SPMC

ENALAPRIL MALEATE TABLETS USP 5 mg

PRESENTATION:

Enalapril maleate tablets USP 5 mg,
Bulk pack -500 tablets,
White, circular, Flat beveled edge tablets of 8.50 mm diameter each tablets contains Enalarpril maleate 5mg.

MECHANISM OF ACTION:

While the mechanism through which Enalapril lowers blood pressure is believed to be primarily suppression of the renin-angiotensin-aldosterone system, Enalapril is antihypertensive even in patients with low-renin hypertension.

INDICATIONS AND DOSE:

Hypertension

Adult: Initially 5 mg once daily, lower initial doses may be required when used in addition to diuretic or in renal impairment; maintenance 20 mg once daily; maximum 40 mg per day

Heart failure

Adult (under close medical supervision): Initially 2.5 mg once daily, increased if tolerated to 10–20 mg twice daily, dose to be increased gradually over 2–4 weeks

Prevention of symptomatic heart failure in patients with asymptomatic left ventricular dysfunction

Adult (under close medical supervision): Initially 2.5 mg once daily, increased if tolerated to 10–20 mg twice daily, dose to be increased gradually over 2–4 weeks

SIDE EFFECTS:

Common or very common
Depression. Hypersensitivity. Vision blurred
Uncommon
Anaemia. appetite decreased. asthma. bone marrow disorders. flushing. gastrointestinal disorders. hoarseness. hypoglycaemia. malaise. muscle cramps. nervousness. proteinuria. rhinorrhoea. sleep disorders, throat pain
Rare or very rare
Autoimmune disorder. gynaecomastia, hepatic disorders lymphadenopathy. oral disorders. Raynaud's Phenomenon. Toxic epidermal necrolysis
Frequency not known
Arthritis. Leuco cytosis. Myositis .serositis . SIADH. Vasculitis

HEPATIC IMPAIRMENT:

Enalapril is a prodrug..

RENAL IMPAIRMENT:

Dose adjustments Max. initial dose 2.5mg daily if eGFR less than 30 mL/minute/1.73m2.
Dosage in Renal Insufficiency
Generally, the intervals between the administration of enalapril should be prolonged and/or the dosage reduced.

Creatinine Clearance (CrCL) mL/min	**Initial Dose mg/day**
30 <CrCL <80 ml/min.	5 - 10 mg
10 <CrCL≤30 ml/min.	2.5 mg
CrCL≤10 ml/min.	2.5 mg on dialysis days*

Enalapril is dialyzable. Dosage on nondialysis days should be adjusted depending on the blood pressure response.

Elderly The dose should be in line with the renal function of the elderly patient

DIRECTIONS FOR ADMINISTRATION

Tablets may be crushed and suspended in water immediately before use.

SPECIAL PRECAUTIONS:

Vol-depleted patients. Severe degrees of heart failure, aortic stenosis or hypertrophic cardiomyopathy, renal dysfunction. Pregnancy & lactation.

CONTRA-INDICATIONS:

The concomitant use of enalapril 2.5mg tablets with aliskiren-containing products is contraindicated in patients with diabetes mellitus or renal impairment (GFR < 60 ml/min/1.73 m²). Hypersensitivity to enalapril, to any of the excipients listed or any other ACE inhibitor History of angioedema associated with previous ACE inhibitor therapy Hereditary or idiopathic angioedema Second and third trimesters of pregnancy. Concomitant use with sacubitril/valsartan therapy. Enalapril must not be initiated earlier than 36 hours after the last dose of sacubitril/ valsartan

PREGNANCY:

The use of ACE inhibitors is not recommended during the first trimester of pregnancy. The use of ACE inhibitors is contra-indicated during the second and third trimester of pregnancy. Epidemiological evidence regarding the risk of teratogenicity following exposure to ACE inhibitors during the first trimester of pregnancy has not been conclusive; however a small increase in risk cannot be excluded. Unless continued ACE inhibitors therapy is considered essential, patients planning pregnancy should be changed to alternative anti-hypertensive treatments which have an established safety profile for use in pregnancy. When pregnancy is diagnosed, treatment with ACE inhibitors should be stopped immediately, and, if appropriate, alternative therapy should be started. ACE inhibitors therapy exposure during the second and third trimesters is known to induce human foetotoxicity (decreased renal function, oligohydramnios, skull ossification retardation) and neonatal toxicity (renal failure, hypotension, hyperkalaemia). Maternal oligohydramnios, presumably representing decreased foetal renal function, has occurred and may result in limb contractures, craniofacial deformations and hypoplastic lung development. Should exposure to ACE inhibitors have occurred from the second trimester of pregnancy, ultrasound check of renal function and skull is recommended. Infants whose mothers have taken ACE inhibitors should be closely observed for hypotension

BREAST FEEDING:

Avoid in first few weeks after delivery,
Particularly in preterm infants—risk of profound neonatal hypotension; can be used in mothers breast-feeding older Infants if essential but monitor infant are blood pressure.

DRUG INTERACTIONS:

Antihypertensive, K supplements, K-sparing diuretics or K-containing salts. NSAIDs, lithium**.**

OVERDOSAGE:

Limited data are available for overdosage in humans. The most prominent features of overdosage that have been reported to date are marked hypotension, beginning some six hours after ingestion of tablets, concomitant with blockade of the renin-angiotensin system and stupor. Symptoms associated with overdosage of ACE inhibitors may include circulatory shock, electrolyte disturbances, renal failure, hyperventilation, tachycardia, palpitations, bradycardia, dizziness, anxiety, and cough. Serum enalaprilat levels 100 times and 200 times higher than usually seen after therapeutic doses have been reported after ingestion of 300 mg and 440 mg of enalapril, respectively. The recommended treatment of overdosage is intravenous infusion of normal saline solution. If hypotension occurs, the patient should be placed in the shock position. If available, treatment with angiotensin II infusion and/or intravenous catecholamines may also be considered. If ingestion is recent, take measures aimed at eliminating enalapril maleate (e.g., emesis, gastric lavage, administration of absorbents, and sodium sulphate). Enalapril can be removed from the general circulation by haemodialysis .(See 4.4 'special warnings and precautions for use',haemodialysis patients.). Pacemaker therapy is indicated for therapy-resistant bradycardia. Vital signs, serum electrolytes and creatinine concentrations should be monitored continuously**.**

STORAGE:

Keep tightly closed in in a cool & dry place at a temperature not exceeding 30 ^{0}C.

Keep all the medicines away from the reach of children

Manufactured by:
State Pharmaceuticals Manufacturing Corporation
No.11, Sir John Kotalawala Mawatha,
Kadawala Estate,
Ratmalana, Sri lanka.