

## LEZYNCET-M

**For the use of a Registered Medical Practitioner or Hospital or a Laboratory only**  
Abbreviated Prescribing information for **LEZYNCET-M** (Levocetirizine Dihydrochloride and Montelukast Tablet)

[Please refer the complete prescribing information available at [www.torrentpharma.com](http://www.torrentpharma.com)]

**PHARMACOLOGICAL PROPERTIES:** Levocetirizine, the (R) enantiomer of cetirizine, is a potent and selective antagonist of peripheral histamine (H<sub>1</sub>)-receptors. H<sub>1</sub> 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. Montelukast is the leukotriene receptor antagonist. The cysteinyl leukotrienes are potent inflammatory eicosanoids released from various cells including mast cells and eosinophils

### **DOSAGE AND ADMINISTRATION:**

#### **Children aged 15 years and above and adults**

The daily recommended dose is one film-coated tablet.

#### **Elderly**

Adjustment of the dose is recommended in elderly patients with moderate to severe renal impairment.

#### **Renal impairment**

The dosing intervals must be individualised according to renal function. In paediatric patients suffering from renal impairment, the dose will have to be adjusted on an individual basis taking into account the renal clearance of the patient and his body weight. There are no specific data for children with renal impairment.

#### **Hepatic impairment**

No dose adjustment is needed in patients with solely hepatic impairment. In patients with hepatic impairment and renal impairment, adjustment of the dose is recommended

**CONTRAINDICATION:** Known hypersensitivity to levocetirizine, montelukast 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, epilepsy, and neuropsychiatric events.

**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). Caution should be exercised when Montelukast is co-administered with inducers of CYP 3A4, 2C8, and 2C9, such as phenytoin, phenobarbital and rifampicin.

**ADVERSE REACTIONS:** Headache, somnolence, mouth dry, fatigue, asthenia, abdominal pain, constipation, diarrhoea, hypersensitivity including anaphylaxis, aggression, agitation, hallucination, depression, insomnia, suicidal ideation, nightmare, convulsion, paraesthesia, dizziness, syncope, tremor, dysgeusia, pyrexia, rash, elevated levels of serum transaminases, upper respiratory infection, Churg-Strauss Syndrome, pulmonary eosinophilia.

#### **MARKETED BY:**

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**IN/LEZYNCET-M 5, 10 mg/Apr-20/01/ABPI**  
(Additional information is available on request)