Summary Product Characteristics (SPC):

1.1 Name of the medicinal product

a. Product Name

CETRIPINN 10 (Cetirizine Tablets BP)

b. Strength

10 mg

c. Pharmaceutical dosage form

Tablet for oral administration

1.2 Quality and Quantitative Composition

Label claim

Each Film coated tablet contains,
Cetirizine Hydrochloride BP.....10 mg
Excipients.....qs
Batch Size : 10 ,00,000 lacs Tablets

Sr. No.	Ingredients	Specification $	Qty. Per tab in mg	Qty. Per Batch in Kg	Function
Dry Mixing					
1.	Cetirizine Hydrochloride *	BP	10.00	10.00	API
2.	Colloidal Anhydrous silica	BP	1.20	1.20	Filler
3.	Lactose**	BP	32.63	32.63	Filler
Binder					
4.	Maize Starch	BP	61.97	61.97	Binder
5.	Purified water****	BP	q.s.	q.s.	Solvent for Binder
Lubrication					
6.	Talc	BP	1.10	1.10	Lubricant
7.	Magnesium Stearate	BP	1.10	1.10	Lubricant
8.	Sodium Starch Glycolate	BP	4.00	4.00	Disintegrating agent
Total Core Weight			**112.00 mg**		
Coating Material					
9	Sheffcoat PVA Yellow (5Y00935)***	IH	2.00	2.00	Coating Material
10	Purified water ****	BP	q.s	q.s	Solvent for Coating
Total Average Weight			**114.00 mg**		

$ Current pharmacopoeial monograph implies.
*The given quantity is calculated on the basis of 100 % w/w Assay (on dried basis) & Nil% LOD

**Quantity to be adjusted on the basis of actual of Cetirizine Hydrochloride to keep average weight constant.
*** 20% Extra to taken for process loss.
**** Loss during Processing.

1.3 Pharmaceutical Form : Tablet

Visual Description : Yellow colour, Round, Biconvex film coated tablet.

1.4 Clinical Particulars

a. Therapeutic indication

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.

b. Posology and method administration

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 in patients with renal impairment. Since cetirizine is mainly excreted via renal route (see section 5.2), in cases 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. To use this dosing table, an estimate of the patient's creatinine clearance (CL_{cr}) in ml/min is needed. The CL_{cr} (ml/min) may be estimated from serum creatinine (mg/dl) determination using the following formula:

$$CL_{cr} = \frac{[140 - age(years)]\, x\, weight\,(kg)}{72\, x\, serum\, creatinine\,(mg/dl)} (x0.85\ for\ women)$$

Dosing adjustments for adult patients with impaired renal function

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

In pediatric 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, his age and his 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).

c. Contraindication

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.

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

d. Special Warning and precautions for use

As 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.

e. Interaction with other medicinal products and other forms of interactions :

Allergy test: The use of cetirizine should be stopped 3 days prior to skin test procedures. Cetirizine may increase the effects of alcohol. Therefore caution is required when alcohol is used concomitantly. Caution is recommended when drugs with inhibiting effects on the CNS are administered concurrently with cetirizine.

f. Pregnancy and Lactation

Pregnancy Data on limited number of exposed pregnancies indicate no adverse effects of cetirizine on pregnancy or on health of 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, embryonic/foetal development,

parturition or post natal development. Caution is recommended when the drug is prescribed to pregnant women.

Lactation

The medicine passes into breast milk and can affect the breast-fed baby. Don't use Histasin during breast-feeding unless it has been prescribed for you by a doctor.

g. Undesirable effects

Common (>1/100,)

Gastrointestinal tract: Dry mouth.

Nervous system: Tiredness and sleepiness.

Uncommon (>1/1000,)

Gastrointestinal tract: Gastric discomfort and gastrointestinal disorders.

Nervous system: Headache, dizziness, restlessness.

Very rare (>1/10.000)

Immune system: allergic reactions such as cutaneous reactions and quincke's oedema.

h. Overdose and special antidotes

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.

1.5 Pharmacological Properties Clinical Particulars

a. **Pharmacodynamic Properties**

It is a metabolite of hydroxyzine, is an anti-allergic agent with a histamine H1 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 H1 receptors. Cetirizine reduces eosinophil recruitment induced by an antigenantibody reaction.

b. Pharmacokinetic properties

Peak blood levels of 300 ng/mL are reached within one hour after oral administration of cetirizine. Cetirizine does not undergo extensive first pass metabolism. The terminal half life is approximately 10 hours in adults, 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 drug. The cumulative urinary excretion represents about two thirds of the dose given in both adults and children. The apparent plasma clearance in children is higher than that measured in adults. Plasma levels are linearly related to the dosage given. A high proportion of cetirizine is bound to human plasma proteins. In patients with impaired renal clearance (less than 40 mL/min) and hepatic

insufficiency, an increase in half-life and decrease in total creatinine clearance occurs.

c. Pre clinical safety data

1.6 Pharmaceutical Particulars

a. List of Excipients

1	Colloidal Anhydrous silica BP
2	Lactose BP
3	Maize Starch BP
4	Purified water BP
5	Talc BP
6	Magnesium Stearate BP
7	Sodium Starch Glycolate BP
8	Sheffcoat Yellow (5Y00935) In-House

b. Incompatibilities
None

c. Shelf Life
24 months

Shelf life after dilution or reconstitution according to directions.
Not applicable

Shelf-life first opening the container.
Not applicable.

d. Special precaution for storage
Store below 30^0C. Protect from light.

e. Nature and content of container
PVC blister of 10 tablets. 10 such PVC blister are packed in a printed carton along with the pack insert.

1.7 Marketing Authorization Holder

Pinnacle Life Science Pvt. Ltd.
Mahendra Industrial Estate, Ground Floor
Plot no .109-D, Rd no 29
Sion (East), Mumbai 400 022, INDIA

1.8 Marketing Authorization Number :

MNB/08/729

1.9 Manufacturer Name :
Pinnacle Life Science Pvt. Ltd.
Khasra No. 1328-1330, Village Manpura, Tehsil-Baddi,
Distt. Solan, Himachal Pradesh (H.P.) - 174101, India.

1.10 Date of first authorization/ renewal of the authorization

20-13-2014

1.11 Date of the revision of the text
17.05.2022