APPROVED PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

LISORETIC 10/12,5 tablets

LISORETIC 20/12,5 tablets

Lisinopril dehydrate and hydrochlorothiazide

LISORETIC contains sugar (mannitol 18,70 mg and 38,30 mg respectively)

Read all of this leaflet carefully before you start taking LISORETIC

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist, nurse or other healthcare provider.
- LISORETIC 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 LISORETIC is and what it is used for

Lisinopril belongs to a group of medicines called angiotensin converting enzyme inhibitors (ACEI). 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.

LISORETIC is used to treat mild to moderate high blood pressure (hypertension).
Your doctor will usually prescribe LISORETIC when your blood pressure has already been controlled after taking both the individual active ingredients of this medicine separately.

2. What you need to know before you take LISORETIC

Do not take LISORETIC:

- if you are hypersensitive (allergic) to lisinopril, hydrochlorothiazide, or any of the other ingredients of LISORETIC (see section 6)
- if you have had skin cancer or you develop an unexpected skin lesion during the treatment with LISORETIC
- if you are hypersensitive (allergic) to sulphonamides (used to treat certain infections) and medicines made from sulphonamide

- 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 LISORETIC or other medicines containing the same active ingredients as LISORETIC 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.
- 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 anuria (a condition where your kidneys cannot produce urine, and you stop passing urine)
- 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
- 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)

- if you are receiving lithium therapy (a mood stabilizer) concomitant administration with LISORETIC 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)
- if you are taking a blood pressure medicine containing aliskiren
- if you are taking antibiotic medicine containing fluoroquinolones (e.g. ciprofloxacin, levofloxacin) and have a history of moderate or severe kidney injury
- if you have taken or are currently taking sacubitril/valsartan, a medicine used to treat a type of long-term (chronic) heart failure in adults, as the risk of angioedema (rapid swelling under the skin in an area such as the throat) is increased
- if you are, or think you may be, pregnant or if you are planning to become pregnant or if you are breastfeeding.

Warnings and precautions

Take special care with LISORETIC:

If you become pregnant while taking LISORETIC, you should stop taking LISORETIC immediately and inform your doctor. He/she may have to switch you to a different medicine.

Tell your doctor if any of the following applies to you:

- if you have recently had a kidney transplant, require dialysis or have renal failure
- 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 aliskiren as this may lower your blood pressure (see Other medicines with LISORETIC)
- if you have kidney problems
- if you are taking antibiotics called flouroquinolones (e.g. ciprofloxacin, levofloxacin), the combined use with LISORETIC may increase the risk of sudden and severe kidney injury, especially if you have moderate or severe kidney impairment such as in elderly patients
- if you are on any other water tablets as this needs to be stopped before taking LISORETIC
- 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, which include symptoms such as yellowing of the skin and eyes

- since treatment with hydrochlorothiazide as in LISORETIC, 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 LISORETIC
- if you are about to undergo major surgery or anaesthetic
- 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 are taking sacubitril/valsartan (used to treat chronic heart failure), your doctor will change the frequency of therapy
- if you are taking medicines called mammalian target of rapamycin (mTOR) inhibitors (for example temsirolimus, everolimus, sirolimus) or medicines containing neprilysin inhibitors (NEP) inhibitors (for example racecadotril) as they may increase the risk of angioedema (swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing)
- if you have problems with your blood vessels (collagen vascular disease)

- if you are about to undergo desensitisation therapy (due to an allergy e.g. insect bites). If you take LISORETIC while you are having this treatment, it may cause a severe allergic reaction
- if you suffer from an arthritis type disease called collagen vascular disease
- if you develop an infection
- as a continuous cough may develop while taking LISORETIC. The cough may usually stop when you complete your LISORETIC treatment
- if you develop sensitivity to the sun e.g. your skin becomes itchy or reddens and swelling occurs when exposed to the sun. Inform your healthcare provider about any reactions to the sun. Should your health provider advise you to continue with LISORETIC, it is necessary to protect exposed areas of your body from the sun
- if you experience visual disturbances or pressure in the eyes, severe eye pain, headaches, nausea and vomiting, and your eyes are constantly tearing
- if you are a black patient as LISORETIC may not effectively lower your blood pressure. You may also more easily get the side effect “angioedema” (a severe allergic reaction with swelling of the hands, feet, ankles, face, lips, tongue or throat)
- hydrochlorothiazide contained in LISORETIC could produce a positive result in an anti-doping test.

