

RAMIPRIL-GA

Ramipril

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Ramipril-GA.

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 taking Ramipril-GA 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 need to read it again.

What Ramipril-GA is used for

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

Ramipril-GA is used to treat:

- high blood pressure (hypertension)
- heart failure after a heart attack
- kidney problems in some patients
- reduce the risk of cardiovascular problems and complications in patients aged over 55 years with heart or blood vessel disease, or diabetes.

Hypertension

Ramipril-GA 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, depending on how busy or worried you are. You have hypertension (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 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-GA can 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 can not 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-GA 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-GA may be used to reduce the risk of some of the problems and complications that may arise in patients who are over 55 years of age and 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-GA may also be used to reduce the risk of cardiovascular problems and complications in patients with diabetes who are over 55 years of age 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-GA works

Ramipril-GA works by widening your blood vessels, which reduces 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 which may reduce the risk of further damage to your heart after you have had a heart attack.

By reducing blood pressure, Ramipril-GA may also slow down the kidney damage caused by diabetes or high blood pressure.

Your doctor may have prescribed Ramipril-GA for another reason. **Ask your doctor if you have any questions about why Ramipril-GA has been prescribed for you.**

Ramipril-GA is not addictive.

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

Use in children

The safety and effectiveness of Ramipril-GA in children have not been established.

Before you take Ramipril-GA

When you must not take it

Do not take Ramipril-GA if:

- **you have an allergy to Ramipril-GA or any other medicine containing ramipril, or any of the ingredients listed at the end of this leaflet.** Symptoms of an allergic reaction to Ramipril-GA may include skin rash, itchiness, shortness of breath, swelling of the face, lips or tongue, muscle pain or tenderness or joint pain.
- **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-GA.

- **you have a history of swelling of the face, lips, tongue, throat, intestines, hands or feet, for no apparent reason. (idiopathic angioedema)**
- **you have kidney problems or a condition called 'renal artery stenosis'**
- **you have problems or conditions affecting the flow of blood in and out of your heart (e.g. aortic or valvular stenosis)**
- **are diabetic or have kidney problems and are being treated with aliskiren-containing medicines or a group of medicines known as AIIRAs (a medicine also used to treat high blood pressure).**
- **you have low blood pressure**
- **you are undergoing dialysis using certain high-flux membranes**

Do not take Ramipril-GA if you are pregnant.

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

Do not take Ramipril-GA if you are breastfeeding.

Ramipril-GA passes into breast milk and therefore there is a possibility that the breast-fed baby may be affected.

Do not take Ramipril-GA after the expiry date printed on the pack.

Do not take Ramipril-GA 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-GA, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes

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

- kidney problems, or are having dialysis (note that your doctor may give Ramipril-GA because of your kidney problems)
- liver problems
- heart problems (note that your doctor may give Ramipril-GA 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 you Ramipril-GA 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 tell your doctor if you:

- are following a very low or very high salt diet
- are dehydrated, or have had a recent bout of vomiting or diarrhoea
- are about to have surgery or a general anaesthetic
- are about to receive desensitisation therapy for an allergy
- plan to become pregnant or breastfeed

If you have not told your doctor about any of the above, tell them before you start taking Ramipril-GA.

Taking other medicines

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

Some medicines and Ramipril-GA may interfere with each other. These include:

- other medicines used to treat high blood pressure
- diuretics, also known as fluid or water tablets
- non-steroidal anti-inflammatory drugs (NSAIDs), medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis
- potassium supplements or potassium-containing salt substitutes
- lithium, a medicine used to treat mood swings and some types of depression
- insulin and tablets used to treat diabetes
- general anaesthetics
- heparin
- medicines which affect blood cells, such as allopurinol, procainamide, corticosteroids, immunosuppressants, or medicines to treat cancer
- temsirolimus
- if you are taking Ramipril-GA for high blood pressure, do not take any medicines (including any 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-GA, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while taking Ramipril-GA.

How to take Ramipril-GA

How much to take

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

Depending on the condition being treated and how you respond to Ramipril-GA, your doctor will advise an appropriate dose for you.

The usual dosage is one capsule daily or one to two capsules daily, up to a maximum of 10 mg daily.

If you are taking Ramipril-GA because you have a heart or blood vessels disease, have

had a heart attack or stroke, or diabetes and one other risk factor; the usual maintenance dose is 10 mg per day.

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 on the box, ask your doctor or pharmacist for help.

