

# Ambrox<sup>®</sup>

## Ambroxol Hydrochloride

### COMPOSITION

**Ambrox<sup>®</sup>** Paediatric Drops: Each ml of drop contains 6 mg Ambroxol Hydrochloride BP. **Ambrox<sup>®</sup>** Syrup: Each 5 ml of syrup contains 15 mg Ambroxol Hydrochloride BP. **Ambrox<sup>®</sup> 75 SR** Capsule: Each capsule contains sustained release pellets of Ambroxol Hydrochloride equivalent to Ambroxol Hydrochloride BP 75 mg.

### PHARMACOLOGY

Ambroxol is the active metabolite of bromhexine and it has been proven that this metabolite possesses a greater bronchosecretolytic effect than bromhexine. It improves sputum rheology by hydrating mechanism leading to liquefaction of mucus in the lumen of respiratory tract, thus facilitating expectoration of mucus and reducing dyspnea. It stimulates production of phospholipids of surfactant by alveolar cells, thus contributing to the lowering of superficial tension in the alveoli. It also reduces bronchial hyperactivity. Ambroxol has anti-inflammatory properties owing to the inhibitory effect on the production of cellular cytokines and arachidonic acid metabolites. In patients with COPD it traditionally improves airway patency.

### 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 etc.

### DOSAGE AND ADMINISTRATION

Average daily dose (preferably after meal):

**Ambrox<sup>®</sup>** Paediatric Drops:

- 0 - 6 months old :0.5 ml, 2 times a day
- 6 - 12 months old :1 ml, 2 times a day
- 1 - 2 years old :1.25 ml, 2 times a day

**Ambrox<sup>®</sup>** Syrup:

- 2 -5 years old :2.5 ml (1/2 teaspoonful), 2-3 times a day
- 5 - 10 years old :5 ml (1 teaspoonful), 2-3 times a day
- 10 years old and adults :10 ml (2 teaspoonful), 3 times a day

**Ambrox<sup>®</sup> 75 SR** Capsule:

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

### SIDE EFFECTS

Gastrointestinal side effects like epigastric pain, stomach overfill feeling may occur occasionally. Rarely allergic responses such as eruption, urticaria or angioneurotic edema has been reported.

### CONTRAINDICATIONS

Contraindicated in known hypersensitivity to Ambroxol or Bromhexine.

### PRECAUTIONS

Ambroxol 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.

### DRUG INTERACTION

Ambroxol should not be taken simultaneously with antitussives (e.g. Codeine) because phlegm, which has been liquefied by Ambroxol might not be expectorated.

### USE IN PREGNANCY AND LACTATION

Teratogenic and foetal toxicity studies have shown no harmful effect of Ambroxol. However, it is advised not to use it in pregnancy, especially during the 1st trimester. Safety during lactation has not been established yet.

### STORAGE CONDITION

Protect from direct light exposure, Store in dry place at a temperature not exceeding 30°C, Keep out of the reach of children.

### HOW SUPPLIED

**Ambrox<sup>®</sup>** Paediatric Drops: Each bottle contains 15 ml paediatric drops and a calibrated dropper.

**Ambrox<sup>®</sup>** Syrup: PET bottle contains 100 ml syrup and a measuring cup.

**Ambrox<sup>®</sup> 75 SR** Capsule: Box containing 30 capsules in blister strips.

Manufactured by



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PHARMACEUTICALS LTD.  
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