APPROVED PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

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

SCHEDULING STATUS

S3

1. NAME OF THE MEDICINE

RAMIPRIL1,25 mg AUSTELL CAPSULES

RAMIPRIL 2,5 mg AUSTELL CAPSULES

RAMIPRIL 5 mg AUSTELL CAPSULES

RAMIPRIL 10 mg AUSTELL CAPSULES

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

RAMIPRIL1,25 mg AUSTELL : Each capsule contains ramipril 1,25 mg.

RAMIPRIL 2,5 mg AUSTELL : Each capsule contains ramipril 2,5 mg.

RAMIPRIL 5 mg AUSTELL : Each capsule contains ramipril 5 mg.

RAMIPRIL 10 mg AUSTELL : Each capsule contains ramipril 10 mg.

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

Sugar free.

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Capsules.

RAMIPRIL1,25 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".

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

- Mild to moderate hypertension.
- Cardiac failure following myocardial infarction.
- To reduce proteinuria and the decline in glomerular filtration rate in patients with diabetic nephropathy and hypertension.
- To reduce the risk of myocardial infarction, stroke or cardiovascular death and to reduce the need for revascularisation procedures in patients with an increased cardiovascular risk [such as manifest coronary heart disease (with or without a history of myocardial infarction), a history of stroke or a history of peripheral vascular disease.
- To reduce the risk of myocardial infarction, stroke or cardiovascular death in diabetic patients.

4.2 Posology and method of administration

RAMIPRIL AUSTELL may be taken with or without meals preferably at the same time every day.

Adults

In patients who are currently being treated with a diuretic, symptomatic hypotension may occur occasionally following the initial dose of RAMIPRIL AUSTELL . The diuretic should, if possible, be discontinued for two to three days before beginning therapy with RAMIPRIL AUSTELL to reduce the likelihood of hypotension. In case the diuretic therapy cannot be discontinued the initial dose of RAMIPRIL AUSTELL should be 1,25 mg. The dose should be adjusted according to blood pressure response. 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.

Special populations

Hypertension

Administration of RAMIPRIL AUSTELL to hypertensive patients results in a reduction of both supine and erect blood pressure. The antihypertensive effect is evident within one or two hours after intake of the medicine, peak effect occurs three to six hours after intake, and has been shown to be maintained for at least 24 hours at recommended doses.

The dose range is 2,5 mg to 10 mg RAMIPRIL AUSTELL as a single daily dose.

The recommended initial dosage in patients not on diuretics is 2,5 mg RAMIPRIL AUSTELL once a day. Dosage should be increased to 5 mg and up to a maximum of 10 mg once a day, at intervals of one to two weeks, based on patient response. A maximum dose of 10 mg should not be exceeded.

Post-myocardial infarction

The treatment with RAMIPRIL AUSTELL should be initiated in hospital 3 to 10 days after an acute myocardial infarction if the patient manifests with evidence of heart failure and is haemodynamically stable.

The recommended dosage is 2,5 mg twice daily for two days. If well tolerated, increase the dose to 5 mg twice daily. If patients are unable to tolerate 2,5 mg initially, 1,25 mg RAMIPRIL AUSTELL may be given twice daily initially and later increased to 2,5 mg twice daily.

Dosing in high-risk individuals:

Non-diabetic and diabetic nephropathy

Recommended initial dose: 1,25 mg once daily.

Depending on how the patient tolerates the medicine, the dose should be increased. It is recommended that the dose, if increased, be doubled at intervals of 2 to 3 weeks.

Maximum permitted daily dose: 10 mg RAMIPRIL AUSTELL

In patients pre-treated with a diuretic

In order to minimize the possibility of sudden and severe hypotension which may occur in the first 1 to 5 hours after the initial dose of RAMIPRIL AUSTELL, diuretics should be discontinued 2 to 3 days before beginning therapy with RAMIPRIL AUSTELL. In patients where diuretic therapy cannot be discontinued, treatment with RAMIPRIL AUSTELL should be initiated with a dose of 1,25 mg.

