

Mucosolvan®

30mg/5ml Liquid

ambroxol hydrochloride

(a) What Mucosolvan Liquid 30mg/5ml contains

The active substance is:
ambroxol hydrochloride

5ml of solution contains 30 mg ambroxol hydrochloride.

The other ingredients are:
Benzoic acid,
hydroxyethylcellulose,
sucralose, strawberry cream
flavour and vanilla flavour
(including propylene
glycol), purified water.

(b) What Mucosolvan Liquid 30mg/5ml is and what it is used for

Mucosolvan is used in conditions where there are a lot of thick secretions or mucus in your air passages.

Mucosolvan contains ambroxol hydrochloride, which helps to clear the chest by thinning the mucus in your air passage.

(c) What you need to know before you take Mucosolvan Liquid 30mg/5ml

Do not take Mucosolvan Liquid 30mg/5ml:

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

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 Liquid 30mg/5ml 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 Liquid 30mg/5ml 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 Liquid 30mg/5ml should only be used under medical supervision because of the risk that secretions may accumulate.

Children

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

Other medicines and Mucosolvan Liquid 30mg/5ml

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

Mucosolvan may increase the amount of antibiotic penetration. Antibiotics are medicines used to treat infections.

Ambroxol/antitussives

Simultaneous use of Mucosolvan Liquid 30mg/5ml and cough suppressants (antitussives) may lead to the development of a dangerous accumulation of secretion in patients with respiratory illnesses that are associated with an increased formation of mucus, such as cystic fibrosis or bronchiectasis, due to reduction of the cough reflex.

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. Clinical experience after the 28th week of gestation has produced no evidence of any harmful effects on the unborn child. Nonetheless, 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. Even if no harmful effects to the child are expected, 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.

Mucosolvan Liquid 30mg/5ml contains benzoic acid.

This medicine contains 2.5 mg of benzoic acid in each 5 ml of solution. Benzoic acid may increase jaundice (yellowing of the skin and eyes) in new-born babies (up to 4 weeks old).

Mucosolvan Liquid 30mg/5ml contains propylene glycol.

This medicine contains 28.8 mg of propylene glycol in each 5 ml of solution. If your baby is less than 4 weeks old, talk to your doctor or pharmacist before giving them this medicine, in particular if the baby is given other medicines that contain propylene glycol or alcohol.

(d) How to take Mucosolvan Liquid 30mg/5ml

The recommended dose for adults and children are stated below:

Adult and children over 12 years:
10ml 2 times daily.

For children under 12 years the following dosage regimen is recommended depending on severity of the disease.

Children 6-12 years:
5ml 2-3 times daily.

Children 2-5 years:
2.5 ml 3 times daily.

Mucosolvan is not recommended for children under 2 years of age without medical advice.

Mucosolvan can be taken with or without food.

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

If you take more Mucosolvan Liquid 30mg/5ml 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 e). In case of overdose, please consult a doctor as symptomatic treatment may be required.

If you forget to take Mucosolvan Liquid 30mg/5ml

If you forget to take Mucosolvan Liquid 30mg/5ml or take too small a dose, wait until it is time to take your next dose and then continue taking Mucosolvan Liquid

30mg/5ml as described in the dosage instructions above.

If you stop taking Mucosolvan Liquid 30mg/5ml

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

(e) Possible side effects

Like all medicines, Mucosolvan Liquid 30mg/5ml can cause side effects, although not everybody gets them.

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

Very common:
May affect more than 1 in 10 people
Common:
May affect up to 1 in 10 people
Uncommon:
May affect up to 1 in 100 people
Rare:
May affect up to 1 in 1,000 people
Very rare:
May affect up to 1 in 10,000 people
Not known:
Frequency cannot be estimated from the available data

Side effects

Occasional, mild side effects from Mucosolvan include:

- Nausea
- Oral and pharyngeal hypoesthesia

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
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 Liquid 30mg/5ml.

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

Storage conditions

This medicinal product does not require any special storage conditions.

Shelf life after first opening the bottle

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

Manufactured by
Delpharm Reims
Reims, France

Product Registrant
Opella Healthcare
Singapore Pte Ltd
38 Beach Road #18-11
Singapore 189767

Revision date: Jan 2023

(f) How to store Mucosolvan Liquid 30mg/5ml

Mucosolvan should be kept in a dry place where the