

Enalapril BP 20 mg Tablets

Vitapril

Composition: Each uncoated tablet contains:

Enalapril Maleate BP	20 mg
Excipients	q.s.

Therapeutic Indications

Treatment of hypertension: all grades of essential hypertension and renovascular hypertension.
Treatment of heart failure: enalapril should be used in conjunction with potassium-sparing diuretics. Enalapril improves symptoms, delays disease progression, and reduces associated mortality and hospitalization. Prevention of symptomatic heart failure: in asymptomatic patients with left ventricular dysfunction, enalapril delays the development of symptomatic heart failure and also reduces hospitalization due to heart failure.

Contraindications

Hypersensitivity to enalapril, to any of the excipients, or to any other ACE inhibitor
History of angioedema associated with previous ACE inhibitor therapy
Hereditary or idiopathic angioedema

Dosage and method of administration

Food does not interfere with the absorption of enalapril.
The dosage should be individualized according to the patient's profile and blood pressure response.

Warnings and special precautions for use

Dual blockade of the renin-angiotensin-aldosterone system (RAAS)
There is evidence that the concomitant use of ACE inhibitors and angiotensin II receptor blockers increases the risk of hypotension, hyperkalemia, and decreased renal function (including acute renal failure). If dual-blockade therapy is considered absolutely necessary, it should be undertaken only under specialist supervision and subject to frequent and close monitoring of renal function, electrolytes, and blood pressure. ACE inhibitors and angiotensin II receptor blockers should not be used concomitantly in patients with diabetic nephropathy.

Pregnancy and Breastfeeding

The use of ACE inhibitors is not recommended during the first trimester of pregnancy. The use of ACE inhibitors is contraindicated during the second and third trimesters 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 therapy with ACE inhibitors is considered essential, patients planning pregnancy should be switched to alternative antihypertensive treatments that have an established safety profile for use in pregnancy. When pregnancy is diagnosed, treatment with ACE inhibitors should be discontinued immediately and, if appropriate, alternative therapy should be initiated. Exposure to ACE inhibitor therapy during the second and third trimesters is known to induce human fetotoxicity (decreased renal function, oligohydramnios, delayed skull ossification) and toxicity.

neonatal effects, hypotension, hyperkalemia. If exposure to ACE inhibitors occurred during the second trimester of pregnancy, ultrasound monitoring of renal function and the skull is recommended. Infants whose mothers took ACE inhibitors should be closely monitored for hypotension.

Lactation

Limited pharmacokinetic data demonstrate very low concentrations in breast milk. Although these concentrations appear to be clinically irrelevant, the use of enalapril during breastfeeding—particularly in the first few weeks postpartum—is not recommended, due to the hypothetical risk of cardiovascular and renal effects and because there is insufficient clinical experience. In the case of a child older than 12 years, the use of enalapril in a breastfeeding mother may be considered if this treatment is necessary for the mother and the child is monitored for any adverse effects.

Storage: Store below 30°C in a cool, dry place. Protect from light.

Dosage: As directed by a physician.

Keep medicines out of the reach of children.

Presentation: Blister pack of 10 tablets.

Manufactured by:

