

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Ramipril Sandoz. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risk of you taking Ramipril Sandoz against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may want to read it again.

What Ramipril Sandoz is used for

This medicine is used to treat:

- high blood pressure (hypertension)
- some heart conditions such as heart failure after a heart attack
- kidney problems in some patients.

Ramipril Sandoz is also used to reduce the risk of cardiovascular problems and complications in patients aged 55 years or more with heart or blood vessel disease, or diabetes.

Hypertension

Ramipril Sandoz is used to lower high blood pressure (hypertension). Everyone has blood pressure. This pressure helps get your blood all around your body. Your blood pressure may be different at different times of the day and can be influenced by how busy or worried you are. You have hypertension when your blood pressure stays higher than is needed, even when you are calm or relaxed.

There are usually no symptoms of hypertension. The only way of knowing that you have hypertension is to have your blood pressure checked on a regular basis. If high blood pressure is not treated it can lead to serious health problems, including stroke, heart disease and kidney failure.

Heart Failure after a Heart Attack

Ramipril Sandoz may be used after a heart attack. A heart attack occurs when one of the major blood vessels supplying blood to your heart becomes blocked. This means that your heart muscle cannot receive the oxygen it needs and becomes damaged. This may lead to further problems, such as heart failure, irregular heart rhythms and blood clots.

Heart failure means that the heart muscle is weak and cannot pump blood strongly enough to supply all the blood needed throughout the body. Heart failure is not the same as heart attack and does not mean that the heart stops. Heart failure may start off with no symptoms, but as the condition progresses, patients may feel short of breath or may get tired easily after light physical activity such as walking. Some patients may wake up short of breath at night. Fluid may collect in different parts of the body, often first noticed as swollen ankles and feet.

Kidney Problems

Ramipril Sandoz may be used to treat some kidney problems. Some conditions such as diabetes and hypertension can lead to kidney problems. These problems develop slowly over several years. Good control of your

blood sugar and blood pressure are important in keeping your kidneys healthy, but may not always prevent kidney damage from occurring.

Prevention of Cardiovascular Problems and Complications

Ramipril Sandoz may be used to reduce the risk of some of the problems and complications that may arise in patients aged 55 or more who have problems such as coronary artery disease (heart disease caused by poor blood flow in the blood vessels of the heart), peripheral vascular disease (poor circulation in the hands or feet), or stroke.

Ramipril Sandoz may also be used to reduce the risk of cardiovascular problems and complications in patients with diabetes aged 55 years or more who may be considered at risk because of one or more additional factors such as high blood pressure, high cholesterol levels, kidney problems, a current smoker, or previous disease of the blood vessels.

How Ramipril Sandoz works

It contains the active ingredient ramipril. Ramipril belongs to a group of medicines called angiotensin converting enzyme (ACE) inhibitors.

It works by widening the blood vessels, which reduces the pressure in the vessels, making it easier for your heart to pump blood around your body. This helps to increase the supply of oxygen to your heart, so that when you place extra demands on your heart, such as during exercise, your heart may cope better and you may not get short of breath as easily.

By increasing the supply of oxygen to your heart, your heart does not have to work as hard and it is under less stress, which may reduce the risk of further damage occurring to it following a heart attack.

Ramipril Sandoz also improves blood flow through the small blood vessels found in the kidneys, which helps the kidneys to work more efficiently. This in turn can help to slow down the progression of kidney damage that might result from having diabetes or high blood pressure.

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

Your doctor may have prescribed it for another reason.

There is no evidence that this medicine is addictive.

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

Before you take Ramipril Sandoz

When you must not take it

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

- ramipril, the active ingredient, or to any of the inactive ingredients listed at the end of this leaflet under Product description
- any other similar medicines.

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:

- history of swelling of the face, lips, tongue, throat, intestines, hands or feet for no apparent reason
- kidney problems or a condition called 'renal artery stenosis'
- problems or conditions affecting the flow of blood in and out of your heart (e.g. aortic or valvular stenosis)
- low blood pressure
- are diabetic or have kidney problems and are being treated with aliskiren-containing medications or angiotensin II receptor antagonists (AIIRAs) (a medication also used to treat high blood pressure).

