

AMTUSS 30 mg Tablet**MUCOLYTIC**

Each tablet contains:
Ambroxol hydrochloride 30 mg

❖ PRODUCT DESCRIPTION:

White, round, flat tablet, bevelled on both sides with engraved manufacturer's logo on one side and 30 on the other

❖ MECHANISM OF ACTION:**Pharmacology**

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.

❖ INDICATION:

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

❖ DOSAGE AND ADMINISTRATION:

Oral

Adult dose

1 tablet 3 times daily. The therapeutic effect may be enhanced by administering 2 tablets 2 times daily. The tablets should be taken with liquid.

In acute respiratory indications, medical advice should be sought if symptoms do not improve or worsen in the course of therapy.

AMTUSS can be taken with or without food.

❖ WARNING AND PRECAUTION:**Use in pregnancy and lactation**

Preclinical studies as well as extensive clinical experience after the 28th week have shown no evidence of ill-effects during pregnancy. Nonetheless, the usual precautions regarding the use of drug during pregnancy, especially during the 1st trimester, should be observed. During lactation, AMTUSS should be used only if absolutely necessary.

^Very rare cases of chronically associated severe skin impairments such as Stevens Johnson Syndrome, Toxic Epidermal Necrolysis (TEN), Erythema Multiforme (EM) and Acute Generalized Exanthematous Pustulosis (AGEP) have been reported. In most cases, these could be explained by the severity of the underlying disease or concomitant administration of another drug. In the early stages of such severe skin reactions, initially only nonspecific flu-like symptoms appear, e.g. fever, arthralgia, runny nose, cough and sore throat. If skin or mucous membrane damage occurs, seek medical advice immediately and discontinue treatment as a precaution.

❖ SIDE EFFECT:

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.

Immune system disorders[^]

Frequency not known: Anaphylactic reactions including anaphylactic shock.

Skin and subcutaneous skin disorders[^]

Frequency not known: Severe skin reactions [including Stevens Johnson Syndrome, Toxic Epidermal Necrolysis (TEN), Erythema Multiforme (EM) and Acute Generalized Exanthematous Pustulosis (AGEP)].

❖ CONTRAINDICATION:

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

❖ DRUG INTERACTION:

Administration of Ambroxol together with antibiotics (Amoxicillin, Cefuroxime, Erythromycin, Doxycycline) leads to higher antibiotic concentration in the lung tissue. No clinically relevant unfavorable interaction with other medications have been reported.

❖ OVERDOSE AND TREATMENT:

No symptoms of overdosage have been reported in man to date. If they occur, symptomatic treatment should be provided.

❖ STORAGE:

Store at temperature of not more than 30°C.

❖ DOSAGE FORM AND PACKAGING AVAILABLE:

30 mg Tablet, Blister 50x10's

❖ DATE OF REVISION:

March 07, 2023

Manufactured by:

UNISON LABORATORIES CO., LTD.

39 Moo 4, Klong Udomcholjorn, Muang Chachoengsao,
Chachoengsao 24000 Thailand

| Product | Code No. | Dimension | Packaging Type | Thickness |
|--|-----------|-----------------|-----------------------------------|-----------------|
| AMTUSS 30 mg Tablet | IAMY 0042 | W 15 x L 27 cm. | Wood Free Paper (กระดาษไม่กรด) | 60 g (0.08 mm.) |
| Designed by: _____ <small>(PDM, ASPD, PDCM, PDC-A, PDCM, PDC-A)</small> | | | | |
| Checked by: _____ <small>(PDM/ASPD)</small> | | | | |
| Approved by: _____ <small>(PLC)</small> | | | | |
| Approved by: _____ <small>(LRA)</small> | | | | |
| Approved by: _____ <small>(GCC-PMI)</small> | | | | |
| Approved by: _____ <small>(CUSTOMER/SALES DEPT.)</small> | | | | |