Sitagliptin/Metformin 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/Metformin Sandoz?

Sitagliptin/Metformin Sandoz contains the active ingredient sitagliptin (as hydrochloride monohydrate) and metformin (as hydrochloride). Sitagliptin/Metformin Sandoz is used to lower blood sugar levels in adults with diabetes mellitus.

For more information, see Section 1. Why am I using Sitagliptin/Metformin Sandoz? in the full CMI.

2. What should I know before I use Sitagliptin/Metformin Sandoz?

Do not use if you have ever had an allergic reaction to Sitagliptin/Metformin 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/Metformin Sandoz? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Sitagliptin/Metformin 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 take Sitagliptin/Metformin Sandoz?

- Your doctor will tell you how many Sitagliptin/Metformin Sandoz tablets to take and how often to take them.
- Take Sitagliptin/Metformin Sandoz with meals to lower your chance of an upset stomach.

More instructions can be found in Section 4. How do I take Sitagliptin/Metformin Sandoz? in the full CMI.

5. What should I know while taking Sitagliptin/Metformin Sandoz?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are taking Sitagliptin/Metformin Sandoz. • Call your doctor straight away if you become pregnant while taking Sitagliptin/Metformin Sandoz.
Things you should not do	• Do not stop taking this medicine suddenly. • Do not give this medicine to anyone else, even if they have the same condition as you.
Driving or using machines	• There is no information to suggest that Sitagliptin/Metformin 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 blister pack until it is time to take them. • Store it in a cool dry place away from moisture, heat or sunlight below 30°C.

For more information, see Section 5. What should I know while taking Sitagliptin/Metformin 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.
- Blisters or the breakdown of your skin (erosion).
- Low blood sugar when used in combination with a sulfonylurea medicine or with insulin.
- Kidney problems (sometimes requiring dialysis).

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/Metformin Sandoz®

Active ingredient(s): *sitagliptin hydrochloride monohydrate/ metformin hydrochloride*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using Sitagliptin/Metformin Sandoz?

Sitagliptin/Metformin Sandoz contains two active ingredients: sitagliptin and metformin.

Sitagliptin is a member of a class of medicines you take by mouth called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors) and metformin which belongs to a class of medicines called biguanides. Sitagliptin and metformin work together to control blood sugar levels in adults with type 2 diabetes mellitus.

Sitagliptin/Metformin Sandoz is used to lower blood sugar levels in adults with type 2 diabetes mellitus. Sitagliptin/Metformin Sandoz can be taken 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/Metformin Sandoz?

Warnings

Do not use Sitagliptin/Metformin Sandoz if:

- you are allergic to sitagliptin or metformin, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine. Symptoms of an allergic reaction may include skin rash, itchiness, shortness of breath, swelling of the face, lips, mouth, tongue or throat.

Check with your doctor if you:

- have or have had type 1 diabetes mellitus or
- have or have had increased ketones in the blood (diabetic ketoacidosis).
- have or have had severe kidney problems
- have any liver or heart problems including congestive heart failure or any past or present medical problems
- have a known or suspected mitochondrial disease e.g. Mitochondrial Encephalopathy with Lactic acidosis, and Stroke-like episodes (MELAS) or Maternal Inherited Diabetes and Deadness (MIDD)
- drink excessive alcohol (all the time or short term "binge" drinking)
- are going to get or receive an injection of dye or contrast agent for an X-ray procedure, or if you plan to have surgery. Talk to your doctor about when to stop Sitagliptin/Metformin and when to start again.
- take any medicines for any other condition.

If you have not told your doctor about any of the above, tell him/ her before you take any Sitagliptin/Metformin Sandoz.

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/Metformin Sandoz is not recommended for use during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed. You should not take Sitagliptin/Metformin Sandoz while breastfeeding or if planning to breastfeed.

Children

Children and adolescents below 18 years should not use this medicine. Sitagliptin/Metformin Sandoz is not effective in children and adolescents 10 to 17 years of age with type 2 diabetes. Sitagliptin/Metformin Sandoz 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.

Sitagliptin/Metformin Sandoz may affect how well other drugs work and some drugs can affect how well Sitagliptin/Metformin Sandoz works.

Medicines that may cause low blood sugar when used in combination with Sitagliptin/Metformin 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/Metformin Sandoz.

4. How do I take Sitagliptin/Metformin Sandoz?

How much to take

- Your doctor will tell you how many Sitagliptin/Metformin Sandoz tablets to take and how often to take them.

When to take Sitagliptin/Metformin Sandoz

- Take your Sitagliptin/Metformin Sandoz tablets at about the same time each day.

If you forget to take Sitagliptin/Metformin Sandoz

Sitagliptin/Metformin 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 have trouble remembering to take your tablet, ask your pharmacist for some hints.

If you use too much Sitagliptin/Metformin Sandoz

If you think that you have used too much Sitagliptin/Metformin 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.

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

5. What should I know while using Sitagliptin/Metformin Sandoz?

Things you should do

Call your doctor straight away if you:

- become pregnant while taking Sitagliptin/Metformin Sandoz, or

Tell your doctor if you:

- become ill
- become dehydrated
- are injured
- have a fever
- have a serious infection
- plan to have surgery

Your blood glucose may become difficult to control at these times. You may also be at greater risk of developing a serious condition called lactic acidosis. During these times, your doctor may temporarily replace Sitagliptin/Metformin Sandoz with insulin.