Do not take this medicine if you currently undergo dialysis using certain high-flux membranes.

Do not take this medicine if you are pregnant or intend to become pregnant. It may affect your developing baby if you take it during pregnancy.

Do not breastfeed if you are taking this medicine.

The active ingredient in Ramipril Sandoz may pass into breast milk and there is the possibility that your baby may be affected.

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 Ramipril Sandoz, 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.

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

- kidney problems or having dialysis (note that your doctor may give Ramipril Sandoz because of your kidney problems)
- liver problems
- heart problems (note that your doctor may give Ramipril Sandoz because of your heart problems)
- low blood pressure, which you may notice as dizziness or light-headedness
- low white blood cell counts
- diabetes (note that your doctor may give Ramipril Sandoz because of your diabetes)
- high levels of potassium in your blood
- Systemic Lupus Erythematosus (SLE), scleroderma or other autoimmune conditions.

Tell your doctor if you have a family history of swelling of the face, lips, tongue, throat, intestines, hands or feet.

You must also tell your doctor if:

- you are following a very low or very high salt diet
- you are dehydrated or have had a recent bout of vomiting or diarrhoea
- you are about to have surgery or a general anaesthetic
- you are pregnant, breastfeeding or planning to become pregnant.

If you have not told your doctor about any of the above, tell him/ her before you start taking Ramipril 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 Ramipril Sandoz may interfere with each other. These include:

- other medicines used to treat high blood pressure, including those containing the active ingredient aliskiren and Angiotensin II receptor antagonists (AIIRAs)
- diuretics, also known as fluid or water tablets
- lithium, a medicine used to treat mood swings and some types of depression
- potassium supplements or potassium-containing salt substitutes
- non-steroidal anti-inflammatory drugs (NSAIDs), medicines used to relieve pain, swelling and other symptoms of inflammation
- insulin and tablets used to treat diabetes
- heparin
- general anaesthetics
- temsirolimus, a medicine used to treat cancer
- medicines which may affect the blood cells, such as allopurinol, procainamide, corticosteroids, immunosuppressants, or medicines used to treat cancer.

If you are taking Ramipril Sandoz for high blood pressure, do not take any medicines (including the ones bought without a prescription) for appetite control, asthma, colds, coughs, hayfever or sinus problems unless you have discussed it with your doctor or pharmacist.

These medicines may be affected by Ramipril 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 or pharmacist may have more information on medicines to be careful with or avoid while taking your medicine.

How to take Ramipril 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

Your doctor or pharmacist will tell you how many tablets you will need to take each day. This depends on your condition and whether or not you are taking any other medicines.

Take Ramipril Sandoz only when prescribed by your doctor.

Your doctor will select a dose when they prescribe Ramipril Sandoz for you. Some patients may need a lower starting dose.

The usual dose is:

- for high blood pressure: 2.5mg to 10mg per day
- for heart failure: 5mg to 10mg per day
- for kidney problems: 1.25mg to 5mg per day
- for cardiovascular risk: 2.5mg to 10mg per day.

Depending on your response, your doctor may adjust the dose.

If two tablets are prescribed, your doctor may want you to take them both together or at different times. This will depend on the condition being treated and how you respond to Ramipril Sandoz.

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, Ramipril Sandoz may not work as well and your problem may not improve.

How to take it

Swallow the tablets whole with a full glass of water.

If you need to break Ramipril Sandoz tablets, hold tablet with both hands and snap along break line.

When to take Ramipril 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.

It does not matter if you take Ramipril Sandoz before or after food.

How long to take Ramipril 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. 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 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 Ramipril 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:

- dizziness / light-headedness
- fainting
- slow heart beat.

While you are taking Ramipril 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 Ramipril Sandoz.

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

Make sure you drink enough water during exercise and hot weather when you are taking Ramipril Sandoz, especially if you sweat a lot.

If you do not drink enough water while taking this medicine, you may feel faint, light-headed or sick. This is because your blood pressure is dropping suddenly. If you continue to feel unwell, tell your doctor.

If you have excess vomiting or diarrhoea while taking this medicine, tell your doctor.

You may lose too much water and salt and your blood pressure may drop too much.

