# **MUCONIL ORAL LIQUID 30MG/5ML**

Ambroxol Hydrochloride (30mg/5ml)

#### What is in this leaflet?

- What MUCONIL is used for?
- 2. How MUCONIL works?
- 3. Before you use MUCONIL
- 4. How to use MUCONIL
- 5. While you are using MUCONIL
- 6. Side effects
- Storage and Disposal of MUCONIL
- 8. Product description
- 9. Manufacturer and Product Registration Holder
- 10. Date of Revision

This leaflet answers some common questions about MUCONIL. It does not contain all the available information. It does not take the place of talking to your pharmacist or doctor.

All medicines have risks and benefits. Your pharmacist or doctor has weighed the risks of you taking MUCONIL against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your pharmacist or doctor.

Keep this leaflet with the medicine.

You may need to read it again.

### What MUCONIL is used for?

MUCONIL is used in conditions where there are a lot of thick secretions or mucus in your air passages.

#### How MUCONIL works?

MUCONIL contains ambroxol hydrochloride, which helps to clear the chest by thinning the mucus in your air passage.

#### Before you use MUCONIL

#### When you must not use it

Do not take MUCONIL if you are allergic to ambroxol or to any of the other ingredients in MUCONIL.

If this applies to you talk to your pharmacist.

Do not take MUCONIL if you have hereditary fructose intolerance.

#### Before you start to use it

Tell your pharmacist or doctor if you have:

- Liver problems
- Kidney problems

### Taking other medicines

Taking of Muconil together with antibiotics (amoxicillin, cefuroxime, erythromycin, doxycycline) drives to higher antibiotic concentration in the lung tissue.

It is important to tell your doctor or pharmacist if you are taking any other medicines, obtained with or without a doctor's prescription.

#### How to use MUCONIL

## How much to use

Adult and children over 12 years: 10ml (2 teaspoons) 2 times daily.

For children under 12 years the following dosage regimen is recommended.

Children 6-12 years: 5ml (1 teaspoon) 2-3 times daily.

Children 2-6 years: 2.5ml (1/2 teaspoon) 3 times daily.

Children 1-2 years: 2.5ml (1/2 teaspoon) 2 times daily.

MUCONIL is not recommended for children under 2 years old without medical advice.

Dosage recommendation should be provided by your doctor or pharmacist.

#### When to use it

MUCONIL should be taken at mealtimes.

#### How long to use it

Medical advice should be sought if the symptoms last longer than 14 days and/or if the symptoms increase in spite of treatment with MUCONIL.

#### If you forget to use it

If you forget to take a dose, you should take one as soon as you remember, but wait at least 24 hours before taking the next dose.

If you have any other questions about taking this medicine, ask your pharmacist.

## If you use too much (overdose)

Seek medical advice if you have taken more than the recommended or prescribed dose of MUCONIL.

# While you are using MUCONIL $\,$

#### Things you must do

If you are about to start taking on any other medicine, tell your pharmacist or doctor that you are using MUCONIL.

Ask for your doctor's advice if you are pregnant, or likely to become pregnant during your course of medication. The use of MUCONIL in the first trimester is not recommended.

Ask for your doctor's advice if you are breastfeeding, or likely to breastfeed during your course of medication.

Ambroxol hydrochloride is excreted in breast milk. MUCONIL is not recommended for use in nursing mothers.

The benefits of MUCONIL must be assessed against possible effects on your child.

#### Things you must not do

Do not take MUCONIL to treat any other complaints unless your doctor tell you to.

#### Things to be careful of

If new skin or mouth lesion happens, seek medical advice immediately.

If you have impaired renal (kidney) function, consult your doctor before taking MUCONIL.

#### **Side effects**

Ask for the advice of your doctor or pharmacist if you have any concerns about the effects of taking MUCONIL.

Occasionally, MUCONIL may cause side effects on:

- gastrointestinal tract (nausea, vomiting, diarrhea)
- respiratory system (dry mouth and dry throat)
- nervous system
- immune system
- skin and subcutaneous tissue (rash)

In very rare cases, severe skin disorders such as Stevens-Johnson syndrome and Lyell's syndrome reported have been administration of Muconil, which in most cases could be explained by the underlying disease or the concomitant medication. If new skin or mouth lesion occur, medical advice should he sought immediately and treatment with Muconil discontinued as precaution.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public  $\rightarrow$ Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety.)

# Storage and Disposal of MUCONIL

#### Storage

Store below 30°C. Keep out of reach of children.

## **Disposal**

Dispose the medication after expiry date. Consult your pharmacist on the safety disposal of any medicines no longer required.

## **Product description**

#### What it looks like

MUCONIL is a clear orange coloured liquid with orange flavour, available in 90ml PET plastic bottle.

#### **Ingredients**

Active ingredient: Each 5ml contains 30mg of Ambroxol Hydrochloride.

Inactive ingredients:
Sodium Benzoate, Glycerin, Sodium citrate, Citric acid anhydrous, Sucralose, Sunset Yellow FCF, Orange flavour, Disodium edentate, Vanillin, Gamma-Cyclodextrin and Purified Water.

#### MAL number: MAL13095083X

## Manufacturer and Product Registration Holder

#### Manufacturer

HOE Pharmaceuticals Sdn. Bhd. Lot 10, Jalan Sultan Mohamed 6, Bandar Sultan Suleiman, 42000 Port Klang, Selangor, MALAYSIA.

## <u>Product Registration Holder</u>

HOE Pharmaceuticals Sdn. Bhd. Lot 10, Jalan Sultan Mohamed 6, Bandar Sultan Suleiman, 42000 Port Klang, Selangor, MALAYSIA.

**Date of revision** 06/03/2017

Serial Number BPFK(R4/1)060317/00011