# Leviva™
(Levocetirizine Dihydrochloride)

Highnoon

**COMPOSITION**
**Leviva 5mg Tablet:** Each film-coated tablet contains:
Levocetirizine Dihydrochloride 5mg
**Leviva 2.5mg/5ml Syrup:** Each 5ml Syrup contains:
Levocetirizine Dihydrochloride 2.5mg

**DESCRIPTION**
Levocetirizine dihydrochloride, is an orally active $H_1$-receptor antagonist. Levocetirizine dihydrochloride is the R enantiomer of cetirizine hydrochloride, a racemic compound with antihistaminic properties.

**MECHANISM OF ACTION**
Levocetirizine, the active enantiomer of cetirizine, is an antihistamine; its principal effects are mediated via selective inhibition of $H_1$ receptors. The antihistaminic activity of levocetirizine has been documented in a variety of animal and human models.

**PHARMACOKINETICS**
Levocetirizine is rapidly and extensively absorbed following oral administration. The peak plasma concentration occur within about an hour. Food delays the time to peak plasma concentrations but does not decrease the amount of drug absorbed. It is highly bounds to plasma proteins and has an elimination half-life of about 10 hours.it has been detected in the breast milk. It is excreted primarily in the urine.

**INDICATIONS AND USAGE**
- It is indicated for the relief of symptoms associated with perennial allergic rhinitis in children 6 months to 2 years of age.
- It is indicated for the treatment of the uncomplicated skin manifestations of chronic idiopathic urticaria in adults and children 6 months of age and older.

**DOSAGE AND ADMINISTRATION**
*It can be taken without regard to food consumption.*

**Perennial Allergic Rhinitis**
*Children 6 months to 2 Years of Age*
The recommended initial dose of Levocetirizine is half teaspoon oral solution 1.25 mg (2.5 ml) once daily in the evening. The 1.25 mg once daily dose should not be exceeded based on comparable exposure to adults receiving 5 mg.

**Chronic Idiopathic Urticaria**
***Adults and Children 12 Years of Age and Older***
The recommended dose of Levocetirizine is one tablet 5 mg or 2 teaspoons (10 ml) oral solution, once daily in the evening. Some patients may be adequately controlled by 2.5 mg (1/2 tablet) or 1 teaspoon (5 ml) oral solution once daily in the evening.

***Children 6 to 11 Years of Age***
The recommended dose of Levocetirizine is half tablet 2.5 mg or 1 teaspoon (5 ml) oral solution once daily in the evening. The 2.5 mg dose should not be exceeded because the systemic exposure with 5 mg is approximately twice that of adults.

***Children 6 Months to 5 Years of Age***
The recommended initial dose of Levocetirizine is half teaspoon 1.25 mg oral solution (2.5 ml) once daily in the evening. The 1.25 mg once daily dose should not be exceeded based on comparable exposure to adults receiving 5 mg.

***Dose Adjustment for Renal and Hepatic Impairment***
In adults and children 12 years of age and older with:
- Mild renal impairment (creatinine clearance [$CL_{CR}$] = 50-80 mL/min): a dose of 2.5 mg once daily is recommended.
- Moderate renal impairment ($CL_{CR}$ = 30-50 mL/min): a dose of 2.5 mg once every other day is recommended;
- Severe renal impairment ($CL_{CR}$ = 10-30 mL/min): a dose of 2.5 mg twice weekly (administered once every 3-4 days) is recommended;
- End-stage renal disease patients ($CL_{CR}$ <10 mL/min) and patients undergoing hemodialysis should not receive Levocetirizine.

No dose adjustment is needed in patients with solely hepatic impairment. In patients with both hepatic impairment and renal impairment, adjustment of the dose is recommended.

