Unicorn Pharmaceuticals (Pty) Ltd
LISO 2,5/5/10/20

PROPOSED FINAL PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S3

PROPRIETARY NAME AND DOSAGE FORM:

LISO 2,5 tablets

LISO 5 tablets

LISO 10 tablets

LISO 20 tablets

Read all of this leaflet carefully before you start taking LISO.

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

The active substance is lisinopril.

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

LISO 5: Each tablet contains lisinopril dihydrate equivalent to 5,0 mg lisinopril.

LISO 10: Each tablet contains lisinopril dihydrate equivalent to 10,0 mg lisinopril.

LISO 20: Each tablet contains lisinopril dihydrate equivalent to 20,0 mg lisinopril.

The other ingredients are calcium hydrogen phosphate dihydrate, colloidal silica anhydrous, mannitol, magnesium stearate, maize starch, red iron oxide (excluding 2,5 mg tablet), starch pre-gelatinised.

LISO contains sugar (mannitol) in the following quantities; **LISO 2,5** and **LISO 5** (44,00 mg), **LISO 10** and **LISO 20** (88,00 mg).

2. WHAT LISO IS USED FOR:

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

LISO can be used:

- to treat high blood pressure (hypertension)
- to treat heart failure
- if you have recently had a heart attack (myocardial infarction).

3. BEFORE YOU TAKE LISO:

Do not take LISO:

- if you are hypersensitive (allergic) to lisinopril or any of the other ingredients of **LISO** (see **WHAT LISO CONTAINS**).
- if you are taking an antibiotic of the fluoroquinolone group of antibiotics (e.g. ciprofloxacin, moxifloxacin and levofloxacin), to treat a bacterial infection (such as respiratory tract infections, urinary tract infections and skin infections), as taking these medicines while taking Angiotensin Converting Enzyme (ACE) inhibitors,

such as **LISO**, may result in kidney injury, especially if you have kidney problems or if you are elderly.

Contact your doctor to re-evaluate your treatment if you are treated with an Angiotensin Converting Enzyme (ACE) inhibitor, such as **LISO**, together with a fluoroquinolone antibiotic.

- if you or anyone in your family have a history of angioedema (swellings similar to hives beneath the surface of the skin) related to previous therapy with **LISO** or other medicines containing the same active ingredient as **LISO** or with certain medicines used to treat heart conditions, called ACE-inhibitors (angiotensin-converting enzyme inhibitors), or ARBs (angiotensin receptor blockers). If this is the case you may never take these medicines again (see **Take special care with LISO**).
- if you suffer from hypertrophic obstructive cardiomyopathy (HOCM - thickening of the muscle of the heart).
- if you have severe kidney disease, narrowing of the blood vessels of both kidneys, are undergoing haemodialysis or you have only one kidney left, of which the blood vessels are narrowed.
- if you have a disease of the heart valves called aortic stenosis in which the opening is narrowed (see **Taking special care with LISO**).
- if you are also being treated with medicines called potassium sparing diuretics (e.g. spironolactone, triamterene or amiloride) that increase the rate of urination.
- if you have porphyria (a rare hereditary disease in which your urine becomes dark and your skin is extremely sensitive to light).

- if you are receiving lithium therapy (a mood stabilizer) concomitant administration with **LISO** may lead to toxic blood concentrations of lithium.
- if you are pregnant or breastfeeding (see **Taking special care with LISO** and **Pregnancy and breastfeeding**)
- if you are taking renin-inhibiting medicines used for treatment of high blood pressure.

Take special care with LISO:

- if you become pregnant while taking **LISO** you should stop taking **LISO** immediately and inform your doctor. Your doctor may have to switch you to a different medicine (see **Do not take LISO** and **Pregnancy and breastfeeding**).
- if you are taking an antibiotic of the fluoroquinolone group of antibiotics (e.g. ciprofloxacin, moxifloxacin and levofloxacin), to treat a bacterial infection (such as respiratory tract infections, urinary tract infections and skin infections), as taking these medicines while treated with **LISO** may result in kidney injury, especially if you have kidney problems or if you are elderly.

