

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Sandoz Metformin.

It does not contain all the available information. It does not take the place of talking to your doctor, pharmacist or diabetes educator.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Sandoz Metformin against the benefits expected for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist or diabetes educator.

Keep this leaflet with your medicine.

You may need to read it again.

What Sandoz Metformin is used for

Sandoz Metformin is used to control blood glucose (the amount of sugar in the blood) in adults with diabetes mellitus.

Diabetes Mellitus is a condition in which the blood glucose levels are not adequately controlled. There are two types of diabetes

- Type 1 which is called insulin dependent diabetes or juvenile onset diabetes, when insulin alone is not enough to control blood glucose levels.
- Type 2 which is called Non-insulin Dependent Diabetes Mellitus (NIDDM) or maturity onset diabetes. People with type 2 diabetes are not able to make enough insulin or respond normally to the insulin their bodies make. When this happens, sugar (glucose) builds up in the blood. This can lead to serious medical problems including kidney damage, amputation and blindness. Diabetes is also closely linked to heart disease. The main goal of treating diabetes is to lower your blood sugar to a normal level. High blood sugar can be lowered by diet and exercise, by a number of medicines taken by mouth, and by insulin injections.

Sandoz Metformin tablets are used for the treatment of type 2 diabetes which usually only occurs in adults and does not need insulin but does respond to diet and exercise.

Sandoz Metformin is especially useful in people who are overweight and in whom diet and exercise alone are not enough to lower high blood glucose levels (hyperglycaemia).

Sandoz Metformin can be used alone, or in combination with other medicines for treating diabetes. Sandoz Metformin can also be used in patient with type 1 diabetes mellitus where insulin alone is not enough to control blood glucose levels. Sandoz Metformin is not recommended for use in children, except for those with insulin resistant diabetes who are being treated in hospital.

Ask your doctor if you have any questions about why Sandoz Metformin has been prescribed for you.

Your doctor may have prescribed Sandoz Metformin for another reason.

Sandoz Metformin is available only with a doctor's prescription.

There is no evidence that Sandoz Metformin is addictive.

How Sandoz metformin works

Sandoz Metformin belongs to a group of medicines called biguanides. Sandoz Metformin lowers high blood glucose (hyperglycaemia) by helping your body make better use of the insulin produced by your pancreas.

People with type 2 diabetes are unable to make enough insulin or their body does not respond properly to the insulin it does make. This causes a build up of glucose in the blood, which can lead to serious medical problems.

Signs of hyperglycaemia may include:

- Lethargy or tiredness
- Headache
- Thirst
- Passing large amounts of urine
- Blurred vision

Long term hyperglycaemia can lead to serious problems with your heart, eyes, kidneys or blood circulation.

Before you take Sandoz Metformin

When you must not take it

Do not take Sandoz Metformin if you are allergic to:

- medicines containing metformin or any other biguanide
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath.

Do not take Sandoz Metformin if you have any of the following conditions

- type 1 diabetes mellitus that is well controlled by insulin alone
- type 2 diabetes that is well controlled by diet alone
- any type of metabolic acidosis such as lactic acidosis, diabetic ketoacidosis (a symptom of uncontrolled diabetes, in which substances called ketone bodies build up in the blood - you may notice this as an unusual fruity odour on your breath, difficulty breathing, confusion and frequent urination)
- severe liver disease
- Do you drink alcohol excessively? Alcohol intake, binge drinking, alcohol dependence Alcohol can affect the control of your diabetes. Drinking excessive amounts of alcohol while you are being treated with Sandoz Metformin may also lead to serious side effects. Your doctor may suggest you stop drinking or reduce the amount of alcohol you drink.
- Do you have any problem with your liver or kidney failure or severe kidney disease?
- Dehydration, severe blood loss, shock
- a severe infection

