ASTHAFEN SYRUP

For the use only of a Registered Medical Practitioner or Hospital or a Laboratory

Abbreviated Prescribing information for ASTHAFEN SYRUP (Kitotifen 1 mg in 5ml Syrup) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Ketotifen second-generation noncompetitive H1-antihistamine and mast cell stabilizer. It exerts anti-allergic property.

INDICATION: Symptomatic treatment of allergic conditions including rhinitis and conjunctivitis.

DOSAGE AND ADMINISTRATION: <u>Adults:</u> 1 mg twice daily with food. If necessary the dose may be increased to 2 mg twice daily; <u>Children</u>: (From 3 years of age): 1 mg twice daily with food; <u>Use in the elderly</u>: No evidence exists that elderly patients require different dosages or show different side-effects from younger patients. Patients known to be easily sedated should be given 0.5 -1 mg at night for the first few days.

CONTRAINDICATION: Hypersensitivity to ketotifen or any of the excipients; reversible fall in the thrombocyte count with oral anti-diabetic agents reported thus combination avoided.

WARNINGS & PRECAUTIONS: ASTHAFEN SYRUP contains maltitol. Patients with rare hereditary problems of fructose intolerance should not take this medicine. Convulsions have been reported very rarely during ASTHAFEN SYRUP therapy. As ASTHAFEN SYRUP may lower the seizure threshold it should be used with caution in patients with a history of epilepsy; Use with alcoholic beverages; Cautious while operating heavy machineries and driving.

DRUG INTERACTIONS: ASTHAFEN SYRUP may potentiate the effects of sedatives, hypnotics, antihistamines, alcohol.

ADVERSE REACTIONS: Cystitis, erythema multiforme, stevens-Johnson syndrome, severe skin reaction, weight increased, excitation, irritability, insomnia, nervousness, dizziness, sedation, convulstion, dry mouth, hepatitis, increase in liver enzymes. Symptoms of CNS stimulation, such as excitation, irritability, insomnia, and nervousness, have been observed particularly in children.

MARKETED BY:



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IN/ASTHAFEN SYRUP/FEB 2015/01/AbPI

(Additional information is available on request)