

Tembrox[®]

Ambroxol Hydrochloride BP

COMPOSITION:

Tembrox[®] Syrup: Each 5 ml of syrup contains 15 mg Ambroxol Hydrochloride BP.

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.

INDICATION:

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.

DOSE & ADMINISTRATION:

Average daily dose (preferably after meal):

Tembrox[®] 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.

CONTRA-INDICATION:

Contraindicated in known hypersensitivity to Ambroxol or Bromhexine.

WARNING AND 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:

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.

USE IN PREGNANCY & 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.

USE IN CHILDREN & ADOLESCENTS:

Recommended use of Ambroxol syrup for children in children under two years going after consulting a doctor or pharmacist.

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.

OVERDOSE:

Symptoms may include blurred vision; confusion; hallucinations; seizures; severe dizziness, lightheadedness, or headache; severe drowsiness; unusually fast, slow, or irregular heartbeat; vomiting.

No specific overdose symptoms have been reported in man to date.

Based on accidental overdose and/or medication error reports the observed symptoms are consistent with the known side effects of Ambroxol at recommended doses and may need symptomatic treatment.

STORAGE:

Store in a dry and cool place below 30^o C temperature and keep away from light and moisture. Keep out of reach of children.

PACKING:

Tembrox[®] Syrup: Each bottle containing 100 ml syrup with a measuring cup.