PROFESSIONAL INFORMATION

SCHEDULING STATUS

S1

1 NAME OF THE MEDICINE

Cetirizine 10 Unicorn (Film-coated tablets)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 10 mg cetirizine dihydrochloride.

Contains sugar (as lactose 63,5 mg per film-coated tablet)

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

White to off white, film coated capsule shaped tablet, with score on one face of the tablet.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Allergic processes responding to a histamine H_1 receptor antagonist.

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

4.2 Posology and method of administration

Posology

Adults or children 12 years of age or older: one 10 mg tablet daily.

Children 6 to 12 years old: 10 mg (one tablet) once daily or 5 mg (half a tablet) twice daily.

Special populations

Elderly patients:

No dose adjustment is required in elderly patients provided that the renal function is normal.

Patients with renal impairment:

In patients with renal impairment, where the creatinine clearance is less than 40 ml/min, the recommended daily dose of cetirizine should be halved.

Patients with hepatic impairment

In moderate to severe hepatic impairment, half the recommended daily dose should be used.

Paediatric population

Cetirizine 10 Unicorn is contraindicated in children younger than 2 years, as safety and efficacy have not been established (see section 4.3).

This dosage form is not suitable for children younger than 6 years.

Method of administration

For oral use

4.3 Contraindications

Cetirizine 10 Unicorn is contraindicated in:

- Patients who have a history of hypersensitivity or are hypersensitive to cetirizine dihydrochloride, hydroxyzine, any piperazine derivative or any of the excipients listed in section 6.1.
- Patient with severe renal impairment at less than 30 ml/min creatinine clearance.
- Lactating women since the active ingredient is excreted in breast milk.
- In pregnancy as safety has not been established.
- In children under 2 years of age, as safety and efficacy have not been demonstrated.

4.4 Special warnings and precautions for use

This medicine lacks significant sedative effects. Patients should be warned; however, a small number of patients may experience sedation.

At therapeutic doses, no significant interactions have been demonstrated with alcohol (for a blood alcohol level of 0,5 g/L) Nevertheless, caution is recommended if alcohol is taken concomitantly.

Caution in epileptic patients and patients at risk of convulsions is recommended.

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 (see section 4.8)
Pruritus and/or urticaria may occur when cetirizine is stopped, even if those symptoms were not present before treatment initiation (see section 4.8). In some cases, the symptoms may be intense and may require treatment to be restarted. The symptoms should resolve when the treatment is restarted.
Allergy skin tests are inhibited by antihistamines and a wash-out period (of 3 days) is required before performing them.

Lactose:
Cetirizine 10 Unicorn contains lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take Cetirizine 10 Unicorn.

4.5 Interaction with other medicines 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 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.

Alcohol and other CNS depressants
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 (see Section 4.4).

4.6 Fertility, pregnancy and lactation

Pregnancy

Cetirizine 10 Unicorn is contraindicated in pregnancy (see section 4.3)

Breastfeeding

Cetirizine 10 Unicorn is contraindicated in lactation (see section 4.3).

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

Patients should be warned that some 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 depressants.

4.8 Undesirable effects

Summary of safety profile

Cetirizine 10 Unicorn has potential adverse effects on the CNS, including somnolence, fatigue, dizziness and headache. In some cases, paradoxical CNS stimulation may occur. Cetirizine 10 Unicorn is a selective antagonist of peripheral H_1-receptors and is relatively free of anticholinergic activity. Nevertheless, cases of micturition difficulty, eye accommodation disorders and dry mouth may occur**.** Instances of abnormal hepatic function with elevated hepatic enzymes accompanied by elevated bilirubin may occur.

Tabulated summary of adverse reactions.

MEDRA SOC	**Adverse reactions**	**Frequency**
Blood and lymphatic disorders	Thrombocytopenia, Leucopoenia, haemolytic anaemia, agranulocytosis	Less Frequent
Immune system	Hypersensitivity,	Less frequent

disorders	Anaphylactic shock	
Metabolism and nutrition disorders	Increased appetite	Frequency unknown
Psychiatric disorders:	Somnolence	Frequent
	Agitation, aggression, confusion, depression, hallucinations, insomnia, tic	Less Frequent
	Suicidal ideation, nightmare	Frequency unknown
Nervous system disorders:	Dizziness, headache	Frequent
	Drowsiness Paraesthesia, Convulsions, movement disorders, Dysgeusia, syncope, tremor, dystonia, dyskinesia	Less Frequent
	Amnesia, memory impairment	Frequency unknown
Eye disorders:	Accommodation disorders, blurred vision, oculogyration	Less Frequent
Ear and Labyrinth disorders:	Vertigo	Frequency unknown
Cardiac disorders:	Tachycardia, palpitations, dysrhythmias	Less frequent
Respiratory, thoracic, and mediastinal	Pharyngitis	Frequent

