



AMCOSOL TABLET 30mg

Description: White, round, biconvex and top-scored tablet. Diameter = 9.00mm

Contents:

Amcosol Tablet : Ambroxol HCl 30mg/tablet

Indications:

For treatment of acute or chronic bronchitis accompanied by abnormal bronchial secretions, and silicosis.

Pharmacology:

Ambroxol, a metabolite of bromhexine, produces a marked reduction in coughing and dyspnoea as well as an improvement in expectoration for patients with bronchitis. Its twofold action as a secretolytic and surfactant stimulant accounts for its activity in silicosis patients.

Elimination is mainly by renal excretion.

Adverse effects:

Hypersensitivity reactions to ambroxol may occur.

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).

Warnings and Precautions:

Safety for use in pregnancy and lactation has not been established.

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.

Dosage and Administration:

Adults : Oral, 1 tablet three times daily.

Children 5 to 10 years : Oral, ½ tablet three times daily.

Children under 5 years : As directed by physician.

Storage

: Keep container tightly closed. Keep out of reach of children.

: Store in a cool, dry place away from light, below 30°C.

Presentation/Packing

: Tablet 30mg x 500's; 1000's (EXPORT)

Shelflife

: 3 years

Product registration holder & Manufacturer:

: Prime Pharmaceutical Sdn. Bhd.
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Taman Perindustrian Bukit Tengah,
14000 Bukit Mertajam, Penang, Malaysia.

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