

APO-Glimepiride

Contains the active ingredient, glimepiride

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 glimepiride.

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 glimepiride is used for

The name of your medicine is Apo-Glimepiride. It contains the active ingredient, glimepiride.

It 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.

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

How it works

Glimepiride belongs to a group of medicines called sulphonylureas.

Glimepiride 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 glimepiride.

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 glimepiride affects you.

If you have to be alert, e.g. when driving, be especially 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. Drinking alcohol can make this worse. Your vision may also be temporarily affected.

Use in children

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

Before you take glimepiride

When you must not take it

Do not take this medicine if you have had an allergic reaction to:

- * Glimepiride or other sulfonylureas
- * antibiotics called sulfonamides
- * thiazide diuretics (a type of "fluid" or "water" tablet)
- * lactose - these tablets contain lactose
- * 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 this medicine if you have or have had any of the following conditions:

- * type 1 diabetes mellitus (insulin dependent diabetes mellitus, also known as IDDM, or juvenile or growth onset diabetes)
- * a history of ketoacidosis
- * unstable diabetes
- * diabetic ketoacidosis
- * diabetic coma or pre-coma
- * severe kidney disease or undergoing dialysis
- * severe liver disease.

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

Glimepiride may affect your developing baby if you take it during pregnancy. Your doctor will usually replace glimepiride with insulin while you are pregnant.

Do not take this medicine if you are breast-feeding or planning to breast-feed.

Glimepiride can pass into breast milk and may harm your baby.

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
- * lactose
- * any other substances, such as foods, preservatives or dyes.

2. You have or have had any medical conditions, especially the following:

- * liver problems
- * kidney problems
- * adrenal, thyroid or pituitary problems
- * a deficiency of the enzyme in your body called glucose-6-phosphate dehydrogenase (G6PD).

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 glimepiride 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 or pharmacist 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 glimepiride may interfere with each other. These include:

- * other medicines used to treat diabetes (tablets and insulin)
- * some medicines used to treat high blood pressure or heart conditions, e.g. beta-blockers, ACE inhibitors, calcium channel blockers, amiodarone, disopyramide, reserpine or guanethidine
- * some hormones used in hormone replacement therapy and oral contraceptives (oestrogens and progestogens)
- * monoamine oxidase inhibitors (MAOIs), used for treating depression, Parkinson's Disease or infections
- * some medicines used for mental illness (e.g. phenothiazines)

- * barbiturates, used for epilepsy and sedation during anaesthetics
- * phenytoin, used for epilepsy
- * medicines for treating high cholesterol / blood fats
- * some medicines used to treat arthritis, pain and inflammation (diclofenac, naproxen, ibuprofen, azapropazone, fenyramidol, oxyphenbutazone, phenylbutazone, salicylates)
- * antibiotics called sulfonamides, quinolones, sulfonpyrazone, tetracyclines, rifampicin, isoniazid, clarithromycin or chloramphenicol
- * miconazole, or fluconazole, used to treat fungal infections
- * some medicines used to prevent or treat blood clots (warfarin and similar medicines)
- * cimetidine, famotidine, nizatidine and ranitidine, used to treat acid reflux and stomach ulcers
- * medicines called corticosteroids (e.g. prednisolone, cortisone)
- * anabolic steroids, male sex hormones
- * thyroid hormones, used to treat thyroid problems
- * oxpentifylline used to prevent or treat blood vessel problems
- * clonidine, used for high blood pressure or migraine
- * diuretics, also known as fluid tablets (e.g. chlorothiazide)
- * diazoxide, used mainly for treating very high blood pressure
- * acetazolamide, used to treat glaucoma, epilepsy and oedema (swelling due to fluid)
- * some antidepressants
- * weight reduction medicines
- * tritoqualine, an antihistamine
- * trofosfamide, cyclophosphamide, ifosfamide, used for treating certain cancers
- * laxatives (long-term use)
- * probenecid, used for treating gout
- * clonidine, used for high blood pressure or migraine
- * glucagon, used to help balance blood sugar levels

- * medicines used in asthma medicines and cold remedies.

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

In addition, beta- blockers, clonidine, guanethidine or reserpine, may mask the warning symptoms of a hypoglycaemic attack.

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 and pharmacist 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 glimepiride.

Drinking alcohol can also affect your blood sugar levels and how well glimepiride works.

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 starting dose for adults is one 1 mg tablet each day. Your doctor may increase this dose up to 4 mg a day, depending on your blood glucose levels.

How to take it

Swallow the tablets with a glass of water.

When to take it

Take glimepiride immediately before a meal.

If you only eat a light breakfast, you should delay taking the tablet until the first main meal of the day (e.g. lunch).

Take it at about the same time each day.

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

It will also help you remember when to take them.

It is important that you eat regular meals.

How long to take it for

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

Glimepiride will help control your Type 2 diabetes but will not cure it. Most people will need to take glimepiride for long periods of time.

Make sure you have enough 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 (immediately before food), and then go back to taking your medicine as you would normally.

Skipping a dose may result in hyperglycaemia. If you experience any symptoms of hyperglycaemia, contact your doctor immediately.

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

If you double a dose, this may cause 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 glimepiride.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much glimepiride, you may experience symptoms of hypoglycaemia (low blood glucose). See the end of this leaflet for a list of symptoms.

