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 Subcutaneous 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

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INHALEX Respules

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