APPROVED PATIENT INFORMATION LEAFLET

Ramipril 1,25/2,5/5/10 mg Capsules Austell

SCHEDULING STATUS:

S3

RAMIPRIL1,25 mg AUSTELL CAPSULES

RAMIPRIL 2,5 mg AUSTELL CAPSULES

RAMIPRIL 5 mg AUSTELL CAPSULES

RAMIPRIL 10 mg AUSTELL CAPSULES

Ramipril

Contains methyl paraben (0,37 %) and propyl paraben (0,09 %) as preservatives

Sugar free

Read all of this leaflet carefully before you start taking RAMIPRIL AUSTELL

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- RAMIPRIL AUSTELL 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

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2. What you need to know before you take RAMIPRIL AUSTELL

3. How to take RAMIPRIL AUSTELL

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1. What RAMIPRIL AUSTELL is and what it is used for

RAMIPRIL AUSTELL contains a medicine called ramipril. This belongs to a group of medicines called ACE inhibitors (Angiotensin Converting Enzyme Inhibitors).

RAMIPRIL AUSTELL 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.

RAMIPRIL AUSTELL is used:

- For the management of mild to moderate high blood pressure.
- To treat heart failure following a heart attack.
- To reduce proteinuria and the decline in glomerular filtration rate (kidney problems) in patients with diabetic nephropathy and high blood pressure.
- To reduce the risk of a heart attack, stroke or cardiovascular death and to reduce the need for revascularisation procedures in patients with an increased cardiovascular risk.
- To reduce the risk of heart attack, stroke or cardiovascular death in diabetic patient.

2. What you need to know before you take RAMIPRIL AUSTELL

Do not take RAMIPRIL AUSTELL capsules:

- if you are hypersensitive (allergic) to ramipril or any of the other ingredients of RAMIPRIL AUSTELL (listed in section 6),
- if you ever had a serious allergic reaction called "angioedema". The signs include itching, hives (urticaria), red marks on the hands, feet and throat, swelling of the throat and tongue, swelling around the eyes and lips, difficulty breathing and swallowing,

- if you suffer from aortic stenosis (narrowing of the aortic valve branching of the heart),
- if you have hypertrophic obstructive cardiomyopathy (a condition in which the heart muscle becomes abnormally thick),
- if you have severe kidney disease,
- if you have kidney problems where the blood supply to your kidney is reduced (renal artery stenosis),
- if you are taking potassium saving water tablets (diuretics) such as spironolactone, triamterene, amiloride,
- porphyria (a type of liver disease where porphyrins build up in the body),
- if you are taking medicine containing lithium as this may lead to toxic blood levels of lithium,
- if you are pregnant or breastfeeding,
- if you are taking a blood pressure lowering medicine containing aliskiren,
- if you have a problem with your kidney(s), you should not take an antibiotic (medicine used to treat an infection) from the fluoroquinolone class such as moxifloxacin or levofloxacin, while taking RAMIPRIL AUSTELL.

Warnings and precautions

Take special care with RAMIPRIL AUSTELL capsules:

- if you are pregnant, you must stop your treatment with RAMIPRIL AUSTELL immediately and your doctor should change your medicine,
- if you are planning to become pregnant, you cannot take RAMIPRIL AUSTELL and should speak to your doctor,
- if you are taking aliskiren-containing medicines as this will increase your risk of low blood pressure, increased potassium levels and decreased kidney function, including kidney failure,
- if you suffer from heart problems, as the decrease in blood pressure could worsen this and cause a heart attack,

