



Unison Laboratories Co., Ltd.

PACKAGING MATERIALS

Revision	00
Date	15/01/07
Code	MA02168710703 (BP)
Page	Page 1 of 2

AMTUSS (Syrup)

Each teaspoonful (5 ml) syrup contains:
Ambroxol Hydrochloride 30 mg

AMTUSS (Syrup)

Each teaspoonful (5 ml) syrup contains:
Ambroxol Hydrochloride.....30 mg

❖ What is AMTUSS (Syrup)?

Preclinically, Ambroxol has been shown to increase respiratory tract secretion. It enhances pulmonary surfactant production and stimulates ciliary activity. These actions result in improved mucus flow and transport (mucociliary clearance). Improvement of mucociliary clearance has been shown in clinical pharmacologic studies. Enhancement of fluid secretion and mucociliary clearance facilitates expectoration and eases cough.

❖ How much strength of AMTUSS (Syrup) is available?

AMTUSS (Syrup) is supplied as a clear colorless solution. Each teaspoonful (5 ml) contains 30 mg Ambroxol Hydrochloride. Each teaspoonful (5 ml) contains 30 mg Ambroxol Hydrochloride. It is supplied as PET bottle of 60 ml.

❖ What is AMTUSS (Syrup) for?

Secretolytic therapy in acute and chronic bronchopulmonary diseases associated with abnormal mucus secretion and impaired mucus transport.

❖ How much and how often should you use AMTUSS (Syrup)?

Adult and Children >12 years:

2 teaspoonful 2 times daily.

This regimen is suitable for the initial treatment of chronic conditions up to 14 days.

Children <12 years:

The following dosage regimen is recommended depending on the severity of the disease.

Children 6-12 years : 1 teaspoonful 2-3 times daily;

2-6 years : ½ teaspoonful 3 times daily;

1-2 years : ¼ teaspoonful 2 times daily.

This dosage regimen is for initial treatment; the dosage may be halved after 14 days.

Amtuss liquid should be taken at mealtimes.

❖ When should you not take AMTUSS (Syrup)?

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

❖ What are the possible side effects of AMTUSS (Syrup)?

Amtuss is generally well tolerated. Mild upper gastrointestinal side effects (primarily pyrosis, dyspepsia and occasionally nausea, vomiting) have been reported, principally following parenteral administration. Allergic reactions have occurred rarely, primarily skin rashes.

There have been extremely rare case reports of severe acute anaphylactic-type reactions but their relationship to ambroxol is uncertain. Some of these patients have also shown allergic reactions to other substances.

*** LEAFLET ***

dd/mm/yy



Unison Laboratories Co., Ltd.

PACKAGING MATERIALS

Revision	00
Date	15/01/07
Code	MAL/100107_03 (BP)
Page	Page 2 of 2

AMTUSS (Syrup)

Each teaspoonful (5 ml) syrup contains:
Ambroxol Hydrochloride 30 mg

❖ What other medicine or food should be avoided while taking AMTUSS (Syrup)?

Administration of Ambroxol together with antibiotics (Amoxicillin, cefuroxime, erythromycin, doxycycline) leads to higher antibiotic concentration in the lung tissue. No clinically relevant unfavourable interaction with other medications have been reported.

❖ What should you do if you miss a dose of AMTUSS (Syrup)?

Taking as soon as possible; not taking if almost time for next dose; not doubling doses.

❖ How should you keep AMTUSS (Syrup)?

Store at a temperature not more than 30°C in well closed container.

❖ What are the signs and symptoms of AMTUSS (Syrup) overdose?

No symptoms of overdosage have been reported in man to date.

❖ What to do when you have taken more than the recommended dosage of AMTUSS (Syrup)?

If they occur, symptomatic treatment should be provided.

❖ Care that should be taken when taking AMTUSS (Syrup)?

Use in pregnancy and lactation: Preclinical studies as well as extensive clinical experience after the 28th week have shown no harmful effects on the developing foetus. However, caution should be observed regarding the use of drug during pregnancy, especially during the 1st trimester. During lactation, Amtuss should be used only if absolutely necessary.

❖ When should you consult your doctor?

See Warning and Precautions.

❖ AMTUSS (Syrup) is manufactured by:



UNISON LABORATORIES COMPANY, LIMITED
30 Ladkrabung Rd., Ladkrabung, Bangkok 10520 THAILAND

❖ Imported and distributed by:

MEDISPEC (M) SDN. BHD
No. 55& 57, Lorong Sempadan 2 (Off Boundary Road) 11400
Ayer Itam, Penang, Malaysia

MAL/100107_01 (BP)

*** LEAFLET ***