



# **MONTEGRESS**

Montelukast 4 mg / 5 mg Mouth dissolving tablet and 10 mg tablet

# **MONTEGRESS-LC-4/10**

Montelukast 4 mg and Levocetirizine 2.5 mg dispersible Tablet Montelukast 10 mg and Levocetirizine 5 mg Tablet

# **MONTEGRESS-FX-120**

Montelukast 10 mg and Fexofenadine 120 mg Tablet

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## **MONTEGRESS-FX-120**

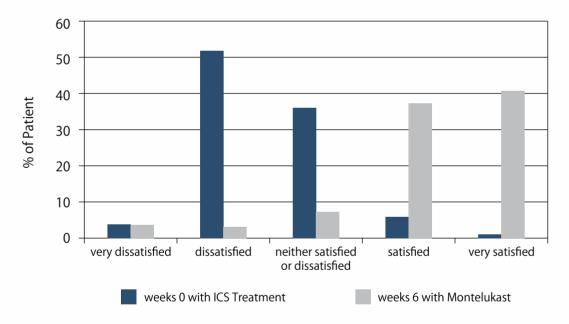
Montelukast 10 mg and Fexofenadine 120 mg Tablet



### **Clinical Studies**

1. Montelukast is an effective and well-tolerated alternative to ICS treatment in patients with mild asthma who are uncontrolled or unsatisfied with low-dose ICS therapy.

Graph - Investigator global satisfaction with inhaled corticosteroids (ICS) and Montelukast Treatment

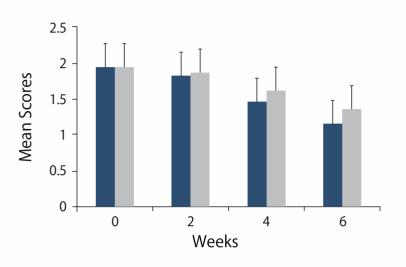


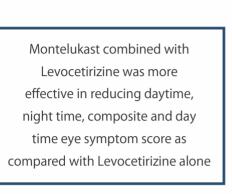
Patients	Therapy	Uncontrolled Asthma Symptoms	Patient Compliance	Physician Satisfaction	Patient Satisfaction
534 Patients with mild to Persistent Asthma who remain uncontrolled while on Inhaled Corticosteroids ( ICS ) monotherapy	Montelukast 5 mg Tablets ( 6 to 14 years of Patients ) and Montelukast 10 mg Tablets ( 15 years and older patients ) once a day for six weeks	Significantly decreased (P=0.001)	Significantly increased (P=0.001)	Significantly increased ( P=0.001 )	Significantly increased (P=0.001)

### 2. Efficacy of Montelukast and Levocetirizine as Treatment for Allergic Rhinitis

102 Patients with Allergic Rhinitis has been treated with Montelukast 10mg and Levocetirizine 5mg once daily at bed time for six week

Graph - Mean Night time Nasal Symptom Score





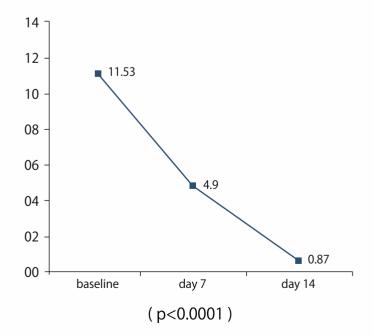
Control Group

**Treatment Group** 

\*p<0.5 as compared to control group comparison of scores within group was done by Mann Whitney U test comparison of scores between group was done by Wikoxon Sign Rank test

### 3. Efficacy and Safety of Montelukast Plus Fexofenadine Fixed Dose Combination in Allergic Rhinitis

Graph - Reduction in total symptom score (TSS)



- Total 809 patients of Allergic rhinitis treated with Montelukast 10mg and Fexofenadine 120mg tablet once a day for 14 days
- Fixed dose combination of Montelukast with fexofenadine was significantly efficacious in reducing total Symptom score, Total nasal symptom score and Total ocular symptom score

References:

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## **MONTEGRESS-FX-120**

Montelukast 10 mg and Fexofenadine 120 mg Tablet

### INDICATIONS AND USAGE

Asthma | Exercise-Induced Bronchoconstriction (EIB) Allergic Rhinitis | COPD (Chronic Obstructive Pulmonary Disorder)



### MECHANISM OF ACTION

Montelukast is an orally active compound that inhibits physiologic actions of LTD4 at the CysLT1 receptor without any agonist activity. Levocetirizine and Fexofenadine: an orally active potent, selective and long acting H1-Histamine receptor antagonist with no anticholinergic activity.

#### DOSAGE AND ADMINISTRATION

Patients	Asthma , Allergic Rhinitis and COPD		
Adults and adolescents 15 years of age and older	Montegress-10 once a day Montegress-LC-10 once a day Montegress-FX-120 once a day		
Pediatric patients 6 to 14 years of age	Montegress-5 MD tablet once a day		
Pediatric patients 2 to 5 years of age	Montegress-4 once a day Montegress-LC- 4 once a day		

### DOSAGE FORMS AND STRENGTHS

MONTEGRESS-10: Montelukast 10 mg Film coated tablet MONTEGRESS-5: Montelukast 5 mg Mouth dissolving tablet MONTEGRESS-4: Montelukast 4 mg Mouth dissolving tablet

MONTEGRESS-LC-10: Montelukast 10 mg and Levocetirizine 5 mg Film coated tablet MONTEGRESS-LC-4: Montelukast 4 mg and Levocetirizine 2.5 mg Dispersible tablet MONTEGRESS-FX-120: Montelukast 10 mg and Fexofenadine 120 mg Film coated tablet

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