SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

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1. NAME OF THE MEDICINAL PRODUCT

Codimex- CT tablets (CETIRIZINE DIHYDROCHLORIDE Ph Eur)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet Cetirizine Dihydrochloride 10 mg

For excipients, see 6.1.

3. PHARMACEUTICAL FORM

Film coated tablets

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Cetirizine is used to temporarily relieve the following symptoms:

1. *Seasonal allergic rhinitis:* This is due to allergens such as ragweed, grass and tree pollens in adults and children 2 years of age and older. Symptoms treated effectively include sneezing, rhinorrhea, nasal pruritis, occular pruritis, tearing and redness of the eyes.

2. *Perennial allergic rhinitis:* This is due to allergens such as dust mites, animal dander and molds in adults and children 6 months of age and older. Symptoms treated effectively include sneezing, rhinorrhea, postnasal discharge, nasal pruritis, occular pruritis and tearing.

3. *Chronic urticaria:* Codimex-CT is also used in the treatment of the uncomplicated skin manifestations of chronic idiopathic urticaria in adults and children 6 months of age and older. It significantly reduces the occurrence, severity and duration of hives and significantly reduces prulitis

4.2. Posology and method of administration

Route of administration: Oral

Method of administration:

Cetirizine can be taken without regard to food consumption.

Adults and children over 6 years

One tablet daily

Children 2 to 6 years:

Half a tablet daily

Or as directed by the doctor

4.3. Contraindications

In patients who have shown hypersensitivity or idiosyncracy to cetirizine or its parent compound – Hydroxyzine

4.4. Special warnings and precautions for use

Patients who have shown hypersensitivity or idiosyncracy to cetirizine or its parent compound – Hydroxyzine

4.5. Interaction with other medicinal products and other forms of interaction

No significant drug interactions have been found since cetirizine appears to have low hepatic metabolism and little arrythmogenic potential

4.6. Pregnancy and lactation

Data on a limited number of exposed pregnancies indicate no adverse effects of cetirizine on pregnancy or on the health of the foetus/new born child. To date no other relevant epidemiological data are available.

Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy; embryo/foetal development, parturition or post natal development. Caution should be exercised when prescribing to pregnant women.

Breast feeding

No data concerning the excretion of cetirizine into human milk are available. Cetirizine should be avoided during lactation.

4.7. Effects on ability to drive and use machines

Cetirizine may have minor or moderate influence on the patient's ability to react. This should be considered when extra alertness is required e.g. when driving. Cetirizine may potentiate the effects of alcohol and CNS depressants

4.8. Undesirable effects

Drowsiness occurs in 14% of the patients. Fatigue, dry mouth, stomach pain, diarrhoea, nausea and vomiting, headache have been reported with cetirizine.

4.9. Overdose

Drowsiness can be symptoms of overdosage. In case of overdosage, gastric lavage should be performed with the usual supportive measures.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

ATC code: RO6AEO7

Pharmacotherapeutic group: Antihistamine piperazine derivatives.

Cetirizine hydrochloride is a racemate and an anti-allergic with specific histamine H_1-receptor blocking characteristics.

Cetirizine inhibits cutaneous reactions in allergic individuals through VIP (Vasoactive Intestinal Polypeptide) and substance P, neuropeptides that are considered to be involved in the allergic

reaction. Effect is reached within 2 hours with a maximum effect after 4 hours, and remains for at least 24 hours. In allergic individuals, cetirizine inhibits the recruitment of eosinophils after stimulation with allergens and non-selective histamine liberators, by a mechanism that is not primarily explained by the H_1-receptor blocking characteristics of the pharmaceutical.

5.2. Pharmacokinetic properties

Cetirizine is rapidly absorbed from the gastro-intestinal tract after oral administration, peak plasma concentration being attained in about one hour. Food delays the time to peak plasma concentrations but does not decrease the amount of drug absorbed. It is highly bound to plasma proteins and has an elimination half-life of about 10 hours. Trace quantities of cetirizine have been detected in breast milk .Excretion is primarily through urine mainly as unchanged drug. Cetirizine does not appear to cross the blood brain barriers to a significant extent.

5.3. Preclinical safety data

Preclinical information has not been included because the safety profile of Cetirizine dihydrochloric 10 mg tablets has been established after many years of clinical use. Please refer to section 4.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Cetirizine Dihydrochloride 10.00mg

Starch 30.0mg

Lactose 62.0mg

Starch 6.0mg

Sodium Benzoate 0.20mg

Purified water Q.S.

Starch 4.5mg

Magnesium stearate 2.0mg

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

4years.

6.4. Special precautions for storage

Store below 30°C away from light and moisture

6.5. Nature and contents of container

Aluminium foil

Length: 96±1mm

Thickness: 0.3mm

Weight of the material: 0.735 gsm

PVC

Type: Rigid PVC film

Length: 96±1 mm

Thickness: 250 microns ±7%

Colour: Clear

Unit carton

Length: 103±2mm

Width: 65±2mm

Height: 13 ±2mm

Weight of the material: 220 gsm

Caliper: 400 microns

Leaflet

Length148± 2mm

6.6. Width: 105±2mm

Weight of the material: 50gsm

Caliper: 55 microns

6.7. Special precautions for disposal and other handling

No special requirements.

7. REGISTRANT

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