

# Single column

W=100 mm

## X-Cold

Syrup/Paediatic Drops

Ambroxol Hydrochloride

### COMPOSITION

**Syrup:** Each 5 ml contains Ambroxol Hydrochloride BP15 mg.

**Paediatic Drops:** Each ml of drop contains Ambroxol Hydrochloride BP 6 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. X-COLD (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

### DOSAGE & ADMINISTRATION

**Route of administration:** Oral.

**Average daily dose (preferably after meal):**

**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

**OR AS DIRECTED BY THE PHYSICIAN.**

### CONTRAINDICATIONS

Contraindicated in known hypersensitivity to Ambroxol or Bromhexine.

### WARNING & 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.

### SIDE EFFECTS

**Common:** Gastrointestinal side effects like Epigastric Pain, Stomach overfill feeling may occur occasionally.

**Rare:** Rarely allergic responses such as Eruption, Urticaria or Angioneurotic Edema has been reported.

### USE IN PREGNANCY & LACTATION

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

### USE IN CHILDREN & ADOLESCENTS

Age and gender do not affect the pharmacokinetics of ambroxol; therefore adjustment of the dose is unnecessary.

### DRUG INTERACTION

**With medicine:** May increase the concentrations of antibiotics (e.g. Cefuroxime, Doxycycline, Erythromycin, Amoxicillin) in the lung tissue.

**With food & others:** There is no data found on interaction with food and others.

### OVERDOSE

Symptoms and signs: Manifestations of poisoning are so far unknown in humans. Treatment: Symptomatic treatment is recommended.

### STORAGE

Keep all medicines out of reach of children.

Store below 30°C, protected from light.

### PACKING

**Syrup:** 100 ml syrup in amber glass bottle.

**Paediatic Drops:** Each bottle contains 15 ml paediatric drops and a calibrated dropper.

**\*Further information is available on request.**



Manufactured by:

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