

APO-Gliclazide MR Tablets

30 mg Tablets

Modified Release tablets containing the active ingredient gliclazide

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about gliclazide. It does not contain all the available information. It does not take the place of talking to your doctor, pharmacist or diabetes educator.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Gliclazide MR. It contains the active ingredient gliclazide.

The tablets release the gliclazide gradually over 24 hours.

The medicine is used to control, blood glucose in patients with Type II diabetes mellitus.

This type of diabetes is also known as non-insulin-dependent diabetes mellitus (NIDDM) or maturity onset diabetes.

Gliclazide is used when diet and exercise are not enough to control your blood glucose.

Gliclazide can be used alone, or together with other medicines for treating diabetes

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed this medicine for another reason.

This medicine is available only with a doctor's prescription.

How it works

Gliclazide belongs to a group of medicines called the sulfonylureas.

Gliclazide lowers high blood glucose by increasing the amount of insulin produced by your pancreas.

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. This is called hyperglycaemia.

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

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.

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 gliclazide.

This is known as hypoglycaemia.

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

There is no evidence that this medicine is addictive.

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

Gliclazide may cause dizziness and drowsiness in some people.

Use in children

This medicine should not be used in children.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You have or have had any of the following:**
 - Type I diabetes mellitus (insulin dependent diabetes mellitus, also known as IDDM, or juvenile or growth onset diabetes)
 - unstable or brittle diabetes
 - diabetic ketoacidosis (a problem which affects the acidity of your blood and can lead to coma)
 - diabetic coma or pre-coma/coma
 - severe kidney disease
 - severe liver disease
- **You are pregnant or planning to become pregnant.**

Gliclazide may affect your developing baby if you take it during pregnancy. Your doctor will usually replace gliclazide with insulin while you are pregnant.
- **You are breastfeeding or plan to breastfeed.**

It is not known whether gliclazide passes into human breast milk.
- **You are using miconazole to treat fungal infections.**
- **You are taking medicines called phenylbutazone or danazol. You should not take these while taking gliclazide.**
- **The expiry date (EXP) printed on the pack has passed.**
- The packaging is torn, shows signs of tampering or it does not look quite right.
- **You are hypersensitive to, or have had an allergic reaction to:**
 - gliclazide or other sulfonylureas
 - antibiotics called sulfonamides
 - thiazide diuretics (a type of "fluid" or "water" tablet)
 - any of the ingredients listed at the end of this leaflet.Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing;

swelling of the face, lips, tongue, throat or other parts of the body, rash, itching or hives on the skin; fainting or hayfever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - kidney problems
 - liver problems
 - a growth in your pancreas, called an insulinoma
 - adrenal, pituitary or thyroid problems
 - heart failure
 - a condition called Glucose-6-Phosphate dehydrogenase Deficiency (G6PD)
3. You have any medical condition, or do anything, that may increase the risk of hyperglycaemia (high blood sugar) - for example:
 - you are ill or feeling unwell (especially with fever or infection)
 - you are injured
 - you are having surgery
 - you are taking less gliclazide than prescribed
 - you are doing less exercise than normal
 - you are eating more carbohydrate than normal.
4. You are taking a medicine called a beta-blocker.

Taking this may mask the symptoms of diabetes.

5. You have any medical condition, or do anything, that may increase the risk of hypoglycaemia (low blood sugar) - for example:

- drinking alcoholic drinks
 - not eating regular meals, including breakfast
 - doing more exercise than usual
 - eating less carbohydrate than normal.
- Alcohol, diet, exercise, and your general health all strongly affect the control of your diabetes.
6. You do not have regular meals
 7. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Taking other medicines

Some medicines may interact with gliclazide. These include:

- other medicines used to treat diabetes (tablets and insulin)
- some medicines used to treat high blood pressure and other heart conditions, such as beta-blockers, ACE inhibitors
- some hormones used in hormone replacement therapy and oral contraceptives (oestrogens and progestogens)
- monoamine oxidase inhibitors (MAOIs), used for treating depression, Parkinsons Disease or infections
- some medicines used for mental illness (e.g. chlorpromazine)
- clofibrate, a medicine for lowering cholesterol
- medicines used to treat arthritis, pain and inflammation (e.g. oxyphenbutazone, phenylbutazone, high dose salicylates)
- antibiotics called quinolones, sulfonamides, or chloramphenicol
- miconazole, or fluconazole, used to treat fungal infections
- some medicines used to prevent blood clots (warfarin and similar medicines)

