1.3.1

Summary of Product Characteristics (SmPC)

1. Name of the medicinal Product

1.1 Name of the medicinal Product

Cetirizine Hydrochloride Syrup 5 mg/ 5 ml

1.2 Strength

Each ml contains:

Cetirizine Hydrochloride BP 5 mg

Flavoured Syrupy Base Q.S.

Colour: Sunset Yellow FCF

2. Qualitative and Quantitative Composition

2.1 Qualitative Declaration

Cetirizine Hydrochloride BP

2.2 Quantitative Declaration

Sr. No.	Ingredients Chemical Name	Specification	Standard Quantity (mg/5 ml)	Reason for Inclusion
01	Cetirizine Hydrochloride	BP	5.000	Antihistaminic (Histamine H1 Antagonist)
02	Propylene Glycol	BP	500.000	Co-solvent
03	Glycerin	BP	1000.000	Solvent
04	Methyl Hydroxybenzoate	BP	9.000	Antimicrobial preservative
05	Propyl Hydroxybenzoate	BP	1.000	Antimicrobial preservative
06	Glacial Acetic Acid	BP	0.005 ml	Buffering agent
07	Sodium Acetate (Anhydrous)	USP	8.000	Buffering agent
08	Sucrose (PG)	BP	2000.000	Syrup base, Sweetener
09	Colour Sunset Yellow Supra	IH	10.000	Colouring agent

Sr. No.	Ingredients Chemical Name	Specification	Standard Quantity (mg/5 ml)	Reason for Inclusion
10	Flavour Sweet Orange DC 25.2667	IH	0.200	Flavouring agent
11	Purified water	BP	Q.S to 5 ml	Solvent

3. Pharmaceutical Form

Solution For Liquid,

Light orange coloured clear liquid filled in bottle.

4. Clinical Particulars

4.1 Therapeutic Indications

To alleviate conditions such as urticarial rashes and nasal allergy, hay fever, rhinorrhoea, sneezing (and ocular symptom such as conjunctivitis).

4.2 Posology and Method of Administration

Cetirizine Hydrochloride syrup is generally given in dosage as directed by a Physician.

Adult and Child (over 6 years), by mouth, 10 mg or two 5 ml spoonful once daily or 5 mg or 5 ml teaspoonful twice daily. Child (2-6 years) seasonal allergic rhinitis 5 mg once one 5 ml spoonful or 2.5 mg or half 5 ml spoonful twice daily. Reduce dosage by half in renal impairment.

Dose Adjustment for Renal and Hepatic impairment: In patients 12 years of age and older with decreased renal function a dose of 5 mg once daily is recommended. Similarly, pediatric patients aged 6 to 11 years with impaired renal or hepatic function should use the lower recommended dose. Because of the difficulty in reliably administering doses of less than 2.5 mg (1/2 teaspoon) of Cetirizine hydrochloride syrup, its use in this impaired patient population is not recommended.

Dose Adjustment for Geriatric Patients: In patients 77 years of age and older, a dose of 5 mg once daily is recommended.

4.3 Contraindications

Cetirizine Hydrochloride syrup is contraindicated for patient with known Hypersensitivity to Cetirizine, hydroxyzine or any of the constituents of the formulations.

Gastric disturbance

Liver dysfunctions.

Renal impairment.

4.4 Special Warnings and Special Precautions for Use

Cetirizine Hydrochloride lacks significant sedative effects. Patients should, however, be warned that a small number of 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.

Antihistamines should be discontinued several days before allergic skin testing as they may suppress the cutaneous histamine response to allergen extracts.

Use with caution in CNS depression: May cause CNS depression, which may impair physical or mental abilities; patients must be cautioned about performing tasks which require mental alertness (e.g. , operating machinery or driving).

Hepatic Impairment: Use with caution in patients with hepatic impairment; dosage adjustment recommended.

Renal Impairment: Use with caution in patients with renal impairment; dosage adjustment recommended.

Use with caution fort he elderly patient as they may be more sensitive to adverse effect

Pregnancy And Lactation: Use in pregnancy and lactation only on doctor's advice.

4.5 Interaction with other medicinal products and other forms of interaction

Do not prescribe or use Cetirizine Hydrochloride syrup with other medicines that also cause drowsiness because they may increase the sedative effect of Cetirizine i.e. medicines like certain antidepressants, Amphetamines or alcohol.

Do not prescribe or use Cetirizine hydrochloride syrup with anticholinergic drugs as they may enhance the anticholinergic adverse/toxic effects.

Do not prescribe or use Cetirizine Hydrochloride syrup with Acetyl cholinesterase Inhibitors (Central) as Cetirizine anti-cholinergic effect may diminish the therapeutic effect of Acetyl cholinesterase.

