

AMBROXOL HCl

MUCOVIS™

30 mg Tablet

MUCOLYTIC

FORMULATION:

Each tablet contains:
Ambroxol (as hydrochloride) 30 mg

PRODUCT DESCRIPTION:

White to off-white, round, biconvex, uncoated tablet, plain on both sides.

PHARMACODYNAMICS AND PHARMACOKINETICS:

Ambroxol HCl, as a mucolytic has been shown to increase respiratory tract secretions and facilitates the expectoration of abnormal secretions present in the upper and lower respiratory tract. Ambroxol enhances pulmonary surfactant production and stimulates ciliary activity resulting in improved mucus flow and transport.

Ambroxol HCl breaks and liquefies the acid mucopolysaccharide fibers of the mucus, making it thinner and less viscid. The sputum becomes less tenacious and less sticky, thus allowing easier expectoration.

Ambroxol stimulates mucociliary activity and enhances production of naturally occurring pulmonary surfactants. It alters the structure of mucus to reduce its viscosity. Enhancement of mucociliary function and fluid secretion results in improved mucus flow and facilitates expectoration of mucus in the upper and lower respiratory tract.

Ambroxol is rapidly and completely absorbed in the gastrointestinal tract and concentrates in the lungs. Maximum plasma level is reached within 1 - 2.5 hours. Its plasma half-life is eight to twelve hours. Ambroxol HCl is metabolized mainly in the liver and eliminated thru the urine.

INDICATIONS:

Ambroxol is used in the treatment of acute and chronic respiratory tract disorders associated with abnormal bronchial mucus secretions such as bronchitis, bronchial asthma, pneumonia and other pulmonary diseases. It is also used as an adjuvant in the treatment of sinusitis, rhinitis and other inflammatory diseases of the nasal cavity and throat when treatment of such conditions require a mucolytic.

DOSAGE AND ADMINISTRATION:

Usual adult dose: One tablet three times daily after meals, or as prescribed by the physician.

CONTRAINDICATIONS/PRECAUTIONS/WARNINGS:

Ambroxol should not be used in patients with history of hypersensitivity to ambroxol and bromhexine.

There have been few cases of severe lesions such as Stevens-Johnson syndrome and toxic epidermal necrolysis have been reported with the use of ambroxol hydrochloride. Medical consultation should be sought if new skin or mucosal lesions are observed.

In cases of impaired renal function, ambroxol hydrochloride may be used only after consulting a physician.

Ambroxol should be given cautiously to patients with history of peptic ulcer disease.

Patients with a rare hereditary condition of galactose intolerance.

PREGNANCY AND LACTATION:

Ambroxol hydrochloride crosses the placental barrier and is excreted in breast milk. Mucovis is not recommended especially during the first trimester of pregnancy. It is not recommended for use in nursing mothers.

ADVERSE DRUG REACTIONS:

Ambroxol hydrochloride is generally well tolerated. Gastrointestinal disorders like diarrhea, abdominal pain, dyspepsia, nausea and vomiting may occur.

There are reported cases of adverse reactions which include immune system disorder, skin and subcutaneous reactions, anaphylactic reactions including shock, angioedema, urticaria, pruritus, rashes and other forms of hypersensitivity reactions. There is a small risk of severe allergic reactions and severe cutaneous adverse reactions (SCARs), including erythema multiforme, Stevens-Johnson syndrome/ toxic epidermal necrolysis and acute generalized exanthematous pustulosis.

Other adverse effects include nervous system disorder such as dysgeusia (e.g. change taste), oral and pharyngeal hypesthesia.

DRUG INTERACTIONS:

There is no reported clinically significant drug to drug interaction.

OVERDOSE AND TREATMENT:

Ambroxol hydrochloride has a low index for acute toxicity. There are no specific overdose symptoms reported.

Symptoms of overdose are consistent with known adverse effects of ambroxol hydrochloride. Symptomatic and supportive management is valuable in cases of overdosage.

If someone takes dose larger than the recommended, call a doctor, emergency medical services (EMS), or the nearest poison control center immediately.

AVAILABILITY:

Alu-Clear PVC Blister pack x 10's (Box of 100's)

CAUTION:

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

DR-XY37663

STORE AT TEMPERATURES NOT EXCEEDING 30°C.

PROTECT FROM LIGHT.

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph

Manufactured for:

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