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

AVIL® NU 10mg

Cetirizine Hydrochloride Tablets I.P. 10mg

THERAPEUTIC CATEGORY
Antihistaminic

COMPOSITION
Each film coated tablet contains: Cetirizine Hydrochloride I.P. 10mg, Excipients q.s, Colour: Titanium Dioxide I.P.

THERAPEUTIC INDICATIONS
Seasonal rhinitis and conjunctivitis, perennial allergic rhinitis, pruritis and urticaria.

DOSAGE AND ADMINISTRATION
Children aged from 6 to 12 years: 5 mg twice daily (a half tablet twice daily).
Adults and adolescents over 12 years of age: 10 mg once daily (1 tablet).

SAFETY-RELATED INFORMATION
Contraindications:
- Hypersensitivity to the active substance, to any of the excipients, to hydroxyzine or to any piperazine derivatives.
- Patients with severe renal impairment at less than 10 ml/min creatinine clearance.

Precautions: At therapeutic doses, no clinically significant interactions have been demonstrated with alcohol (for a blood alcohol level of 0.5 g/l). However, precaution is recommended if alcohol is taken concomitantly. Caution should be taken in patients with predisposition factors of urinary retention (e.g. spinal cord lesion, prostatic hyperplasia), in epileptic patients and patients at risk of convulsions. Allergy skin tests are inhibited by antihistamines and a wash-out period (of 3 days) is required before performing them. Pruritus and/or urticaria may occur when cetirizine is stopped. In some cases, the symptoms may be intense and may require treatment to be restarted. Acute Generalized Exanthematous Pustulosis (AGEP) has been reported and patients should be informed about the signs and symptoms of serious skin manifestations. Treatment should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of skin hypersensitivity.
Paediatric population
Not recommended in children aged less than 6 years since this formulation does not allow for appropriate dose adaptation. Cetirizine contains lactose monohydrate. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Pregnancy & Lactation:
Caution should be exercised when prescribing to pregnant and lactating women.

Adverse Reactions: Adverse reactions were reported for cetirizine 10 mg in the placebo-controlled trials are Fatigues, dizziness, headache, dry mouth, nausea, somnolence and pharyngitis
Adverse experiences reported in paediatric patients aged 6 to 12 years in Placebo-Controlled cetirizine trials are gastrointestinal disorder, Fatigue, Rhinitis, Somnolence and Diarrhoea

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

Updated: Jan 2022

Sources:

1. CCDS V2 LRC dated 9th Dec 2021
2. UKPAR Cetirizine Hydrochloride 10mg Film-Coated tablets https://mhraproducts4853.blob.core.windows.net/docs/92f0b151160d66cc95a1184385b28601dc92724f (as accessed on 5th January 2022)