- cimetidine and similar medicines used to treat acid reflux and stomach ulcers
- steroid medicines called glucocorticoids (e.g. prednisolone, cortisone)
- barbiturates, medicines used for sedation
- some medicines for hormonal disturbances (such as danazol)
- salbutamol and terbutaline (intravenous), medicines for asthma.
- St Johns wort (*hypericum perforatum*), a medicine used to treat depression

If you are taking any of these you may need a different dose or you may need to take different medicines.

Remember to keep checking your blood glucose levels.

Drinking alcohol can also affect your blood sugar levels and how well gliclazide works. If taken with gliclazide, it can also cause flushing of the face, throbbing headache, giddiness, fast breathing, fast heart rate, angina, stomach pains or feeling sick or vomiting.

Other medicines not listed above may also interact with gliclazide.

How to take this medicine

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

Their instructions may be different to the information in this leaflet.

How much to take

Your doctor or pharmacist will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

The starting dose is usually 30 mg per day. This will be adjusted slowly over several weeks, depending on how well your body responds to the dose.

The usual dose of this medicine may vary from one to four tablets taken daily.

Your doctor may increase or decrease the dose, depending on your blood glucose levels.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

How to take it

Swallow the tablets whole with a glass of water.

Do not crush the tablets or break them.

When to take it

Take it at about the same time each day, usually with breakfast.

Taking these tablets with food can help to minimise the risk of hypoglycaemia.

It will also help you remember when to take them.

Do not skip meals while taking these tablets.

How long to take it for

Gliclazide can help to control your blood glucose level, but it cannot cure your Type 2 diabetes.

Gliclazide treatment is usually for a long period of time - so you should keep taking the tablets regularly unless advised otherwise by your doctor.

Make sure you have enough of this medicine to last over weekends and holidays.

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time.

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

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

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

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

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

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency Department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too much gliclazide you may experience symptoms of hypoglycaemia (low blood glucose).

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 (low blood glucose), raise your blood glucose quickly by following the instructions at the end of this leaflet.

Note that artificial sweeteners will NOT help to raise your blood sugar levels.

While you are taking this medicine

Things you must do

Follow carefully all directions given to you by your doctor.

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, pharmacist 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 (low blood glucose) and hyperglycaemia (high blood glucose) and know what to do.

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

Visit your doctor for regular blood tests and checks of your eyes, feet, kidneys, heart, circulation, blood, and blood pressure.

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 gliclazide, or if your blood sugar levels are high.

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

If you are elderly or are taking other medicines for diabetes such as insulin or metformin, the risk of hypoglycaemia (low blood glucose) is increased.

The risk of hypoglycaemia (low blood glucose) is also increased in the following situations:

- too much gliclazide
- too much or unexpected exercise
- delayed meal or snack
- too little food.

If you experience any of the signs of high blood glucose (hyperglycaemia), contact your doctor immediately.

The risk of hyperglycaemia (high blood glucose) is increased in the following situations:

- undiagnosed or uncontrolled diabetes
- illness, infection or stress
- too little gliclazide
- certain other medicines
- too little exercise

- eating more carbohydrate than normal.

If you become ill or experience extra stress, injury, fever, infection or need surgery, tell your doctor.

Your blood glucose may become difficult to control at these times.

Your doctor may decide to change your treatment and use insulin instead of gliclazide.

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you become pregnant or are planning to become pregnant (tell your doctor immediately)
- you are breastfeeding or are planning to breastfeed
- you are about to have any blood tests
- you are going to have surgery or are going into hospital.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours
- Take your medicine to treat any other condition unless your doctor tells you to
- Stop taking your medicine, or change the dosage, without first checking with your doctor
- Skip meals while taking gliclazide.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

Gliclazide may cause dizziness and drowsiness in some people.

Drinking alcohol can make this worse. If you do feel dizzy or drowsy, 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.