Children

The safety and efficacy of LISORETIC in children has not yet been established.

Other medicines and LISORETIC

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

LISORETIC can interact with the following medicines:

- lithium, may result in toxic blood concentrations if used in combination with LISORETIC (see Do not take LISORETIC)
- 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 medicines to lower your blood pressure may increase effects of LISORETIC to lower your blood pressure, you may experience symptoms such as light-headedness or dizziness, fainting, nausea, fatigue and lack of concentration. Inform your doctor if you are taking any of these
- 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 drugs e.g. aspirin) as the effect of LISORETIC may be reduced

- medicines that contain gold, such as sodium aurothiomalate, which may be given to you as an injection, may cause flushing of the skin, nausea and light-headedness
- medicines called sympathomimetics, used to treat nose or sinus congestion or other cold remedies (including those you can buy in the pharmacy), may prevent LISORETIC from lowering your blood pressure
- medicines used to treat diabetes (e.g. metformin, insulin and diazoxide), when taken together with LISORETIC, may significantly reduce your blood sugar levels which might lead to hypoglycaemia, you may experience symptoms such as dizziness, headaches and mood changes
- corticosteroids (used to reduce inflammation, suppress the immune system, and replacement therapy)
- calcium containing medicines and vitamin D supplements may increase calcium levels in the blood resulting in dehydration, fatigue, loss of appetite or thirst
- pressor amines, e.g. adrenaline (epinephrine adrenaline) used for the treatment of hypotension, shock, cardiac failure, asthma or allergies, may become less effective when used together with LISORETIC
- muscle relaxants (e.g. tubocurarine), as the effect of these medicines may be increased when used together with LISORETIC
- certain antibiotics (such as trimethoprim) and medicines which reduce high cholesterol (such as lovastatin), may increase the risk of low blood potassium levels, which may include symptoms such as weakness, fatigue, tingling and numbness and breathing difficulties

- medicines for the treatment of gout or muscular pain (such as indomethacin or allopurinol) may cause the risk of a decreased urine output or fluid retention and may lower your immune system
- medicines to suppress the body's immune response (immunosuppressants, such as ciclosporin), NSAIDs and anti-convulsion medicines to treat seizures (such as ACE inhibitors) may cause decreased urine output, fluid retention, causing swelling in your legs and the risk of low blood potassium which may cause symptoms such as weakness, fatigue, tingling and numbness and breathing difficulties
- medicines used to control heart rhythm (such as procainamide) and those used for chemotherapy for cancer (such as cytostatics), may lower your immune system and you may become more prone to infection
- amphotericin B injection (used to treat fungal infections), carbenoxolone (used to treat ulcers or inflammation in or around the mouth), corticosteroids (steroid medicines), corticotropin (a hormone) or stimulant laxatives (medicines used to treat constipation) may intensify your electrolyte imbalance which may cause symptoms such as irregular heartbeat, fatigue, nausea, vomiting, diarrhoea or constipation
- medicines used to treat heart failure (digoxin) increase the risk of digitalis toxicity which may cause symptoms such as fatigue, malaise and visual disturbances
- medicines used to lower cholesterol (cholestyramine and colestipol) may delay the absorption of LISORETIC, therefore LISORETIC should be taken at least 1 hour before or 4 - 6 hours after taking these medicines

- antibiotic medicines called fluoroquinolones ciprofloxacin, moxifloxacin and levofloxacin) may increase the risk of sudden and severe kidney injury
- sedatives, narcotics or excessive alcohol may lead to further lowering of blood pressure, which is suddenly triggered by a change in posture, such as when a person stands up quickly
- sacubitril/valsartan (used to treat chronic heart failure) increases the risk of angioedema (a severe allergic reaction with swelling of the hands, feet, ankles, face, lips, tongue or throat) (see Do not take LISORETIC and Warnings and precautions)
- medicines which are most often used to avoid rejection of transplanted organs (temsirolimus, sirolimus, everolimus and other medicines belonging to the class of mTOR inhibitors) (see Warnings and precautions)
- medicines to break up blood clots (tissue plasminogen activator), usually given in hospital.

