AGOG Pharma Ltd.
(WHO - GMP CERTIFIED - GOVT RECOGNISED EXPORT HOUSE)
Regd. Office & Factory : Plot No. 33, Sector II, The Vasai Taluka Industrial Co-op. Estate Ltd. Gauraipada, Vasai (E), Dist. Thane - 401 208. INDIA.
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LEAFLET

AGOPRIL

(Captopril Tablets BP 25 mg)

COMPOSITION:
Each uncoated tablet contains:
Captopril BP ..... 25 mg
Excipients ..... q.s.

CLINICAL PHARMACOLOGY:
Captopril is an inhibitor of angiotensin converting enzyme (ACE) which converts angiotensin I to angiotensin II, a potent endogenous vasoconstrictor substance.

INDICATIONS AND USAGE:
Mild to Moderate Hypertension: Agopril is indicated for the treatment of mild to moderate hypertension in adult patients. It may be used alone or in combination with other antihypertensive agents, especially thiazide-type diuretics.
Congestive Heart Failure: Agopril is indicated for the treatment of patients with congestive heart failure.
Left Ventricular dysfunction after Myocardial Infarction: Captopril is indicated to improve survival following myocardial infarction in clinically stable patients with left ventricular dysfunction.
Diabetic Nephropathy: Agopril is indicated for the management of diabetic in patients with Type I diabetes mellitus that also have retinopathy due to insulin dependent diabetes mellitus. In these patients, Agopril decreases the rate of progression of renal insufficiency.

DOSAGE AND ADMINISTRATION:
Hypertension: The initial dose of Agopril is 25 mg two or three times a day. If a satisfactory reduction of blood pressure has not been achieved after two weeks the dose of Agopril may be increased to 50 mg two or three times a day. If after an additional two weeks a further reduction in blood pressure is desirable, a diuretic may be added. For patients already receiving a diuretic, the initial dose of Agopril should be lower and administered with care. The dose of Agopril in mild to moderate hypertension must not exceed 150 mg per day. When Agopril is used alone, concomitant sodium restriction may be beneficial. Agopril may be used advantageously in conjunction with other anti-hypertensive agents.
Congestive Heart Failure: Agopril therapy must be started under close medical supervision. It should be added to conventional treatment with diuretic (and digitalis where indicated). In patients with either normal or low blood pressure, who have been vigorously treated with diuretics and who may be hyponatremic and/or hypovolemic, a starting dose of 6.25 mg or 12.5 mg three times a day may minimize the duration of any transient hypotensive effect. This dosage may be increased over a period of one to two weeks to 75 - 300 mg per day. For most patients the usual initial daily dosage is 25 mg three times a day.
Left Ventricular Dysfunction after Myocardial Infarction: Therapy may be initiated as early as three days following a myocardial infarction. After an initial dose of 6.25 mg, Captopril therapy should be increased to 12.5 mg three times daily as tolerated. Captopril should then be increased as tolerated to 75 mg a day in divided doses during the next several days and to a final target dose of 150 mg daily in divided doses over the next several weeks.
Diabetic Nephropathy: In patients with diabetic nephropathy with or without hypertension, the recommended daily dose of captopril is 75 to 100 mg in divided doses. If further blood pressure reduction is required; other antihypertensive agents such as diuretics, beta adrenoceptor blockers, centrally acting agents or vasodilators may be used in conjunction with Captopril.

SIDE EFFECTS AND ADVERSE REACTIONS:
Dermatologic: A rash may occur which is dose related. The rash is usually pruritic and maculopapular, sometimes with fever, arthralgia, and eosinophilia, but rarely urticarial and generally occurs during the first 4 weeks of treatment. It usually is self-limited and reversible and may respond to antihistamine therapy. Pruritus with or without rash, flushing, a reversible pemphigoid-like lesion, photosensitivity, angioedema may occur.
Gastro-Intestinal: Reversible taste impairment has occurred. Loss of mass may be associated with loss of taste. Stomatitis, resembling aphthous ulcers, has been reported. Elevation of liver enzymes has been noted in patients receiving the drug

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although no causal relationship has been found. Cases of hepatocellular injury with secondary cholestasis have been reported in association with Capoten administration. Gastric irritation and abdominal pain may occur.
Renal: Proteinuria Renal insufficiency, renal failure, nephrotis syndrome, polyuria, oligieria and urinary frequency.
Haematologic: Anemia, thrombocytopenia, pancytopenia and neutropenia/agranulocytosis have been reported.
Respiratory: Irritating cough, fatal angioneurotic oedema.
Cardiovascular: Hypotension may occur during Agopril therapy in patients with heart failure, renin-dependent hypertension or who are significantly volume depleted. Tachycardia, chest pain, and palpitations have been observed. Other events which have occurred include angina pectoris, myocardial infarction, Raynaud's syndrome, and congestive heart failure. Tachycardia has been observed in volume-depleted patients.

OVERDOSAGE AND TREATMENT :
In the event of overdosage, hypotension would be the most important problem. Volume expansion with an intravenous infusion of normal saline is the treatment of choice. Captopril is removed by haemodialysis. Treatment is symptomatic and supportive.

CONTRAINDICATIONS:
Hypersensitivity to the product or its components, or other angiotensin-converting enzyme inhibitors. Safety and effectiveness in individuals less than 18 years of age have not been established.Patients with a history of angioneurotic oedema relating to previous treatment with an ACE-inhibitor. since it may permit organic closure of the angle to occur while the worsening glaucoma is masked by lowered intraocular pressure.

DRUG INTERACTIONS:
Patients on Diuretic Therapy: Patients on diuretics and especially those in whom diuretic therapy was recently instituted, as well as those on severe dietary salt restrictions or dialysis, may experience a precipitous reduction of blood pressure often within the first hour after receiving the initial dose of Captopril.
Agents Having Vasodilator Activity: Nitroglycerin or other nitrates or other drugs having vasodilator activity should be administered cautiously, and at low dosage.
Agents Affecting Sympathetic Activity: The sympathetic nervous system may be especially important in supporting blood pressure in patients receiving Captopril alone or with diuretics. Therefore, agents affecting sympathetic activity (e.g., ganglionic blocking agents or adrenergic neuron blocking agents) should be used with caution.
Agents Increasing Serum Potassium: Since Captopril decreases aldosterone production, elevation of serum potassium may occur. Potassium-sparing diuretics such as Spironolactone, triamterene, or amiloride, or potassium supplements are generally contra-indicated and should be given only for documented hypokalemia, and then with caution, since they may lead to a significant increase of serum potassium. Salt substitutes containing potassium should also be used with caution.
Lithium: Increased serum lithium levels and symptoms of lithium nephrotoxicity have been reported in patients receiving concomitant lithium and ACE inhibitor therapy. These drugs should be co administered with caution and frequent monitoring of serum lithium levels is recommended. If a diuretic is also used, it may increase the risk of lithium toxicity.

STORAGE: Store under normal storage conditions (15°C to 30°C)
Protect from light.

Keep all medicines out of reach of children.

PRESENTATION: Blister pack of 10 x 10 Tablets.
Jar pack of 1000 Tablets.

Manufactured in India by:
AGOG PHARMA LTD.
Plot No. 33, Sector II, The Vasai Taluka Indl.
Co-op. Estate Ltd., Vasai (E), Dist. Thane. INDIA.