

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

## AVIL® NU

Cetirizine Tablets

### THERAPEUTIC CATEGORY

Antihistaminic

### COMPOSITION

Each film tablet contains Cetirizine hydrochloride IP 10mg

### THERAPEUTIC INDICATIONS

Relief of symptoms associated with seasonal allergic rhinitis and perennial allergic rhinitis, treatment of uncomplicated skin manifestations of chronic idiopathic urticaria in adults and children 6 years of age and older.

### DOSAGE AND ADMINISTRATION

5 mg or 10 mg per day as a single daily dose. Daily dose not to exceed 10mg.

**Dose Adjustment for Renal and Hepatic Impairment:** In patients 6 years of age and older with decreased renal function and in hepatically impaired patients, a dose of 5 mg once daily is recommended.

**Dose Adjustment for Geriatric Patients:** In patients 77 years of age and older, a dose of 5 mg once daily is recommended.

### SAFETY-RELATED INFORMATION

**Contraindications:** Known hypersensitivity to cetirizine or any of the ingredients of Avil NU 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.

Paediatric population

The use of the film-coated tablet formulation is not recommended in children aged less than 6 years since this formulation does not allow for appropriate dose adaptation.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

**Pregnancy & Lactation:** Avil Nu 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  $\geq 2\%$  are headache, pharyngitis, abdominal pain, coughing, somnolence, diarrhea, epistaxis, bronchospasm, nausea and vomiting.

For full prescribing information, please write to: Sanofi House, CTS No. 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai - 400072

Updated: May 2017

Sources: 1. CCSI version dated 27<sup>th</sup> January 2017

2. <http://www.mhra.gov.uk/home/groups/par/documents/websiteresources/con062894.pdf> (as on 28 Aug 2014)

3. SmPC of Cetirizine 10mg film coated tablets, marketed by Teva UK limited (accessed on 22 Aug 2014)

4. Zirtek SmPC, <https://www.medicines.org.uk/emc/medicine/11533>