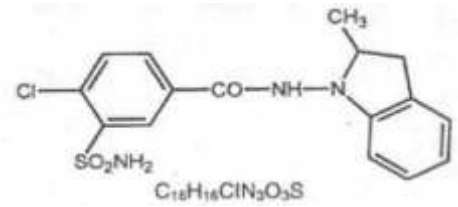
Indapamide tablets film-coated

Description :

Indapamide is an oral antihypertensive/diuretic. Its molecule contains both a polar sulfamoyl chlorobenzamide moiety and a lipid-soluble methylindoline moiety. It differs chemically from the thiazides in that it does not possess the thiazide ring system and contains only one sulfonamide group. The chemical name of indapamide is 4-Chloro-N-(2-methyl-1-indolinyl)-3-sulfamoylbenzamide, and its molecular weight is 365.84. The compound is a weak acid, pKa = 8.8, and is soluble in aqueous solutions of strong bases. It is a white to yellow-white crystalline (tetragonal) powder.



Each tablet, for oral administration, contains indapamide 1.25 mg or 2.5 mg. In addition, each tablet contains the following inactive ingredients: FD&C Yellow No. 6 (1.25 mg), hypromellose, lactose monohydrate, magnesium stearate, maize starch, microcrystalline cellulose, polyethylene glycol, povidone and titanium dioxide.

Clinical Pharmacology :

Indapamide is the first of a new class of antihypertensive/diuretics, the indolines. It has been reported that the oral administration of 2.5 mg (two 1.25 mg tablets) of indapamide to male subjects produced peak concentrations of approximately 115 ng/mL of the drug in blood within two hours. It has been reported that the oral administration of 5 mg (two 2.5 mg tablets) of indapamide to healthy male subjects produced peak concentrations of approximately 260 ng/mL of the drug in the blood within two hours. A minimum of 70% of a single oral dose is eliminated by the kidneys and an additional 23% by the gastrointestinal tract, probably including the biliary route. The half-life of indapamide in whole blood is approximately 14 hours.

Indapamide is preferentially and reversibly taken up by the erythrocytes in the peripheral blood. The whole blood/plasma ratio is approximately 6:1 at the time of peak concentration and decreases to 3.5:1 at eight hours. From 71 to 79% of the indapamide in plasma is reversibly bound to plasma proteins.

Indapamide is an extensively metabolized drug with only about 7% of the total dose administered, recovered in the urine as unchanged drug during the first 48 hours after administration. The urinary elimination of 14C-labeled indapamide and metabolites is biphasic with a terminal half-life of excretion of total radioactivity of 26 hours.
In a parallel design double-blind, placebo controlled trial in hypertension, daily doses of indapamide between 1.25 mg and 10 mg produced dose-related antihypertensive effects. Doses of 5 mg and 10 mg were not distinguishable from each other although each was differentiated from placebo and 1.25 mg indapamide. At daily doses of 1.25 mg, 5 mg and 10 mg, a mean decrease of serum potassium of 0.28, 0.61 and 0.76 mEq/L, respectively, was observed and uric acid increased by about 0.69 mg/100 mL.

In other parallel design, dose-ranging clinical trials in hypertension and edema, daily doses of indapamide between 0.5 and 5 mg produced dose-related effects. Generally, doses of 2.5 and 5 mg were not distinguishable from each other although each was differentiated from placebo and from 0.5 or 1 mg indapamide. At daily doses of 2.5 and 5 mg a mean decrease of serum potassium of 0.5 and 0.6 mEq/Liter, respectively, was observed and uric acid increased by about 1 mg/100 mL.

At these doses, the effects of indapamide on blood pressure and edema are approximately equal to those obtained with conventional doses of other antihypertensive/diuretics.
In hypertensive patients daily doses of 1.25, 2.5 and 5 mg of indapamide have no appreciable cardiac inotropic or chronotropic effect. The drug decreases peripheral resistance, with little or no effect on cardiac output, rate or rhythm. Chronic administration of indapamide to hypertensive patients has little or no effect on glomerular filtration rate or renal plasma flow.
Indapamide had an antihypertensive effect in patients with varying degrees of renal impairment, although in general, diuretic effects declined as renal function decreased.
In a small number of controlled studies, indapamide taken with other antihypertensive drugs such as hydralazine, propranolol, guanethidine, and methyldopa, appeared to have the additive effect typical of thiazide-type diuretics.

Indications :

Indapamide is indicated for the treatment of hypertension, alone or in combination with other antihypertensive drugs.
Indapamide is also indicated for the treatment of salt and fluid retention associated with congestive heart failure.

Usage in Pregnancy:

The routine use of diuretics in an otherwise healthy woman is inappropriate and exposes mother and fetus to unnecessary hazard (see PRECAUTIONS). Diuretics do not prevent development of toxemia of pregnancy, and there is no satisfactory evidence that they are useful in the treatment of developed toxemia.

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According to the Indian Trade Mark the company owns about 450 brands and 4600 generic manufacturing permissions in India. According to the export data analysis the company was the largest exporter of generic medicines to the Europe and Middle East countries. www.tajpharma.com

The company medicines are present in France, Georgia, Egypt and CIF countries.

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