  Contact your doctor to re-evaluate your treatment if you are treated with an Angiotensin Converting Enzyme (ACE) inhibitor, such as **LISO**, together with a fluoroquinolone antibiotic.
- if you have a narrowing (stenosis) of the aorta (an artery in your heart) or a narrowing of the heart valves (mitral valves) (see **Do not take LISO**)
- if you have an increase in thickness of the heart muscle (hypertrophic cardiomyopathy (see **Do not take LISO**)

- if your blood tests show increased potassium levels. This is seen if you are using medicines containing potassium called potassium sparing diuretics (e.g spironolactone, triamtrene or amiloridine) or medicine associated with increasing potassium levels in combination with **LISO** (see **Do not take LISO** and **Taking LISO with other medicines**)
- if you are receiving lithium therapy (mood stabiliser) (see **Do not take LISO** and **Taking LISO with other medicines**)
- if you are currently being treated for hypertension with other medicines used to lower blood pressure, such as valsartan, irbesartan and telmisartan, and with water tablets (diuretics)
- if you experience angioedema any time during your treatment. You should stop using **LISO** immediately and tell your doctor (see **Do not take LISO** and **POSSIBLE SIDE EFFECTS**)
- if you are of black ethnicity you may have a higher risk of angioedema
- if you have impaired kidney function as **LISO** may result in a very low blood pressure
- if you are elderly, have impaired kidney function and suffer from atherosclerosis (disease caused by build-up of cholesterol inside your artery walls; you may feel pain on your legs when walking)
- if you have lost a lot of fluids due to vomiting, diarrhoea, low salt intake, excessive perspiration or you had dialysis treatment
- if you suffer from low blood pressure (you may feel dizzy or light-headed, especially when standing up)
- if you are going to have major surgery or receive anaesthetic

- if you have diabetes. You should be aware that the use of **LISO** may cause lowering of your blood sugar levels. Monitor your blood glucose regularly and adjust your diabetic treatment accordingly
- if you are about to receive treatment called LDL apheresis, which removes cholesterol from your blood using a machine
- if you are about to undergo desensitisation therapy (due to an allergy e.g. insect bites). If you take **LISO** while you are having this treatment, it may cause a severe allergic reaction
- if you develop a persistent cough
- if you have a severe autoimmune disease, such as systemic lupus erythematosus, scleroderma or other collagen vascular disease
- if you bruise more easily, bleed for longer than normal, experience any signs of bleeding (e.g. bleeding from the gums), purple spots blotching on the skin or get infections more easily than usual, sore throat, fever, feel tired, faint, dizzy or have pale skin. These can be signs of blood or bone marrow problems
- if you have liver failure (symptoms include yellowing of the skin and/or eyes (jaundice) along with stomach pain and swelling) which may be caused by an allergic reaction (see **POSSIBLE SIDE EFFECTS**)

Taking LISO with food and drink:

The tablet can be taken with or without meals, preferably at the same time every day. You should avoid alcoholic drinks when treated with **LISO** as the combination may enhance the side effects.

Pregnancy and breastfeeding:

Do not take **LISO** if you are pregnant or breastfeeding (see **Do not take LISO**). If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before taking **LISO**.

Driving and using machinery:

LISO may cause you to feel dizzy. You should therefore be careful when driving or operating machinery.

Important information about some of the ingredients of LISO:

LISO contains mannitol and may have a laxative effect.

Taking other medicines with LISO:

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

LISO should not be taken with the following medicines (see **Do not take LISO**):

- fluoroquinolone antibiotics (e.g. ciprofloxacin, moxifloxacin and levofloxacin), which are used in treatment of bacterial infections such as respiratory tract infections, urinary tract infections and skin infections.

  Contact your doctor to re-evaluate your treatment if you are treated with a fluoroquinolone antibiotic together with **LISO**.
- renin inhibiting medicines (for treatment of high blood pressure)
- lithium (for treatment of anxiety and depression)

- potassium supplements, potassium-sparing water tablets (such as spironolactone, triamterene and amiloride) or potassium-containing salt substitutes.

LISO can interact with the following medicines:

- water tablets (diuretics) or other blood pressure lowering medicines
- medicines for diabetes, such as oral glucose lowering medicines or insulin
- medicines used to treat pain and inflammation (such as non-steroidal anti-inflammatory drugs (NSAIDs) and indomethacin)
- nitrate medicines (for heart problems)
- medicines that contain gold (such as sodium aurothiomalate), which may be given to you as an injection
- medicines for depression and for mental problems
- anaesthetics
- medicines used to treat nose or sinus congestion or other cold remedies (including those you can buy in the pharmacy)
- medicines used to break up blood clots (usually given in hospital).

4. HOW TO TAKE LISO:

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

Always take **LISO** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is 10 mg once daily.

Your doctor will tell you how long your treatment with **LISO** will last. Do not stop taking the tablets, even if you are feeling well.

If you have the impression that the effect of **LISO** is too strong or too weak, talk to your doctor or pharmacist.

For best results, take **LISO** at the same time each day.

The safety and effectiveness of **LISO** in children have not been established.

