PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: [S3]

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

LISINOPRIL CO UNICORN 10/12,5 tablets.
LISINOPRIL CO UNICORN 20/12,5 tablets.

Read this entire leaflet carefully before you start taking

LISINOPRIL CO UNICORN.

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

Active ingredients:

The active ingredients in **LISINOPRIL CO UNICORN** are lisinopril and hydrochlorothiazide.

LISINOPRIL CO UNICORN 10/12,5:

Each tablet contains 10 mg lisinopril (as the dihydrate) and 12,5 mg hydrochlorothiazide.

LISINOPRIL CO UNICORN 20/12,5:

Each tablet contains 20 mg lisinopril (as the dihydrate) and 12,5 mg

hydrochlorothiazide.

LISINOPRIL CO UNICORN 10/12,5

contains sugar (mannitol 18,7 mg/tablet)

LISINOPRIL CO UNICORN 20/12,5

contains sugar (mannitol 38,30 mg/tablet)

The other ingredients are:

Croscarmellose sodium, dibasic calcium phosphate dihydrate, magnesium stearate, Pigment blend PB-27222 Beige (10 mg tablet only), pregelatinised maize starch.

2. WHAT LISINOPRIL CO UNICORN IS USED FOR:

Lisinopril belongs to a group of medicines called ACE inhibitors. It works by making your blood vessels widen. Hydrochlorothiazide belongs to a group of medicines called diuretics (water tablets). It helps your body get rid of water and salts, like sodium, in your urine.

- **LISINOPRIL CO UNICORN** is used to treat high blood pressure (hypertension) that cannot be sufficiently treated with one medicine alone.

3. BEFORE YOU TAKE LISINOPRIL CO UNICORN:

Do not take LISINOPRIL CO UNICORN:

- If you are hypersensitive (allergic) to lisinopril,

hydrochlorothiazide or any of the other ingredients of **LISINOPRIL CO UNICORN** (see **WHAT LISINOPRIL CO UNICORN CONTAINS**).

- If you or anyone in your family have a history of previous and/or current cancer of the skin and lip.
- 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 **LISINOPRIL CO UNICORN** or other medicines containing the same active ingredients as **LISINOPRIL CO UNICORN** or with certain medicines used to treat heart conditions, called ACE inhibitors (angiotensin-converting enzyme inhibitors), sulphonamide medicines or ARBs (angiotensin receptor blockers). If this is the case you may never use these medicines again.
- If you suffer from hypertrophic obstructive cardiomyopathy (HOCM - thickening of the muscle of the heart).
- If you don't pass or pass very little urine per day.
- 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 moderate or severe renal impairment (your kidneys are not functioning normally) and are also taking a fluoroquinolone (a class of antibiotic used to combats a bacterial infection) together with an angiotensin-converting enzyme (ACE) inhibitor (a class of heart medicine) or a renin-angiotensin receptor blocker (such as **LISINOPRIL CO UNICORN**) (see **Take special care with**

LISINOPRIL CO UNICORN).

- If you have a disease of the heart valves called aortic stenosis in which the opening is narrowed.
- If you are also being treated with medicines called potassium sparing diuretics (e.g. spironolactone, triamterene or amiloride) that increases 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 have Addison's disease (a hormone disease with symptoms such as chronic fatigue, loss of appetite and weight loss) or are hypersensitive (allergic) to sulphonamide-type medicines.
- If you are receiving lithium therapy (a mood stabilizer); concomitant administration with **LISINOPRIL CO UNICORN** may lead to toxic blood concentrations of lithium.
- If you have severely impaired liver function or liver cirrhosis (an advanced liver disease with symptoms such as yellowing of the skin, easy bruising and fatigue).
- If you suffer from biliary obstruction (a problem with the drainage of the bile from the gall bladder).
- You are taking a blood pressure medicine containing aliskiren and you have diabetes or kidney problems.
- If you suffer from gout.
- If you are, or think you may be, pregnant or if you are planning to become pregnant or if you are breastfeeding.
- Children (Safety and efficacy have not been established).

Take special care with LISINOPRIL CO UNICORN:

If you become pregnant while taking **LISINOPRIL CO UNICORN**, you should stop taking **LISINOPRIL CO UNICORN** immediately and inform your doctor. Your doctor may want to switch you to a different medicine.

