MUCOSOLVAN® 24 Hours

ambroxol hydrochloride
75mg Prolonged-release hard capsule

Patient Information Leaflet

(a) What MUCOSOLVAN once-daily prolonged-release capsules contain

The active substance is:
Ambroxol hydrochloride.

One prolonged-release hard capsule contains 75 mg ambroxol hydrochloride.

The other excipients are:
Capsule content:
Crospovidone
Carnauba wax
Stearyl alcohol
Magnesium stearate

Capsule shell:
Gelatin
Water, purified
Titanium dioxide E 171
Red iron oxide E172
Yellow iron oxide E 172

Printing ink:
Shellac
Isopropyl alcohol
n-Butyl alcohol
Propylene glycol
Titanium dioxide

(b) What MUCOSOLVAN once-daily prolonged-release capsules are and what they are used for

Mucosolvan is used in conditions where there are a lot of thick secretion 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 once-daily prolonged-release capsules

MUCOSOLVAN once-daily prolonged-release capsules should not be taken:

- If you are hypersensitive (allergic) to the active substance ambroxol hydrochloride or to 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 mucosal lesions in the mouth, throat, nose, eyes and genital region), stop taking MUCOSOLVAN once-daily prolonged-release capsules and seek medical advice immediately.

Patients with impaired kidney or liver function
If you suffer from impaired kidney function or a severe liver disease, MUCOSOLVAN once-daily prolonged-release capsules should only be used on medical advice. As with any medicine that is metabolised by the liver and then excreted via the kidneys, an accumulation of the metabolic products (metabolites) of ambroxol produced in the liver can be expected in patients with severe renal failure.

In some rare bronchial disorders that are associated with excessive accumulation of secretions (e.g. malignant ciliary syndrome), MUCOSOLVAN once-daily prolonged-release capsules should only be used under medical supervision due to possible secretion congestion.

Taking MUCOSOLVAN once-daily prolonged-release capsules with other medicines

Please tell your doctor or pharmacist if you are taking/using any other medicines, have recently taken/used any other medicines, or are intending to take/use other medicines.

Ambroxol/Cough suppressants
Simultaneous use of MUCOSOLVAN once-daily prolonged-release capsules and cough suppressants (antitussives) may lead to the development of dangerous secretion congestion 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, lactation and fertility

If you are pregnant or breastfeeding, 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 reaches 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 not during the first three months.

Breastfeeding
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 not provided any evidence of harmful effects with respect to fertility.

Driving and using machines

There is no evidence of an effect on the ability to drive or use machines; appropriate studies have not been performed.

sanofi

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

(d) How to take MUCOSOLVAN once-daily prolonged-release capsules

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

The recommended dose is:
The usual dosage is one prolonged-release capsule (equivalent to 75 mg ambroxol hydrochloride/day) once daily.

Method and duration of treatment

MUCOSOLVAN once-daily prolonged-release capsules can be taken with or without food and should be swallowed whole with sufficient amounts of liquid (e.g., water, tea or fruit juice).

You should consult a doctor if your symptoms worsen or if there is no improvement after 4-5 days.

Please speak to your doctor or pharmacist if you feel that the effect of MUCOSOLVAN once-daily prolonged-release capsules is too strong or too weak.

If you take more MUCOSOLVAN once-daily prolonged-release capsules 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 at the recommended dose (see Section (e)). In the event of an overdose, please consult a doctor as symptomatic treatment may be required.

If you forget to take MUCOSOLVAN once-daily prolonged-release capsules

If you forget to take MUCOSOLVAN once-daily prolonged-release capsules or have taken an insufficient amount, please continue to take MUCOSOLVAN once daily prolonged-release capsules as described in the dosage instructions at the next scheduled time.

If you stop taking MUCOSOLVAN once-daily prolonged-release capsules

The symptoms may worsen if the treatment is discontinued prematurely.

(e) Possible side effects

Like all medicines, MUCOSOLVAN once-daily prolonged-release capsules can cause side effects, although not everybody gets them.

The following categories are used for stating the frequency of undesirable 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: Allergic reactions including anaphylactic shock, angioedema (rapidly developing swelling of the skin, subcutaneous tissue, mucosa or tissue under the mucous membrane) and pruritus.

Skin and subcutaneous tissue Disorders

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

Gastrointestinal disorders

Common: Nausea
Uncommon: Vomiting, diarrhoea, digestive disorders, abdominal pain
Very rare: Increased salivation

Respiratory, thoracic and mediastinal disorders

Not known: Dyspnoea (as a symptom of a hypersensitivity reaction)

General disorders and administration site conditions

Uncommon: Fever, mucous membrane reactions

Countermeasures

At the first signs of a hypersensitivity reaction, you should stop taking MUCOSOLVAN once-daily prolonged-release capsules.

(f) How to store MUCOSOLVAN once-daily prolonged-release capsules

Mucosolvan should be kept in a dry place.

Keep this medication out of reach of children.

Do not use this medicine after the expiry date which is stated after the words “Use by” on the outer package/blister pack.

The expiry date refers to the last day of that month.

Storage conditions

Do not store above 30°C.

(g) What MUCOSOLVAN once-daily prolonged-release capsules look like

- **Product description**
  Oblong hard gelatin capsules consisting of a red opaque cap and an orange opaque body. The cap is printed with ‘MUC 01’ in white.

  The capsule content consists of round, yellowish-white pellets with a smooth, shiny surface, mixed with a small quantity of powder.

  Manufactured by
  Sanofi Winthrop Industrie
  196 Rue Du Marechal Juin,
  Amilly, 45200, France

  Product Registrant:
  Opella Healthcare
  Singapore Pte. Ltd.
  38 Beach Road #18-11
  South Beach Tower
  Singapore 189767

  Date of revision: May 2022
  (CCDS V1)
  Oct 2022