UVNIL® Syrup

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

Abbreviated Prescribing information for UVNIL® Syrup [Levocetirizine Dihydrochloride 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 histamine (H1)-receptors. H1 receptors are activated by the biogenic amine histamine. Levocetirizine prevent binding of histamine to these receptors and this in turn prevent relief from the typical symptoms of allergic rhinitis.

INDICATIONS: For the Treatment of Allergic Rhinitis and Chronic Urticaria in Children aged 2 years and above.

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). *Adults and adolescents 12 years and above:* The daily recommended dose is 5 mg (10 ml of solution). *Elderly:* Adjustment of the dose is recommended in elderly patients with moderate to severe renal impairment. **Method of administration:** Shake well before use. The appropriate volume of syrup should be measured with dosing cup and poured in a spoon or in a glass of water. The oral syrup must be taken orally immediately after dilution and may be taken with or without food.

CONTRAINDICATION: Hypersensitivity to the active substance, 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, epilepsy and patients at risk of convulsion as levocetirizine may cause seizure aggravation. Pruritus may occur when levocetirizine is stopped even if those symptoms were not present before treatment initiation.

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 Disturbances, Blurred Vision, Oculogyration, Palpitations, Tachycardia, Dyspnea, Nausea, Vomiting, Diarrhoea, Hepatitis, Dysuria, Urinary Retention, Angioneurotic Oedema, Fixed Drug Eruption, Pruritus, Rash, Urticaria, Myalgia, Arthralgia, Oedema, Weight Increased, Abnormal Liver Function Tests.

MARKETED BY:

Torrent Pharmaceuticals Limited.

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IN/ UVNIL SYRUP 2.5mg/FEB 2025/01/ABPI

(Additional information is available on request)