How to take it

Swallow Ramipril-GA capsules whole with plenty of water.

When to take it

Ramipril-GA should be taken at about the same time each day.

Taking your capsules at the same time each day will have the best effect. It will also help you remember when to take your medicine.

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

How long to take it

Ramipril-GA helps control your condition, but does not cure it. Therefore you must take Ramipril-GA every day. Continue taking your medicine for as long as your doctor tells you.

If you forget to take it

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

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 the dose you missed.

If you are not sure what to do, or if you have trouble remembering when to take Ramipril-GA, ask your doctor or pharmacist for some hints.

If you take too much (overdose)

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

You may need urgent medical attention.

If you take too much Ramipril-GA, you may feel light-headed, dizzy or you may feel faint. You may also experience a slow heart beat.

While you are taking Ramipril-GA

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are taking Ramipril-GA.

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

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

If you do not drink enough water while taking Ramipril-GA, 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-GA, 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-GA, or when your dose is increased, tell your doctor immediately.

This is especially important if you are taking Ramipril-GA for heart failure.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking Ramipril-GA. Your blood pressure may drop suddenly.

If you become pregnant while taking Ramipril-GA, tell your doctor immediately.

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

Ramipril-GA may interfere with the results of some tests.

Have your blood pressure checked when your doctor says, to make sure Ramipril-GA is working.

Go to your doctor regularly for a check-up.

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 Ramipril-GA to anyone else, even if they have the same condition as you.

Do not take Ramipril-GA to treat any other complaints unless your doctor or pharmacist tells you to.

Do not stop taking Ramipril-GA, or lower the dosage, without 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 driving or operating machinery until you know how Ramipril-GA affects you.

As with other ACE inhibitor medicines, Ramipril-GA may cause dizziness, light-headedness, tiredness or drowsiness in some people. Make sure you know how you react to Ramipril-GA 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.
- **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.

- **Diet** - eat a healthy low-fat diet which includes plenty of fresh vegetables, fruit, bread, cereals and fish. Also eat less fat and sugar.
- **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.
- **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 program for you.
- **Smoking** - your doctor may advise you to stop smoking or at least cut down.

Side Effects

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

Ramipril-GA helps most people, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, 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.

The 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
- dry cough
- headache
- feeling sick (nausea) or vomiting
- stomach pain
- diarrhea
- indigestion
- loss of taste or taste disturbances
- upper respiratory tract infections
- muscle cramps or spasms
- aching muscles, muscle tenderness or weakness, not caused by exercise
- unusual tiredness or weakness, fatigue
- ringing or buzzing in the ears
- forgetfulness or confusion

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

These may be serious side effects. You may need medical attention. Serious side effects are rare.

If any of the following happen, stop taking Ramipril-GA and either 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 pains

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

After using Ramipril-GA

Storage

Keep the capsules in the blister pack until it is time to take them.

If you take them out of the pack they may not keep well.

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

Do not store Ramipril-GA or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on windowsills.

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 or pharmacist tells you to stop taking Ramipril-GA, or the capsules have passed their expiry date, ask your doctor or pharmacist what to do with any that are left over.

Product Description

What it looks like

Ramipril-GA capsules are available in four different strengths:

2.5 mg capsule: Size '4' capsules with orange cap, imprinted with "RAMI" in black ink and orange body, imprinted with "2.5" in black ink, containing white to off-white powder.

5 mg capsule: Size '4' capsules with red cap, imprinted with "RAMI" in black ink and

red body, imprinted with "5" in black ink, containing white to off-white powder

10 mg capsule: Size '4' capsules with light blue cap, imprinted with "RAMI" in black ink and light blue body, imprinted with "10" in black ink, containing white to off-white powder.

Ramipril-GA is available in blister packs of 30 capsules.

Ingredients

Active ingredient:

- Ramipril

Inactive ingredients:

- Meglumine
- Pregelatinised starch
- Gelatin
- Yellow iron oxide (E172)
- Titanium dioxide (E171)
- Quinoline Yellow CI47005
- Allura Red AC
- Brilliant Blue FCF

Ramipril-GA capsules do not contain lactose, sucrose, gluten or tartrazine.

Supplier

Amneal Pharma Australia Pty Ltd
12 River Street
South Yarra VIC 3141
Australia

Ramipril-GA 2.5 mg

- AUST R 134793

Ramipril-GA 5 mg

- AUST R 134798

Ramipril-GA 10 mg

- AUST R 134803

This leaflet was updated in July 2015.