

Summary of Product Characteristics
MEDRIZINE
(Cetirizine Hydrochloride BP 10 mg)

1. Name of the medicinal product

MEDRIZINE (Cetirizine Hydrochloride BP 10 mg)

2. Qualitative and quantitative composition

Each uncoated tablet contains 10mg Cetirizine Hydrochloride

Excipients of known effect:

Each uncoated tablet contains 10.45 mg of lactose.

3. Pharmaceutical form

Tablet.

White Colored, Round Shaped & Film coated Tablets

4. Clinical Particulars:

4.1 Therapeutic indications

In adults and paediatric patients 6 years and above:

Cetirizine is indicated for the relief of nasal and ocular symptoms of seasonal and perennial allergic rhinitis.

Cetirizine is indicated for the relief of symptoms of chronic idiopathic urticaria.

4.2 Posology and method of administration

Children aged from 6 to 12 years: 5mg twice daily (a half tablet twice daily). Adults and adolescents over 12 years of age: 10mg 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 moderate to severe renal impairment: there are no data to document the efficacy/safety ratio patients with renal impairment. Since cetirizine is mainly excreted via renal route in cases where no alternative treatment can be used, the dosing intervals must be individualized according to renal function. Refer to the following table and adjust the dose as indicated.

Group	Creatinine clearance (ml/min)	Dosage and frequency
Normal	≥80	10 mg once daily
Mild	50-79	10 mg once daily
Moderate	30-49	5 mg once daily
Severe	< 30	5 mg once every 2 days
End-stage renal disease - Patients undergoing dialysis	< 10	Contra-indicated

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In paediatric patients suffering from renal impairment, the dose will have to be adjusted on an individual basis taking into account the renal clearance of the patient, their age and body weight. 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 (see Patients with moderate to severe renal impairment above).

Method of administration For oral administration.

4.3 Contraindications

Hypersensitivity to cetirizine hydrochloride, to any of the excipients listed in section 6.1, to hydroxyzine or to any piperazine derivatives.

Patients with severe renal impairment at less than 10 ml/min creatinine clearance

4.4 Special warnings and precautions 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 or urinary retention (e.g. spinal cord lesion, prostatic hyperplasia) as cetirizine may increase the risk of urinary retention.

Caution in epileptic patients and patients who are at risk of convulsions is recommended. Response to allergy skin tests are inhibited by antihistamines and a wash-out period (of 3 days) is required before performing them.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Pruritus and/or urticaria may occur when cetirizine is stopped, even if those symptoms were not present before treatment initiation. In some cases, the symptoms may be intense and may require treatment to be restarted. the symptoms should resolve when the treatment is restarted.

Paediatric 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 paediatric formulation of cetirizine.

4.5 Interaction with other medicinal products and other forms of interaction

Due to 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.

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In sensitive patients, the concurrent use of alcohol or other CNS depressants may cause additional reductions in alertness and impairment of performance, although cetirizine does not potentiate the effect of alcohol (0.5 g/L blood levels).

4.6 Fertility Pregnancy and Lactation

Fertility

Limited data is available on human fertility but no safety concern has been identified. **Pregnancy**

For cetirizine prospectively collected data on pregnancy outcomes do not suggest potential for maternal or foetal/embryonic toxicity above background rates.

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. **Breast-feeding**

Cetirizine is excreted in human milk at concentrations representing 25% to 90% those measured in plasma, depending on sampling time after administration. Therefore, caution should be exercised when prescribing cetirizine to lactating women.

4.7 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.

However patients who experience somnolence should refrain from driving, engaging in potentially hazardous activities or operating machinery. They should not exceed the recommended dose and should take their response to the medicinal product into account

4.8 Undesirable effects

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, hallucinations, insomnia

Very rare: tics

Not known: suicidal ideation, nightmare

Nervous system disorders:

Uncommon: paraesthesia

Rare: convulsions

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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 phosphatases, γ-GT and bilirubin) Not known: hepatitis

Skin and subcutaneous tissue disorders:

Uncommon: pruritis, rash

Rare: urticaria

Very rare: angioneurotic oedema, fixed drug eruption

Not known: acute generalized exanthematous pustulosis

Musculoskeletal and connective tissue disorders Not known: arthralgia

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

Description of selected adverse reactions

After discontinuation of cetirizine, pruritus (intense itching) and/or urticaria have been reported.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to National Regulatory Agents.

