

VASCALACE

Ramipril

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about VASCALACE.

It does not contain all the available information about this medicine.

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 VASCALACE 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 VASCALACE is used for

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

VASCALACE is used to treat:

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

VASCALACE 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

VASCALACE 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 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

VASCALACE 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

VASCALACE 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

VASCALACE 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.

VASCALACE 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 VASCALACE works

VASCALACE 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 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.

VASCALACE 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 VASCALACE decided to treat you with VASCALACE. Your doctor may have also prescribed this medicine for another reason.

Ask your doctor or pharmacist if you have any questions about why VASCALACE has been prescribed for you.

VASCALACE is not addictive.

VASCALACE is available only with a doctor's prescription.

Before you take VASCALACE

When you must not take it

Do not take VASCALACE if you:

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

- **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 VASCALACE.
- **or your family have a history of swelling of the face, lips, tongue, throat, intestines, hands or feet, for no apparent reason.**
- **have kidney problems or a condition called "renal artery stenosis".**
- **have problems or conditions affecting the flow of blood in and out of your heart (e.g. aortic or valvular stenosis).**
- **have low blood pressure.**
- **undergo dialysis using certain high-flux membranes.**
- **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).**
- **are pregnant or intend to become pregnant.** VASCALACE may affect your developing baby if you take it during pregnancy.
- **are breastfeeding.** VASCALACE may pass into the breast milk and affect your breastfed baby.

Do not use VASCALACE 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 use VASCALACE if the packaging is torn or shows signs of tampering.

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 you VASCALACE because of your kidney problems)
- liver problems
- heart problems (note that your doctor may give you VASCALACE 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 VASCALACE 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
- are dehydrated, or have had a recent bout of vomiting or diarrhoea

- are about to have surgery or a general 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 VASCALACE.

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 store.

Some medicines and VASCALACE 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
- temsirolimus
- if you are taking VASCALACE 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 VASCALACE, or may affect how well it works. You may need to use different amounts of your medicine, or you may need to take different medicines. Your doctor or pharmacist will advise you.

Your doctor or pharmacist may have more information on medicines to be careful with or to avoid while taking VASCALACE.

How to take VASCALACE

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.

Take VASCALACE only when prescribed by your doctor.

Your doctor will select a dose when they prescribe VASCALACE for you. Some patients may need a lower starting dose. The usual dose of VASCALACE 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 them both together or at different times. This will depend on the condition being treated and how you respond to VASCALACE.

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

VASCALACE should be swallowed whole with plenty of fluid.

When to take it

Take VASCALACE 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 VASCALACE before or after food.

How long to take it

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

If you forget to take it

If it is almost 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 that you missed.

If you are not sure what to do or if you have trouble remembering when to take VASCALACE, ask your doctor or pharmacist.

If you take too much (Overdose)

Immediately telephone your doctor or the Poisons Information Centre (in Australia telephone 13 11 26), or go to Accident and Emergency at the nearest hospital if you think that you or anyone else may have taken too much VASCALACE. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

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

While you are taking VASCALACE

Things you must do

Tell all the doctors, dentists and pharmacists who are treating you that you are taking VASCALACE.

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

Make sure you drink enough water during exercise and hot weather when you are taking VASCALACE, especially if you sweat a lot. If you do not drink enough water while taking VASCALACE, 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 VASCALACE, 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 VASCALACE, 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 VASCALACE.

Your blood pressure may drop suddenly.

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

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

VASCALACE may interfere with the results of some tests.

Have your blood pressure checked when your doctor says, to make sure VASCALACE 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 VASCALACE to anyone else, even if they have the same condition as you.

Do not take VASCALACE to treat any other complaints unless your doctor or pharmacist tells you to. Do not stop taking VASCALACE, or lower or increase 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 VASCALACE affects you.

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

VASCALACE 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.

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 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 or discomfort
- diarrhoea
- 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

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

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

If any of the following happen, stop taking VASCALACE 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 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.

After using VASCALACE

Storage

Keep your VASCALACE tablets or capsules in the pack until it is time to take them.

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

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

Do not store VASCALACE or any other medicine in the bathroom or near a sink. Do not leave it on window sills 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 or pharmacist tells you to stop taking VASCALACE, or the tablets or capsules have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product Description

What it looks like

VASCALACE is available in four different strengths containing 1.25, 2.5, 5 & 10 mg ramipril.

VASCALACE is available in tablet formulation as VASCALACE tablets and in capsule formulation as VASCALACE CAPS.

VASCALACE is available in blister packs of 28 & 30 and bottle packs of 30 tablets or capsules.

- **VASCALACE tablets 1.25**
(Blister pack: AUST R 175217 & Bottle: AUST R 175218)
White to off-white colored, flat faced bevel edged round uncoated tablet debossed with "H" and "17" on one side and plain on other side.
- **VASCALACE tablets 2.5**
(Blister pack: AUST R 175221 & Bottle: AUST R 175223)
Light yellow to yellow colored flat faced bevel edged, round uncoated tablet debossed with "H" and "18" separated by score line on one side and plain on other side.

- **VASCALACE tablets 5**
(Blister pack: AUST R 175224 & Bottle: AUST R 175237)
Light pink colored mottled, flat faced bevel edged round uncoated tablet debossed with "H" and "19" separated by score line on one side and plain on other side.
- **VASCALACE tablets 10**
(Blister pack: AUST R 175238 & Bottle: AUST R 175240)
White to off-white colored, flat faced bevel edged round uncoated tablet debossed with "H" and "20" separated by score line on one side and plain on other side.
- **VASCALACE CAPS 1.25**
(Blister pack: AUST R 203720 & Bottle: AUST R 203718)
Yellow / White size '4' hard gelatin capsules imprinted with 'D' on yellow cap and '40' on white body with black edible ink filled with white to almost white powder.
- **VASCALACE CAPS 2.5**
(Blister pack: AUST R 203712 & Bottle: AUST R 203702)
Orange / White size '4' hard gelatin capsules imprinted with 'D' on orange cap and '41' on white body with black edible ink filled with white to almost white powder.
- **VASCALACE CAPS 5**
(Blister pack: AUST R 203713 & Bottle: AUST R 203716)
Red / White size '4' hard gelatin capsules imprinted with 'D' on Red cap and '42' on white body with black edible ink filled with white to almost white powder.
- **VASCALACE CAPS 10**
(Blister pack: AUST R 203719 & Bottle: AUST R 203717)
Blue / White size '4' hard gelatin capsules imprinted with 'D' on Blue cap and '43' on white body with black edible ink filled with white to almost white powder.

Ingredients

Active ingredient

Ramipril

Inactive ingredients

VASCALACE tablets contains following inactive ingredients.

- Pregelatinised maize starch
- Lactose
- Sodium bicarbonate
- Croscarmellose sodium
- Sodium stearyl fumarate
- Iron oxide yellow (2.5 mg tablets only)
- Iron oxide red (5 mg tablets only)

VASCALACE CAPS contains colloidal anhydrous silica & pregelatinised maize starch.

The capsules are made of gelatin, sodium lauryl sulphate and are coloured with titanium dioxide, iron oxide yellow (1.25 mg & 2.5 mg capsules), brilliant scarlet 4R (2.5 mg, 5 mg & 10 mg capsules) and patent blue V (5 mg & 10 mg capsules).

Name and Address of the Sponsor

Aurobindo Pharma Australia Pty Ltd
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277-283 Lane Cove Road
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NSW 2113

Date of Approval

VASCALACE tablets:
4 October 2011

VASCALACE CAPS:
9 August 2013

Date of Most Recent Amendment
1 May 2014