

APO-Gliclazide Tablets

Gliclazide

Consumer Medicine Information

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

What is in this leaflet

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.

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.

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

Keep this leaflet with the medicine.

You may want to read it again.

What this medicine is used for

Gliclazide belongs to a group of medicines called sulfonylureas.

It 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 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

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.

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

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.

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 called 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.

Your doctor may have prescribed this medicine for another reason.

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

This medicine is not addictive.

There is not enough information to recommend the use of this medicine in children.

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:

- gliclazide
- other sulfonylureas
- sulphonamides, such as sulfa antibiotics or thiazide diuretics
- any of the ingredients listed at the end of this leaflet.

Some of the 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

Do not take this medicine if you have or have had any of the following medical 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 or ketosis
- diabetic coma or pre-coma
- a history of repeated ketoacidosis or coma

- severe kidney disease
- severe liver disease.

Do not take this medicine if you are pregnant or plan to become pregnant or are breastfeeding.

Gliclazide may affect your developing baby if you take it during pregnancy. Your doctor will usually replace gliclazide with insulin while you are pregnant. It is not known whether gliclazide passes into human breast milk.

Do not take this medicine if you are using miconazole, a medicine used to treat fungal infections.

Do not take this medicine if you are taking medicines called phenylbutazone or danazol.

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

If you are not sure whether you should start taking gliclazide, talk to your doctor.

Before you start to take 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:

- kidney problems
- liver problems
- a growth in your pancreas, called an insulinoma
- a history of diabetic coma
- adrenal, pituitary or thyroid problems
- heart failure
- a condition called Glucose-6-Phosphate Dehydrogenase Deficiency (G6PD).

Tell your doctor if you have any medical condition, or do anything, that may increase the risk of hyperglycaemia (high blood glucose). This may include:

- illness or feeling unwell (especially with fever or infection)
- injury
- surgery
- taking less gliclazide than prescribed
- doing less exercise than normal
- eating more carbohydrates than normal

Tell your doctor if you have any medical condition, or do anything, that may increase the risk of hypoglycaemia (low blood glucose).

This may include:

- 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.

Tell your doctor if you are taking a medicine called a beta-blocker.

Taking this medicine may mask the symptoms of diabetes.

Tell your doctor if you suffer from lactose intolerance or malabsorption.

These tablets contain lactose

Taking other medicines

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

Some medicines and gliclazide may interfere with each other. These include:

- miconazole or fluconazole, used to treat fungal infections
- other medicines used to treat diabetes (e.g. insulin)
- some medicines used to treat high blood pressure and other heart conditions (e.g. beta-blockers, ACE inhibitors)

- monoamine oxidase inhibitors (MAOIs), used for treating depression, Parkinson's Disease or infections
- clofibrate, a medicine for lowering cholesterol
- medicines used to treat arthritis, pain and inflammation (e.g. oxyphenbutazone, phenylbutazone, high dose salicylates)
- some antibiotics (e.g. sulphonamides, tetracyclines, chloramphenicol)
- cimetidine and similar medicines used to treat acid reflux and stomach ulcers
- diuretics, also known as fluid tablets (e.g. chlorothiazide)

Some medicines may lead to high blood glucose levels (hyperglycaemia) by weakening the blood glucose-lowering effect of gliclazide. These include:

- alcohol
- some medicines for epilepsy (e.g. phenobarbitone)
- some medicines for hormonal disturbances (e.g. danazol)
- some medicines used for mental illness (e.g. chlorpromazine)
- some hormones used in hormone replacement therapy and oral contraceptives (oestrogens and progestogens)
- St John's wort, (hypericum perforatum), used to treat depression
- salbutamol and terbutaline, medicines for asthma
- steroid medicines called glucocorticoids (e.g. prednisolone, cortisone)

Some medicines may lead to unstable blood glucose (low blood sugar and high blood sugar) when taken at the same time as gliclazide, especially in elderly patients. These include:

- quinolone antibiotics (e.g. ciprofloxacin, norfloxacin or moxifloxacin)

Gliclazide may change the effects of some other medicines:

- some medicines used to prevent blood clots (warfarin and similar medicines)

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 glucose levels and how well gliclazide works.

Other medicines not listed above may also interact with gliclazide.

