For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory xxxxxxxx-8883

LISTRIL

(Lisinopril Tablets U.S.P., 2.5 mg, 5 mg and 10 mg)

Listril (lisinopril), a lysine derivative of enalaprilat, is an oral long acting angiotensin converting enzyme inhibitor. It is indicated in various grades of essential hypertension.

CLINICAL PHARMACOLOGY :

Listril inhibits the conversion of angiotensin I to the vasoconstictor substance angiotensin II by inhibiting the angiotensin converting enzyme (ACE). Inhibition of ACE results in decreased plasma angiotensin II which leads to decreased vasopressor activity and aldosterone secretion. These actions of Listril reduce after load through its vasodilator action while they reduce preload by preventing compensatory retention of fluid and solute.

The ability of Listril to cause afterload and pre-load reduction without increasing heart rate make it a very useful drug in the treatment of patient with congestive heart failure.

About 25 to 50% of an oral dose is bioavailable and peak serum concentrations are reached in about 7 hours. Food does not affect the absorption of Listril. It is not bound to plasma proteins. Listril does not undergo metabolism and is excreted unchanged entirely in the urine. Most of the drug is eliminated during initial rapid phase with an effective half-life of 12 hours, followed by a terminal late phase with a half-life of about 30 hours.

INDICATIONS :

Listril is indicated for the treatment of various grades of essential hypertension. It may be used alone as initial therapy or concomitantly with other classes of antihypertensive agents. Listril is effective in patients with congestive heart failure when added to digitalis and/or diuretics. Listril is also indicated in acute myocardial infarction in haemodynamically stable patients to prevent development of left ventricular dysfunction or heart failure.

CONTRAINDICATIONS :

Listril is contraindicated in patients who are hypersensitive to angiotensin converting enzyme inhibitor.

WARNINGS :

Angioedema of the face, extremities, lips, tongue, glottis and/or larynx have been reported in patients treated with Listril. In such cases Listril should be promptly discontinued. Where there is involvement of the tongue, glottis or larynx, likely to cause airway obstruction, appropriate therapy, e.g., subcutaneous epinephrine solution 1:1000 (0.3 ml to 0.5 ml) and/or measures necessary to ensure a patent airway, should be promptly provided.

PRECAUTIONS :

In patients with severe congestive heart failure, associated with renal insufficiency, excessive hypotension has been observed following Listril. Therapy should be started under very close medical supervision in such patients with minimum dose of 2.5mg of Listril.

Reduced dosage or frequency of administration of Listril is necessary in patients with impaired renal function.

Evaluation of patients with hypertension, heart failure, or myocardial infarction should always include assessment of renal function.

USE IN PREGNANCY, LACTATION AND CHILDREN :

There are no adequate and well-controlled studies in pregnant women. It is not known whether it is secreted in human milk. Caution should be observed when Listril is given to a nursing mother. Safety and effectiveness in children have not been established.

When used in pregnancy during the second and third trimersters, ACE inhibitors can cause injury and even death to the developing fetus. When pregnancy is detected, the drug should be discontinued as soon as possible.

ADVERSE REACTIONS :

Listril has been found to be generally well tolerated. The most frequent adverse reactions are dizziness, headache, fatigue, diarrhoea and cough.

DRUG INTERACTIONS :

Patients on diuretics may occasionally experience an excessive reduction of blood pressure after initiation of therapy with Listril. It attenuates potassium loss caused by thiazide- type diuretics. Use of Listril with potassium- sparing diuretics, potassium supplements or potassium-containing salt substitutes may lead to significant increases in serum potassium.

DOSAGE AND ADMINISTRATION :

Hypertension

Initial Therapy :

In patients with uncomplicated essential hypertension, not on diuretic therapy, the recommended initial dose is 10 mg once a day. Dosage should be adjusted according to blood pressure response. The usual dosage range is 20 to 40 mg per day administered in a single daily dose. If blood pressure is not controlled by Listril alone, a low dose of thiazide diuretic may be added.

In Renal Impairment :

The usual dose of Listril (10 mg) is recommended for patients with a creatinine clearance > 30 mL/min. For patients with creatinine clearance > 10 mL/min < 30 mL/min, the first dose is 5mg once daily. For patients with creatinine clearance < 10 mL/min the recommended initial dose is 2.5 mg. The dosage may be titrated upward until blood pressure is controlled or to a maximum of 40 mg daily.

Congestive heart failure :

Adults: Initially 2.5 mg once daily increasing gradually over 2-4 weeks to maintenance of 5-20 mg once daily according to response.

Acute myocardial infarction :

Initially 2.5 - 5mg may be given within 24 hrs of onset of symptoms, then 2.5-5 mg after 24 hrs and 5-10 mg after 48 hrs. Thereafter 5-10 mg once daily may be administered for six weeks.

OVERDOSAGE :

The most likely manifestation of overdosage is hypotension, for which the usual treatment would be intravenous infusion of normal saline solution.

PRESENTATION :

Listril is available as 2.5 mg, 5 mg & 10 mg in blister strip of 10 & 15 tablets.

torrent PHARMA

Manufactured by :
TORRENT PHARMACEUTICALS LTD.
Baddi 173 205, Dist. Solan (H.P.) INDIA.

PRODUCT NAME	Listril