1.0 NAME OF THE MEDICINAL PRODUCT

1.1	**Brand Name**	**:**	Levocetirizine Dihydrochloride Syrup
1.2	**Generic Name**	**:**	Levocetirizine Dihydrochloride Syrup
1.2	**Strength**	**:**	2.5mg/5ml
1.3	**Pharmaceutical Form**	**:**	Oral liquid (syrup)

2.0 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains

Levocetirizine Dihydrochloride USP … 2.5mg

Flavored syrupy base……qs

Colour: Quinoline Yellow WS

3.0 PHARMACEUTICAL FORM

Oral liquid (syrup) **-** Yellow colored, clear, transparent, syrupy liquid.

4.0 CLINICAL PARTICULARS

4.1 Therapeutic indications

- Relief of nasal and ocular symptoms of seasonal and perennial allergic rhinitis;
- Relief of symptoms of chronic idiopathic urticaria.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION

Adults and adolescents 12 years and above:

The daily recommended dose is 5 mg i.e. 2 teaspoon full

Children aged 6 to 12 years:

The daily recommended dose is 5 mg i.e. 2 teaspoon full.

Children aged 2 to 6 years:

The daily recommended dose is 2.5 mg to be administered in 2 intakes of 1.25 mg (1/2 teaspoon twice daily).

Method of administration

Route of Administration: Oral.

The Syrup must be taken orally may be with or without food.hours before or after iron salts, zinc salts, magnesium- or aluminium-containing antacids, or didanosine (only didanosine formulations with aluminium or magnesium containing buffering agents), and sucralfate administration since reduction of absorption can occur.

4.3 CONTRAINDICATIONS

Hypersensitivity to levocetirizine, 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 levocetirizine syrup.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Do not exceed the stated dose. The use of levocetirizine is not recommended in children aged less than 2 years since the currently available syrup data do not yet allow dose adaptation. At therapeutic doses, no clinically significant interactions have been demonstrated with alcohol. Nevertheless, precaution is recommended if alcohol is taken concomitantly. Caution in epileptic patients and patients at risk of convulsions is recommended.

4.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

Due to the pharmacokinetic, pharmacodynamic and tolerance profile of levocetirizine, 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 levocetirizine is not reduced with food, although the rate of absorption is decreased.

4.6 PREGNANCY AND LACTATION

Pregnancy

Very rare clinical data on exposed pregnancies are available. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/fetal development, parturition or postnatal development.

Breastfeeding

Caution should be exercised when prescribing to pregnant or breast-feeding women because levocetirizine passes into breast milk.

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.

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. In these sensitive patients, concurrent use with alcohol or other CNS depressants may cause additional reductions in alertness and impairment of performance.

4.8 UNDESIRABLE EFFECTS

Somnolence, Dizziness, Headache, Pharyngitis, Rhinitis, Abdominal pain, Dry mouth, Nausea, Fatigue.

4.9 OVERDOSE

Symptoms

Symptoms observed after an overdose of levocetirizine 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.

There is no known specific antidote to levocetirizine.

Should overdose occur, symptomatic or supportive treatment is recommended. Gastric lavage should be considered following ingestion of a short occurrence. Levocetirizine is not effectively removed by dialysis.

5. PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Levocetirizine, the active enantiomer of cetirizine, is an anti-histamine; its principal effects are mediated via selective inhibition of H1 receptors. Levocetirizine inhibits the histamine-mediated early phase of the allergic reaction and also reduces the migration of certain inflammatory cells and the release of certain mediators associated with the late allergic response.

5.2 PHARMACOKINETIC PROPERTIES

Absorption

Levocetirizine is rapidly and extensively absorbed following oral administration. Peak plasma concentrations are achieved 0.9 h after dosing.

Distribution

No tissue distribution data are available in humans, neither concerning the passage of levocetirizine through the blood-brain-barrier. Levocetirizine is 90% bound to plasma proteins. The distribution of levocetirizine is restrictive, as the volume of distribution is 0.4 l/kg.

Metabolism

The extent of metabolism of levocetirizine in humans is less than 14% of the dose and therefore differences resulting from genetic polymorphism or concomitant intake of enzyme inhibitors are expected to be negligible. Metabolic pathways include aromatic oxidation, N- and O- dealkylation and taurine conjugation. Dealkylation pathways are primarily mediated by CYP 3A4 while aromatic oxidation involved multiple and/or unidentified CYP isoforms. Levocetirizine had no effect on the activities of CYP isoenzymes 1A2, 2C9, 2C19, 2D6, 2E1 and 3A4 at concentrations well above peak concentrations achieved following a 5 mg oral dose.

Elimination

The plasma half-life in adults is 7.9 ± 1.9 hours. The mean apparent total body clearance is 0.63 ml/min/kg. The major route of excretion of levocetirizine and metabolites is via urine, accounting for a mean of 85.4% of the dose. Excretion via feces accounts for only

12.9% of the dose. Levocetirizine is excreted both by glomerular filtration and active tubular secretion.

5.3 PRECLINICAL SAFETY DATA

Not applicable

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Name of Ingredients	Specification
Glycerine	USP
Methylparaben	USP
Propyl Paraben	USP
Saccharin Sodium	USP
Propylene Glycol	USP
Sorbitol Solution 70 %	USP
Col. Quinoline Yellow	IH
Flavour mixed fruit	IH
Glucose Liquid	USP
Sucrose	USP
Citric Acid Monohydrate	USP
Sodium Citrate	USP
Edetate Disodium	USP
Purified Water	USP

6.2 INCOMPATIBILITIES

No effect noted to date.

6.3 SHELF LIFE

24 months

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 30°C.

6.5 NATURE AND CONTENTS OF CONTAINER

30 ml Amber colour PET bottle. 1 such bottle packed in a mono carton with pack insert.

6.6 SPECIAL PRECAUTION FOR DISPOSAL

Not Applicable

7. MARKETING AUTHORIZATION HOLDER:

Name	:	UNOSOURCE PHARMA NIGERIA LIMITED
Address	:	# 47 Babapomile Street, Onipetesi Estate, Mangoro-Lagos, Nigeria.
Phone	:	002348038540440 002348129126660
E-mail	:	bennaworeogbokor@yahoo.com

NAME AND ADDRESS OF THE MANUFACTURE

Name	:	AKUMS DRUGS & PHARMACEUTICALS LTD.
Address	:	Plot No. 22, Sector 6-A, IIE, Sidcul, Ranipur, District: Haridwar, Uttarakhand.
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