

**Consumer Medicine Information**

For a copy of a large print leaflet, Ph: 1800 195 055

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**What is in this leaflet**

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This leaflet answers some common questions about ramipril. 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 risks of you using this medicine 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.

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**What this medicine is used for**

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Ramipril belongs to a group of medicines called angiotensin converting enzyme (ACE) inhibitors.

Ramipril 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 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.

**High Blood Pressure**

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 high blood pressure when your blood pressure stays higher than is needed, even when you are calm and relaxed.

There are usually no symptoms of high blood pressure. The only way of knowing that you have high blood pressure is to have your blood pressure checked on a regular basis. Untreated high blood pressure can lead to serious health problems, including stroke, heart disease and kidney failure.

**Heart Failure after a Heart Attack**

Ramipril may be used after a heart attack, which 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**

Some conditions, such as diabetes and high blood pressure, 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 may be used to reduce the risk of some of the problems and complications that may arise in patients aged 55 years 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.

**Patients with Diabetes**

Ramipril 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 they have one or more additional risk factors (e.g. high blood pressure, high cholesterol levels, kidney problems, a current smoker or previous disease of the blood vessels).

**How it works**

Ramipril works by widening the blood vessels, which then reduces the pressure in the vessels to make 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 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 this medicine has been prescribed for you.**

Your doctor may have prescribed ramipril for another reason.

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

This medicine is not addictive.

This medicine should not be used in children.

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**Before you take this medicine**

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**When you must not take it**

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

- ramipril
- any other ACE inhibitors
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

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

**Do not take ramipril if you or your family have a history of swelling of the face, lips, tongue, throat, intestines, hands or feet for no apparent reason (angioedema).**

**Do not take ramipril if you are also taking:**

- aliskiren-containing medications and have kidney problems or Type 2 diabetes
- angiotensin II receptor antagonists (e.g. candesartan, irbesartan, olmesartan), and have kidney problems caused by diabetes
- sacubitril/valsartan

**Do not take ramipril if you have any of the following medical conditions:**

- you or your family have a history of swelling of the face, lips, tongue, throat, intestines, hands or feet, for no apparent reason
- kidney problems or 'renal artery stenosis'
- problems affecting the flow of blood in and out of your heart (e.g. aortic or valvular stenosis)
- low blood pressure
- undergoing dialysis using certain high-flux membranes.

**Do not take ramipril if you are pregnant or intend to become pregnant.**

Ramipril may affect your developing baby if you take it during pregnancy.

**Do not take ramipril if you are breastfeeding.**

Ramipril may pass into breast milk and affect your breastfed baby.

**Do not take your 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.**

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

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

- kidney problems, or are having dialysis (your doctor may give you ramipril because of your kidney problems)
- liver problems
- heart problems (your doctor may give you ramipril because of your heart problems)
- low blood pressure, which you may notice as dizziness or light-headedness
- low white blood cell counts
- diabetes (note: your doctor may give you ramipril because of your diabetes)
- high levels of potassium in your blood
- you are taking other medicines that have a risk of angioedema (swelling of the face, lips, tongue, throat, intestines, hands or feet)
- you are following a very low or very high salt diet
- you are dehydrated, or have had a recent bout of vomiting or diarrhoea

- Systemic Lupus Erythematosus (SLE), scleroderma or other autoimmune conditions
- you are planning to have surgery or an anaesthetic.
- plan to become pregnant or breastfeed

**If you have not told your doctor about any of the above, tell them before you start taking this medicine.**

### *Taking other medicines*

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

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

- sacubitril/valsartan or other neprilysin inhibitors, used for heart failure
- other medicines used to treat high blood pressure, including those containing the active ingredient aliskiren
- diuretics, also known as fluid or water tablets
- lithium, used to treat mood swings and depression
- potassium supplements or potassium-containing salt substitutes
- non-steroidal anti-inflammatory drugs (NSAIDs), used to relieve pain and inflammation
- insulin and tablets used to treat diabetes
- heparin
- general anaesthetics
- medicines affecting blood cells (e.g. allopurinol, procainamide, corticosteroids, cancer treatments, immunosuppressants)
- temsirolimus
- if you are taking ramipril for high blood pressure, do not take any medicines (including the ones bought without a prescription) for appetite control, asthma, colds, coughs, hay fever or sinus problems unless you have discussed it with your doctor or pharmacist

These medicines may be affected by ramipril or may affect how well it works. If you are taking any of these, you may need a different dose, or you may need to take different medicines. Your doctor will advise you.

Other medicines not listed above may also interact with ramipril.

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### **How to take this medicine**

**Follow all directions given to you by your doctor carefully.**

They may differ to the information contained in this leaflet.

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

#### *How much to take*

Your doctor will tell you how many tablets you will need to take, depending on your condition and whether you are taking any other medicines.

The usual dose is:

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

If two tablets are prescribed, your doctor may want you to take both together or at different times.

#### *How to take it*

The tablets should be removed from the blister by applying gentle pressure, using thumb from one side of blister corner, carefully to avoid crumbling of tablets.

The tablets should be swallowed whole with plenty of fluid.

#### *When to take it*

**Take your tablets at about the same time each day.**

Taking your tablets at the same time each day will have the best effect. It will also help you remember when to take the tablets. It does not matter if you take ramipril before or after food.