LISORETIC with food and drink

LISORETIC can be taken with or without food.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking LISORETIC.

You should not take LISORETIC if you are pregnant or breastfeeding (see Do not take LISORETIC).

LISORETIC 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.

Treatment with LISORETIC is not recommended during breast-feeding (see Do not take LISORETIC).

Driving and using machines

As with other blood pressure lowering medicines, LISORETIC may have a mild to moderate influence on the ability to drive and use machines. Especially at the start of the treatment or when the dose is modified, and also when used in combination with alcohol, but these affects depend on the individual's susceptibility.

Medicines which lower blood pressure may cause dizziness or drowsiness.

It is not always possible to predict to what extent LISORETIC 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 LISORETIC affects them.

LISORETIC contains sodium

LISORETIC contains less than 1 mmol sodium (0,023 g) per tablet, that is to say essentially 'sodium free'.

3. How to take LISORETIC

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

Always take LISORETIC exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Adults

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

The dose of LISORETIC 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 sufficient fluid.

Patients on diuretic (water tablets) therapy

Inform your doctor if you are taking water tablets as he may want to stop your water tablet before starting you on LISORETIC therapy.

Patients with severe kidney disease

LISORETIC is not recommended for patients with severe kidney problems (See Do not take LISORETIC).

Use in the elderly

No dosage reduction is usually necessary in the elderly.

Children

LISORETIC 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 LISORETIC will last. Do not stop treatment early because your high blood pressure may return.
If you have the impression that the effect of LISORETIC is too strong or too weak, tell your doctor or pharmacist.

If you take more LISORETIC than you should

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

Symptoms of overdose may include:

- hypotension (dizziness, fainting, nausea), rapid breathing (hyperventilating), pale or sweaty skin, bluish lips and nails (circulatory shock), decreased urine output, fluid retention, causing swelling in your legs, ankles or feet, abnormally slow, fast or irregular heart rate or anxiety and cough.

The most common signs of overdosage, related to decreased electrolytes in the body, are weakness, tiredness, cramping of muscles, tingling or numbness, bloating or constipation, dehydration, diarrhoea or vomiting, confusion, seizures and dehydration due to frequent passing of urine. Your healthcare provider will advise you on precautionary measures to take in the case of overdose.

If you forget to take LISORETIC

If you forget to take LISORETIC, 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 dose to make up for forgotten individual doses.

If you stop taking LISORETIC

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

4. Possible side effects

LISORETIC can have side effects.

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

If any of the following happens, stop using LISORETIC 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
- rash or itching
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to LISORETIC. 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:

- fever, unexplained wide spread of skin pain, red or purple rash that spreads or blisters on your skin and the mucous membranes of your mouth, nose, eyes, genitals or shedding of your skin within days after blisters form which are symptoms for Stevens-Johnson syndrome
- jaundice (yellow discolouration of the skin and eyes)
- heart attack or stroke
- increased or fast heartbeat (tachycardia)
- low blood pressure or fainting when getting up from a lying or sitting position (orthostatic hypotension/dizziness)
- chest pain (angina)

- weakness, fatigue, weight loss, headache (symptoms of a condition called vasculitis)
- kidney problems (passing less urine than is normal for you)
- hepatitis (inflammation of the liver with symptoms such as nausea, mild fever, abdominal pain).

