Approved Patient Information Leaflet for Medicines for Human Use:

AUSTELL LISINOPRIL

SCHEDULING STATUS: S3

AUSTELL LISINOPRIL 2,5 mg tablets

AUSTELL LISINOPRIL 5 mg tablets

AUSTELL LISINOPRIL 10 mg tablets

AUSTELL LISINOPRIL 20 mg tablets

Lisinopril

Sugar free

Contains excipient: mannitol 36 mg per tablet.

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- AUSTELL LISINOPRIL 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 AUSTELL LISINOPRIL is and what it is used for
2. What you need to know before you take AUSTELL LISINOPRIL
3. How to take AUSTELL LISINOPRIL
4. Possible side effects
5. How to store AUSTELL LISINOPRIL
6. Contents of the pack and other information

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

AUSTELL LISINOPRIL contains the active substance called lisinopril which belongs to the group of medicines called ACE inhibitors (Angiotensin Converting Enzyme inhibitors).

AUSTELL LISINOPRIL works by widening your blood vessels, which helps reduce your blood pressure and makes it easier for your heart to pump blood to all parts of your body.

AUSTELL LISINOPRIL is used for:

- treatment of high blood pressure (hypertension) that is mild or moderate. It can be used together with other medications to treat your high blood pressure
- management of a heart condition called congestive heart failure when your heart does not pump blood around your body as well as it is needed
- treatment after you have had a heart attack (myocardial infarction) to prevent heart failure.

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

Do not take AUSTELL LISINOPRIL

- if you are hypersensitive (allergic) to lisinopril or other ACE inhibitors (such as captopril, ramipril) or any of the other ingredients of AUSTELL LISINOPRIL (listed in section 6).
- if you have previously been treated with a medicine in the same group as AUSTELL LISINOPRIL (ACE Inhibitors or angiotension receptor blockers) and have had allergic reactions with itching, hives, sudden fall in blood pressure, swelling of the hands, feet or ankles, the face, lips, tongue and/or throat with difficulty in swallowing or breathing or if you or a member of your family have had a similar reaction.
- If you have a condition known as bilateral renal artery stenosis or stenosis in the presence of a single kidney. This is a narrowing of the kidney arteries supplying blood to the kidney/s leading to a reduced blood flow, resulting in impaired kidney function and high blood pressure.
- if you have any of the following heart diseases: heart failure, narrowing (stenosis) of the opening of the aortic or mitral valve or enlarged heart (hypertrophic cardiomyopathy).
- if you have reduced kidney function, narrowing of the arteries supplying the kidneys or

renovascular hypertension (high blood pressure).

- 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 AUSTELL LISINOPRIL.
- if you are pregnant, trying to fall pregnant, or are breastfeeding.
- If you have porphyria
- if you are taking the following medicines:
  - lithium – medicines used for depression and mental conditions
  - aliskiren – medicine used to lower blood pressure
  - potassium sparing diuretics e.g. spironolactone, triamterene, amiloride.
- if you have taken or are currently taking sacubitril/valsartan, a medicine used to treat a type of long-term (chronic) heart failure in adults, as the risk of angioedema (rapid swelling under the skin in an area such as the throat) is increased.

Warnings and precautions

Should a woman become pregnant while receiving an ACE-inhibitor, the treatment must be stopped promptly and changed to a different medicine. (see pregnancy and breastfeeding)

Take special care with AUSTELL LISINOPRIL

Talk to your doctor, pharmacist or other healthcare provider:

- if you have kidney problems or are having dialysis
- if you have liver problems
- if you have heart problems
- if you have low blood pressure (you may notice this as faintness or dizziness, especially when standing
- if you have high levels of potassium in your body
- suffered from any diarrhoea or vomiting, have taken any water tablets (diuretics) or decreased the

