

PATIENT INFORMATION LEAFLET

Please read this leaflet carefully before you use Lisoretic. This leaflet tells you the main points about the medicine. If you have any questions or are worried about any of this information, please ask your doctor or pharmacist.

SCHEDULING STATUS

Schedule 3

PROPRIETARY NAME (AND DOSAGE FORM)

LISORETIC 10/12,5: (tablets)

LISORETIC 20/12,5: (tablets)

COMPOSITION

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.

MEDICINE USES

LISORETIC is used against increased blood pressure that cannot be sufficiently treated with one drug alone.

BEFORE TAKING THIS MEDICINE

LISORETIC should not be used if:

- You have experienced an allergic reaction towards one or more of the ingredients of the tablet, or if you are hypersensitive to sulphonamide derivatives which are used for treatment of infections.
- You previously have been treated with medicines of the same type as **LISORETIC** and have experienced allergic reactions with difficulties of breathing or swallowing, swelling of hands, feet or ankles, or if you or your family have had this reaction due to other circumstances.
- The arteries of the kidneys are strictured.
- You are pregnant or breast feeding.

Before you take this medicine, you must inform your doctor if you suffer from the following:

- Stricture of the main artery at the heart.
- Atrophy of the cardiac muscle.
- Low blood pressure.
- Diarrhoea.
- Vomiting.
- Gout.
- Kidney or liver problems.

Or if you:

- Are dialysed.
- Are about to undergo desensitization therapy due to allergy against e.g. insect bites.
- Have diabetes, as the need for insulin and other treatment against diabetes may be altered.

The first dose may cause a bigger fall in blood pressure than the following doses. You may notice this as a feeling of weakness or dizziness, and it may help to lie down. Contact your doctor if you are worried. In order to prevent a profound fall in blood pressure with the first dose, existing therapy with diuretics should be discontinued 2 to 3 days prior to initiation of

therapy with **LISORETIC**. The doctor should check the *electrolyte content of your blood hereafter*.

If you are hospitalized, please inform the staff that you are treated with **LISORETIC**. Also inform the dentist if you are going to be anaesthetized.

Tell your pharmacist or doctor if you have any other illness, or if you are taking any medicine either prescribed by your doctor or bought from your pharmacist or elsewhere, or are seeing a doctor regularly. Concomitant use of medicine may cause undesirable interactions.

Special attention should be paid when you receive the following drugs:

- Diuretics or other blood pressure lowering drugs.
- Indomethacine or other drugs for treatment of gout or muscular pain.
- Lithium (is used for treatment of certain psychiatric diseases)
- Potassium supplement or products containing potassium.

HOW TO USE THIS MEDICINE

The usual dosage for treatment of increased blood pressure is 1 tablet once daily. The dose may be increased to tablets once daily.

The tablets should be swallowed with sufficient liquid. Try to take the tablets at the same time every day.

WHAT DO TO IF YOU USE TOO MUCH

If you accidentally use much more of the medicine than recommended, contact your doctor immediately.

SIDE EFFECTS

Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen while using this medicine, please consult your doctor, pharmacist or other health care professional for advice.

If any of the side-effects mentioned below are severe to both you, or if you notice any other side effects, speak to your doctor or pharmacist.

The side effects are usually mild and transient and do not cause interruption of treatment.

The most common side effect is dizziness. Headache, fatigue, low blood pressure (is possibly experienced as dizziness when standing up) and cough may occur.

Side effects that occur less frequently are: diarrhoea, nausea, vomiting, dry mouth, rash, gout, discomfort in the chest, muscular cramps and weakness, numbness or tingling in fingers and toes, general weakness and impotence. Allergic reactions including swelling of the face, hands, feet or ankles, lips, tongue and/or throat have been reported. Anaemia, joint pain as well as inflammation of the joints may occur.

For each of the active ingredients, the following side effects have been seen:

Lisinopril: thrombosis in the heart or brain, rapid pulse rate, abdominal pain, indigestion, mood alterations, dizziness, taste disturbances, nightmares, respiratory distress, rhinitis or pain in the sinuses, loss of hair, increased sweating, itching, skin diseases, reduced or stopped urine productions and jaundice.

Hydrochlorothiazide: Loss of appetite, irritation of the stomach, constipation, jaundice, dizziness, yellow vision (objects are seen in a yellowy tinge), anaemia, light sensitive and itching skin, fever, respiratory and breathing disturbances, pneumonia, allergic reactions, high content of blood sugar, excretion of blood sugar in the urine, muscular cramps, transient blurred vision and impaired renal function.

STORAGE AND DISPOSAL

Store below 25 °C and protect from light. Store all medicine out of reach of children.

Do not use the tablets after the expiry date shown on the carton. Return the expired medicine to your pharmacist for safe disposal.

PRESENTATION

LISORETIC is available in blister packs of 30 tablets.

IDENTIFICATION

LISORETIC 10/12,5: A peach coloured, round, uncoated 6 mm biconvex scored tablet.

LISORETIC 20/12,5: A white coloured, round, uncoated 8 mm biconvex scored tablet.

REGISTRATION NUMBER

To be allocated

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF APPLICANT

Pharma Dynamics

1st Floor Grapevine House

Steenberg Office Park

Silverwood Close

Westlake

7945

DATE OF PUBLICATION OF THE INFORMATION LEAFLET