

SINACET

LEVOCETIRIZINE DIHYDROCHLORIDE INN

Compositions:

Sinacet 5 mg tablet: Each tablet contains Levocetirizine dihydrochloride INN 5 mg. Sinacet 60 ml syrup: Each 5 ml solution contains 2.5 mg Levocetirizine dihydrochloride INN.

Pharmacology:

Levocetirizine, the active enantiomer of cetirizine, is an anti-histamine; its principal effects are mediated via selective inhibition of H₁-receptors. That levocetirizine has an affinity for the human H₁-receptor 2-fold higher than that of cetirizine.

Indications:

Allergic rhinitis: Levocetirizine is indicated for the relief of symptoms associated with allergic rhinitis (seasonal and perennial) in adults and children 6 years of age and older. Chronic idiopathic urticaria: Levocetirizine is indicated for the treatment of the uncomplicated skin manifestations of chronic idiopathic urticaria in adults and children 6 years of age and older.

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 [10 ml] oral solution) once daily in the evening. Children 6 to 11 years of age: The recommended dose of levocetirizine is 2.5 mg (1/2 tablet or 1 teaspoon [5 ml] oral solution) once daily in the evening.

Contraindications:

Levocetirizine is contraindicated in patients with a history of hypersensitivity of levocetirizine to any of the components in this medication

Warning And Precaution:

Epileptic patients and patients at risk of convulsions. Renal impairment Pregnancy and lactation

Side Effects:

Somnolence, fatigue, and asthenia, drowsiness, tiredness, dry mouth, even fever and cough, nasopharyngitis, epistaxis.

Use in Pregnancy and Lactation:

Pregnancy category B. Levocetirizine should be used during pregnancy only if clearly needed. No peri- and post-natal animal studies have been conducted with levocetirizine. Cetirizine has been reported to be excreted in human breast milk. Because levocetirizine is also expected to be excreted in human milk, use of levocetirizine in nursing mothers is not recommended.

Drug Interaction:

Antipyrine, azithromycin, cimetidine, erythromycin, ketoconazole, theophylline, and pseudoephedrine, ritonavir.

Overdosage:

No clinically relevant adverse events have been reported in case of overdose. However in the event of overdosage, symptomatic and supportive treatment is recommended.

Storage:

Store Sinacet tablet and syrup at room temperature.

Packing:

Sinacet 5 mg tablet: Each box contains 100 film coated tablets in blister pack. Sinacet 60ml syrup: Each bottle contains 60 ml syrup.

Manufactured By:

The IBN SINA Pharmaceutical Industry PLC.

Shafipur, Gazipur, Bangladesh.