disorders		
Gastro-intestinal disorders:	Dry mouth, nausea	Frequent
	Diarrhoea, abdominal pain	Less Frequent
Hepatobiliary disorders:	Hepatic function abnormal (increased transaminases, alkaline phosphates, y-GT and bilirubin)	Less Frequent
	Hepatitis	Frequency unknown
Skin and subcutaneous tissue disorders	Pruritis, rash, urticaria, Angioneurotic oedema, fixed drug eruption	Less Frequent
	Acute generalized exanthematous pustulosis (AGEP)	Frequency unknown
Musculoskeletal and connective tissue disorders	Arthralgia	Frequency unknown
Renal and urinary disorders	Dysuria, enuresis	Less Frequent
	Urinary retention (see section 4.4)	Frequency unknown
General disorders and administration site conditions	Fatigue	Frequent
	Asthenia, malaise, Oedema	Less Frequent
Investigations	Weight increased	Less Frequent

Skin reactions occurring after discontinuation of cetirizine

After discontinuation of cetirizine, pruritus (intense itching) and/or urticaria may occur *(see section 4.4)*.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za

4.9 Overdose

Symptoms: Symptoms observed after an overdose of Cetirizine 10 Unicorn are mainly associated with CNS effects that suggest an anticholinergic effect.

Adverse events reported after an overdose are: confusion, diarrhoea, dizziness, fatigue, headache, malaise, mydriasis, pruritus, restlessness, sedation, somnolence tachycardia, tremor and urinary retention.

Management: There is no known specific antidote to Cetirizine 10 Unicorn.

Should overdose occur, symptomatic or supportive treatment is recommended.

Cetirizine is not effectively removed by dialysis.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacological classification: A.5.7.1 Antihistaminics

Pharmacotherapeutic group: Antihistamine for systemic use, Piperazine derivatives, ATC code: R06A E07

Cetirizine dihydrochloride, a metabolite of hydroxyzine, is an anti-allergic medicine, with a histamine H_1 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, the 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_1 receptors. Cetirizine reduces

eosinophil recruitment induced by an antigen-antibody reaction.

5.2 Pharmacokinetic properties

Absorption

Peak blood levels of 300 ng/ml are reached within one hour after oral administration of cetirizine.

Distribution

A high proportion of cetirizine is bound to human plasma proteins.

Biotransformation

Cetirizine does not undergo extensive first pass metabolism.

Elimination

The terminal half-life is approximately 10 hours. These data are consistent with the urinary excretion half-life of the medicine. The cumulative urinary excretion represents about two thirds of the dose given.

Linearity/non-linearity

Plasma levels are linearly related to the dosage given.

Special populations

Paediatric population

The terminal half-life is approximately 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 medicine. The cumulative urinary excretion represents about two thirds of the dose given.

The apparent plasma clearance in children is higher than that measured in adults.

Renal impairment

In patients with impaired renal clearance (less than 40 ml/min), an increase in half-life and decrease in total clearance occurs.

Hepatic impairment

In patients with hepatic insufficiency, an increase in half-life and decrease in total clearance occurs.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dry mixing: Cellulose microcrystalline, colloidal anhydrous silica, croscarmellose sodium, lactose, magnesium stearate.

Film coating: Tabcoat TC film coating product TC – 580034 white (Hypromellose, polydextrose, titanium dioxide, polyethylene Glycol/macrogol)

6.2 Incompatibilities

Not Applicable

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store at or below 25° C

Keep tablets in a dry place.

6.5 Nature and contents of container

Cetirizine dihydrochloride 10 mg tablets are packages in clear transparent PVC/PVDC foil blister packs.

Each blister contains 15 tablets, which are placed in an outer carton containing 30 tablets.

6.6 Special precautions for disposal and other handling

No special requirements

7 HOLDER OF CERTIFICATE OF REGISTRATION

Unicorn Pharmaceuticals (Pty) Ltd

Corner of Searle & Pontac streets

Cape Town, 8001

South Africa

8 REGISTRATION NUMBER

56/5.7.1/0739

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

27 February 2024

10 DATE OF REVISION OF THE TEXT

Not applicable