

Information For the Use  
Montelukast (4mg/5ml) + Fexofenadine (60mg/5ml)

# Monclip FX Suspension

**Montelukast (4 mg/5 ml) + Fexofenadine (60 mg/5 ml) Suspension**

## Description:

This suspension combines Montelukast, a leukotriene receptor antagonist, and Fexofenadine, a second-generation antihistamine. It is used to manage symptoms of allergic rhinitis, hay fever, and asthma by reducing inflammation and controlling allergic responses.

## Composition (Each 5 ml Contains):

- Montelukast Sodium equivalent to Montelukast: 4 mg
- Fexofenadine Hydrochloride: 60 mg
- Excipients: q.s.

## Indications:

- Allergic rhinitis (seasonal and perennial)
- Hay fever
- Adjunct therapy for asthma and prevention of exercise-induced bronchoconstriction
- Relief of symptoms such as sneezing, runny nose, nasal congestion, itchy eyes, and throat

## Dosage and Administration:

### Recommended Dosage:

- Children (6 months to 5 years):
  - As prescribed by the physician, typically 5 ml once daily in the evening.
- Adults and Children >5 years:
  - Dosage adjustment may be needed for individual cases.

## Route of Administration:

- Oral. Shake well before use. Administer using the provided measuring device.

## Contraindications:

- Hypersensitivity to Montelukast, Fexofenadine, or any component of the formulation.
- Severe renal or hepatic impairment (use with caution or avoid).

## Warnings and Precautions:

1. Neuropsychiatric Events:
  - Montelukast may rarely cause agitation, anxiety, depression, or suicidal thoughts; monitor behavior changes.
2. Renal and Hepatic Impairment:
  - Fexofenadine is excreted renally; dose adjustments may be required.
3. Concurrent Antihistamine Use:
  - Avoid combining with other antihistamines to prevent excessive sedation or side effects.
4. Asthma Control:
  - Not for acute asthma attacks; continue other prescribed rescue medications as needed.

## Side Effects:

- Common Side Effects:
  - Headache
  - Drowsiness or dizziness
  - Nausea
  - Abdominal pain
  - Dry mouth
- Serious Side Effects:

- Allergic reactions (rash, swelling, or difficulty breathing)
- Neuropsychiatric symptoms (associated with Montelukast)
- Severe drowsiness or tachycardia (rare with Fexofenadine)

**recommended dosage. Regular follow-ups may be necessary to monitor efficacy and safety.**

Manufactured in India for:



**Cafoli Lifecare Pvt. Ltd.**

**(An ISO 9001: 2015 Certified Co.)**

Plot no.: 367-FF, Industrial Area Phase-I,  
Panchkula-134113

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### **Drug Interactions:**

- **Antacids:**
  - Avoid concurrent use with magnesium- or aluminum-containing antacids as they may reduce Fexofenadine absorption.
- **CYP450 Inducers:**
  - Drugs like rifampin may reduce Montelukast levels.
- **Erythromycin and Ketoconazole:**
  - May increase Fexofenadine levels without clinical relevance.

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### **Use in Specific Populations:**

- **Pregnancy:** Use only if clearly needed and prescribed by a physician.
- **Lactation:** Not recommended; consult a healthcare provider.
- **Pediatrics:** Safe for children under appropriate supervision; adjust dosage as per age group.
- **Geriatrics:** Monitor for renal function and side effects; no specific dose adjustment required.

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### **Storage Instructions:**

- Store at a temperature of 15°C to 30°C (59°F to 86°F).
- Protect from light and moisture.
- Keep out of reach of children.

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### **Note:**

**This is a prescription-only medication. Use under medical supervision and follow the**