

Apo-Gliclazide MR

Modified Release tablets containing the active ingredient gliclazide (gli-cla-zide)

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

Consumer Medicine Information

What is in this leaflet

Read this leaflet carefully before taking your medicine. Ask your doctor or pharmacist if you do not understand anything or are worried about 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. Some more recent information on your medicine may be available. Speak to your pharmacist or doctor to obtain the most up-to-date information.

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.

Keep this leaflet with your medicine.

You may want to read it again.

What gliclazide 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.

Gliclazide 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.

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.

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

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

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

The use of this gliclazide in children is not recommended.

Before you take gliclazide

When you must not take it

Do not take this medicine if you 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; muscle pain or tenderness or joint pain; or rash, itching or hives on the skin.

If you are not sure if you have an allergy to any of the above, check with your doctor.

Do not take gliclazide if you are using miconazole to treat fungal infections.

You should not take gliclazide in combination with medicines called phenylbutazone or danazol.

Do not take gliclazide if you have or have had any of the following conditions:

- * Type I diabetes mellitus (insulin dependent diabetes mellitus, also known as IDDM, or juvenile or growth onset diabetes)
- * unstable or brittle diabetes
- * diabetic acidosis
- * diabetic coma or pre-coma
- * a history of repeated ketoacidosis or coma
- * severe kidney disease
- * severe liver disease.

If you are not sure if you have any of the above, ask your doctor.

Do not take gliclazide if 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.

Do not take gliclazide if you are breast-feeding or plan to breast-feed.

It is not known whether gliclazide passes into human breast milk.

Do not take this medicine after the expiry date (EXP) printed on the pack.

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

Do not take this medicine if the packaging is torn, shows signs of tampering or if it does not look quite right.

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

If you are not sure whether you should start taking this medicine, talk to your doctor or pharmacist.

Before you start to take it

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
 - * a history of diabetic coma.
 - * adrenal, pituitary or thyroid problems.
 - * heart failure.
- 3. 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 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 - 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 plan to become pregnant or breast-feed.

If you have not told your doctor, pharmacist or diabetes educator about any of the above, tell them before you start taking this medicine.

Taking other medicines

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

Some medicines and gliclazide may interfere with each other. 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)
- * some medicines for epilepsy such as phenobarbitone
- * clofibrate, a medicine for lowering cholesterol
- * some medicines used to treat arthritis, pain and inflammation (oxyphenbutazone, phenylbutazone, high dose salicylates)
- * antibiotics called sulfonamides, or chloramphenicol
- * miconazole, or fluconazole, used to treat fungal infections
- * some medicines used to prevent blood clots (warfarin and similar medicines)
- * cimetidine, used to treat acid reflux and stomach ulcers
- * steroid medicines called glucocorticoids (e.g. prednisolone, cortisone)
- * some medicines for hormonal disturbances (such as danazol)
- * salbutamol and terbutaline, medicines for asthma
- * diuretics, also known as fluid tablets (e.g. chlorothiazide)

These medicines may be affected by gliclazide or may affect how well it works. This may result in levels of blood sugar which are too high or too low.

Remember to keep checking your blood glucose levels.

You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor, pharmacist or diabetes educator can tell you if you are taking any of these medicines. They may also have more information on medicines to be careful with or avoid while taking gliclazide.

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 interactions not listed above may also occur.

How to take this medicine

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

They may be different to the information in this leaflet.

If you do not understand any written instructions, ask your doctor or pharmacist for help.

How much to take

Your doctor or pharmacist will tell you how many tablets you will need to take. This depends on your condition and whether or not you are taking any other medicines.

The usual dose of this medicine may vary from one to four tablets each day.

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

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 to last over weekends and holidays.

If you forget to take it

Take your next planned dose at the usual time and continue as normal.

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.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 for Australia) for advice, or go to the Accident and Emergency Department at the nearest hospital, if you think that you or anyone else may have taken too much gliclazide.

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 taking jelly beans, sugar or honey,

(non-diet) soft drink or glucose tablets.

While you are taking gliclazide

Things you must do

Take your tablets exactly as your doctor has prescribed.

Otherwise you may not get the full benefits from treatment.

Tell your doctor immediately if you become pregnant.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

If you are about to start taking any new medicines, tell your doctor and pharmacist that you are taking gliclazide.

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

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 (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.

Things you must not do

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

Do not take your medicine to treat any other complaints unless your doctor or pharmacist tells you to.

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

Do not skip meals while taking gliclazide.

Things to be careful of

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

Gliclazide 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.

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.

Side effects of gliclazide

All medicines may have some unwanted side effects. Sometimes they are serious, but most of the time, they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

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

Gliclazide helps most people with Type 2 diabetes, but it may have unwanted side effects in a few people.

Ask your doctor or pharmacist to answer any questions you may have.

Following is a list of possible side effects. Do not be alarmed by this list. You may not experience any of them.

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

- * Stomach upset including nausea and vomiting (feeling or being sick), heartburn, diarrhoea, constipation or a feeling of fullness in the stomach
- * weariness
- * dizziness or giddiness
- * headache
- * mild rash.

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

- * 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.

These may be serious side effects. You may need medical attention.

If any of the following happen, stop taking your medicine and either tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- * Severe rash or itching of the skin (this could mean that you are allergic to gliclazide)
- * yellowing of the skin or eyes, also called jaundice
- * vomiting blood or passing bloody or black, tarry stools
- * angina.

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

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

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

After taking this medicine

Storage

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

If you take the tablets out of their original packaging, they may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 30 degrees C.

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 it 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 tells you to stop taking this medicine or it has passed its expiry date, ask your pharmacist what to do with any medicine that is left over.

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

Product description

What Apo-Gliclazide MR looks like

Apo-Gliclazide MR 30 mg Tablets:

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

Blister packs of 100 tablets.

Ingredients

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

It also contains the following inactive ingredients:

- hypromellose
- stearic acid
- colloidal anhydrous silica

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

Australian Registration Numbers

Apo-Gliclazide MR 30mg tablets

Blister packs

AUST R 151303

Sponsor

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ABN 52 096 916 148

66 Waterloo Road

North Ryde, NSW 2113

Australia

Distributor

Distributor

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Australia

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Recognising and treating hypoglycaemia (very low blood sugar levels)

Hypoglycaemia may occur during treatment with gliclazide.

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.

These symptoms can occur suddenly.

If not treated promptly, these may progress to:

- * loss of co-ordination
- * slurred speech
- * confusion
- * 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

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 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.

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 prepared in June 2009.