## 1.3.2 PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS**

**S3**

**RAMPIL 1,25 mg hard gelatin capsules**

**RAMPIL 2,5 mg hard gelatin capsules**

**RAMPIL 5 mg hard gelatin capsules**

**RAMPIL 10 mg hard gelatin capsules**

**Ramipril**

**Sugar free**

**Read all of this leaflet carefully before you start taking RAMPIL**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- RAMPIL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

**What is in this leaflet**


1. What RAMPIL is and what it is used for
2. What you need to know before you take RAMPIL
3. How to take RAMPIL
4. Possible side effects
5. How to store RAMPIL
6. Contents of the pack and other information

## 1. What RAMPIL is and what it is used for

RAMPIL belongs to a group of medicines called ACE inhibitors

RAMPIL works by:

- Decreasing your body's production of substances that could raise your blood pressure.
- Making your blood vessels relax and widen.
- Making it easier for your heart to pump blood around your body.

RAMPIL can be used:

- To treat high blood pressure.
- To help your heart when it cannot pump enough blood to the rest of your body (heart failure).
- To reduce the amount of protein in the urine and the decline in kidney function in patients with diabetic kidney damage and increased blood pressure.
- To reduce the risk of you having a heart attack, stroke or death if you have an increased risk of heart disease, a history of stroke or blood circulatory problems.
- To reduce the risk of you having a heart attack, stroke or death if you have diabetes.

## 2. What you need to know before you take RAMPIL

**Do not take RAMPIL:**

- if you are hypersensitive (allergic) to ramipril or any of the other ingredients of RAMPIL (listed in section 6).
- if you have previously suffered from angioedema (swelling of the face, lips or tongue).
- if you have heart problems.
- if you are taking potassium sparing diuretics such as spironolactone, triamterene or amiloride.
- if you have porphyria.

- if you have severe kidney impairment, impaired kidney function or kidney disease.
- if you are taking lithium as it may lead to toxic blood concentrations of lithium.
- if you are taking aliskiren-containing medicines (medicines used to treat high blood pressure).
- if you have kidney problems and/or are elderly and you are taking medicine used to treat bacterial infections (antibiotics) belonging to the fluoroquinolone group.
- if you are pregnant or breastfeeding.
- if you are on sacubitril/valsartan therapy, medicines used for the treatment of high blood pressure and heart failure.
- if you are undergoing extracorporeal treatment, a procedure where toxins are removed from the body to support or temporarily replace a vital organ.

RAMPIL is not recommended for use in children.

**Warnings and precautions**

**Take special care with RAMPIL:**

- if you are taking diuretics (water tablets) or if you are dehydrated. Your doctor may advise that dehydration be corrected before you start taking RAMPIL. This helps avoid symptoms of dizziness or light headedness, especially when you get up from a sitting or lying position.
- if you have fluid or electrolyte imbalances due to excessive perspiration, vomiting or diarrhoea, etc. The electrolyte imbalance must be corrected before you start treatment with RAMPIL.
- if you have diabetes mellitus (sugar diabetes) or if you have gout. These conditions may be made worse by RAMPIL.
- if you have a history of allergy or asthma. You may be at higher risk of an allergic reaction from RAMPIL.
- if you go for dialysis (procedure which removes waste products and excess fluid from your blood when your kidneys stop working properly).

- if you experience swelling of the face, lips, tongue or throat (angioedema), you may need emergency treatment and you should be monitored until these symptoms go away.
- if you have any heart disease as the reduction in blood pressure may aggravate it.
- if you have severe high blood pressure.
- if you have a severe autoimmune disease such as systemic lupus erythematosus(an inflammatory disease caused when the immune system attacks its own tissues) or scleroderma (chronic hardening and tightening of the skin and connective tissue) as RAMPIL may make these conditions worse.
- if you have bone marrow disorders.
- if you are taking medicines or have conditions which may increase potassium levels in your blood or decrease sodium levels in your blood. Your doctor may carry out regular blood tests, especially if you are elderly.
- if you have abnormal changes in the regular blood flow to the kidneys or kidney impairment.
- if you have impaired liver function.
- if you think that you are (or might become) pregnant.
- if you are going to undergo surgery or if you are going to receive anaesthesia, you should tell your doctor that you are taking RAMPIL.
- if your ethnic group is black, as you may be at an increased risk of having an allergic reaction to RAMPIL.
- if you have a non-productive, persistent cough, you should tell your doctor that you are taking RAMPIL.

The treatment of hypertension with RAMPIL must be carried out under regular medical supervision.

