CITRICIAN

Cetirizine Hydrochloride Tablets BP 10 mg

QUALITATIVE AND QUANTITATIVE COMPOSITION:

Label claim:

Each film coated tablets contains:

Cetirizine Hydrochloride BP 10 mg

Excipients q.s.

Colour: Titanium Dioxide BP

List of Excipients:

Lactose BP
Maize Starch BP
Microcrystalline Cellulose BP
Croscarmellose Sodium BP
Povidone (PVP K-30) BP
Purified Talc BP
Magnesium Stearate BP
Colloidal Anhydrous Silica BP
Sodium Starch Glycolate BP
Fine Coat
Titanium Dioxide BP
Macrogols (PEG-6000) BP

INDICATION:

Cetirizine Hydrochloride Tablets BP 10 mg is indicated in adults and paediatric patients 6 years and above:

- For the relief of nasal and ocular symptoms of seasonal and perennial allergic rhinitis.
- For the relief of symptoms of chronic idiopathic urticaria.

PHARMACEUTICAL FORM:

White coloured, round, biconvex film coated tablets plain on both sides.

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)
The tablets need to be swallowed with a glass of liquid.
Elderly subjects: data do not suggest that the dose needs to be reduced in elderly subjects provided that the renal function is normal.
Patients with hepatic impairment:
No dose adjustment is needed in patients with solely hepatic impairment.
Patients with hepatic impairment and renal impairment
Dose adjustment is recommended.
Method of Administration: Oral

CONTRAINDICATION:

Hypersensitivity to cetirizine hydrochloride, to any of the excipients, to hydroxyzine or to any piperazine derivatives. Patients with severe renal impairment with a creatinine clearance below 10 ml/min.
Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take cetirizine film-coated tablet.

SPECIAL WARNING AND PRECAUTION FOR USE:

At therapeutic doses, no clinically significant interactions have been demonstrated with alcohol (for a blood alcohol level of 0.5 g/L). Nevertheless, 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) as cetirizine may increase the risk of urinary retention.
Caution in epileptic patients and patients at risk of convulsions are recommended.
Allergy skin tests are inhibited by antihistamines and a wash-out period (of 3 days) is required before performing them.
Pediatric 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. It is recommended to use a pediatric formulation of cetirizine.

ADVERSE REACTION:

The following frequency rating has been used, when applicable:
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 disorders:
Not known: vertigo
Cardiac disorders:
Rare: tachycardia
Gastro-intestinal 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

INTERACTION WITH OTHER MEDICINE AND CONCOMITANT USE:

Due to the pharmacokinetic, pharmacodynamic and tolerance profile of cetirizine, no interactions are expected with this antihistamine. Actually, neither pharmacodynamic nor significant pharmacokinetic interaction was reported in drug-drug interactions studies performed, notably with pseudoephedrine or theophylline (400 mg/day).
The extent of absorption of cetirizine is not reduced with food, although the rate of absorption is decreased.

PREGNANCY AND LACTATION:

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/foetal development, parturition or post natal 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.

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.

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. Alternatively consider activated charcoal.
Cetirizine is not effectively removed by dialysis.

PHARMACOLOGICAL PROPERTIES:

PHARMACOKINETICS:

The steady-state peak plasma concentrations is approximately 300 ng/ml and is achieved within 1.0 ± 0.5 h. No accumulation is observed for cetirizine following daily doses of 10 mg for 10 days. The distribution of pharmacokinetic parameters such as peak plasma concentration (Cmax) and area under curve (AUC) is unimodal in human volunteers.
The extent of absorption of cetirizine is not reduced with food, although the rate of absorption is decreased. The extent of bioavailability is similar when cetirizine is given as solutions, capsules or tablets.
The apparent volume of distribution is 0.50 l/kg. Plasma protein binding of cetirizine is 93 ± 0.3%. Cetirizine does not modify the protein binding of warfarin.
Cetirizine does not undergo extensive first pass metabolism. About two thirds of the dose are excreted unchanged in urine. The terminal half-life is approximately 10 hours.
Cetirizine exhibits linear kinetics over the range of 5 to 60 mg.

PHARMACODYNAMICS:

Pharmacotherapeutic group: Piperazine derivatives.
ATC code: R06A E07
Cetirizine, a human metabolite of hydroxyzine, is a potent and selective antagonist of peripheral H1-receptors. In vitroreceptor binding studies have shown no measurable affinity for other than H1-receptors.
In addition to its anti-H1 effect, cetirizine was shown to display anti-allergic activities: at a dose of 10 mg once or twice daily, it inhibits the late phase recruitment of eosinophils, in the skin and conjunctiva of atopic subjects submitted to allergen challenge.
At the recommended dosage, cetirizine has demonstrated that it improves the quality of life of patients with perennial and seasonal allergic rhinitis.

PACKAGING:

10 tablets are packed in Alu-PVC blister pack and such 10 blisters are packed in a printed carton along with pack insert.

STORAGE CONDITION:

Store in dry place below 30°C. Keep out of reach of children.

SHELF LIFE:

36 Months

MANUFACTURED BY:

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