4.6 Fertility, Pregnancy and Lactation

Pregnancy And Lactation: Use in pregnancy and lactation only on doctor's advice.

4.7 Effects on ability To Drive and use Machines

No studies on the effects on the ability to drive and use machines have been performed.

4.8 Undesirable Effects

Common Side Effects: Headache

Rare Side Effects:

Central Nervous System: Insomnia, fatigue, malaise, dizziness.

Gastrointestinal: Abdominal pain, dry mouth, diarrhea, nausea, vomiting.

4.9 Overdose

Restlessness and irritability followed by drowsiness, hallucinations, excitement, ataxia, incoordination, athetosis, and convulsions can be symptoms of overdosage. Fixed, dilated pupils with a flushed face, together with sinus tachycardia, urinary retention, dry mouth, and fever, lend the syndrome a remarkable similarity to that of atropine poisoning. Terminally, there is deepening coma with cardiorespiratory collapse and death usually within 2-18 hours. Treatment should be symptomatic and supportive. Cetirizine is not effectively removed by dialysis.

5. Pharmacological Properties

5.1 Pharmacodynamics Properties

Antihistamine (Histamine H1 antagonist)

Cetirizine Hydrochloride, a metabolite of hydroxyzine, is an anti-allergic agent with a histamine H1 receptor antagonism devoid of any significant anticholinergic and anti-serotonin effects as demonstrated in experimental and clinical pharmacology. It exhibits greater affinity for peripheral H1 -receptors than for central H1-receptors. Hence devoid of sedative effect commonly observed in anti histaminic drugs.

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 HI receptors. Cetirizine hydrochloride reduces eosinophil production stimulated by an antigen-antibody reaction.

5.2 Pharmacokinetic Properties

Cetirizine hydrochloride is rapidly absorbed from the gastro- intestinal tract after oral administration with peak plasma levels after a I 0 mg dose are approximately 300 ng/mL and occur about one

hour after dosing. Cetirizine pharmacokinetics were linear for oral doses ranging from 5 to 60 mg. Food had no effect on the extent of Cetirizine exposure (AUC) but T max was delayed by 1.7 hours and C_{max} , was decreased by 23% in the presence of food. The onset of activity occurs within 20 to 60 minutes. Cetirizine does not readily penetrate into the CNS. Plasma protein binding is about 93%.

It does not undergo extensive first pass metabolism. The terminal half life is approximately I 0 hours in adults, 6 hours in children aged 6 to 12 years and 5 hours in children aged 2 to 6 years. Plasma elimination half-life is approximately 8-9 hours. 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.

5.3 Preclinical Safety Data

Not Applicable

6 Pharmaceutical Particulars

6.1 List of Excipients

Propylene Glycol BP

Glycerin BP

Methyl Hydroxybenzoate BP

Propyl Hydroxybenzoate BP

Glacial Acetic Acid BP

Sodium Acetate (Anhydrous) USP

Sucrose (PG) BP

Colour Sunset Yellow Supra IH

Flavour Sweet Orange DC 25.2667 IH

Purified water BP

6.2 Incompatibilities

Not Applicable

6.3 Shelf Life

36 months

6.4 Special Precautions for Storage

Store below 30^0C. Protect from light.

6.5 Nature and Contents of Container

Light Orange coloured clear liquid filled in 60 ml amber PET bottle having 25 mm, plain (Silver) P.P. Cap & 10 ml measuring cup. Such one labeled bottle is packed in a printed carton with Packing Insert.

6.6 Special precaution for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

7. Registrant (Marketing Authorization Holder And Manufacturing Site Addresses)

7.1 Name and Address of Marketing Authorization Holder

GENERICS AND SPECIALITIES LTD.

31, AWONIYI ELEMO STREET,

OFF LATEEF SALAMI STREET.

AJAO ESTATE, LAGOS,

NIGERIA.

E-mail: info@zolonhealthcare.com

7.2 Name and Address of manufacturing site(s)

Lincoln Parenteral Limited

11, Trimul Estate, Khatraj, Taluka: Kalol,

District: Gandhinagar Gujarat, India.

Telephone no.: +91-02764-665000

Fax: +91-02764-281809

Email: info@lincolnpharma.com

Website: www.lincolnpharma.com

7.3 Marketing Authorization Number

To be included after obtaining first registration.

7.4 Date of First <Registration> / Renewal of The <Registration>

It will be applicable after registration of this product.

8. Date of Revision of the Text

----

9. Dosimetry (If Applicable)

Not Applicable

10. Instructions for preparation of radiopharmaceuticals (if Applicable)

Not Applicable