

Bilastuff M Suspension

Bilastine (10mg/5ml) + Montelukast (4mg/5ml) Suspension: Product Information

Brand Name: Bilastine 10 mg + Montelukast 4 mg
Suspension

Generic Name: Bilastine and Montelukast

Strength:

- **Bilastine:** 10 mg per 5 mL
 - **Montelukast:** 4 mg per 5 mL
- Dosage Form:** Oral Suspension

Indications:

This combination suspension is used to manage symptoms of allergic conditions in children, including:

1. **Allergic Rhinitis:**
 - For the treatment of **seasonal and perennial allergic rhinitis**, it helps alleviate symptoms such as **sneezing, itchy or watery eyes, runny nose, and nasal congestion**.
2. **Chronic Urticaria (Hives):**
 - For the relief of **itching and skin rashes** associated with **chronic idiopathic urticaria** (chronic hives), a condition that causes skin rashes without a known cause.
3. **Asthma (in children):**
 - **Montelukast**, a leukotriene receptor antagonist, helps prevent asthma attacks and manage chronic asthma by reducing inflammation and constriction in the airways.
 - **Bilastine** helps reduce the allergic responses that can trigger asthma symptoms.

Mechanism of Action:

- **Bilastine** is a **second-generation antihistamine** that selectively blocks **H1 receptors**, which are involved in allergic reactions. By preventing histamine from binding to these receptors, Bilastine helps reduce allergic symptoms such as

itching, swelling, and increased mucus production with minimal sedation.

- **Montelukast** is a **leukotriene receptor antagonist** that works by blocking the action of **leukotrienes**, chemicals in the body that contribute to inflammation and constriction of the airways, thus helping prevent asthma attacks and reducing symptoms of allergic rhinitis and asthma.

Dosage and Administration:

For Children (6 months to 5 years):

- **Recommended Dose:**
 - **Bilastine 10 mg + Montelukast 4 mg Suspension: 5 mL (containing 10 mg Bilastine and 4 mg Montelukast)** once daily, preferably in the evening, for optimal symptom control.
- The suspension should be **taken orally**, either **with or without food**.
- **Shake the bottle well** before each use to ensure the proper dose is taken.

Contraindications:

This combination suspension should not be used if:

- The patient is **hypersensitive to Bilastine, Montelukast**, or any of the excipients of the suspension.
- The patient has **severe hepatic (liver) impairment**.

Warnings and Precautions:

- **Sedation and Drowsiness:** Although **Bilastine** is a non-sedating antihistamine, some children may experience mild drowsiness. It is important to monitor for any drowsiness or sedation.
- **Liver Function:** Since **Montelukast** and **Bilastine** are metabolized by the liver, caution is

advised in patients with **liver disease**. The dosage may need to be adjusted based on the severity of the liver condition.

- **Asthma Patients:** If the child has **asthma**, it is important to note that **Montelukast** helps control asthma symptoms, but it should not be used as a **primary treatment for acute asthma attacks**. Immediate medical attention is needed in case of an asthma attack.
- **Mood or Behavioral Changes:** Montelukast has been associated with **mood changes**, including irritability, aggression, or anxiety in some children. These effects should be monitored closely, and if any signs of behavioral changes occur, discontinuation of the medication should be considered.

Side Effects:

Common side effects:

- **Headache.**
- **Gastrointestinal discomfort** such as **nausea**, **vomiting**, or **stomach pain**.
- **Drowsiness** or **fatigue** (especially with Bilastine).
- **Mild respiratory symptoms**, such as a sore throat or cough.

Serious but rare side effects:

- **Severe allergic reactions:** Swelling of the face, lips, tongue, or throat, difficulty breathing, or severe rash. Seek medical help immediately if these occur.
- **Liver-related side effects:** Yellowing of the skin or eyes (jaundice), dark urine, or severe stomach pain. Contact a doctor immediately if these symptoms develop.

Drug Interactions:

- **Erythromycin** or **Ketoconazole:** These medications may increase the concentration of **Bilastine** in the blood. If these drugs are taken together, the healthcare provider may monitor the patient more closely or adjust the dosage.
- **Corticosteroids** or **other leukotriene modifiers:** Avoid combining with other leukotriene inhibitors or corticosteroids unless advised by a healthcare provider.
- **Rifampicin:** This antibiotic may reduce the levels of **Montelukast** in the body, which could

make the drug less effective. Consult your healthcare provider before combining these medications.

- **Antacids:** Antacids containing **aluminum or magnesium** can reduce the absorption of **Bilastine**, so it is best to take them at least **2 hours apart**.

Storage:

- Store the **suspension** at **room temperature** (15°C to 30°C / 59°F to 86°F), and protect it from light.
- Once opened, use the suspension within **30 days**.
- Keep the bottle tightly closed and out of reach of children.

Patient Counseling Information:

- **Take as directed:** Ensure the correct dose is given as prescribed. Do not exceed the recommended dose.
- **Monitor for side effects:** Watch for any mood changes or behavior changes in children. Inform the healthcare provider if any concerning symptoms arise.
- **Shake before use:** Always shake the bottle well to ensure the proper dose of the medication.

This information for **Bilastine (10 mg) + Montelukast (4 mg) Suspension** is intended to provide an overview of the product's uses, dosages, precautions, and side effects. Always consult your healthcare provider before starting treatment to ensure that this medication is appropriate for your child.

Manufactured in India for:

CafoliTM
L I F E C A R E

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(An ISO 9001: 2015 Certified Co.)

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