amount of salt that you eat in your food

- if you have problems with your blood vessels (collagen vascular disease)
- if you are diabetic
- 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 an ACE inhibitor as it may cause or aggravate kidney problems
- if you are of black origin as AUSTELL LISINOPRIL may be less effective. You may also more readily get the side effect 'angioedema' (a severe allergic reaction)
- are undergoing any surgery where an anaesthetic is being used
- are undergoing/or will undergo desensitisation treatment for an allergy, for example to insect stings. The desensitisation treatment reduces the effects of the allergy (e.g. bee or wasp stings) but sometimes it can cause a more severe allergic reaction if you are taking AUSTELL LISINOPRIL during the desensitisation treatment
- if you have high levels of cholesterol and you are having a treatment called 'LDL apheresis'
- if you are taking any of the following medicines, the risk of angioedema (rapid swelling under the skin in area such as the throat) is increased:
    - temsirolimus, sirolimus, everolimus and other medicines belonging to the class of mTOR inhibitors (used to avoid rejection of transplanted organs and for cancer)
    - racecadotril, a medicine used to treat diarrhoea
    - vildagliptin, a medicine used to treat diabetes.
- if you are taking an angiotensin II receptor blocker (ARBs) (also known as sartans – for example valsartan, telmisartan, irbesartan), which are used to treat high blood pressure in particular if you have diabetes-related kidney problems.

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

Children

Safety and efficacy in children have not been established.

Other medicines and AUSTELL LISINOPRIL

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

- Other medicines for your high blood pressure (antihypertensives) including an angiotensin II receptor blocker (ARB) or aliskiren (see “Do not take AUSTELL LISINOPRIL”)
- Diuretics (water tablets) – cause a large drop in blood pressure. Dosage adjustments may be necessary during concurrent use or when one medicine is discontinued.
- Indomethacin and non-steroidal anti-inflammatory drugs (NSAIDs – pain killer and anti-inflammatory medicine) including aspirin – may reduce the blood pressure lowering effect of AUSTELL LISINOPRIL.
- Potassium supplements – sparing diuretics (e.g. spironolactone, triamterene or amiloride), potassium salts or any other medicines that can increase levels of potassium in the blood (such as heparin, a medicine used to thin blood to prevent clot; trimethoprim and co-trimoxazole for infections caused by bacteria; ciclosporin, an immunosuppressant medicine used to prevent organ transplant rejection)
- Lithium (used to treat depression) – when taken with AUSTELL LISINOPRIL an increase of lithium levels may occur (see “Do not take AUSTELL LISINOPRIL”).
- Fluoroquinolone antibiotics (medicines used to treat infections) such as moxifloxacin or levofloxacin (see “Do not take AUSTELL LISINOPRIL”)
- Medicines to suppress the body’s immune response (immunosuppressants)
- Medicines that contain gold, such as sodium aurothiomalate, which may be given to you as an injection.
- Nitrate medicines (for heart problems)
- Medicines for diabetes, including insulin. Your dose of anti-diabetic may need to be changed.
- Beta-blocker medicines, such as atenolol and propranolol.

The following medicines may increase the risk of angioedema (signs of angioedema include swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing):

- medicines to break up blood clots (tissue plasminogen activator), usually given in hospital
- medicines which are most often used to avoid rejection of transplanted organs (temsirolimus, sirolimus, everolimus and other medicines belonging to the class of mTOR inhibitors). See section 2 - “Warnings and precautions”
- racecadotril used to treat diarrhoea
- vildagliptin, a medicine used to treat diabetes
- sacubitril/valsartan, a medicine used to treat a type of long-term (chronic) heart failure in adults (see “Do not take AUSTELL LISINOPRIL”).

AUSTELL LISINOPRIL with food and drink

Tablets may be taken before, during or after meals.

Pregnancy and lactation: breastfeeding

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 AUSTELL LISINOPRIL.

You must not take AUSTELL LISINOPRIL if you are pregnant or breastfeeding.
If you become pregnant while using AUSTELL LISINOPRIL, then you must inform your doctor so that he can prescribe an alternative medicine to control your high blood pressure.
You must advise your doctor if you are planning to become pregnant, so that an alternative high blood pressure medicine can be prescribed for you.
Exposure of your unborn baby to AUSTELL LISINOPRIL during the first trimester of pregnancy may lead to defects of the heart, brain or kidneys.
It may also cause a disturbance in your unborn baby’s blood pressure.

The following has been observed in newborn babies when AUSTELL LISINOPRIL was given to pregnant women during the second and third trimester: low blood pressure, kidney problems (the kidneys produce little to no urine), skull defects and low birth mass.

Driving and using machines

AUSTELL-LISINOPRIL may cause tiredness, dizziness or confusion which may affect your ability to drive or operate machinery.

AUSTELL LISINOPRIL contains mannitol

Contains mannitol and may have a laxative effect.

3. How to take AUSTELL LISINOPRIL

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

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

Mild to Moderate Hypertension:

Adults: Initial dose is 10 mg per day given as a single dose. The dose should be adjusted according to the blood pressure response. The usual effective maintenance dose is 20 mg per day given as a single dose with a maximum of 40 mg per day.

