

Sitagliptin/Metformin Sandoz® XR

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 XR?

Sitagliptin/Metformin Sandoz XR contains the active ingredient sitagliptin (as hydrochloride monohydrate) and metformin hydrochloride. Sitagliptin/Metformin Sandoz XR helps lower blood sugar levels in patients with type 2 diabetes mellitus along with diet and exercise.

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

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

Do not use if you have ever had an allergic reaction to sitagliptin or metformin 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 XR?](#) in the full CMI.

3. What if I am taking other medicines?

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

- Sitagliptin/Metformin Sandoz XR should only be taken once a day.
- Take Sitagliptin/Metformin Sandoz XR with meals to lower your chance of an upset stomach.
- Swallow Sitagliptin/Metformin Sandoz XR tablets whole with a glass of water. Do not chew, cut or crush the tablets. More instructions can be found in Section [4. How do I use Sitagliptin/Metformin Sandoz XR?](#) in the full CMI.

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

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Sitagliptin/Metformin Sandoz XR.• Make sure you, your friends, family and work colleagues can recognise the symptoms of hypoglycaemia and hyperglycaemia and know how to treat them.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking this medicine or change your dose without checking with your doctor.• Do not give this medicine to anyone else, even if they have the same condition as you.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how Sitagliptin/Metformin Sandoz XR affects you.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none">• Store where the temperature stays below 30°C.

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

6. Are there any side effects?

Common side effects: signs of infection, upper respiratory tract infection, nausea and vomiting, headache, diarrhoea.

Serious side effects: allergic reactions, severe and persistent stomach pain often with nausea and vomiting.

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® XR

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

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using Sitagliptin/Metformin Sandoz XR?

Sitagliptin/Metformin Sandoz XR contains two active ingredients sitagliptin (as hydrochloride monohydrate) and metformin hydrochloride. Sitagliptin belongs to a class of medicines called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors), and metformin belongs to a class of medicines called biguanides. Sitagliptin and metformin work together to control blood sugar levels in patients with type 2 diabetes mellitus.

- Sitagliptin/Metformin Sandoz XR helps to improve the levels of insulin after a meal.
- Sitagliptin/Metformin Sandoz XR decreases the amount of sugar made by the body
- Sitagliptin/Metformin Sandoz XR 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/Metformin Sandoz also lowers blood sugar between meals.

Sitagliptin/Metformin Sandoz XR helps lower blood sugar levels in patients with type 2 diabetes mellitus along with diet and exercise. Sitagliptin/Metformin Sandoz XR can be used alone, or in combination with ertugliflozin, insulin or sulfonylurea medicines such as glimepiride, gliclazide and glibenclamide.

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

Warnings

Do not use Sitagliptin/Metformin Sandoz XR 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
- the packaging is torn or shows signs of tampering
- the expiry date on the pack has passed. If you take this medicine after the expiry date has passed, it may not work.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition
- have or have had type 1 diabetes mellitus or a condition called diabetic ketoacidosis (increased ketones in the blood or urine)
- have severe kidney problems
- have any liver or heart problems including congestive heart failure or any past or present medical problems
- have or have had an allergic reaction to sitagliptin, metformin, Sitagliptin/Metformin Sandoz or Sitagliptin/Metformin Sandoz XR or you have any allergies to any other medicines or any other substances such as foods, preservatives or dyes.
- 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 XR and when to start again.

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

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 XR is not recommended for use during pregnancy.

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

Sitagliptin/Metformin Sandoz XR should not be used while breastfeeding or if planning to breastfeed.

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

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 XR.

4. How do I use Sitagliptin/Metformin Sandoz XR?

How much to take

- Your doctor will tell you how many Sitagliptin/Metformin Sandoz XR tablets to take.
- Sitagliptin/Metformin Sandoz XR should only be taken once a day.
- Follow the instructions provided and use Sitagliptin/Metformin Sandoz XR until your doctor tells you to stop.
- If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How to take Sitagliptin/Metformin Sandoz XR

- Take Sitagliptin/Metformin Sandoz XR with meals to lower your chance of an upset stomach
- Swallow Sitagliptin/Metformin Sandoz XR tablets whole with a glass of water. Do not chew, cut or crush the tablets. Tell your doctor if you cannot swallow Sitagliptin/Metformin XR whole.
- You may see something that looks like the Sitagliptin/Metformin Sandoz XR tablet in your stool (bowel movement). If you see tablets in your stool several times, talk to your doctor. Do not stop taking Sitagliptin/Metformin Sandoz XR without talk to your doctor.
- Follow all directions given to you by your doctor and pharmacist carefully.

How long to take it

- Continue to take Sitagliptin/Metformin Sandoz XR as long as your doctor prescribes it so you can continue to help control your blood sugar.

- Make sure you keep enough Sitagliptin/Metformin Sandoz XR to last over weekends and holidays.
- 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 XR.

If you forget to use Sitagliptin/Metformin Sandoz XR

Sitagliptin/Metformin Sandoz XR 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.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

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 XR

If you think that you have used too much Sitagliptin/Metformin Sandoz XR, 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 take too much Sitagliptin/Metformin Sandoz XR, you may feel sick, vomit, have trouble breathing and have stomach pain or diarrhoea. These may be the early signs of a serious condition called lactic acidosis.

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

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

Things you should do

- If you become pregnant while taking Sitagliptin/Metformin Sandoz XR, tell your doctor immediately.
- If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Sitagliptin/Metformin Sandoz XR.
- Make sure you, your friends, family and work colleagues can recognise the symptoms of hypoglycaemia and hyperglycaemia and know how to treat them.

