

MUCOSOLVAN[®] TABLET 30MG

Ambroxol hydrochloride (30mg)

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What MUCOSOLVAN TABLET 30MG is used for

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

How MUCOSOLVAN TABLET 30MG 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 TABLET 30MG

- When you must not use it

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

this medicine (listed in Inactive ingredient(s)).

CHECK WITH YOUR DOCTOR OR PHARMACIST IF YOU ARE NOT SURE.

- Before you start to use it

Warnings and precautions

There have been reports of serious skin reactions associated with the administration of ambroxol hydrochloride. If a rash appears on your skin (including mucosal lesions, such as around the mouth, throat, nose, eyes and genitals), stop using MUCOSOLVAN TABLET 30MG and contact your doctor immediately.

If you have renal impairment or severe liver disease, do not take MUCOSOLVAN TABLET 30MG without seeking the opinion of your doctor.

Precautions for use

Combining antitussives or medicines that dry up bronchial secretions with this medicine is not recommended.

In acute bronchial indications, medical advice should be sought if symptoms do not improve or worsen over the course of therapy.

CHECK WITH YOUR DOCTOR OR PHARMACIST IF YOU ARE NOT SURE

Children and adolescents

Not applicable.

- Taking other medicines

Other medicines and MUCOSOLVAN TABLET 30MG

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

MUCOSOLVAN TABLET 30MG with food and drink

Not applicable.

MUCOSOLVAN TABLET 30MG contain lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Pregnancy, breast-feeding and fertility

This medicine should preferably not be used during pregnancy and breast-feeding.

If you discover that you are pregnant during treatment, talk to your doctor because only he/she can decide whether it is necessary to continue this treatment.

Ask your doctor or pharmacist for advice before taking any medicine.

How to use MUCOSOLVAN TABLET 30MG

- How much to use

Always take this medicine exactly as described in this leaflet. Check

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with your doctor or pharmacist if you are not sure.

The recommended dose for adults and adolescents over 12 years of age is 1 tablet 3 times daily. For better effect, you may administer 2 tablets 2 times daily. The tablets should be taken with liquid.

Mucosolvan can be taken with or without food and should be swallowed whole with plenty of liquid.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

You should contact a doctor if your symptoms worsen or do not improve after 4-5 days.

If you feel that the effect of MUCOSOLVAN TABLET 30MG 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 TABLET 30MG or take too small a dose, wait until it is time to take your next dose and then continue taking MUCOSOLVAN TABLET 30MG 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 TABLET 30MG.

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 TABLET 30MG to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

Postmarketing surveillance revealed no effects on the ability to drive and use machines with Mucosolvan.

Studies on the effects on the ability to drive and use machines have not been performed.

Side effects

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

- 1) severe allergy: breathing difficulties, light headedness, skin swellings or rash
- 2) severe skin reaction: skin reddening, blisters, rash, fever, sore throat or eye irritation

Rare: may occur in up to 1 in 1 000 people

Hypersensitivity reactions
Rash, hives

Very rare: may occur in up to 1 in 10 000 people

Headache, dizziness.

Not known (cannot be estimated from the available data)

Anaphylactic reactions including anaphylactic shock, angioedema (rapid swelling of the skin, subcutaneous tissue, mucosa or submucosal tissue) and pruritus. Severe skin reactions (including erythema multiforme, Stevens-Johnson syndrome/toxic epidermal necrolysis and acute generalised exanthematous pustulosis). If these reactions occur, treatment must absolutely be discontinued.

Other side effects may occur:

Common (less than 1 in 10 patients treated, but more than 1 in 100 patients treated)

- feeling sick (nausea)

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Uncommon (less than 1 in 100 patients treated, but more than 1 in 1 000 patients treated)

- diarrhoea,
- vomiting,
- indigestion (dyspepsia),
- tummy ache.

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

Storage and Disposal of MUCOSOLVAN TABLET 30MG

- Storage

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

Keep this medicine out of the sight and reach of children.

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

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.

- What it looks like

MUCOSOLVAN TABLET 30MG are round, white tablets, both faces flat, with bevelled edges; one face is scored and impressed with “67C” above and below the score; the other face is blank.

- Ingredients

- Active ingredient(s)
Each Mucosolvan tablet contains ambroxol hydrochloride 30mg.
- Inactive ingredient(s)

Mucosolvan tablet also contains lactose monohydrate, maize starch dried, colloidal anhydrous silica, magnesium stearate, and purified water.

- MAL number:

MAL06071101XC

Manufacturer

Delpharm Reims
10 rue Colonel Charbonneaux
Reims 51100, France

Product Registration Holder

DKSH Malaysia Sdn Bhd
B-11-01, The Ascent, Paradigm,
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Product Description