Ambroxol

Core Safety Profile

4.3 Contraindications

MUCOSOLVAN® / MUCOANGIN® should not be used in patients known to be hypersensitive to ambroxol hydrochloride or other components of the formulation.

< In case of rare hereditary conditions that may be incompatible with an excipient of the product (please refer to Special warnings and precautions) the use of the product is contraindicated. >
(only to be included if excipients (carbohydrates) are included in the product that need to be labeled)

Additionally for Mucosolvan® infusion solution concentrate, 1000 mg/50ml:
MUCOSOLVAN® infusion solution concentrate should not be administered if the patient suffers from convulsions of various aetiology.

4.4 Special warnings and precautions for use

All formulations except for Mucosolvan® infusion solution concentrate, 1000 mg/50ml and Mucosolvan® Ampoules, 15 mg/2 ml:

There have been very few reports of severe skin lesions such as Stevens-Johnson Syndrome and toxic epidermal necrolysis (TEN) in temporal association with the administration of expectorants such as ambroxol hydrochloride. Mostly these could be explained by the severity of the patient's underlying disease and/or concomitant medication. In addition during the early phase of a Stevens-Johnson Syndrome or TEN a patient can first experience non-specific influenza-like prodromes like e.g. fever, aching body, rhinitis, cough and sore throat. Misled by these non-specific influenza-like prodromes it is possible that a symptomatic treatment is started with a cough and cold medication. Therefore, if new skin or mucosal lesions occur, medical advice should be sought immediately and treatment with ambroxol hydrochloride discontinued as a precaution.

All formulations except for Mucosolvan® infusion solution concentrate, 1000 mg/50ml and Mucosolvan® Ampoules, 15 mg/2 ml:
In the presence of impaired renal function or severe hepatopathy, Mucosolvan®/Mucoangin® may be used only after consulting a physician. As for any medication with hepatic metabolism followed by renal elimination, accumulation of the metabolites of ambroxol generated in the liver can be expected in the presence of severe renal insufficiency.

Mucosolvan® infusion solution concentrate, 1000 mg/50ml and Mucosolvan® Ampoules, 15 mg/2 ml:
In the presence of impaired renal function or severe hepathopathy Mucosolvan® should be administered with precaution.

As for any medication with hepatic metabolism followed by renal elimination, accumulation of the metabolites of ambroxol generated in the liver can be expected in the presence of severe renal insufficiency.

Additionally for Mucosolvan® infusion solution concentrate, 1000 mg/50ml:
MUCOSOLVAN® infusion solution concentrate is only designed for slow intravenous drip.
Rapid i.v. bolus injections should be avoided, as central nervous reaction cannot be ruled out.
Accidental undiluted bolus administration may cause haemolysis due to the high concentration of active ingredient at the site of injection.
Intra-arterial use should also be avoided, as local oedema and slight cicatrisation around the administration site has been observed in preclinical studies.

All formulations:
< Special warnings regarding the excipients that need to be labeled should be included – if appropriate.>

4.5 Interaction with other medicinal products and other forms of interaction

No clinically relevant unfavourable interaction with other medications has been reported.

4.6 Pregnancy and Lactation

Only for Mucosolvan® Ampoules, 15 mg/2 ml:
Not applicable.

All formulations except for Mucosolvan® Ampoules, 15 mg/2 ml:
Ambroxol hydrochloride crosses the placental barrier. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development.
Extensive clinical experience after the 28th week of pregnancy has shown no evidence of harmful effects on the foetus.

All formulations except for Mucosolvan® Ampoules, 15 mg/2 ml and Infusion solution concentrate,1000 mg/50 ml:
Nonetheless, the usual precautions regarding the use of drugs during pregnancy should be observed.
Especially during the first trimester, the use of MUCOSOLVAN® / MUCOANGIN® is not recommended.

All formulations except for Mucosolvan® Ampoules, 15 mg/2 ml:
Ambroxol hydrochloride is excreted in breast milk.
Although unfavourable effects on breastfed infants would not be expected, MUCOSOLVAN® /MUCOANGIN® is not recommended for use in nursing mothers.

