

#### COMPOSITION

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

#### INDICATION

**Alatrol**<sup>®</sup> is indicated for the relief of symptoms associated with seasonal allergic rhinitis due to allergen. Symptoms treated effectively include sneezing, rhinorrhea, pruritus, ocular pruritus, tearing and redness of the eves.

**Alatrol**<sup>®</sup> is indicated for the relief of symptoms associated with perennial allergic rhinitis due to allergens. Symptoms treated effectively include sneezing, rhinorrhea, post-nasal discharge, nasal pruritus, ocular pruritus and tearing.

**Alatrol**® is indicated for the treatment of the uncomplicated skin manifestations of chronic idiopathic urticaria. It is also used in allergen induced asthma.

### DOSAGE AND ADMINISTRATION

**Alatrol**<sup>®</sup> is administered with or without food. **Adults** and **Children 6 years and older:** 

Alatrol® Tablet: 1 tablet daily.

Alatrol® Syrup: 10 ml (2 teaspoons full) once daily or 5 ml (1 teaspoon full) 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 teaspoon full) once daily is recommended.

Children 2-6 years: Alatrol® Syrup: 5 ml (1 teaspoon full) once daily or 2.5 ml (half teaspoon full) twice daily. Children 6 months to less than two years: Alatrol® Syrup: 2.5 ml (half teaspoon full) once daily. The dose in children 12-23 months of age can be increased to a

maximum dose as 2.5 ml (half teaspoon full) 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.

#### 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.

#### 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:

Protect from direct light exposure. Store in dry place at a temperature not exceeding  $30^{\circ}$  C. Keep out of the reach of children.

#### HOW SUPPLIED

Alatrol<sup>®</sup> Tablet: Each box contains 100's tablets. Alatrol<sup>®</sup> Syrup: Each bottle contains 60 ml syrup and a measuring cup.
Alatrol<sup>®</sup> Paediatric Drops: Each bottle contains 15 ml paediatric drops and a calibrated dropper.

Manufactured by :

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