

# GLIMEPIRIDE SANDOZ®

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using Glimepiride Sandoz?

Glimepiride Sandoz contains the active ingredient glimepiride. Glimepiride Sandoz is used to control blood glucose (sugar) in patients with type 2 diabetes mellitus.

For more information, see Section [1. Why am I using Glimepiride Sandoz?](#) in the full CMI.

### 2. What should I know before I use Glimepiride Sandoz?

Do not use if you have ever had an allergic reaction to glimepiride or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use Glimepiride Sandoz?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Glimepiride Sandoz and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use Glimepiride Sandoz?

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

More instructions can be found in Section [4. How do I use Glimepiride Sandoz?](#) in the full CMI.

### 5. What should I know while using Glimepiride Sandoz?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are taking Glimepiride Sandoz.</li><li>• If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.</li><li>• Make sure all your friends, relatives, work colleagues or carers know that you have diabetes and can recognise the symptoms of hypoglycaemia and know how to treat them.</li><li>• Always carry some sugary food or drink with you.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop taking Glimepiride Sandoz or change the dose without first checking with your doctor.</li><li>• Do not give Glimepiride Sandoz to anyone else even if they have the same condition as you.</li><li>• Do not skip meals while taking Glimepiride Sandoz.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful driving or operating machinery until you know how Glimepiride Sandoz affects you.</li><li>• This medicine may cause dizziness, light-headedness and tiredness if your blood glucose levels fall too low.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Be careful when drinking alcohol while you are taking this medicine.</li><li>• If you drink alcohol, your blood glucose levels may fall and you may experience symptoms of hypoglycaemia.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep Glimepiride Sandoz in a cool dry place where the temperature stays below 25°C.</li></ul>

For more information, see Section [5. What should I know while using Glimepiride Sandoz?](#) in the full CMI.

### 6. Are there any side effects?

**Common side effects:** stomach upset (nausea, vomiting), abdominal pain, discomfort, diarrhoea, eye problems.

**Serious side effects:** yellowing of skin or eyes, shortness of breath, pale, sore throat, mouth ulcers, bleeding or bruising more easily, itching, paleness, wheezing, swelling of face/lips/tongue/other parts of the body.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# Glimepiride Sandoz®

Active ingredient(s): *glimepiride*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Glimepiride Sandoz. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Glimepiride Sandoz.**

**Where to find information in this leaflet:**

- [1. Why am I using Glimepiride Sandoz?](#)
- [2. What should I know before I use Glimepiride Sandoz?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Glimepiride Sandoz?](#)
- [5. What should I know while using Glimepiride Sandoz?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using Glimepiride Sandoz?

**Glimepiride Sandoz contains the active ingredient glimepiride.** Glimepiride Sandoz belongs to a group of medicines called sulfonylureas. It works by increasing the amount of insulin produced by your pancreas.

**Glimepiride Sandoz is used to control blood glucose (sugar) in patients with type 2 diabetes mellitus.**

Your doctor may have prescribed it for another reason.

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

## 2. What should I know before I use Glimepiride Sandoz?

### Warnings

**Do not use Glimepiride Sandoz if:**

- you are allergic to glimepiride, other sulfonylureas, other similar medicines such as sulfonamides (e.g. sulfur antibiotics or thiazide diuretics) or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine. Some 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
- the package is torn or shows signs of tampering

**Do not take this medicine if you have or have any of the following medical conditions:**

- a previous reaction to glimepiride, other sulfonylureas or sulfonamides
- type 1 diabetes mellitus
- diabetic ketoacidosis
- diabetic coma or pre-coma
- severe kidney disease or if you require dialysis
- severe liver failure
- hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption.

**Check with your doctor if you:**

- have any other medical conditions
  - kidney problems
  - liver problems
  - unstable diabetes
  - adrenal, pituitary or thyroid problems
  - heart failure
  - glucose-6-phosphate dehydrogenase (G6PD) deficiency
  - diabetic coma
- take any medicines for any other condition
- are allergic to any other medicines, foods, dyes or preservatives
- drink alcohol in any amount
- do not eat regular meals
- do a lot of exercise or heavy exercise or work
- are ill or feeling unwell.

Alcohol, diet, exercise and your general health all strongly affect the control of your diabetes.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

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

It may affect your developing baby if you take it during pregnancy.

Insulin is more suitable for controlling blood glucose during pregnancy. Your doctor will replace Glimepiride Sandoz with insulin.

**Do not take this medicine if you are breastfeeding or intend to breastfeed.**

The active ingredient in Glimepiride Sandoz passes into breast milk and there is a possibility that your baby may be affected.

### Use in children

Do not give this medicine to children.

Safety and effectiveness in children have not been established.

