

PACKAGE INSERT

MUCOCLEAR SYRUP / TABLET 30MG

	Mucoclear Syrup	Mucoclear Tablet 30mg
Ambroxol HCl	30mg/5ml	30mg/tablet
Preservative: Methyl Paraben	5.0mg/5ml	-
Propyl Paraben	0.4mg/5ml	-

Product Description:

Syrup : A clear colourless syrup with cherry flavour.

Tablet : Round, convex, pink, plain tablet with single score on one side and "SW" debossed on the other side.

Pharmacodynamics:

Ambroxol HCl is trans-4-[(2-amino-3, 5-dibromobenzyl) amino] cyclohexanol hydrochloride. 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). Enhancement of fluid secretion and mucociliary clearance improves expectoration and eases cough.

Pharmacokinetics:

Ambroxol is a metabolite of bromhexine and has similar actions and uses.

Indication:

It is indicated in acute and chronic bronchopulmonary diseases associated with abnormal mucus secretion and impaired mucus transport.

Recommended Dosage:

	Tablet	Syrup
Children up to 2 years		Half teaspoonful (2.5ml) twice daily.
Children 2-5 years		Half teaspoonful (2.5ml) thrice daily.
Children > 5 years	One tablet thrice daily.	One teaspoonful (5ml) thrice daily.
Adults	At the start of treatment, 2 tablets twice daily. In maintenance therapy, 1 tablet thrice a day. Tablet to be taken after meals	At the start of treatment, 2 teaspoonfuls (10ml) twice daily, then one teaspoonful (5ml) thrice daily.

Route of Administration:

Oral

Contraindications:

It should not be used in patients known to be hypersensitive to ambroxol or other components of the product.

Warnings and Precautions:

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.

Interactions with Other Medicaments:

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.

Pregnancy and Lactation:

Ambroxol should not be used during pregnancy unless the potential benefits outweighs the potential risks to the foetus. The use of ambroxol in lactating mother should only be considered if absolutely necessary.

Side Effects:

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

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)

Symptoms and Treatment for Overdose:

Symptoms of overdosage have not been reported in man to date. If they occur, symptomatic treatment should be instituted.

Effects on Ability to Drive and Use Machine:

Not applicable.

Storage Conditions:

Store at or below 30°C. Protect from light.

Pack Size:

Syrup: A bottle of 60ml, 100ml and 120ml.

Tablet: Blister pack: A box of 10 x 10, 50 x 10 and 100 x 10 tablets per strip.

Pack Size (export only): Syrup: A bottle of 1 litre. Tablet: A bottle of 500 tablets.

Shelf-life:

Syrup : 2 years Tablet : 3 years

FURTHER INFORMATION CONCERNING THIS DRUG CAN BE OBTAINED FROM YOUR FAMILY PHYSICIAN / LOCAL GENERAL PRACTITIONER / PHARMACIST.

Manufacturer & Product Registration Holder:

SUNWARD PHARMACEUTICAL SDN. BHD.

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