

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Metformin Sandoz.

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 this medicine against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

WHAT METFORMIN SANDOZ IS USED FOR

This medicine is used to control blood sugar (glucose) in patients with diabetes mellitus. Metformin Sandoz is used to treat Type 2 diabetes when it cannot be properly controlled by diet and exercise. It can also be used in patients with Type 1 diabetes mellitus where insulin alone is not enough to control your blood glucose levels. Metformin Sandoz can be used alone, or in combination with other medicines for treating diabetes.

How Metformin Sandoz works

It contains the active ingredient metformin hydrochloride.

Metformin belongs to a group of medicines called oral hypoglycaemics.

It works to reduce high levels of blood glucose by helping your body to make better use of the insulin produced by your pancreas. Diabetes mellitus is a condition in which the blood glucose levels are not adequately controlled.

People with type 2 diabetes are not able to make enough insulin or do not 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 heart disease, kidney damage, poor blood circulation, gangrene, amputation and blindness.

If your blood glucose is not properly controlled, you may experience hypoglycaemia (low blood glucose) or hyperglycaemia (high blood glucose).

Hypoglycaemia:

Hypoglycaemia (low blood glucose) can occur suddenly. Initial signs 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 promptly, these may progress to:

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

Hyperglycaemia:

Hyperglycaemia (high blood glucose) usually occurs more slowly than hypoglycaemia. 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.

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 levels can be lowered by diet and exercise, by a number of oral medicines, and by insulin injections.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

This medicine is available only with a doctor's prescription.

Metformin Sandoz is not recommended for use in children, except for those with insulin-resistant diabetes who are being treated in hospital.

BEFORE YOU TAKE METFORMIN SANDOZ

When you must not take it

Do not take this medicine if you have an allergy to:

- metformin hydrochloride, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product Description.
- any other similar medicines such as biguanides.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take this medicine if you have or have had any of the following medical conditions:

- type 1 diabetes mellitus that is well controlled by insulin alone
- type 2 diabetes that is already 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)
- diabetic coma or pre-coma
- severe kidney disease or kidney failure
- severe liver disease
- dehydration, severe blood loss, shock

- high blood pressure
- gangrene
- severe breathing difficulties
- a severe infection
- excessive alcohol intake or suffer from alcohol dependence
- a heart disorder such as heart failure or you have suffered a heart attack recently
- blood vessel problems
- problems with your circulation causing, for example, frequent cramps in your calves or leg ulcers that do not heal
- a fever or you are ill in any other way
- excessive loss of body water
- blood clots in the lungs (symptoms include coughing, shortness of breath, chest pain and a fast heart rate)
- inflammation of the pancreas (symptoms include severe stomach pain often with nausea and vomiting).

Do not breastfeed if you are taking this medicine.

Metformin Sandoz is not recommended while you are breastfeeding. Your doctor will discuss other treatment options with you.

Do not take this medicine 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 Metformin Sandoz 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.

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 this medicine, talk to your doctor.

Before you start to take it

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

Before starting this medicine your doctor will ask you to have a blood test to check your kidney function.

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

- kidney problems
- heart failure.

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

Tell your doctor if you are pregnant or plan to become pregnant.

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

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 Metformin Sandoz 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 Metformin Sandoz.

Taking other medicines

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

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

- other antidiabetic drugs (e.g. insulin), sulphonylureas such as gliclazide, glipizide, glimepiride, meglitinide
- 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
- NSAIDs (non-steroidal anti-inflammatory drugs) medicines used to relieve pain, swelling and other symptoms of inflammation such as aspirin, diclofenac, ibuprofen, meloxicam, naproxen, piroxicam, salicylates or pyrazolones
- medicines used to treat high blood pressure and some heart conditions (beta blockers, calcium channel blockers and ACE inhibitors e.g. metoprolol, nifedipine, enalapril, lisinopril)
- cimetidine a medicine used to treat reflux and ulcers
- corticosteroids such as prednisone and cortisone
- tablets that thin the blood (anticoagulants such as warfarin)
- diuretics known as fluid tablets (thiazide diuretics such as Moduretic®, Amizide®)
- chlorpromazine, a medicine used to treat schizophrenia and other mental illnesses
- thyroid preparations such as thyroxine
- medication used to treat asthma (beta-2 agonists)
- iodinated contrast materials used for some radiological procedures
- 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 Metformin Sandoz or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

HOW TO TAKE METFORMIN SANDOZ

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

They may differ from the information contained in this leaflet.

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

How much to take

The standard dose for this medicine varies from patient to patient. The usual starting dose is one 500mg tablet once or twice a day with breakfast and the evening meal.

Your doctor may have prescribed a different dose depending on your blood glucose levels. The maximum recommended dose is 1000mg three times a day.

Elderly patients and people with kidney problems may need smaller doses.

If your child has diabetes which is resistant to insulin and is being treated in hospital, your child's doctor will decide the dose.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, Metformin Sandoz may not work as well and your problem may not improve.

How to take it

The 500 mg and 1000 mg tablet may be divided in half along the breakline, if advised by your doctor.

Swallow the tablets whole with a full glass of water.

Do not chew them.

When to take Metformin Sandoz

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.

Take your medicine during or immediately after a meal, at about the same time each day.

