Kapril tablet 25 mg, 48 tablets

**COMPOSITION:** Each tablet contains 25 mg captopril.

**PHARMACOLOGICAL PROPERTIES:** Prevents the conversion of angiotensin I to angiotensin II by inhibition of ACE.
- Decreases aldosterone secretion.
- Increases diuresis, prevents sodium and fluid retention.
- Decreases preload and afterload.
- Balances hyponatremia during chronic heart failure.
- Provides a balanced vasodilatation.
- Well tolerated.

**INDICATIONS:** Moderate and severe hypertension
- Refractory hypertension in patients who have not responded to treatment with other antihypertensive agents. Congestive heart failure.

**CONTRAINDICATIONS:** Is contraindicated in patients with known hypersensitivity to captopril.
- Administration should be done with great caution in patients with renal impairment and with diseases of immune system (especially systemic lupus erythematosus).

**WARNINGS AND PRECAUTIONS:** Neutropenia due to the effect of captopril on the hematopoetic system is observed generally in auto-immune and collagen system disorders. Therefore, KAPRIL tablet should be administered with extreme caution in patients with impaired renal function, auto-immune and collagen system disorders (especially systemic lupus erythematosus) and in patients receiving the drugs that affect leukocytes. Haemogram should be performed before starting the treatment and repeated at two week intervals during the therapy. In certain hypertension cases associated with renal artery stenosis, although arterial hypertension returns to normal with KAPRIL therapy, elevations in serum creatinine and BUN levels may be observed; in such cases KAPRIL tablet dosage should be decreased and/or concomitant diuretic therapy should be discontinued. Patients should be closely monitored during surgical interventions and anesthesia for hypotension. Patients should be reminded to consult their physician promptly at the first sign of any infection, suspected peripheric edema or difficulties concerning the administration of the drug and advised to take adequate amounts of liquid during the treatment period. Other reasons of fluid loss such as vomiting and diarrhea may also lead to a fall in blood pressure; patients should be advised to consult a doctor. In these cases, use of KAPRIL tablet may cause hypotension within one or two hours. Captopril may cause an elevation in serum potassium levels. Patients who have been treated with spironolactone before starting therapy with captopril should be closely monitored for their serum potassium levels when they start taking captopril. Non-steroidal anti-inflammatory drugs (especially indomethacin and aspirin) may reduce the antihypertensive effect of captopril. Elderly patients should be monitored carefully during captopril treatment because of a possible decrease in the renin-plasma activity and levels. There are no adequate and well-controlled studies in pregnant women, and about the penetration of captopril into breast milk.

**SIDE EFFECTS / ADVERSE EFFECTS:**
- Hematologic: Neutropenia, agranulocytosis.
- Renal: Proteinuria, poliuria, oliguria, renal impairment.
- Dermatologic: Maculopapular rash, urticaria, pruritus, photosensitivity, angioedema of the extremities, face and mouth.
- Cardiovascular: Hypotension, tachycardia, chest-pain, palpitations.
- Gastrointestinal: Anorexia, nausea, vomiting, diarrhea, constipation, gastric irritation, aphthous ulcers.
- Other: Headache, cough, bronchospasm, dizziness, dyspnea, insomnia, parasthesia, serum sickness-like syndrome.
These side effects are very rare and disappear when the treatment is stopped and the dose adjustments are made. SGOT, SGPT and LDH enzyme increases may be seen but no certain relationship to captopril use has been established. Especially in renovascular hypertension cases, temporary increases in BUN, serum creatinine and potassium levels may be seen.

**DRUG INTERACTIONS:** Non-steroidal anti-inflammatory drugs, especially indomethacin and aspirin, may reduce the antihypertensive effect of captopril. Captopril’s antihypertensive effect will be augmented by other antihypertensive agents such as diuretics, beta-adrenergic blocking agents, methyl-dopa and calcium antagonists. Potassium-sparing agents such as spironolactone and triamterene may lead to a significant increase in serum potassium levels. The renal clearance of captopril decreases in the presence of probenecid.

**DOSAGE AND ADMINISTRATION:** KAPRIL tablet should be taken one hour before meals. The initial dose of KAPRIL tablet in hypertension is 12.5-25 mg bid or tid; if satisfactory reduction of blood pressure has not been achieved within one or two weeks, the dose may be increased to 50 mg tid or more if needed. Total maximum daily dose is 450 mg. The initial dose of KAPRIL tablet in congestive heart failure is 12.5 mg bid or tid.

**STORAGE CONDITIONS:** Should be kept out of reach of children, at room temperature (< 25°C), and in its package.

**AVAILABLE FORMS:** KAPRIL tablet 25 mg, blister packs of 48 tablets.

**NAME AND ADDRESS OF THE AUTHORISATION HOLDER:** Mustafa Nevzat İlaç Sanayii A.Ş. Prof. Dr. Bülent Tarcan Sok., Pak İş Merkezi No: 5/1 34349 Gayrettepe/Istanbul.

**NAME AND ADDRESS OF THE MANUFACTURING COMPANY:** Mustafa Nevzat İlaç Sanayii A.Ş. Çobançeşme Mah. Sanayi Cad. No:13 Yenibosna-Istanbul.