### 3. What if I am taking other medicines?

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

**Some medicines may interfere with Glimepiride Sandoz and affect how it works.**

These medicines include:

- alcohol
- other medicines used to treat diabetes such as metformin or insulin
- some medicines used to treat reflux and stomach ulcers
- some anti-inflammatory medicines, such as aspirin, ibuprofen, naproxen or mesalazine
- some medicines used to treat arthritis and gout
- some antibiotics, such as clarithromycin or rifampicin
- anabolic steroids
- oral contraceptives
- corticosteroids, glucagon, thyroid hormones and other hormonal medications
- some cancer and organ transplant treatments
- some cholesterol-lowering and weight reduction medicines
- some antidepressants, psychiatric and sedating medicines
- some medicines used to treat epilepsy
- some medicines used to treat high blood pressure and some heart conditions, such as ACE inhibitors and beta-blockers
- some medicines used to treat blood clots, blood vessel problems and irregular heart rhythms such as coumarin derivatives
- some fluid and glaucoma medications
- large doses of laxatives.

Certain medicines such as beta-blockers and clonidine may hide the warning symptoms of hypoglycaemia (low blood glucose).

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Glimepiride Sandoz.**

### 4. How do I use Glimepiride Sandoz?

#### How much to take

- Your doctor will tell you how many tablets to take each day. Depending on your blood glucose levels, your doctor may increase or decrease the dose.
- If you take the wrong dose, Glimepiride Sandoz may not work as well and your condition may not improve.

#### When to take Glimepiride Sandoz

- **Take your medicine at about the same time each day.** Taking it at the same time each day will have the

best effect. It will also help you remember when to take it.

- **Take your medicine during or immediately after a meal, at about the same time each day.** Glimepiride Sandoz tablets are usually taken once a day, immediately before breakfast. If your breakfast is very light, you may wait until lunch to take the tablet.
- **Do not skip meals while taking Glimepiride Sandoz.**

#### How to take Glimepiride Sandoz

- Swallow the tablets whole with a full glass of water.

#### How long to take Glimepiride Sandoz

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

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

#### If you forget to use Glimepiride Sandoz

Take your dose as soon as you remember, and continue to take it as you would normally.

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

Tell your doctor if you have missed several doses. Missed doses can cause hyperglycaemia (high blood glucose).

**Do not take a double dose to make up for the dose that you missed.** This may increase the risk of hypoglycaemia (low blood glucose).

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

#### If you use too much Glimepiride Sandoz

If you think that you have used too much Glimepiride Sandoz, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

Symptoms of an overdose may include symptoms of hypoglycaemia (low blood glucose), such as:

- weakness, trembling or shaking
- sweating
- lightheadedness, dizziness, headache or lack of concentration
- tearfulness, crying, irritability
- hunger
- numbness around the lips and tongue
- loss of co-ordination or confusion
- slurred speech
- loss of consciousness or seizures.

## 5. What should I know while using Glimepiride Sandoz?

### Things you should do

- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Glimepiride Sandoz.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine
- **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 regular tests to make sure the medicine is working and to prevent unwanted side effects. These include:
  - blood glucose testing
  - checks of your eyes, feet, kidneys, heart, circulation, blood and blood pressure.
- **Make sure all your friends, relatives, work colleagues or carers know that you have diabetes. Make sure they can recognise the symptoms of hypoglycaemia and know how to treat them. Provide them with the telephone number for your doctor, the Poisons Information Centre (13 11 26) and Emergency Services.** Symptoms of hypoglycaemia can occur suddenly. These may include:
  - weakness, trembling or shaking
  - sweating
  - lightheadedness, dizziness, headache or lack of concentration
  - tearfulness, crying, irritability
  - hunger
  - numbness around the lips and tongue.
- **Always carry some sugary food or drink with you.** If you experience any of the symptoms of hypoglycaemia, raise your blood glucose quickly by taking one of the following:
  - 5-7 jelly beans
  - 3 teaspoons of sugar or honey
  - 1/2 can of sugar-containing soft drink
  - 2-3 concentrated glucose tablets.

Unless you are within 10-15 minutes of your next meal or snack, follow up with extra carbohydrates such as plain biscuits, fruit or milk. Taking this extra carbohydrate will prevent a second drop in your blood glucose level.

### Call your doctor straight away if you:

- become pregnant while taking Glimepiride Sandoz.
- become ill or experience extra stress, injury, fever, infection or need surgery.
- **experience hypoglycaemia that is severe; it can result in seizures or a loss of consciousness. In this case, an ambulance should be called immediately.** The risk of hypoglycaemia is increased in the following situations:
  - too much Glimepiride Sandoz
  - certain other medicines
  - too much or unexpected exercise
  - delayed meal or snack
  - too little food.

- notice the return of any symptoms you had before starting Glimepiride Sandoz (signs of hyperglycaemia (high blood glucose)). Signs of hyperglycaemia may include:
  - lethargy or tiredness
  - headache
  - thirst
  - passing large amounts of urine
  - blurred vision.

The risk of hyperglycaemia is increased in the following situations:

- uncontrolled diabetes
- illness, infection or stress
- taking less Glimepiride Sandoz than prescribed
- certain other medicines
- too little exercise or sudden immobilisation, e.g. after an accident
- eating more carbohydrates than normal.

