Alatrol®

Cetirizine Dihydrochloride

Antihistamine

COMPOSITION

Alatrol® Tablet : Each film coated tablet contains Cetirizine Dihydrochloride BP 10 mg.

Alatrol® Syrup : Each 5 ml syrup contains Cetirizine Dihydrochloride BP 5 mg.

PHARMACOLOGY

Cetirizine dihydrochloride is rapidly absorbed reaching peak plasma concentrations of 257 µgm/L within 1 hour of administration of 10 mg dose. Food does not affect the extent of absorption, but it may slightly reduce the rate. Plasma protein binding is 93 %, at concentrations ranging from 25 to 1000 µgm per litre. The terminal elimination half-life ranges from 6.7 h to 10.9 h. The half-life of cetirizine is slightly shorter in children than in adults, with values of 6.9-7.1 h reported. The half-life is increased markedly in renal dysfunction, with values of 19 and 21 h in patient with mild and moderate renal impairment respectively (creatinine clearance 1.9-3.6 and 0.42-1.8 litre per h). The half-life may be slightly prolonged in hepatic dysfunction. Cetirizine is eliminated mainly by renal excretion of the unchanged drug, although there is a small amount of metabolism in the liver.

Cetirizine is a potent H_1 receptor antagonist without any significant anticholinergic and antiserotonin effects. At pharmacologically active dose levels, it has almost no drowsiness effect and does not cause behavioural changes which may be explained by the absence of passage through the blood brain barrier. Cetirizine inhibits the histamine mediated 'early' phase of the allergic reaction and also reduces the migration of inflammatory cells and the release of mediators associated with the 'late' phase of the allergic reaction. Cetirizine also provides a protective effects from bronchospasm induced by inhaled histamine in asthmatics.

INDICATION

Alatrol® is indicated for the treatment of seasonal allergic rhinitis and conjunctivitis, perennial allergic rhinitis, pruritus and urticaria. It is also used in allergen induced asthma.

DOSAGE AND ADMINISTRATION

Alatrol® is administered with or without food. The time of administration varies to suit individual patient needs.

Adults and children over 6 years and older : Alatrol® tablet: 1 tablet daily . Alatrol® syrup: 2 teaspoonful once daily.

In patients with decreased renal function (Creatinine clearance 11-31 ml/min), patients on haemodialysis, (Creatinine clearance less than 7 ml/min) and in hepatically impaired patients, a dose of 5 mg once daily is recommended.

Children 2-6 years: Alatrol® syrup: 1 teaspoonful once daily.

CONTRAINDICATION AND PRECAUTION

Cetirizine is contraindicated in patients who have shown hypersensitivity or idyosyncrasy to it or to its parent compound ,hydroxyzine.

Caution should be exercised when driving a car or operating a heavy machinery. Concurrent use of cetirizine with alcohol or other CNS depressants should be avoided because additional reduction in alertness and CNS performance may occur.

SIDE EFFECT

Cetirizine seems to cause an incidence of sedation similar to that observed with placebo and with other 'non-sedating' antihistamines such as astemizole and terfenadine and causes a lower incidence of sedation than that observed with ketotifen, clemastine, pheniramine, chlorpheniramine or mequitazine. Alatrol® does not produce anticholinergic effects.

DRUG INTERACTION

No clinically significant drug interactions have been found with theophylline, azithromycin, pseudoephedrine, ketoconazole or erythromycin and with some other drugs.

USE IN PREGNANCY AND LACTATION

There are no adequate and well-controlled studies in pregnant women using cetirizine . Therefore cetirizine should be used in pregnancy only if clearly needed. Cetirizine has been reported to be excreted in human milk and thus, use of cetirizine in lactating mother is not recommended.

STORAGE CONDITION

Should be stored in a dry place below 30˚ C.

HOW SUPPLIED

Alatrol® Tablet : Box containing 10 x 10 tablets in blister pack.

Alatrol® Syrup : Bottle containing 60 ml syrup.