HYBROX Syrup/Paediatric Drops

Ambroxol Hydrochloride BP

COMPOSITION:
Hybrox Syrup: Each 5 ml contains Ambroxol hydrochloride BP 15 mg.
Hybrox Paediatric Drops: Each ml contains Ambroxol hydrochloride BP 6 mg.

DESCRIPTION:
Ambroxol is a metabolite of 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. The mucolytic effect is associated with depolymerization and splitting of mucoproteins and mucopolysaccharide fibres, which leads to reduction in the viscosity & expectoration of mucus and breathing is eased considerably. Ambroxol stimulates the production of phospholipids of surfactant by alveolar cells and it has anti-inflammatory properties. In patients with COPD, it improves airway patency. Beside these, Ambroxol also exhibits anti-oxidant activity and long-term use is possible because of the good tolerability of the preparation.

INDICATIONS:
Hybrox is indicated in:
- Acute and chronic diseases of respiratory tracts associated with viscid mucus including acute and chronic bronchitis
- Productive cough
- Inflammatory diseases of Rhinopharyngeal tract (e.g. Laryngitis, Pharyngitis, Sinusitis and Rhinitis) associated with viscid mucus
- Asthmatic bronchitis
- Bronchial asthma with difficult expulsion of mucus
- Chronic pneumonia
- Bronchiectasis

DOSAGE AND ADMINISTRATION:

Age	Hybrox 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
	Hybrox Syrup
2-5 years	2.5 ml (1/2 teaspoonful) 2-3 times a day
5-12 years	5 ml (1 teaspoonful) 2-3 times a day
More than 12 years and adults	10 ml (2 teaspoonful) 3 times a day

At the onset of treatment i.e. 2-3 days later, the doses may be reduced for children.

SIDE-EFFECTS:
Gastrointestinal side-effects like epigastric pain and stomach overfills feeling may occur occasionally. A rarely allergic response such as eruption, urticaria or angioneurotic edema has been reported. Headache, nausea and gastrointestinal troubles are seldom reported.

USE IN PREGNANCY AND LACTATION:
There are no adequate and well-controlled studies in pregnant women with ambroxol. So, special care is recommended for the administration of Hybrox (Ambroxol) during pregnancy particularly during the first 3 months. Ambroxol should be used in pregnancy if the potential benefit to the mother justifies the potential risk to the foetus. It is not known whether ambroxol is secreted in human milk. As many drugs are excreted in human milk, So Ambroxol should not be administered to a breastfeeding woman.

CONTRAINDICATIONS:
Contraindicated in patients having hypersensitivity to Ambroxol or bromhexine.

PRECAUTIONS:
Caution is necessary when bronchomotoric function is impaired. Patients with hepatic and renal insufficiency should take it with caution. Ambroxol should not be given with cough suppressants, since a dangerous increase of bronchial secretion occur if administered simultaneously. Ambroxol should be given with care to patients suffering from peptic ulcer.

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

PHARMACEUTICAL PRECAUTION:
Store in a cool (below 300 C) and dry place. Keep away from light and out of reach of children.

HOW SUPPLIED:
Hybrox Syrup: Amber color bottle containing 100 ml syrup and a measuring cup.
Hybrox Paediatric Drops: Amber color bottle containing 15 ml paediatric drops and a graduated dropper.

Manufactured by :
KEMIKO PHARMACEUTICALS LTD.
KEMIKO Bangladesh