UVNIL 5

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for UVNIL 5 [Levocetirizine Dihydrochloride Tablets I.P. 5 mg]
[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.

INDICATIONS: UVNIL 5 is indicated For the treatment of allergic rhinitis & chronic urticaria in adults.

DOSAGE AND ADMINISTRATION: The film-coated tablet must be taken orally, swallowed whole with liquid and may be taken with or without food. It is recommended to take the daily dose in one single intake. Duration of use: Intermittent allergic rhinitis (symptoms experienced for less than four days a week or for less than four weeks a year) has to be treated according to the disease and its history; it can be stopped once the symptoms have disappeared and can be restarted when symptoms reappear. In case of persistent allergic rhinitis (symptoms experienced for more than four days a week or for more than four weeks a year), continuous therapy can be proposed to the patient during the period of exposure to allergens**.**

CONTRAINDICATION: Hypersensitivity to levocetirizine, to cetirizine, to any of the other excipients. Patients with end stage renal disease with estimated Glomerular Filtration Rate (eGFR) below 15 ml/min (requiring dialysis treatment).

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. Caution should be taken 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. Pruritus may occur when levocetirizine is stopped even if those symptoms were not present before treatment initiation. The symptoms may resolve spontaneously. In some cases, the symptoms may be intense and may require treatment to be restarted. The symptoms should resolve when the treatment is restarted. Levocetirizine contains lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose- galactose malabsorption should not take levocetirizine film-coated tablets Paediatric population The use of film-coated tablets is not recommended in children aged less than 6 years since this formulation does not yet allow for appropriate dose adaptation. It is recommended to use a paediatric formulation of levocetirizine

DRUG INTERACTIONS: 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). 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: Hypersensitivity including anaphylaxis, increased appetite, aggression, agitation, hallucination, depression, insomnia, suicidal ideation, nightmare, convulsion, paraesthesia, dizziness, syncope, tremor, dysgeusia, vertigo, visual disturbance, blurred vision, oculogyration, palpitation, tachycardia, dyspnoea, nausea, vomiting, diarrhea, hepatitis, dysuria, urinary retention, Angioneurotic oedema, fixed drug eruption, pruritus, rash, urticaria, myalgia, arthralgia, oedema, weight increased abnormal liver function tests**.**

MARKETED BY:

TORRENT PHARMA

Torrent Pharmaceuticals Limited.

IN/UVNIL 5mg/MAR 2026/02/ABPI

(Additional information is available on request)