ALLENIL

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

Abbreviated Prescribing information for ALLENIL (olopatadine hydrochloride 5mgTablets) [Please refer the complete prescribing information available at <u>www.torrentpharma.com</u>]

PHARMACOLOGICAL PROPERTIES: Olopatadine is an antihistaminic and antiallergic agent possessing inhibitory effects on the release of inflammatory lipid mediators such as leukotrienes, thromboxane, platelet activating factor (PAF), etc.

INDICATION: For allergic rhinitis, urticaria and itching accompanied by skin diseases (eczema, dermatitis, pruritus cutaneous, psoriasis vulgaris and erythema exudativum multiforme).

DOSAGE AND ADMINISTRATION: Dosage should be adjusted according to individual patient response and tolerability. The usually recommended dose for adults is 5 mg twice a day, given in morning and in the night before sleeping.

CONTRAINDICATION: Hypersensitivity to olopatadine or any other ingredients of this formulation.

WARNINGS & PRECAUTIONS: Caution is advised in patients with impaired renal function, liver malfunction, elderly, renal dysfunction, impaired liver function, jaundice, receiving steroid treatment. olopatadine causes drowsiness, patients should be asked to avoid driving an automobile or operating machinery, while taking the drug. Prolonged use and before performing allergic skin testing should be avoided.

DRUG INTERACTION: Olopatadine did not inhibit P450 activities. Spectral analysis revealed that neither olopatadine nor M1 formed an MIC (metabolic intermediate complex). Therefore, it is unlikely that olopatadine will cause drug-drug interactions involving P450 isozymes.

ADVERSE REACTIONS: Sleepiness, fatigue, dry mouth, stomach pain, discomfort in stomach, rise in AST(GOT), ALT(GPT), g-GTP, LDH, AI-P, etc., increase in W.B.C and eosinophils, occult blood, protein in urine, increased serum cholesterol, urine sugar positive, redness, swelling of face or limbs, labored breathing, headache, heaviness, giddiness, numbness, less concentration, diarrhea, mouth ulcer, angular stomatitis, heartburn, hyperphagia, constipation, increase in total bilirubin, reduced lymphocyte & W.B.C. count, increased urinary creatinine and BUN, dysuria, rise in blood pressure, discomfort in chest, increase in body weight, involuntary movement of face or limbs, taste perversion, abnormal menstruation, burning, muscle pain and joint pain.

MARKETED BY:

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(Additional information is available on request)