

PACKAGE LEAFLET: INFORMATION FOR THE USER

MUCOSOLVAN[®]

SANOFI 

cough syrup 30 mg/5 ml
Oral solution

Active substance: Ambroxol hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you. Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 4 - 5 days.

What is in this leaflet:

1. What MUCOSOLVAN cough syrup 30 mg/5 ml is and what it is used for
2. What you need to know before you take MUCOSOLVAN cough syrup 30 mg/5 ml
3. How to take MUCOSOLVAN cough syrup 30 mg/5 ml
4. Possible side effects
5. How to store MUCOSOLVAN cough syrup 30 mg/5 ml
6. Contents of the pack and other information

1. What MUCOSOLVAN cough syrup 30 mg/5 ml is and what it is used for

MUCOSOLVAN cough syrup 30 mg/5 ml is a medicine used to thin mucus in respiratory tract diseases where tenacious mucus is a problem (expectorant).

2. What you need to know before you take MUCOSOLVAN cough syrup 30 mg/5 ml

Do not take MUCOSOLVAN cough syrup 30 mg/5 ml:

- if you are allergic to the active substance, ambroxol hydrochloride, or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine.

There have been reports of severe skin reactions associated with the administration of ambroxol hydrochloride. If you develop a skin rash (including lesions of the mucous membranes such as mouth, throat, nose, eyes, genitals), stop using MUCOSOLVAN cough syrup 30 mg/5 ml and contact your doctor immediately.

Patients with impaired kidney or liver function

If you have impaired kidney function or severe liver disease, you must not take MUCOSOLVAN cough syrup 30 mg/5 ml 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 (metabolites) of ambroxol 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 cough syrup 30 mg/5 ml should only be used under medical supervision because of the risk that secretions may accumulate.

Children

MUCOSOLVAN cough syrup 30 mg/5 ml must not be used in children under 2 years of age except on medical advice.

Other medicines and MUCOSOLVAN cough syrup 30 mg/5 ml

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

Ambroxol/antitussives

Simultaneous use of MUCOSOLVAN cough syrup 30 mg/5 ml and cough suppressants (antitussives) 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, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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

The active substance, ambroxol, has been shown to pass into breast milk in animal studies. Use while breast-feeding is not recommended.

Fertility

Non-clinical studies have produced no evidence of any harmful effects on fertility.

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.

3. How to take MUCOSOLVAN cough syrup 30 mg/5 ml

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

The recommended dose is:

Children up to 2 years of age: on medical advice only
1.25 ml of solution should be taken twice daily (equivalent to 15 mg ambroxol hydrochloride per day)

**cough syrup 30 mg/5 ml**

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1.25 ml of solution should be taken twice daily (equivalent to 15 mg ambroxol hydrochloride per day)

Children from 2 to 5 years of age:

1.25 ml of solution should be taken three times daily (equivalent to 22.5 mg ambroxol hydrochloride per day)

Children from 6 to 12 years of age:

2.5 ml of solution should be taken two to three times daily (equivalent to 30 - 45 mg ambroxol hydrochloride per day)

Adults and adolescents from 12 years of age:

The usual dosage is 5 ml of solution three times daily (equivalent to 90 mg ambroxol hydrochloride per day) for the first 2 - 3 days and 5 ml of solution twice daily (equivalent to 60 mg ambroxol hydrochloride per day) thereafter.

For adults and adolescents from 12 years of age, the therapeutic effect may be enhanced by increasing the dosage to 10 ml twice daily (equivalent to 120 mg ambroxol hydrochloride per day).

Dosage scheme Age	Daily dose
0 - 2 years: On medical advice only	2 x 1.25 ml
2 - 5 years	3 x 1.25 ml
6 - 12 years	2 - 3 x 2.5 ml
From 12 years: On the first 2 - 3 days Thereafter	3 x 5 ml 2 x 5 ml

Method of administration and duration of treatment

MUCOSOLVAN cough syrup 30 mg/5 ml is an oral solution.

MUCOSOLVAN cough syrup 30 mg/5 ml 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.

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 cough syrup 30 mg/5 ml is too strong or too weak, talk to your doctor or pharmacist.

If you take more MUCOSOLVAN cough syrup 30 mg/5 ml 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 cough syrup 30 mg/5 ml

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

If you stop taking MUCOSOLVAN cough syrup 30 mg/5 ml

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

4. Possible side effects

Like all medicines, MUCOSOLVAN cough syrup 30 mg/5 ml can cause side effects, although not everybody gets them.

