

PACKAGE LEAFLET: INFORMATION FOR THE USER

Mucoangin® Mint
20 mg/lozenge



Ambroxol hydrochloride

For use in adults and adolescents over 12 years of age

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 3 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 MUCOANGIN throat mints are and what they are used for
2. Before you take MUCOANGIN throat mints
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1. What MUCOANGIN throat mints are and what they are used for

MUCOANGIN throat mints contain ambroxol hydrochloride, which is responsible for the therapeutic effect.

MUCOANGIN throat mints act as a local anaesthetic in acute sore throats.

MUCOANGIN throat mints provide relief from the pain associated with acute sore throats.

2. Before you take MUCOANGIN throat mints

Do not take MUCOANGIN throat mints:

- if you are hypersensitive (allergic) to the active substance (ambroxol hydrochloride)
- if you are hypersensitive (allergic) to any of the other ingredients of MUCOANGIN throat mints. These ingredients are listed in section 6: "Further information".
- if you are intolerant to fructose.

Special care must be taken with MUCOANGIN throat mints in the following circumstances:

MUCOANGIN throat mints should not be used by children under 12 years of age.

You should not take MUCOANGIN throat mints for more than 3 days. If your symptoms last for more than 3 days or you have a high fever, please contact a doctor.

If you have been told that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. Please also take note of the "Important information about some of the ingredients of MUCOANGIN throat mints" later in this section.

If you have impaired kidney function or severe liver disease, do not take MUCOANGIN throat mints except on medical advice.

MUCOANGIN throat mints are not licensed for the treatment of painful lesions of the oral cavity such as ulcers or sores. If you have mouth ulcers or sores, seek medical advice.

You may feel short of breath if you have an underlying condition such as a swollen throat. The local anaesthetic effect of MUCOANGIN throat mints may cause a feeling of tightness in the throat. Allergic reactions may also occur, causing swelling in the mouth and throat.

MUCOANGIN throat mints may make your mouth and throat feel numb and alter your sense of taste.

If new skin or mucous membrane changes occur or you already have severe skin reactions, you should stop taking MUCOANGIN throat mints as a precaution and consult a doctor immediately. 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, which is the active substance used in MUCOANGIN throat mints. In most cases, these skin reactions were due to severe underlying diseases (various infections) or to the medicines used to treat these diseases or accompanying diseases or severe pre-existing skin reactions associated with early non-specific flu-like symptoms.

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.

Taking MUCOANGIN throat mints with food and drink

There are no known relevant interactions.

Pregnancy and breast-feeding

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

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.

Ambroxol has been shown to pass into breast milk. Therefore, you should not take MUCOANGIN throat mints while breast-feeding.

Driving and using machines

MUCOANGIN throat mints are not known to affect the ability to drive or use machines.

Important information about some of the ingredients of MUCOANGIN throat mints

Each lozenge contains 1.37 g sorbitol (equivalent to 8.2 g if the maximum recommended daily dose is taken). Sorbitol is a source of fructose (a type of sugar). If you are intolerant to fructose, you should not take this medicine.

Each lozenge contains less than 1 mg lactose monohydrate (a type of sugar). This quantity of lactose does not normally cause any problems in people who are intolerant to lactose.

If you have been told that you have an intolerance to some sugars, contact your doctor before taking MUCOANGIN throat mints.

3. How to take MUCOANGIN throat mints

Always take MUCOANGIN throat mints 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, adults and children over 12 years of age should suck 1 lozenge for pain relief, up to a maximum of 6 lozenges per day.

You should not take MUCOANGIN throat mints for more than 3 days. If your symptoms last for more than 3 days or you have a high fever, please contact a doctor.

MUCOANGIN throat mints normally start to relieve the pain of sore throat within 20 minutes. The effect lasts for at least 3 hours.

If you take more MUCOANGIN throat mints than you should

No specific symptoms of overdose are known. If you have taken too many lozenges (more than 6 in a day) and you think you may have symptoms of an overdose, contact your doctor or pharmacist.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, MUCOANGIN throat mints can have side effects although not everybody gets them.

