Mucosolvan® LA (long acting)

Composition

1 LA capsule (long acting)
contains 75 mg
trans-4-[(2-Amino-3,5-dibromo-benzyl)amino]cyclohexanol hydrochloride
(= ambroxol hydrochloride)

Properties

Preclinically, ambroxol, the active ingredient of MUCOSOLVAN, has been shown to increase respiratory tract secretion. It enhances pulmonary surfactant production and stimulates ciliary activity. These actions result in improved mucus flow and transport (mucociliary clearance). Improvement of mucociliary clearance has been shown in clinical pharmacological studies. Enhancement of fluid secretion and mucociliary clearance facilitates expectoration and cases cough.

Indications

Secretolytic therapy in acute and chronic bronchopulmonary diseases associated with abnormal mucus secretion and impaired mucus transport, such as acute exacerbation of chronic bronchitis, bronchiectasis, asthmoid bronchitis and bronchial asthma.

Contraindications

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

Side effects

Following the administration of ambroxol hydrochloride rare cases of hypersensitivity reactions have been reported and in single cases acute anaphylactic-type signs of shock. The following signs have been observed: skin reactions and/or mucosal reactions, swelling of the face, dyspnoea, rise in temperature with chills. Gastrointestinal complaints have been reported in very rare cases.

Interactions

Administration of ambroxol together with antibiotics (amoxicilline, cefuroxime, erythromycin, doxycycline) leads antibiotic concentration in the lung tissue. No clinically relevant unfavourable interaction with other medications have been reported.

Pregnancy and Lactation

Preclinical studies as well as extensive clinical experience after the 28th week have shown no evidence of ill-effects during pregnancy. Nonetheless, the usual precautions regarding the use of drugs during pregnancy, especially during the first trimester, should be observed.



The drug enters breast milk, but is not likely to affect the infant when therapeutic doses are used.

Dosage and Administration

Adults: 1 LA capsule once daily, either in the morning or evening after a meal. The capsules should not be opened or chewed, but swallowed whole with ample liquid. The "carrier tablets" which are occasionally present in the stools have released the active substance during their passage through the digestive system and are therefore without significance.

MUCOSOLVAN LA capsules are not suitable for children.

Overdosage

a) Signs of overdosage

Intoxications in man are not known.

Ambroxol was well tolerated up to a dosage of 15 mg/kg/body weight/day with parenteral administration. The acute toxic symptoms in case of extreme overdosage were in preclinical investigations increased salivation, retching, vomiting, and drop in blood pressure.

b) Treatment of overdosage

In case of accidental or intentional extreme overdosage the cardiovascular system should be monitored and if necessary symptomatic measures should be taken.

Availability

LA capsules (long acting) 75 mg

Manufacturer:

Boehringer Ingelheim Pharma KG for

Boehringer Ingelheim International GmbH Ingelheim am Rhein Germany

This is a medicament

- Medicament is a product which affects your health, and its consumption contrary to instructions 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 experts in medicine, its 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 medicament out of reach of children!

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