AMBROXOL HCl

MYRACOF®

30 mg Tablet

MUCOLYTIC

FORMULATION
Each tablet contains:
Ambroxol (as hydrochloride) ..... 30 mg

PRODUCT DESCRIPTION
Ambroxol hydrochloride (Myracof®) 30 mg Tablet is a white, round, flat, bevel-edged tablet, bisected on one side and plain on the other side.

WHAT IS IN THE MEDICINE?
This medicine contains Ambroxol, a mucolytic, which stimulates fluid secretion in the respiratory tract and breaks down mucus resulting in the production of less thick and less sticky mucus/phlegm. Ambroxol improves mucociliary clearance (mucus flow and transport) making phlegm easier to cough up and expel.

STRENGTH OF THE MEDICINE See Formulation

WHAT IS THIS MEDICINE USED FOR?
This medicine is used for the relief of cough secondary to acute and chronic diseases of the respiratory tract accompanied by excessive lung secretions such as chronic bronchitis, asthmatic bronchitis and bronchial asthma.

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?
Adults and children above 12 years: Orally, 1 tablet every 8 hours, or, as recommended by a doctor.

Doses are best taken after meals.

WHEN SHOULD YOU NOT TAKE THIS MEDICINE?
If you are allergic to ambroxol or other ingredients in the product.

UNDESIRABLE EFFECTS
Immune system disorders: Anaphylactic reactions (rare, life-threatening allergic reactions) [including anaphylactic shock, angioedema (rapid swelling of the skin), pruritus (itchiness), rash, urticaria, and other hypersensitivity], severe allergic reactions, severe cutaneous allergic reactions (SCARs) [which includes erythema multiforme and Stevens-Johnson syndrome]

Gastrointestinal disorders: Abdominal pain, diarrhea, dyspepsia (indigestion, feeling of fullness), heartburn, nausea, vomiting

WHAT OTHER MEDICINES OR FOOD SHOULD BE AVOIDED WHILE TAKING THIS MEDICINE?
Administration of Ambroxol with antibiotics (e.g., Amoxicillin, Cefuroxime, Erythromycin) leads to higher antibiotic concentration in bronchopulmonary secretions and in sputum.

Tell your doctor if you are taking other medicines, including vitamins, supplements, and herbal medicines.

WHAT SHOULD YOU DO IF YOU MISS A DOSE?
If you miss a dose, just take the next dose if still needed for the condition being treated and the subsequent doses at the recommended time or schedule.

Do not double the dose.

HOW SHOULD YOU KEEP THIS MEDICINE?
- Keep the product out of sight and reach of children
- Store at temperatures not exceeding 30°C

SIGNS AND SYMPTOMS OF OVERDOSE
Symptoms of overdose are consistent with the known undesirable effects of ambroxol at recommended doses.

WHAT TO DO IF YOU HAVE TAKEN MORE THAN THE RECOMMENDED DOSAGE?
If you have taken more than the recommended dosage, consult a doctor.

CARE THAT SHOULD BE TAKEN WHEN TAKING THIS MEDICINE
- Severe skin lesions such as Stevens-Johnson syndrome and Lyell's syndrome have been reported rarely with the administration of mucolytics such as ambroxol. These may be due to the severity of the underlying disease or concomitant medication. If new skin or mucosal lesions appear, discontinue ambroxol and consult a doctor immediately.
- In the presence of impaired kidney function, a doctor must be consulted.
- Do not take this medicine if you are pregnant or breastfeeding unless advised by your doctor. The use of ambroxol in the first trimester is not recommended.
- Do not take more than the recommended dose.
- Do not use after the expiry date on the label.

WHEN SHOULD YOU CONSULT YOUR DOCTOR?
- Ask a doctor before use if:
  - You have kidney or liver disease
  - You are pregnant or breastfeeding
- Stop use and ask a doctor if:
  - Symptoms worsen or do not improve
  - New symptoms occur
  - Any undesirable effect occurs

For suspected adverse drug reaction, seek medical attention immediately and report to the FDA at www.fda.gov.ph AND Unilab at (+632) 858-1000 or productsafety@unilab.com.ph. By reporting undesirable effects, you can help provide more information on the safety of this medicine.

AVAILABILITY: Box of 100's (in alu foil strip by 10's)
DATE OF REVISION OF PATIENT INFORMATION LEAFLET (PIL): June 2018
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Manufactured by Amherst Laboratories, Inc.
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