# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE MEDICINAL PRODUCT

Ambroxon Syrup

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml of syrup contains Ambroxol Hydrochloride 30 mg

## 3. PHARMACEUTICAL FORM

(Oral Solution) Syrup

## 4. CLINICAL PARTICULARS

### 4.1. Therapeutic indications

Ambroxon is indicated for secretory therapy of acute and chronic broncho-pulmonary diseases, associated with bronchial secretion disturbance and abatement of mucus discharge.

### 4.2 Posology and method of administration

**Dosage:**

Unless otherwise prescribed, the following dosage is recommended for Ambroxon Syrup 30 mg/5ml

**Children from 2 to 5 years of age**: 1.25ml of syrup 2-3 times daily (corresponding to 22.5 mg Ambroxol hydrochloride/day)

**Children from 6 to 12 years of age**: 2.5ml of syrup 2-3 times daily (corresponding to 30-45 mg Ambroxol hydrochloride/day)

**Adults and adolescents over 12 years**

As a rule, 5ml of the syrup is taken 3 times daily for first 2-3 days (corresponding to 90 mg Ambroxol hydrochloride/day)

Treatment is then continued with 5 ml of syrup twice daily (corresponding to 60 mg Ambroxol hydrochloride/day).if necessary the efficacy of the dose for adults & adolescents can be increased by taking 10 ml syrup twice a day (corresponding to 120 mg Ambroxol hydrochloride/day)

Ambroxon Cough Syrup is taken with the aid of the attached measuring device (measuring cup) after food. Ambroxon Syrup 30 mg/5 ml is not be taken for more than 4 to 5 days with out medical advice.

## 4.3 Contraindications

Ambroxol Hydrochloride should not be used in patients known to be hypersensitive to Ambroxol or any of the components. Ambroxon Syrup 30 mg/5 ml is not recommended for children below 2 years of age.

## 4.4 Special warnings and precautions for use

Caution should be advised during the first trimester of pregnancy and in patients with gastric ulceration.

Ambroxon Syrup 30mg/5ml Should be used with caution in patients with renal impairments or severe liver diseases.

Patients with rare hereditary galactose intolerance, the lapp lactase deficiency or glucose galactose malabsorption should not take Ambroxol Hydrochloride. Also patients with rare hereditary fructose intolerance should not take Ambroxol hydrochloride.

## 4.5 Interaction with other medicinal products and other forms of interaction

The combined use of Ambroxon syrup & antitussives can cause a dangerous accumulation of secretions as a consequence of the impaired cough reflex. Therefore this combination should only be used after very careful consideration.

## 4.6 Fertility, pregnancy and lactation

It is advisable to avoid use of Ambroxol during the first trimester of pregnancy. The usual precautions regarding the use of drugs during pregnancy should be observed.

Ambroxol is excreted in breast milk. Therefore, Ambroxon is not recommended for use in nursing mothers. However unfavourable effects on breastfed infants would not be expected. Ambroxol Hydrochloride crosses the Placental barrier.

## 4.7 Effects on ability to drive and use machines

There are no data that Ambroxon affects the ability to drive and operate machines.

## 4.8 Undesirable effects

Gastrointestinal disorders: Dyspepsia, nausea, vomiting, Diarrhoea and abdominal pain.

Respiratory, Mediastinal and Thoracic Disorders: Oral & pharyngeal hypoaesthesia, dry mouth & dry throat.

Nervous System Disorders: dysgeusia (eg. Changed taste).

Immune system Disorders: Anaphylactic reactions including anaphylactic shock Skin & subcutaneous Tissue Disorders: Angioedema, rash, urticaria, pruritis, and other hypersensitivity.

### 4.9. Overdosage:

**Symptoms of Overdosage**

No severe signs of intoxication have been observed following overdose of Ambroxol. Short term restlessness and diarrhea have been reported.

Ambroxol was well tolerated on parenteral administration of doses of up to 15 mg/kg/day and oral doses of up to 25 mg/kg/day.

By analogy with preclinical studies, extreme overdose could cause increased salivary secretion, retching, vomiting and a drop in blood pressure.

**Treatment of Overdosage**

Acute measures, such as induced vomiting and gastric lavage, are not generally indicated and should only be considered in case of an extreme overdose. Symptomatic treatment is recommended.

## 5. Pharmacological properties

### 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: expectorants, excl. combinations with cough suppressants, mucolytics.

ATC code: R05CB06.
Ambroxol, a substituted benzylamine, is a metabolite of bromhexine.
It differs from bromhexine by the absence of a methyl group and the introduction of a hydroxyl group in the para-trans position of the cyclohexyl ring. Although its mechanism of action has yet to be completely elucidated, secretolytic and secretomotor effects have been found in various investigations, however.

On average, action following oral administration commences after 30 minutes and persists for 6 -12 hours depending on the extent of the single dose.

In preclinical investigations, it increases the proportion of serous bronchial secretion. The transport of mucus is thought to be promoted by the reduction of viscosity and the activation of the ciliated epithelium.

### 5.2. Pharmacokinetic properties

Absorption of Ambroxol is rapid and complete, it corresponds to a dose administrated peak plasma concentration are reached within 0.5 to 3 hours. About 90% of Ambroxol is bound to plasma proteins in therapeutic doses.
Distribution after P.O., I.M. and I.V. administration from blood to organs is rapid with maximal concentrations in the lungs. Plasma half-life is 7- - 12 hours, accumulation has not been observed.

Approximately 30% of oral dose is eliminated by first passage by liver (first pass effect).
Primary metabolism of ambroxol takes place in the liver by conjugation. Total renal excretion is about 90%.

### 5.3. Preclinical safety data

Preclinical data based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity and carcinogenic potential show no particular risk for humans.

a) Acute toxicity

Investigations of Ambroxol hydrochloride has a low index for acute toxicity on animals has produced no particular sensitivity

b) Chronic toxicity/sub chronic toxicity

Investigations of chronic toxicity on two animal species have shown no substance-induced changes.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1. List of excipients

Glycerol , Liquid Sorbitol (Non-crystallizing), Benzoic Acid , Hydroxyethylcellulose , Sodium Citrate , Tartaric Acid , Propylene Glycol , Sodium Metabisulphite , Raspberry Flavour.

### 6.2.Incompatibilities

Not applicable.

### 6.3. Shelf life

36 Months.

### 6.4. Special precautions for storage

Store below $30^0$C.

Protect from light.

Keep out of reach of children

### 6.5. Nature and contents of container

Amber glass bottle contains 100 ml of syrup.

125 ml amber glass bottle labeled and fitted with child-resistant cap (CRC), and plastic measuring cup placed in a printed carton along with a pack insert.

### 6.6 Special precautions for disposal

No special requirements.

## 7. MARKETING AUTHORISATION HOLDER

**Lagap SA, UAE**
Po. Box 46222
Abu Dhabi, UAE

## 8. MARKETING AUTHORISATION NUMBER(S)

05414/6167/NMR/2018

## 9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of Approval : 14-10-2020