Dosage adjustment in renal impairment

RAMIPRIL AUSTELL is not recommended for use in dialysis patients.

To reduce the risk of myocardial infarction, stroke or cardiovascular death:

The recommended initial dose is 2,5 mg RAMIPRIL AUSTELL once daily. Depending on the tolerability, the dose is gradually increased. The increase should be implemented by doubling the dose after one week of treatment. Three weeks later, it should be doubled again to the usual maintenance dose of 10 mg RAMIPRIL AUSTELL once daily.

4.3 Contraindications

- Hypersensitivity to ramipril or any of the ingredients listed in section 6.1.
- Patients with a history of angioedema related to previous therapy with ACE inhibitors or angiotensin receptor blockers (ARBs): These patients must never again be given RAMIPRIL AUSTELL.
- Hereditary or idiopathic angioedema.
- Aortic stenosis.
- Hypertrophic obstructive cardiomyopathy (HOCM).
- Severe renal function impairment (creatinine clearance less than 30 mL/min).
- Bilateral renal artery stenosis.
- Renal artery stenosis in patients with a single kidney.
- Concomitant therapy with potassium sparing diuretics such as spironolactone, triamterene, amiloride (see section 4.5).
- Porphyria.
- Lithium therapy: Concomitant administration with RAMIPRIL AUSTELL may lead to toxic blood concentrations of lithium.
- Pregnancy and lactation (see section 4.6).
- The concomitant use of RAMIPRIL AUSTELL with aliskiren-containing products is contraindicated (see section 4.4 and section 4.5).

- Concomitant use of RAMIPRIL AUSTELL with fluoroquinolones is contraindicated in patients with moderate to severe renal impairment.

4.4 Special warnings and precautions for use

Dual

Should a woman become pregnant while receiving RAMIPRIL AUSTELL, the treatment must be stopped promptly and switched to a different class of antihypertensive medicine (see section 4.3 and section 4.6). If a woman is contemplating pregnancy, a different class of medicine should be used (see section 4.6).

blockade of the renin-angiotensin-aldosterone system (RAAS)

There is evidence that the concomitant use of ACE-inhibitors, angiotensin II receptor blockers (ARBs) or aliskiren may increase the risk of hypotension, hyperkalaemia and decreases renal function (including acute renal failure). Dual blockade of RAAS through the combined use of RAMIPRIL AUSTELL and aliskiren is therefore contraindicated (see section 4.3).

RAMIPRIL AUSTELL should not be used concomitantly with aliskiren (see section 4.3).

RAMIPRIL AUSTELL should be used with caution in the following conditions:

- Cerebrovascular disease of ischaemic heart disease – Reduction in blood pressure could aggravate these conditions and may result in myocardial infarction and cerebrovascular accidents.
- Volume depleted patients (e.g by diuretic therapy, dietary salt restriction, dialysis, diarrhoea or vomiting) – Although it may occur in normovolemic patients, hypotension is more likely in volume depleted patients. A sudden reduction in angiotensin ll may result in sudden and severe hypotension. There is also an increased risk of RAMIPRIL AUSTELL induced renal failure, especially in those with congestive heart failure.

