

# Sitagliptin 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 Sitagliptin Sandoz?

Sitagliptin Sandoz contains the active ingredient sitagliptin (as hydrochloride monohydrate). Sitagliptin Sandoz is used to lower blood sugar levels in patients with type 2 diabetes mellitus.

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

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

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

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

Some medicines may interfere with Sitagliptin 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 Sitagliptin Sandoz?

- Take Sitagliptin Sandoz once a day by mouth, with or without

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

### 5. What should I know while using Sitagliptin 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 using Sitagliptin Sandoz.</li><li>• Call your doctor straight away if you become pregnant while taking Sitagliptin Sandoz.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop taking this medicine suddenly.</li><li>• Do not give Sitagliptin Sandoz to anyone else, even if they have the same condition as you.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep Sitagliptin Sandoz tablets in a cool dry place below 30°C away from moisture, heat or sunlight.</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?](#) in the full CMI.

### 6. Are there any side effects?

Serious side effects in particular that need to be noted are:

- Allergic reactions including rash, hives, swelling of the face, lips, tongue, and throat with difficulty in breathing or swallowing.
- Severe and persistent stomach pain, often with nausea and vomiting.
- Low blood sugar when used in combination with a sulfonylurea medicine or with insulin.
- Blisters or breakdown of your skin (erosion).
- Kidney problems.

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®

Active ingredient: *sitagliptin (as hydrochloride monohydrate)*

## Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

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

Sitagliptin Sandoz contains the active ingredient **sitagliptin (as hydrochloride monohydrate)**. Sitagliptin Sandoz 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 is used to lower blood sugar levels in adults with type 2 diabetes mellitus. Sitagliptin Sandoz can be used alone or in combination with certain other medicines that lower blood sugar along with a recommended diet and exercise program.

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

#### Warnings

Do not use Sitagliptin Sandoz 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 or have had type 1 diabetes mellitus
- Have or have had increased ketones in the blood or urine (diabetic ketoacidosis).
- Have or have had any kidney problems or any past or present medical problems. If you have kidney problems.
- Take any medicines for any other condition

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 is not recommended for use during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Sitagliptin Sandoz 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.

### 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 include:

- Sulfonylureas
- Insulin

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

**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.**

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

#### How much to take

- Take Sitagliptin Sandoz once a day by mouth, with or without food.
- If you have kidney problems, your doctor may prescribe lower doses, and monitor your kidney function.
- Your doctor may prescribe Sitagliptin Sandoz on its own, or with certain medicines that lower blood sugar.

#### When to take Sitagliptin Sandoz

- Take your Sitagliptin Sandoz 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.

## If you forget to use Sitagliptin Sandoz

Sitagliptin Sandoz 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

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

**You should immediately:**

- phone the National Poisons Centre (**by calling 0800 764766**), 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?

### 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.

### Call your doctor straight away if you:

- Become pregnant while taking Sitagliptin Sandoz.

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

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

### Things you should not do

- Do not stop taking this medicine suddenly. Continue to take Sitagliptin Sandoz as long as your doctor prescribes it so it can continue to help control your blood sugar.
- Do not give Sitagliptin Sandoz to anyone else, even if they have the same condition as you.

### Driving or using machines

There is no information to suggest that Sitagliptin Sandoz affects your ability to drive a car or operate machinery.

### Drinking alcohol

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

## Looking after your medicine

- 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 below 30°C 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, soreness in the back of the nose and throat and discomfort when swallowing</li><li>• Stomach discomfort and vomiting, diarrhoea or constipation</li><li>• Muscle aches or pain in the joints, back, arm, or leg</li><li>• Itching, or blisters or the breakdown of your skin (erosion).</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

### Serious side effects

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

<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>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 New Zealand Pharmacovigilance Centre online at <https://nzphvc.otago.ac.nz/reporting/>. 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 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 looks like

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

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

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

### Who distributes Sitagliptin Sandoz

Sandoz New Zealand Limited

12 Madden Street

Wynyard Quarter, Auckland 1010

New Zealand

Telephone: 0800 726 369

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