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

Very common:	More than 1 in 10 patients
Common:	1 to 10 in 100 patients
Uncommon:	1 to 10 in 1000 patients
Rare:	1 to 10 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***

Rare: Hypersensitivity reactions
Not known: Anaphylactic reactions including anaphylactic shock, angioedema (rapidly developing swelling of the skin, subcutaneous, mucosa or submucosal tissues) and pruritus

Skin and subcutaneous tissue disorders

Rare: Rash, urticaria
Not known: Severe cutaneous adverse reactions (including erythema multiforme, Stevens-Johnson syndrome/toxic epidermal necrolysis and acute generalised exanthematous pustulosis).

Nervous system disorders

Common: Taste disturbances

Gastrointestinal disorders

Common: Nausea, feeling of numbness in the mouth
Uncommon: Vomiting, diarrhoea, indigestion, abdominal pain, dry mouth

Rare: Dry throat
Very rare: Increased salivation

Respiratory, thoracic and mediastinal disorders

Common: Feeling of numbness in the throat
Not known: Shortness of breath (as symptom of a hypersensitivity reaction)

General disorders and administration site conditions

Uncommon: Fever, mucous membrane reactions

Action to be taken in the event of side effects

At the first signs of a hypersensitivity reaction, stop taking MUCOSOLVAN cough syrup 30 mg/5 ml.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store MUCOSOLVAN cough syrup 30 mg/5 ml

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 label and carton after EXP. The expiry date refers to the last day of that month.

Storage conditions

Do not store above 25°C

Shelf life after first opening the bottle

The shelf life after first opening the bottle is 6 months.

Do not throw away this medicine via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information**What MUCOSOLVAN cough syrup 30 mg/5 ml contains:**

The active substance is:
ambroxol hydrochloride

5 ml of solution contains 30 mg ambroxol hydrochloride.

The other ingredients are:
Benzoic acid, hydroxyethylcellulose, sucralose, flavouring agents, purified water.

Notes:

MUCOSOLVAN cough syrup 30 mg/5 ml is suitable for diabetics. 5 ml of solution is equivalent to 0 carbohydrate exchanges.
MUCOSOLVAN cough syrup 30 mg/5 ml does not contain alcohol.

What MUCOSOLVAN cough syrup 30 mg/5 ml looks like and contents of the pack:

MUCOSOLVAN cough syrup 30 mg/5 ml is a colourless liquid with a fruity odour in an amber glass bottle with child-resistant screw closure.

MUCOSOLVAN cough syrup 30 mg/5 ml is available in packs containing 100 ml and 250 ml.
Not all pack sizes maybe marketed

Marketing Authorisation Holder and Manufacturer

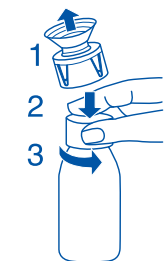
Marketing Authorisation Holder
Sanofi-Aventis Deutschland GmbH
Brüningstrasse 50
D - 65926 Frankfurt am Main, Germany

Manufacturer
Delpharm Reims
10 rue Colonel Charbonneaux
51100 Reims, France

This leaflet was last revised in June 2017.

Child-resistant bottle cap:

1. Remove measuring cup from cap
2. To open, push down on cap
3. At the same time, twist cap in the direction of the arrow

**Dear Patient**

Thank you for buying Mucosolvan® to treat your symptoms. Let us tell you a bit more about the product and its active substance.

Where Mucosolvan® comes from:

The active substance of Mucosolvan® is ambroxol, which is a derivative of vasicine. Vasicine is a naturally-occurring substance isolated from *Adhatoda vasica*, a plant drug used in Ayurvedic medicine. Ambroxol is used in many countries around the world for treating conditions in which thick, tenacious mucus is a problem (such as colds). Millions of doses of Mucosolvan® have been taken worldwide and the product has proved to be both effective and well tolerated.

What Mucosolvan® does:

Breathing in provides the body with the oxygen it needs and breathing out again removes carbon dioxide. When we breathe in, particles of dust and dirt enter our body together with the air. These particles are trapped by the sticky mucus in our airways and transported upwards by millions of tiny hairs called cilia, which act like an endless natural conveyor-belt system. A natural protective factor called surfactant helps to stop the mucus sticking to the cilia. This self-cleaning system becomes less efficient when have a cold. The structure of the mucus changes and it becomes too thick. Surfactant can no longer keep the mucus and the cilia apart. The cilia stick together and the mucus in which the dust and dirt are trapped can no longer be transported upwards. Coughing now takes over as the main way of cleansing the airways. But the mucus is thick and tenacious, requiring heavy coughing to clear it from the airways. This damages the airways and is painful as well.

How Mucosolvan® works:

Mucosolvan® helps to solve the mucus problem.

1. It makes the mucus thinner so that the cilia can transport it upwards more easily (secretolytic activity).
2. It activates the cilia, allowing them to beat more strongly and at a faster rate (secretomotor activity).
3. It stimulates surfactant, the natural protective factor.

We wish you a speedy recovery!

Your **Mucosolvan®** team

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