Levohistam®

Levocetirizine Dihydrochloride 5 mg

Film-coated Tablets & Syrup

Company Name: Medizen Pharmaceutical Industries.

Trade Name: Levohistam®.

Generic Name: Levocetirizine dihydrochloride 5 mg.

Pharmaceutical Form: Film-coated tablets & syrup.

Composition:

Each tablet contains:

Active Ingredients: Levocetirizine 2 Hcl

5mg.

Inactive Ingredients: Lactose monohydrate, maize starch, magnesium stearate, PEG 6000, H.P.M.C and titanium dioxide.

Each (10ml syrup) contains:

Active Ingredients:

Levocetirizine 2 Hcl 5mg.

Inactive Ingredients: Sorbitol, citric acid, sucrose, methyl propyl parapen sodium, peach liquid flavor, propylene glycol, F. D & C yellow, sodium citrate and dihydrate purified water.

Pharmacological Action:

Levohistam is an anti-histaminic; its principal effects are mediated via selective blocking of H1 receptors.

Pharmacokinetics:

Absorption: Levocetirizine was rapidly absorbed following oral administration. In adults, peak plasma concentrations are achieved 0.9 hours after administration of the oral tablet. Dose of 5mg (10ml) of Levohistam syrup is bioequivalent to a 5mg dose of Levohistam tablets. Food has no effect on absorption.

Distribution: The mean plasma protein binding of levocetirizine ranged from 91% to 92%.

Metabolism: The extent of metabolism of levocetirizine in humans is less than 14%.

Elimination: The plasma half -life is about 8 to 9 hours after administration of oral tablets and syrup. The major route of excretion of levocetirizine and its metabolites is via urine, with a mean of 85.4% of the dose. Excretion via feces accounts for only 12.9% of the dose.

Indications and Usage:

Allergic Rhinitis: Levohistam is indicated for the relief of symptoms of allergic seasonal and perennial rhinitis in adults and children above 6 years.

Chronic Idiopathic Urticaria: Levohistam is indicated for the treatment of chronic idiopathic urticaria in adults and children above 6 years.

Dosage and Administration:

Adults and Children 12 Years of age and older: The recommended dose of levocetirizine is 5 mg (1

tablet or 2 teaspoons 10ml oral solution) once daily in the evening.

Children 6 to 11 Years: The recommended dose of levocetirizine is 1 teaspoonl (5ml) once daily in the evening. The dose can be divided to 1.25mg (2.5ml of syrup) twice daily.

Dose Adjustment for Renal Impairment:

- Mild renal impairment: 2.5mg once daily.
- Moderate renal impairment: 2.5mg once every other day.
- Severe renal impairment: 2.5mg twice weekly (administrated once every 3-4 days.)

Contraindications:

Levohistam is contraindicated in:

- Patients with known hypersensitivity to levocetirizine or any of the ingredients of the drug.
- Patients with end-stage renal disease and patients undergoing hemodialysis.

Adverse Reactions:

Adults and adolescents 12 years of age and older: Adverse reactions are ≥2% and may be in the form of somnolence, nasopharyngitis, fatigue, dry mouth and pharyngitis.

Uncommon: weight gain (0.5%.)

Pediatric patients 6 to 12 years of age: Adverse reactions ≥2% and may be in the form of pyrexia, cough, somnolence and epistaxis.

Drug-Drug Interactions:

In vitro data indicate that levocetirizine is unlikely to have drug interactions. Drug interaction studies have been performed with cetirizine. There was a small decrease in the clearance of ceterizin caused by theophylline. Ritonavir increased the plasma AUC of cetirizin by 42% accompanied by an increase in half-life (53%.)

Pregnancy & Lactation:

Pregnancy Category B

There are no adequate and well-controlled studies in pregnant woman regarding Levohistam. That's why it should not be used during pregnancy except if the physician recommends it and the benefit outweighs the risk.

Nursing Mothers

Cetirizin has been reported to be excreted in human milk, its use in nursing mothers is not recommended.

Pediatric Use:

The safety and effectiveness of pediatric patients under 6 years have not been established, so it is contraindicated.

Precautions and Warnings:

Patients should be cautious during activities requiring mental alertness and motor coordination such as operating machinery or driving a motor vehicle.

Concurrent use with alcohol or other central nervous system depressants should be avoided because additional reduction in mental alertness may occur.

Dose should be adjusted in elderly patients, especially those who have renal failure.

Package:

- Carton box containing 2 pvdc /aluminum strips; each strip has 10 tablets.
- Carton box containing 120 ml syrup.

Storage:

Keep out of reach and sight of children.

Store at a temperature not exceeding 30ºc in a dry place.

Instructions for Patients:

- Use tablets or syrup as directed.
- Do not increase the dose or dose frequency.

Produced by Medizen Pharmaceutical Industries