

# Brox™

Ambroxol Hydrochloride BP

## Composition:

Brox™ syrup: Each 5 ml syrup contains Ambroxol Hydrochloride BP 15 mg.

Brox™ paediatric drops: Each ml contains Ambroxol Hydrochloride BP 6 mg.

## Pharmacology:

Brox™ (Ambroxol) is the active metabolite of Bromhexine and it has been proven that this metabolite possesses a greater bronchosecretolytic effect than bromhexine. It possesses mucokinetic (improvement in mucus transport) and secretolytic (liquefies secretions) properties. Ambroxol stimulates the serous cells of the glands of the mucous membrane of bronchi, increasing the content of mucus secretion. 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 potency. Beside these, Ambroxol also exhibits anti-oxidant activity. Long-term use is possible because of the tolerability of the preparation.

## Indication:

- Productive cough
- Acute and chronic diseases of respiratory tracts associated with viscid mucus including acute and chronic bronchitis.
- Inflammatory diseases of rhinopharyngeal tract (e.g. laryngitis, pharyngitis, sinusitis and rhinitis) associated with viscid mucus.
- Asthmatic bronchitis, bronchial asthma with difficult departure of mucus
- Bronchiectasis
- Chronic pneumonia

## Dose & Administration:

Average daily dose (preferably after meal):

Brox 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

Brox 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

Above 10 years old: 10 ml (2 teaspoonful) 3 times a day

**Or as directed by the physician.**

## Contraindication:

It is 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. Hepatic and renal insufficiency patients should take it with caution.

## Side Effects:

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

## Use in Pregnancy & Lactation:

No harmful effect of Ambroxol have shown from teratogenic and foetal toxicity studies. However, it is advised not to use it in pregnancy, usually during the 1st trimester. Safety data for lactation has not been established yet.

## Use in Children & Adolescents:

This medicine should be used with caution in children.

## Drug Interactions:

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

## Overdosage:

No specific overdose symptoms have been reported in man to date. Based on accidental overdose or medication error reports the observed symptoms are consistent with the known side effects of Ambroxol hydrochloride at recommended doses and may need symptomatic treatment.

## Storage:

Store below 30°C, protected from light & in a dry place. Keep all medicine out of the reach of children.

## Packing

**Brox™ Syrup:** Each bottle contains 100 ml syrup with a measuring spoon and an insert.

**Brox™ Paediatric Drops:** Each bottle contains 15 ml drops with a calibrated dropper and an insert.