#### *How long to take it for*

**Continue taking ramipril for as long as your doctor tells you.**

Ramipril helps control your condition but does not cure it. Therefore, you must take the tablets every day.

It is important to keep taking your medicine even if you feel well.

Make sure you have enough to last over weekends and holidays.

#### *If you forget to take it*

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time.

Otherwise, take it as soon as you remember and then go back to taking your medicine as you would normally.

**Do not take a double dose to make up for missed doses.**

This may increase the chance of you experiencing side effects.

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 the Emergency department at your nearest hospital if you think that you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

If you take too much ramipril, you may feel light-headed, dizzy, experience a slow heartbeat or faint.

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### **While you are taking this medicine**

#### *Things you must do*

**Tell any other doctors, dentists and pharmacists who are treating you that you are taking ramipril.**

**If you are about to be started on any new medicine, tell your doctor, and pharmacist that you are taking ramipril.**

**Tell your doctor immediately if you become pregnant.**

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

If you do not drink enough water while taking ramipril, 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 ramipril, tell your doctor.**

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

**Tell your doctor immediately if you feel light-headed or dizzy after taking your first dose of ramipril, or when your dose is increased.**

**If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking ramipril as your blood pressure may drop suddenly.**

Ramipril may also affect other medicines used during surgery.

**If you are about to have any blood tests, tell your doctor that you are taking ramipril as it may interfere with the results of some tests.**

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

Your doctor may do some test to make sure the medicine is working and to prevent side effects.

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 give this medicine to anyone else, even if they have the same condition as you.**

**Do not take your medicine to treat any other complaint unless your doctor tells you to.**

**Do not stop taking your medicine, or change the dosage, without first checking with your doctor.**

#### *Things to be careful of*

**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.

**Be careful while driving or operating machinery until you know how ramipril affects you.**

Ramipril may cause dizziness, light-headedness, tiredness or drowsiness in some people. Make sure you know how you react to ramipril before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy or light-headed. If you drink alcohol, dizziness or light-headedness may be worse.

#### *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. Eat less fat and sugar.
- Exercise - regular exercise helps to reduce blood pressure and helps get the heart fitter, but it is 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 exercise 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 must do. Some people may need a dietician's help to lose weight.

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## Side effects

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

Ramipril helps most people, but it may have unwanted side effects in a few people. Sometimes they are serious, but most of the time, they are not. You may need medical treatment if you get some of the side effects.

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

**Do not be alarmed by this list. You may not experience any of them.**

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

- feeling light-headed, dizzy or faint
- persistent dry cough and/or tickling cough
- headache
- feeling sick (nausea) or vomiting
- reflux
- stomach pain or discomfort
- diarrhoea
- indigestion
- upper respiratory tract infections
- muscle cramps or spasms
- aching muscles, muscle tenderness or weakness, not caused by exercise
- taste disturbance
- unusual tiredness or weakness, fatigue, drowsiness
- ringing or buzzing in the ears
- forgetfulness or confusion
- skin reactions
- increase in nasal congestion or asthma symptoms

The above list includes the more common side effects of your medicine.

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

- disturbed vision
- changes to your sleeping pattern, including drowsiness
- 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
- yellowing of the skin and/or eyes
- severe upper stomach pain, often with nausea and vomiting
- fast or irregular heart beat
- shortness of breath or tightness in the chest
- tiredness, being short of breath and looking pale (signs of anaemia)
- numbness, tingling and colour change (white, blue then red) in the fingers or toes when exposed to the cold
- 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
- mood changes

The above list includes serious side effects that may need medical attention.

**If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Emergency department at your nearest hospital:**

- cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; hay fever-like symptoms (signs of an allergic reaction)
- 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
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- severe dizziness and confusion with visual disturbances and speech problems
- fainting within a few hours of taking a dose
- severe dizziness and confusion with visual disturbances and speech problems
- chest pain.

These are 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 that is making you feel unwell.**

Other side effects not listed above may occur in some patients.

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## Storage and disposal

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### Storage

**Keep your medicine in its pack until it is time to take it.**

If you take your medicine out of its pack it may not keep well.

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

**Do not store your medicine, 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 this medicine 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 leftover.

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## Product description

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### What it looks like

#### 2.5 mg Tablet:

Pink to red mottled, oblong tablet with R and 18 on either side of score line on one side and score line on the other side. AUST R 231161.

#### 5 mg Tablet:

Light yellow to yellow mottled, oblong tablet with R and 19 on either side of score line on one side and score line on the other side. AUST R 231163,

#### 10 mg Tablet:

Light yellow to yellow mottled, oblong tablet with R and 10 on either side of score line on one side and score line on the other side. AUST R 231162.

Available as blister pack of 30 tablets.

### Ingredients

Each tablet contains 2.5 mg, 5 mg or 10 mg of ramipril as the active ingredient.

It also contains the following:

- hypromellose

- microcrystalline cellulose
- pregelatinised maize starch
- iron oxide red (2.5 mg tablet only)
- iron oxide yellow (5 mg and 10mg tablet only)
- sodium stearyl fumarate

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

### Sponsor

Apotex Pty Ltd

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