INHALEX Respules (Ambroxol hydrochloride)

**Composition**

Each 2 ml respule contains
Ambroxol Hydrochloride ..................... 15 mg
In an isotonic solution

**Dosage Form**

Solution for inhalation via a nebulizer

**Pharmacology**

► Pharmacodynamics

Ambroxol is an active N-desmethyl metabolite of the mucolytic bromhexine. Although its mechanism of action has not been fully defined, it may increase the quantity and decrease the viscosity of tracheobronchial secretions. It may also act as an expectorant, increasing mucociliary transport via stimulation of ciliary motility.

Ambroxol may stimulate the synthesis and secretion of pulmonary surfactant; the drug has been referred to as a “surfactant activator”.

The effects of ambroxol in preventing bronchial hyper-reactivity were investigated. Methacholine provocation doses were significantly higher (p <0.01) after ambroxol treatment versus placebo. It was postulated that ambroxol decreased airway hyper-reactivity by either increasing lysophosphatidyl-choline turnover and/or modifying epithelial secretions. Recent research attributes antioxidative characteristics to ambroxol. Ambroxol has been demonstrated to be a direct scavenger of reactive oxygen metabolites. In an in vitro study using specimens from 46 healthy human volunteers, ambroxol significantly reduced reactive oxygen species (ROS) produced by activated human polymorphonuclear cells (PMN) after 1 hour (p <0.001); after 2 hours, the level was comparable to that of non-activated PMN (p <0.001); the reduction of mononuclear cells mimicked that of PMNs; reduction in the pro-oxidative metabolism of inflammatory cells is another postulated mechanism of action.

► Pharmacokinetics

Absorption
Time to peak concentration after oral administration is approximately 2 hours. In a study, it was found that after a single 30 mg oral dose of ambroxol, the mean peak plasma concentration was 88.8 ng/ml.
Bioavailability of ambroxol administered orally is approximately 70–80%. Ambroxol is rapidly absorbed after oral administration.

Distribution
The distribution half-life of ambroxol is 1.3 hours.

Metabolism
The metabolite is dibromoanthranilic acid (activity unspecified).

Excretion
Elimination of ambroxol is biphasic, with an alpha half-life of 1.3 hours and a beta half-life of 8.8 hours. Excretion is primarily by the kidneys. Renal clearance (rate) is approximately 53 ml/minute; approximately 5–6% of a dose is excreted unchanged in the urine. The elimination half-life of the parent compound is 8.8 hours.

Indications
INHALEX Respules are indicated for acute and chronic respiratory tract disease, spasmodic stenosis, abnormal bronchial mucous production, especially bronchial asthma, and emphysema. INHALEX Respules are also indicated for treatment of secretion disorders in acute and chronic bronchopulmonary infections.

Dosage And Administration

- Adults and Children (Above 5 years of age)
  1 respule (15 mg) twice daily

- Children (Below 5 years of age)
  ½ respule (7.5 mg) twice daily

INHALEX Respules are inhaled with the aid of a nebulizer. They can also be diluted with distilled water in the ratio of 1:1.

Contraindications
Hypersensitivity to ambroxol, and in patients with epilepsy.

Warnings And Precautions
INHALEX Respules must be administered with precaution to patients suffering from peptic ulcers. INHALEX Respules should not be allowed as prolonged treatment for protracted illnesses. If the results are not appreciable within a short treatment period, it is advisable to consult the doctor. INHALEX Respules should be used carefully in patients with gastric ulcers.

Care to be taken to avoid contact with eye, skin, serious ingestion or inhalation.

Drug Interactions
None known

- Pregnancy
  Teratogenic and foetal toxicity studies have shown no harmful effects of INHALEX Respules.

- Lactation
  INHALEX Respules should not be administered to nursing mothers.

Undesirable Effects
At the recommended doses, INHALEX Respules are well tolerated. Nausea, epigastric distress, headache, and
gastrointestinal disorders have rarely been observed.
INHALEX Respules may cause skin, eye or respiratory tract irritation. Ingestion of large doses may cause gastrointestinal tract irritation with decreased motility or constipation, ulceration or bleeding from the stomach or duodenum, and peritonitis. May affect behaviour/central nervous system (tremor, convulsions, ataxia, and somnolence), respiration (dyspnoea, respiratory stimulation), liver, blood (changes in white blood cell count), and the urinary system. Under individual hypersensitivity to Ambroxol allergic reactions such as skin rash, nettle-rash, and angioneurotic oedema are possible. Under the prolonged administration in large doses pain in epigastrial area, nausea, vomiting can appear. Gastrointestinal Disorders: Dyspepsia, constipation, nausea, vomiting, diarrhea, excessive salivation, xerostomia and abdominal pain.
Respiratory, Mediastinal and Thoracic Disorders: Rhinorrhoea, Oral and pharyngeal hypoaesthesia, dry mouth and dry throat.
Nervous System Disorders: Dysgeusia (eg, changed taste), fatigue.
Immune System Disorders: Anaphylactic reactions including anaphylactic shock.
Skin and Sub cutaneous Tissue Disorders: Angioedema, rash, urticaria, contact dermatitis, pruritus and other hypersensitivity.
Renal Effects: Dysuria

**Overdosage**

No information is available on overdosage with INHALEX Respules.

**Packaging Information**

INHALEX Respules .......... available as respule of 2 ml
Last Updated:  Mar 2016
Last Reviewed:  Mar 2016

**INHALEX Respules**

Source URL: https://ciplamed.com/content/inhalex-respules