

CETIRIZINE HYDROCHLORIDE TABLETS

Allercet

COMPOSITION:

Each film-coated tablet contains:

Cetirizine Hydrochloride BP 10 mg.

CHEMISTRY:

Dihydrochloride of 2-[4-(4-chlorobenzhydryl) piperazin-1-yl] ethoxyacetic acid.

PHARMACOLOGICAL CATEGORY:

Selective H1- histamine receptor antagonist.

PHARMACOLOGY:

Cetirizine is a potent anti-histamine with a low potential for drowsiness at pharmacologically active doses and with additional anti-allergic properties. It is selective H1- receptor antagonist with negligible effects on other receptors and so is virtually free from anti-cholinergic and anti-serotonin effects. Cetirizine inhibits the histamine-mediated "early" phase of the allergic reaction and also reduces the migration of inflammatory cells and the release of mediators associated with the "late" allergic response.

Pharmacokinetics:

About 70% of an oral dose of Cetirizine is rapidly absorbed with peak plasma levels occurring within 30-40 minutes. After a 10 mg dose, a peak plasma level of 300 mg/L is reached. Its plasma half-life is approximately 11 hours. Cetirizine is highly bound to plasma proteins. It undergoes minimal metabolism and most of it is excreted unchanged mostly in the urine. Its renal clearance is 30 ml/min and elimination half-life is approximately 9 hours.

INDICATIONS AND USES :

Cetirizine is indicated for the symptomatic treatment of perennial allergic rhinitis, seasonal allergic rhinitis and chronic idiopathic urticaria.

CONTRAINDICATIONS :

Cetirizine tablets are contraindicated in patients with a history of hypersensitivity to any of its constituents.

SIDE EFFECTS / ADVERSE REACTIONS :

There have been occasional reports of mild and transient side effects such as headache, dizziness, drowsiness, agitation, dry mouth, and gastro intestinal discomfort. Occasional symptoms of hypersensitivity have been reported.

PRECAUTIONS AND WARNINGS :

Since the drug rarely causes sedation patients are advised not to exceed the recommended dose if driving or operating machinery.

DRUG INTERACTIONS :

To date, there are no known interactions with other drugs. Studies with diazepam and cimetidine have revealed no evidence of interaction. As with other anti-histamines, it is advisable to abstain from alcohol consumption.

USE IN PREGNANCY AND LACTATION :

Pregnancy: No adverse effects have been reported from animal studies. As with other drugs the use of Cetirizine in pregnancy should be avoided. Cetirizine is contraindicated in lactating woman since the active ingredient is excreted in breast milk.

DOSAGE AND ADMINISTRATION :

One 10 mg tablet daily. At present, there are no data to suggest that the dose need be reduced in elderly patients with normal renal function. In patients with renal insufficiency dosage should be reduced to half a tablet (5 mg) daily.

OVERDOSAGE, SYMPTOMS AND ANTIDOTE :

Drowsiness can be caused in cases of Cetirizine overdosage with single doses of over 50 mg. There is no specific antidote to Cetirizine. In case of massive overdosage, gastric lavage should be done as early as possible and the patient managed with supportive therapy with dose monitoring.

STORAGE:

Store upto 30°C.

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