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

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 (low blood glucose) 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 gliclazide tablets readily available.

If you become sick with a cold, fever or flu, it is very important to continue taking gliclazide, even if you feel 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.

Possible side effects

Tell your doctor, pharmacist, or diabetes educator as soon as possible if you do not feel well while you are taking gliclazide or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor or pharmacist if you notice any of the following:

- stomach upset including nausea and vomiting (feeling or being sick), heartburn, diarrhoea,

- constipation or a feeling of fullness in the stomach
- sight problems (this may happen when you first start taking this medicine and your blood sugar levels change)
- weariness
- dizziness or giddiness
- headache
- mild rash or redness of the skin.

Tell your doctor as soon as possible if you notice any of the following.

These may be serious side effects and you may need medical attention.

- hypoglycaemia or hyperglycaemia. A section at the end of this leaflet contains advice about recognising and treating hypoglycaemia or hyperglycaemia.
- signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers
- signs of anaemia such as tiredness, being short of breath and looking pale
- bleeding or bruising more easily than normal, reddish or purplish blotches under the skin
- itchy, red veins.

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

These are very serious side effects and you may need urgent medical attention or hospitalisation.

- yellowing of the skin or eyes, also called jaundice, and/or pale stools and dark urine.
- vomiting blood or passing bloody or black, tarry stools
- angina (chest pain caused by reduced blood flow to the heart)
- flu like symptoms, with quickly developing red rashes, blisters or ulcers, particularly around the mucous membranes (mouth and lips, genital and anal regions). These conditions are life-threatening.

Other side effects not listed above may occur in some patients.

Allergic reactions

If you think you are having an allergic reaction to gliclazide, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- shortness of breath, wheezing or difficulty breathing.
- swelling of the face, lips, tongue, throat or other parts of the body
- severe rash, itching or hives on the skin
- fainting
- hayfever-like symptoms

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 30°C. Protect it from moisture.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.

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

Disposal

If your doctor or pharmacist tells you to stop taking this medicine or it has passed its expiry date, your

pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Gliclazide MR looks like

White to off-white, flat faced, radial edge, capsule shaped tablets, engraved "APO 30" on one side and plain on the other side.

Blister pack of 100 tablets.

Bottles of 100 tablets.

* Not all pack types may be available.

Ingredients

Each tablet contains 30 mg of gliclazide as the active ingredient.

It also contains the following inactive ingredients:

- hypromellose
- stearic acid
- silica-colloidal anhydrous.

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

APO-Gliclazide MR
30 mg Tablets

Blister packs
AUST R 151303.

Bottles
AUST R 151307

Sponsor

Apotex Pty Ltd
16 Giffnock Avenue
Macquarie Park NSW 2113

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Recognising and treating hypoglycaemia (very LOW blood glucose levels)

Hypoglycaemia may occur during treatment with gliclazide.

The first signs of hypoglycaemia may include weakness, trembling or shaking, sweating, anxiety, changes in heart rate and breathing, light-headedness, dizziness, problems with sight, headache or lack of concentration, irritability, depression, aggression, tearfulness, hunger, nausea, vomiting, chest pain and/ or numbness around the lips and tongue.

These symptoms can occur suddenly.

If not treated promptly, these may progress to:

- loss of co-ordination
- slurred speech
- confusion, drowsiness
- loss of consciousness or fitting.

At the first signs of hypoglycaemia take some sugar to raise your blood sugar level quickly.

Do this by taking one of the following:

- 5-7 jelly beans
- 3 teaspoons of sugar or honey
- half a can of ordinary (non-diet) soft drink
- 2-3 concentrated glucose tablets
- a tube of glucose gel.

Note that taking artificial sweeteners will not help raise your blood sugar levels.

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 hypoglycaemia symptoms do not get better straight away after taking sugar, or the symptoms are severe or prolonged, 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 glucose levels)

Some people may feel fine when their glucose levels are high.

High blood glucose usually occurs more slowly than low blood glucose.

Signs of high blood glucose may include:

- lethargy or tiredness
- headache
- thirst
- passing large amounts of urine
- 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.

This leaflet was last updated in: February 2017