



Ambroxol HCl

Zobrixol®

30mg Tablet
 30mg/5mL DS (Syrup)
 15mg/5mL (Syrup)
 6mg/mL (Syrup Oral Drops)
Mucolytic

Description of the Product

Ambroxol HCl (Zobrixol) 30mg tablet is white to off-white, round, plain on both sides, uncoated tablet.

Ambroxol HCl (Zobrixol) 30mg/5mL DS (Syrup) is colorless to yellowish syrup with raspberry/peppermint flavor.

Ambroxol HCl (Zobrixol) 15mg/5mL (Syrup) is colorless syrup with raspberry alcoholic typical odor and sweet taste.

Ambroxol HCl (Zobrixol) 6mg/ml (Syrup Oral drops) is colorless to yellowish syrup with raspberry/peppermint flavor.

What is in the Medicine?

This medicine contains Ambroxol, which stimulates respiratory fluid secretion, resulting to a less sticky mucus. Ambroxol makes the mucus/ phlegm easier to cough out and breathing is eased considerably.

Strength of the Medicine

Each Zobrixol tablet contains	
Ambroxol hydrochloride.....	30mg
Each 5mL Zobrixol DS contains	
Ambroxol hydrochloride	30mg
Each 5mL Zobrixol Syrup contains	
Ambroxol hydrochloride	15mg
Each mL Zobrixol Syrup Oral drops contains	
Ambroxol hydrochloride	6mg

What is this Medicine used for?

This medicine is used for the relief of cough caused by acute and chronic disorder of the respiratory tract accompanied with thick and sticky mucus such as acute and chronic bronchitis, asthmatoïd bronchitis and bronchial asthma.

How much and how often should you use this Medicine?

Tablet (30mg)

Children 6-12 yrs: ½ tablet 2-3 times daily

Adults & children over 12 years: 1 tablet thrice a day for the first 2-3 days and then 1 tablet twice daily or ½ tablet thrice daily.

Double Strength (DS) syrup (30mg/5mL)

Children 6-12 years: 2.5mL 2-3 times a day.

Adults & children over 12 years: 5mL thrice a day for 2-3 days, then 5mL twice daily or 2.5mL thrice a day.

Syrup (15mg/5mL)

Children under 2 years: 2.5mL twice a day

Children 2-5 years: 2.5mL thrice a day

Children 6-12 years: 5mL 2-3 times a day

Adults & children over 12 years: 10mL thrice daily during the first 2-3 days, then 10mL twice daily or 5mL thrice daily.

Syrup Oral drops (6mg/mL)

Children 6 months and under: 0.5mL twice a day

Children 7-12 months: 1mL twice a day

Children 13-24 months: 1.25mL twice a day

When should you not take this Medicine?

If you are allergic to any component in the product.

Care that should be taken when taking this Medicine?

Do not take more than the recommended dose.

Consult a physician if any adverse effect occurs.

Not recommended during the first three month of pregnancy.

Do not use after expiry date.

Undesirable Effects of this Medicine

Ambroxol is generally well tolerated. Gastro-intestinal disturbances (diarrhea, nausea, vomiting), transient rise in serum aminotransferase. In rare cases weakness, headache and skin rash.

What other Medicine or food should be avoided while taking this Medicine?

Ambroxol HCl (Zobrixol) should not be taken simultaneously with antitussive (e.g codeine), because it could lead to non-expectoration of phlegm or mucus previously liquified by Zobrixol.

What should you do if you miss a dose?

If you miss a dose, just take the dose if still needed and subsequent doses at the usual recommended schedule. Do not exceed recommended dose.

Signs and Symptoms of Overdose

Symptoms of Ambroxol overdose include extension of undesirable effects such as Gastro-intestinal disturbances (diarrhea, nausea, vomiting) and skin rashes.

What to do when you have taken more than the recommended dosage?

If you have taken more than the recommended dosage, consult a physician.

How should you keep this Medicine?

Store at temperatures not exceeding 30°C. Keep out of reach of children.

When should you consult your doctor?

If symptoms persist and if any undesirable effects occur.

Availability

30mg tablet: Blister Pack x 10's (Box of 100's)

30mg/5mL DS Syrup: Amber Bottle of 60mL

15mg/5mL Syrup: Amber Glass Bottle of 60mL

6mg/mL Syrup Oral drops: Amber Bottle of 15mL

Manufactured for

Natrapharm Inc.

The Patriot Building Km 18, West Service Road SLEX, Sucat, Paranaque City.

Name and Address of Manufacturer

Hizon Laboratories Inc.

Assumption Road Sumulong Highway, Antipolo City

ADR Reporting Statement

"For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph"

Registration Number:

30mg tablet: DR-XY5348

30mg/5mL DS syrup: DR-XY17160

15mg/5mL Syrup: DR-XY5346

6mg/mL Syrup Oral Drops: DR-XY17093

Date of First Authorization:

30mg tablet: July 1992

30mg/5mL DS Syrup: December 1993

15mg/5mL Syrup: September 1992

6mg/mL Syrup Oral Drops: December 1993

Date of Revision of Patient Information Leaflet

June 2021