How to take this medicine

Follow all directions given to you by your doctor carefully.

They may differ to the information contained in this leaflet.

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

How much to take

Your doctor 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 40 mg (half a tablet) per day. This will be adjusted slowly over several weeks, depending on how well your body responds to the dose.

How to take it

Swallow the tablets whole with a glass of water.

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

Do not skip meals while taking these tablets.

When to take it

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

Taking it at the same time each day will have the best effect. It will also help you remember when to take them.

How long to take it for

Continue taking your medicine for as long as your doctor tells you.

Gliclazide can help control your diabetes but cannot cure it. Therefore you may have to take it for a long time.

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

Missed doses can cause hyperglycaemia (high blood glucose).

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)

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

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.

While you are taking this medicine

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking gliclazide.

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

If you become pregnant while taking this medicine, tell your doctor immediately.

Tell your doctor if you are about to have any blood tests.

Tell your doctor if you are going to have surgery or are going into hospital.

Take your tablets 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 (low blood glucose) and hyperglycaemia (high blood glucose) and know how to treat them.

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.

Follow carefully your doctor'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.

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

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

Things you must not do

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

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 first checking with your doctor.

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

Gliclazide may cause dizziness and drowsiness in some people.

Hypoglycaemia 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.

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 drink alcohol while taking gliclazide, you may get flushing, headache, breathing difficulties, rapid heartbeat, stomach pains or feel sick and vomit.

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

Gliclazide 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 severe sunburn.

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

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 gliclazide 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

Tell your doctor or pharmacist as soon as possible if you do not feel

well while you are taking gliclazide.

Gliclazide helps most people with diabetes, however it may have unwanted side effects. All medicines can have side effects. Sometimes they are serious but most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following list of side effects. You may not experience any of them.

Ask your doctor or pharmacist if you have any concerns.

Tell your doctor if you notice any of the following:

- hypoglycaemia.
A section at the end of this leaflet contains advice about recognising and treating hypoglycaemia
- stomach upset with symptoms like feeling sick, heartburn, diarrhoea or constipation
- headache
- runny or blocked nose, sneezing, facial pressure or pain, sore throat and discomfort when swallowing, coughing
- arthralgia
- dizziness
- 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
- tiredness, weariness.

The above list includes the more common side effects of your medicine.

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

- high blood pressure, chest pain
- urinary tract infection
- sinus, throat or upper lung infection

The above list includes serious side effects that may require medical attention.

If any of the following happen, stop taking this medicine and tell your

doctor immediately or go to the Accident and Emergency department at your nearest hospital:

- 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 (symptoms of a severe allergic reaction)
- 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
- widespread blistering rash or peeling of the skin - 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 sulphonylurea but may lead to life-threatening liver failure in isolated cases.

If you notice anything else that is making you feel unwell - you should consult your doctor or pharmacist.

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

Storage and disposal

Storage

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

If you take your medicine out of the pack it may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°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 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 tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

White, round, flat-sided tablets with bevelled edges, engraved "APO" over "80" on one side, cross-scored on the other side.

Blister packs of 100 tablets. AUST R 80084

Ingredients

Each tablet contains 80 mg of gliclazide as the active ingredient.

It also contains the following:

- croscarmellose sodium
- magnesium stearate
- colloidal anhydrous silica
- lactose monohydrate
- microcrystalline cellulose

This medicine does not contain gluten, sucrose, tartrazine or other azo dyes.

This medicine contains lactose as sugar.

Sponsor

Apotex Pty Ltd

16 Giffnock Avenue

Macquarie Park NSW 2113

Recognising and treating hypoglycaemia (low blood glucose)

Hypoglycaemia may occur during gliclazide treatment.

The first signs of hypoglycaemia may include weakness, trembling or shaking, sweating, anxiety, changes in heart rate or breathing, problems with sight, depression, aggression, nausea, vomiting, chest pain, 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
- 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 Accident and Emergency at your nearest hospital - if necessary by calling an ambulance.

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

problems, which can involve the heart, eyes, circulation, and/or kidneys.

This leaflet was prepared in September 2018.

Recognising and treating hyperglycaemia (high blood glucose)

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:

- tiredness or lethargy
- lack of energy
- thirst
- passing large amounts of urine
- headache
- 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