Vasopril®

Enalapril Maleate

COMPOSITION
Vasopril 5 mg tablet : Each tablet contains Enalapril Maleate USP 5 mg.
Vasopril10 mg tablet : Each tablet contains Enalapril Maleate USP 10 mg.

PHARMACOLOGY
Enalapril, after hydrolysis to enalaprilate, inhibits Angiotensin Converting Enzyme (ACE). ACE is a peptidyl dipeptidase that catalyses the conversion of angiotensin I to the vasoconstrictor substance angiotensin II. Angiotensin II also stimulates aldosterone secretion by the adrenal cortex. The beneficial effects of enalapril in hypertension and heart failure appear to result primarily from suppression of the renin-angiotensin aldosterone system.
Following oral administration of Enalapril, peak serum concentration of Enalapril occurs within about one hour while levels of the active form (Enalaprilate) are maximum at about 4 hours. Minimum absorption is about 60% based on the urinary excretion of Enalapril and Enalaprilate, about 70% of which is Enalaprilate. Bioavailability is not affected by food. Serum profiles of Enalaprilate show a prolonged terminal half-life of about 35 hours. This is due to binding to ACE and hence would not contribute to accumulation of the drug. Excretion of Enalapril is primarily renal. About 94% of an oral dose of Enalapril is recovered in the urine (61%) and faeces (33%) as either Enalapril or Enalaprilate.

INDICATION
Enalapril (Vasopril) is indicated in-
- All grades of essential hypertension and renovascular hypertension either alone or in combination with other antihypertensive agents especially thiazide diuretics.
- Prevention of symptomatic heart failure.
- Treatment of congestive heart failure (adjunct), usually in combination with diuretics and digitalis.
- Prevention of coronary ischaemic events in patients with left ventricular dysfunction.

Enalapril (Vasopril) is also used either alone or as an adjunct in the treatment of angina, diabetic nephropathy and Raynaud's disease.

DOSAGE AND ADMINISTRATION
Hypertension: Initially 5 mg once daily if used alone or 2.5 mg daily if used in addition to diuretic, in elderly patients or in patients with renal impairment. Usual maintenance dose is 10-20 mg once daily. However, in severe hypertension it may be increased to a maximum of 40 mg once daily.
Heart failure (adjunct) and asymptomatic left ventricular dysfunction: Initially 2.5 mg under close medical supervision. Usual maintenance dose is 20 mg daily in 1-2 divided doses.

CONTRAINDICATION AND PRECAUTION
Enalapril Maleate is contraindicated in patients who are hypersensitive to this product and in patients with a history of angioedema related to previous treatment with an ACE inhibitor.
After the initial dose of Enalapril, the patient should be observed under medical supervision for at least two hours and until blood pressure has been stabilized for at least an additional hour.
Renal function should be assessed before and during treatment and dose and dosing interval should be adjusted accordingly if the patient is found to have renal insufficiency.
Hypotension may result shortly after initiation of the treatment in patients with severe heart failure or those who have been volume depleted by diuretic therapy, dietary salt restriction, dialysis, diarrhoea or vomiting. The risk of hypotension is also present in patients undergoing major surgery or during anesthesia with agents that produce hypotension.
Renal failure is reported in patients with severe congestive heart failure of underlying renal disease including renal artery stenosis.
A high incidence of anaphylactoid reaction is found if the patients under ACE inhibitor therapy are dialyzed with high-flux membrane (e.g. AN 69).
Patients with a history of angioedema unrelated to ACE inhibitor therapy may be at high increased risk of angioedema after receiving ACE inhibitors.
Safety and effectiveness of the drug have not been established in children.

This product contains Lactose.

SIDE EFFECT
Dizziness and headache are more commonly reported side effects. Fatigue and asthenia were reported in 2-3% of patients. Other side effects occurred in less than 2% of patients and included hypotension, orthostatic hypotension, syncope, nausea, diarrhoea, muscle cramps, rash and cough.
Less frequently renal dysfunction, renal failure and oliguria have been reported. Angioedema, hyperkalemia and hyponatremia have also been reported rarely.

DRUG INTERACTION
Patients on diuretics may experience hypotension on concomitant Enalapril Maleate therapy. Either discontinuing the diuretic therapy or significantly reducing the diuretic dose for two to three days prior to initiating Enalapril therapy can minimize the risk.
Potassium loss caused by thiazide diuretics is attenuated by Enalapril Maleate.
On the other hand, concomitant use of potassium-sparing diuretics, potassium supplements and potassium containing salt substitutes may lead to significant increase in serum potassium.
Simultaneous therapy with lithium may increase serum lithium concentration and lead to lithium toxicity.

USE IN PREGNANCY AND LACTATION
Enalapril is contraindicated in pregnancy. The drug is excreted in trace amount in human milk and caution should be exercised if given to nursing mothers.

STORAGE
Store below 30°C. Protect from light & moisture.
Keep out of children's reach.

HOW SUPPLIED
Vasopril 5 tablet : Box containing 3 x 10 / 5 x 10 / 10 x 10 / 15 x 10 tablets in blister pack.
Vasopril 10 tablet : Box containing 3 x 10 / 5 x 10 / 10 x 10 / 15 x 10 tablets in blister pack.

SQUARE