

PACKAGE LEAFLET: INFORMATION FOR THE USER

Mucosolvan®
tablets 30 mg



Tablets for oral use

For use in adults and children over 6 years of age

Active substance: Ambroxol hydrochloride
30 mg / tablet

Read all of this leaflet carefully because it contains important information for you.

- . Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after 4 - 5 days.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What MUCOSOLVAN tablets 30 mg are and what they are used for
2. Before you take MUCOSOLVAN tablets 30 mg
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6. Further information

1. What MUCOSOLVAN tablets 30 mg are and what they are used for

MUCOSOLVAN tablets 30 mg contain an expectorant which is used to thin the mucus in acute and chronic bronchial and lung diseases where thick, tenacious mucus is a problem.

2. Before you take MUCOSOLVAN tablets 30 mg

Do not take MUCOSOLVAN tablets 30 mg:

- if you are hypersensitive (allergic) to the active substance (ambroxol hydrochloride) or to any of the other ingredients of MUCOSOLVAN tablets 30 mg.

Take special care with MUCOSOLVAN tablets 30 mg

In a very small number of cases, there have been reports of severe skin reactions such as Stevens-Johnson syndrome and toxic epidermal necrolysis (TEN) occurring in temporal association with the use of expectorants such as ambroxol hydrochloride. Most of these cases were attributable to the underlying disease and/or to other medication being taken concomitantly. In addition, during the early phase of Stevens-Johnson syndrome or TEN, patients may initially experience non-specific influenza-like symptoms such as fever, joint pain, rhinitis, cough and sore throat. Because of these non-specific in-

fluenza-like initial symptoms, symptomatic treatment with cough and cold medications, which is inappropriate, may be started. If new skin or mucosal lesions appear, therefore, medical advice should be sought immediately and the use of ambroxol hydrochloride discontinued.

Patients with impaired kidney or liver function

If you have impaired kidney function or severe liver disease, you must not take MUCOSOLVAN tablets 30 mg except on medical advice. With ambroxol, as with any medicine which is broken down in the liver and then eliminated via the kidneys, accumulation of the breakdown products which are formed in the liver can be expected to occur in patients with severely impaired kidney function.

In some rare bronchial diseases which are associated with excessive accumulation of secretions (such as primary ciliary dyskinesia), MUCOSOLVAN tablets 30 mg should only be used under medical supervision because of the risk that secretions may accumulate.

Use in children

MUCOSOLVAN tablets 30 mg are not suitable for children under 6 years of age on account of their strength. MUCOSOLVAN syrup 30 mg/5 ml is available for use in children under 6 years of age.

Taking other medicines

Please tell your doctor or pharmacist if you are taking/using or have recently taken/used any other medicines, including medicines obtained without a prescription.

Ambroxol and cough suppressants

Simultaneous use of MUCOSOLVAN tablets 30 mg and cough suppressants may lead to the development of a dangerous accumulation of secretions owing to reduction of the cough reflex and should be undertaken only after careful risk-benefit assessment.

Pregnancy and lactation

Pregnancy

Ambroxol passes through the placenta to the unborn child. You should not take this medicine while you are pregnant, especially during the first 3 months.

Breast-feeding

Ambroxol has been shown to pass into breast milk in animal studies. Use while breast-feeding is not recommended.

Driving and using machines

There is no evidence of any effect on the ability to drive or use machines. No relevant studies have been performed.

Important information about some of the ingredients of MUCOSOLVAN tablets 30 mg

This medicine contains lactose. If you have been told that you have an intolerance to some sugars, please consult your doctor before taking MUCOSOLVAN tablets 30 mg.

3. How to take MUCOSOLVAN tablets 30 mg

Always take MUCOSOLVAN tablets 30 mg exactly as described in this package leaflet. You should check with your doctor or pharmacist if you are not sure.

Unless otherwise prescribed by the doctor, the recommended dose is as follows:

Children from 6 to 12 years of age:

The usual dose is ½ a tablet 2 - 3 times daily (equivalent to 2 - 3 x 15 mg ambroxol hydrochloride per day).

