

APO-Ramipril

Contains the active ingredient, ramipril

Consumer Medicine Information

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

What is in this leaflet

Read this leaflet carefully before taking your medicine.

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.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up-to-date leaflet from www.apotex.com.au.

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.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Ramipril tablets. It contains the active ingredient, ramipril.

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 (Hypertension)

Ramipril 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 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. 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 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 may be used to treat some 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 in Patients aged 55 years or more

Patients with Heart or Blood Vessel Disease

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, making it easier for your heart to pump blood around your body. This helps 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.

Therefore, there are quite a few reasons why your doctor might have decided to treat you with ramipril.

However, your doctor may have prescribed ramipril for another reason.

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

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

There is no evidence that this medicine is addictive.

Use in children

This medicine should not be used in children.

Before you take this medicine

When you must not take it

Do not take this medicine if you have had an allergic reaction to it or to any other medicine containing ramipril or to 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; or rash, itching or hives on the skin.

Do not take ramipril if you have taken any other 'ACE inhibitor' medicine before which caused your face, lips, tongue, throat, hands or feet to swell up, or made it hard for you to breathe.

If you have had an allergic reaction to an ACE inhibitor before, you may be allergic to ramipril.

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 etc.), and have kidney problems caused by diabetes.

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.

Do not take ramipril if you have kidney problems or a condition called 'renal artery stenosis'.

Do not take ramipril if you have problems or conditions affecting the flow of blood in and out of your heart (e.g. aortic or valvular stenosis).

Do not take ramipril if you have low blood pressure.

Do not take ramipril if you undergo 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 (EXP) printed on the pack.

If you take this medicine after the expiry date has passed, it may not work as well.

Do not take this medicine if the packaging is torn, shows signs of tampering or if it does not look quite right.

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

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - kidney problems, or are having dialysis (note: your doctor may give you ramipril because of your kidney problems)
 - liver problems
 - heart problems (note: 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
 - Systemic Lupus Erythematosus (SLE), scleroderma or other autoimmune conditions.
3. You are planning to have surgery or an anaesthetic.
4. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.
5. You are following a very low or very high salt diet.
6. You are dehydrated, or have had a recent bout of vomiting or diarrhoea.
7. You 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:

- other medicines used to treat high blood pressure
- 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
- medicines which may affect the blood cells, such as allopurinol, procainamide, corticosteroids, immunosuppressants or medicines used to treat cancer

- 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.

How to take this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

How much to take

Your doctor or pharmacist will tell you how many tablets you will need to take. This depends on your condition and whether you are taking any other medicines.

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

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

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

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

How to take it

Ramipril tablets should be swallowed whole with plenty of fluid.

When to take it

Take ramipril 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

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

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

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

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

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 or you may faint. You may also experience a slow heartbeat.

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, dentist or 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.

If you feel light-headed or dizzy after taking your first dose of ramipril, 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.

Your blood pressure may drop suddenly.

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

Ramipril may interfere with the results of some tests.

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

Go to your doctor regularly for a check-up.

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

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- 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.

As with other ACE inhibitor medicines, 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 this occurs, do not drive. 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. Also, 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 has to do. Some people may need a dietician's help to lose weight.

Possible side effects

All medicines may have some unwanted side effects. Sometimes they are serious, but most of the time, they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

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. All medicines may have some unwanted side effects.

Your doctor has weighed the risks of using this medicine against the benefits he/she expects it will have for you. 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.

Following is a list of possible side effects. 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
- diarrhoea
- taste disturbance
- unusual tiredness or weakness, fatigue
- ringing or buzzing in the ears
- forgetfulness or confusion
- skin reactions
- increase in nasal congestion or asthma symptoms.

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
- 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
- signs of anaemia such as tiredness, being short of breath and looking pale
- 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.

These may be serious side effects. You may need medical attention.

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department 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.

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

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Allergic reactions

If you think you are having an allergic reaction to ramipril, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- 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.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging 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 it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Ramipril Ramipril tablets 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.
- **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.
- **10 mg Tablet**
Light yellow to yellow mottled, oblong tablet with R and 20 on either side of score line on one side and score line on the other side.

Ingredients

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

It also contains the following inactive ingredients:

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

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

- APO-Ramipril 2.5 mg tablets (blister pack of 30 tablets):
AUST R 231161.
- APO-Ramipril 5 mg tablets (blister pack of 30 tablets):
AUST R 231163.

- APO-Ramipril 10 mg tablets (blister pack of 30 tablets):
AUST R 231162.

Sponsor

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