- Patients at a high risk of symptomatic hypotension e.g. patients with salt or volume depletion with or without hyponatremia should have these conditions corrected before therapy with RAMIPRIL AUSTELL. Monitoring is required after initiating therapy.
- Severe auto-immune disease, especially systemic lupus erythematosus, other collagen vascular disease or scleroderma: Increase the risk for development of neutropenia or agranulocytosis.
- In acute myocardial infarction, treatment with RAMIPRIL AUSTELL should not be initiated in patients with evidence of renal dysfunction (serum creatinine concentrations exceeding 177 micromol/L or proteinuria exceeding 500 mg/24 hours). If renal dysfunction develops during treatment (serum creatinine concentrations exceeding 177 micromol/L or doubling of the pre-treatment value) then RAMIPRIL AUSTELL may need to be withdrawn (see section 4.3).
- In acute myocardial infarction, patients may develop persistent hypotension and/or impaired renal function.
- Hypotension in acute myocardial infarction- Treatment with RAMIPRIL AUSTELL must not be initiated in acute myocardial infarction patients who are at risk of further serious haemodynamic deterioration after treatment with a vasodilator. These include patients with systolic blood pressure of 13,33 kPa or lower or cardiogenic shock. During the first 3 days following the infarction, the dose should be reduced if the systolic blood pressure is 15,99 kPa or lower. Maintenance doses should be reduced to 5 mg or temporarily to 2,5 mg if systolic blood pressure is 13,33 kPa or lower. If hypotension persists (systolic blood pressure less than 11,99 kPa or more than 1 hour) then RAMIPRIL AUSTELL should be withdrawn.
- Bone marrow depression – Increased risk of agranulocytosis and neutropenia.
- Diabetus mellitus – Increased risk of hyperkalaemia, as well as hypoglycaemia may occur.
- Hyperkalaemia - RAMIPRIL AUSTELL may cause an increase in serum potassium levels.

- Renovascular disease - RAMIPRIL AUSTELL should not be used in patients with renovascular disease or suspected renovascular disease but may be used cautiously in severe resistant hypertension in such patients. In this instance RAMIPRIL AUSTELL should only be used under specialist supervision. The elderly, patients with peripheral vascular diseases or generalized atherosclerosis may have asymptomatic renovascular disease (see section 4.2).
- Renal artery stenosis, bilateral or in one kidney or renal transplant – increased risk of renal function impairment may cause increases in blood urea and serum creatinine concentrations, which may be reversible upon discontinuation of therapy. There is also an increased risk of agranulocytosis and neutropenia when immunosuppressants are concurrently administered.
- Renal function impairment – Decreased elimination of RAMIPRIL AUSTELL resulting in an increased risk of hyperkalaemia. These patients may require lower doses.
- Anaphylactoid reactions have occurred in patients using ACE inhibitors during desensitising protocols involving for example, hymenoptera venom.
- Anaphylactoid reactions have been reported in patients exposed to either high-flux membrane dialysis or low-density lipoprotein apheresis with dextran sulphate absorption.
- Hypersensitivity/Angioedema – If angioedema of the face, extremities, lips, tongue, glottis and/or larynx is observed in patients treated with RAMIPRIL AUSTELL , RAMIPRIL AUSTELL should be discontinued promptly. These patients should be monitored to ensure complete resolution of symptoms.
- Angioedema associated with laryngeal oedema may be fatal. Where there is involvement of the tongue, glottis or larynx, likely to cause airway obstruction, appropriate emergency therapy should be administered. This may include the administration of adrenaline and/or the maintenance of a patent airway. The patient should be under close medical supervision until complete and sustained resolution of

symptoms has occurred. **These patients should never receive any RAMIPRIL AUSTELL again.**

- RAMIPRIL AUSTELL causes a higher rate of angioedema in black patients that in non-black patients.
- Safety and efficacy in children have not been established.
- Concomitant therapy with potassium sparing diuretics such as spironolactone, triamterene, amiloride may lead to hyperkalaemia, which may be severe and lead to cardiac conduction abnormalities, dysrythmia and cardiac arrest.
- Concomitant use of fluoroquinolones with ACE inhibitors, such as RAMIPRIL AUSTELL , may precipitate acute kidney injury in patients, especially those with moderate to severe renal impairment and elderly patients (see section 4.3). Renal function should be assessed before initiating treatment and monitored during concomitant treatment with fluoroquinolones or RAMIPRIL AUSTELL.