- If you have had skin cancer or if you develop an unexpected skin lesion during treatment. Treatment with hydrochlorothiazide particularly long-term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Protect your skin from sun exposure and UV rays while taking **LISINOPRIL CO UNICORN**.
- If you have recently had a kidney transplant, require dialysis or have renal failure.
- Acute kidney failure (a serious condition resulting in your kidneys losing their function) may be caused by the simultaneous use of fluoroquinolones (a class of antibiotic that combats a bacterial infection) and an angiotensin-converting enzyme (ACE) inhibitor (a class of heart medicine) or a renin-angiotensin receptor blocker (such as **LISINOPRIL CO UNICORN**) (see **Do not take LISINOPRIL CO UNICORN)**.
- Your doctor will assess your kidney function prior to starting simultaneous treatment with such medicines and will monitor your kidney function during treatment with fluoroquinolones (a class of antibiotic that combats a bacterial infection) and an ACE inhibitor (a class of heart medicine) or a renin-

angiotensin receptor blocker (such as **LISINOPRIL CO UNICORN**) (see **Do not take LISINOPRIL CO UNICORN)**.

- If you are being treated with a diuretic (water tablet) or are on a salt restricted diet as you may experience a serious drop in blood pressure (hypotension).
- If you have a heart condition called mitral valve stenosis (narrowing of a heart valve causing a blockage in blood flow).
- If you suffer from a hormonal disorder called primary aldosteronism.
- If you take a medicine called aliskrien as this may lower your blood pressure (see **Taking other medicines with LISINOPRIL CO Unicorn**).
- If you have kidney problems.
- If you are on any other water tablets as this needs to be stopped before taking **LISINOPRIL CO Unicorn**.
- If you have high levels of cholesterol and you are having a treatment called 'LDL apheresis' (a process to remove cholesterol from the blood).
- If you have liver problems.
- If you are about to undergo major surgery and will be given anaesthetics.
- If you have gout.
- If you experience fatigue, muscle weakness, drowsiness, nausea, vomiting or cramps as these may be symptoms of a condition called electrolyte imbalance. Your doctor may want

to do regular blood tests.

- If you are about to have a thyroid test.
- If you experience swelling in any part of your body.
- If you have ever had a condition called systemic lupus erythematosus (SLE) with symptoms such as joint pain, extreme fatigue and a rash over the nose and cheeks).
- If you have problems with your blood vessels (collagen vascular disease).
- If you are about to undergo desensitisation therapy because you are allergic to bee stings or other insect bites.
- If you suffer from an arthritis type disease called collagen vascular disease.
- If you develop an infection.
- If you experience visual disturbances or eye pain.
- If you are a black patient as **LISINOPRIL CO UNICORN** may not effectively lower your blood pressure.
- Hydrochlorothiazide contained in **LISINOPRIL CO UNICORN** may produce a positive result in an anti-doping test.

Your doctor may request tests to monitor your condition before or during treatment.

Taking LISINOPRIL CO UNICORN with food and drink:

LISINOPRIL CO UNICORN can be taken with or without food.

Pregnancy and Breastfeeding:

Do not take **LISINOPRIL CO UNICORN** if you are pregnant, suspect that

you are pregnant or breastfeeding your baby and please consult your doctor or pharmacist or other healthcare professional for advice before using this medicine.

If you are pregnant, or become pregnant whilst taking **LISINOPRIL CO UNICORN**, stop taking **LISINOPRIL CO UNICORN** and talk to your doctor as soon as possible.

You should not take LISINOPRIL CO UNICORN if you are pregnant, planning to become pregnant or breastfeeding your baby.

Driving and using machinery:

LISINOPRIL CO UNICORN may make you feel dizzy or tired. This is especially true at the start of treatment or if your doctor changes your dosage, or if you should drink alcohol while receiving treatment with **LISINOPRIL CO UNICORN**.

Taking other medicines with LISINOPRIL CO UNICORN:

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

Medicine that may interact with **LISINOPRIL CO UNICORN**:

- Fluoroquinolones (a class of antibiotic that combats a bacterial infection) (see **Take special care with LISINOPRIL CO UNICORN** and **Do not take LISINOPRIL CO UNICORN)**.
- An angiotensin-converting enzyme (ACE) inhibitor (a class of heart medicine) (see **Take special care with LISINOPRIL CO UNICORN** and **Do not take LISINOPRIL CO UNICORN)**.

