Summary of Product Characteristics (SmPC) for Pharmaceutical Products

1. Name of the medicinal product:

Cetirizine Tablets BP 10 mg

2. Qualitative and Quantitative composition:

Composition:
Each Film coated Tablet Contains:
Cetirizine Hydrochloride BP ... 10 mg
Excipients… ..... QS

3. Pharmaceutical Form: Solid dosage form (Tablet)

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.
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	**Estimated Glomerular Filtration Rate (eGFR) (ml/min)**	**Dosage and frequency**
Normal renal function	≥ 90	10 mg once daily
Mildly decreased renal function	60 – < 90	10 mg once daily
Moderately decreased renal function	30 – < 60	5 mg once daily
Severely decreased renal function	15 - < 30 not requiring dialysis treatment	5 mg once every 2 days
End-stage renal disease	< 15 requiring dialysis treatment	Contraindicated

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

Paediatric Population

The tablet formulation should not be used in children under 6 years of age as it does not allow

the necessary dose adjustments.

4.3 Contraindications

Hypersensitivity to cetirizine hydrochloride, to any of the excipients

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 of 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, total 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.

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 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 passes into breast milk. A risk of side effects in breastfed infants cannot be excluded. 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.

Fertility

Limited data is available on human fertility but no safety concern has been identified. Animal data show no safety concern for human reproduction.

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

Very rare: dysgeusia, syncope, tremor, dystonia, dyskinesia Not known: amnesia, memory impairment
Eye disorders:

Very rare: accommodation disorder, blurred vision, oculogyric crisis Ear and labyrinth disorders:
Not known: vertigo Cardiac disorders: Rare: tachycardia

Gastro-intestinal disorders:

Uncommon: diarrhea
Hepatobiliary disorders:
Rare: hepatic function abnormal (increased transaminases, alkaline phosphatase, γ -GT and bilirubin)

Not known: hepatitis

Skin and subcutaneous tissue disorders:

Uncommon: pruritus, rash Rare: urticaria
Very rare: angioneurotic oedema, fixed drug eruption
Not known: acute generalized exanthematous pustulosis Musculoskeletal and connective tissue disorders
Not known: arthralgia, myalgia 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 of suspected adverse reactions: Healthcare professionals are requested to report any suspected adverse reactions via pharmacy and poisons board,Pharmacovigilance Electronic Reporting System

(PvERS) https://pv.pharmacyboardkenya.org

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 be considered shortly after ingestion of the drug.

Cetirizine is not effectively removed by haemodialysis.

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 anti-allergic 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 (Cmax) 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 ± 0.3%. Cetirizine does not modify the protein binding of warfarin.

Biotransformation

Cetirizine does not undergo extensive first pass metabolism.

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

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction and development.

6. Pharmaceutical particulars

6.1 List of excipients

Lactose
Maize
starch
Dibasic Calcium
Phosphate
Cros Carmellose
Sodium Colloidal Silicon
Dioxide Maize Starch
Gelatin
Methyl paraben
Propyl paraben
Purified Talc
Magnesium
Stearate
Colloidal Silicon
Dioxide

Cros Carmellose Sodium
Hydroxy Propyl Methyl Cellulose E15CPS Titanium Dioxide
Purified Talc
Polyethylene Glycol 4000
Propylene Glycol
Methylene Chloride
Isopropyl Alcohol

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 Months

6.4 Special precautions for storage

Store at a temperature not exceeding 25°C. Protect from light & moisture. This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

3 x 10 tablets packed in monocarton with literature.

6.6 Special precautions for disposal and other handling

Store at temperature not exceeding 30°C, protect from moisture

7 Marketing Authorization Holder:

Harley's Limited P.O. Box42718-00100 GPO, Westlands Road, Nairobi, Kenya

8 Marketing Authorization Number:

H2014/ CTD1643/726

9 Date of first Authorization /renewal of the authorization:

02/2019

10 Date of revision of text:

28/02/2026