Special precautions:

- Myocardial infarction and cerebrovascular accidents may be due to severe falls in blood pressure in high-risk patients e.g. those with ischaemic heart disease or cerebrovascular disease.
- In volume depleted patients or patients with ischaemic heart disease or cerebrovascular disease, therapy should be monitored especially when the dose of RAMIPRIL AUSTELL or diuretic is adjusted.
- If hypotension occurs, the patient should be placed in the supine position and if necessary receive an intravenous infusion of 0.9 % saline.
- Increases in blood urea and serum creatinine have been seen in patients with no apparent pre-existing vascular disease, especially when RAMIPRIL AUSTELL has been given concomitantly with a diuretic. Dosage reduction or discontinuation of RAMIPRIL AUSTELL or the diuretic therapy may be required.

- Signs of facial or extremity swelling or difficulty in swallowing or breathing, requires immediate attention, because of the risk of angioedema.
- Caution when driving or performing tasks requiring alertness because of possible dizziness.
- In patients undergoing major surgery or during anaesthesia with agents that produce hypotension,RAMIPRIL AUSTELL may block angiotensin ll formation secondary to compensatory rennin release. If hypotension occurs and is considered to be due to this mechanism, it can be corrected by volume expansion.

4.5 Interaction with other medicines and other forms of interaction

Dual blockade of the RAAS with ARBs, ACE inhibitors, or aliskiren

Clinical trial data has shown that dual blockade of the renin-angiotensin-aldosterone-system (RAAS) through the combined use of ACE inhibitors, angiotensin II receptor blockers or aliskiren is associated with a higher frequency of adverse events such as hypotension, hyperkalaemia and decreased renal function (see section 4.3 and section 4.4).

Concomitant use of RAMIPRIL AUSTELL with:

- Diuretics, alcohol and hypotension-producing medications – The antihypertensive effect is additive. Dosage adjustments may be necessary during concurrent use or when one medicine is discontinued.
- Loop, thiazide or related diuretics – “First dose hypotension” may occur (see section 4.2).
- Indomethacin and nonsteroidal anti-inflammatory drugs (NSAIDs) – reduce the antihypertensive effects of RAMIPRIL AUSTELL Blood pressure monitoring should be increased when any NSAID is added or discontinued in a patient treated with RAMIPRIL AUSTELL**.**
- Potassium supplements or potassium sparing diuretics such as spironolactone, triamterene or amiloride – Concurrent administration may result in hyperkalaemia.

- Lithium – Increases in lithium concentrations have been reported. Frequent monitoring of serum lithium concentrations is recommended.
- Concomitant use of fluoroquinolones and ACE inhibitors, such as RAMIPRIL AUSTELL , may precipitate acute kidney injury (see section 4.3).

4.6 Fertility, pregnancy and lactation

The use of RAMIPRIL AUSTELL is contraindicated during pregnancy. Pregnant women should be informed of the potential hazards to the foetus and must not take RAMIPRIL AUSTELL during pregnancy (see section 4.3). Patients planning pregnancy should be changed to alternative anti-hypertensive treatments which have an established safety profile for use in pregnancy. When pregnancy is diagnosed, treatment with RAMIPRIL AUSTELL should be stopped immediately and if appropriate, alternative therapy should be started. Foetal exposure to ACE inhibitors during the first trimester of pregnancy has been reported to be associated with an increased risk of malformations of the cardiovascular (atrial and/or ventricular septal defect, pulmonic stenosis, patent ductus arteriosus) and central nervous system (microcephaly spins bifida) and of kidney malformations. RAMIPRIL AUSTELL passes through the placenta and can be presumed to cause disturbance in foetal blood pressure regulatory mechanisms. Oligohydramnios as well as hypotension, oliguria and anuria in new-borns, have been reported after administration of RAMIPRIL AUSTELL during the second and third trimester. Cases of defective skull ossification have been observed. Prematurity and low birth mass can occur (see section 4.3).

Safety in lactation has not been established.

