

ARDIX[®] GLICLAZIDE 60 mg MR

Modified Release tablets containing gliclazide (pronounced gli-cla-zide)

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about ARDIX GLICLAZIDE 60 mg MR.

It does not contain all the available information

Reading this leaflet does not take the place of talking to your doctor, pharmacist, or diabetes educator.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking ARDIX GLICLAZIDE 60 mg MR against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

WHAT ARDIX GLICLAZIDE 60 MG MR IS

The name of your medicine is ARDIX GLICLAZIDE 60 mg MR.

ARDIX GLICLAZIDE 60 mg MR contains the active ingredient 'gliclazide'.

Gliclazide belongs to a group of medicines called sulphonylureas. The medicine releases the active ingredient gliclazide progressively over 24 hours.

WHAT ARDIX GLICLAZIDE 60 MG MR IS USED FOR

ARDIX GLICLAZIDE 60 mg MR is used to control blood glucose (sugar) in patients with Type II diabetes mellitus. This type of diabetes is also known as non-insulin-dependent diabetes (NIDDM), or maturity-onset diabetes).

Why ARDIX GLICLAZIDE 60 mg MR is used for Type II diabetes mellitus

ARDIX GLICLAZIDE 60 mg MR is used when diet and exercise are not enough to control your blood glucose.

ARDIX GLICLAZIDE 60 mg MR can be used alone or together with insulin or other medicines for treating diabetes.

How it works

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, which is also known as hyperglycaemia.

If your blood glucose is not properly controlled, you may experience hypoglycaemia (low blood glucose) or hyperglycaemia (high blood glucose). High blood glucose can lead to serious problems with our heart, circulation and/or kidneys.

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.

A section at the end of this leaflet contains advice about recognising and treating hyperglycaemia.

ARDIX GLICLAZIDE 60 mg MR is used when diet and exercise are not enough to control your blood glucose properly. It 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 ARDIX GLICLAZIDE 60 mg MR. This is known as hypoglycaemia.

A section at the end of this leaflet contains advice about recognising and treating hypoglycaemia.

ARDIX GLICLAZIDE 60 mg MR is available only with a doctor's prescription.

ARDIX GLICLAZIDE 60 mg MR is not addictive

Ask your doctor if you have any questions about why ARDIX GLICLAZIDE 60 mg MR has been prescribed for you.

BEFORE YOU TAKE ARDIX GLICLAZIDE 60 MG MR

There are some people who should not take ARDIX GLICLAZIDE 60 mg MR. Please read the lists below.

If you think any of these situations apply to you, or you have any questions, please consult your doctor, pharmacist, or diabetes educator.

Do not take ARDIX GLICLAZIDE 60 mg MR if

- you are allergic to: gliclazide, or any of the other ingredients listed at the end of this leaflet.
- you have had an allergic reaction to any other sulphonylureas, or related medicines such as sulfa antibiotics or to thiazide diuretics (a type of "fluid" or "water" tablet).

Symptoms of an allergic reaction to ARDIX GLICLAZIDE 60 mg MR or to these medicines may include skin rash, itchiness or hives, shortness of breath, swelling of the face, lips or tongue, muscle pain or tenderness or joint pain. If you are not sure if you have an allergy to ARDIX GLICLAZIDE 60 mg MR, check with your doctor.

- are pregnant or trying to become pregnant.

ARDIX GLICLAZIDE 60 mg MR may affect your developing baby if you take it during pregnancy. Insulin is more suitable for controlling blood glucose during pregnancy. Your doctor will usually replace ARDIX GLICLAZIDE 60 mg MR with insulin while you are pregnant.

- are breastfeeding or plan to breast-feed. ARDIX GLICLAZIDE 60 mg MR is not recommended while you are breastfeeding. It is not known whether ARDIX GLICLAZIDE 60 mg MR passes into breast milk.
- you have Type 1 diabetes mellitus (also known as insulin-dependent diabetes (IDDM), or juvenile-onset diabetes).
- you have unstable diabetes
- you have diabetic ketoacidosis (a problem which affects the acidity of your blood and can

lead to coma - which is mainly associated with Type 1 diabetes).

- you have severe kidney disease
- you have severe liver disease
- you are taking an antibiotic medicine containing the active ingredient miconazole
- the expiry date (EXP) printed on the pack.

If you take it after the expiry date has passed, it may not work as well.

- the packaging is torn or shows signs of tampering.

