SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

CETRIFED-10 (Cetirizine 10 mg Film coated tablets)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film coated tablet contains 10 mg cetirizine hydrochloride

Excipient(s) with known effect:

Each tablet contains 59.73 mg lactose.

Colour: Titanium Dioxide.

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Film-coated tablet

A White coloured, oblong, biconvex film coated tablets, having half line mark on each 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 subjectsprovided that the renal function is normal.

Patients with moderate to severe renal impairment: there are no data to document theefficacy/safety ratio patients with renal impairment. Since cetirizine is mainly excreted viarenal route (see section 5.2), in cases where no alternative treatment can be used, thedosing intervals must be individualized according to renal function. Refer to the followingtable and adjust the dose as indicated. To use the dosing table, an estimate of the patient'screatinine clearance (CL) in ml/min is needed.

In paediatric patients suffering from renal impairment, the dose will have to be adjustedon an individual basis taking into account the renal clearance of the patient, their age andbody weight.
Patients with hepatic impairment: no dose adjustment is needed in patients with solelyhepatic impairment.
Patients with hepatic impairment and renal impairment: dose adjustment is recommended

4.3 CONTRAINDICATION

Cetirizine Tablet is contraindicated in patients with hypersensitivity to cetirizine or hydroxyzine.

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 3days) is required before performing them.
Patients with rare hereditary problems of galactose intolerance, the Lapp lactasedeficiency or glucose-galactose malabsorption should not take this medicine.
Pruritus and/or urticaria may occur when cetirizine is stopped, even if those symptomswere not present before treatment initiation. In some cases, the symptoms may be intenseand may require treatment to be restarted. the symptoms should resolve when thetreatment is restarted.
Paediatric population
The use of the film-coated tablet formulation is not recommended in children aged lessthan 6 years since this formulation does not allow for appropriate dose adaptation. It isrecommended to use a paediatric formulation of cetirizine.

Due to pharmacokinetic, pharmacodynamic and tolerance profile of cetirizine, nointeractions are expected with this antihistamine. Actually, neither pharmacodynamic norsignificant pharmacokinetic interaction was reported in drug-drug interactions studiesperformed, notably with pseudoephedrine or theophylline (400 mg/day).

The extent of absorption of cetirizine is not reduced with food, although the rate ofabsorption is decreased.
In sensitive patients, the concurrent use of alcohol or other CNS depressants may causeadditional reductions in alertness and impairment of performance, although cetirizinedoes not potentiate the effect of alcohol (0.5 g/L blood levels).

4.5. INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

Due to the 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.
Paediatric population
No data available

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 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. Studies in healthy volunteers at 20 and 25mg/day have not revealed adverse effects on alertness or reaction time.

Patients intending to drive, engaging in potentially hazardous activities or operating machinery should not exceed the recommended dose and should take their response to the medicinal product into account even though cetrizine has no or negligible influence on these parameters.. In sensitive patients, concurrent use with alcohol or other CNS depressants may cause additional reductions in alertness and impairment of performance.

4.8 UNDESIRABLE EFFECTS:

Clinical studies have shown that Cetirizine at the recommended dosage has minor undesirable effects on the CNS, including somnolence, fatigue, dizziness and headache. In some cases, paradoxical CNS stimulation has been reported.

Although Cetirizine is a selective antagonist of peripheral H_1-receptors and is relatively free of Anticholinergic activity, isolated cases of micturition difficulty, eye accommodation disorders and dry mouth have been reported.

Instances of abnormal hepatic function with elevated hepatic enzymes accompanied by elevated bilirubin have been reported. Mostly this resolves upon discontinuation of the treatment with Cetirizine hydrochloride.

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

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

5. PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Cetirizine is a potent and selective antagonist of peripheral H_1-receptors.
In addition to its anti-H_1 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.

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.

5.2 PHARMACOKINETIC PROPERTIES

Cetirizine is rapidly absorbed from the gastrointestinal tract after oral administration, peak plasma concentration being attained about one hour. Food delays the time to peak plasma concentration but does not decreases the amount of the drug absorbed. It is highly bound to plasma protein and has been detected in breast milk. Cetirizine is excreated primarily in the urine

mainly as unchanged drug. Cetirizine does not appear to cross the blood brain barrier to a significant extent

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.

Preclinical results were observed only at exposures considered sufficiently in excess of the maximum human exposure indicating little relevance to clinical use.

6. PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Cetirizine Hydrochloride
Lactose
Microcrystalline Cellulose
Maize Starch
Povidone K-30
Sodium Methyl Paraben
Sodium Propyl Paraben
Purified Water
Magnesium Stearate
Colloidal Anhydrous Silica
Sodium Starch Glycolate
Hypromellose 15 CPS
Titanium Dioxide
Purified Talc
Polyethylene Glycol - 400
Isopropyl Alcohol
Dichloromethane

6.2 INCOMPATIBILITIES

Not applicable.

6.3 SHELF LIFE

36 Months

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 30^0 C in dry place protect from light.

6.5 NATURE AND CONTENTS OF CONTAINER

Alu-PVC Blister

Pack size:10×10 tablets

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL AND OTHER HANDLING

No special requirements.

7 MARKETING AUTHORISATION HOLDER

CORAL LABORATORIES LTD.

Plot No.57 / 1 (16),

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8 MARKETING AUTHORIZATION NUMBER

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9 DATE OF FIRST AUTHORIZATION / RENEWAL OF AUTHORIZATION

26/05/2018

10. DATE OF REVISION OF THE TEXT

03/07/2023

11. REFERENCES