

Adtrizin[®]

Cetirizine Dihydrochloride BP

COMPOSITION:

Adtrizin[®] 10 mg Tablet: Each film coated tablet contains Cetirizine Dihydrochloride BP 10 mg.

PHARMACOLOGY:

Adtrizin[®] 10 mg Tablet (Cetirizine), a piperazine derivative and carboxylated metabolite of hydroxyzine. It is a potent antihistamine with distinguishing features are: (1) Exquisite anti-H₁ specificity: Adtrizin[®] 10 mg Tablet appears unique in being devoid of action on receptors other than the H₁-receptor, (2) Potency: at unit dose Adtrizin[®] 10 mg Tablet is the most potent antihistamine in the skin and lungs. (3) Absence of metabolism. Therefore, Adtrizin[®] 10 mg Tablet is the choice of H₁ antagonist for the management of the immediate allergic reactions. Adtrizin[®] 10 mg Tablet, a new second generation H₁ antagonist, is the only antihistamine that possesses activity against both the histamine mediated early, phase of the allergic reaction and the late phase response of immediate hypersensitivity characterized by migration of inflammatory cells to the site of the reaction. It is an effective and well tolerated treatment of seasonal and perennial allergic rhinitis and chronic idiopathic urticaria. The nonsedating antihistamine Adtrizin[®] 10 mg Tablet is also effective on the treatment of allergen-induced asthma. It has no significant anticholinergic and antiserotonic effects.

INDICATION:

Adtrizin[®] 10 mg Tablet is indicated for the treatment of seasonal allergic rhinitis and conjunctivitis, perennial allergic rhinitis, pruritus and urticaria. It is also used in allergen induced asthma.

DOSE & ADMINISTRATION:

Adults and children over 6 years: 1 tablet once daily or 1/2 tablet twice daily. Children 2-6 years: 1/2 tablet once daily.

Use in 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.

CONTRA-INDICATION:

Cetirizine is contraindicated in patients who have shown hypersensitivity or idiosyncrasy to it or to its parent compound, hydroxyzine.

WARNING AND PRECAUTION:

The drug is not usually administered to neonates. Patients are advised not to exceed the recommended dose if driving car or operating machinery. At therapeutic dose levels, Cetirizine does not show any potentiation of Alcohol. However, care should be exercised.

SIDE EFFECTS:

Cetirizine is well tolerated and associated with fewer adverse effects compared with first generation antihistamines. Adverse effects include headache, dry mouth, dizziness, agitation and gastrointestinal upset. Cetirizine does not produce anticholinergic effects.

USE IN PREGNANCY & LACTATION:

No evidence of teratogenicity of Cetirizine in animals. There is inadequate information about its safety during pregnancy. It should be used only if the potential benefit justifies the potential risk to the fetus. The extent of Cetirizine excretion in human breast milk is unknown but some animal studies have shown excretion in breast milk. Nursing mothers are advised not to take this medicine.

USE IN CHILDREN & ADOLESCENTS:

Cetirizine is not recommended for use in children under 6 months of age. For children 12 years to 17 years Cetirizine can be administered without any problem.

DRUG INTERACTION:

There was a small decrease in the clearance of cetirizine caused by a 400 mg dose of theophylline. It is possible that larger theophylline doses could have a greater effect. Caution should be taken with concomitant use of sedatives.

OVERDOSE:

In the occasional cases patient taking a massive intentional overdose (150-300 mg), sedation has been the only adverse effect and complete recovery has ensured. When overdose occurs, treatment should be symptomatic or supportive. Like other H₁ receptor antagonists, Cetirizine has no specific antidote.

STORAGE:

Store in a dry and cool place below 30° C temperature and keep away from light and moisture. Keep out of reach of children.

PACKING:

Adtrizin[®] 10 mg Tablet: Box containing 10x10's tablets in blister pack.



Manufactured by

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