## COMPOSITION :

**MONLATE- LC JUNIOR:**
Each uncoated dispersible tablet contains:
Montelukast Sodium IP
Equivalent to Montelukast……. 5 mg
Levocetirizine Dihydrochloride IP……..2.5 mg
Excipients……..q.s.
Colour: Titanium Dioxide I.P.
Monlate- lc ff

**MONLATE- LC :**

Each film coated tablet contains:
Montelukast Sodium IP
Equivalent to Montelukast……. 10 mg
Levocetirizine Dihydrochloride IP……. 5 mg
Excipients……..q.s.
Colour : Titanium Dioxide I.P.

## DESCRIPTION :

MONLATE- LC/ MONLATE-LC Junior Tablets is a combination of Montelukast Sodium & Levocetirizine Dihydrochloride. Montelukast sodium is an orally active compound that binds with high affinity and selectivity to the CysLT1 receptor. Montelukast inhibits physiologic actions of LTD 4 at the CysLT1 receptor without any agonist activity. It therefore acts as a leukotriene receptor antagonist Levocetirizine, the R-enantiomer of cetirizine, is a potent and selective antagonist of peripheral H1-receptors. It has been demonstrated by recent studies that the treatment of AR with concomitant administration of an antileukotriene (montelukast) and an antihistamine (levocetirizine), shows significantly better symptom relief compared with the modest improvement of rhinitis symptomatology with each of the treatments alone.

## PHARMACOLOGY :

As MONLATE- LC is a combination of Montelukast and Levocetirizine, the pharmacological properties of both the molecules are given separately.

## Pharmacodynamics :

**Montelukast:**
The cysteinyl leukotrienes (LTC4, LTD4, LTE4) are potent inflammatory eicosanoids released from various cells including mast cells and eosinophils. These important pro-asthmatic mediators bind to cysteinyl leukotriene (CysLT) receptors. The CysLT type-1 (CysLT1) receptor is found in the human airway (including airway smooth muscle cells and airway macrophages) and on other pro-inflammatory cells (including eosinophils and certain myeloid stem cells). CysLTs have been correlated with the pathophysiology of asthma and allergic rhinitis.

In allergic rhinitis, CysLTs are released from the nasal mucosa after allergen exposure during both early- and late-phase reactions and are associated with symptoms of allergic rhinitis. Intranasal challenge with CysLTs has been shown to increase nasal airway resistance and symptoms of nasal obstruction.

Montelukast is an orally active compound that binds with high affinity and selectivity to the CysLT1 receptor. Montelukast inhibits physiologic actions of LTD4 at the CysLT1 receptor without any agonist activity.

**Levocetirizine:**
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 receptor occupancy of 90% at 4 hours and 57% at 24 hours. The onset of action of levocetirizine 5 mg in controlling pollen-induced symptoms has been observed at 1 hour post drug intake in placebo controlled trials in the model of the allergen challenge chamber.

In vitro studies (Boyden chambers and cell layers techniques) show that levocetirizine inhibits eotaxin-induced eosinophil transendothelial migration through both dermal and lung cells. A pharmacodynamic experimental study in vivo (skin chamber technique) showed three main inhibitory effects of levocetirizine 5 mg in the first 6 hours of pollen-induced reaction, compared with placebo in 14 adult patients: Inhibition of VCAM-1 release, modulation of vascular permeability, and a decrease in eosinophil recruitment.

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.

Pharmacokinetic/pharmacodynamic relationship 5 mg levocetirizine provide a similar pattern of inhibition of histamine-induced wheal and flare than 10 mg cetirizine. As for cetirizine, the action on histamine-induced skin reactions was out of phase with the plasma concentrations. ECGs did not show relevant effects of levocetirizine on QT interval.