**Children and adolescents**

The safety and efficacy of RAMPIL in children has not been established.

**Other medicines and RAMPIL**

Always tell your healthcare provider if you are taking any other medicines (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following:

- Other antihypertensive medicines (used for high blood pressure) belonging to the angiotensin II receptor blocker (ARB) group (e.g. losartan, valsartan), medicines containing aliskiren, medicines belonging to the angiotensin converting enzyme group (ACE inhibitors) (e.g. captopril): as it may add to the blood pressure lowering effects of RAMPIL.
- Sacubitril/ valsartan: medicine for use in heart failure as the risk of angioedema (swelling of the face, lips, tongue or throat with difficulty in swallowing or breathing) may be increased.
- Antibiotics (fluoroquinolones e.g. ciprofloxacin, moxifloxacin, levofloxacin): medicine used to treat bacterial infections.
- Potassium supplements or other medicines that increase or may increase potassium levels in the blood. Your doctor may want to monitor the levels of potassium in your blood especially if you are elderly or have kidney problems.
- Water tablets (diuretics), alcohol, or other medicines which reduce blood pressure (such as nitrates, tricyclic antidepressants, anaesthetics, baclofen, alfuzosin, doxazosin, prazosin, tamsulosin, terazosin): as it may have a further reduction in the blood pressure and so dosage adjustments may be necessary.
- Over-the-counter medicines for asthma, colds, cough, hayfever or sinus problems as it may increase blood pressure. Check with your doctor before taking these medicines.
- Non-steroidal anti-inflammatory medicines (NSAIDs), as it may interfere with the blood pressure lowering effects of RAMPIL.
- Antidiabetic medicines as dosage adjustment of the antidiabetic medicine may be necessary.
- Lithium: medicine used for the treatment of some mood disorders

- Allopurinol for gout as this may lead to an increased risk of blood disorders.
- Medicines used for cancer or organ transplants and corticosteroids which may lead to blood disorders.

**RAMPIL with food and drink**

RAMPIL may be taken with or without meals.

**Pregnancy and breastfeeding**

You should not take RAMPIL if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

**Driving and using machines**

Since adverse reactions such as dizziness and visual disturbances have been reported in patients receiving RAMPIL you should not drive, use machinery or perform any tasks that require concentration, until you are certain that RAMPIL does not adversely affect your ability to do so safely.

It is not always possible to predict to what extent RAMPIL may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which RAMPIL affects you (see section 4).

## 3. How to take RAMPIL

Do not share medicines prescribed for you with any other person.

Always take RAMPIL exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

RAMPIL may be taken alone or in combination with other medicines for high blood pressure.

The usual dose of RAMPIL is:

*Treatment of high blood pressure:*

*Adults:* Initial dose is 2,5 mg RAMPIL once daily (for patients not on diuretics). The dose should be adjusted according to blood pressure response. Dosage should be increased to 5 mg RAMPIL and up to a maximum of 10 mg once daily at intervals of 1 to 2 weeks. The dose range is 2,5 mg to 10 mg. The full therapeutic effect may take several weeks. Therefore, if the desired effect has not been achieved within 2 to 4 weeks the dose may be increased.

**To reduce the risk of having a heart attack or stroke:**

*Adults:* Initial dose is 2,5 mg RAMPIL once daily. This may be increased at intervals of 4 weeks until the therapeutic effect is reached. Adjustments should be based on clinical response. The increase should be implemented by doubling the dose after one week of treatment. Three weeks later, it should be doubled again to the normal maintenance dose of 10 mg once daily.

**Non-diabetic kidney damage and kidney damage caused by diabetes:**

*Adults:* Initial dose is 1,25 mg RAMPIL once daily. Adjustments should be based on clinical response. The dose, if increased, should be implemented by doubling the dose at intervals of two to three weeks. The maximum permitted daily dose is 10 mg.

**Treatment after you have had a heart attack:**

Treatment with RAMPIL should be initiated in hospital three to ten days after a heart attack if the patient manifests with evidence of heart failure and is stable.

*Adults:* 2,5 mg twice daily for two days. If well tolerated the dose may be increased to 5 mg RAMPIL twice daily.

If you are unable to tolerate 2,5 mg initially, 1,25 mg RAMPIL twice daily may be given initially and later increased to 2,5 mg twice daily.

