ARTWORK RECORD

Colour	Product : Throzz Ambroxol 30mg	Language : English
C:00 M:00 Y:00 K:100	Generic Name :	Country : Malaysia
	Material : Insert	Note:
	Size : 137 L x 208 H mm	
	Pack size : 50x10 Tab	
	Date : 19-05-2026	
	A/W Code : 52875I01-00	
	Revision No. :	

Reason for Revision :

Front 137 x 208

THROZZ®

Ambroxol 30mg

Tablet

MUCOLYTIC

PRODUCT INSERT

THROZZ Ambroxol 30mg Tablet

NAME AND STRENGTH OF ACTIVE SUBSTANCE
Each uncoated tablet contains: Ambroxol Hydrochloride BP 30mg.

DESCRIPTION
White coloured round flat uncoated tablets with beveled edges embossed 'Z1' on one side.

PHARMACODYNAMICS
Pharmacotherapeutic group: Mucolytics, ATC code: R05CB06

Ambroxol is a metabolite of bromhexine and is used similarly as a mucolytic. 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.

PHARMACOKINETICS
Ambroxol hydrochloride is completely absorbed after oral administration. It reaches maximum plasma concentration in 9 to 10 hours. Time to peak concentration after oral administration is approximately two hours. After oral administration, 85% of the active substance is eliminated in the urine.

INDICATION
Secretolytic treatment for acute and chronic bronchopulmonary disease associated with abnormal mucus secretion and impaired mucus transport.

RECOMMENDED DOSAGE
For oral use.
The recommended dose for adults is 1 tablet 3 times daily. The therapeutic effect may be enhanced by administering 2 tablets twice daily and should be taken after meals with liquid.

ROUTE OF ADMINISTRATION
Oral

CONTRAINDICATIONS
Hypersensitivity to ambroxol or other ingredients of the tablet.

WARNING AND PRECAUTIONS
• Medical advice should be sought for patients with liver and kidney problems before taking this medication.
• Ambroxol may increase the amount of antibiotic penetration.
• Medical advice should be sought if the symptoms last longer than 14 days and/or if the symptoms increase in spite of the treatment.
• 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 MEDICINES
• Ambroxol administered together with antibiotics such as amoxicillin, cefuroxime, erythromycin, doxycycline will lead to higher antibiotic concentration in the lung tissue.
• No clinically relevant unfavourable interaction with other medications have been reported.

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PREGNANCY AND LACTATION
Use in pregnancy
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 drugs during pregnancy, especially during the 1st trimester, should be observed.

Use in lactation
For breastfeeding or likely to breastfeed during course of medication, consult doctor's advice. The risk benefits of ambroxol must be assessed against possible effects on your child. This medication should be used only if absolutely necessary during lactation.

SIDE EFFECTS
• Mild upper gastrointestinal side effects such as primarily pyrosis, dyspepsia and occasionally nausea, vomiting, diarrhea, bloated feeling have been reported, principally following parenteral administration.
• Allergic reactions, primarily skin rashes, difficulty in breathing, swelling of the face, lips, mouth, tongue or throat which may cause difficulty swallowing or breathing have occurred rarely.
• Reports of severe acute anaphylactic-type reactions but their relationship to ambroxol is uncertain and are extremely rare case.
• 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 OF OVERDOSAGE
No symptoms of overdosage have been reported. If symptoms occur, treatment should be provided by doctor or pharmacist.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINE
There is no evidence from post marketing data for an effect on the ability to drive and use machines.
Studies on the effects on the ability to drive and use machines have not been performed.

PRESENTATION
Blister of 10 tablets. Box of 10 blisters, 50 blisters, 100 blisters

STORAGE CONDITION
Store below 30°C

SHELF LIFE
The expiry date of this pack is printed on the box. Do not use this pack after this date.

PRODUCT REGISTRATION HOLDER
Medicinspire Global Sdn Bhd
B-5-28, Ativo Plaza, No.1, Jalan PJU 9/1, Damansara Avenue, Bandar Sri Damansara, 52200 Kuala Lumpur, Malaysia

MANUFACTURED BY:
Saga Lifesciences Limited:
Survey No. 198/2 & 198/3, Chachrawadi Vasna, Tal.: Sanand, Dist.: Ahmedabad 382210 India

MAL26056040X
Date of Revision: 29 June 2026
Artwork No.: 52875I01-00