

Information For the User
Doxofylline (400mg) + Montelukast (10mg)

Dozyfyle M Tablet

Doxofylline (400 mg) + Montelukast (10 mg) Tablet

Composition: Each tablet contains:

- Doxofylline: 400 mg
- Montelukast: 10 mg

Pharmacological Class:

- Doxofylline: Bronchodilator (Xanthine Derivative)
- Montelukast: Leukotriene Receptor Antagonist

Indications: This combination is indicated for the management of respiratory conditions, particularly those involving airway inflammation and bronchoconstriction, such as:

- Chronic Obstructive Pulmonary Disease (COPD)
- Bronchial Asthma (including prevention of exercise-induced bronchoconstriction)
- Allergic Rhinitis
- Chronic bronchitis and other conditions with symptoms of airway inflammation

Mechanism of Action:

- Doxofylline is a bronchodilator that works by relaxing the smooth muscles in the airways, inhibiting phosphodiesterase enzymes, and increasing cyclic AMP levels, leading to improved airflow and easier breathing.
- Montelukast works by blocking the action of leukotrienes, which are inflammatory chemicals released during allergic reactions. Leukotrienes can cause bronchoconstriction and airway inflammation, and Montelukast helps to reduce these effects, making it easier to breathe, particularly in asthma patients.

Dosage and Administration:

- Adults and Children over 15 years: 1 tablet (Doxofylline 400 mg + Montelukast 10 mg) once daily in the evening, or as prescribed by the healthcare provider.
- Children (6–14 years): Consult a healthcare provider for the appropriate dosage.
- The tablet should be taken orally with or without food. It is important to follow the prescribed dosage to achieve the best results.

Contraindications:

- Hypersensitivity to Doxofylline, Montelukast, or any other components of the formulation.
- Not recommended for patients with severe heart conditions, including arrhythmias.
- Should not be used in patients with active liver disease, especially if related to Montelukast.
- Caution is advised in pregnant and breastfeeding women; consult a healthcare provider before use.

Warnings and Precautions:

- Asthma and Respiratory Conditions: Doxofylline and Montelukast should not be used to treat acute asthma attacks or acute exacerbations. Patients should have a rescue inhaler available for such situations.
- Allergic Reactions: Rarely, Montelukast can cause allergic reactions like rash, itching, or more severe reactions like angioedema.
- Liver Function: Both drugs should be used with caution in patients with impaired liver function.
- Pregnancy and Lactation: Pregnancy Category C for Montelukast. Doxofylline should be used cautiously in pregnancy. Both medications should only be used

during pregnancy or breastfeeding if clearly needed, and under medical supervision.

Side Effects: Common side effects may include:

- Headache
- Dizziness
- Nausea
- Dry mouth
- Gastrointestinal discomfort
- Mild abdominal pain
- Fatigue

Serious side effects (rare but requiring medical attention):

- Allergic reactions (skin rash, itching, swelling)
- Severe chest pain, irregular heartbeat
- Mental health changes (mood swings, depression, anxiety)
- Unusual bleeding or bruising

Drug Interactions:

- **Corticosteroids:** May increase the risk of side effects like fluid retention, elevated blood pressure, and heart rate.
- **Anticoagulants (e.g., warfarin):** Doxofylline may interact with blood thinners and affect clotting parameters.
- **Phenytoin and Rifampicin:** These medications may reduce the effectiveness of Doxofylline.
- **Aspirin and other NSAIDs:** May increase the risk of gastrointestinal side effects.
- **Other Bronchodilators:** Use with caution in combination with other bronchodilators to avoid overstimulation of the heart and nervous system.

Storage:

- Store at room temperature (below 25°C) in a dry place, away from direct light and moisture.
- Keep the tablets in their original packaging.
- Keep out of reach of children.

Overdose: Signs of overdose may include symptoms like tremors, nausea, vomiting, restlessness, dizziness, and an elevated heart rate. Immediate medical attention is required in case of overdose.

Packaging:

- Available in blister packs or bottles, typically containing 10 or 20 tablets.

Manufacturer:

- [Manufacturer Name]

Note: Always follow the dosage instructions provided by your healthcare provider and report any side effects or concerns during treatment. Regular monitoring by your healthcare provider is recommended, especially for individuals with pre-existing respiratory or cardiovascular conditions.

Manufactured in India for:

CafoliTM
L I F E C A R E

Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.)

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