Mucospel®

Bromhexine Hydrochloride

PRESENTATION

Mucospel® Syrup : Each 5 ml syrup contains Bromhexine Hyrdochloride BP 4 mg.
Mucospel® Tablet : Each tablet contains Bromhexine Hyrdochloride BP 8 mg.

PHARMACOLOGY

Mechanism of Action

Bromhexine is an oral mucolytic agent with a low level of associated toxicity. It acts on the mucus at the formative stages in the glands, within the mucus secreting cells. Bromhexine disrupts the structure of acid mucopolysaccharide fibres in mucoid sputum & produces less viscous mucus, which is easier to expectorate.

Pharmacodynamics

Preclinically, it has been shown to increase the proportion of serous bronchial secretion. Bromhexine enhances mucus transport by reducing mucus viscosity and by activating the ciliated epithelium (mucociliary clearance).

In clinical studies, bromhexine showed a secretolytic and secretomotor effect in the bronchial tract area, which facilitates expectoration and eases cough.

Following the administration of Bromhexine antibiotic concentrations (amoxicillin, erythromycin, oxytetracycline) in the sputum and bronchopulmonary secretions are increased.

Pharmacokinetics

Bromhexine shows dose proportional pharmacokinetics. It is rapidly and completely absorbed from the gastrointestinal tract. After administration of radiolabeled bromhexine about 97.4 + 1.9% of the dose was recovered as radioactivity in urine, with less than 1% as parent compound. Bromhexine is a high clearance drug (CL ~ 843-1073 mL/min) resulting in high inter and intraindividual variability (CV>30%). After oral administration solid and liquid formulations show similar bioavailability. The absolute bioavailability of bromhexine hydrochloride was about 22.2 + 8.5 % up to 26.8 + 13.1 % for Bromhexine tablets and solution, respectively. Intravenous administrations showed a mean volume of distribution (Vss) of up to 1209 + 206 L. The distribution in lung tissue (bronchial and parenchymal) was investigated after i.v. (8 mg, 16 mg) and oral (32 mg, 64 mg) administration. Bromhexine tissue concentrations two hours post dose were three to four times higher in lung tissue compared to plasma. Parenchymal tissue seemed to show a higher enrichment of bromhexine than bronchial tissue especially after oral absorption. Unchanged bromhexine is bound to plasma proteins by 95 % (non-restrictive binding). Bromhexine is almost completely metabolized to a variety of hydroxylated metabolites and to dibromanthranilic acid. All metabolites and bromhexine itself are conjugated most probably in form of N-glucuronides and O-glucuronide. A minor part of bromhexine is metabolized to dibromanthranilic acid most probably via cytochrome P450 3A4. There are no substantial hints for a change of the metabolic pattern by a sulphonamide or oxytetracyclin. There is insufficient pharmacokinetic data to evaluate a possible drug-drug interaction between bromhexine and erythromycin.

Bromhexine plasma concentrations showed a multiexponential decline. The relevant half-life to predict the multiple dose pharmacokinetics is about 1 hour, thus no accumulation was seen after multiple dosing (accumulation factor 1.05). There are no data for bromhexine pharmacokinetics in the elderly or in patients with renal or liver insufficiency. Concomitant food leads to an increase of bromhexine plasma concentrations.

INDICATION

Mucospel® is indicated in the treatment of respiratory disorders associated with viscid or excessive mucus or productive cough. These include :

- Tracheobronchitis
- Bronchitic with emphysema
- Bronchiectasis
- Bronchitis with bronchospasm
- Chronic inflammatory pulmonary conditions
- Pneumoconiosis

DOSAGE AND ADMINISTRATION

Mucospel® Syrup :

Adults and Children over 10 years : 2 to 4 teaspoonfuls (8 -16 mg), 3 times daily. Initially 4 teaspoonfuls, 3 times daily, then as required.
Children 5 - 10 years : 1 teaspoonful (4 mg), 3 times daily
Children 2 - 5 years : ½ teaspoonful (2 mg), 3 times daily
Children below 2 years : ¼ teaspoonful (1 mg), 3 times daily.

Mucospel® Tablet :

Adults and Children over 10 years: 1-2 tablets (8 -16 mg), 3 times daily.
Children 5 - 10 years: ½ tablet (4 mg), 3 times daily.

SIDE EFFECTS

Gastrointestinal side effects may occur occasionally with bromhexine and a transient rise in serum aminotransferase values has been reported. Other reported adverse effects include headache, vertigo (dizziness), sweating and allergic reactions.

CONTRAINDICATION

Bromhexine is contraindicated for use in patients with known hypersensitivity or idiosyncratic reaction to bromhexine hydrochloride (or any of the other ingredients in the product).

PRECAUTION

Since mucolytics may disrupt the gastric mucosal barrier, bromhexine should be used with caution in patients with a history of gastric ulceration. Clearance of bromhexine or its metabolites may be reduced in patients with severe hepatic or renal impairment.

USE IN PREGNANCY AND LACTATION

Category B. Bromhexine has been taken by a large number of pregnant women and women of child bearing age without any proven increase in the frequency of malformations or other direct or indirect harmful effects on the fetus having been observed.

It is not known whether bromhexine is excreted in breast milk or whether it has a harmful effect on the breastfeeding infant. Therefore it is not recommended for breastfeeding mothers unless the potential benefits to the patient are weighed against the possible risk to the infant.

STORAGE CONDITION

Mucospel® Syrup : Store below 30°C in dry place. Keep away from light. Keep out of reach of children.
Mucospel® Tablet : Store below 30°C in dry place. Keep away from light. Keep out of reach of children.

HOW SUPPLIED

Mucospel® Syrup : Box containing 100 ml syrup in PET bottle and a measuring cup.
Mucospel® Tablet : Each box contains 10 x 10 tablets in blister pack.

SQUARE