

Presentation:

Ambroxol Paediatric Drops: Each ml of drop contains 6 mg Ambroxol hydrochloride BP.

Ambroxol Syrup: Each 5 ml of syrup contains 15 mg Ambroxol hydrochloride BP.

Ambroxol 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

Dosage and administration:

Average daily dose (preferably after meal):

Ambroxol 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

Ambroxol 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

Ambroxol 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:

Ambroxol Paediatric Drops: Amber color glass bottle containing 15 ml paediatric drops and a calibrated dropper.

Ambroxol Syrup: PET bottle contains 100 ml syrup and a measuring cup.

Ambroxol 75 SR Capsule: Box containing 3 x 10 capsules in blister strips.