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.

Congestive Heart Failure:

Adults: Initial dose is 2,5 mg per day as a single dose.

This may be increased at intervals of no less than 2 weeks until the therapeutic effect is reached up to a max dose of 35 mg once daily. Adjustments should be based on clinical response. Maintenance dosing range is 5 to 20 mg per day administered as a single dose.

Acute Myocardial Infarction:

Adults: 5 mg within 24 hours of the onset of an acute myocardial infarction, followed by 5 mg after 24 hours of the first dose, 10 mg after 48 hours of the first dose and then 10 mg per day for six weeks.
In patients with low systolic blood pressure (less than or equal to 120 mm Hg), an initial dose of 2,5 mg should be used during the first three days after the infarction.
If hypotension occurs (systolic blood pressure less than or equal to 100 mm Hg), a daily maintenance dose of 5 mg may be given with temporary reductions to 2,5 mg if needed. If prolonged hypotension occurs (systolic blood pressure less than 90 mm Hg for more than 1 hour), AUSTELL LISINOPRIL should be withdrawn.

Dosing in high-risk individuals:

Diuretic-treated patients:

In order to minimise the possibility of sudden and severe hypotension which may occur within the first 1 to 5 hours after the initial dose of AUSTELL LISINOPRIL, diuretics should be discontinued 2 to 3 days before beginning therapy with AUSTELL LISINOPRIL. In patients where diuretic therapy cannot be discontinued, treatment with AUSTELL LISINOPRIL should be initiated with a 5 mg dose. Subsequent dosage adjustments will depend on the therapeutic response. If required, diuretic therapy may be resumed.

Renal Impairment:

A lower dose is required. If creatinine clearance is 31 – 70 mL/min the starting dose is 5 mg to 10 mg per day.

The dose may be increased as needed according to therapeutic response to a maximum of 20 mg/day.

Renovascular hypertension:

Dose should be lowered to 2,5 mg or 5 mg and the patient should be monitored.

Method of administration

AUSTELL LISINOPRIL is not affected by the presence of food and may be taken with or without meals.

AUSTELL LISINOPRIL should be administered as a single daily dose at approximately the same time every day.

If you take more AUSTELL LISINOPRIL than you should

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

If you forget to take AUSTELL LISINOPRIL

Take the next dose as usual.

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

4. Possible side effects

AUSTELL LISINOPRIL can have side effects.

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

If any of the following happens, stop taking AUSTELL LISINOPRIL 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 or itching
- an infection with symptoms such as fever and serious deterioration of your general condition, or fever with local infection symptoms such as sore throat/pharynx/mouth or urinary problems

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

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

- blood disorders including bone marrow problems and anaemia
- yellowing of the skin or eyes (jaundice), hepatitis (inflammation of liver), liver failure.

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
- feeling dizzy or light-headed, especially if you stand up quickly
- tiredness
- nausea (feeling sick)
- vomiting (being sick)
- diarrhoea
- a dry cough that does not go away
- kidney problem including kidney failure.

Less frequent side effects:

- too little sodium in the blood
- too much potassium in the blood
- low levels of sugar in your blood (hypoglycaemia)
- mental confusion
- mood changes
- numbness or tingling in your fingers or toes
- hallucinations
- changes in the way things smell

- spinning feeling (vertigo)
- sleep disorders
- heart attack
- stroke
- an excessive drop in blood pressure may be experienced in patients with coronary heart disease, or those with a narrowing of the aorta, the kidney artery or the heart valves, or those patients with an increase in the thickness of the heart muscle
- fast heartbeat
- change of colour in your fingers or toes (pale blue followed by redness)
- blocked or runny nose (sinusitis)
- inflammation of the lungs. The signs include cough, feeling short of breath and high temperature (fever)
- stomach pain
- indigestion
- dry mouth
- inflammation of the pancreas - this causes moderate to severe pain in the stomach
- taste disturbances
- rash
- itching (pruritis)
- hair loss
- psoriasis (skin disease with raised rough scaly areas)
- sweating
- severe skin disorder including serious blistering skin disease, irregular red patches on the skin (erythema multiforme), blisters or ulcers (Steven-Johnson syndrome)
- pain and tenderness in the skin area
- muscle pain, joint pain / inflammation (arthritis/arthralgia)
- weakness (asthenia)

- passing less urine than usual (oliguria)
- sexual dysfunction (impotence)
- development of breasts in men.

