

Acitrin-L[®]

Levocetirizine Dihydrochloride

Description

Acitrin-L[®] is a preparation of Levocetirizine Dihydrochloride. Levocetirizine is the active (Levo) isomer of Cetirizine. It has an affinity for the human H₁-receptor 2-fold higher than that of Cetirizine. It is a new highly effective and well tolerated non-sedating antihistamine with potent antiallergic properties.

Indications and Uses

Acitrin-L[®] is indicated for the relief of symptoms associated with seasonal allergic rhinitis, perennial allergic rhinitis and for the treatment of the uncomplicated skin manifestations of chronic idiopathic urticaria in adults and children.

Dosage and administration

Adult & children over 6 years of age: One **Acitrin-L[®]** tablet (5 mg) once daily

Paediatric use: **Acitrin-L[®]** tablet is not recommended for use in children less than 6 years of age

Acitrin-L[®] Oral solution

Adult & children above 12 years of age: 10 ml (2 teaspoonfuls) once daily

Children 6 - 11 years of age: 5 ml (1 teaspoonful) once daily

Children 6 months - 5 years of age: 2.5 ml (1/2 teaspoonful) once daily

Note: Children below 6 months of age Levocetirizine is not recommended

Patients with renal and hepatic impairment

In patients with severe renal impairment, the dose should be 5 mg on alternate days if eGFR 30–50 mL/minute/1.73 m²; 5 mg every 3 days if eGFR 10–30 mL/minute/1.73 m² and should be avoided if eGFR less than 10 mL/minute/1.73 m². 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.

Use in pregnancy and lactation

The safety of Levocetirizine in pregnancy has not been established. Therefore, it should be used with caution during pregnancy and only if the potential benefits to the mother outweigh any risks to the foetus. Levocetirizine passes into breast milk. So it should be used with caution in nursing mothers and only if the expected benefit to the mother is greater than the risk to the nursing infant.

Side effects

Generally Levocetirizine is well tolerated. However, a few side effects like headache, dry mouth, fatigue and skin rash have been reported rarely.

Precautions

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.

Drug interactions

Levocetirizine is unlikely to produce pharmacokinetic interactions through inhibition or induction of liver drug-metabolizing enzymes and no drug-drug interaction have been reported with Levocetirizine.

Contraindications

The use of Levocetirizine is contraindicated in patients with known hypersensitivity to Levocetirizine or any of its ingredients, or to Cetirizine. Observed reactions range from urticaria to anaphylaxis. It is also contraindicated in patients with end-stage renal disease ($CL_{CR} < 10$ mL/min) and patients undergoing hemodialysis and children with impaired renal function.

Over dosage

Symptoms of overdose may include drowsiness in adults and initially agitation and restlessness, followed by drowsiness in children. There is no known specific antidote to Levocetirizine. In case of overdose occurrence, 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.

Pharmaceutical precautions

Store in a cool and dry place. Protect from light. It should be kept out of the reach of children.

Presentation

Acitrin-L[®] Tablet: Each film coated tablet contains Levocetirizine Dihydrochloride INN 5 mg

Acitrin-L[®] Oral solution: Each 5 ml contains Levocetirizine Dihydrochloride INN 2.5 mg

Package quantities

Acitrin-L[®] Tablet: Carton of 100 tablets.

Acitrin-L[®] Oral solution: Bottle of 60 ml.

® Registered Trade Mark



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