

**CTD MODULE 1**  
**ADMINISTRATIVE INFORMATION AND**  
**PRODUCT INFORMATION**

<b>Product Name :</b>	<b>CETRIREN TABLETS</b> <b>(Cetirizine Hydrochloride 10mg)</b>
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**Pack insert**

**CETRIREN TABLETS**

**COMPOSITION:** Each film coated tablet contains Cetirizine hydrochloride 10mg.

**PHARMACOLOGICAL CLASSIFICATION:** Antihistaminics

**PHARMACOLOGICAL ACTION:**

Cetirizine, a metabolite of hydroxyzine, is an anti-allergic agent, with a histamine H<sub>1</sub> receptor antagonism devoid of any significant anticholinergic and antiserotonin effects as demonstrated in experimental and clinical pharmacology.

At the present stage of research into the mode of action of cetirizine, anti-allergic activity seems to be exerted mainly via its effects on the release of certain mediators, such as histamine, together with a selective action on the H<sub>1</sub> receptors. Cetirizine reduces eosinophil recruitment induced by an antigen-antibody reaction.

**PHARMACOKINETIC PROPERTIES:**

Peak blood levels of 300 ng/ml are reached with in one hour after oral administration of cetirizine. Cetirizine does not undergo extensive first pass metabolism. The terminal half-life is approximately 10 hours in adults, 6 hours in children aged 6 to 12 years and 5 hours in children aged 2 to 6 years. These data are consistent with the urinary excretion half-life of the drug. The cumulative urinary excretion represents about two thirds of the dose given in both adults and children. The apparent plasma clearance in children is higher than that measured in adults. Plasma levels are linearly related to the dosage given. A high proportion of cetirizine is bound to human plasma proteins. In patients with impaired renal clearance (less than 40ml/min) and hepatic insufficiency, an increase in half-life and decrease in total clearance occurs.

**INDICATIONS:**

Allergic processes responding to a histamine H<sub>1</sub> receptor antagonist.

- Respiratory: Allergic rhinitis, hay fever.
- Cutaneous: Allergic skin conditions associated with pruritus e.g. urticaria.

**CONTRA-INDICATIONS**

History of hypersensitivity to any of the constituents of the formulations.  
Hypersensitivity to hydroxyzine.

Cetirizine is contra-indicated in lactating women since the active ingredient is excreted in breast milk.

Cetirizine is contra-indicated in pregnancy as the safety has not been established.

**DOSAGE AND DIRECTIONS FOR USE:**

- Adults or Children 12 years of age or older: One tablet daily
- Children 6 to 12 years old: 10mg (One Tablets) once daily or 5mg (half a tablet) twice daily.

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At present there are no data to suggest that the dose needs to be reduced in elderly patients with normal renal function. In patients with renal insufficiency (creatinine clearance less than 40ml/min), the dosage should be reduced to half the usual recommended dose. Half the recommended daily dose should be used in patients with moderate to severe hepatic impairment.

**SIDE-EFFECTS AND SPECIAL PRECAUTIONS:**

Cetiriren lacks significant sedative effects. Patients should, however, be warned that a small number of individuals may experience sedation. It is therefore advisable to determine individual response before driving or performing complicated tasks. This effect may be compounded by the simultaneous intake of alcohol or other central nervous system depressant. There have been occasional reports of mild and transient subjective side effects such as headache, dizziness, drowsiness, agitation, dry mouth, increased appetite, nervousness, fatigue, asthenia, malaise, nausea and gastro-intestinal discomfort. In some individuals, hypersensitivity reactions including skin reactions, urticaria, pruritus and angioedema may develop.

**Interactions:** To date there are no known interactions with other drugs. Studies with diazepam, glipizide, pseudoephedrine, ketoconazole, azithromycin, erythromycin and cimetidine have revealed no evidence of pharmacokinetic interactions. As with other antihistamines it is advisable to avoid excessive alcohol consumption.

**KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:**

Drowsiness can be a symptom of over dosage. Over dosage in children may produce agitation, somnolence, pruritus, rash, urinary retention, fatigue, tremor and tachycardia. In the case of massive over dosage, gastric lavage should be performed together with the usual supportive measures. To date there is no specific antidote. Cetirizine is not effectively removed by dialysis.

**IDENTIFICATION:**

Cetiriren Tablets: White oblong, film coated tablet, break line on one side and plain on another side.

**PRESENTATION:**

Cetiriren Tablets 10mg is available in pack of 10 x 10's.

**STORAGE:**

Store below 30°C. Keep tablets in a dry place. Keep Out of Reach of Children.

**MANUFACTURED BY:-**



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