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

This package insert is continually updated: Please read carefully before using a new pack.

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Cetirizine Hydrochloride Tablets I.P. 10mg

Avil® NU 10mg

COMPOSITION

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

INDICATION

Avil® NU is indicated in the symptomatic relief from perennial and seasonal allergic rhinitis, pruritus, allergic asthma, allergic conjunctivitis and urticaria.

DOSAGE AND ADMINISTRATION

Avil® NU can be taken without regard to food consumption. The time of administration may be varied to suit individual patient needs.

Adults and Children 12 Years and Older:
The recommended initial dose of Avil® NU is 5 mg (1/2 tablet) or 10 mg per day in adults and children 12 years and older, depending on symptom severity.
Avil® NU is given as a single daily dose.

Children 6 to 11 Years:
The recommended initial dose of Avil® NU in children aged 6 to 11 years is 5 mg or 10 mg once daily depending on symptom severity.

Dose Adjustment for Renal and Hepatic Impairment:
In patients 12 years of age and older with decreased renal function (creatinine clearance 11-31 mL/min), patients on hemodialysis (creatinine clearance less than 7 mL/min), and in hepatically impaired patients, a dose of 5 mg once daily is recommended.
Similarly, pediatric patients aged 6 to 11 years with impaired renal or hepatic function should use the lower recommended dose.

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

CONTRAINDICATIONS

Avil® NU is contraindicated in -
- Patients with hypersensitivity to cetirizine hydrochloride or any of the excipients, or hydroxyzine or piperazine derivatives.
- In children under six years of age
- Patients with severe renal impairment

SPECIAL WARNINGS AND PRECAUTIONS

In some patients, long term treatment with cetirizine tablets may lead to an increased risk of caries due to mouth dryness. The patients should therefore be informed about the importance of oral hygiene.

At impaired hepatic function and renal function, the elimination of cetirizine may be impaired. Caution should be exercised when administering cetirizine to these patients.

At therapeutic doses, no clinically significant interactions have been demonstrated with alcohol (for a blood alcohol level of 0.5 g/l). Therefore caution is recommended at concomitant use of alcohol.

Caution should be taken in patients with predisposition factors of urinary retention (e.g. spinal cord lesion, prostatic hyperplasia) as cetirizine may increase the risk of urinary retention.

Caution in epileptic patients and patients at risk of convulsions is recommended.

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, even if those symptoms were not present before treatment initiation. In some cases, the symptoms may be intense and may require treatment to be restarted. The symptoms should resolve when the treatment is restarted.

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.

DRUG INTERACTIONS

No clinically significant drug interactions have been found with theophylline at a low dose, azithromycin, pseudoephedrine, ketoconazole, or erythromycin. There was a small decrease in the clearance of cetirizine caused by a 400-mg dose of theophylline or pseudoephedrine; it is possible that larger theophylline doses could have a greater effect.

The extent of absorption of cetirizine is not reduced with food, although the rate of absorption is decreased.

In sensitive patients, the concurrent use of alcohol or other CNS depressants may cause additional reductions in alertness and impairment of performance, although cetirizine does not potentiate the effect of alcohol (0.5 g/l blood levels).

PREGNANCY

For cetirizine very rare clinical data on exposed pregnancies are available. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/fetal development, parturition or postnatal development. Caution should be exercised when prescribing to pregnant women.

LACTATION

Cetirizine is excreted in human milk at concentrations representing 0.25 to 0.90 those measured in plasma, depending on sampling time after administration. Therefore, caution should be exercised when prescribing cetirizine to lactating women.

FERTILITY

Limited data is available on human fertility but no safety concern has been identified. Animal data show no safety concern for human reproduction.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Objective measurements of driving ability, sleep latency and assembly line performance have not demonstrated any clinically relevant effects at the recommended dose of 10 mg. Patients intending to drive, engaging in potentially hazardous activities or operating machinery should not exceed the recommended dose and should take their response to the medicinal product into account. In sensitive patients, concurrent use with alcohol or other CNS depressants may cause additional reductions in alertness and impairment of performance.

ADVERSE REACTIONS

Clinical studies

Overview

Clinical studies have shown that cetirizine at the recommended dosage has minor adverse effects on the CNS, including somnolence, fatigue, dizziness and headache. In some cases, paradoxical CNS stimulation has been reported.

Although cetirizine is a selective antagonist of peripheral H1-receptors and is relatively free of anticholinergic activity, isolated cases of micturition difficulty, eye accommodation disorders and dry mouth have been reported.

Instances of abnormal hepatic function with elevated hepatic enzymes accompanied by elevated bilirubin have been reported. Mostly this resolves upon discontinuation of the treatment with cetirizine dihydrochloride.

a) Clinical trials

Double blind controlled clinical trials comparing cetirizine to placebo or other antihistamines at the recommended dosage (10 mg daily for cetirizine), of which quantified safety data are available, included more than 3200 subjects exposed to cetirizine.

