

**PATIENT INFORMATION LEAFLET****SCHEDULING STATUS:****S3****PROPRIETARY NAME AND DOSAGE FORM:****LISORETIC 10/12,5** tablets**LISORETIC 20/12,5** tablets**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.
- **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.

**1. WHAT LISORETIC CONTAINS:**

The active substances in **LISORETIC** are lisinopril and hydrochlorothiazide.

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

**LISORETIC 20/12,5:** Each tablet contains 20 mg lisinopril (as the dihydrate) and 12,5 mg hydrochlorothiazide.

The other ingredients are 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.

**LISORETIC 10/12,5** contains sugar (mannitol 18,70 mg/tablet)

**LISORETIC 20/12,5** contains sugar (mannitol 38,30 mg/tablet)

## 2. WHAT LISORETIC 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.

- **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.

## 3. BEFORE YOU TAKE LISORETIC:

### Do not take LISORETIC:

- if you have had skin cancer or you develop an unexpected skin lesion during the treatment with **LISORETIC**.
- if you are hypersensitive (allergic) to lisinopril, hydrochlorothiazide or any of the other ingredients of **LISORETIC** (see **WHAT LISORETIC CONTAINS**).
- 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, or think you may be, pregnant or if you are planning to become pregnant or if you are breastfeeding.
- if you are taking antibiotic medicine containing fluoroquinolones (e.g ciprofloxacin, levofloxacin) and have a history of moderate or severe kidney injury.

**Take special care with LISORETIC:**

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

- 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 **Taking other medicines with LISORETIC**).
- if you have kidney problems.
- if you are taking antibiotics called fluoroquinolones (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 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.

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

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

#### **Taking LISORETIC with food and drink:**

**LISORETIC** can be taken with or without food.

#### **Pregnancy and breastfeeding:**

You should not take **LISORETIC** if you are pregnant or breastfeeding.

If you are pregnant, or breastfeeding your baby, please consult your healthcare provider for advice before taking **LISORETIC**.

#### **Driving and using machinery:**

Medicines which lower blood pressure may cause dizziness or drowsiness. Please make sure you know how **LISORETIC** affects you before driving or using machinery.

#### **Taking other medicines with 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. 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), 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 before 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.

#### **4. HOW TO TAKE LISORETIC:**

Do not share medicines prescribed for you with any other person. Always take **LISORETIC** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

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.

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

**If you take more LISORETIC 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 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 a dose of LISORETIC:**

If you forget to take a dose of **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 or larger dose to make up for the forgotten individual doses.

**Effects when treatment with LISORETIC 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:**

**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 taking **LISORETIC** please consult your healthcare provider for advice.

If any of the following happens, stop taking **LISORETIC** 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
- 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).

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

- 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)
- 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)
- fever, headache, feeling unwell, raw sores in your mouth, swollen lips covered in crusts, sores on the genitals making it painful to pass urine (erythema multiforme)
- high cholesterol.

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

Tell your doctor if you notice any of the following:

- abnormal blood test results including anaemia
- headache, dizziness, light-headedness
- abnormal liver function (clay coloured stool, dark urine, itching, loss of appetite, yellow eyes or skin)
- abnormal kidney function including inflammation of the kidneys, urinary infection, sugar in the urine
- decreased appetite, anorexia
- gout
- restlessness, depression
- vertigo (loss of balance), dizziness
- 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 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 in taste perception (including loss of taste)
- 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.

Side effects of unknown frequency:

- 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.

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

## **6. STORING AND DISPOSING OF LISORETIC:**

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from light.

Keep the blisters in the carton until required for use.

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).