Approved Patient Information Leaflet for Medicines for Human Use:

[PRODUCT NAME]

SCHEDULING STATUS: S3

[PRODUCT NAME] 25 25 mg TABLETS

[PRODUCT NAME] 50 50 mg TABLETS

[PRODUCT NAME] 100 100 mg TABLETS

Losartan potassium

Sugar free

Read all of this leaflet carefully before you start taking [PRODUCT NAME]

- 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.
- [PRODUCT NAME] 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 [PRODUCT NAME] is and what it is used for

2. What you need to know before you take [PRODUCT NAME]

3. How to take [PRODUCT NAME]

4. Possible side effects

5. How to store [PRODUCT NAME]

6. Contents of the pack and other information

1. What [PRODUCT NAME] is and what it is used for

Losartan, the active ingredient of [PRODUCT NAME], belongs to a group of medicines known as angiotensin-II receptor antagonists. Angiotensin-II is a substance produced in the body which binds to receptors in blood vessels, causing them to tighten. This results in an increase in blood pressure. Losartan prevents the binding of angiotensin-II to these receptors, causing the blood vessels to relax which in turn lowers the blood pressure. Losartan slows the decrease of kidney function in patients with high blood pressure and type 2 diabetes.

[PRODUCT NAME] tablets are indicated for:

- the treatment of hypertension (high blood pressure)
- to protect the kidney in hypertensive type 2 diabetic patients with laboratory evidence of impaired renal function and proteinuria ≥ 0,5 g per day (a condition in which urine contains an abnormal amount of protein).

2. What you need to know before you take [PRODUCT NAME]

Do not take [PRODUCT NAME]:

- if you are hypersensitive (allergic) to losartan potassium or any of the other ingredients of [PRODUCT NAME] (listed in section 6).
- if you have a history of angio-oedema (an area of swelling of the lower layer of skin and tissue just under the skin or mucous membranes) related to ACE-inhibitors or angiotensin receptor antagonists such as [PRODUCT NAME]
- if you have hypertrophic obstructive cardiomyopathy (a disease where the heart muscle thickens) or other heart problems
- [PRODUCT NAME] is not recommended for patients with severe renal impairment or for patients with hepatic impairment

- concomitant therapy with potassium sparing diuretics such as spironolactone, triamterene and amiloride
- if you are pregnant or a nursing mother
- if you are planning to become pregnant
- 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 [PRODUCT NAME].

Warnings and precautions

Take special care with [PRODUCT NAME]:

- if you suffer from liver or kidney problems
- if you have a condition known as ‘aortic stenosis’ or ‘outflow obstruction’
- if you have recently suffered from excessive vomiting or diarrhoea
- if you know you have high levels of potassium in your blood (hyperkalaemia) or you are on a low potassium diet
- 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 [PRODUCT NAME] as it may cause or aggravate kidney problems (see “Do not take [PRODUCT NAME]”).

If you are pregnant or breastfeeding your baby while taking [PRODUCT NAME], please consult your doctor, pharmacist or health care professional for advice

Children

The safety and efficacy of [PRODUCT NAME] in children have not yet been established.

Other medicines and [PRODUCT NAME]

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

If you are taking other medicines on a regular basis, concomitant use of [PRODUCT NAME] tablets may cause undesirable interactions.

Please consult your doctor or a pharmacist if you are taking any of the following:

Non-steroidal anti-inflammatory drugs (NSAIDs)

NSAIDs (medicines that reduce inflammation and can be used to help relieve pain) may reduce the blood pressure lowering effect of [PRODUCT NAME].

Sympathomimetic medicines

Concurrent use with sympathomimetic medicines may reduce the blood pressure lowering effects of [PRODUCT NAME]. Sympathomimetic medicines include a large variety of medicines i.e., some of the active ingredients in cold and flu preparations, some heart medicines, medicines used to treat glaucoma, etc.

Potassium sparing diuretics

Potassium-sparing diuretics, potassium containing medication or potassium supplements used concurrently with [PRODUCT NAME] may result in hyperkalaemia (elevation of serum potassium).

Other angiotensin II receptor antagonists

Concomitant use of other blood pressure lowering medicines should be used with caution since the blood pressure may be lowered too much.

Fluoroquinolones

Fluoroquinolone antibiotics (medicines used to treat infections) such as moxifloxacin or levofloxacin.

Concomitant use of fluoroquinolones and ACE inhibitors, such as [PRODUCT NAME], may cause kidney damage.

Lithium

Lithium (a medicine used to treat a certain kind of depression) excretion may be reduced. Therefore, the lithium levels in your blood should be monitored by your doctor.

[PRODUCT NAME] with food and drink

Refer to section 3. “How to take [PRODUCT NAME]”.

Pregnancy and, breastfeeding and fertility

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 [PRODUCT NAME].

[PRODUCT NAME] may not be used during pregnancy or breastfeeding (see section 2. “Do not take [PRODUCT NAME”.

Women of childbearing age should ensure adequate contraception.

Driving and using machines

Medicines that are used to treat high blood pressure such as losartan, the active ingredient in [PRODUCT NAME], cause some patients to experience dizziness or drowsiness when starting or altering treatment. It is not always possible to predict to what extent [PRODUCT NAME] may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which [PRODUCT NAME] affects them.