- certain heart or blood vessel problems, including a recent heart attack or severe heart failure (when the heart fails to pump blood effectively)
- Are you, or could you be pregnant? Insulin is more suitable for controlling blood glucose during pregnancy. Your doctor will replace Sandoz Metformin with Insulin while you are pregnant.
- Are you breastfeeding? Sandoz Metformin is not recommended while you are breastfeeding. Your doctor will discuss with you the other options of treatment.
- Are you likely to have surgery or a scan involving the use of X-rays, including dental surgery within the next few days? Some types of X-ray procedures require an injection of iodinated contrast (dye). Using this type of dye while you are taking Sandoz Metformin may cause severe kidney problems and increase the risk of a serious condition called lactic acidosis. Your doctor will tell you when to temporarily stop taking the tablets before the X-ray and when it is safe to restart them.
- Do you have any problems with your circulation causing, for example, frequent cramp in your calves or leg ulcers that do not heal?
- Do you have a fever or are you ill in any other way?
- Are you on a special diet?
- severe breathing difficulties
- blood clots in the lungs (symptoms include coughing, shortness of breath, chest pain and a fast heart rate)
- gangrene
- inflammation of the pancreas (pancreatitis), symptoms include severe upper stomach pain, often with nausea and vomiting.

Do not take Sandoz Metformin if you need to have major surgery or an examination such as an X-ray or a scan requiring an injection of iodinated contrast (dye).

You must stop taking Sandoz Metformin for a certain period of time before and after the examination or the surgery. Your doctor will decide whether you need any other treatment for this time. It is important that you follow your doctor's instructions precisely.

Patients who are already on insulin should only be started on a course of treatment with Metformin tablets in hospital. Metformin tablets should not be taken by children, except for those with insulin-resistant diabetes who are being treated in hospital.

Do not take this medicine if you are pregnant or plan to become pregnant. The safety of Sandoz Metformin in pregnant women has not been established.

Insulin is more suitable for controlling blood glucose during pregnancy. Your doctor will replace Sandoz Metformin with insulin while you are pregnant.

Do not take Sandoz Metformin if you are breastfeeding.

Do not take this medicine after the expiry date printed on the pack or if the

packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking Sandoz Metformin, ask your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, dyes or preservatives.

Tell your doctor if you have or have had any of the following medical conditions:

- heart failure
- kidney problems

Your doctor may want to take special care if you have any of these conditions.

Tell your doctor if you drink alcohol.

Alcohol can affect the control of your diabetes. Drinking excessive amounts of alcohol while you are being treated with Sandoz Metformin may also lead to serious side effects. Your doctor may suggest you stop drinking or reduce the amount of alcohol you drink.

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

Taking other Medicines

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

Some medicines and Sandoz Metformin may interact with each other. These include:

- other medicines used to treat diabetes
- medicines that contain alcohol, such as cough and cold syrups
- tetracosactrin, a medicine used in people with multiple sclerosis, and in young children to treat some types of seizures (fits)
- danazol, a medicine used to treat endometriosis
- some medicines used to treat high blood pressure and some heart conditions including beta-blockers, calcium channel blockers and ACE inhibitors
- medicines used to prevent blood clots, such as warfarin
- diuretics, also called fluid tablets
- chlorpromazine, a medicine used to treat schizophrenia and other mental illnesses
- NSAIDs (non-steroidal anti-inflammatory drugs), medicines used to relieve pain, swelling and other symptoms of inflammation, such as aspirin, diclofenac, ibuprofen, meloxicam, naproxen or piroxicam
- cimetidine a medicine used to treat reflux and ulcers
- corticosteroids such as prednisone and cortisone.
- some medicines used to treat asthma such as salbutamol or terbutaline
- medicines that are substrates/inhibitors of organic cation transporters - OCT 1 such as verapamil; OCT 2 such as dolutegravir, crizotinib, olaparib, daclatasvir or vandetanib
- medicines that are inducers of OCT 1 such as rifampicin

- medicines that may increase the risk of lactic acidosis when concomitantly used with metformin hydrochloride such as topiramate and other carbonic anhydrase inhibitors

These medicines may be affected by Sandoz Metformin or may affect how well it works. You may need different amounts of your medicines or you may need to take different medicines.

- One ingredient called "propylene glycol" may cause allergic reactions.

Your doctor or pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take medicine Sandoz Metformin

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

The dose varies from patient to patient. The usual starting dose is one 500 mg tablet once or twice a day with breakfast and the evening meal. Your doctor may increase or decrease the dose depending on your blood glucose levels. The maximum recommended dose is 1000 mg three times a day. Elderly patients may need smaller doses.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

How much to take

The dose varies from person to person. Your doctor will decide the right dose for you.

Your doctor may increase or decrease the dose, depending on your blood glucose levels. The maximum recommended dose is 1000 mg three times a day.

The elderly and people with kidney problems may need smaller doses.

