

# Safoxol



Ambroxol Hydrochloride

## Composition

**Safoxol Capsule:** Each capsule contains Ambroxol Hydrochloride BP 75 mg.

**Safoxol Syrup:** Each 5 ml syrup contains Ambroxol Hydrochloride BP 15 mg.

## Pharmacological Action

Ambroxol Hydrochloride is a metabolite of Bromhexine. It possesses mucokinetic (improvement in mucus transport) and secretolytic (liquefies secretions) properties. Ambroxol Hydrochloride stimulates the serous cells of the glands of the mucous membrane of bronchi, increasing the content of mucus secretion. The mucolytic effect is associated with depolymerization and splitting of mucoproteins and mucopolysaccharide fibres, which leads to reduction in the viscosity of mucus. Expectoration of mucus is facilitated and breathing is eased considerably. Ambroxol Hydrochloride stimulates production of phospholipids of surfactant by alveolar cells. Ambroxol Hydrochloride has anti-inflammatory properties. In patients with COPD, it improves airway patency. Beside these, Ambroxol Hydrochloride also exhibits anti-oxidant activity. Long-term use is possible because of the good tolerability of the preparation.

## Indications

Productive cough, acute and chronic inflammatory disorders of upper and lower respiratory tracts associated with viscid mucus including acute and chronic bronchitis, inflammatory disease of rhinopharyngeal tract (laryngitis, pharyngitis, sinusitis and rhinitis) associated with viscid mucus, asthmatic bronchitis, bronchial asthma with thick expectoration, bronchiectasis, chronic pneumonia.

## Dosage and Administration

### Capsule

Adults and children over 12 years: 1 capsule, once daily.

### Syrup

2-5 years : 2.5 ml syrup, 2-3 times a day

5-10 years : 5 ml syrup, 2-3 times a day

10 years and adults : 10 ml syrup, 2-3 times a day

## Side Effects

Gastrointestinal side-effects like epigastric pain, gastric fullness may

occur occasionally. Rarely allergic responses such as eruption, urticaria or angioneurotic edema may occur.

### **Contraindications**

Contraindicated in known hypersensitivity to Ambroxol Hydrochloride or Bromhexine.

### **Drug Interaction**

Ambroxol Hydrochloride has no interaction with cardio active glycosides, corticosteroids, bronchodilators, diuretics and antibiotics (normally used in the treatment of bronchopulmonary affections). But Ambroxol Hydrochloride should not be taken simultaneously with antitussives (e.g. Codeine) because mucus, which has been liquefied by Ambroxol Hydrochloride, might not be expectorated.

### **Precautions**

Ambroxol Hydrochloride should be given cautiously to patients with gastric and duodenal ulceration or convulsive disorders. Patients with hepatic and renal insufficiency should take it with caution.

### **Use in pregnancy**

Teratogenic and fetal toxicity studies have shown no harmful effect of Ambroxol Hydrochloride. However, it is advised not to use during pregnancy, especially in the 1st trimester.

### **Use in lactation**

Safety during lactation has not been established.

### **Overdosage**

Until now, no symptoms of overdosage have been reported in humans. If they occur, symptomatic treatment must be provided.

### **Pharmaceutical Information**

#### **Storage Conditions**

Store in a cool and dry place, away from light. Keep out of the reach of children.

#### **Presentation & Packing**

**Safoxol Capsule:** Each commercial box contains 32 capsules in Alu-Alu blister pack.

**Safoxol Syrup:** Each commercial box contains a PET Bottle containing 100 ml syrup and a measuring cup.

Manufactured By

**BEACON**<sup>®</sup>

*Pharmaceuticals PLC*

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