- A renin-angiotensin receptor blocker (a class of heart medicine) (see **Take special care with LISINOPRIL CO UNICORN** and **Do not take LISINOPRIL CO UNICORN)**.

- Other medicines from the same class (angiotensin II receptor antagonists or ACE inhibitors) to lower blood pressure, including those that contain aliskiren.
- Other water tablets or medicine to lower blood pressure. (Inform your doctor if you are taking any of these).
- Lithium, as this may result in toxic blood concentrations if used in combination with **LISINOPRIL CO UNICORN** (see **BEFORE YOU TAKE LISINORIL CO UNICORN**).
- Potassium supplements or salt substitutes containing potassium (these may lead to increased potassium concentrations in the blood).
- Medicines that alter the heart rate and certain medicines used to treat mental conditions, antidepressants and certain anaesthetic medicines, as this may lower your blood pressure below normal (Discuss with your doctor if you are unsure).
- Certain medicines used to treat pain and inflammation called NSAIDs (non-steroidal anti-inflammatory medicines) as the effect of **LISINOPRIL CO UNICORN** may be reduced.
- Gold injections, such as sodium aurothiomalate, usually used to treat rheumatoid arthritis.
- Medicines called sympathomimetics, used to treat nose or sinus congestion or other cold remedies (including those you can buy in the pharmacy).

- Medicine to treat diabetes including insulin.
- Amphotericin B injection (to treat fungal infections), carbenoxolone (to treat ulcers for example), corticosteroids (used to reduce inflammation, suppress the immune system, and replacement therapy), corticotropin (a hormone) or stimulant laxatives,
- Calcium supplements or Vitamin D.
- Pressor amines, such as adrenaline used for the treatment of hypotension, shock, cardiac failure, asthma or allergies.
- Muscle relaxants such as tubocurarine.
- Certain antibiotics (such as trimethoprim/sulfamethoxazole).
- Sotalol used for an abnormal heartbeat.
- Medicines for the treatment of gout (such as allopurinol).
- Medicines to suppress the body's immune response (immunosuppressants, such as ciclosporin).
- Medicines which reduce high cholesterol (such as lovastatin, colestyramine or colestipol).
- Medicines to control heart rhythm (such as procainamide, or digoxin).
- Medicines used in chemotherapy for cancer (cytostatics).
- Anti-convulsion medicines to treat seizures.
- Sedatives, narcotics or excessive alcohol may lead to further lowering of blood pressure.
- Amantadine (used both as an antiviral and an antiparkinsonian medicine).

4. HOW TO TAKE LISINOPRIL CO UNICORN:

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

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

The usual dose is:

Adults:

The usual starting dose is one tablet daily, taken at the same time every day with or without food.

The dose of **LISINOPRIL CO UNICORN** can be increased to 2 tablets per day, depending on your blood pressure response.

Your doctor will decide on the dose depending on your condition.

The tablets should be swallowed with a drink of water.

Patients on diuretic (water tablets) therapy:

Inform your doctor if you are taking water tablets as he/she may want to stop your water tablet before starting you on **LISINOPRIL CO UNICORN** treatment.

Patients with severe kidney disease:

LISINOPRIL CO UNICORN is not recommended for patients with severe kidney problems.

Use in the elderly:

No dosage reduction is generally necessary in the elderly.

Children:

LISINOPRIL CO UNICORN is not recommended for use in children and adolescents due to a lack of data on safety and efficacy.

Your doctor will tell you how long your treatment with **LISINOPRIL CO UNICORN** will last.

If you have the impression that the effect of **LISINOPRIL CO UNICORN** is too strong or too weak, tell your doctor or pharmacist.

If you take more LISINOPRIL CO UNICORN than you should:

In the event of an overdose, contact your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Symptoms may include dizziness, rapid breathing (hyperventilating), anxiety and cough.

If you forget to take a dose of LISINOPRIL CO UNICORN:

If you forget to take a dose of **LISINOPRIL CO UNICORN** take one as soon as you remember. If it is almost time for your next dose, skip the missed dose and continue to take the tablet or tablets at the usual time. Do not take a double or larger dose to make up for the forgotten individual doses.

Effects when treatment with LISINOPRIL CO UNICORN is stopped:

It is important that you continue the course of treatment even if you begin to feel better after a few days.

