

MUCOSOLVAN® 24 Hours

Consumer Medication Information Leaflet (RiMUP)

Ambroxol hydrochloride (75mg)

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What MUCOSOLVAN 24 Hours is used for

MUCOSOLVAN 24 Hours is used to thin the mucus in acute and chronic bronchial and lung diseases where thick and tenacious mucus is a problem.

How MUCOSOLVAN 24 Hours 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.

Before you use MUCOSOLVAN 24 Hours

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

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 problems, check with your doctor before taking this medicine.

In some rare lung diseases which are associated with excessive accumulation of secretions (e.g. primary ciliary dyskinesia), MUCOSOLVAN 24 Hours should only be used under medical supervision because of the risk that secretions may accumulate.

• **Pregnancy**

The use of Mucosolvan in the first trimester is not recommended. Ask for your doctor's 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 do not indicate direct or indirect harmful effects with respect to 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.

- Taking other medicines

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. Mucosolvan may cause mucus build-up if taken together with cough suppressants, especially in people with lung conditions.

How to use MUCOSOLVAN 24 Hours

- How much to use

Always take this medicine exactly as described in this leaflet. Check with your doctor or pharmacist if you are not sure.

The recommended dose for adults and adolescents from 12 years of age is 1 capsule once daily.

The capsules should not be opened or chewed, but swallowed whole with ample liquid. The "carrier pellets" which are occasionally present in the stools have released the active substance during their passage through the digestive system and are therefore without significance.

Mucosolvan can be taken with or without food.

- 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 24 Hours is too strong or too weak, talk to your

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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 24 Hours or take too small a dose, wait until it is time to take your next dose and then continue taking MUCOSOLVAN 24 Hours 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 24 Hours

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 24 Hours to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of
Driving and using
machines

There is no evidence that MUCOSOLVAN 24 Hours has any effect on the ability to drive and use machines.

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 24 Hours include:

- Nausea,
- Diarrhoea,
- Dyspepsia (e.g. indigestion, bloated feeling)
- Vomiting
- Abdominal pain

Hypersensitivity has occurred with the use of Mucosolvan. Symptoms of hypersensitivity may include:

- Rash
- Pruritus
- Urticaria
- Anaphylactic shock
- Swelling

At the first signs of a hypersensitivity reaction, stop taking MUCOSOLVAN 24 Hours

MUCOSOLVAN 24 Hours may cause severe allergy and serious skin reactions. Stop using MUCOSOLVAN 24 Hours 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

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 by visiting the website nptra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of MUCOSOLVAN 24 Hours

- Storage

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.

- 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.

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Product Description

- What it looks like

- Oblong hard capsules consisting of a red opaque cap and an orange opaque body; the cap is printed with 'MUC 01' in white.

Capsule contents:

Round, yellowish-white pellets with a smooth, shiny surface, mixed with a small quantity of powder.

- Ingredients

- Active ingredient(s)
 - Each sustained release capsule contains 75mg ambroxol hydrochloride .

- Inactive ingredient(s)
MUCOSOLVAN 24 Hours also contains :

Capsule contents :

Crospovidone , carnauba wax, stearyl alcohol, magnesium stearate

Capsule shell :

Gelatin, purified water, titanium dioxide (E 171), iron oxides (E 172)

Capsule printing :

Shellac, titanium dioxide (E 171)

- MAL number:

MAL07050193XCR

Manufacturer

Sanofi Winthrop Industrie 196 Rue du
Maréchal Juin 45200 Amilly
France

Product Registration Holder

DKSH Malaysia Sdn Bhd
B-11-01, The Ascent, Paradigm, No.
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Date of revision

30/09/2025 (Based on German PIL Mar 2020)

Serial Number

NPRA(R2/1)230823/1128