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

If you are not sure whether you should start taking ARDIX GLICLAZIDE 60 mg MR, talk to your doctor.

For children

Do not give ARDIX GLICLAZIDE 60 mg MR to a child.

There is no experience with the use of ARDIX GLICLAZIDE 60 mg MR in children.

For older people

Elderly people can generally use ARDIX GLICLAZIDE 60 mg MR safely.

There are no special instructions for older people taking ARDIX GLICLAZIDE 60 mg MR.

Tell your doctor straight away if:

- you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

- you are allergic to any of the ingredients listed at the end of this leaflet; to any other medicines; or to any other substances, such as foods, preservatives or dyes
- you have an intolerance to some sugars as ARDIX

GLICLAZIDE 60 mg MR contains lactose

- 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.
- you have had any of the following medical conditions:
 - kidney disease
 - liver disease
 - a history of diabetic coma.
 - adrenal, pituitary or thyroid problems
 - heart failure
- you have any medical condition, or do anything, that may increase the risk of hyperglycaemia - for example:
 - you are ill or feeling unwell (especially with fever or infection)
 - you are injured
 - you are having surgery.
 - you are taking less ARDIX GLICLAZIDE 60 mg MR than prescribed
 - you are taking less exercise than normal
 - you are eating more carbohydrate than normal.
 - drinking alcoholic drinks.
 - not eating regular meals.
 - taking more exercise than usual.

If you have not told your doctor, pharmacist or diabetes educator about any of the above, tell them before you start taking ARDIX GLICLAZIDE 60 mg MR.

Taking other medicines

Tell your doctor, pharmacist or diabetes educator if you are taking any other medicines, including medicines you buy without a

prescription from a pharmacy, supermarket or health food shop.

Taking ARDIX GLICLAZIDE 60 mg MR may change the effect of some medicines, and some medicines may affect how well ARDIX GLICLAZIDE 60 mg MR works. You may need different amounts of your medication or to take different medicines.

Some medicines may lead to low blood glucose (hypoglycaemia) by increasing the blood-glucose-lowering effect of ARDIX GLICLAZIDE 60 mg MR.

These include:

- some medicines used to treat fungal or yeast infections (miconazole which is contraindicated)
- alcohol
- other medicines used to treat diabetes (such as biguanides and insulin)
- some medicines used to treat high blood pressure and other heart conditions (including angiotensin receptor blocker, beta-blockers)
- some medicines used to treat depression and other mental illness (MAOIs)
- some cholesterol-lowering medicines [clofibrate]
- some medicines used to treat arthritis, pain and inflammation (including high dose aspirin, ibuprofen, phenylbutazone)
- some antibiotics (chloramphenicol; tetracyclines; long-acting sulphonamides)
- some medicines used to treat acid reflux and stomach ulcers

Some medicines may lead to high blood glucose levels (hyperglycaemia) by weakening the blood glucose-lowering effect of ARDIX GLICLAZIDE 60 mg MR.

These include:

- alcohol

- some medicines for epilepsy (danazol)
- some medicines used to treat depression and other mental illness (chlorpromazine)
- St John's Wort (Hypericum perforatum) preparations used to treat depression
- some hormones used in hormone replacement therapy and oral contraceptives (oestrogen, progesterone)
- some medicines for asthma (salbutamol, intravenous terbutaline).
- barbiturates, medicines used for sedation
- glucocorticoids

Some medicines may lead to unstable blood glucose (low blood sugar and high blood sugar) when taken at the same time as ARDIX GLICLAZIDE 60 mg MR, especially in elderly patients.

These include:

- A class of antibiotics called fluoroquinolones.

ARDIX GLICLAZIDE 60 mg MR may change the effects of some other medicines.

These include:

- some medicines used to prevent blood clots (warfarin)

You may need different amounts of your medicine or you may need to take different medicines. Your doctor, pharmacist or diabetes educator can tell you what to do if you are taking any of these medicines. They also have a more complete list of medicines to be careful with or avoid while taking ARDIX GLICLAZIDE 60 mg MR.

Ask your doctor or pharmacist if you are not sure if you are taking any of these medicines.

HOW TO TAKE ARDIX GLICLAZIDE 60 MG MR

Follow all directions given to you by your doctor, pharmacist, and diabetes educator carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

Your doctor will tell you how many tablets to take each day. They may increase or decrease the dose, depending on your blood glucose levels.

