SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Guaifenesin <TRADE NAME> <STRENGTH> Syrup

<REGARDING THE APPROVAL>

1. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each <ml> contains <STRENGTH> of Guaifenesin

For the full list of excipients, see section 6.1.

<REGARDING THE APPROVAL>

1. PHARMACEUTICAL FORM

Syrup <REGARDING THE APPROVAL>

1. CLINICAL PARTICULARS
   1. Therapeutic indications

Expectorant for the treatment of coughs.

* 1. Posology and method of administration

**Adults, the elderly and children over 12 years**: 200 mg up to four times daily

**Paediatric population**

The safety and efficacy of Guaifenesin 100 mg/5 ml Syrup in children under 12 years has not yet been established. No data is available.

**Hepatic/renal impairment**

Caution should be exercised in severe hepatic and severe renal impairment (see Section 5.2).

If cough persists for more than 7 days, tends to recur, or is accompanied by a fever, rash, or persistent headache, a physician should be consulted.

**Method of administration**

For oral administration.

* 1. Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

* 1. Special warnings and precautions for use

This product should not be used for persistent or chronic cough, such as occurs with asthma, or where cough is accompanied by excessive secretions, unless directed by a physician.

A persistent cough may be a sign of a serious condition. If cough persists for more than one week, tends to recur, or is accompanied by a fever, rash, or persistent headache, a physician should be consulted.

Caution should be exercised when using the product in the presence of severe renal or severe hepatic impairment.

The concomitant use of cough suppressants is not recommended.

**Excipient information**

<REGARDING THE APPROVAL>

* 1. Interaction with other medicinal products and other forms of interaction

If urine is collected within 24 hours of a dose of this product a metabolite of guaifenesin may cause a colour interference with laboratory determinations of urinary 5-hydroxyindoleacetic acid (5-HIAA) and vanillylmandelic acid (VMA).

Expectorants such as guaifenesin should not be combined with cough suppressants in the treatment of cough since the combination is illogical and patients may be exposed to unnecessary adverse effects.

No interaction studies have been performed showing an interaction with guaifenesin.

* 1. Fertility, pregnancy and lactation

**Pregnancy**

There are no or limited amount of data from the use of guaifenesin in pregnant women. Animal studies are insufficient with respect to reproductive toxicity (see section 5.3). Guaifenesin Syrup is not recommended during pregnancy and in women of childbearing potential not using contraception.

**Breast-feeding**

Guaifenesin is excreted in breast milk in small amounts. There is insufficient information on the effects of guaifenesin in newborns/infants. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Guaifenesin Syrup therapy, taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

**Fertility**

There is insufficient information available to determine whether guaifenesin has the potential to impair fertility.

* 1. Effects on ability to drive and use machines

This product has no or negligible influence on the ability to drive and use machines.

* 1. Undesirable effects

**Summary of the safety profile**

Anaphylaxis has been reported.

The undesirable effects have been reported spontaneously during post-marketing use. Due to limited clinical trial data, a frequency cannot be estimated from the available data and is therefore classified as “not known”.’ The following side effects may be associated with the use of guaifenesin:

**Immune System Disorders**

Not known: Hypersensitivity reactions including pruritus, urticaria, Rash, Anaphylactic reaction

**Gastrointestinal Disorders**

Not known: Abdominal pain upper, diarrhoea, nausea, vomiting

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Health Product Vigilance Center; HPVC.

* 1. Overdose

**Symptoms**

The symptoms and signs of overdose may include abdominal pain, nausea and drowsiness. When taken in excess, guaifenesin may cause renal calculi.

**Management**

Treatment should be symptomatic and supportive.

1. PHARMACOLOGICAL PROPERTIES
   1. Pharmacodynamic properties

Pharmacotherapeutic Group: Cough and cold preparations, Expectorants. ATC Code: R05CA03

Mechanism of action

This product is thought to exert its pharmacological action by stimulating receptors in the gastric mucosa. This increases the output from secretory glands of the gastrointestinal system and reflexly increases the flow of fluids from glands lining the respiratory tract. The result is an increase in volume and decrease in viscosity of bronchial secretions. Other actions may include stimulating vagal nerve endings in bronchial secretory glands and stimulating certain centres in the brain, which in turn enhance respiratory fluid flow. Guaifenesin produces its expectorant action within 24 hours.

* 1. Pharmacokinetic properties

**Absorption**

Guaifenesin is well absorbed from the gastro-intestinal tract following oral administration, although limited information is available on its pharmacokinetics. After the administration of 600 mg guaifenesin to healthy adult volunteers, the Cmax was approximately 1.4 ug/ml, with tmax occurring approximately 15 minutes after drug administration.

**Distribution**

No information is available on the distribution of guaifenesin in humans.

**Biotransformation and elimination**

Guaifenesin appears to undergo both oxidation and demethylation. The drug is rapidly metabolized in the liver via oxidation to β-(2-methoxyphenoxy)-lactic acid. The demethylation of GGE (hydroxyguaifenesin) is performed by O-demethylase, localized in liver microsomes. Following an oral dose of 600 mg guaifenesin to 3 healthy male volunteers, the t½ was approximately 1 hour and the drug was not detectable in the blood after approximately 8 hours. Guaifenesin is excreted predominantly in the urine Approximately 40% of a dose is excreted as the metabolite beta-2-methoxyphenoxy-lactic acid in the urine within 3 hours. Following oral dosing of 400mg guaifenesin, more than 60% of a dose is hydrolysed within 7 hours, with no parent drug detectable in the urine.

**Special Populations**

No information regarding guaifenesin’s pharmacokinetics in special

populations is available.

* 1. Preclinical safety data

Carcinogenicity

There is insufficient information available to determine whether guaifenesin has carcinogenic potential.

Mutagenicity

There is insufficient information available to determine whether guaifenesin has mutagenic potential.

Teratogenicity

There is insufficient information available to determine whether guaifenesin has teratogenic potential.

Fertility

There is insufficient information available to determine whether guaifenesin has the potential to impair fertility.

1. PHARMACEUTICAL PARTICULARS
   1. List of excipients

<REGARDING THE APPROVAL>

* 1. Incompatibilities

Not applicable.

* 1. Shelf life

<REGARDING THE APPROVAL>

* 1. Special precautions for storage

<REGARDING THE APPROVAL>

* 1. Nature and contents of container

<REGARDING THE APPROVAL>

* 1. Special precautions for disposal

<REGARDING THE APPROVAL>

1. MARKETING AUTHORISATION HOLDER

<REGARDING THE APPROVAL>

1. MARKETING AUTHORISATION NUMBER(S)

<REGARDING THE APPROVAL>

1. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

<REGARDING THE APPROVAL>

1. DATE OF REVISION OF THE TEXT1

<REGARDING THE APPROVAL>