MUCOSOLVAN®
30mg Tablets

ambroxol hydrochloride

Patient Information Leaflet

(a) What MUCOSOLVAN tablets 30 mg contain

The active substance is ambroxol: Ambroxol hydrochloride.

Each tablet contains 30 mg ambroxol hydrochloride.

The other ingredients are:
Lactose monohydrate,
Maize starch, dried Silica colloidal anhydrous
Magnesium stearate
Purified water.

(b) What MUCOSOLVAN tablets 30 mg are and what they are 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 tablets 30 mg

Do not take MUCOSOLVAN tablets 30 mg

- if you are allergic (hypersensitive) 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 tablets 30 mg 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 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.

Other medicines and MUCOSOLVAN tablets 30 mg

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

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 in patients with respiratory illnesses that are associated with an increased formation of mucus, such as cystic fibrosis or bronchiectasis, due to the 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
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 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 tablets 30 mg contain lactose

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

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

(d) How to take MUCOSOLVAN tablets 30 mg

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

The recommended dose for adults is 1 tablet 3 times daily.

For better effect, you may administer 2 tablets 2 times daily.

Mucosolvan liquid formulation is available for children.

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

Method and duration of administration

MUCOSOLVAN 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

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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 (e)). 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.

(e) 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:
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

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)

Gastrointestinal disorders

Common: Nausea

Uncommon: Vomiting, diarrhoea, indigestion, abdominal pain

Very rare: Increased salivation

Respiratory, thoracic and mediastinal disorders

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 tablets 30 mg.

(f) How to store MUCOSOLVAN tablets 30 mg

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

Please refer to packaging for information on shelf-life

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