Ambroxol

Composition: each tablet contains ambroxol hydrochloride 30 mg
Each 5 ml of the syrup contains ambroxol hydrochloride 15 mg

Ambroxol is a clinically proven systemically active mucolytic agent. When administered orally onset of action occurs after about 30 minutes. The breakdown of acid mucopolysaccharide fibers makes the sputum thinner and less viscous and therefore more easily removed by coughing. Although sputum volume eventually decreases, its viscosity remains low for as long as treatment is maintained.

Ambroxol is a metabolite of bromhexine with similar actions and uses. It is chemically described as trans-4-[(2-Amino-3,5-dibromobenzyl)amino]-cyclohexanol. It is an expectoration improver and a mucolytic agent used in the treatment of acute and chronic disorders characterized by the production of excess or thick mucous. It has been successfully used for decades in the form of its hydrochloride as a secretion-releasing expectorant in a variety of respiratory disorders. Its short biological half life (4 h) that calls for frequent daily dosing (2 to 3 times) and therapeutic use in chronic respiratory diseases necessitates its formulation into sustained release dosage form.

The development of sustained/controlled release formulations of ambroxol hydrochloride is therefore of therapeutic relevance and can be used to provide a consistent dosage through sustaining an appropriate level of the drug over time. The simplest and least expensive way to control the release of the drug is to disperse it within an inert polymeric matrix and hydrophilic matrices are an interesting option when formulating an oral sustained release (SR) of a drug. The dosage release properties of matrix devices may be dependent upon the solubility of the drug in the polymer matrix or, in case of porous matrices, the solubility in the sink solution within the particle’s pore network. Hydroxypropylmethylcellulose (HPMC)

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is the dominant hydrophilic vehicle used for the preparation of oral controlled drug delivery systems. Numerous studies have been reported in literature investigating the HPMC matrices to control the release of a variety of drugs from matrices.

**Indications**
All forms of tracheobronchitis, emphysema with bronchitis pneumoconiosis, chronic inflammatory pulmonary conditions, bronchiectasis, and bronchitis with bronchospasm asthma. During acute exacerbations of bronchitis it should be given with the appropriate antibiotic.

**Contraindications**
There are no absolute contraindications but in patients with gastric ulceration relative caution should be observed.

**Side effects**
Occasional gastrointestinal side effects may occur but these are normally mild.

**Precautions**
It is advisable to avoid use during the first trimester of pregnancy.

**Dosage**
Adults: daily dose of 30 mg (one Ambroxol tablet) to 120 mg (4 tablets) taken in 2 to 3 divided doses
Children up to 2 years: half teaspoonful syrup twice daily
Children 2 - 5 years: half teaspoonful Ambroxol syrup 3 times daily
Children over 5 years: One teaspoonful Ambroxol syrup 2-3 times daily.