Low blood sugar or high blood sugar

Make sure that you, your friends, family and work colleagues can recognise the symptoms of low blood sugar and high blood sugar and know how to treat them.

Low blood sugar

Signs of low blood sugar may include:

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

If not treated quickly, these symptoms may progress to:

- loss of co-ordination
- slurred speech
- confusion
- fits or loss of consciousness

At first signs of hypoglycaemia, you need to raise your blood glucose quickly. You can do this by taking one of the following:

- 5-7 jellybeans
- 3 teaspoons of sugar or honey
- half a can of non-diet soft drink
- 2-3 concentrated glucose tablets

Unless you are within 10 to 15 minutes of your next meal or snack, follow up with extra carbohydrates such as plan biscuits, fruit or milk.

Taking this extra carbohydrate will prevent a second drop in your blood glucose level.

High blood sugar

If you notice the return of any signs of hyperglycaemia, contact your doctor immediately.

The risk of hyperglycaemia is increased with:

- uncontrolled diabetes
- illness, infection or stress

- taking less Sitagliptin/Metformin Sandoz than prescribed
- taking certain other medicines
- too little exercise
- eating more carbohydrates than normal

Your blood glucose sugar may become difficult to control at these times. You may also be at greater risk of developing a serious condition called lactic acidosis. During these times, your doctor may temporarily replace Sitagliptin/Metformin Sandoz with insulin.

Stop taking Sitagliptin/Metformin Sandoz if you have symptoms of lactic acidosis, such as feeling very weak and tired, unusual (not normal) muscle pain, trouble breathing, stomach pain with nausea and vomiting, or diarrhoea, feeling cold, especially in your arms and legs, feeling dizzy or lightheaded, a slow or irregular heart beat or your medical condition suddenly changes.
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/Metformin Sandoz.
Make sure you check your blood glucose sugar levels regularly.
Visit your doctor for regular checks of your eyes, feet, kidneys, heart, circulation, blood and blood pressure. See you doctor once a year for a check on your body's level of vitamin B12.
If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Sitagliptin/Metformin Sandoz.

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

Things you should not do

- Do not stop using this medicine or change your dose without checking with your doctor.
- Do not skip meals while taking Sitagliptin/Metformin Sandoz.
- Do not give Sitagliptin/Metformin 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/Metformin 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 packaging until it is time to take them. If you take the tablets out of the package they may not keep well.

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.

Store where the temperatures stays below 30°C.
Heat and dampness can destroy some medicines.

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.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Sitagliptin/Metformin Sandoz.

Less serious side effects

Less serious side effects	What to do
Infection related: • signs of infection of the breathing passages, including runny nose, sore throat, cough • upper respiratory tract infection **Gut or Gastrointestinal related:** • nausea and vomiting, stomach discomfort, diarrhoea or constipation **Others:** • headache • muscle aches or joint, arm, leg or back pain • itching or blisters • reduction of TSH level in patients with treated or untreated hypothyroidism	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
Allergic reaction related: • Allergic reactions including rash, hives, and swelling of the face, lips, tongue, and throat that may cause	**Call your doctor straight away, or go straight to the**

difficulty in breathing or swallowing. **Pancreas related:** • 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. **Kidneys related:** • Kidney problems (sometimes requiring dialysis) **Skin related:** • Itching, blisters or the breakdown of your skin (erosion) to serious AEs. **Low blood sugar related:** • Low blood sugar when Sitagliptin/Metformin Sandoz is used in combination with a sulfonylurea medicine or with insulin.	**Emergency Department at your nearest hospital if you notice any of these serious side effects.**

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. 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/Metformin Sandoz contains

Active ingredient (main ingredient)	Each tablet contains sitagliptin 50 mg and metformin 500, 850 or 100 mg
Other ingredients (inactive ingredients)	• microcrystalline cellulose • povidone • sodium lauryl sulfate • sodium stearylfumarate • croscarmellose sodium **Ingredients of film-coating:** • hypromellose • hyprolose • triethyl citrate • titanium dioxide • talc • iron oxide yellow • iron oxide red
Potential allergens	Sitagliptin/Metformin Sandoz does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

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

What Sitagliptin/Metformin Sandoz looks like

Sitagliptin/Metformin Sandoz 50 mg/500 mg – A pink, oval, film coated tablet debossed with "SM1" on one side and plain on the other (Aust R 326502).

Sitagliptin/Metformin Sandoz 50 mg/850 mg – A light orange, oval, film coated tablet debossed with "SM2" on one side and plain on the other (Aust R 326501).

Sitagliptin/Metformin Sandoz 50 mg/ 1000 mg – A light red, oval, film coated tablet debossed with "SM3" on one side and plain on the other (AUST R 326500).

A box of Sitagliptin/Metformin Sandoz contains 56 tablets.

Who distributes Sitagliptin/Metformin Sandoz

Sandoz Pty Ltd
100 Pacific Highway
North Sydney, NSW 2060
Australia

Tel 1800 726 369

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