Adults and adolescents over 12 years of age:

The usual dose is 1 tablet 3 times daily (equivalent to 3 x 30 mg ambroxol hydrochloride per day) for the first 2 - 3 days and 1 tablet twice daily (equivalent to 2 x 30 mg ambroxol hydrochloride per day) thereafter.

For adults and adolescents over 12 years of age, the therapeutic effect may be enhanced by increasing the dose to 2 tablets twice daily (equivalent to 120 mg ambroxol hydrochloride per day).

Method and duration of administration

MUCOSOVAN tablets 30 mg are for oral use.

MUCOSOLVAN tablets 30 mg can be taken with or without food and should be swallowed whole with plenty of liquid (e.g. water, tea or fruit juice).

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 tablets 30 mg is too strong or too weak, talk to your doctor or pharmacist.

If you take more MUCOSOLVAN tablets 30 mg than you should

No specific symptoms of overdose have been reported to date. The symptoms observed in cases of accidental overdose or medication error are consistent with the side effects which may occur at recommended doses (see section 4). In case of overdose, please consult a doctor as symptomatic treatment may be required.

If you forget to take MUCOSOLVAN tablets 30 mg

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

If you stop taking MUCOSOLVAN tablets 30 mg

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

4. Possible side effects

Like all medicines, MUCOSOLVAN tablets 30 mg can have side effects although not everybody gets them.

The following categories are normally used when reporting the frequencies of side effects:

Very common:	More than 1 in 10 patients
Common:	Between 1 in 10 and 1 in 100 patients
Uncommon:	Between 1 in 100 and 1 in 1000 patients
Rare:	Between 1 in 1000 and 1 in 10,000 patients

Very rare:	Fewer than 1 in 10,000 patients
Not known:	Frequency cannot be estimated from the available data

Side effects

Immune system disorders / Skin and subcutaneous tissue disorders

Rare:	Skin rash, urticaria (nettle rash)
Not known:	Swelling of the skin and mucous membranes, itching, anaphylactic reactions (severe allergic reactions) including shock, other hypersensitivity reactions

Gastrointestinal disorders

Common:	Nausea
Uncommon:	Vomiting, diarrhoea, indigestion, abdominal pain
Very rare:	Constipation, increased salivation
Not known:	Dry throat

Respiratory, thoracic and mediastinal disorders

Very rare:	Increased nasal discharge
Not known:	Shortness of breath (as symptom of a hypersensitivity reaction)

Renal and urinary disorders

Very rare:	Difficulty urinating
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General disorders and administration site conditions

Uncommon:	Fever, mucous membrane reactions
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Action to be taken in the event of side effects

At the first signs of a hypersensitivity reaction, stop taking MUCOSOLVAN tablets 30 mg.

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

5. How to store MUCOSOLVAN tablets 30 mg

Keep out of the reach and sight of children.

Do not use MUCOSOLVAN tablets 30 mg after the expiry date which is stated on the carton and the blister.

Storage conditions

Store below 30°C

Medicines should not be disposed of via wastewater. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What MUCOSOLVAN tablets 30 mg contain

The active substance is ambroxol hydrochloride.

Each tablet contains 30 mg ambroxol hydrochloride.

The other ingredients are:

Colloidal anhydrous silica, lactose monohydrate, maize starch, magnesium stearate

What MUCOSOLVAN tablets 30 mg look like and contents of the pack

MUCOSOLVAN tablets 30 mg are round, white, scored tablets marked "67 C".

MUCOSOLVAN tablets 30 mg are available in original packs containing 20 and 50 tablets.

Not all pack sizes may be marketed

Marketing authorisation holder

Boehringer Ingelheim International GmbH
Binger Straße 173
55216 Ingelheim am Rhein, Germany

Manufacturer

Delpharm Reims
10 Rue Colonel Charbonneaux
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France

For any information about this medicine, please contact the local representative of the Marketing

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This leaflet was last revised in June 2013

This is a Medicament

- Medicament is a product which affects your health and its consumption contrary to an instruction is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the Pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists