SUMMARY OF PRODUCT CHARACTRISTICS

1. NAME OF THE MEDICINAL PRODUCT
ZYNCET (Cetirizine Hydrochloride Tablets 10 mg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Label Claim:
Each film coated tablet contains:
Cetirizine Hydrochloride BP…… 10 mg
For Full list of Excipients see section 6.1.

3. Pharmaceutical Form
Tablets
Oblong, biconvex, white, film coated tablets with score on one side.

4. Clinical particulars
4.1 Therapeutic indications:
Cetirizine is indicated for the symptomatic treatment of seasonal allergic rhinitis and perennial allergic rhinitis, allergic conjunctivitis, pruritus and chronic urticaria.

4.2 Posology and method of administration:
For adults and children above 12 years: 10 mg daily. For children below 12 years: 5 - 10 mg daily.
At present there is no data to suggest that the dose need to be reduced in elderly patients. In patients with renal insufficiency dosage should be reduced to half a tablet (5 mg) daily.

4.3 Contraindications
Cetirizine tablets are contraindicated in patients with a history of hypersensitivity to any of their constituents or hydroxyzine.
Cetirizine is contraindicated in lactating women since the active ingredient is excreted in breast milk.

4.4 Special warning and precautions for use
Studies in healthy volunteers on 20 and 25 mg/day dose of Cetirizine have not revealed effects on alertness or reaction time. However patients are advised not to exceed the recommended dose if driving or operating machinery

4.5 Interaction with other medicinal products and other forms of interactions
To date there are no known interactions with other drugs. Studies with Diazepam and Cimetidine have revealed no evidence of interactions. As with other antihistamines, it is advisable to avoid excessive alcohol consumption.

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

4.6 Pregnancy and lactation

Pregnancy

No adverse effects have been reported from animal studies. There has been little or no use of cetirizine in pregnancy. As with other drugs, the use of cetirizine in pregnancy should be avoided.

4.7 Effects on ability to drive and use machine

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4.8 Undesirable effects

There have been occasional reports of mild and transient subjective adverse effects such as headache, dizziness, drowsiness, agitation, dry mouth, gastro-intestinal discomfort, pharyngitis and fatigue. If desired the dose may be taken as 5 mg in the morning and 5 mg in the evening. In objective tests of psychomotor function, the incidence of sedation with Cetirizine was similar to that of placebo.

4.9 Overdose

Overdosage may include asymptomatic symptoms such as gastrointestinal symptoms including stomach and abdominal pain, vomiting, and diarrhea. Rash, hyperactivity, or drowsiness may also be observed.

In case of overdosage, discontinue medication, treat symptomatically, and institute supportive measures as required. If the overdosage is very recent and there is no contraindication, an attempt at emesis or other means of removal of the drug from the stomach may be performed.

Interstitial nephritis resulting in oliguric renal failure may occur after overdosage with amoxicillin. Renal impairment appears to be reversible with cessation of drug administration. High blood levels may occur more readily in patients with impaired renal function because of decreased renal clearance of both amoxicillin and clavulanic acid. Both amoxicillin and clavulanic acid may be removed from circulation by hemodialysis.

5. Pharmacological Properties

5.1 Pharmacodynamics Properties

Pharmacotherapeutic group: Antihistamines for systemic use, Piperazine derivatives,
ATC-Code: R06A E07

Pharmacodynamics:

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

5.2 Pharmacokinetic Properties

Peak blood levels of the order of 0.3 mcg/ml are reached between 30 to 60 minutes after oral administration of a 10 mg dose of Cetirizine. Its plasma half-life is approximately 11 hours. Absorption is very consistent from one subject to the next. Its renal clearance is 53ml/min and the excretion half life is approximately 8.3 hours. Cetirizine is strongly bound to plasma proteins(93%).

5.3 Preclinical Safety Data

There are no preclinical data of relevance to the prescriber other than those already mentioned in other sections of the SPC.
For more information, see sections, Contraindications and Pregnancy and lactation.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Lactose, Maize starch, Povidone, Magnesium stearate, Eudragit E-100, Polyethylene Glycol 6000 (Macrogol), Titanium dioxide, Purified talc, Methylene Chloride, Acetone, Isopropyl Alcohol.

6.2 Incompatibilities
Not applicable.

6.3 Shelf-life
36 Months from the date of manufacture.

6.4 Special precautions for storage
Store below 30ºC. Protect from light and moisture.

6.5 Nature and contents of containers
Inner Carton containing 5 blister of 10 tablets each long with pack insert 4 such inner carton are packed in an outer carton.

6.6 Instruction for use/handling
No special requirements.

7. Marketing Authorization Holder
Manufacturer address:
UNICHEM LABORATORIES LIMITED
Unit-II, Village Bhatauli Kalan,
Baddi, Dist. Solan (H.P) – 173 205
Himachal Pradesh - 173205
INDIA
Phone: 00-91-1795-245322/244507

Corporate office address:

UNICHEM LABORATORIES LIMITED
47, Kandivli Industrial Estate
Kandivli (West),
Mumbai - 400 067. India

Marketing Authorization Number: - A4-1595

Date of first authorization/renewal of the authorization: - 27 May, 2021

Date of revision of the text: 29 September, 2025