The following side-effects can also occur with AUSTELL LISINOPRIL, and they are seen when a blood test is taken:

- decrease in the number of platelets in the blood
- decrease in the amount of white blood cells and volume of red blood cells
- decrease in the quantity of oxygen-carrying pigment, haemoglobin, in the blood
- increases in the amount of liver enzymes, blood urea, serum creatinine and breakdown products of red blood cell.

Side effects with frequency unknown:

- depressive symptoms
- syncope (fainting)

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 via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of AUSTELL LISINOPRIL.

Suspected side effects can also be reported directly to the Holder of the Certificate of Registration via medsafety@austell.co.za

5. How to store AUSTELL LISINOPRIL

- Store all medicines out of reach of children.
- Store at or below 25 °C. Protect from light.
- Keep the blister packs in the outer carton until required for use.
- Do not transfer the medicine to any other container. Keep the HDPE container well closed.
- Return all unused medicines to your pharmacist.
- Do not dispose unused medicines in drains and sewerage system (e.g. toilets).
- Do not use after the date which is stamped on the pack.

6. Contents of the pack and other information

What AUSTELL LISINOPRIL contains

- The active substance is lisinopril.
- The other ingredients are calcium hydrogen phosphate, mannitol, maize starch, maize starch (~~for~~ paste), maize starch (dried) and magnesium stearate.
- 5 mg, 10 mg and 20 mg also contain ferric oxide (EEC. No. 172).

AUSTELL LISINOPRIL 2,5 mg tablet

Each tablet contains lisinopril dihydrate equivalent to 2,5 mg lisinopril.

AUSTELL LISINOPRIL 5 mg tablet

Each tablet contains lisinopril dihydrate equivalent to 5 mg lisinopril.

AUSTELL LISINOPRIL 10 mg tablet

Each tablet contains lisinopril dihydrate equivalent to 10 mg lisinopril.

AUSTELL LISINOPRIL 20 mg tablet

Each tablet contains lisinopril dihydrate equivalent to 20 mg lisinopril.

What AUSTELL LISINOPRIL looks like and contents of the pack

AUSTELL LISINOPRIL 2,5 mg:

White to almost white circular biconvex uncoated tablets with “2.5” embossing on one side and “BL” embossing on the other side.

AUSTELL LISINOPRIL 5 mg:

Light pink coloured circular biconvex uncoated tablets with “5” embossed and break line on one side, and “BL” embossed on the other side.

AUSTELL LISINOPRIL 10 mg:

Light pink circular biconvex uncoated tablets with “10” embossed on one side and “BL” embossed on the other side.

AUSTELL LISINOPRIL 20 mg:

Pink circular biconvex uncoated tablets with “20” embossed on one side and “BL” embossed on the other side.

PRESENTATION

AUSTELL LISINOPRIL 2,5 mg: is supplied in blister packs (Clear PVC film, Printed Aluminium foil) of 2 x 14 and 3 x 10 tablets.

Bulk packs (HDPE jars) of 30 and 60 tablets.

AUSTELL LISINOPRIL 5 mg: is supplied in blister packs (Clear PVC film, Printed Aluminium foil) of 2 x 14 and 3 x 10 tablets.

Bulk packs (HDPE jars) of 30 and 60 tablets.

AUSTELL LISINOPRIL 10 mg: is supplied in blister pack (Clear PVC film, Printed Aluminium foil) of 2 x 14 and 3 x 10 tablets.

Bulk pack (HDPE jars) of 30 and 60 tablets.

AUSTELL LISINOPRIL 20 mg: is supplied in blister pack (Clear PVC film, Printed Aluminium foil) of 2 x 14 and 3 x 10 tablets.

Bulk pack (HDPE jars) of 30 and 60 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Austell Pharmaceuticals (Pty) Ltd

1 Sherborne Road

Parktown

Johannesburg, 2193

Tel: +27 11 611 1400 or +27 860 287 835

This leaflet was last revised in

16 May 2025

Registration numbers

AUSTELL LISINOPRIL 2,5 mg: 37/7.1.3/0391

AUSTELL LISINOPRIL 5 mg: 38/7.1.3/0033

AUSTELL LISINOPRIL 10 mg: 38/7.1.3/0032

AUSTELL LISINOPRIL 20 mg: 37/7.1.3/0392

Access to the corresponding Professional Information and Afrikaans Patient Information Leaflet

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

Austell Pharmaceuticals (Pty) Ltd

Tel: +27 11 611 1400 or +27 860 287 835