Information For the User Doxofylline (400mg) + Ambroxol (30mg)

Dozyfyle AX Tablet

Doxofylline (400 mg) + Ambroxol (30 mg) Tablet

Composition: Each tablet contains:

- Doxofylline: 400 mg
- Ambroxol: 30 mg

Pharmacological Class:

- Doxofylline: Bronchodilator (Xanthine Derivative)
- Ambroxol: Mucolytic Agent

Indications: This combination is indicated for the treatment of respiratory conditions associated with excessive mucus production and bronchoconstriction. It is commonly used in:

- Chronic Obstructive Pulmonary Disease (COPD)
- Bronchial Asthma
- Chronic Bronchitis
- Acute Exacerbations of Chronic Respiratory Conditions
- Other respiratory disorders with difficulty in expectoration of mucus

Mechanism of Action:

- Doxofylline works as a bronchodilator by relaxing the smooth muscles of the airways. It inhibits phosphodiesterase enzymes, leading to increased levels of cyclic AMP, which helps to dilate the airways and improve airflow.
- Ambroxol is a mucolytic agent that helps in breaking down and thinning the mucus in the airways, making it easier to clear out and improving the patient's ability to breathe. Ambroxol also has an expectorant effect, stimulating the production of surfactant, which helps in clearing mucus from the lungs.

Dosage and Administration:

- Adults: 1 tablet (Doxofylline 400 mg + Ambroxol 30 mg) once or twice daily, as prescribed by the physician.
- Children: The use in children should be based on the healthcare provider's recommendations.
- The tablet should be taken orally with or without food. It is important to follow the prescribed dosage to ensure maximum therapeutic benefit.

Contraindications:

- Hypersensitivity to Doxofylline, Ambroxol, or other xanthine derivatives.
- Not recommended in patients with a history of severe heart disorders, particularly arrhythmias.
- Caution is advised in patients with liver or kidney dysfunction.
- Not recommended during the first trimester of pregnancy, unless absolutely necessary.

Warnings and Precautions:

- Cardiovascular Conditions: Use with caution in patients with a history of arrhythmias, as Doxofylline can increase heart rate.
- Liver and Kidney Function: Ambroxol should be used with caution in patients with impaired liver or kidney function.
- Pregnancy Category C: This combination should only be used if the potential benefit justifies the potential risk to the fetus.
- Breastfeeding: This combination should only be used with caution during breastfeeding as both components are excreted in milk.

Side Effects: Common side effects may include:

- Nausea or vomiting
- Headache

- Dizziness
- Dry mouth
- Abdominal discomfort or bloating
- Increased heart rate (tachycardia)

Less common but more serious side effects include:

- Allergic reactions (skin rash, itching, swelling)
- Severe breathing difficulties
- Chest pain or irregular heartbeat
- Seizures (in case of overdose)

Drug Interactions:

- Caffeine: Excessive consumption of caffeine may increase the side effects, such as restlessness and jitteriness.
- Corticosteroids: Concurrent use may increase the risk of side effects on the cardiovascular system.
- Antibiotics: Some antibiotics may interfere with the metabolism of Doxofylline and Ambroxol.
- Antacids: Can reduce the absorption of Doxofylline.

Storage:

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

Overdose: In case of overdose, symptoms may include increased heart rate, nausea, vomiting, tremors, and potential seizures. Immediate medical intervention is required.

Packaging:

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

Manufacturer:

• [Manufacturer Name]

Note: Always consult with a healthcare professional before starting treatment with this

combination tablet to ensure it is appropriate for your condition and to adjust the dosage if necessary.

Manufactured in India for:



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