your doctor or diabetes educator for advice if you are concerned about hypoglycaemia.

Recognising and treating hyperglycaemia (high blood sugar levels):

Some people may feel fine even when their glucose levels are high. Others notice symptoms of hyperglycaemia like tiredness, lack of energy, thirst, passing large amounts of urine, headache, and/or blurred vision.

If you notice symptoms of hyperglycaemia, or your blood sugar levels are high, tell your doctor immediately. You may need adjustments of the dose or type of medicines you are taking.

It is very important to control high blood glucose whether or not you feel unwell. This really helps to avoid serious long-term health problems, which can involve the heart, eyes, circulation, and/or kidneys.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking OZICLIDE MR.

Ask your doctor or pharmacist any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- **Feeling sick (nausea), being sick (vomiting), constipation, diarrhoea (loose stools)**
- **Headache, tiredness, generalized weakness, dizziness**
- **Back ache, joint pains and joint swelling**
- **Runny or stuffy nose, sore throat, cough, difficulty in breathing, chest infection**
- **Urinary disturbances (associated with burning sensation or pain on passing urine)**
- **Injury**

These are the more common side effects of gliclazide. These side effects are usually mild and occur at the start of treatment.

Tell your doctor immediately if you notice any of the following

- Unusual bleeding or increased tendency to bleed, persistent sore throat and frequent infections, and/or anaemia
- Yellowing of skin and whites of eyes with decreased appetite with passage of clay-colored stools and dark-colored urine
- Angina (feeling of tightness, heaviness, dull discomfort, or crushing pain that is felt behind the breastbone and may spread to the arms, neck and jaw. It is often brought on by exercise, eating, or stress; or may occur at rest. Angina occurs due to narrowing of blood vessels, which supply the muscles of the heart, and the resulting failure to deliver enough oxygen for normal functioning of the heart.)
- Tiredness, uncontrolled shaking, cold sweats, fast heart beat, feeling faint or lightheaded, hunger pangs, anxiety, inability to concentrate, blurred vision, or nervousness (symptoms of hypoglycaemia). If not treated promptly, may progress to confusion, or coma. If you experience any of these symptoms, you should immediately take sugar (glucose) tablets or sweetened juices. To avoid hypoglycaemia do not miss or delay meals or change your diet, or take more OZICLIDE MR tablets than needed, or do a more intense, or rigorous physical exercise or more work than normal.

Tell your doctor immediately or go to Emergency department at your nearest hospital if you notice any of the following:

- Some of the symptoms of an allergic reaction may include rashes, hives, itching, chest constriction, shortness of breath or swelling of face, lips, tongue, hands/feet, fainting, dizziness.

These are very serious side effects. You may need urgent medical attention or hospitalisation. All these side effects are very rare.

Changes in laboratory tests

- Abnormal liver function tests
- Increased blood levels of glucose
- Abnormal kidney function tests

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After using it

Storage

Keep your tablets in the original pack until it is time to take them.

If you take the tablets out of the box or the original pack they may not keep well.

Keep your OZICLIDE MR in a cool, dry place where it stays below 25°C.

Do not store it, or any other medicine, in the bathroom or near a sink.

Do not leave it in the car on hot days.

Heat and dampness can destroy some medicines.

Keep this medicine where young children cannot reach it.

Disposal

If your doctor tells you to stop taking OZICLIDE MR tablets or you find that they have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

Product description

What it looks like

OZICLIDE MR tablets are white to off-white biconvex, uncoated caplet with 'G30' debossed on one side and plain on the other side. Available in a pack of 100 tablets.

Ingredients

Active ingredient:

Gliclazide 30 mg

Inactive ingredients:

Povidone, calcium hydrogen phosphate, purified water, hypromellose, colloidal anhydrous silica, magnesium stearate

Australian Registration Number

OZICLIDE MR 30 mg tablet blister pack:

AUST R 124592

Sponsor

OZICLIDE MR tablets are supplied in Australia by:

Ranbaxy Australia Pty Ltd.

Suite 4.02, Building D, Level 4

12 - 24 Talavera Road

North Ryde, NSW 2113

OZICLIDE® is a trade mark owned by Ranbaxy Laboratories Limited.

This leaflet was prepared in Oct 2008.