If you take it on an empty stomach, it may cause stomach upset.

How long to take Metformin Sandoz

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

This medicine helps to control your condition, but does not cure it. Most people will need to take Metformin Sandoz on a long-term basis. It is important to keep taking your medicine even if you feel well.

If you forget to take it

Take your dose as soon as you remember (with food), and continue to take it as you would normally.

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 that you missed.

This may increase the chance of you getting an unwanted side effect.

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

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

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 that you or anyone else may have taken too much Metformin Sandoz. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include:

- feeling sleepy
- feeling very tired and sick
- vomiting
- having trouble breathing
- 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 Metformin Sandoz 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 METFORMIN SANDOZ

Things you must do

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

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

If you become pregnant while taking this medicine, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests to check your kidneys, liver, heart, blood and vitamin B12 levels from time to time to make sure the medicine is working and to prevent unwanted side effects.

Prolonged treatment with Metformin Sandoz can deplete reserves of vitamin B12 and this may cause anaemia. Regular blood tests for kidney function and vitamin B12 should therefore be carried out.

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 Metformin Sandoz, it can take up to two weeks for your blood glucose levels to be properly controlled.

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

If you do experience any signs of hypoglycaemia (low blood glucose), raise your blood glucose quickly by taking one of the following:

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

Unless you are within 10-15 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 usually occurs more slowly than hypoglycaemia. If you experience any of the signs of hyperglycaemia (passing large amounts of urine, excessive thirst and having a dry mouth and skin), contact your doctor immediately.

Your doctor may need to consider additional or other treatments for your diabetes.

The risk of hyperglycaemia is increased in the following situations:

- uncontrolled diabetes
- illness, infection or stress
- taking less Metformin Sandoz 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 Metformin Sandoz with insulin.

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

Things you must not do

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

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking Metformin Sandoz without your doctor's permission.

Do not skip meals while taking Metformin Sandoz.

Things to be careful of

Be careful driving or operating machinery until you know how Metformin Sandoz affects you.

Low blood glucose levels may slow your reaction time and affect your ability to drive or operate machinery. If your blood glucose levels fall too low, do not drive, operate machinery or do anything else that could be dangerous.

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

Your diabetes educator 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 Metformin Sandoz with you, so you don't miss any doses.

SIDE EFFECTS

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

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 lists 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:

- stomach upset such as feeling sick (nausea), vomiting
- diarrhoea
- stomach pain
- taste disturbance
- skin rash, itching, and redness of the skin
- loss of appetite.

These are mild side effects of the medicine. Stomach upset and diarrhoea are short-lived, they generally get better after the first few weeks. Taking Metformin Sandoz with meals can help reduce stomach pain, nausea and diarrhoea. Rarely skin reactions may occur.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- severe nausea, vomiting, stomach pain
- trouble breathing, rapid, shallow breathing
- feeling weak, tired, or uncomfortable
- sleepiness
- unusual muscle pain
- dizziness, light-headedness or loss of balance
- slow heart beat
- shivering, feeling extremely cold.

Lactic acidosis is a very rare but serious side effect requiring urgent medical treatment in hospital. The risk of lactic acidosis is higher in some people, including the elderly, those taking doses greater than 2000 mg a day, those whose diabetes is poorly controlled, those with prolonged fasting, those drinking excessive amounts of alcohol, those with certain heart conditions and people with kidney or liver problems.

Tell your doctor or pharmacist if you notice anything else 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 METFORMIN SANDOZ

Storage

Keep your medicine in the original container.

If you take it out of its original container it may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C.

Do not store Metformin Sandoz or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

PRODUCT DESCRIPTION

What it looks like

Metformin Sandoz comes in three types of tablets:

Metformin Sandoz 500 mg - white, film coated, biconvex capsule shaped tablet with central breakline on one side and '500' embossed on the other side.

Available in blisters and bottles of 100 tablets.

Metformin Sandoz 850 mg - white, film coated, round, biconvex tablet plain on one side and '850' embossed on the other side.

Available in blisters and bottles of 60 tablets.

Metformin Sandoz 1000 mg - white, capsule-shaped filmcoated tablets, with a breakline on one side.

Available in blisters of 10, 30, 60 and 90 tablets.

Ingredients

Active ingredients:

- Metformin Sandoz 500 mg - 500 mg metformin hydrochloride
- Metformin Sandoz 850 mg - 850 mg metformin hydrochloride
- Metformin Sandoz 1000 mg - 1000 mg metformin hydrochloride

Inactive ingredients:

- sodium starch glycollate
- maize starch
- povidone
- colloidal anhydrous silica
- magnesium stearate
- hypromellose
- titanium dioxide
- propylene glycol
- macrogol 6000
- purified talc.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes

Supplier

Sandoz Pty Ltd
ABN 60 075 449 553
54 Waterloo Road
Macquarie Park NSW 2113
Australia
Tel: 1800 634 500

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Australian Register Numbers

500 mg tablet: AUST R 125661 (blisters)
500 mg tablet: AUST R 148268 (bottles)
850 mg tablet: AUST R 125662 (blisters)
850 mg tablet: AUST R 148270 (bottles)
1000 mg tablet: AUST R 292865 (blisters)