4.7 Effects on ability to drive and use machines

Some adverse effects (e.g. symptoms of a reduction in blood pressure such as dizziness) may impair the patient's ability to concentrate and react and, therefore, constitute a risk in situations where these abilities are of particular importance (e.g. operating a vehicle or machinery).

This can happen especially at the start of treatment, or when changing over from other preparations. After the first dose or subsequent increases in dose it is not advisable to drive or operate machinery for several hours.

4.8 Undesirable effects

The frequency of adverse reactions reported with RAMIPRIL AUSTELL are summarised in Table 1 below by system organ class (in MedDRA) and by frequency.

Table 1: Tabulated list of adverse reactions		
System organ class	**Adverse reaction**	**Frequency**
Blood and lymphatic system disorders	Eosinophilia, decrease in white blood cell count (including neutropenia or agranulocytosis), decrease in haematocrit, decrease in red blood cell count, decreased haemoglobin, thrombocytopenia, elevated erythrocyte sedimentation rate, leucocytosis	Less frequent
	Bone marrow depression, pancytopenia, haemolytic anaemia	Unknown
Immune system disorders	Anaphylactic or anaphylactoid reactions, positive antinuclear antibodies (ANA)	Unknown
Endocrine disorders	Syndrome of inappropriate antidiuretic	Unknown

	hormone secretion (SIADH)	
Metabolism and nutrition disorders	Hyperkalaemia, increase in blood urea, increase in serum creatinine	Frequent
	Anorexia, decreased appetite	Less frequent
	Hyponatraemia	Unknown
Psychiatric disorders	Depressed mood, mood alterations, anxiety, nervousness, restlessness, sleep disorder including somnolence, confusion	Less frequent
	Disturbance in attention	Unknown
Nervous system disorders	Headache, dizziness, fatigue	Frequent
	Vertigo, paraesthesia, ageusia, dysgeusia, tremor, balance disorder	Less frequent
	Cerebral ischaemia including ischaemic stroke and transient ischaemic attack, impairment of psychomotor skills, burning sensation, parosmia	Unknown
Eye disorders	Visual disturbance including blurred vision, conjunctivitis	Less frequent

Ear and labyrinth disorders	Impaired hearing, tinnitus	Less frequent
Cardiac disorders	Myocardial ischaemia including angina pectoris or myocardial infarction, tachycardia, arrhythmia, palpitations, peripheral oedema	Unknown
Vascular disorders	Hypotension, decreased orthostatic blood pressure, syncope	Frequent
	Flushing, vascular stenosis, hypoperfusion, vasculitis	Less frequent
	Raynaud's phenomenon	Unknown
Respiratory, thoracic and mediastinal disorders	Cough, bronchitis, sinusitis, dyspnoea	Frequent
	Bronchospasm including aggravated asthma, nasal congestion, rhinitis	Less frequent
Gastrointestinal disorders	Gastrointestinal inflammation, digestive disturbances, indigestion, abdominal discomfort, dyspepsia, diarrhoea, nausea, vomiting, taste disturbances	Frequent
	Pancreatitis, increase in pancreatic enzymes, small bowel angioedema, upper abdominal pain	Less frequent

	upper including gastritis, constipation, dry mouth	
	Aphthous stomatitis	Unknown
Hepatobiliary disorders	Increase in hepatic enzymes/serum bilirubin, cholestatic jaundice, hepatocellular damage	Less frequent
	Acute hepatic failure, hepatitis (hepatocellular or cholestatic)	Unknown
Skin and subcutaneous tissue disorders	Maculo-papular rash	Frequent
	Hypersensitivity/angioedema reactions: angioedema of the face which may be fatal, extremities, lips, tongue, glottis and/or larynx and intestinal angioedema, pruritus, hyperhidrosis, exfoliative dermatitis, urticaria, diaphoresis, alopecia, onycholysis, photosensitivity	Less frequent
	Toxic epidermal necrolysis, Stevens-Johnson syndrome, erythema multiforme, pemphigus, psoriasis, dermatitis psoriasiform,	Unknown