3. How to take [PRODUCT NAME]

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

Always take use [PRODUCT NAME] exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

Adult patients with high blood pressure

The usual starting and maintenance dose is 50 mg once daily for most patients. The maximum blood pressure lowering effect is achieved 3-6 weeks aftertreatment was started. In some patients the dose may be required to be increased to 100 mg once daily.

Adult patients with high blood pressure and Type 2 diabetes

The usual starting dose is 50 mg once daily. The dose may be increased to 100 mg once daily based on your blood pressure response.

Dosage in special patient groups

In certain patients such as those over 75 years of age or those with kidney or liver problems, the doctor may prescribe a lower dose of 25 mg once a day.

Duration of administration

Your doctor will tell you how long your treatment with [PRODUCT NAME] will last. Do not stop treatment early because your blood pressure may increase again. If you have the impression that the effect of [PRODUCT NAME] is too strong or too weak, tell your doctor or pharmacist.

Method of administration

[PRODUCT NAME] should be taken by mouth with or without food.

It is recommended that you take your tablet at the time each day.

If you take more [PRODUCT NAME] than you should

The symptoms of an overdosage of [PRODUCT NAME] would be hypotension and fast or irregular heart rate.

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 [PRODUCT NAME]

If you accidentally miss a daily dose, just take the next dose as normal. Do not take a double dose to make up for forgotten individual doses.

If you stop taking [PRODUCT NAME]

Your blood pressure may gradually rise again if treatment is stopped and no medicine is taken for high blood pressure.

4. Possible side effects

[PRODUCT NAME] can have side effects.

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

If any of the following happens, stop taking [PRODUCT NAME] 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

- fainting.

These are very serious side effects. If you have them, you may have had a serious reaction to [PRODUCT NAME]. 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:

- chest pain
- changes in the way your heart beats, for example, if you notice it beating faster
- difficulty breathing
- signs of recurrent infections such as fever or sore throat
- less urine than is normal for you
- yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems.

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:

- insomnia (sleeplessness)
- headache, dizziness
- cough, nasal congestion, sinus disorder.

Less frequent side effects:

- low blood platelet count
- orthostatic (low blood pressure – you may be feeling dizzy when standing upright from a sitting position)
- diarrhoea, indigestion/heartburn, nausea, abdominal pain
- back pain, muscle cramps, leg pain, muscle pain

- feeling of body fatigue or tiredness
- high blood potassium levels and altered liver enzymes.

Side effects with frequency unknown:

- low blood counts
- migraine
- taste disturbances, vomiting
- skin rash due to sensitivity to sunlight
- joint stiffness
- erectile dysfunction

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. 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 [PRODUCT NAME]**.**

5. How to store [PRODUCT NAME]

Store in a dry place at or below 25 ºC.

Protect from light, heat and moisture.

Keep blister packs in carton until required for use.

KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN.

Return all unused medicines to your pharmacist.

Do not dispose of unused medicines in drains or sewerage system (e.g toilets).

6. Contents of the pack and other information

What [PRODUCT NAME] contains

- The active ingredient is losartan potassium.
- The other ingredients are: colloidal anhydrous silica, magnesium stearate, maize starch (dried), microcrystalline cellulose (Avicel PH200), purified talc, sodium starch glycollate.
- Film coating: hypromellose (15 cps), macrogol 6000, purified talc and titanium dioxide (C.I No. 77891).

What [PRODUCT NAME] looks like and contents of the pack

[PRODUCT NAME] 25:

White to off white, oval, biconvex film-coated tablets with “25” debossing on one side and “BL” on the other side.

[PRODUCT NAME] 50:

White to off white, oval, biconvex film-coated tablets with “50” debossing on one side and “BL” on the other side.

[PRODUCT NAME] 100:

White to off white, almond shaped, biconvex film-coated tablets with “100” debossing on one side and “BL” on the other side.

[PRODUCT NAME] 25:

Blister pack (White Opaque PVC film and Aluminium foil) of 2 x 14 and 3 x 10 tablets.

[PRODUCT NAME] 50:

Blister pack (White Opaque PVC film and Aluminium foil) of 2 x 14 and 3 x 10 tablets.

[PRODUCT NAME] 100:

Blister pack (White Opaque PVC film and Aluminium foil) of 2 x 14 and 3 x 10 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Austell Pharmaceuticals (Pty) Ltd

1 Sherborne Rd

Parktown

JOHANNESBURG

2193

South Africa

Tel: 0860287835

www.austell.co.za

This leaflet was last revised in

09 November 2022

Registration numbers

AUSTELL LOSARTAN 25 mg: 41/7.1.3/0496

AUSTELL LOSARTAN 50 mg: 41/7.1.3/0497

AUSTELL LOSARTAN 100 mg: 41/7.1.3/0498

LORTELL 25 mg: 41/7.1.3/0502

LORTELL 50 mg: 41/7.1.3/0503

LORTELL 100 mg: 41/7.1.3/0517

Access to the corresponding Professional Information

Professional Information 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