Alatrol®

Cetirizine Hydrochloride BP

COMPOSITION

Alatrol® Tablet : Each film coated tablet contains Cetirizine Hydrochloride BP 10 mg. **Alatrol®** Syrup : Each 5 ml syrup contains Cetirizine Hydrochloride BP 5 mg.
Alatrol® Paediatric Drops : Each ml drops contains Cetirizine Hydrochloride BP 2.5 mg.

PHARMACOLOGY

Alatrol® is a potent H_1 receptor antagonist without any significant anticholinergic and antiserotonic effects. At pharmacologically active dose levels, it has almost no drowsiness effect and does not cause behavioral changes which may be explained by the absence of passage through the blood brain barrier. **Alatrol®** 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. **Alatrol®** also provides a protective effect from bronchospasm induced by inhaled histamine in asthmatics. **Alatrol®** absorbs very rapidly. Plasma half-life of Cetirizine is 6.7 to 10.90 hours.

INDICATION

Seasonal Allergic Rhinitis: **Alatrol®** is indicated for the relief of symptoms associated with seasonal allergic rhinitis due to allergens such as ragweed, grass and tree pollens. Symptoms treated effectively include sneezing, rhinorrhea, pruritus, ocular pruritus, tearing and redness of the eyes. *Perennial Allergic Rhinitis:* **Alatrol®** is indicated for the relief of symptoms associated with perennial allergic rhinitis due to allergens such as dust, mites, animal dander, and molds. Symptoms treated effectively include sneezing, rhinorrhea, post-nasal discharge, nasal pruritus, ocular pruritus and tearing. *Chronic Idiopathic Urticaria:* **Alatrol®** is indicated for the treatment of the uncomplicated skin manifestations of chronic idiopathic urticaria. It significantly reduces the occurrence, severity and duration of hives and significantly reduces pruritus. 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 6 years and older:
Alatrol® Tablet : 1 tablet daily.
Alatrol® Syrup : 10 ml (2 teaspoonfuls) once daily or 5 ml (1 teaspoonful) twice daily. In patients with decreased renal function (Creatinine clearance 11-31 ml/min), patients on hemodialysis (Creatinine clearance less than 7 ml/min) and in hepatically impaired patients, a dose of 1/2 tablet or 5 ml (1 teaspoonful) once daily is recommended.
Children 2-6 years:
Alatrol® Syrup : 5 ml (1 teaspoonful) once daily or 2.5 ml (1/2 teaspoonful) twice daily. *Children 6 months to less than two years:*
Alatrol® Syrup : 2.5 ml (1/2 teaspoonful) once daily. The dose in children 12-23 months of age can be increased to a maximum dose as 1/2 teaspoonful every 12 hours.
Alatrol® Paediatric Drops: 1 ml, once daily. The dose in children 12-23 months of age can be increased to a maximum dose as 1 ml, every 12 hours.
Dosage in Renal and Hepatic Impairment: Dosing adjustment is necessary in patients with moderate or severe renal impairment, hepatic impairment and patients on dialysis.

PRECAUTION

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 additional impairment of CNS performance may occur.

DRUG INTERACTION

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

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 with ketotifen, clemastine, pheniramine, chlorpheniramine or mequitazine. Cetirizine does not cause anticholinergic effects.

CONTRAINDICATION

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

USE IN PREGNANCY AND LACTATION

Pregnancy category B. 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

Alatrol® Tablet : Store below 30°C. Protect from light and moisture.
Alatrol® Syrup : Store below 30°C. Protect from light.
Keep out of the reach of children.

HOW SUPPLIED

Alatrol® Tablet : Each box contains 150 tablets.
Alatrol® Syrup : Each bottle contains 60 ml syrup and a measuring cup.
Alatrol® Paediatric Drops : Each bottle contains 15 ml paediatric drops and a dropper.

Manufactured by
SQUARE
PHARMACEUTICALS LTD.
BANGLADESH