MUCOVIC® / MUCOVIC FORTE®

ACTIVE INGREDIENT
Mucovic®: Ambroxol HCl .....15mg/5mL.
Mucovic Forte®: AmbroxoHCl…….30mg/5mL.

EXCIPIENTS
Mucovic®: Citric acid (monohydrate), sucralose, methyl & propyl parabens, sorbitol (non crystallizing), glycerol, ethanol, apricot flavor, purified water.
Mucovic Forte®: Citric acid (monohydrate), sucralose, methyl & propyl parabens, sorbitol (non crystallizing), ethanol, apricot flavor, purified water.

PHARMACEUTICAL FORM
Mucovic®: Oral solution, 200mL bottle.
Mucovic Forte®: Oral solution, 100mL bottle.

PHARMACOTHERAPEUTIC CLASS
Mucolytic and mucoregulator.

PHARMACOLOGICAL ACTION
Ambroxol, due to its secretomotor and secretolytic properties, makes easier the excretion of the viscous mucus obstructing the airways, increasing the expectoration and, consequently, improving the respiratory function. Treatment with Mucovic® and Mucovic Forte® normalizes, both quantitatively and qualitatively, the bronchial mucous secretion and stimulates the ciliary activity, thus improving the mucus flow and transport (mucociliary clearance) reducing the tussive stimulation and permitting the reconstitution and production of the pulmonary surfactant which is the natural protective mucous layer covering the surface of the bronchial mucosa.
Mucovic® and Mucovic Forte® present a high degree of tolerance and, therefore, they are especially advisable also for prolonged treatments.

PHARMACOKINETICS
Ambroxol is well and rapidly absorbed after oral administration with a bioavailability of 70% compared to an intravenous injection due to the hepatic first pass metabolism. Mean peak levels occur after approximately 2 hours and are dose-proportional.
At therapeutic doses, serum protein binding averages 90%.
The volume of distribution (VD) is very important due to the large extravascular diffusion, especially in the lungs.
No drug accumulation was noticed after repeated administration.
Ambroxol is partially metabolized through CYP 3A4 hepatic enzymes.
Ambroxol has an elimination half-life ($t_{1/2}$) of 7 to 12 hours.
The principal route of excretion is the urine (83% of the administered dose); Ambroxol is eliminated as unchanged and as two major glucuroconjugated metabolites.

INDICATIONS
Mucovic® and Mucovic Forte® are indicated in:
• Acute and chronic airways affections presenting increased or altered mucus production, particularly acute and chronic bronchitis, asthmatic bronchitis, bronchiectasis;
• Catarrhal rhinopharingeal, laryngeal, and tracheal affections;
• Sinusitis, otitis, tubal catarrh;
• Pre- and postoperative treatment, especially in geriatric surgery and for the prophylaxis of respiratory complications during intensive therapies.

ADVERSE REACTIONS
Mucovic® and Mucovic Forte® are generally well tolerated. Mild upper gastro-intestinal side effects (primarily pyrosis, dyspepsia, and occasionally nausea, vomiting) have been reported.
Allergic reactions have occurred rarely, primarily skin rashes.

OVERDOSAGE
No symptoms of overdosage have been reported in man to date. If they occur, symptomatic treatment should be provided.

DRUG INTERACTIONS
Administration of Ambroxol together with antibiotics (amoxicilline, cefuroxime, erythromycin) leads to higher antibiotic concentrations in the bronchopulmonary secretions and in the sputum.
No clinically relevant unfavorable interactions with other medications have been reported.

PRECAUTIONS
The association of a mucoregulator (Ambroxol) with an anti-tussive and/or any substance drying secretions (e.g. atropinics) is irrational.
Mucovic® and Mucovic Forte® should be carefully administered to patients with peptic ulcer.
Mucovic Forte® should be used with caution in patients with renal impairment or severe liver diseases.

CONTRA - INDICATIONS
Mucovic® and Mucovic Forte® are contraindicated for patients known to have hypersensitivity to the drug or any of the ingredients of the formulation.
Mucovic® and Mucovic Forte® should not be used in infants and children less than 2 years of age.

PREGNANCY AND LACTATION
Ambroxol had neither embryotoxic nor teratogenic effects in animal studies even at high doses. 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 it is not likely to affect the infant when therapeutic doses are used. Nevertheless, the use of Ambroxol is not recommended in lactating women.

DOSAGE AND ADMINISTRATION
Mucovic® and Mucovic Forte® should be taken at mealtimes.
Mucovic®:
- For adults and children over 12 years: 10mL (2 teaspoons) 3 times daily.
- For children under 12 years, the following dosage regimen is recommended depending on the severity of the disease:
• From 6 - 12 years: 5mL (1 teaspoon) 2 - 3 times daily;
• From 2 - 6 years: 2.5mL (1/2 teaspoon) 3 times daily.

Mucovic Forte®:
- Adults and children over 12 years: 10mL (2 teaspoons) 2 times daily for the therapy of acute respiratory tract disorders and for the initial treatment of chronic conditions up to 14 days.
- Children from 6 to 12 years: 2.5mL (1/2 teaspoon) 2 - 3 times daily depending on the severity of the disease.
Mucovic Forte® formula is for initial treatment, the dosage may be halved after 14 days.
Mucovic Forte® is not recommended for children under 6 years of age because of the high content of active ingredient.

CONSERVATION
All medicines should be kept out of children's reach.
Do not use when expired (expiry date on the box).