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 eating jelly beans, sugar or honey, drinking non-diet soft drink or taking glucose tablets.

While you are taking glimepiride

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 glimepiride.

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

Make sure 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.

Tell your doctor immediately if you notice the return of any symptoms of hyperglycaemia that you had before starting glimepiride, or if your blood sugar levels are high.

These may be signs that glimepiride 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 (e.g. insulin or metformin), the risk of hypoglycaemia (low blood sugar) is increased.

The risk of hypoglycaemia is also increased in the following situations:

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

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

The risk of hyperglycaemia is increased in the following situations:

- * undiagnosed or uncontrolled diabetes
- * illness, infection or stress
- * too little glimepiride
- * taking certain other medicines
- * too little exercise
- * eating more carbohydrates than normal.

Tell your doctor if any of the following happen:

- * you become ill
- * you become dehydrated
- * you are excessively stressed
- * you are injured
- * you have a fever
- * you have a serious infection
- * you are having surgery.

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

Your doctor may decide to replace glimepiride with insulin.

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

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.

Carefully follow your doctor's and dietician's advice on diet, drinking alcohol and exercise.

Things you must not do

Do not skip meals while taking glimepiride.

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

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

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

Things to be careful of

Protect your skin when you are outdoors or in the sun, especially between 10 am and 3 pm. Wear protective clothing and use a 15+ sunscreen. If your skin appears to be burning, tell your doctor immediately.

Glimepiride may cause your skin to be more sensitive to sunlight than it is normally. Exposure to sunlight

may cause skin rash, itching, redness or severe sunburn.

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

If you have to be alert, e.g. when driving, be especially 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. Drinking alcohol can make this worse. Your vision may also be temporarily affected.

However, glimepiride by itself is unlikely to affect how you drive or operate machinery.

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

1. Wear some form of identification showing you have diabetes
2. carry some form of sugar to treat hypoglycaemia (low blood glucose) if it occurs, for example, sugar sachets or jelly beans
3. carry emergency food rations in case of a delay, for example, dried fruit, biscuits or muesli bars
4. keep glimepiride tablets readily available.

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

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 glimepiride.

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:

- * nausea, vomiting, abdominal pain or discomfort, diarrhoea, or a feeling of fullness in the stomach
- * blurred or double vision.

The above list includes the more common side effects. Mostly, these are mild.

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.
- * symptoms of sunburn such as redness, itching, swelling or blistering which may occur more quickly than normal after being in the sun
- * bleeding or bruising more easily than normal, or reddish or purplish blotches under the skin
- * 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.

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:

- * rash, sores, redness or itching of

the skin, itchy hives-like rash or spots (this could mean that you are allergic to glimepiride)

- * yellowing of the skin or eyes, also called jaundice

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

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

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

After taking this medicine

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 25 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 or pharmacist 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-glimepiride looks like

APO-Glimepiride 1 mg Tablets:

Round pink tablet with G1 on one side and > on the other.

APO-Glimepiride 2 mg Tablets:

Green oblong tablet with G2|G2 on one side and >|> on the other.

APO-Glimepiride 3 mg Tablets:

Yellow oblong tablet with G3|G3 on one side and >|> on the other.

APO-Glimepiride 4 mg Tablets:

Blue oblong tablet with G4|G4 on one side and >|> on the other.

Blister packs of 30 tablets.

Ingredients

Each tablet contains 1, 2, 3 or 4 mg of glimepiride as the active ingredient.

It also contains the following inactive ingredients:

- * lactose
- * microcrystalline cellulose
- * povidone
- * sodium starch glycollate
- * magnesium stearate
- * iron oxide red (1 mg tablets)(172)
- * iron oxide yellow (2 mg, 3 mg tablets)(172)
- * indigo carmine (2 mg, 4 mg tablets)(120).

This medicine is gluten-free, sucrose-free, tartrazine-free and free

of other azo dyes.

Australian Registration Numbers

APO-Glimepiride 1 mg Tablets

Blister packs

AUST R 151570

APO-Glimepiride 2 mg Tablets

Blister packs

AUST R 151571

APO-Glimepiride 3 mg Tablets

Blister packs

AUST R 151572

APO-Glimepiride 4 mg Tablets

Blister packs

AUST R 151573

Sponsor

Sigma Pharmaceuticals (Australia)
Pty Ltd
96 Merrindale Drive
Croydon VIC 3136
Australia

Distributor

Apotex Pty Ltd
66 Waterloo Road
North Ryde, NSW 2113
Australia

Apotex Pty Ltd is the licensee of the registered trade marks APO and APOTEX from the registered proprietor, Apotex Inc.

Recognising and treating hypoglycaemia (very low blood sugar levels)

Hypoglycaemia may occur during treatment with glimepiride. It can occur suddenly.

The first signs of hypoglycaemia are usually weakness, trembling or shaking, sweating, light-headedness, dizziness, headache or lack of concentration, irritability, tearfulness, crying, hunger and/ or numbness around the lips and tongue.

Other possible symptoms are nausea, vomiting, sleep problems, clammy skin, anxiety, restlessness, aggressiveness, impaired alertness or reactions, depression, confusion, sight problems, helplessness, loss of self control, delirium, slow breathing, fast, slow or unusual heart beat, palpitations, angina,

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