

LEZYNCET SYRUP

To be sold by retail on prescription of R.M.P only

Abbreviated Prescribing information for LEZYNCET SYRUP (Levocetirizine Dihydrochloride Syrup)

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Levocetirizine, the (R) enantiomer of cetirizine, is a potent and selective antagonist of peripheral histamine (H₁)-receptors. H₁ receptors are activated by the biogenic amine histamine. Levocetirizine prevent binding of histamine to this receptors and this in turn prevent relief from the typical symptoms of allergic rhinitis.

DOSAGE AND ADMINISTRATION:

Children aged 6 to 12 years:

The daily recommended dose is 5 mg (10 ml of solution).

Children aged 2 to 6 years:

The daily recommended dose is 2.5 mg to be administered in 2 intakes of 1.25 mg (2.5 ml of solution twice daily). Even if some clinical data are available in children aged 6 months to 12 years, these data are not sufficient to support the administration of levocetirizine to infants and toddlers aged less than 2 years.

Adults and adolescents 12 years and above:

The daily recommended dose is 5 mg (10 ml of solution).

CONTRAINDICATION: Known hypersensitivity to Levocetirizine or to any of the excipients. Severe renal impairment at less than 10 ml/min creatinine clearance.

WARNINGS & PRECAUTIONS: Concurrent intake of alcohol, urinary retention, and epilepsy.

DRUG INTERACTION: No interaction studies have been performed with levocetirizine (including no studies with CYP3A4 inducers); studies with the racemate compound cetirizine demonstrated that there were no clinically relevant adverse interactions (with antipyrine, azithromycin, cimetidine, diazepam, erythromycin, glipizide, ketoconazole and pseudoephedrine).

ADVERSE REACTIONS: Headache, somnolence, mouth dry, fatigue, asthenia, abdominal pain, constipation, hypersensitivity including anaphylaxis, aggression, agitation, hallucination, depression, insomnia, suicidal ideation, nightmare, convulsion, paraesthesia, dizziness, syncope, tremor, dysgeusia, dysuria, urinary retention, abnormal liver function tests.

MARKETED BY:

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IN/LEZYNCET SYRUP 2.5 mg/Apr-20/01/ABPI

(Additional information is available on request)