PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

LIZRO 5 mg (Tablet)

LIZRO 10 mg (Tablet)

LIZRO 20 mg (Tablet)

Lisinopril Dihydrate.

Read all of this leaflet carefully before you start taking LIZRO

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

1. WHAT LIZRO CONTAINS

The active substance is lisinopril dihydrate.

- **LIZRO 5 mg:** Each tablet contains 5,44 mg lisinopril dihydrate equivalent to anhydrous lisinopril 5 mg.
- **LIZRO 10 mg**: Each tablet contains 10,87 mg lisinopril dihydrate equivalent to anhydrous lisinopril 10 mg.
- **LIZRO 20 mg**: Each tablet contains 21,74 mg lisinopril dihydrate equivalent to anhydrous lisinopril 20 mg.

The other ingredients are calcium hydrogen phosphate anhydrous; ferric oxide yellow; magnesium stearate; maize starch; mannitol and starch pregelatinised.

2. WHAT LIZRO IS USED FOR

LIZRO is used for the treatment of:

- Mild to moderate hypertension – alone or in combination with other antihypertensives.
- Congestive heart failure – as adjunctive therapy with diuretics and where appropriate, digitalis.
- Acute myocardial infarction – **LIZRO** administered with 24 hours to haemodynamically stable patients reduces the risk of left ventricular dysfunction or heart failure.

3. BEFORE YOU TAKE LIZRO

Do not take LIZRO:

- If you are sensitive to any of the components of **LIZRO**.
- If you have a history of angioedema related to previous ACE-inhibitor therapy or angiotensin receptor blocker. You should never take these medicines again.
- If you suffer from hereditary or idiopathic angioedema.
- If you suffer from aortic stenosis.
- If you suffer from hypertrophic obstructive cardiomyopathy.
- If you suffer from moderate to severe kidney function impairment (creatinine clearance below 30 ml/min).
- If you suffer from kidney artery stenosis of both kidneys.
- If you suffer from kidney artery stenosis with a single kidney.
- If you are using spironolactone, triamterene, amiloride.
- If you suffer from porphyria.
- If you are using thiazide diuretics and have Addison's disease you should not take **LIZRO** in combination with thiazide diuretics. This therapy is also contraindicated in patients with severe renal impairment or anuria, and in patients who show hypersensitivity to other sulphonamide-derived medicines.
- If you are using lithium. Concomitant use of lithium with **LIZRO** may lead to toxic blood concentrations of lithium.
- If you are pregnant or breastfeeding.

Take special care with LIZRO:

If you are contemplating pregnancy. **LIZRO** should not be used during pregnancy or breastfeeding. Your doctor will prescribe you a different class of medicine if you are planning to fall pregnant.

LIZRO should be used with caution in the following conditions:

- Heart disease.
- Volume depleted patients (e.g. diuretic therapy, dietary salt restriction, dialysis, diarrhoea or vomiting).
- Patient 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 **LIZRO**. Monitoring is required after initiating therapy.
- Severe autoimmune disease, especially systemic lupus erythematosus, other collagen vascular disease or scleroderma: Increase the risk for development of neutropenia or agranulocytosis.
- In acute myocardial infarction (heart attack), treatment with **LIZRO** should not be initiated in patients with evidence of kidney dysfunction. If kidney dysfunction develops during treatment then **LIZRO** may need to be withdrawn.
- In acute myocardial infarction (heart attack), patients may develop persistent low blood pressure and/or impaired kidney function.
- Bone marrow depression – Increased risk of agranulocytosis and neutropenia.
- Diabetes mellitus – Increased risk of hyperkalaemia, as well as hypoglycaemia may occur.
- Hyperkalaemia – **LIZRO** may cause an increase in serum potassium levels.
- Kidney problems/diseases.
- 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 **LIZRO**, **LIZRO** should be discontinued promptly.

- 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. These patients should never receive any **LIZRO** again.
- **LIZRO** causes a higher rate of angioedema in black patients than in non-black patients.
- Porphyria: Use with caution.
- Safety and efficacy in children has 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, dysrhythmias and cardiac arrest.

Taking LIZRO with food and drink:

LIZRO tablets may be taken with/without meals preferably at the same time every day.

Pregnancy and Breastfeeding:

Safety during pregnancy and lactation has not been established.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **LIZRO**.

Important information about some of the ingredients of LIZRO:

LIZRO contains sugar (i.e. mannitol).

Taking other medicines with LIZRO:

LIZRO interacts with diuretics (e.g. spironolactone, triamterene or amiloride), alcohol, indomethacin and lithium.

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

4. HOW TO TAKE LIZRO

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

Always take **LIZRO** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **LIZRO** is too strong or too weak, talk to your doctor or pharmacist.

May be taken with/without meals preferably at the same time every 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 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 mg 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 mmHg), 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 mmHg), a daily maintenance dose of 5 mg may be given with temporary reductions of 2,5 mg if needed. If prolonged hypotension occurs (systolic blood pressure less than 90 mmHg for more than 1 hour) **LIZRO** should be withdrawn.

LIZRO is compatible with intravenous or transdermal glyceryl trinitrate.

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 **LIZRO**, diuretics should be discontinued 2 to 3 days before beginning therapy with **LIZRO**. In patients where diuretic therapy cannot be discontinued, treatment with **LIZRO** 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 ml - 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 per day.

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

LIZRO is not affected by the presence of food. **LIZRO** should be administered as a single daily dose at approximately the same time every day.

If you take more LIZRO than you should:

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

Treatment of overdose: Please consult your doctor or pharmacist.