When to take it

Swallow the tablets with a glass of water. ARDIX GLICLAZIDE 60 mg MR tablets can be broken in half. However they should not be crushed or chewed.

Crushing or chewing the tablets may change the effectiveness of the tablet.

It is important to take your ARDIX GLICLAZIDE 60 mg MR at the same time each day - usually with breakfast. Taking ARDIX GLICLAZIDE 60 mg MR with food can help to minimise the risk of hypoglycaemia.

Do not skip meals while taking ARDIX GLICLAZIDE 60 mg MR.

How long to take it

Continue taking ARDIX GLICLAZIDE 60 mg MR for as long as your doctor recommends. Make sure you keep enough ARDIX GLICLAZIDE 60 mg MR to last over weekends and holidays.

ARDIX GLICLAZIDE 60 mg MR will help control your diabetes but will not (cure) it. Therefore, you may have to take it for a long time.

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 you

remember (with food), then go back to taking your tablets as you would normally.

Missed doses can cause high blood glucose (hyperglycaemia).

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

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

If you double a dose, this may cause low blood glucose (hypoglycaemia).

If you take too much (overdose)

Immediately telephone your doctor, Diabetes Australia or Poisons Information Centre (telephone in Australia: 13 11 26) for advice if you think that you or anyone else may have taken too much ARDIX GLICLAZIDE 60 mg MR. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much ARDIX GLICLAZIDE 60 mg MR together with other medicines for diabetes or alcohol, you may experience symptoms of low blood glucose (hypoglycaemia).

If not treated quickly, these symptoms may progress to loss of co-ordination, slurred speech, confusion, loss of consciousness and fitting.

At the first signs of hypoglycaemia, raise your blood glucose quickly by following the instructions at the end of this leaflet.

If you experience any of these symptoms, immediately get medical help.

WHILE YOU ARE TAKING ARDIX GLICLAZIDE 60 MG MR

Things you must do

If you become pregnant while you are taking ARDIX GLICLAZIDE 60 mg MR, tell your doctor.

Tell all doctors, dentists, pharmacists and diabetes educators who are involved with your treatment that you are taking ARDIX GLICLAZIDE 60 mg MR.

If you are about to start taking any new medicines, tell you doctor and pharmacist that you are taking ARDIX GLICLAZIDE 60 mg MR.

Take ARDIX GLICLAZIDE 60 mg MR exactly as your doctor has prescribed. Otherwise you may not get the full benefits from treatment.

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 how to treat them.

Instructions at the end of this leaflet can help you with this.

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

Carefully follow your doctor's and dietician'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 ARDIX GLICLAZIDE 60 mg MR.

These may include lethargy or tiredness, headache, thirst, passing large amounts of urine and blurred vision.

These may be signs that ARDIX GLICLAZIDE 60 mg 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 ARDIX GLICLAZIDE 60 mg MR to anyone else, even if they have the same condition as you.

Do not use ARDIX GLICLAZIDE 60 mg MR to treat other complaints unless your doctor tells you to.

Do not stop taking ARDIX GLICLAZIDE 60 mg MR, or change the dosage, without checking with your doctor.

Do not skip meals while taking ARDIX GLICLAZIDE 60 mg MR.

Things to be careful of

If you drink alcohol while taking ARDIX GLICLAZIDE 60 mg MR, you may get flushing, headache, breathing difficulties, rapid heart beat, stomach pains or feel sick and vomit.

Protect your skin when you are in the sun, especially between 10am and 3pm.

Sulphonylureas (the group of medicines that ARDIX GLICLAZIDE 60 mg MR belongs to) may cause your skin to be more sensitive to sunlight than it is normally. Exposure to sunlight may cause a skin rash, itching, redness, or a severe sunburn.

If outdoors, wear protective clothing and use a 30+ sunscreen. If your skin does appear to be burning, tell your doctor immediately.

Be careful driving or operating machinery until you know how ARDIX GLICLAZIDE 60 mg MR affects you.

Also, be especially careful not to let your blood glucose levels fall too low.

ARDIX GLICLAZIDE 60 mg MR may cause dizziness and drowsiness in some people. Low blood glucose levels may also slow your reaction time and affect your ability to drive or operate machinery. A section at the end of this leaflet contains advice about recognising and treating hypoglycaemia.

Drinking alcohol can make this worse. If either of these occurs, do not drive, operate machinery or do anything else that could be dangerous.

