Losarva® Plus

Losartan Potassium USP 50 mg &
Hydrochlorothiazide BP 12.5 mg

COMPOSITION

Each film coated tablet contains Losartan Potassium USP 50 mg & Hydrochlorothiazide BP 12.5 mg

PHARMACOLOGY

Angiotensin II (formed from angiotensin I in a reaction catalyzed by angiotensin converting enzyme ACE), is a potent vasoconstrictor, the primary vasoactive hormone of the renin-angiotensin system and an important component in the pathophysiology of hypertension. It also stimulates aldosterone secretion by the adrenal cortex. Losartan and its principal active metabolite block the vasoconstrictor and aldosterone-secreting effects of angiotensin II by selectively blocking the binding of angiotensin II to the AT_1 receptor found in many tissues, (e.g. vascular smooth muscle, adrenal gland). In vitro binding studies indicate that losartan is a reversible, competitive inhibitor of the AT_1 receptor. Neither Losartan nor its active metabolite inhibits ACE (kinase II, the enzyme that converts angiotensin I to angiotensin II and degrades bradykinin); nor do they bind to or block other hormone receptors or ion channels known to be important in cardiovascular regulation.

Hydrochlorothiazide is a thiazide diuretic. Thiazides affect the renal tubular mechanisms of electrolyte reabsorption, directly increasing excretion of sodium and chloride in approximately equivalent amounts. Indirectly, the diuretic action of Hydrochlorothiazide reduces plasma volume, with consequent increases in plasma renin activity, increases in aldosterone secretion, increases in urinary potassium loss, and decreases in serum potassium. The renin-aldosterone link is mediated by angiotensin II, so co-administration of an angiotensin II receptor antagonist tends to reverse the potassium loss associated with these diuretics.

INDICATIONS

Losarva Plus is indicated for the treatment of hypertension. It is also indicated to reduce the risk of stroke in patients with hypertension and left ventricular hypertrophy.

DOSAGE AND ADMINISTRATION

Hypertension: The usual dose of Losarva Plus is one tablet daily. Then if necessary increase to two tablets once daily. The maximum dose is two tablets once daily. In general the antihypertensive effect is attained within three weeks after initiation of therapy. No initial dosage adjustment of Losarva Plus is necessary for elderly patients.

Use in Patients with Renal Impairment: The usual regimens of therapy with Losarva Plus may be followed as long as the patient's creatinine clearance is > 30 ml/min. In patients with more severe renal impairment, loop diuretics are preferred to thiazides. In that case, Hydrochlorothiazide is not recommended.

Use in patients with Hepatic Impairment: The combination of Losartan and Hydrochlorothiazide is not recommended for titration in patients with hepatic impairment because starting dose of Losartan (25 mg) cannot be given in this case.

Severe Hypertension: The starting dose for initial treatment of severe hypertension is one tablet of Losarva Plus once daily. For patients who do not respond adequately to this dose after 2 to 4 weeks of therapy, the dosage may be increased to Losarva Plus two tablets once daily. The maximum dose is two tablets once daily. Losarva Plus may be administered with other antihypertensive agents. Losarva Plus may be administered with or without food.

CONTRAINDICATIONS

The combination of Losartan and Hydrochlorothiazide is contraindicated in patients who are hypersensitive to any component of this product. Because of the Hydrochlorothiazide component, this product is contraindicated in patients with anuria or hypersensitivity to other sulfonamide-derived drugs.

WARNING AND PRECAUTION

- Hypersensitivity: Angioedema
- Periodic determination of serum electrolytes to detect possible electrolyte imbalance should be performed at appropriate intervals.
- Hypokalemia may develop, especially with brisk diuresis, when severe cirrhosis is present, or after prolonged therapy.
- Impaired renal function.
- Symptomatic hypotension.

SIDE EFFECTS

In clinical trials with Losartan potassium and Hydrochlorothiazide, no adverse experiences have been observed. The overall incidence of adverse experiences reported with the combination is comparable to placebo.

USE IN PREGNANCY AND LACTATION

When pregnancy is detected, discontinue Losartan Potassium & Hydrochlorothiazide as soon as possible. Can be given to nursing mother considering the risk and benefit.

USE IN CHILDREN AND ADOLESCENTS

The safety and efficacy of Losartan Potassium & Hydrochlorothiazide in children & adolescent patients have not been established.

DRUG INTERACTIONS

Losartan Potassium: No significant drug-drug pharmacokinetic interactions have been found in interaction studies with Hydrochlorothiazide, Digoxin, Warfarin, Cimetidine and Phenobarbital.

Hydrochlorothiazide: Alcohol, Barbiturates, or Narcotics - potentiation of Orthostatic hypotension may occur.

Antidiabetic drugs (oral agents and Insulin) - dosage adjustment of the antidiabetic drug may be required.

Other antihypertensive drugs - additive effect or potentiation.

Cholestyramine and Colestipol resins - absorption of Hydrochlorothiazide is impaired in the presence of anionic exchange resins.

OVERDOSAGE

If symptomatic hypotension occurs because of Losartan overdose, supportive treatment should be given. In Hydrochlorothiazide overdose electrolyte depletion and dehydration resulting from excessive diuresis is most common.

STORAGE

Store below 30°C temperature in a cool & dry place. Protect from light & moisture. Keep out of the reach of children.

HOW SUPPLIED

Each box contains 50 tablets in Alu-PVDC blister pack.

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NIPRO JMI Pharma

Manufactured by:
NIPRO JMI Pharma Ltd.
Chauddagram, Cumilla, Bangladesh.