How to take it

Swallow the tablets with a glass of water.

The 1000 mg tablets can be divided in half along the breakline, if advised by your doctor or pharmacist.

When to take it

Take Sandoz Metformin tablets during or immediately after food.

This will reduce the chance of a stomach upset.

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.

How long to take it for

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

This medicine helps control diabetes but will not cure it. Most people need to take Sandoz Metformin on a long-term basis.

If you forget to take it

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

Otherwise, take the missed dose as soon as you remember (with food), and then go back to taking your tablets as you would normally.

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

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

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13-11-26) for advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Sandoz Metformin. Do this even if there are no signs of discomfort or poisoning.

If you take too much Sandoz Metformin, you may feel sleepy, very tired, and sick, vomit, have trouble breathing and have unusual muscle pain, stomach pain or diarrhoea. These may be early signs of a serious condition called lactic acidosis (build up of lactic acid in the blood).

You may also experience symptoms of hypoglycaemia (low blood glucose). This usually only happens if you take too much Sandoz Metformin together with other medicines for diabetes or with alcohol.

If you do experience any signs of hypoglycaemia, raise your blood glucose quickly by eating jelly beans, sugar or honey, drinking a non-diet soft drink or taking glucose tablets.

While you are taking Sandoz Metformin

Things you must do

Make sure that you, your friends, family and work colleagues can recognise the symptoms of hypoglycaemia and hyperglycaemia and know how to treat them.

HYPOGLYCAEMIA

Sandoz Metformin does not normally cause hypoglycaemia, although you may experience it if you take other medicines for diabetes such as sulfonylureas or repaglinide; or if you also use insulin.

Hypoglycaemia can occur suddenly. Initial signs may include:

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

If not treated promptly, these may progress to:

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

If you experience any symptoms of hypoglycaemia, you need to raise your blood glucose immediately.

You can do this by doing one of the following:

- eating 5 to 7 jelly beans
- eating 3 teaspoons of sugar or honey
- drinking half a can of non-diet soft drink
- taking 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 of the signs of hyperglycaemia, contact your doctor immediately.

Your doctor may need to consider additional or other treatments for your diabetes. Long-term hyperglycaemia can lead to heart disease, blindness, kidney damage, poor blood circulation and gangrene.

The risk of hyperglycaemia is increased in the following situations:

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

Tell your doctor if you:

- become ill
- become dehydrated
- are injured
- have a fever
- have a serious infection
- are having surgery (including dental surgery)

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

If you are about to be started on any new medicines, remind your doctor or pharmacist that you are taking Sandoz Metformin.

Tell all the other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking Sandoz Metformin, tell your doctor immediately.

Tell your doctor if any of the following happen:

- you become ill
- you become dehydrated (for instance due to persistent or severe diarrhoea or recurrent vomiting)
- you are injured
- you have a fever
- you have a serious infection such as influenza, respiratory tract infection or urinary tract infection
- you are having major surgery
- you are having an examination such as an X-ray or a scan requiring an injection of an iodinated contrast agent (dye)

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

Visit your doctor regularly for check-ups. Your doctor may want to perform blood tests to check your kidneys, liver, heart and vitamin B12 levels while you are taking Sandoz Metformin.

Check your blood glucose levels regularly. This is the best way to tell if your diabetes is being controlled properly. Your doctor or

diabetes educator will show you how and when to do this.

When you start treatment with Sandoz Metformin, it can take up to two weeks for your blood glucose levels to be properly controlled.

Carefully follow the advice of your doctor and dietician on diet, drinking alcohol and exercise.

Things you must not do

Do not take Sandoz Metformin to treat any other complaints unless your doctor tells you to.

Do not give Sandoz Metformin to anyone else even if they have the same condition as you.

Do not skip meals while taking Sandoz Metformin.

Do not stop taking Sandoz Metformin or change the dosage without checking with your doctor.

Things to be careful of:

Sandoz Metformin tablets on their own should not affect your ability to drive, but if you are also taking other medicines which lower the blood sugar it is possible that their combined effects could make you feel faint, dizzy, weak or jittery.

If this happens you should not drive or operate any machinery until you have recovered. If you have to be alert, for example when driving, be especially careful not to let your blood glucose levels fall too low.

Low blood glucose levels may slow your reaction time and affect your ability to drive or operate machinery. Drinking alcohol can make this worse.