If you experience any of the side effects described below, stop taking MUCOANGIN throat mints and contact a doctor immediately:

- allergic reaction with angioedema (localised swelling of the face, lips, mouth, tongue and/or throat); this may cause a feeling of tightness in the throat or difficulties in breathing and swallowing.
- anaphylactic reactions including anaphylactic shock (allergic reactions of rapid onset affecting the whole body).

Allergic reactions may be more severe if you have taken the product before or if you are taking another product containing the same active substance (see section 2: "Before you take MUCOANGIN throat mints").

Other possible side effects:

Common (may affect up to 1 in 10 people):

- Nausea
- Numbness of the mouth, tongue and throat
- Taste disturbances

Uncommon (may affect up to 1 in 100 people):

- Diarrhoea
- Indigestion

- Abdominal pain
- Dry mouth

Not known (frequency cannot be estimated from the available data):

- Itching
- Skin rash
- Other hypersensitivity reactions (allergic reactions)
- Vomiting
- Dry throat

5. How to store MUCOANGIN throat mints

Keep out of the reach and sight of children.

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

Storage conditions

Do not store above 30°C.

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.

6. Further information

What MUCOANGIN throat mints contain:

The active substance is ambroxol hydrochloride.

Each lozenge contains 20 mg ambroxol hydrochloride.

The other ingredients are:

- Sorbitol 1.37 g (equivalent to about 1.44 g of carbohydrate)
- Macrogol 6000
- Saccharin sodium
- Talc
- Peppermint flavouring agent (contains acacia, Chinese peppermint oil, maltodextrin and lactose monohydrate)

What MUCOANGIN throat mints look like and contents of the pack:

MUCOANGIN throat mints are flat, round, white tablets with bevelled edges.

MUCOANGIN throat mints are available in aluminium/aluminium blister packs.

MUCOANGIN throat mints are available in packs containing 18 mints (N1).

Marketing Authorisation Holder

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

Manufacturer

Delpharm Reims
10 Rue Colonel Charbonneaux
51100 Reims
France

This leaflet was last revised in November 2010.

Information for patients

Mucoangin[®] throat mints

Mucoangin[®] throat mints, which are available in pharmacies, are designed to provide relief from an acute sore throat.

About sore throat:

Sore throats normally come on suddenly. They make it hard to swallow, hard to eat and hard to talk and can be an uncomfortable interruption to daily life. They are usually the first sign of a cold or flu and, if this is the case, it means that a virus will have entered your throat, penetrated the mucous membranes that line it and then multiplied. Your body tries to fight the infection by means of an inflammatory reaction, and this is what makes your throat feel hot, painful and red.

Sore throats of this type normally last about 3 days and are soon followed by other typical signs of a cold or flu, such as coughing and sneezing

Important: If your sore throat lasts more than 3 days or you have other symptoms such as a high fever, you should contact a doctor as you probably have a bacterial throat infection such as tonsillitis. Your doctor will then decide whether you need an antibiotic. You should also discuss with your doctor whether to keep taking Mucoangin[®] throat mints for your sore throat.

How Mucoangin® throat mints work:

Mucoangin® throat mints

1. spread over the inflamed throat tissues to give rapid pain relief
2. keep working for at least 3 hours
3. reduce reddening in throat inflammations.

How to get the best results from Mucoangin® throat mints:

Mucoangin® throat mints have a slightly rough surface which makes it easy to put them on the back of your tongue and keep them there so that they can dissolve slowly. The longer you can keep them on your tongue without actually sucking, the better - this will help them to reach the inflamed tissues in the throat more effectively. The mints should be placed as far back on the tongue as is comfortable.

Other tips:

- Wear a scarf round your neck to keep your throat area warm.
- Avoid irritants such as alcohol, nicotine and spicy foods.
- Drink plenty of fluids to keep the mucous membranes in your throat moist.
- Get plenty of rest if you can, or at least take short breaks.

We wish you a speedy recovery!

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