

# Enaril®

Tablet

## Description

Enaril is a preparation of Enalapril Maleate which is the maleate salt of Enalapril, the ethyl ester of a long acting angiotensin converting enzyme (ACE) inhibitor, enalaprilat. It is highly effective in the management of hypertension and heart failure.

## Indications

Enaril is indicated for the treatment of all grades of essential hypertension, renovascular hypertension and heart failure.

## Dosage and Administration

*Essential and renovascular hypertension* : Treatment should be initiated with 5 mg once a day. Where concomitant therapy is a diuretic, the recommended initial dose of Enaril is 2.5 mg. The dose should be titrated to give optimum control of blood pressure. The usual maintenance dose is 10-20 mg given once daily. In severe hypertension, the dosage may be increased incrementally to a maximum of 40 mg once daily.

*Heart failure* : Enaril can be used as an adjunctive therapy with non-potassium-sparing diuretics and/or digitalis. The recommended starting dose of Enaril is 2.5 mg once daily. The dose of Enaril should be gradually increased depending upon tolerability to the recommended maintenance dose (10-20 mg) given as a single or twice daily dose.

The absorption of Enaril is not affected by food. The maximum daily dose is 40 mg.

*Use in the elderly (over 65 years)* : The starting dose should be 2.5 mg. Enaril is effective in the treatment of hypertension in the elderly. The dose should be titrated according to need for the control of blood pressure.

## Contraindications

*Pregnancy* : Enalapril is contraindicated in pregnancy and treatment should be stopped if pregnancy is suspected, because it has been found to be foetotoxic in rabbits.

*Hypersensitivity* : Enaril is also contraindicated in patients who are hypersensitive to any component of this product and in patients with a history of angioneurotic oedema relating to previous treatment with an ACE inhibitor.

### **Precautions**

*Hypotension* : Symptomatic hypotension has been reported mainly in patients with severe heart failure. In these patients, by discontinuing diuretic therapy or significantly reducing the diuretic dose for two to three days prior to initiating Enalapril, the possibility of this occurrence is reduced. By initiating therapy with a small dose (2.5 mg), the duration of any hypotensive effect may be lessened.

If hypotension develops, the patient should be placed in a supine position. Volume repletion with oral fluids or intravenous normal saline may be required.

*Impaired renal function* : Enalapril should be used with caution in patients with renal insufficiency as they may require reduced or less frequent doses. Renal failure has been reported in association with Enalapril and has been mainly in patients with severe congestive heart failure or underlying renal disease, including renal artery stenosis. If recognized promptly and treated appropriately, renal failure is usually reversible.

*Angioneurotic oedema* : Angioneurotic oedema has been reported with ACE inhibitors including Enalapril. In such cases, Enaril should be discontinued immediately and appropriate monitoring should be instituted to ensure complete resolution of symptoms prior to dismissing the patient. Where swelling is confined to the face, lips and mouth, the condition will usually resolve without further treatment, although antihistamines may be useful in relieving symptoms. However, where there is involvement of the tongue, glottis or larynx, likely to cause airways obstruction, appropriate therapy such as subcutaneous adrenaline 1 : 1000 (0.5 ml) should be administered promptly.

*Cough* : Cough has been reported with the use of ACE inhibitors.

*Surgery/Anaesthesia* : In patients undergoing major surgery or during anaesthesia with agents that produce hypotension, Enalapril blocks

angiotensin II formation secondary to compensatory renin release. This may lead to hypotension which can be corrected by volume expansion.

### **Drug Interactions**

Combination with other antihypertensive agents such as  $\beta$  blockers, Methyldopa, calcium antagonists and diuretics may increase the antihypertensive efficacy. Adrenergic blocking drugs should only be combined with Enalapril under careful supervision. Concomitant Propranolol may reduce the bioavailability of Enalapril, but this does not appear to be of any clinical significance. Concomitant therapy with Lithium may increase the serum Lithium concentration.

### **Side Effects**

The commonly reported side effects are dizziness and headache. Other side effects occurring less frequently include orthostatic hypotension, nausea, rash, cough etc.

*Cardiovascular*: Myocardial infarction or cerebrovascular accident, possibly secondary to severe hypotension in high risk patients. Palpitation, rhythm disturbances. *Gastrointestinal* : Abdominal pain, dyspepsia, hepatitis, jaundice. *Nervous system* : Confusion, nervousness, insomnia, somnolence. *Respiratory system* : Sore throat, hoarseness of voice. *Skin* : Urticaria, pruritus. *Special senses* : Blurred vision. *Renal* : Oliguria, renal dysfunction, renal failure are reported in rare cases.

### **Use in Special Population**

*Lactation* : Enalapril and Enalaprilat are excreted in breast milk; caution should be exercised if Enaril is given to lactating mothers.

### **Commercial Pack**

Enaril® Tablet : Box containing 10 blister strips of 10 tablets, each tablet contains 5 mg of Enalapril Maleate USP.