If you feel light-headed or dizzy after taking your first dose of Ramipril Sandoz or when your dose is increased, tell your doctor immediately.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking Ramipril Sandoz.

Your blood pressure may drop suddenly.

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

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Have your blood pressure checked when your doctor says so, to make sure your medicine is working.

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

Your doctor may occasionally do a blood test to check your potassium levels and see how your kidneys are working.

Things you must not do

Do not take Ramipril 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 your medicine or lower the dosage without checking with your doctor.

Things to be careful of

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

As with other ACE inhibitor medicines, Ramipril Sandoz may cause dizziness, light-headedness, tiredness or drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are taking this medicine.

If you drink alcohol, dizziness or light-headedness may be worse.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Things that may help your condition

Some self help measures suggested below may help your condition. Talk to your doctor or pharmacist about these measures and for more information.

- Alcohol - your doctor may advise you to limit your alcohol intake.
- Diet - eat a healthy low-fat diet which includes plenty of fresh vegetables, fruit, bread, cereals and fish. Also eat less fat and sugar.
- Exercise - regular exercise helps to reduce blood pressure and helps get the heart fitter, but is it important not to overdo it. Walking is good exercise, but try to find a route that is reasonably flat. Before starting any exercise, ask your doctor about the best kind of programme for you.
- Salt - your doctor may advise you to watch the amount of salt in your diet. To reduce your salt intake you should avoid using salt in cooking or at the table.
- Smoking - your doctor may advise you to stop or at least cut down smoking.
- Weight - your doctor may suggest losing some weight to help lower your blood pressure and help lessen the amount of work your heart has to do. Some people may need a dietician's help to lose weight.

Side effects

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

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:

- feeling light-headed, dizzy or faint
- dry cough
- headache
- feeling sick (nausea), vomiting

- stomach pain or discomfort
- diarrhoea
- indigestion
- decreased appetite
- loss of taste or taste disturbances
- upper respiratory tract infections
- muscle cramps or spasms
- aching muscle, muscle tenderness or weakness, fatigue
- fever
- unusual tiredness or weakness, fatigue
- ringing or buzzing in the ears
- forgetfulness or confusion
- change in mood, including feeling depressed, anxious or nervous.

These side effects are usually mild.

Tell your doctor as soon as possible if you notice any of the following:

- disturbed vision
- symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly than normal
- itchy or raised skin rash, hives or nettle rash
- signs of anaemia such as tiredness, being short of breath and looking pale
- yellowing of the skin and/or eyes
- fast or irregular heart beat
- shortness of breath or tightness in the chest
- numbness, tingling and colour change (white, blue then red) in the fingers or toes when exposed to the cold
- severe upper stomach pain, often with nausea and vomiting
- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- passing little or no urine or more urine than is normal for you
- bleeding or bruising more easily than normal.

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

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

- fainting within a few hours of taking a dose
- severe dizziness and confusion with visual disturbances and speech problems
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- pink or red itchy spots on the skin which may blister and progress to form raised, red, pale-centred marks
- severe blisters and bleeding in the lips, eyes, mouth, nose and genitals
- chest pain.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

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.

After taking Ramipril 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 Ramipril 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

Ramipril Sandoz 1.25mg, 2.5mg, 5mg, 10mg tablets - white, oblong, biplane with facet, both sides with breaking notch, embossed on one-sided with "R 1.25" (for 1.25mg), "R 2.5" (for 2.5mg), "R 5" (for 5mg) and "R 10" (for 10mg).

Available in blister packs of 30 tablets.

Ingredients

Active ingredient:

- Ramipril Sandoz 1.25mg - 1.25mg ramipril.
- Ramipril Sandoz 2.5mg - 2.5mg ramipril.
- Ramipril Sandoz 5mg - 5mg ramipril
- Ramipril Sandoz 10mg - 10mg ramipril.

Inactive ingredients:

- sodium bicarbonate
- hypromellose
- microcrystalline cellulose
- pregelatinised maize starch
- sodium stearyl fumarate.

Supplier/Distributor

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 Number

1.25mg tablets: AUST R 122016 (blisters)
2.5mg tablets: AUST R 122018 (blisters)
5mg tablets: AUST R 122020 (blisters)
10mg tablets: AUST R 127519 (blisters)