LEZYNCET

For the use of a Registered Medical Practitioner or Hospital or a Laboratory only.

Abbreviated Prescribing information for LEZYNCET (Levocetirizine Tablets I.P.**)**

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

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: Levocetirizine, the (R) enantiomer of cetirizine, is a potent and selective antagonist of peripheral H1-receptors. Binding studies revealed that levocetirizine has high affinity for human H1-receptors (Ki = 3.2 nmol/l). Levocetirizine has an affinity 2-fold higher than that of cetirizine (Ki = 6.3 nmol/l). Levocetirizine dissociates from H1-receptors with a half-life of 115 ± 38 min. After single administration, levocetirizine shows a receptor occupancy of 90% at 4 hours and 57% at 24 hours. Pharmacodynamic studies in healthy volunteers demonstrate that, at half the dose, levocetirizine has comparable activity to cetirizine, both in the skin and in the nose.

DOSAGE AND ADMINISTRATION: One tablet once daily or as directed by physician.

CONTRAINDICATION: Hypersensitivity to the active substance, to cetirizine, to hydroxyzine, to any other piperazine derivatives or to any of the other excipients. Severe renal impairment at less than 10 ml/min creatinine clearance.

WARNINGS & PRECAUTIONS: Precaution is recommended with concurrent intake of alcohol. Caution should be taken in patients with predisposing factors of urinary retention (e.g. spinal cord lesion, prostatic hyperplasia) as levocetirizine may increase the risk of urinary retention, in patients with epilepsy and patients at risk of convulsion as levocetirizine may cause seizure aggravation. Response to allergy skin tests are inhibited by antihistamines and a wash-out period (of 3 days) is required before performing them. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. Pruritus may occur when levocetirizine is stopped even if those symptoms were not present before treatment initiation.

DRUG INTERACTION: A small decrease in the clearance of cetirizine (16%) was observed in a multiple dose study with theophylline (400 mg once a day); while the disposition of theophylline was not altered by concomitant cetirizine administration. In a multiple dose study of ritonavir (600 mg twice daily) and cetirizine (10 mg daily), the extent of exposure to cetirizine was increased by about 40% while the disposition of ritonavir was slightly altered (-11%) further to concomitant cetirizine administration. The extent of absorption of levocetirizine is not reduced with food, although the rate of absorption is decreased. In sensitive patients the concurrent administration of cetirizine or levocetirizine and alcohol or other CNS depressants may cause additional reductions in alertness and impairment of performance.

ADVERSE REACTIONS: Headache, Somnolence, Mouth dry, Fatigue, asthenia or abdominal pain, nausea, diarrhoea, vomiting, constipation, sleep disorder, hypersensitivity including anaphylaxis, increased appetite, aggression, agitation, hallucination, depression, insomnia, suicidal ideation, nightmare, convulsion, paraesthesia, dizziness, syncope, tremor, dysgeusia, vertigo, visual disturbances, blurred vision, oculogyration, palpitations, tachycardia, dyspnoea, hepatitis, dysuria, urinary retention, angioneurotic oedema, fixed drug eruption, pruritus, rash, urticarial, myalgia, arthralgia, oedema, weight increased, abnormal liver function tests.

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IN/LEZYNCET 5 mg/FEB-21/01/ABPI
(Additional information is available on request)