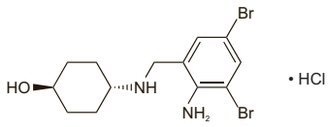
Rx AMBROXOL

6 mg/mL Syrup (Oral Drops)
MUCOLYTIC

FORMULATION
Each mL contains:
Ambroxol Hydrochloride, EP…….....6 mg

PRODUCT DESCRIPTION
Clear colorless, sweet with bitter aftertaste, cherry flavored syrup containing 6mg of Ambroxol Hydrochloride in each mL.

DESCRIPTION
A white or yellowish crystalline powder. Sparingly soluble in water; practically insoluble in dichloromethane; soluble in methyl alcohol. A 1% solution in water has a pH of 4.5 to 6.0. Protect from light.
Trans -4-(2-Amino-3,5-di-bromobenzylamino) cyclohexanol hydrochloride (Ambroxol hydrochloride)



PHARMACOKINETICS
Oral bioavailability is approx. 60% owing to the first-pass effect. Plasma concentrations are in a linear relationship to the dose. Peak plasma levels are attained after 0.5 to 3 hours. Ambroxol modified-release capsules, on the other hand, has delayed absorption (Tmax 6.5 ± 2.2 h) and a relative bioavailability of 95% compared with the tablets. Plasma protein binding is around 90% in the therapeutic range. After oral, intravenous and intramuscular administration ambroxol is distributed swiftly and extensively from the blood into the tissues. The highest active ingredient concentrations are measured in the lung. Studies in human liver microsomes showed that CYP3A4 is the predominant isoform for ambroxol metabolism. Otherwise ambroxol is metabolised in the liver mainly by conjugation. Around 30% of an oral dose is eliminated via the first-pass effect. The terminal half-life is about 10 hours. Total clearance is in the region of 660 ml/min, and renal clearance is 8% of total clearance.

PHARMACODYNAMICS
Ambroxol is the active metabolite of bromhexine. Ambroxol causes an increase in secretion in the respiratory tract. It promotes surfactant production and stimulates ciliary activity. These effects assist the flow of mucus and its removal (mucociliary clearance). An improvement in mucociliary clearance was demonstrated in clinical pharmacological studies. The increase in secretion and mucociliary clearance facilitate expectoration and reduce the cough. In vitro studies ambroxol showed a significant reduction in cytokine release, both in the blood and in mononuclear and polynuclear cells. The clinical relevance of these findings is unclear.

INDICATIONS
For acute and chronic disorders of the respiratory tract associated with abnormal bronchial secretions particularly of chronic bronchitis, asthmatic bronchitis and bronchial asthma. This preparation is also useful in the prophylactic treatment of patients in intensive care for the prevention of post-operative complications.

DOSAGE AND MODE OF ADMINISTRATION
INFANTS:
1-2 years old: 1.25 mL (two times a day)
7-12 months old: 1 mL (two times a day)
0-6 months old: 0.5 mL (two times a day)
To be taken at meal times. Or as prescribed by a physician.

PRECAUTIONS
Ambroxol should be given cautiously to patients with gastric ulceration. Use in pregnancy and lactation.
Pre-clinical studies have shown no hazard, but safety during human pregnancy has not yet been established. The usual precautions regarding the use of drugs at this time especially during 1st trimester should be observed.

CONTRAINDICATIONS
Should not be used in patients known to be hypersensitive to Ambroxol or to other components of the formulation.

PREGNANCY AND LACTATION
Pregnancy
Caution is advised when ambroxol is used during pregnancy. Use during the first trimester of pregnancy is not recommended.
Ambroxol crosses the placenta. Animal studies do not show either a direct or indirect harmful effect on pregnancy, embryofoetal development, parturition or postnatal development. Comprehensive controlled studies in pregnant women after the 28th week have not shown any harmful effects on the foetus.
Lactation
Ambroxol is excreted in breast milk and should not be taken during lactation.
However, no adverse effects on the breastfed infant are expected.

DRUG INTERACTIONS
The combination of Ambroxol with other drugs is possible. This refers particularly to preparations used as standard medication for bronchitis syndrome, cardiac glycosides, corticosteroids, bronchospasmolytic, diuretics and antibiotics.

ADVERSE EFFECTS
Ambroxol is generally well tolerated. Mild gastrointestinal side effects have occasionally been reported. Allergic reactions have occurred rarely, some of the affected patients also showed allergic reactions to other substances.

OVERDOSAGE AND TREATMENT
Symptoms and signs
Manifestations of poisoning are so far unknown in humans.
Treatment
Symptomatic treatment is recommended.

AVAILABILITY
Boston Round Amber Bottle x 15 mL with dropper (Box of 1's)

CAUTION
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

ADR REPORTING STATEMENT:
"For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph"
Seek medical attention immediately at the first sign of any adverse drug reaction.

STORAGE CONDITIONS
Store at temperatures not exceeding 30°C.

REGISTRATION NUMBER
DRP-2347

DATE OF FIRST AUTHORIZATION/ RENEWAL
JULY 20, 2010

DATE OF REVISION
SEPTEMBER 2020

Manufactured by:
JM TOLMANN LABORATORIES, INC.
#95 North Zuzuarregui St., Diliman, Q. C.

INSERT Required size:
105mm x 170mm
Required folding:
2 Folds crosswise (facing the text)