

# Onecof

## Ambroxol Hydrochloride BP

### Composition

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

### Pharmacology

Ambroxol is the active metabolite of Bromhexine and it has a greater bronchosecretolytic effect than Bromhexine. Ambroxol 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 stimulates production of phospholipids of surfactant by alveolar cells. Ambroxol has anti-inflammatory properties. In patients with COPD, it improves airway patency. Beside these, Ambroxol also exhibits anti-oxidant activity. Long-term use is possible because of the good tolerability of the preparation.

### Indication

- Acute and chronic diseases of respiratory tracts associated with viscid mucus including acute and chronic bronchitis
- Productive cough
- Inflammatory diseases of Rhinopharyngeal tract (e.g. Laryngitis, Pharyngitis, Sinusitis and Rhinitis)
- Asthmatic bronchitis, Bronchial asthma with difficult departure of mucus
- Bronchiectasis
- Chronic pneumonia

### Dose and Administration

a) *Route of Administration:* Oral

Average daily dose (preferably after meal):

Age	Onecof Paediatric Drops
0-6 months	0.5 ml 2 times a day
6-12 months	1 ml 2 times a day
1-2 years	1.25 ml 2 times a day
Age	Onecof Syrup
2-5 years	2.5 ml (½ teaspoonful) 2-3 times a day
5-10 years	5 ml (1 teaspoonful) 2-3 times a day
10 years old and adults	10 ml (2 teaspoonful) 3 times a day

### Contra-indication

Contraindicated in known hypersensitivity to Ambroxol or Bromhexine.

### Warning & Precaution

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

a) *Common:* Gastrointestinal side-effects like epigastric pain, gastric fullness may occur occasionally.

b) *Rare:* Allergic responses such as eruption, urticaria or angioneurotic edema may occur.

### Use in Pregnancy and Lactation

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

*Lactation:* Safety during lactation has not been established yet.

### Use in children & adolescent

See dosage guideline.

### Drug Interaction

a) *With medicine:* Ambroxol has no interaction with cardioactive glycosides, corticosteroids, bronchodilators, diuretics and antibiotics (normally used in the treatment of bronchopulmonary infections). But Ambroxol should not be taken simultaneously with antitussives (e.g. Codeine) because mucus, which has been liquefied by Ambroxol, might not be expectorated.

b) *With food & others:* No adequate data found.

### Overdose

Serious intoxication symptoms have not been observed following overdose of ambroxol. Brief restlessness and diarrhoea have been reported. Ambroxol has been tolerated well on parenteral administration up to a dosage of 15 mg/kg/day, and on oral administration up to a dosage of 25 mg/kg/day. In analogy to preclinical examinations, increased salivation, retching, vomiting and a drop in blood pressure may occur following extreme overdose.

### Storage

Store below 30°C. Protect from light and moisture. Keep all medicines out of reach of children.

### Packing

**Onecof Syrup:** Each box contains a PET bottle of 100 ml syrup with a measuring cup.



Manufactured by

**ONE PHARMA LTD.**

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Bogura, Bangladesh.

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