Call your doctor straight away if you:

- become ill
- become dehydrated, such as being sick with severe vomiting, diarrhoea or if you drink fluids a lot less than normal
- 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 XR with insulin.

- Make sure you check your blood glucose levels regularly.
- Visit your doctor for regular checks of your eyes, feet, kidneys, heart, circulation, blood and blood pressure.
- See your doctor once a year for a check on your body's level of vitamin B12.
- Carefully follow your doctor's and/or dietician's advice on diet, drinking alcohol and exercise.

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

Things you should not do

- Do not stop using this Sitagliptin/Metformin Sandoz XR or change your dose without checking with your doctor.
- Do not give Sitagliptin/Metformin Sandoz XR to anyone else, even if they have the same condition as you.

Hypoglycaemia

- Sitagliptin/Metformin Sandoz XR does not normally cause hypoglycaemia, although you may experience it if you take certain other medicines.
- When Sitagliptin/Metformin Sandoz XR is used with insulin, low blood sugar (hypoglycaemia) due to the insulin, can occur. Lower doses of insulin may be required.

Signs of hypoglycaemia 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 plain biscuits, fruit or milk.

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

Hyperglycaemia

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

The risk of hyperglycaemia is increased in the following situations:

- uncontrolled diabetes
- illness, infection or stress
- taking less Sitagliptin/Metformin Sandoz XR than prescribed
- taking certain other medicines
- too little exercise
- eating more carbohydrates than normal

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Sitagliptin/Metformin Sandoz XR affects you.

The effect of Sitagliptin/Metformin Sandoz XR on the ability to drive a car or operate machinery has not been studied, although it is thought to be unlikely to have any effect on these activities.

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 XR.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • signs of infection of the breathing passages, including runny nose, sore throat, cough • upper respiratory tract infection • nausea and vomiting • headache • diarrhoea • indigestion, wind, uncomfortable feeling in the stomach • cases of a skin reaction called bullous pemphigoid that can require treatment in a hospital have been reported in patients receiving Sitagliptin/Metformin Sandoz XR. Tell your doctor if you develop blisters or the breakdown of your skin (erosion). Your doctor may tell you to stop taking Sitagliptin/Metformin Sandoz XR. 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> <p>They are generally mild and do not cause patients to stop taking Sitagliptin/Metformin Sandoz XR.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • 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. If you have an allergic reaction, stop taking Sitagliptin/Metformin Sandoz XR and call your doctor right away. Your doctor may prescribe a medication to treat your allergic reaction and different medication for your diabetes. 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

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| <ul style="list-style-type: none"> • 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. Stop taking Sitagliptin/Metformin Sandoz XR and call your doctor right away if you experience these symptoms. | |
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Risk of lactic acidosis

Sitagliptin/Metformin Sandoz XR may cause a very rare, but very serious side effect called lactic acidosis, particularly if your kidneys are not working properly.

The risk of developing lactic acidosis is also increased with uncontrolled diabetes, serious infections, prolonged fasting or alcohol intake, dehydration, liver problems and any medical conditions in which a part of the body has a reduced supply of oxygen (such as acute severe heart disease).

If any of the above apply to you, talk to your doctor for further instructions.

Stop taking Sitagliptin/Metformin Sandoz XR for a short time if you have a condition that may be associated with dehydration (significant loss of body fluids) such as severe vomiting, diarrhoea, fever, exposure to heat or if you drink less fluid than normal. Talk to your doctor for further instructions.

Stop taking Sitagliptin/Metformin Sandoz XR if you get any of the following symptoms of lactic acidosis and see your doctor immediately:

- You feel very weak and tired.
- You have unusual (not normal) muscle pain.
- You have trouble breathing.
- You have stomach pain with nausea and vomiting, or diarrhoea.
- You feel cold, especially in your arms and legs.
- You feel dizzy or lightheaded.
- You have a slow or irregular heartbeat.
- Your medical condition suddenly changes.

Additional side effects have been reported in general use with Sitagliptin/Metformin XR or sitagliptin, one of the medicines in Sitagliptin/Metformin XR. These side effects have been reported when Sitagliptin/Metformin XR or sitagliptin have been used by themselves and/or with other diabetes medicines:

- Kidney problems (sometimes requiring dialysis)
- Constipation
- Joint pain
- Muscle aches
- Arm or leg pain
- Back pain
- Itching
- Blisters

Common side effects in patients taking metformin alone include:

- Diarrhoea
- Nausea/vomiting
- Flatulence
- Weakness
- Indigestion
- Abdominal discomfort
- Headache

Diarrhoea and nausea/vomiting were seen in patients treated with modified-release metformin products.

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.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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 XR contains

Active ingredient (main ingredient)	Each tablet contains 50 mg sitagliptin as free base and 1000 mg metformin hydrochloride or 100 mg sitagliptin as free base and 1000 mg metformin hydrochloride
Other ingredients (inactive ingredients)	povidone hypromellose colloidal anhydrous silica sodium stearyl fumarate propyl gallate macrogol 3350 purified talc hypolose titanium dioxide

	iron oxide, yellow (Sitagliptin/Metformin Sandoz XR 50/1000 only) indigo carmine
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Do not take this medicine if you are allergic to any of these ingredients.

What Sitagliptin/Metformin Sandoz XR looks like

Sitagliptin/Metformin Sandoz XR 50mg/1000mg – A green, bi-convex oval, film coated tablet. (Aust R 369591)

Sitagliptin/Metformin Sandoz XR 100mg/1000mg – A blue, bi-convex oval, film coated tablet. (Aust R 369590)

Who distributes Sitagliptin/Metformin Sandoz XR

Sandoz Pty Ltd

100 Pacific Highway

North Sydney, NSW 2060

Australia

Tel 1800 726 369

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