AMXOL TABLETS/SYRUP

Ambroxol Hydrochloride (30mg, 30mg/5ml)

What is in this leaflet

- 1. What AMXOL is used for
- 2. How AMXOL works
- 3. Before you use AMXOL
- 4. How to use AMXOL
- 5. While you are using it
- 6. Side effects
- 7. Storage and Disposal of AMXOL
- 8. Product Description
- 9. Manufacturer and Product Registration Holder
- 10. Date of revision

What AMXOL is used for

AMXOL is used in respiratory tract diseases especially during inflammation and asthma.

How AMXOL works

AMXOL contains medicine called ambroxol hydrochloride. It makes the mucus less viscous and thus facilitates it expectoration.

Before you use AMXOL

- When you must not use it

Do not use AMXOL and tell your doctor if:

- You are allergic (hypersensitive) to ambroxol or any of the other ingredients of AMXOL.
- you are in first trimester of pregnancy.

Pregnancy and lactation

Do not take AMXOL if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take AMXOL if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

 Read this entire leaflet carefully before you start taking the medicine.

- Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

How to use AMXOL

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

<u>AMXOL TABLETS:</u> Adults and children over 6 years: 1 tablet three times daily at the beginning of treatment.

AMXOL SYRUP:

Adults: 1 teaspoonful (30 mg), 3 times daily.

Children over 5 years: ½ teaspoonful (15 mg), 2-3 times daily.

Children 2 to 5 years: ¹/₄ teaspoonful (7.5 mg), 3 times daily.

The daily dose may be increased or doubled if necessary. The dosage recommendations for children are based on a daily dose of 1.2 to 1.6 mg of Ambroxol per kg body weight.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking AMXOL for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking AMXOL.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give AMXOL to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

AMXOL syrup contains sodium metabisulfite.

Ingestion may result in gastric irritation, while ingestion of large amounts of sodium metabisulfite can cause gastro-intestinal upsets, blood flow problems and central nervous system disturbances.

Treatment with AMXOL will expect an increase in the flow of secretions.

Side effects

Like all medicines, AMXOL can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Occasional gastrointestinal side effect may occur but these are almost invariably mild.

AMXOL may cause severe allergy and serious skin reactions. Stop using AMXOL and seek medical assistance immediately if you experience any of the following symptoms:

- Severe allergy: breathing difficulties, light headedness, skin swellings or rash
- · Severe skin reaction: skin reddening, blisters, rash, fever, sore throat or eye irritation

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website

<u>npra.moh.gov.my</u> (Public-> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)

Storage and Disposal of AMXOL

- Storage

Keep out of the reach and sight of children.

Store in a dry place at temperature not exceeding 30°C. Protect from light and excessive heat.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like
- AMXOL TABLETS: Round, flat, white, bisected on one face and impressed Biolab's logo on the obverse.
- <u>AMXOL SYRUP</u>: A clear colorless pear-flavored solution.

- Ingredients

- Active ingredient
- <u>AMXOL TABLETS:</u>

Ambroxol Hydrochloride 30 mg/tablet

• AMXOL SYRUP:

Ambroxol Hydrochloride 30 mg / 5mL

- Inactive ingredients
- AMXOL TABLETS: Lactose, Tapioca Starch, Purified water, Docusate sodium, Povidone, Sodium starch glycolate and Magnesium stearate.
- AMXOL SYRUP: Menthol, Sodium citrate dihydrate, Citric acid monohydrate, Glycerin, Methylparaben, Pearade flavor, Sorbitol solution 70%, Edetate sodium, Sodium metabisulfite and Purified water.

- MAL numbers:

• AMXOL TABLETS: MAL19911700X

AMXOL SYRUP: MAL19911701X

Manufacturer

Biolab Co. Ltd 625 Soi, 7A ,Bangpoo Industrial Estate, Samutprakarn 10280, Thailand

Product Registration Holder

Medispec (M) Sdn Bhd No. 55 & 57, Lorong Sempadan 2, (Off Boundary Road), 11400 Ayer Itam, Penang, Malaysia.

Date of revision

2.3.2018

Serial Number:

NPRA(R4/1)170118/00017