- if you are volume-depleted (caused by water tablets, reduced salt-diet, dialysis, diarrhoea or vomiting), as you have an increased risk of a decrease in blood pressure,
- if you have severe autoimmune disease, such as systemic lupus erythematosus, vascular disease or scleroderma as this will increase your risk of neutropenia (reduction in white blood cell count) and agranulocytosis (decrease in blood granulocytes),
- if you have kidney problems and you have an acute heart attack, do not take RAMIPRIL AUSTELL,
- if you have a heart attack, you may develop a continuous decrease in your blood pressure or aggravate your kidney problems if given RAMIPRIL AUSTELL,
- if you have bone marrow depression as you are at an increased risk of reduction in your white blood cell count,
- if you are diabetic as you have the risk of increased blood potassium levels and low blood sugar levels,
- if you have high amounts of potassium in your blood,
- if you have renovascular disease or renal artery stenosis (a condition where the artery to one or both kidneys is narrowed) and this can cause high blood pressure and reduced kidney function,
- if you are hypersensitive or if you have a history of anaphylactoid or allergic reactions,
- if you have a history of idiopathic or hereditary angioedema a serious allergic reaction which causes swelling of the face, hands, lips, tongue and the voice box,
- if you are a child, as safety has not been established and RAMIPRIL AUSTELL should not be used,
- if you are taking potassium saving water tablets (diuretics) such as spironolactone, triamterene, amiloride,
- if you are elderly or have moderate to severe kidney problems, you should not take an antibiotic (medicine used to treat an infection) from the fluoroquinolone class such as

moxifloxacin or levofloxacin, while taking RAMIPRIL AUSTELL as it may cause or aggravate kidney problems,

- if you are driving or performing tasks which require you to be alert because RAMIPRIL AUSTELL may cause dizziness,
- if you are going to receive an anaesthetic as RAMIPRIL AUSTELL may cause a decrease in blood pressure.

Other medicines and RAMIPRIL AUSTELL

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor if you are taking any of the following medicines. They can make RAMIPRIL AUSTELL work less well.

- Medicines such as diuretics (water tablets), other antihypertensives (medicines used to decrease blood pressure), or alcohol.
- Non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen, indomethacin and aspirin.
- Potassium sparing medicines or supplements, such as sprinolactone, triamterene or amiloride,
- Fluoroquinolone antibiotics (medicines used to treat infections) such as moxifloxacin or levofloxacin.

Pregnancy and breastfeeding

You should not use RAMIPRIL AUSTELL during pregnancy or when 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 health care provider for advice before taking RAMIPRIL AUSTELL.

Driving and using machines

You may feel dizzy while taking RAMIPRIL AUSTELL. This is more likely to happen when you start taking RAMIPRIL AUSTELL or start taking a higher dose. If this happens, do not drive or use any tools or machines.

3. How to take RAMIPRIL AUSTELL

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

Always take RAMIPRIL AUSTELL exactly as described in this leaflet or as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

Adults

- take the capsules by mouth at the same time each day. Swallow the capsules whole with a sufficient quantity of water,
- RAMIPRIL AUSTELL can be taken with or without food,
- if you are on a water tablet, this should be stopped 2 to 3 days prior to starting treatment with RAMIPRIL AUSTELL, to reduce the lowering of the blood pressure,
- if your water tablet cannot be stopped, the starting dose is one capsule (1,25 mg of ramipril) once daily,
- the dose will be adjusted according to the response on the blood pressure.

Treatment of high blood pressure

- The dose range is one capsule (2,5 mg to 10 mg ramipril) once daily.
- The recommended initial dosage in patients not on diuretics is one capsule (2,5 mg ramipril) once a day.
- Your doctor will adjust the dose until your blood pressure is controlled.

- If the blood pressure is not controlled, the dosage can be increased to one capsule (5 mg ramipril) once daily and up to a maximum of one capsule (10 mg ramipril) once a day.
- A maximum dose of one capsule (10 mg ramipril) once daily should not be exceeded.

Dosage after a heart attack

- One capsule (2,5 mg ramipril) twice daily for 2 days.
- If 2,5 mg cannot be tolerated, one capsule (1,25 mg ramipril) twice daily can be given, which can later be increased to one capsule (2,5 mg) twice daily.
- Can be increased to one capsule (5 mg ramipril) twice daily.

