

# Sitagliptin Sandoz® Pharma Tablets

## 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 Sitagliptin Sandoz Pharma?

Sitagliptin Sandoz Pharma contains the active ingredient sitagliptin (as hydrochloride monohydrate). Sitagliptin Sandoz Pharma is used to lower blood sugar levels in patients with type 2 diabetes mellitus alone or in combination with certain other medicines, when diet plus exercise or the other medicine(s) do not provide adequate blood sugar level control. For more information, see Section [1. Why am I using Sitagliptin Sandoz Pharma?](#) in the full CMI.

### 2. What should I know before I use Sitagliptin Sandoz Pharma?

Do not use if you have ever had an allergic reaction to Sitagliptin Sandoz Pharma 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 Sitagliptin Sandoz Pharma?](#) in the full CMI.

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

Some medicines may interfere with Sitagliptin Sandoz Pharma 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 Sitagliptin Sandoz Pharma?

- Your doctor will tell you how many tablets to take each day. The standard recommended dose is one 100 mg tablet per day. Your doctor may prescribe a lower dose for you.
- Swallow the tablet whole by mouth, with or without food, with a glass of water and take Sitagliptin Sandoz Pharma at about the same time each day

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

### 5. What should I know while using Sitagliptin Sandoz Pharma?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>Remind any doctor, dentist or pharmacist you visit that you are using Sitagliptin Sandoz Pharma.</li><li>If you become pregnant or plan to breastfeed while using Sitagliptin Sandoz Pharma tell your doctor immediately.</li><li>If you are about to be started on any new medicine, tell your doctor and pharmacist you are taking Sitagliptin Sandoz Pharma.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>Do not stop using this medicine without checking with your doctor</li><li>Do not give Sitagliptin Sandoz Pharma to anyone else, even if they have the same condition as you.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>Sitagliptin Sandoz Pharma is not expected to affect the ability to drive and use machines.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>No information of the effects of drinking alcohol while using Sitagliptin Sandoz Pharma.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>Keep Sitagliptin Sandoz Pharma tablets in a cool dry place where the temperature stays below 30°C.</li><li>Keep your tablets in the original packaging until it is time to take them.</li></ul>

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

### 6. Are there any side effects?

Common side effects: signs of an infection of the breathing passages (runny nose, sore throat, cough), soreness in the back of the nose and throat and discomfort when swallowing, headache, flu-like symptoms.

Serious side effects: Low blood sugar (sweating, irritable, fast heartbeat, shaky, nervous or anxious) when Sitagliptin Sandoz Pharma is used in combination with other medicine, skin blisters or breakdown of your skin (bullous pemphigoid), severe allergic reactions (swelling of face, lips, tongue and throat, difficulty breathing or swallowing), severe and persistent stomach pain (pancreatitis). 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.

# Sitagliptin Sandoz<sup>®</sup> Pharma Tablets

Active ingredient: *sitagliptin (as hydrochloride monohydrate)*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Sitagliptin Sandoz Pharma. **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 Sitagliptin Sandoz Pharma.**

Where to find information in this leaflet:

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

## 1. Why am I using Sitagliptin Sandoz Pharma?

Sitagliptin Sandoz Pharma contains the active ingredient **sitagliptin (as hydrochloride monohydrate)**. Sitagliptin Sandoz Pharma is a member of a class of medicines you take by mouth called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors) that lowers blood sugar levels in patients with type 2 diabetes mellitus.

Sitagliptin Sandoz Pharma:

- Helps to improve the levels of insulin after a meal.
- Decreases the amount of sugar made by the body.
- Works when blood sugar is high, especially after a meal. This is when the body needs the greatest amount of help in lowering blood sugar. Sitagliptin Sandoz Pharma also lowers blood sugar between meals.
- By itself is unlikely to cause low blood sugar (hypoglycaemia) because it does not work when your blood sugar is low.

**Sitagliptin Sandoz Pharma is used to lower blood sugar levels in patients with type 2 diabetes mellitus alone or in combination with certain other medicines (metformin, ertugliflozin, medicines such as rosiglitazone and pioglitazone, a sulfonylurea medicine such as glimepiride, gliclazide and glibenclamide, or insulin), when diet plus exercise or the other medicine(s) do not provide adequate blood sugar level control.**

## 2. What should I know before I use Sitagliptin Sandoz Pharma?

### Warnings

**Do not use Sitagliptin Sandoz Pharma if:**

- You are allergic to sitagliptin, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

**Check with your doctor if you:**

- Have any other medical conditions.
- Are pregnant or intend to become pregnant.
- Are breastfeeding or plan to breastfeed.
- Have or have had type 1 diabetes mellitus or a condition called diabetic ketoacidosis (increased ketones in the blood or urine). Sitagliptin Sandoz Pharma should not be used for the treatment of these conditions.
- Have any kidney problems or any past or present medical problems. If you have kidney problems, your doctor may prescribe lower doses.
- Take any medicines for any other condition
- Have allergies to any substances, such as foods, preservatives, or dyes.

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

Check with your doctor if you are pregnant or intend to become pregnant. Sitagliptin Sandoz Pharma is not recommended for use during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Sitagliptin Sandoz Pharma should not be used while breastfeeding or if planning to breastfeed

### Use in children

- Children and adolescents below 18 years should not use this medicine. Sitagliptin Sandoz Pharma is not effective in children and adolescents 10 to 17 years of age with type 2 diabetes. Sitagliptin Sandoz Pharma has not been studied in children younger than 10 years of age.

## 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.

Medicines that may cause low blood sugar when used in combination with Sitagliptin Sandoz Pharma include:

- Sulfonylureas
- Insulin

A reduction in the amount of the sulfonylurea or insulin may be required.

