Austell Pharmaceuticals (Pty) Ltd, 370391-91; 380031-32 Austell Lisinopril Tablets 2,5, 5, 10, 20 mg

Patient Information Leaflet for Medicines for Human Use:

SCHEDULING STATUS

S3

PROPRIETARY NAME AND DOSAGE FORM

AUSTELL-LISINOPRIL 2,5 mg TABLETS

AUSTELL-LISINOPRIL 5 mg TABLETS

AUSTELL-LISINOPRIL 10 mg TABLETS

AUSTELL-LISINOPRIL 20 mg TABLETS

THE COMPOSITION OF AUSTELL-LISINOPRIL

Each tablet contains the active ingredient lisinopril dihydrate equivalent to lisinopril 2,5 mg, 5 mg, 10 mg or 20 mg.

The inactive ingredients are: Calcium hydrogen phosphate, mannitol, maize starch, ferric oxide (EEC. No. 172), maize starch (for paste), purified water, maize starch (dried) and magnesium stearate.

INSTRUCTIONS BEFORE TAKING AUSTELL-LISINOPRIL

Do not take **AUSTELL-LISINOPRIL** if you:

- Are sensitive to or allergic to lisinopril or other ACE inhibitors (such as captopril, ramipril) or any of the other ingredients in the tablets,
- Or any of your family have experienced allergic symptoms,

- Have reduced blood flow to the heart (aortic stenosis),
- 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),
- 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**.

Warnings:

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 LACTATION)

Talk to your doctor or pharmacist if you are suffering from the following:

- Kidney problems or are having dialysis.
- Liver problems.
- Heart problems.
- Low blood pressure (you may notice this as faintness or dizziness, especially when standing.
- High levels of potassium in your body.
- 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 **AUSTELL ENALAPRIL** as it may cause or aggravate kidney problems (see Do not take AUSTELL LISINOPRIL);

Interactions:

Talk to your doctor if you are taking the following medication:

- 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.
- Lithium (used to treat depression) – when taken with **AUSTELL-LISINOPRIL** an increase of lithium levels may occur. Frequent monitoring of lithium levels in blood is necessary.
- Fluoroquinolone antibiotics (medicines used to treat infections) such as moxifloxacin or levofloxacin

Pregnancy and lactation:

If you are pregnant or breastfeeding your baby while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

AUSTELL-LISINOPRIL is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Driving and using machines:

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

INSTRUCTIONS ON HOW TO TAKE AUSTELL-LISINOPRIL

AUSTELL-LISINOPRIL tablets may be taken with or without meals, preferably at the same time each day.

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 4 weeks until the therapeutic effect is reached. 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 mmHg 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.

AUSTELL-LISINOPRIL is not affected by the presence of food.

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

SIDE EFFECTS

All medicines may cause unwanted effects. Check with your doctor, pharmacist or healthcare professional if any of these unwanted effects persist or become bothersome. Do not be alarmed by the list below, you may not get any of them.

Tell your doctor straight away if you notice any of the following:

- Blood disorders including bone marrow problems and anaemia.
- Tiredness, nausea (feeling sick), vomiting (being sick), yellowing of the skin or eyes (jaundice), hepatitis (inflammation of liver), liver failure and stomach pain.

The following side effects occur frequently:

Headache, dizziness, diarrhea, vomiting, kidney problem including kidney failure.

The following side effects occur less frequently:

Mood changes, sleep disorders, increase in blood urea, taste disturbances, itching (pruritis), sexual dysfunction (impotence), weakness (asthenia) and rash.

The following side effects can also occur:

Shortness of breath, sever skin disorder including serious blistering skin disease, irregular red patches on the skin (erythema multiforme), blisters or ulcers (Steven-Johnson syndrome), muscle pain, joint pain / inflammation (arthritis/arthralgia), passing less urine than usual (oliguria), indigestion, dry mouth, mental confusion, pain and tenderness in the skin area, blocked or runny nose (sinusitis).

Not all side-effects reported for **AUSTELL-LISINOPRIL** are included in this leaflet. Should your general health worsen while taking **AUSTELL-LISINOPRIL**, please consult your doctor, pharmacist or other health care professional for advice.

STORAGE AND DISPOSAL INFORMATION

Keep this medicine below 25 ºC. Protect from light.

Keep the blister packs in the 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.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

PRESENTATION

AUSTELL–LISINOPRIL 2,5 mg:

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:

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:

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:

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.

IDENTIFICATION OF AUSTELL-LISINOPRIL

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 breakline 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.

REGISTRATION NUMBER

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

THE DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET

18 April 2008