Dosage in non-diabetic and diabetic nephropathy

- One capsule (1,25 mg ramipril) once daily.
- If this dose is tolerated, the dosage can be increased, or doubled at intervals of 2 to 3 weeks.
- Maximum dose is one capsule (10 mg ramipril) once daily.

To reduce risk of heart attack or stroke

- Initial dose is one capsule (2,5 mg ramipril) once daily.
- If this dose is tolerated, the dose can be increased by doubling the dose after 1 week of treatment.
- 3 weeks later it should be doubled again upto a maximum of one capsule (10 mg ramipril) once daily.

In children:

RAMIPRIL AUSTELL is not recommended for use in children.

If you have the impression that the effect of RAMIPRIL AUSTELL is too strong or too weak, you should talk to your doctor or pharmacist.

If you take more RAMIPRIL AUSTELL than you should

Contact your doctor or pharmacist who will recommend what action you should take.

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

If you forget to take RAMIPRIL AUSTELL

- If you feel that you have missed a dose of treatment, take your normal dose when it is next due.
- Do not take a double dose to make up for the forgotten individual dose.

4. Possible side effects

RAMIPRIL AUSTELL can have side effects.

Not all side effects reported for RAMIPRIL AUSTELL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving RAMIPRIL AUSTELL, please consult your healthcare provider for advice.

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

- severe sudden allergic reactions (e.g.: swelling of the face, lips, tongue, throat) which make it difficult to swallow or breathe, as well as itching and rashes. This could be a sign of a severe allergic reaction to RAMIPRIL AUSTELL,
- severe skin reactions including rash, reddening or blistering of the skin.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- increase in blood potassium,
- headache,
- dizziness,
- decrease in blood pressure,
- decrease in blood pressure when standing up from a resting position (orthostatic hypotension),
- fainting,
- cough,
- bronchitis (chest infection),
- sinusitis,
- shortness of breath,
- inflammation of the digestive system,
- abdominal (stomach) discomfort,
- running stomach (diarrhoea),
- nausea,
- throwing up (vomiting),
- rash,
- muscle spasms,
- muscle pain,
- chest pain,
- tiredness.

Less frequent side effects:

- eosinophilia (increase in eosinophils -a type of white blood cell),
- decreased white blood cells and red blood cells,
- decreased haemoglobin (molecule which carries oxygen from the lung to the rest of the body),
- decreased platelets,

- anorexia (eating disorder), decreased appetite,
- depression, anxiety, nervousness, restlessness, excessive sleepiness,
- confusion,
- vertigo (feeling off balance), ‘pins and needles’, loss of taste, altered taste,
- tremor, balance disorder,
- disturbance in vision, blurred vision, bacterial infection of the eyes,
- reduced hearing, ringing in the ears,
- reduced blood flow to the heart (myocardial ischaemia), heart attack, increase in heart-beat, irregular heart-beat, palpitations, swelling of legs and feet,
- flushing,
- vascular stenosis (blood vessel narrowing),
- hypoperfusion (reduces blood flow),
- vasculitis (inflammation of blood vessels, cutting off blood supply to tissues and organs),
- tightness of the chest,
- worsening of asthma,
- blocked nose/congestion,
- inflammation of the pancreas,
- stomach pain, inflammation of the stomach lining, constipation, dry mouth,
- glossitis (inflammation of the tongue),
- increase in liver enzymes,
- increase in bilirubin, causing jaundice,
- liver damage, acute liver failure,
- angioedema (swelling of skin, lips, tongue, face, tongue, voice box),
- itching, hives,
- excessive sweating,
- onycholysis (detachment of nail from the nail bed),

- photosensitivity,
- painful joints,
- kidney disorders, decrease in urination, increase in proteins in the urine, increase in the levels of blood urea and creatinine,
- sexual dysfunction, decreased sexual drive,
- fever,
- weakness.