From this pooling, the following adverse reactions were reported for cetirizine 10 mg in the placebo-controlled trials at rates of 1.0% or greater:

Adverse event (WHO-ART)	Cetirizine 10 mg (n=3260)	Placebo (n=3061)
Body as a whole – general disorders Fatigue	1.63%	0.95%
Central and peripheral nervous system disorders Dizziness Headache	 1.10% 7.42%	 0.98% 8.07%
Gastrointestinal system disorders Abdominal pain Dry mouth Nausea	 0.98% 2.09% 1.07%	 1.08% 0.82% 1.14%
Psychiatric disorders Somnolence	 9.63%	 5.00%
Respiratory system disorders Pharyngitis	 1.29%	 1.34%

Although statistically more common than under placebo, somnolence was mild to moderate in the majority of cases. Objective tests as demonstrated by other studies have demonstrated that usual daily activities are unaffected at the recommended daily dose in healthy young volunteers.
Adverse drug reactions at rates of 1% or greater in children aged from 6 months to 12 years, included in placebo-controlled clinical trials are:

Adverse drug reaction (WHO-ART)	Cetirizine 10 mg (n=1656)	Placebo (n=1294)
Gastrointestinal system disorders Diarrhoea	 1.0%	 0.6%
Psychiatric disorders Somnolence	 1.8%	 1.4%
Respiratory system disorders Rhinitis	 1.4%	 1.1%
Body as a whole – general disorders Fatigue	 1.0%	 0.3%

b) Post-marketing experience
In addition to the adverse reactions reported during clinical studies and listed above, the following undesirable effects have been reported in post-marketing experience. Undesirable effects are described according to MedDRA System Organ Class and by estimated frequency based on post-marketing experience.

Frequencies are defined as follows: Very common (≥ 1/10); common (≥ 1/100 to < 1/10); uncommon: ≥ 1/1,000 to 1/100, rare: ≥ 1/10,000 to 1/1,000, very rare: 1/10,000), not known (cannot be estimated from the available data).

Blood and lymphatic disorders:
Very rare: Thrombocytopenia.

Immune system disorders:
Rare: Hypersensitivity.
Very rare: Anaphylactic shock.

Metabolism and nutrition disorders:
Not known: Increased appetite.

Psychiatric disorders:
Uncommon: Agitation.
Rare: Aggression, confusion, depression, hallucination, insomnia.
Very rare: Tics.
Not known: Suicidal ideation.

Nervous system disorders:
Uncommon: Paraesthesia.
Rare: Convulsions.
Very rare: Dysgeusia, syncope, tremor, dystonia, dyskinesia.
Not known: Amnesia, memory impairment.

Eye disorders:
Very rare: Accommodation disorder, blurred vision, oculogyration.

Ear and labyrinth disorder
Not known: Vertigo.

Cardiac disorders:
Rare: Tachycardia.

Gastrointestinal disorders:
Uncommon: Diarrhoea.

Hepatobiliary disorders:
Rare: Hepatic function abnormal (increased transaminases, alkaline phosphatase, γ-GT and bilirubin).

Skin and subcutaneous tissue disorders:
Uncommon: Pruritus, rash.
Rare: Urticaria.
Very rare: Angioneurotic oedema, fixed drug eruption.

Renal and urinary disorders:
Very rare: Dysuria, enuresis.
Not known: Urinary retention.

General disorders and administration site conditions:
Uncommon: Asthenia, malaise.
Rare: Oedema.

Investigations:
Rare: Weight increased.

Description of selected adverse reactions
After discontinuation of cetirizine, pruritus (intense itching) and/or urticaria have been reported.

DRUG ABUSE AND DEPENDANCE
There is no information to indicate that abuse or dependency occurs with cetirizine.

OVERDOSE

Symptoms

Symptoms observed after an overdose of cetirizine are mainly associated with CNS effects or with effects that could suggest an anticholinergic effect. Adverse events reported after an intake of at least 5 times the recommended daily dose are: confusion, diarrhoea, dizziness, fatigue, headache, malaise, mydriasis, pruritus, restlessness, sedation, somnolence, stupor, tachycardia, tremor, and urinary retention.

Management

There is no known specific antidote to cetirizine. Should overdose occur, symptomatic or supportive treatment is recommended. Gastric lavage should be considered following ingestion of a short occurrence. Cetirizine is not effectively removed by dialysis.

Manufactured by:

- Zentiva Private Limited, Plot No. 3501-15, 6301-13 & 16 meter road/C, GIDC Estate, Ankleshwar-393002, Gujarat.

- Sanofi India Limited, Plot No. L-121, Phase III, Verna Industrial Estate, Verna Goa - 403722

Marketed by: Sanofi India Limited, Sanofi House, CTS No. 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai - 400072

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Sources:

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