Mucosolvan®
30mg/5ml Liquid
ambroxol hydrochloride

(a) Active Ingredients

Each 5ml of Mucosolvan Liquid contains ambroxol hydrochloride 30mg.

(b) Inactive Ingredients

Mucosolvan Liquid also contains hydroxyethylcellulose, sorbitol solution 70%, glycerol 85%, saccharin sodium dihydrate, apricot flavour, orange essence natural, levomenthol, benzoic acid, propylene glycol and water purified.

(c) What Mucosolvan is used for

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

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

(d) Taking Mucosolvan

The recommended dose for adults and children are stated below:

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

For children under 12 years the following dosage regimen is recommended depending on severity of the disease.

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

Children 2-6 years:
2.5 ml (½ teaspoon) 3 times daily.

Mucosolvan should be taken at mealtimes.

Mucosolvan is not recommended for children under 2 years of age without medical advice.

The use of Mucosolvan without medical supervision is not intended in patients who suffer from such condition chronically.

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

(e) Warnings

- When you must not take Mucosolvan

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

If you are not sure if you have these allergies, you should raise those concerns with your doctor or pharmacist.

You should not use Mucosolvan after the EXPIRY DATE on the carton or container.

Mucosolvan Liquid contains sorbitol. If you have rare hereditary fructose intolerance, you should not take this medicine.

In very rare cases, severe skin disorders such as Stevens-Johnson's syndrome and Lyell's syndrome have been reported after administration of mucolytic substances (e.g. ambroxol), which in most cases could be explained by the underlying disease or the concomitant medication. If new skin or mucosal lesions occur, medical advice should be sought immediately and treatment with ambroxol discontinued as a precaution.

- Before you start to take Mucosolvan

Before taking Mucosolvan, you must tell your doctor or pharmacist if you have, or have had, any of the following conditions:

- Liver problems,
- Kidney problems.

If you are not sure if you have, or have had, any of these conditions, you should raise those concerns with your doctor or pharmacist.

Before using Mucosolvan, it is important to tell your doctor or pharmacist if you are taking any other medicines, obtained with or without a doctor’s prescription.

Mucosolvan may increase the amount of antibiotic penetration. Antibiotics are medicines used to treat infections.

- Side effects

You should be aware that all medicines carry some risks and that all possible risks may not be known at this stage despite thorough testing.
Ask for the advice of your doctor or pharmacist if you have any concerns about the effects of taking Mucosolvan.

Occasional, mild side effects from Mucosolvan include:

- Nausea,
- Diarrhoea,
- Indigestion
- Vomitting
- Heartburn
- A feeling of fullness in the stomach (a bloated feeling).

Very rarely serious allergic reactions have occurred with the use of Mucosolvan. Symptoms of allergic reactions may include:

- Skin rashes,
- Difficulty in breathing
- Swelling of the face, lips, mouth, tongue or throat which may cause difficulty swallowing or breathing.

Tell your doctor or pharmacist as soon as possible if you experience any side effects during or after taking Mucosolvan, so that these may be properly treated.

In addition, unexpected effects, not listed above, can occur with any medicine.

You should tell your doctor or pharmacist if you notice anything unusual, during or after taking Mucosolvan.

• **Pregnancy**

Ask for your doctor’s advice if you are pregnant, or likely to become pregnant during your course of medication.

The use of Mucosolvan in the first trimester is not recommended.

• **Breastfeeding**

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

Ambroxol is excreted in breast milk. Therefore, Mucosolvan is not recommended for use in nursing mothers.

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

• **If you have taken too much Mucosolvan**

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

Advice can be provided by a doctor or pharmacist.

(f) **Storage condition**

Mucosolvan should be kept in a dry place where the temperature stays below 30°C.

Keep out of the reach of children.

Please refer to packaging for information on shelf-life

Manufactured by Delpharm Reims Reims, France for Boehringer Ingelheim International GmbH Ingelheim am Rhein Germany