**CONTRAINDICATIONS**
It is contraindicated in the following:
- Patients with known hypersensitivity to levocetirizine or any of the ingredients of Leviva, or to cetirizine.
- Patients with end-stage renal disease (CLCR <10 mL/min) and patients undergoing hemodialysis.
- Children 6 months to 11 years of age with impaired renal function.
- Acute porphyria

**ADVERSE REACTIONS**
The reported adverse event of levocetirizine are; somnolence, fatigue, asthenia, urinary retention, nasopharyngitis, fatigue, dry mouth, pharyngitis, syncope, weight increased, pyrexia, epistaxis, diarrhoea, vomiting, otitis media, elevations of blood bilirubin and transaminases.
The additional reported adverse event are palpitations, tachycardia, vertigo, blurred vision, visual disturbances, nausea, edema, hepatitis, anaphylaxis & hypersensitivity, increased appetite, arthralgia, myalgia, dizziness, dysgeusia, febrile seizure, movement disorders (including dystonia and oculogyric crisis), paresthesia, seizure (reported in subjects with and without a known seizure disorder), tremor, aggression and agitation, depression, hallucinations, insomnia, nightmare, suicidal ideation, dysuria, dyspnea, angioedema, fixed drug eruption, pruritus, rash, urticaria, severe hypotension, cholestasis, extrapyramidal symptoms, myoclonus, orofacial dyskinesia, stillbirth, glomerulonephritis, acute generalized exanthematous pustulosis, constipation, drowsiness, abdominal pain, skin reactions, sleep disorders and altered taste.

**DRUG INTERACTIONS**
- Cetirizine did not interact with antipyrine, pseudoephedrine, erythromycin, azithromycin, ketoconazole, and cimetidine. There is a possibility that higher theophylline doses could have a greater effect.
- No invivo drug interactions data available with levociterizine.
- Ritonavir increased the plasma AUC of cetirizine. Ritonavir was not altered by concomitant cetirizine administration.

**WARNINGS AND PRECAUTIONS**
- The occurrence of somnolence, fatigue, and asthenia has been reported in some patients under therapy with levocetirizine. Patients should be cautioned against engaging in hazardous occupations requiring complete mental alertness, and motor coordination such as operating machinery or driving a motor vehicle after ingestion of levocetirizine. Concurrent use of levocetirizine with alcohol or other central nervous system depressants should be avoided because additional reductions in alertness and additional impairment of central nervous system performance may occur.
- Urinary retention has been reported with levocetirizine. It should be used with caution in patients with predisposing factors of urinary retention (e.g. spinal cord lesion, prostatic hyperplasia) as levocetirizine may increase the risk of urinary retention. Discontinue medicine if urinary retention occurs.

**USE IN SPECIFIC POPULATIONS**

**Pregnancy**
Available data from published literature with levocetirizine use in pregnant women are insufficient to identify any drug-associated risks of miscarriage, birth defects, or adverse maternal or fetal outcomes.

**Nursing Mothers**
There are no data on the presence of levocetirizine in human milk, the effects on the breastfed infant, or the effects on milk production. However, cetirizine has been reported to be present in human breast milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for levocetirizine and any potential adverse effects on the breastfed child from levocetirizine or from the underlying maternal condition.

**Paediatric Use**
Please see dosage and administration section.

**Geriatric Use**
Dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range reflecting the greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or other drug therapy.

**Renal Impairment**
Levocetirizine is known to be substantially excreted by the kidneys and the risk of adverse reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection and it may be useful to monitor renal function

**Hepatic Impairment**
Levocetirizine is mainly excreted unchanged by the kidneys, it is unlikely that the clearance of levocetirizine is significantly decreased in patients with solely hepatic impairment.

**OVERDOSAGE**
Symptoms of overdose may include drowsiness in adults. In children agitation and restlessness may initially occur, followed by drowsiness. There is no known specific antidote to levocetirizine. Should overdose occur, symptomatic or supportive treatment is recommended. Levocetirizine is not effectively removed by dialysis, and dialysis will be ineffective unless a dialyzable agent has been concomitantly ingested.

**DOSAGE AND INSTRUCTIONS**
To be sold and used on the prescription of a registered medical practitioner only. Keep out of reach of children. Do not store above 30°C. Keep in dry place. Protect from light.

**PRESENTATION**
**Leviva 5mg Tablets:** Alu. Alu Blister Pack of 1 x 10's.
**Leviva 2.5mg/5ml Syrup:** Glass amber bottle of 60ml.

## لیویوا™

(لیووسیٹریزین ڈائی ہائیڈروکلورائیڈ)

**خوراک و ہدایات:**
صرف مستند ڈاکٹر کے نسخہ کے مطابق ہی دوا فروخت اور استعمال کی جائے۔
بچوں کی پہنچ سے دور رکھیں۔ 30°C سے زیادہ درجہ حرارت پر نہ رکھیں۔
خشک جگہ پر رکھیں۔ روشنی سے بچائیں۔

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