4.9 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

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be considered following ingestion of a short occurrence. Alternatively consider activated charcoal. Cetirizine is not effectively removed by dialysis.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antihistamine for systemic use, piperazine derivatives.

ATC code: R06A E07

Mechanism of action: Cetirizine, a human metabolite of hydroxyzine, is a potent and selective antagonist of peripheral H₁-receptors. In vitro receptor binding studies have shown no measurable affinity for other than H₁-receptors.

Pharmacodynamics effects: In addition to its anti-H₁ effect, cetirizine was shown to display antiallergic 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. Clinical efficacy and safety: Studies in healthy volunteers show that cetirizine, at doses of 5 and 10 mg strongly inhibits the wheal and flare reactions induced by very high concentrations of histamine into the skin, but the correlation with efficacy is not established.

In a six-week, placebo-controlled study of 186 patients with allergic rhinitis and concomitant mild to moderate asthma, cetirizine 10mg once daily improved rhinitis symptoms and did not alter pulmonary function. This study supports the safety of administering cetirizine to allergic patients with mild to moderate asthma.

In a placebo-controlled study, cetirizine given at the high daily dose of 60 mg for seven days did not cause statistically significant prolongation of QT interval.

At the recommended dosage, cetirizine has demonstrated that it improves the quality of life of patients with perennial and seasonal allergic rhinitis.

Paediatric population: In a 35-day study in children aged 5 to 12, no tolerance to the antihistamine effect (suppression of wheal and flare) of cetirizine was found. When a treatment with cetirizine is stopped after repeated administration, the skin recovers its normal reactivity to histamine within 3 days.

5.2 Pharmacokinetic properties

Absorption

The steady-state peak plasma concentrations is approximately 300 ng/ml and is achieved within 1.0 ± 0.5 h. The distribution of pharmacokinetic parameters such as peak plasma concentration (C_{max}) and area under curve (AUC) is unimodal.

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.

Distribution

The apparent volume of distribution is 0.50 l/kg. Plasma protein binding of cetirizine is $93 \pm 0.3\%$. Cetirizine does not modify the protein binding of warfarin.

Biotransformation

Cetirizine does not undergo extensive first pass metabolism.

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Elimination

The terminal half-life is approximately 10 hours and no accumulation is observed for cetirizine following daily doses of 10 mg for 10 days. About two thirds of the dose are excreted unchanged in urine.

5.3 Preclinical safety data

No Data Found

6. Pharmaceutical particulars

6.1 List of excipients

Sr. No.	Name of Excipient
1	Di-Basic Calcium Phosphate
2	Microcrystalline Cellulose
3	Lactose
4	Maize Starch
5	PVP K-30
6	Sodium methyl paraben
7	Sodium propyl paraben
8	Aerosil
9	Sodium Starch Glycolate
10	Talc
11	Magnesium Stearate
12	Purified Water

6.2 Incompatibilities

Not Applicable

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 30°C Protect from light & moisture.

6.5 Nature and contents of container

10 Tablets packed in one ALU-PVC blister and such 10blister packed in one carton, along with insert.

6.6 Special precautions for disposal and other handling

No special requirements

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURER

Marketing Authorisation Holder:

ZAIN PHARMA LTD.

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Plot No: 209/13741, Colchester Park,
Go-Down No.1, 2, 3, Off Mombasa Road,
Behind Nice and Lovely House,
P.O. Box: 100167-00101, Nairobi, Kenya

8. Marketing Authorization Number: CTD12852

9. Date of First <Registration> : 1st June, 2026

10. Date of Revision of the Text: 1st June, 2026