	pemphigoid or lichenoid exanthema or enanthema, alopecia	
Musculoskeletal and connective tissue disorders	Muscle spasms, myalgia	Frequent
	Arthralgia, arthritis, asthenia	Less frequent
Renal and urinary disorders	Renal impairment, including acute renal failure, increase in urine output, worsening of pre-existing proteinuria, uraemia, oliguria, anuria, increase in blood creatinine	Less frequent
Reproductive system and breast disorders	Transient erectile impotence, decreased libido	Less frequent
	Gynaecomastia	Unknown
General disorders and administration site conditions	Chest pain, fatigue	Frequent
	Pyrexia, asthenia	Less frequent

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions 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

4.9 Overdose

Symptoms of overdose: Severe hypotension, electrolyte disturbances and renal failure.

Treatment of overdose:

Treatment is symptomatic and supportive. Activated charcoal may be given in severe overdosage if the patient presents within 1 hour of ingestion. Treatment consists of volume expansion to correct hypotension and treating dehydration and electrolyte imbalances. RAMIPRIL AUSTELL is removable by haemodialysis.

5. PHARMACOLOGICAL PROPERTIES

Pharmacological Classification/ Category and Class: A.7.1.3/Other hypotensives.

Pharmacotherapeutic group: ACE Inhibitors

ATC code: C09AA05

5.1 Pharmacodynamic properties

RAMIPRIL AUSTELL inhibits angiotensin I-converting enzyme (ACE) activity. It inhibits the conversion of the relatively inactive angiotensin I to the active angiotensin ll. Angiotensin ll is a potent vasoconstrictor and stimulates the release of aldosterone. Decreased angiotensin ll levels result in a decrease in vasopressor activity and a reduction in aldosterone secretion, which may result in small increases in serum potassium. It is also thought that ACE inhibition may inhibit degradation of bradykinin, leading to increased bradykinin levels.

5.2 Pharmacokinetic properties

The extent of absorption after oral administration is about 30-60 %. The plasma half-life of ramiprilat after multiple once daily administration of ramipril is 13 to 17 hours for 5-10 mg ramipril and several times longer for lower doses such as 1,25 mg to 2,5 mg ramipril, which is increased in renal impairment. The time to achieve peak serum concentration is 1 hour. RAMIPRIL AUSTELL is renally eliminated and excreted 100 % unchanged in the urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule contents:

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

Capsule shell:

RAMIPRIL1,25 mg AUSTELL : Ferric oxide yellow (E172), gelatin, methyl paraben, propyl paraben, titanium dioxide (E171).

RAMIPRIL 2,5 mg : 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).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store in a dry place at or below 25 °C. Protect from light.

Keep blister packs in carton until required for use.

KEEP OUT OF REACH OF CHILDREN

6.5 Nature and contents of container

RAMIPRIL1,25 mg AUSTELL :

Blister pack (Clear PVDC coated PVC film and Aluminium foil) of 2 blister strips, each containing 14 capsules and 3 blister strips, each containing 10 capsules.

RAMIPRIL 2,5 mg AUSTELL:

Blister pack (Clear PVDC coated PVC film and Aluminium foil) of 2 blister strips, each containing 14 capsules and 3 blister strips, each containing 10 capsules.

RAMIPRIL 5 mg AUSTELL :

Blister pack (Clear PVDC coated PVC film and Aluminium foil) of 2 blister strips, each containing 14 capsules and 3 blister strips, each containing 10 capsules.

RAMIPRIL 10 mg AUSTELL :

Blister pack (Clear PVDC coated PVC film and Aluminium foil) of 2 blister strips, each containing 14 capsules and 3 blister strips, each containing 10 capsules.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Autell Pharmaceuticals (Pty) Ltd.
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8. REGISTRATION NUMBER(S)

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

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

29 July 2005

10. DATE OF REVISION OF THE TEXT

27 January 2021