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

Cetgel™
Cetirizine Hydrochloride Capsules

COMPOSITION
Each soft gelatin capsule contains Cetirizine hydrochloride IP 10 mg.

THERAPEUTIC INDICATION
Relief of symptoms associated with seasonal allergic rhinitis and perennial allergic rhinitis, treatment of uncomplicated skin manifestations of chronic idiopathic urticaria in adults.

DOSAGE AND ADMINISTRATION
Adult dose : 10 mg per day as a single daily dose. Daily dose not to exceed 10mg.
5mg od dosing of cetirizine hydrochloride is recommended for any of the following patients:
(a) With decreased renal function (creatinine clearance 11-31 mL/min)
(b) On hemodialysis (creatinine clearance less than 7 mL/min)
(c) Who are hepatically impaired or
(d) 77 years of age and older.

CONTRAINDICATIONS: Known hypersensitivity to cetirizine or any of the ingredients of Cetgel or hydroxyzine.

PRECAUTIONS: Somnolence has been reported in some patients and due caution is to be exercised when driving a car or operating potentially dangerous machinery. Concurrent use with alcohol or other CNS depressants should be avoided. Clinical significance of the long term carcinogenicity studies in mice and rats is not known. Cetirizine is not mutagenic in the Ames test. In a fertility and general reproductive performance study in mice, cetirizine did not impair fertility at an oral dose of 64mg/kg. Pediatric doses are based on cross-study comparison of pharmacokinetics and pharmacodynamics of cetirizine in adults and pediatric subjects and on the safety profile of cetirizine in both adult and pediatric patients at doses equal to or higher than the recommended dose. For elderly patients care should be taken in dose selection, and it may be useful to monitor renal function.

PREGNANCY & LACTATION: Cetgel should be used during pregnancy only if clearly needed. Not recommended in nursing mothers.

ADVERSE REACTIONS: Most adverse reactions reported in clinical trials were mild or moderate. Adverse experiences in patients aged 12 years and older at rates of 2% or greater were somnolence, fatigue, dry mouth, pharyngitis and dizziness. Adverse experiences reported in pediatric patients aged 6 to 11 years in Placebo-Controlled cetirizine trials (5 or 10 mg Dose) which occurred at a frequency of ≥2% are headache, pharyngitis, abdominal pain, coughing, somnolence, diarrhea, epistaxis, bronchospasm, nausea and vomiting.

For full prescribing information write to: Sanofi India Ltd., Sanofi House, CT Survey No. 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai – 400 072

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