**Dosing in high-risk individuals:**

**If you are using water tablets (diuretics):**

In order to minimise the possibility of sudden and severe blood pressure lowering which may occur within the first 1 to 5 hours after the initial dose of RAMPIL, diuretics should be discontinued 2 to 3 days before beginning therapy with RAMPIL. Where diuretic therapy cannot be discontinued, treatment with RAMPIL should be initiated with a 1,25 mg dose. Subsequent dosage adjustments will depend on the therapeutic response.

**High blood pressure caused by abnormal changes in the regular blood flow to the kidneys:**

The dose should be lowered and you should be constantly monitored.

RAMPIL absorption is not affected by the presence of food. RAMPIL should be taken as a single daily dose at approximately the same time every day.

Your doctor will tell you how long your treatment with RAMPIL will last. Do not stop treatment early. If you have the impression that the effect of RAMPIL is too strong or too weak, tell your doctor or pharmacist.

**If you take more RAMPIL than you should:**

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

The most likely symptoms of overdose include severe lowering of blood pressure, electrolyte imbalances, and renal failure.

**If you forget to take RAMPIL:**

Do not take a double dose to make up for forgotten individual doses.

**If you stop taking RAMPIL**

Even when you feel better, do not stop taking RAMPIL. This medicine helps control high blood pressure. You may have to take high blood pressure medicine for the rest of your life. If high blood pressure is not treated, it can cause serious problems such as heart failure, blood vessel disease, stroke or kidney disease.

## 4. Possible side effects

RAMPIL can have side effects.

Not all side effects reported for RAMPIL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking RAMPIL, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop taking RAMPIL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash and itching,
- fainting,
- blistering of skin, mouth, eyes and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN).

These are all very serious side effects. If you have them, you may have had a serious reaction to RAMPIL. You may need urgent medical attention and or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- heart problems including a heart attack, with symptoms such as chest pain, burning sensation in the chest, numbness or tingling in an arm or leg, any changes in the way your heart beats,
- difficulty in breathing,
- blood disorders which can make the skin pale and cause breathlessness, weakness, bruising, an increased risk of bleeding or make infections more likely,
- inflammation of the gastrointestinal tract, stomach, pancreas (pancreatitis), liver (hepatitis) including death of liver tissue or failure of the liver, blockage of flow of bile from the liver (cholestasis) with symptoms such as severe pain in the stomach and back, nausea, vomiting and yellowing of the skin and eyes or pale stools,
- inflammation or narrowing of your blood vessels with symptoms such as fever, fatigue, weight loss and muscle and joint pain,
- kidney failure with symptoms such as decreased urinary output, swelling due to fluid retention, nausea, fatigue and shortness of breath,
- nausea and vomiting, headache, confusion, weakness as your body may be retaining water instead of excreting it normally in urine.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

*Frequent side effects:*

- headache, unusual tiredness or weakness (fatigue), dizziness.
- low blood pressure (hypotension), especially when you stand or sit up quickly,
- dry tickly cough, inflammation of your sinuses (sinusitis) or bronchitis,
- stomach pain or discomfort, diarrhoea, indigestion, feeling or being sick (nausea and vomiting),
- muscle cramps, pain, weakness or spasms

- blood tests showing more potassium than usual in your blood.

*Less frequent side effects:*

- balance problems, a feeling that the environment around you is spinning (vertigo),
- pins and needles,
- loss or change in the way things taste,
- sleep disturbances,
- feeling depressed, anxious, more nervous than usual or restlessness,
- blocked or runny nose, difficulty breathing or worsening of asthma,
- a swelling in your gut presenting with symptoms such as stomach pain, vomiting and diarrhoea,
- heartburn, constipation or dry mouth,
- problems with passing urine such as passing more water (urine) than usual,
- sweating more than usual,
- loss or decrease of appetite (anorexia),
- swollen arms and legs. This may be a sign of your body holding onto more water than usual,
- changes in your vision, blurred vision, pink eyes
- pain in your joints,
- flushing, fever,
- inability to develop or maintain an erection, decrease in sexual desire in men or women,
- blood tests showing changes in the way your liver, pancreas or kidneys are working,
- feeling shaky or confused,
- worsening of a pre-existing skin disease, severe flaking or peeling of the skin, itchy lumps rash, blotches on your skin, increased sensitivity to sunlight,
- loosening or separation of your nail from its nail bed,

- disturbed hearing and ringing in your ears,
- feeling weak or having a of loss of energy,
- hair loss.