If you are travelling, it is a good idea to:

- wear some form of identification showing you have diabetes
- carry some form of sugar to treat hypoglycaemia if it occurs, for example, sugar sachets or jelly beans
- carry emergency food rations in case of a delay, for example, dried fruit, biscuits or muesli bars
- keep ARDIX GLICLAZIDE 60 mg MR readily available

If you become sick with a cold, fever or flu, it is very important to continue taking ARDIX GLICLAZIDE 60 mg MR, even if you fell unable to eat your normal meal. If you have trouble eating solid food, use sugar-sweetened drinks as a carbohydrate substitute or eat small amounts of bland food.

Your diabetes educator or dietician can give you a list of foods to use for sick days.

SIDE EFFECTS

If you do not feel well while you are taking ARDIX GLICLAZIDE 60 mg MR then tell your doctor, pharmacist, or diabetes educator as soon as possible.

All medicines can have side effects. Most of the time they are not serious but sometimes they can be.

ARDIX GLICLAZIDE 60 mg MR helps most people with Type 2 diabetes, but it may sometimes have unwanted side effects. These can include:

- hyPOglycaemia and hyPERglycaemia. A section at the end of this leaflet contains advice about recognising and treating hyPOglycaemia and hyPERglycaemia
- runny or blocked nose, sneezing, facial pressure or pain, bronchitis, sore throat and discomfort when swallowing, upper respiratory infection, coughing
- back pain, arthralgia, arthrosis,
- high blood pressure, chest pain
- headache, unusual weakness
- viral infection, urinary tract infection
- dizziness
- stomach upset with symptoms like feeling sick, stomach pain, vomiting, diarrhoea or constipation
- 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
- increase of some hepatic enzymes levels, and exceptionally a liver disease
- 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

Other side effects are usually mild when they occur. Do not be alarmed by this list of possible side effects. You may not experience any of them.

However if you do - or if you notice anything else that is making you feel unwell - you should consult your doctor or pharmacist. Other uncommon side effects have been reported and you may wish to discuss this issue with your doctor, pharmacist, or diabetes educator.

If any of the signs below occur then tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital:

- **Skin rash, redness itching and/ or 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 and may be the first sign of rare life threatening conditions (e.g. Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and severe hypersensitivity reactions (DRESS).**

As for other sulphonylureas, 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 (e.g. jaundice) which in most cases disappeared after withdrawal of the sulfonylurea, but may lead to life-threatening liver failure in isolated cases.

AFTER TAKING ARDIX GLICLAZIDE 60 MG MR

Storage

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

ARDIX GLICLAZIDE 60 mg MR will not keep as well outside its blister packaging.

Keep them in a cool dry place where the temperature stays below 30°C.

Do not store medicines in the bathroom or near a sink. Do not leave them in a car or on a windowsill.

Heat and dampness can destroy some medicines.

Keep ARDIX GLICLAZIDE 60 mg MR tablets where children cannot reach them.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking ARDIX GLICLAZIDE 60 mg MR, or the tablets have passed their expiry date, return any leftover tablets to your pharmacist for disposal.

PRODUCT DESCRIPTION

What it looks like

ARDIX GLICLAZIDE 60 mg MR tablets are white oblong tablets, scored, with "DIA 60" engraved on both faces.

ARDIX GLICLAZIDE 60 mg MR tablets come in a blister strip. Each box contains 60 tablets.

Ingredients

Each tablet of ARDIX GLICLAZIDE 60 mg MR contains 60 mg of gliclazide as the active ingredient and a number of inactive ingredients.

The inactive ingredients in ARDIX GLICLAZIDE 60 mg MR tablets include lactose monohydrate, maltodextrin, hypromellose, magnesium stearate, colloidal anhydrous silica.

The tablets are gluten free.

Manufacturer/Distributor

ARDIX GLICLAZIDE 60 mg MR is a product discovered and developed by Servier Research International.

It is distributed in Australia by:
Servier Laboratories (Aust) Pty Ltd

8 Cato Street
Hawthorn Victoria 3122
ABN 54 004 838 500

ARDIX GLICLAZIDE 60 mg MR is registered on the Australian Register of Therapeutic Goods.

Australian Register Number:
AUST R 154049

Recognising and treating hyPOglycaemia (very LOW blood sugar levels)

Hypoglycaemia may occur during ARDIX GLICLAZIDE 60 mg 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 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.

If you experience any of the signs of hyperglycaemia (high blood glucose) contact your doctor or diabetes educator for advice immediately.

This leaflet was prepared in March 2017