If you take more LISO than you should:

Symptoms of overdosage are serious low blood pressure, circulatory shock (symptoms include agitation or restlessness, bluish lips and fingernails, chest pains, confusion, light-headedness, pale skin, low or no urine output), shortness of breath, rapid or slower heartbeat, dizziness, anxiety, cough, blood tests showing changes in electrolytes (body salts) and possible kidney failure.

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 a dose of LISO:

If you missed a dose, take it as soon as possible. However, if it is almost time for the next dose, continue to take the next tablet at the usual time. Do not take a double dose to make up for the forgotten individual dose.

5. POSSIBLE SIDE EFFECTS:

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LISO can have side effects.

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

If any of the following happens, stop taking **LISO** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- a swelling in your gut called ‘intestinal angioedema’: you may experience symptoms like abdominal pain, vomiting and diarrhoea
- rash or itching.

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

Black patients are at a greater risk of these allergic reactions.

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

- heart attack (common signs include chest pain or discomfort, pressure or tightness in the chest that may spread to your arm, neck, jaw or back), fast or pounding heartbeat
- stroke (common signs include numbness or weakness of the arm, face or leg, especially on the one side of the body, confusion, trouble speaking, loss of balance)
- difficulty breathing and persistent cough due to lung problems

- liver problems, such as yellowing of skin and eyeballs (jaundice)
- no urine or less urine than is normal for you, swelling of legs, ankles or feet, nausea or extreme tiredness (acute kidney failure)
- Stevens-Johnson syndrome or other serious skin disorders (begins with flu-like symptoms, followed by a painful red or purplish rash that spreads and blisters)
- you look pale and feel tired and breathless (you may have anaemia where you have less haemoglobin in your blood than is normal)
- bleeding from your gums, nose or mouth, any bleeding that will not stop, reddish or pink urine, unexpected bruising (you may have less platelets in your blood than is normal)

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:

- dizziness, headache
- a dry cough that does not go away
- diarrhoea, vomiting

Less frequent side effects:

- blood tests showing a decrease in the number of red blood cells, white blood cells or platelets
- blood tests showing decreases of sodium and sugar levels, as well as increases of potassium levels in your blood

- changes to your mood, confusion, restlessness and depression
- "pins and needles", vertigo (the sensation of spinning when standing still), difficulty sleeping, hallucinations (strange visions or sounds), fainting, changes in the way things smell
- a very big drop in blood pressure causing you to feel very dizzy and lightheaded, especially if you stand up quickly
- a disorder called Raynaud's phenomenon – narrowing of the blood vessels in your fingers and toes when exposed to cold; they may look blue or red and feel cold and numb
- swelling and irritation inside your nose, sinusitis, shortness of breath, wheezing, fever and feeling generally unwell
- nausea, stomach pain, indigestion, dry mouth, loss of taste
- upper abdominal pain that radiates into the back, which may be aggravated by eating foods high in fat, swollen and tender abdomen (signs of pancreatitis)
- pain in your upper right abdomen, abdominal swelling or generally feeling unwell (signs of liver problems)
- redness and itchiness of skin, sweating more than usual, hair loss, blisters
- sexual inability in men, development of breasts in men
- fatigue, a feeling of weakness, pain, swelling, heat and a sense of stiffness in your joints, rash, photosensitivity.

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

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6. STORING AND DISPOSING OF LISO:

Store all medicines out of reach of children.

Store at or below 25 °C. Protect from light and moisture.

Do not store these tablets in the bathroom.

Keep blisters in carton until required for further use.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

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

7. PRESENTATION OF LISO:

LISO tablets are packed in clear transparent PVC/PVDC and silver aluminium blister strips containing 10 tablets. Three blister strips are packed in an outer carton.

8. IDENTIFICATION OF LISO:

LISO 2,5: White to off-white coloured, round, biconvex, uncoated tablets with breakline on one side and “2.5” on other side.

LISO 5: Pink coloured, round, biconvex, uncoated tablets with breakline on one side and “5” on other side.

LISO 10: Pink coloured, round, biconvex, uncoated tablets with breakline on one side and “10” on other side.

LISO 20: Pink coloured, round, biconvex, uncoated tablets with breakline on one side and “20” on other side.

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9. REGISTRATION NUMBERS:

LISO 2,5: A43/7.1.3/0662

LISO 5: A43/7.1.3/0663

LISO 10: A43/7.1.3/0664

LISO 20: A43/7.1.3/0665

10. NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE REGISTRATION HOLDER:

Unicorn Pharmaceuticals (Pty) Ltd

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8001

11. DATE OF PUBLICATION:

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