

NEW ZEALAND CONSUMER MEDICINE INFORMATION

GLIZIDE

Gliclazide tablets 80 mg



What is in this leaflet

Please read this leaflet carefully before you start taking GLIZIDE.

This leaflet answers some common questions about GLIZIDE.

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 GLIZIDE 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 need to read it again.

What GLIZIDE is used for

GLIZIDE is used to control blood glucose in patients with Type II diabetes mellitus when diet and exercise are not enough to control your blood glucose.

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

GLIZIDE can be used alone, or together with insulin or other medicines for treating diabetes.

GLIZIDE contains the active ingredient gliclazide.

It belongs to a group of medicines called sulfonylureas.

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

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 your heart, eyes, circulation or kidneys.

Your doctor may have prescribed GLIZIDE for another reason.

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

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

GLIZIDE is not addictive.

The use of this medicine is not recommended for children.

Before you take GLIZIDE

When you must not take it:

Do not take GLIZIDE if you have an allergy to:

- any medicine containing gliclazide
- sulfonylurea medicines
- related medicines such as sulphur antibiotics or thiazide diuretics
- sulphonamides medicines
- 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 or other parts of the body; rash, itching or hives on the skin.

Do not take GLIZIDE 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 diabetes
- diabetic acidosis
- diabetic coma or pre-coma
- severe kidney disease
- severe liver disease.

Do not take this medicine if you have a fungal condition which is being treated with miconazole.

Do not take this medicine if you are pregnant or intend becoming pregnant.

Insulin is more suitable for controlling blood glucose during pregnancy. Your doctor will usually replace GLIZIDE with insulin while you are pregnant.

Do not breast-feed if you are taking this medicine.

It is not known whether GLIZIDE passes into breast milk and there is a possibility that your baby may be affected.

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

If you are not sure whether you should start taking GLIZIDE, 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 ever drink alcohol

- you do not eat regular meals
- you do a lot of exercise or you do heavy exercise or work
- you are ill or feeling unwell
- you have been previously treated with sulfonylureas or biguanides alone or in combination.

Alcohol, diet, exercise, and your general health all strongly affect the control of your diabetes. Discuss these things with your doctor.

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

Taking other medicines

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

You should also tell any health professional who is prescribing a new medication for you that you are taking GLIZIDE.

Some medicines may interfere with GLIZIDE.

Some medicines may lead to low blood glucose (hypoglycaemia) by increasing the blood-glucose-lowering effect of GLIZIDE. These include:

- alcohol
- some medicines used to treat high blood pressure and other heart conditions (beta blockers, ACE-inhibitors such as captopril or enalapril)
- some medicines used to treat arthritis, pain and inflammation (ibuprofen, phenylbutazone)
- some cholesterol-lowering medicines (clofibrate)
- other medicines used to treat diabetes (e.g. biguanides, insulin)
- some antibiotics (e.g. sulphonamides, clarithromycin, chloramphenicol)

- some medicines used to treat depression (MAOIs)
- some medicines used to treat reflux and ulcers (cimetidine, ranitidine and other H₂-receptor antagonists)
- medicines to treat fungal infections (miconazole, fluconazole)
- salicylates which can be found in aspirin and other pain-relieving medications

Some medicines may lead to loss of control of your diabetes by weakening the blood glucose-lowering effect of GLIZIDE. These include:

- alcohol
- some medicines for epilepsy (danazol)
- some medicines used to treat depression and other mental illness (chlorpromazine)
- some hormones used in hormone replacement therapy and oral contraceptives (oestrogens, progesterones)
- some asthma medicines (salbutamol, intravenous terbutaline)
- barbiturates, medicines used for sedation
- glucocorticoids – steroids that reduce inflammation throughout the body
- St. John's Wort preparations.

Some products may lead to unstable blood glucose.

These include:

- fluoroquinolones, medicines which are used as antibiotics

GLIZIDE may change the effects of some other medicines. These include:

- warfarin, a medicine used to prevent blood clots.

These medicines may interfere with GLIZIDE. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to

be careful with or avoid while taking GLIZIDE.

How to take GLIZIDE

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

They may differ from the information contained in this leaflet.

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

How much to take

The recommended dose is from one half (40 mg) to four tablets (320 mg) each day.