Frequency unknown:

- bone marrow failure,
- pancytopenia (decreased white blood cells, red blood cells and platelets),
- haemolytic anaemia (increase in rate of destruction of red blood cells),
- allergic reactions,
- increase in antinuclear antibodies (ANA), which are proteins produced to fight off bacteria, viruses,
- syndrome of inappropriate antidiuretic hormone secretion (SIADH), which is a condition where the body produces too much of the antidiuretic hormone and causes your body to retain water,
- decreased blood sodium levels,
- disturbance in attention,
- transient ischaemic attach (TIA), which can lead to stroke,
- burning sensation,
- altered or loss of smell (parosmia),
- Raynaud's phenomenon (decreased blood flow to fingers, toes, ears and other parts of the body),
- aphthous stomatitis (mouth ulcers),
- toxic epidermal necrolysis (TEM) and Stevens-Johnson syndrome, which is a severe skin reaction which starts with fever and flu-like symptoms and then causes the skin to blister and peel,
- erythema multiforme (rash on the body where each mark resembles a bullseye),

- pemphigus (blisters or pus-filled bumps on the skin),
- psoriasis, exanthema (skin rash),
- enanthema (ulcer on the inside of the mouth),
- hair loss,
- swelling or enlargement of the breasts,

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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of RAMIPRIL AUSTELL.

5. How to store RAMIPRIL AUSTELL

- Keep this medicine in a dry place at or below 25°C.
- Protect from light.
- Store in the original package.
- Do not use after the expiry date.
- Store all medicines out of reach of children.
- 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 RAMIPRIL AUSTELL contains

- The active substance is ramipril. Each capsule contains 1,25 mg; 2,5 mg; 5 mg or 10 mg of ramipril.

- The other ingredients are:

  Capsule contents:

  RAMIPRIL AUSTELL 1,25 mg/2,5 mg/5 mg/10 mg: pregelatinised starch.

  Capsule shell:

  RAMIPRIL 1,25 mg AUSTELL: ferric oxide yellow (E172), gelatin, methyl paraben, propyl paraben, titanium dioxide (E171).

  RAMIPRIL 2,5 mg AUSTELL: brilliant blue, carmosine (E122), gelatin, methyl paraben, panceau 4R (E124), propyl paraben, sunset yellow (E110), titanium dioxide (E171).

  RAMIPRIL 5 mg AUSTELL: brilliant blue, carmosine (E122), gelatin, methyl paraben, panseau 4R (E124), propyl paraben, titanium dioxide (E171).

  RAMIPRIL 10 mg AUSTELL: Brilliant blue, gelatin, methyl paraben, propyl paraben, titanium dioxide (E171).

What RAMIPRIL AUSTELL looks like and contents of the pack

RAMIPRIL 1,25 mg AUSTELL: Yellow-white colored hard gelatin capsules of size "4".

RAMIPRIL 2,5 mg AUSTELL: Orange-white colored hard gelatin capsules of size "4".

RAMIPRIL 5 mg AUSTELL: Maroon/ white colored hard gelatin capsules of size "4".

RAMIPRIL 10 mg AUSTELL: Blue-white colored hard gelatin capsules of size "4".

RAMIPRIL AUSTELL capsules are available in blister packs containing 28 or 30 capsules.

Holder of Certificate of Registration

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This leaflet was last revised in

Date of registration: 29 July 2005

Date of revision: 27 January 2021

Registration number

RAMIPRIL 1,25 mg AUSTELL**:** A39/7.1.3/0239

RAMIPRIL 2,5 mg AUSTELL: A39/7.1.3/0240

RAMIPRIL 5 mg AUSTELL: A39/7.1.3/0241

RAMIPRIL 10 mg AUSTELL: A39/7.1.3/0242

Access to the corresponding Professional Information

Professional Information for this medicine is available on the following URL: https://austell.co.za/product-info/

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