*Side effects with an unknown frequency:*

- enlargement of the male breast tissue,
- disturbance in attention
- painful sores or ulcers in your mouth,
- fingers and toes feeling numb or changing colour when you are cold (Raynaud's phenomenon),
- slowed or impaired reactions,
- burning sensation,
- change in the way things smell.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

**Reporting of side effects**

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to:

**SAHPRA:** https://www.sahpra.org.za/health-products-vigilance/

**Aspen Pharmacare:**

**E-mail:** Drugsafety@aspenpharma.com

**Tel:** 0800 118 088 / +27 (0)11 239-6200

By reporting side effects, you can help provide more information on the safety of RAMPIL.

## 5. How to store RAMPIL

Store all medicines out of reach of children.

Store at or below 25 °C in tightly closed containers.

Protect from light.

Keep the blisters in the carton until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

## 6. Contents of the pack and other information

**What RAMPIL contains**

RAMPIL 1,25 mg

The active substance is 1,25 mg ramipril.

The other ingredients are gelatin, iron oxide yellow (C.I. 77492), pregelatinised starch, titanium dioxide (C.I. 77891).

Sugar free.

RAMPIL 2,5 mg

The active substance is 2,5 mg ramipril.

The other ingredients are erythrosine (C.I. 45430), gelatin, iron oxide yellow (C.I. 77492), pregelatinised starch, titanium dioxide (C.I. 77891).

Sugar free.

RAMPIL 5 mg

The active substance is 5 mg ramipril.

The other ingredients are carmoisine (C.I. 14720), gelatin, pregelatinised starch, quinolone yellow (C.I. 47005), titanium dioxide (C.I. 77891).

Sugar free.

RAMPIL 10 mg

The active substance is 10 mg ramipril.

The other ingredients are gelatin, indigotine (C.I. 73015), iron oxide black (C.I. 77499), ponceau 4R (C.I. 16255), pregelatinised starch, titanium dioxide (C.I. 77891).

Sugar free.

**What RAMPIL looks like and contents of the pack**

RAMPIL 1,25 mg is a hard gelatin size #4 capsule with yellow opaque body and yellow opaque cap. The cap has radially imprinted “RM 1,25”. Capsules contain a white to off-white powder.
30 or 60 hard gelatin capsules are packed in a white, round, polypropylene securitainer with a white snap-on low density polyethylene cap.

RAMPIL 2,5 mg is a hard gelatin size #4 capsule with orange opaque body and orange opaque cap. The cap has radially imprinted “RM 2,5”. Capsules contain a white to off-white powder.
30 or 60 hard gelatin capsules are packed in clear polyvinylchloride/polyvinylidene chloride blister strips sealed with an aluminium foil backing. The blister strips containing 10 capsules are packed into an outer cardboard carton together with a leaflet.

RAMPIL 5 mg is a hard gelatin size #4 capsule with Swedish orange opaque body and Swedish orange opaque cap. The cap has radially imprinted “RM 5”. Capsules contain a white to off-white powder.
30 or 60 hard gelatin capsules are packed in polyvinylchloride/ACLAR blister strips sealed with an aluminium foil backing. The blister strips containing 10 capsules are packed into an outer cardboard carton together with a leaflet.

RAMPIL 10 mg is a hard gelatin size #4 capsule with blue opaque body and blue opaque cap. The cap has radially imprinted “RM 10”. Capsules contain a white to off-white powder.

30 or 60 hard gelatin capsules are packed in polyamide/aluminium/polyvinylchloride blister strips sealed with an aluminium foil backing. The blister strips containing 10 capsules are packed into an outer cardboard carton together with a leaflet.

Not all packs or pack sizes may be marketed.

**Holder of Certificate of Registration**

PHARMACARE LIMITED

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**Hotline:** 0800 122 912/ +27 (0)11 239-6200

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RAMPIL 1,25 mg: A39/7.1.3/0141

RAMPIL 2,5 mg: A39/7.1.3/0142

RAMPIL 5 mg: A39/7.1.3/0143

RAMPIL 10 mg: A39/7.1.3/0144

**Access to the corresponding Professional Information**

**SAHPRA Repository of Professional Information and**

**Patient Information Leaflets:**

https://www.sahpra.org.za/pi-pil-repository/

**Aspen Pharmacare:**

**E-mail:** Medinfo@aspenpharma.com

**Tel:** 0800 118 088

| Botswana: S3 | |
|---|---|
| 5 mg: | BOT1302411 |
| 10 mg: | BOT1302412 |

| Namibia: | NS2 |
|---|---|
| 1,25 mg: | 10/7.1.3/0496 |
| 2,5 mg: | 10/7.1.3/0497 |
| 5 mg: | 10/7.1.3/0498 |
| 10 mg: | 10/7.1.3/0499 |

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