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

If you forget to take LIZRO:

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

5. POSSIBLE SIDE EFFECTS

LIZRO can have side effects.

Blood and the lymphatic system disorders:

The following side effects have been reported but the frequencies are unknown: Decreases in white blood cell count, haemoglobin and haematocrit, bone marrow depression, anaemia, thrombocytopenia, agranulocytosis.

Less frequent: Haemolytic anaemia.

Cardiac disorders:

Less frequent: Orthostatic effects including hypotension.

The following side effects have been reported but the frequencies are unknown: Myocardial infarction, cerebrovascular accident, palpitations, tachycardia.

Nervous system disorders:

Frequent: Dizziness, headache, fatigue.

The following side effects have been reported but the frequencies are unknown: Mood alterations, mental confusion, paraesthesia, vertigo, sleep disturbances.

Endocrine disorders:

Less frequent: Hyperkalaemia.

The following side effects have been reported but the frequencies are unknown: Hyponatraemia, increases in blood urea, increases in serum creatinine.

Gastrointestinal disorders:

Frequent: Diarrhoea, nausea.

The following side effects have been reported but the frequencies are unknown: Abdominal pain, indigestion, dry mouth, pancreatitis, vomiting, taste disturbances.

Renal and urinary disorders:

The following side effects have been reported but the frequencies are unknown: Uraemia, oligouria, anuria, renal dysfunction, acute renal failure, impotence.

Hepato-biliary disorders:

The following side effects have been reported but the frequencies are unknown: Hepatitis (hepatocellular or cholestatic), jaundice, increases in liver enzymes, increases in serum bilirubin.

Musculoskeletal, connective tissue and bone disorders:

The following side effects have been reported but the frequencies are unknown: Asthenia.

Respiratory, thoracic and mediastinal disorders:

Frequent: Cough.

The following side effects have been reported but the frequencies are unknown: Bronchospasm, rhinitis, sinusitis.

Skin and subcutaneous tissue disorders:

The following side effects have been reported but the frequencies are unknown: Rash, urticaria, diaphoresis, alopecia, pruritus, psoriasis, severe skin disorders including pemphigus, toxic epidermal necrolysis, Stevens - Johnson syndrome and erythema multiforme.

Immune system disorders:

The following side effects have been reported but the frequencies are unknown:

Hypersensitivity/angioedema reactions: angioedema of the face, which may be fatal, extremities, lips, tongue, glottis and/or larynx and intestinal angioedema. A symptom complex has been reported which may include: fever, vasculitis, myalgia, arthritis/arthralgia, a positive antinuclear antibodies (ANA), elevated erythrocyte sedimentation rate, eosinophilia and leucocytosis. Rash, photosensitivity or other dermatological manifestations may occur.

Not all side effects reported for **LIZRO** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **LIZRO**, please consult your doctor, pharmacist or other healthcare professional for advice.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF LIZRO

Store at or below 30 °C. Protect from moisture.

STORE ALL MEDICINES OUT OF THE REACH OF CHILDREN.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF LIZRO

LIZRO 5 mg: 28's & 30's

1. 30's pack (3 blisters of 10 tablets each):

Tablets are packed in Clear 250 microns PVC coated with 60 gsm PVdC (width 178 mm) and 25 microns printed Aluminium foil (width 174 mm). Each blister contains 10 tablets.

2. 28's pack (2 blisters of 14 tablets each):

Tablets are packed in Clear 250 microns PVC coated with 60 gsm PVdC (width 136 mm) and 25 microns printed Aluminium foil (width 136 mm). Each blister contains 14 tablets.

LIZRO 10 mg: 28's & 30's

1. 30's pack (3 blisters of 10 tablets each):

Tablets are packed in Clear 250 microns PVC coated with 60 gsm PVdC (width 178 mm) and 25 microns printed Aluminium foil (width 174 mm). Each blister contains 10 tablets.

2. 28's pack (2 blisters of 14 tablets each):

Tablets are packed in Clear 250 microns PVC coated with 60 gsm PVdC (width 136 mm) and 25 microns printed Aluminium foil (width 136 mm). Each blister contains 14 tablets.

LIZRO 20 mg: 28's & 30's

1. 30's pack (3 blisters of 10 tablets each):

Tablets are packed in Clear 250 microns PVC coated with 60 gsm PVdC (width 207 mm) and 25 microns printed Aluminium foil (width 203 mm). Each blister contains 10 tablets. □

2. 28's pack (2 blisters of 14 tablets each):

Tablets are packed in Clear 250 microns PVC coated with 60 gsm PVdC (width 248 mm) and 25 microns printed Aluminium foil (width 242 mm). Each blister contains 14 tablets.

8. IDENTIFICATION OF LIZRO

LIZRO 5 mg:

Light red coloured, round shaped, biconvex, uncoated tablets, debossed with 'L' on one side and on other side with '5' on one side of the score line.

LIZRO 10 mg:

Light yellow coloured, round shaped, biconvex, uncoated tablets, debossed with 'L' on one side and on other side with '10'.

LIZRO 20 mg:

Light yellow coloured, capsule shaped, biconvex, uncoated tablets, debossed with ‘L’ on one side and on other side with ‘20’.

9. REGISTRATION NUMBER/REFERENCE NUMBER

LIZRO 5 mg: A40/7.1.3/0722

LIZRO 10 mg: A40/7.1.3/0723

LIZRO 20 mg: A40/7.1.3/0724

10. NAME AND ADDRESS OF REGISTRATION HOLDER

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