

# Tensikey 20

Lisinopril

## COMPOSITION

Tablet composition:

Lisinopril (D.C.I.) ..... 20 mg

Excipients: mannitol, dibasic calcium phosphate, maize starch, pre-gelatinised starch, magnesium stearate.

## PHARMACEUTICAL FORMULATION AND PACKAGING CONTENTS

Packages with 28 tablets.

## ACTIVITY

Lisinopril, a synthetic peptide derivative, is an oral long-acting angiotensin converting enzyme inhibitor (ACE). Because of its ACE inhibiting activity, Linosipril reduces the plasma levels of Angiotensin II, as well as the aldosterone excretion. Consequently:

- It reduces arterial pressure in hypertense patients
- It improves symptoms and signs of congestive cardiac insufficiency
- It prevents the development of left ventricular dysfunction or of cardiac insufficiency after myocardial infarct

## PROPRIETER AND MANUFACTURER

PHARMINICIO, S.L.

Paseo de la Habana 9-11

28036 Madrid

Spain

## INDICATIONS

Arterial hypertension (essential and renovascular). It can be used as a single drug or associated with other antihypertensive drugs.

Treatment of congestive cardiac insufficiency not responding to treatment with digital drugs and/or diuretics.

It is also indicated for the treatment of haemodynamically stable patients in the first 24 hours after an acute myocardial infarct, to prevent the subsequent development of left ventricular dysfunction or cardiac insufficiency, and to improve the survival of patients. When appropriate, patients should receive the recommended standard treatments such as aspirin, beta-blockers and thrombolytic drugs.

## CONTRAINDICATIONS

Lisinopril should not be administered to patients suffering from any form of hypersensitivity to any of its components. If previously treated with a medicine belonging to the same pharmacological group (i.e. ACE inhibitors), and showed a reaction of hypersensitivity with inflammation of, for instance, face, lips, tongue and/or larynx the patient should not be treated with Lisinopril.

In case of doubt ask your doctor.

It is not advised to use Lisinopril in children.

Pregnancy and nursing mothers: (see warnings).

## PRECAUTIONS

Never forget that, for this medicine to be effective, it should be taken regularly, and for as long as indicated by the doctor, even if the treatment is long.

Dosage should be strictly respected without any change unless stated by your doctor.

If you suffer from any kind of renal malfunction, you are subjected to dialysis, taking diuretic drugs, or following any diet that includes a restriction of salt, you should inform your doctor before taking Lisinopril. In these cases, dosage should be adjusted to prevent a sudden and excessive decrease of arterial pressure.

If you have recently suffered from vomits and/or diarrhoea, your doctor should be informed.

It is important that patients that suffer alterations of the renal function do not take potassium supplements or potassium saving agents because this can lead to the increase of the potassium levels in blood.

Before being anaesthetised or subjected to surgery you should inform the doctor that you are taking Lisinopril since this could cause a sudden hypotension.

At the beginning of the treatment there may appear symptoms of fatigue and somnolence, or a sensation of instability. For this reason it is advised not to perform tasks requiring special attention (such as driving cars, dangerous machines, etc) until the response to the drug is satisfactory.

## INTERACTIONS

Never take any medicine under your own initiative, and unless recommended by your doctor, since a number of combinations should be avoided.

You should inform your doctor of all the drugs that you are taking, and always before a new medicine is prescribed.

With exceptions, patients taking Lisinopril should not take neither potassium supplements nor dietetic salt with a high potassium content.

## **WARNINGS**

### **Pregnancy and nursing mothers**

If administered during the second and third quarters of pregnancy, inhibitors of Angiotensin converting enzyme (the group to which this product belongs) can cause damage and foetal death.

In case of pregnancy, the administration of this drug should be stopped the as soon as possible.

It is not known whether Lisinopril is excreted by human milk. Since many drugs are excreted in human milk, precautions should be taken when giving Lisinopril to a lactating mother.

Effects on the ability to drive vehicles or use machinery (see Precautions).

Use in children (see contraindications).

## **DOSAGE**

### **Arterial hypertension**

The initial dose usually recommended is 10 mg daily.

The usually effective dose (for maintenance) is 20 mg daily.

When taking a diuretic (drugs inducing the formation of urine), or suffering from renal alterations or renovascular hypertension, it could be advisable to reduce the dose of Lisinopril.

### **Congestive cardiac insufficiency**

First dose: 2.5 mg, daily.

Maintenance dose: generally from 5 to 20 mg, daily.

Lisinopril tablets can be taken after, during or before meals.

Lisinopril is administered as a single daily dose.

The appropriate dose is that recommended by your doctor.

### **Acute myocardial infarction**

Usual dose: 1<sup>st</sup> and 2<sup>nd</sup> days: 5 mg daily. From 3<sup>rd</sup> day onwards: 10 mg daily.

## **OVERDOSE AND ITS TREATMENT**

In case of an overdose of Lisinopril, the most common manifestation would be hypotension. The patient should be immediately brought to a hospital in order to administer the appropriate treatment.

In the event of overdose or accidental ingestion, consult the Poison Centre.

## **ADVERSE REACTIONS**

Lisonopril has been usually well tolerated. Most of the secondary effects have been light and transitory. Frequent secondary effects include: dizziness, headache, fatigue. diarrhoea, nausea and cough.

Other less frequent secondary effects are: orthostatic effects, including hypotension. rash, cutaneous eruption. and asthenia.

Very rare secondary effects include palpitations, impotence, jaundice and hypersensitive reactions. In case of suffering breathing difficulties or inflammation of the face, lips. tongue and/or larynx, the treatment should be immediately stopped and your doctor informed.

If you observe any other adverse reaction not previously described, ask your doctor or pharmacist.

## **CADUCITY**

This medicine should not be used after the expiry date stated in the packaging.

## **OTHER PRESENTATIONS**

Packages of 60 tablets with 5 mg of Lisinopril.

## **LAST REVISION OF THE TEXT**

April 2000

**DRUGS SHOULD BE KEPT OUT OF CHILDREN'S REACH.**

**UNDER PRESCRIPTION**

**PHARMINICIO, S.L.**

Paseo de la Habana 9-11

28036 Madrid

Spain