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
- cough
- changes in the levels of certain chemicals in the blood and urine which are usually detected by blood and urine tests (electrolyte imbalance)
- vertigo (loss of balance), dizziness, tingling sensation in hands, feet or lips (feeling of “pins and needles”), sleep disturbances, light-headedness
- stomach pain or discomfort, constipation
- skin rash.

Less frequent side effects:

- increased immune response (autoimmune disease)
- problems with your bone marrow or a reduced number of blood cells and/or platelets in your blood. You may notice tiredness, an infection (which may be serious), fever, feeling breathless or that you bruise or bleed more easily

- changes to some of the cells or other parts of your blood, abnormal blood test results including anaemia
- low levels of sugar in your blood (hypoglycaemia)
- pancreatitis (inflammation of the pancreas with symptoms such as stomach pain, increased heart rate and fever)
- deficiency of potassium, sodium and magnesium, increased cholesterol levels and excess of uric acid in the bloodstream (seen through blood tests)
- insomnia, sleep disturbances, mood changes, anxiety, depression, confusion, hallucinations (seeing or hearing things that are not there), restlessness, changes to your sense of smell
- flushing, change of colour in your fingers or toes
- upper respiratory tract infections, nasal congestion, sinus disorders, sore throat
- stomach pain or discomfort, inflammation of the stomach, bloating, flatulence (gas)
- wind, stomach spasms, inflammation of a salivary gland
- diarrhoea, vomiting, dry mouth, nausea, indigestion
- abnormal liver function (clay coloured stool, dark urine, itching, loss of appetite, yellow eyes or skin), liver failure
- 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

- abnormal kidney function including inflammation of the kidneys, urinary infection, sugar in the urine, increased protein levels in the urine, liver failure
- blurred vision, worsening eyesight, seeing things in yellow
- problems with your sight for a short time, eye pain with redness
- vertigo (loss of balance)
- problems with sexual performance, enlarged breasts in men.

The following side effects have been reported but the frequency for them to occur is not known:

- skin and lip cancer (non-melanoma skin cancer), with abnormal growth of skin, bump or sores on the lips that persist for a long period of time
- inflammation of a salivary gland
- sudden eye pain and visual loss.

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA

By reporting side effects, you can help provide more information on the safety of LISORETIC. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

5. How to store LISORETIC

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from light.

Keep blisters in carton until required for 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).

6. Contents of the pack and other information

What LISORETIC contains

The active ingredients are lisinopril and hydrochlorothiazide.

LISORETIC 10/12,5: Each tablet contains lisinopril equivalent to lisinopril 10 mg and hydrochlorothiazide 12,5 mg.

LISORETIC 20/12,5: Each tablet contains lisinopril equivalent to lisinopril 20 mg and hydrochlorothiazide 12,5 mg.

The other ingredients are:

Tablet cores:

Croscarmellose sodium, dibasic calcium phosphate dihydrate, magnesium stearate, mannitol, pregelatinised maize starch.

The following colourants are also used in the 10/12,5 mg tablet only: iron oxide red, iron oxide yellow.

What LISORETIC looks like and contents of the pack

LISORETIC 10/12,5: A peach coloured, round, uncoated, biconvex tablet, debossed 'LH' on one side and plain on the other.

LISORETIC 20/12,5: A white coloured, round, uncoated, biconvex tablet, debossed 'LH' on one side and score-line on the other.

LISORETIC 10/12,5 and LISORETIC 20/12,5 are packed into PVC/PVDC/aluminium blister packs of 30 tablets, contained in a printed outer carton.

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LISORETIC 10/12,5: A37/7.1.3/0475

LISORETIC 20/12,5: A37/7.1.3/0476

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NAMIBIA

LISORETIC 10/12.5: NS2 06/7.1.3/0063

LISORETIC 20/12.5: NS2 06/7.1.3/0064

MOZAMBIQUE

LISORETIC 10/12.5: 4648

LISORETIC 20/12.5: 4649

ZAMBIA

LISORETIC 10/12.5: POM 051/021

LISORETIC 20/12.5: POM 051/020