If you become sick with cold, fever or flu, it is very important to continue eating your normal meals.

Your diabetes educator or dietician can give you a list of foods to eat on sick days.

When you are travelling, it is a good idea to:

- Wear some form of identification (e.g. bracelet) showing you have diabetes
- Carry some form of sugar to treat hypoglycaemia if it occurs, for example, sugar sachets or jelly beans
- Carry emergency food rations in case of a delay, for example, dried fruit, biscuits or muesli bars.
- Bring enough Sandoz Metformin with you, so you don't miss any doses.

Lifestyle measures that help reduce heart disease risk

By following these simple measures, you can further reduce the risk from heart disease.

- Quit smoking and avoid secondhand smoke
- Limit alcohol intake
- Enjoy healthy eating by:
 - eating plenty of vegetables and fruit;
 - reducing your saturated fat intake (eat less fatty meats, full fat dairy products, butter, coconut and palm oils, most take-away foods, commercially-baked products)
- Be active. Progress, over time, to at least 30 minutes of moderate intensity physical activity on 5 or more days each week. Can be accumulated in shorter

bouts of 10 minutes duration. If you have been prescribed anti-angina medicine, carry it with you when being physically active

- Maintain a healthy weight
- Discuss your lifestyle and lifestyle plans with your doctor
- For more information and tools to improve your heart health, call Heartline, the Heart Foundation's national telephone information service, on 1300 36 27 87 (local call cost)

Know warning signs of heart attack and what to do:

- Tightness, fullness, pressure, squeezing, heaviness or pain in your chest, neck, jaw, throat, shoulders, arms or back
- You may also have difficulty breathing, or have a cold sweat or feel dizzy or light headed or feel like vomiting (or actually vomit)

If you have heart attack warning signs that are severe, get worse or last for 10 minutes even if they are mild, call triple zero (000). Every minute counts.

Side effects

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

Metformin helps most people with diabetes but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

If you are over 65 years of age, you may have an increased chance of getting side effects.

Do not be alarmed by the following list of side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- feeling sick (nausea)
- vomiting
- diarrhoea
- stomach pain
- taste disturbance
- loss of appetite
- skin reactions such as redness of the skin, itching or an itchy rash (urticaria).

These are generally mild side effects which disappear after the first few weeks. Taking Sandoz Metformin with meals can help reduce stomach pain, nausea and diarrhoea. Skin reactions have been reported rarely.

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following symptoms of lactic acidosis (build-up of lactic acid in the blood):

- stomach pain, nausea, vomiting
- trouble breathing
- feeling weak, tired or generally unwell
- unusual muscle pain
- sleepiness
- dizziness or lightheadedness

- shivering, feeling extremely cold
- slow heart beat

Lactic acidosis is a very rare but serious side effect requiring urgent medical treatment or hospitalisation. Although rare, if lactic acidosis does occur, it can be fatal. The risk of lactic acidosis is higher in elderly, those whose diabetes is poorly controlled, those with prolonged fasting, those with certain heart conditions, those who drink alcohol and those with kidney or liver problems.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Some side effects (e.g. reduced vitamin B12 level) can only be found when your doctor does tests from time to time to check your progress.

After taking Sandoz Metformin

Storage

- Do not take the tablets after the expiry date on the label
- Do not keep the tablets above 25°C
- Store the tablets in their original blister pack in a cool dry place.
- Keep all medicines out of reach of children preferably in a locked cupboard or medicine cabinet
- Do not store Sandoz Metformin or any other medicine in the bathroom or near a sink. Heat and dampness can destroy some medicines.
- Do not leave Sandoz Metformin in the car or on window sills

Disposal

If your doctor tells you to stop taking Sandoz Metformin, or your tablets have reached their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

1000 mg Tablet

AUST R 292865

White, capsule-shaped film-coated tablets, with a breakline on one side, in blister packs of 10, 30, 60 and 90 tablets. The tablets are gluten free.

Ingredients

- Sandoz Metformin 1000 mg: Each film coated tablet contains 1000 mg of the active ingredient metformin hydrochloride
- Other inactive ingredients. Sodium starch glycollate, maize starch, povidone, colloidal anhydrous silica, magnesium stearate, hypromellose, titanium dioxide (E171), propylene glycol, macrogol 6000 and purified talc.

Sponsor

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