5. POSSIBLE SIDE EFFECTS:

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

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

- Swelling of the hands, feet ankles, lips, mouth or throat which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Jaundice (yellow discoloration of the skin and eyes).

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

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

- Heart attack or stroke.
- Increased or fast heart beat (tachycardia).
- Low blood pressure or fainting when getting up from a lying or sitting position (orthostatic hypotension/dizziness).
- Tiredness, an infection, fever, feeling breathless or that you bruise or bleed more easily.

- Weakness, fatigue, weight loss, headache (symptoms of a condition called vasculitis).
- Chest pain (angina).
- Fainting (syncope).
- Kidney problems (passing less urine than is normal for you).
- Pancreatitis (inflammation of the pancreas with symptoms such as stomach pain, increased heart rate and fever).
- Hepatitis (inflammation of the liver with symptoms such as nausea, mild fever, abdominal pain).
- High cholesterol.
- Changes to your skin (new growths or lesions) as this could be a sign of skin cancer
- Severe eye pain with redness and sudden blurred vision.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- feeling tired and skin looking pale,
- flushing of your skin,
- headache, dizziness; light-headedness,
- clay coloured stool, dark urine, itching, loss of appetite, yellow eyes or skin (abnormal liver function),
- abnormal kidney function including inflammation of the kidneys, urinary infection, sugar in the urine, passing less than normal or no urine,
- swollen glands (lymph nodes),

- decreased or loss of appetite, anorexia,
- feeling hungry or weak, sweating and a fast heart rate (signs of low blood sugar),
- gout,
- restlessness, depression,
- vertigo (spinning feeling), dizziness,
- change of colour in your fingers or toes,
- tingling sensation in hands, feet or lips (feeling of “pins and needles”),
- nausea, vomiting,
- stomach pain or discomfort, inflammation of the stomach, bloating, flatulence (gas),
- constipation, wind, stomach pain or discomfort, stomach spasms, dry mouth, inflammation of a salivary gland,
- indigestion,
- diarrhoea,
- mood and/or sleep disorders, confusion, feeling restless and depressed,
- upper respiratory tract infections,
- cough, nasal congestion; sinus disorders; sore throat,
- muscle cramps, spasms, weakness or pain,
- hives, itching, inflammation of the skin, rash, redness of the skin, sensitivity to light, dry skin, blistering or peeling of the skin, hair loss,
- change taste perception (including loss of taste),
- changes in the way things smell,
- changes in the levels of certain chemicals in the blood and urine

which are usually detected by blood and urine tests (electrolyte imbalance),

- blurred vision, worsening eyesight, seeing things in yellow,
- problems with sexual performance,
- enlarged breasts in men.

6. STORING AND DISPOSING OF LISINOPRIL CO UNICORN:

LISINOPRIL CO UNICORN should be stored in the original packaging at or below 25 °C.

(keep blisters in the carton and tablets in the bottle until required for use)

KEEP MEDICINE OUT OF THE REACH OF CHILDREN.

Do not use after the expiry date stated on the label and 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 LISINOPRIL CO UNICORN:

LISINOPRIL CO UNICORN 10/12,5 : are packed into PVC/PVDC/ aluminium blister packs of 30 tablets, contained in a printed outer carton.

LISINOPRIL CO UNICORN 20/12,5 : are packed into PVC/PVDC/ aluminium blister packs of 30 tablets, contained in a printed outer carton.

8. IDENTIFICATION OF LISINOPRIL CO UNICORN:

LISINOPRIL CO UNICORN 10/12,5 : A peach coloured, round, uncoated, 6 mm biconvex tablet, marked ‘LH’.

LISINOPRIL CO UNICORN 20/12,5 : A white coloured, round,

uncoated, 8 mm biconvex scored tablet, marked “LH”.

9. REGISTRATION NUMBER:

LISINOPRIL CO UNICORN 10/12,5 : 37/7.1.3/0477

LISINOPRIL CO UNICORN 20/12,5 : 37/7.1.3/0478

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Unicorn Pharmaceuticals (Pty) Ltd

Cnr Searle and Pontac Streets

Woodstock

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South Africa

11. DATE OF PUBLICATION:

September 2009

12. THIS LEAFLET WAS LAST REVISED IN:

December 2020.