Remind any doctor, dentist or pharmacist you visit that you are using Glimepiride Sandoz.

### Things you should not do

- Do not stop taking Glimepiride Sandoz or change the dose without first checking with your doctor.
- Do not give Glimepiride Sandoz to anyone else even if they have the same condition as you.
- Do not skip meals while taking Glimepiride Sandoz.

### Things to be careful of

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

- Glimepiride Sandoz 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 a severe sunburn.

#### If you become sick with a cold, fever or flu, it is very important to continue taking Glimepiride Sandoz, even if you feel unable to eat your normal meal.

- If you have trouble eating solid foods, use sugar-sweetened drinks as a carbohydrate substitute or eat small amounts of bland food. Your doctor, pharmacist or diabetes educator can give you a list of food to eat for sick days

### Driving or using machines

#### Be careful before you drive or use any machines or tools until you know how Glimepiride Sandoz affects you.

This medicine may cause dizziness, light-headedness and tiredness if your blood glucose levels fall too low. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

### Drinking alcohol

#### Be careful when drinking alcohol while you are taking this medicine.

If you drink alcohol, your blood glucose levels may fall and you may experience symptoms of hypoglycaemia.

Hypoglycaemia may slow your reaction time and affect your ability to drive or operate machinery. Drinking alcohol can also make this worse.

## Looking after your medicine

- Keep your tablets in their container until it is time to take them.  
If you take the tablets out of their container they may not keep well.

Store it in a cool dry place away from moisture, heat or sunlight below 25°C; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

### Keep it where young children cannot reach it.

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

## Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>hypoglycaemia</li> <li>stomach upset including nausea (feeling sick) and vomiting</li> <li>abdominal pain, discomfort, diarrhoea or feeling of fullness in the stomach</li> <li>eye problems, including blurred or double vision</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p> <p><b>They are generally mild and do not cause patients to stop taking Glimepiride Sandoz.</b></p>

### Serious side effects

Serious side effects	What to do
<p><b>Liver related:</b></p> <ul style="list-style-type: none"> <li>yellowing of your skin or eyes, also called jaundice</li> </ul>	<p><b>Call your doctor straight away, or go straight to the</b></p>

<p><b>Blood related:</b></p> <ul style="list-style-type: none"> <li>signs of anaemia such as tiredness, being short of breath and looking pale</li> <li>bleeding or bruising more easily than normal, or reddish or purplish blotches under the skin</li> </ul> <p><b>Skin related:</b></p> <ul style="list-style-type: none"> <li>symptoms of sunburn such as redness, itching, swelling or blistering which may occur more quickly than normal.</li> <li>skin reactions such as itching, redness or itchy hives-like rash or spots</li> </ul> <p><b>Allergy related:</b></p> <ul style="list-style-type: none"> <li>shortness of breath</li> <li>wheezing or difficulty breathing</li> <li>swelling of the face, lips, tongue or other parts of the body</li> </ul> <p><b>Infection related:</b></p> <ul style="list-style-type: none"> <li>signs of frequent or worrying infections, such as fever, severe chills, sore throat or mouth ulcers</li> </ul>	<p><b>Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>
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**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

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

Some side effects (for example changes in liver function or low blood cell counts) can only be found when your doctor does tests from time to time to check your progress

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

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

### What Glimepiride Sandoz contains

<b>Active ingredient (main ingredient)</b>	glimepiride
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>lactose</li> <li>microcrystalline cellulose</li> </ul>

	<ul style="list-style-type: none"> <li>• sodium starch glycollate</li> <li>• magnesium stearate</li> <li>• povidone</li> </ul> <p>Each strength tablet also contains the following colouring agents:</p> <ul style="list-style-type: none"> <li>• 1mg - iron oxide red</li> <li>• 2mg - iron oxide yellow and indigo carmine</li> <li>• 3mg - iron oxide yellow</li> <li>• 4mg - indigo carmine.</li> </ul>
<b>Potential allergens</b>	lactose

**Do not take this medicine if you are allergic to any of these ingredients.**

### **What Glimepiride Sandoz looks like**

Glimepiride Sandoz comes in four types of tablets:

Glimepiride Sandoz 1 mg– Light red, flat, modified oblong, scored tablet encoded G|1 on one side (Aust R 121781).

Glimepiride Sandoz 2 mg– Light green, flat, modified oblong, scored tablet encoded G|2 on one side (Aust R 121786).

Glimepiride Sandoz 3 mg– Light yellow, flat, modified oblong, scored tablet encoded G|3 on one side (Aust R 121788).

Glimepiride Sandoz 4 mg– Light blue, flat, modified oblong, scored tablet encoded G|4 on one side (Aust R 121790).

Each tablet strength comes in blisters packs of 30 tablets.

### **Who distributes Glimepiride Sandoz**

Sandoz Pty Ltd  
100 Pacific Highway  
North Sydney, NSW 2060  
Australia  
Tel 1800 726 369

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