

MUCOSOLVAN[®] LIQUID 30MG/5ML

Ambroxol hydrochloride (30mg/5ml)

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What MUCOSOLVAN LIQUID 30MG/5ML is used for

MUCOSOLVAN LIQUID 30MG/5ML is used to thin the mucus in acute and chronic bronchial and lung diseases where thick and tenacious mucus is a problem.

How MUCOSOLVAN LIQUID 30MG/5ML works

Mucosolvan contains a medicine called ambroxol which helps to make the mucus thinner, activates the cilia to get rid of mucus faster, and stimulates release of a fluid (surfactant) to protect the lungs.

MUCOSOLVAN LIQUID 30MG/5ML works in two ways, firstly by relieving irritation in the throat (the milk and honey effect) and secondly by thinning sticky, tenacious mucus in the bronchial passages.

Before you use MUCOSOLVAN LIQUID 30MG/5ML

- When you must not use it

Do not use Mucosolvan if you are allergic to ambroxol hydrochloride 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.

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

In very few cases, severe skin disorders have been reported after administration of mucolytic substances (e.g. ambroxol hydrochloride). Therefore if new skin or mucosal lesions occur, medical advice should be sought immediately and treatment with ambroxol hydrochloride discontinued as a precaution.

If you have any kidney or liver problems, check with your doctor before taking this medicine.

• **Pregnancy**

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

Ask your doctor or pharmacist for advice if you are pregnant, or likely to become pregnant while taking this medication.

• **Breastfeeding**

Mucosolvan is not recommended for use in nursing mothers.

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

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

• **Fertility**

Studies on animals have produced no evidence of any harmful effects on fertility.

- Before you start use it

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.

Mucosolvan Liquid contain benzoic acid which may increase jaundice (yellowing of the skin and eyes) in new-born babies (up to 4 weeks old).

Mucosolvan Liquid contain propylene glycol. In babies under 4 weeks of age this medicine should be used with caution; in particular if the baby is given other medicines that contain propylene glycol or alcohol.

- Taking other medicines

Before using Mucosolvan, it is important to tell your doctor or pharmacist if you are taking, have recently taken or might take 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.

Ambroxol/antitussives

Simultaneous use of Mucosolvan and cough suppressants (antitussives) may lead to the development of a dangerous accumulation of secretion in patients with respiratory illnesses that are associated with an increased formation of mucus, such as cystic fibrosis or bronchiectasis, due to reduction of the cough reflex.

How to use MUCOSOLVAN LIQUID 30MG/5ML

- How much to use

Always take this medicine exactly as described in this leaflet or as your

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doctor or pharmacist has told you.
Check with your doctor or pharmacist if you are not sure.

Children from 1 to 2 years of age:
2.5ml of solution should be taken two times daily.

Children from 2 to 5 years of age:
2.5ml of solution should be taken three times daily.

Children from 6 to 12 years of age:
5ml of solution should be taken two to three times daily.

Adults and adolescents from 12 years of age:
10ml of solution should be taken two times daily.
This dosage is for first 14 days; the dosage may be halved after 14 days.

Dosage scheme	Daily dose
1 – 2 years	2 x 2.5ml
2 – 5 years	3 x 2.5ml
6 – 12 years	2-3 x 2.5ml
From 12 years	2 x 10 ml

MUCOSOLVAN LIQUID 30MG/5ML can be taken with or without food and is dispensed with the aid of the measuring cup provided.

Please clean the measuring cup after each use by rinsing with warm water.

- When to use it

Use as directed by your doctor or pharmacist

- How long to use it

You must talk to a doctor if you feel worse or if you do not feel better after 4 -5 days.

If you feel that the effect of MUCOSOLVAN LIQUID 30MG/5ML is too strong or too weak, talk to your doctor or pharmacist.

If you stop treatment early, your symptoms may get worse.

- If you forget to use it

If you forget to take MUCOSOLVAN LIQUID 30MG/5ML or take too small a dose, wait until it is time to take your next dose and then continue taking MUCOSOLVAN LIQUID 30MG/5ML as described in the dosage instructions above.

- If you use too much (overdose)

Seek medical advice if you have taken more than the recommended dose of Mucosolvan. You may need symptomatic treatment.

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 MUCOSOLVAN LIQUID 30MG/5ML.

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.

Do not give MUCOSOLVAN LIQUID 30MG/5ML to anyone else, even if they have the same symptoms or condition as you.

MUCOSOLVAN LIQUID 30MG/5ML must not be used in children under 2 years of age except on medical advice.

- Things to be careful of

Driving and using machines
There is no evidence that MUCOSOLVAN LIQUID

30MG/5ML has any effect on the ability to drive and use machines.

Side effects

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

Common side effects ($\geq 1/100$ to $< 1/10$)

- Dysgeusia (e.g. changed taste)
- Nausea
- Oral and throat numbness

Uncommon side effects ($\geq 1/1000$ to $< 1/100$)

- Vomiting
- Diarrhoea
- Dyspepsia
- Abdominal pain
- Dry mouth
- Fever
- Mucous membrane reactions

Rare side effects ($\geq 1/10000$ to $< 1/1000$)

- Hypersensitive reaction (Rash, Urticaria)
- Dry throat

Frequency not known (frequency cannot be estimated from the available data)

- Anaphylactic reactions including anaphylactic shock, angioedema and pruritus
- Shortness of breath (as a symptom of a hypersensitivity reaction)

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

At the first signs of a hypersensitivity reaction, stop taking MUCOSOLVAN LIQUID 30MG/5ML.

MUCOSOLVAN LIQUID 30MG/5ML may cause severe allergy and serious skin reactions. Stop using MUCOSOLVAN LIQUID 30MG/5ML and seek medical assistance immediately if you

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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

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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of MUCOSOLVAN LIQUID 30MG/5ML

- Storage

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

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Keep out of the reach of children.

- 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

MUCOSOLVAN LIQUID

30MG/5ML is colourless liquid with a fruity odour.

MUCOSOLVAN LIQUID

30MG/5ML is available in packs containing 100 ml and 250 ml.

- Ingredients

- Active ingredient(s)

Each 5ml of solution contains 30mg of ambroxol hydrochloride.

- Inactive ingredient(s)

MUCOSOLVAN LIQUID

30MG/5ML also contains benzoic acid, hydroxyethylcellulose, sucralose, flavouring agents (containing propylene glycol), purified water.

- MAL number:

MAL19987339XC

Manufacturer

Delpharm Reims

10 Rue Colonel Charbonneaux 51100

Reims, France

Product Registration Holder

DKSH Malaysia Sdn Bhd

B-11-01, The Ascent, Paradigm

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