

Information For the User  
Ebastine (10mg) + Montelukast (10mg)

# Ebatyle M Tablet

## Ebastine (10 mg) + Montelukast (10 mg) Tablet

### Composition:

#### Each tablet contains:

- **Ebastine: 10 mg**
- **Montelukast: 10 mg**

### Pharmacological Class:

- **Ebastine: Antihistamine (Second-Generation H1-Receptor Antagonist)**
- **Montelukast: Leukotriene Receptor Antagonist**

### Indications:

This combination is indicated for the management of respiratory and allergic conditions, including:

- **Seasonal Allergic Rhinitis (Hay fever)**
- **Perennial Allergic Rhinitis**
- **Allergic Asthma**
- **Chronic Idiopathic Urticaria (hives)**
- **Other allergic conditions with airway inflammation and histamine-mediated symptoms**

### Mechanism of Action:

- **Ebastine: Blocks H1-histamine receptors, preventing histamine's effects, which cause symptoms such as sneezing, itching, and nasal congestion.**
- **Montelukast: Inhibits leukotrienes, inflammatory mediators involved in allergic reactions, reducing bronchoconstriction, mucus production, and inflammation in the airways.**  
The combination offers dual-action relief from both histamine- and leukotriene-mediated allergic responses.

### Dosage and Administration:

- **Adults and children above 15 years: 1 tablet once daily in the evening.**
- **Children (6–14 years): Consult a healthcare provider for appropriate dosage.**

- **The tablet can be taken with or without food. Swallow with water without crushing or chewing.**

### Contraindications:

- **Hypersensitivity to Ebastine, Montelukast, or any ingredients in the formulation.**
- **Severe liver impairment.**

### Warnings and Precautions:

- **Acute Asthma Attacks: This combination is not suitable for treating acute asthma attacks. Patients should have a rescue inhaler for emergency use.**
- **Liver Impairment: Use with caution in patients with liver dysfunction; monitoring is recommended.**
- **Mental Health Effects: Montelukast may be associated with neuropsychiatric events such as mood changes, agitation, or depression. Monitor patients closely.**
- **Pregnancy and Breastfeeding:**
  - **Pregnancy Category B: Use only if clearly needed and under medical supervision.**
  - **Breastfeeding: Limited data; consult a healthcare provider before use.**
- **Cardiac Precautions: Rarely, Ebastine may prolong the QT interval; use cautiously in patients with a history of arrhythmias.**

### Side Effects:

#### Common side effects:

- **Headache**
- **Dizziness**
- **Dry mouth**
- **Fatigue**
- **Nausea**

#### Less common but serious side effects:

- **Allergic reactions (rash, swelling, difficulty breathing)**
- **Neuropsychiatric events (mood swings, depression, anxiety)**

- **QT interval prolongation (rare)**

#### **Drug Interactions:**

- **Macrolide antibiotics (e.g., erythromycin) andazole antifungals (e.g., ketoconazole): May increase the risk of QT prolongation when used with Ebastine.**
- **CYP3A4 inhibitors (e.g., ritonavir): Can elevate Ebastine levels.**
- **Antiepileptic Drugs (e.g., phenytoin, phenobarbital): May reduce the effectiveness of Montelukast.**
- **NSAIDs: Can exacerbate asthma in sensitive individuals; caution is advised.**

#### **Storage:**

- **Store below 25°C in a dry place, away from light and moisture.**
- **Keep out of reach of children.**

#### **Packaging:**

**Available in blister packs containing 10 or 20 tablets.**

#### **Manufacturer:**

- **[Manufacturer Name]**

#### **Note:**

**This medication should be taken as directed by a healthcare provider. If symptoms worsen or unusual side effects occur, seek medical attention immediately. Avoid alcohol and tasks requiring alertness (e.g., driving) if dizziness occurs.**

Manufactured in India for:

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L I F E C A R E

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