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

How to take it

Swallow the tablets with a full glass of water.

GLIZIDE tablets can be broken in half.

Do not skip meals while taking this medicine.

When to take it

Take your medicine at about the same time each day, preferably in the morning with breakfast.

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

If your total daily dose exceeds two tablets, take two equal doses - one dose in the morning and the other in the evening.

How long to take it

Continue taking your medicine for as long as your doctor tells you. Make sure you keep enough GLIZIDE to last over weekends and holidays.

This medicine helps to 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 soon as you remember, and then go back to taking your medicine as you would normally.

Missed doses can cause high blood glucose (hyperglycaemia).

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

This may cause low blood glucose (hypoglycaemia).

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.

While you are taking GLIZIDE

Things you must do

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking GLIZIDE.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

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

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests to measure your glycated haemoglobin levels from time to time to make sure the medicine is

working and to prevent unwanted side effects.

Make sure that you check your blood glucose levels regularly. This is the best way to tell if your diabetes is being controlled properly. Your doctor or pharmacist will show you how and when to do this.

Things you must not do

Do not take GLIZIDE to treat any other complaints unless your doctor tells you to.

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

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

The treatment for diabetes is usually life-long. If you stop taking it you could cause high blood sugar (hyperglycaemia) which increases the risk of developing complications of diabetes.

Things to be careful of

Be careful driving or operating machinery until you know how GLIZIDE affects you. Also, be especially careful not to let your blood glucose levels fall too low.

This medicine 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.

Things that would be helpful for diabetes

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 GLIZIDE readily available.

If you become sick with a cold, fever or flu, it is very important to continue taking GLIZIDE, 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.

Recognising and treating hypoglycaemia (low blood sugar levels)

Hypoglycaemia may occur during GLIZIDE 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 pharmacist 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 contact your doctor or pharmacist for advice immediately.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766), or go to accident and emergency at the nearest hospital, if you think that you or anyone else may have taken too much GLIZIDE. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too much GLIZIDE, you may experience symptoms of low blood glucose (hypoglycaemia) such as weakness, trembling or

shaking, sweating, light-headedness, dizziness, headache or lack of concentration, irritability, tearfulness, hunger, and/or numbness around the lips and tongue.

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 taking jelly beans, sugar or honey, (non-diet) soft drink or glucose tablets.

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

Side effects

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

GLIZIDE helps most people with Type II diabetes, but it may sometimes have unwanted side effects.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

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

- sweating,
- weakness,
- tiredness,
- drowsiness,
- loss of consciousness,
- hunger,
- nausea,
- vomiting,
- dizziness,
- trembling,
- headache,
- flushing or paleness,
- numbness,
- having abnormal heartbeat,
- sleep disorders,
- agitation,

- aggression,
- lack of concentration,
- depression,
- confusion,
- loss of self-control,
- visual disorders,
- language disorders,
- sensory disorders,
- convulsions, fits or seizures,
- shallow breathing,
- clammy skin,
- anxiety,
- chest pain,
- stomach upset with symptoms like feeling sick, indigestion, stomach pain, heartburn, diarrhoea or constipation.

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

If any of the following happen, 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,
- yellowing of the skin and/or eyes.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

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.

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

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Some of these side effects for example, 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) or other changes in blood parameters can only be found when your doctor does tests from time to time to check your progress.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

After taking GLIZIDE

Storage

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

If you take the tablets out of the bottle they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store GLIZIDE 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 the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

GLIZIDE are white to off-white, circular, flat, beveled edged,

uncoated tablets with a breakline on one side and "80" on the reverse.

The tablet can be divided into equal doses.

GLIZIDE is marketed in bottles of 500 tablets.

Ingredients

Active ingredient:

GLIZIDE contains 80 mg of gliclazide as the active ingredient.

Inactive ingredients:

It also contains the following inactive ingredients:

- lactose monohydrate
- microcrystalline cellulose
- povidone
- croscarmellose sodium
- purified talc
- magnesium stearate.

This medicine does not contain sucrose or gluten.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

GLIZIDE is supplied in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland
NEW ZEALAND

Telephone: (09) 579 2792

Date of preparation

This leaflet was revised on 15 October 2019
(Based on datasheet dated 14 October 2019)