4.7 Effects on ability to drive and use machines

Only for Mucosolvan® Ampoules, 15 mg/2 ml:
Not applicable.

Only for Mucosolvan® Infusion solution concentrate, 1000 mg/50 ml:
There is no evidence for an effect on the ability to drive and use machines.
Studies on the effects on the ability to drive and use machines have not been performed.
However, patients should be advised that they may experience "dizziness".
Therefore, caution should be recommended when driving a car or operating machinery. If patients experience "dizziness" they should avoid potentially hazardous tasks such as driving or operating machinery.

All other formulations:
There is no evidence for an effect on the ability to drive and use machines.
Studies on the effects on the ability to drive and use machines have not been performed.

4.8 Undesirable effects

Only for Mucosolvan® Infusion solution concentrate, 1000 mg/50 ml:

Immune System Disorders, Skin and subcutaneous tissue disorders and Respiratory, thoracic and mediastinal disorders:
Uncommon: hypersensitivity
Not known: Anaphylactic reactions including anaphylactic shock, angioedema, rash, urticaria, pruritus

Nervous System Disorders:
Common: Headache
Uncommon: Dizziness

Cardiac Disorders:
Common: Tachycardia

Vascular Disorders:
Common: Flushing
Uncommon: Circulatory disorders

Gastro-intestinal disorders:
Very common: Nausea
Common: Vomiting
Uncommon: Diarrhoea and abdominal pain
Not known: Dyspepsia

Only for Mucosolvan® Ampoules, 15 mg/2 ml:
Immune system disorders, Skin and subcutaneous tissue disorders:
Not known: Anaphylactic reactions including anaphylactic shock, angioedema, rash; urticaria, pruritus and other hypersensitivity.

Gastro-intestinal disorders:
Not known: Nausea, vomiting, diarrhoea, dyspepsia and abdominal pain.

Only for Mucoangin® Lozenges, 20 mg:
Immune system disorder, Skin and subcutaneous tissue disorders:
Not known: Anaphylactic reactions including anaphylactic shock, angioedema, rash, urticaria, pruritus and other hypersensitivity.

Nervous system disorders:
Common: Dysgeusia (e.g. changed taste)

Gastro-intestinal disorders and Respiratory, mediastinal and thoracic disorders:
Common: Nausea, oral and pharyngeal hypoaesthesia
Uncommon: Diarrhoea, abdominal pain upper, dyspepsia and dry mouth
Not known: Vomiting and dry throat

All other formulations:
Immune system disorders, Skin and subcutaneous tissue disorders:
Rare: Rash, urticaria
Not known: Anaphylactic reactions including anaphylactic shock, angioedema, pruritus and other hypersensitivity.

Gastro-intestinal disorders:
Common: Nausea
Uncommon: Vomiting, diarrhoea, dyspepsia and abdominal pain.

Additionally for Mucosolvan® Soft pastilles, 15 mg; Mucosolvan® Granules, 15 mg/3g, 30 mg/3g, 60 mg/3g; Mucosolvan® Syrup, 15 mg/5ml and 30 mg/5ml; Mucosolvan® effervescent tablets, 60 mg; Mucosolvan® Solution for oral use, 15 mg/2ml and 30 mg/2ml; Mucosolvan® Solution for inhalation, 15 mg/2ml:

Nervous system disorders:
Common: Dysgeusia (e.g. changed taste)

Gastro-intestinal disorders and Respiratory, mediastinal and thoracic disorders:
Common: Oral and pharyngeal hypoaesthesia
Uncommon: Dry mouth
Not known: Dry throat

4.9 Overdose

No specific overdose symptoms have been reported in man to date.

Based on accidental overdose and/or medication error reports the observed symptoms are consistent with the known side effects of MUCOSOLVAN®/MUCOANGIN® at recommended doses and may need symptomatic treatment.