Sitagliptin Sandoz Pharma can be taken with most other medicines.

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

## 4. How do I use Sitagliptin Sandoz Pharma?

### How much to take

- Take Sitagliptin Sandoz Pharma only when prescribed by your doctor.
- The recommended dose is to take one 100 mg tablet once a day.
- If you have kidney problems, your doctor may prescribe lower doses, and monitor your kidney function.
- Follow the instructions provided and use Sitagliptin Sandoz Pharma until your doctor tells you to stop.
- If you do not understand the instructions on the box, ask your doctor or pharmacist for help

### When to take Sitagliptin Sandoz Pharma

- Take your Sitagliptin Sandoz Pharma at about the same time each day. Taking your tablet at the same time each day will have the best effect. It will also help you remember when to take the tablets.

### How to take Sitagliptin Sandoz Pharma

- Swallow the tablet whole by mouth with a glass of water. Sitagliptin Sandoz Pharma can be taken with or without food.
- Your doctor may prescribe Sitagliptin Sandoz Pharma on its own, or with certain other medicines that lower blood sugar.
- Continue to take Sitagliptin Sandoz Pharma as long as your doctor prescribes it so you can continue to help control your blood sugar. Diet and exercise can help your body use its blood sugar better. It is important to stay on your doctor's recommended diet, exercise and weight loss program while taking Sitagliptin Sandoz Pharma.

### If you forget to use Sitagliptin Sandoz Pharma

Sitagliptin Sandoz Pharma should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember.

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

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

### If you use too much Sitagliptin Sandoz Pharma

If you think that you have used too much Sitagliptin Sandoz Pharma, 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.**

## 5. What should I know while using Sitagliptin Sandoz Pharma?

### Things you should do

- Diet and exercise can help your body use its blood sugar better. It is important to stay on your doctor's recommended diet, exercise and weight loss program while taking Sitagliptin Sandoz Pharma.
- Remind any doctor, dentist or pharmacist you visit that you are using Sitagliptin Sandoz Pharma.
- If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Sitagliptin Sandoz Pharma.

**Call your doctor straight away if you:**

- Become pregnant while taking Sitagliptin Sandoz Pharma.

### Things you should not do

- Do not give Sitagliptin Sandoz Pharma to anyone else, even if they have the same condition as you.
- Do not stop using this medicine without checking with your doctor.

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how Sitagliptin Sandoz Pharma affects you.**

Sitagliptin Sandoz Pharma is not expected to affect the ability to drive and use machines.

### Drinking alcohol

**Tell your doctor if you drink alcohol.**

There is no information of the effects of drinking alcohol while using Sitagliptin Sandoz Pharma.

### Looking after your medicine

- Keep Sitagliptin Sandoz Pharma tablets in a cool dry place where the temperature stays below 30°C.
- Keep your tablets in the original packaging until it is time to take them.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; 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.**

### 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>• Signs of an infection of the breathing passages, including runny nose, sore throat, cough</li> <li>• Soreness in the back of the nose and throat and discomfort when swallowing</li> <li>• Headache</li> <li>• Flu-like symptoms</li> <li>• stomach discomfort</li> <li>• Diarrhoea</li> <li>• Kidney problems (sometimes requiring dialysis)</li> <li>• Constipation</li> <li>• Vomiting</li> <li>• Pain including joint, muscle aches, arm or leg, back</li> <li>• Itching</li> <li>• Blisters</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 Sitagliptin Sandoz Pharma.</b></p>

### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• Low blood sugar (hypoglycaemia) when Sitagliptin Sandoz Pharma is used in combination with a sulfonylurea medicine or with insulin.</li> <li>• Severe blistering or the breakdown of your skin (erosion).</li> </ul>	<p><b>Stop taking Sitagliptin Sandoz Pharma.</b></p> <p><b>Call your doctor straight away, or go straight to the Emergency Department at</b></p>

<ul style="list-style-type: none"> <li>• Allergic reactions which may be serious including rash, hives, and swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing.</li> <li>• Severe and persistent stomach pain, often with nausea and vomiting. These may be symptoms of pancreatitis. Pancreatitis can be a serious, potentially life-threatening medical condition.</li> </ul>	<p><b>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.

### 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 Sitagliptin Sandoz Pharma contains

<b>Active ingredient (main ingredient)</b>	Each tablet contains sitagliptin (as hydrochloride monohydrate) equivalent to 25 mg, 50 mg or 100 mg of sitagliptin.
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>• calcium hydrogen phosphate</li> <li>• magnesium stearate</li> <li>• microcrystalline cellulose</li> <li>• sodium starch glycolate (Type A)</li> <li>• polyvinyl alcohol</li> <li>• titanium dioxide</li> <li>• macrogol</li> <li>• purified talc</li> <li>• iron oxide yellow</li> <li>• iron oxide red</li> <li>• iron oxide black (50 mg strength)</li> </ul>
<b>Potential allergens</b>	N/A

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

## **What Sitagliptin Sandoz Pharma looks like**

Sitagliptin Sandoz Pharma tablet 25 mg – a pink, round, film-coated tablet with “25” engraved on one side. Pack size of 28 tablets (AUST R 352552)

Sitagliptin Sandoz Pharma tablet 50 mg – a light beige, round, film-coated tablet with “50” engraved on one side. Pack size of 28 tablets (AUST R 352553)

Sitagliptin Sandoz Pharma tablet 100 mg – a beige, round, film-coated tablet with “100” engraved on one side. Pack size of 28 tablets (AUST R 352565)

## **Who distributes Sitagliptin Sandoz Pharma**

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

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