Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Benylin Mucus Cough Honey & Lemon 100mg / 5ml Syrup

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

This product contains 20 mg guaifenesin in each ml. Excipient(s) with known effect

Ethanol 0.1 ml/ml
Glucose 698.4 mg/ml
Sucrose 199.8 mg/ml
Sodium citrate 2.1 mg/ml
Sodium benzoate (E211) 2.0 mg/ml
Propylene glycol (E1520) 5.8 mg/ml

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Syrup

Clear yellow-brown colored syrup with a characteristic taste of honey and lemon.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Benylin Mucus Honey & Lemon 100mg / 5ml Syrup indicated for the symptomatic relief of productive cough in adults and adolescents of 12 years and above.

4.2 Posology and method of administration

Posology

Adults and adolescents of12 years and above:

10 ml (200 mg guaifenesin) 4 times a day. Maximum daily dose: 40 ml (800 mg guaifenesin)

Paediatric population

The safety and efficacy of Benylin Mucus Honey & Lemon 100mg / 5ml Syrup in children under 12 years has not yet been established

No data are available

Elderly:
As per adults.

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:

Oral

4.3 Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1

4.4 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.

Contains approximately 2 g of sucrose and 7 g of glucose in each 10 ml dose. This should be taken into account in patients with diabetes mellitus. Patients with rare hereditary problems of fructose intolerance, glucose galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine. Sucrose and glucose may be harmful to the teeth.

This medicine contains 393 mg of alcohol (ethanol) in each 10 ml dose which is equivalent to 39.3 mg/ml. The amount in 10 ml of this medicine is equivalent to less than 10 ml beer or 4 ml wine.
The small amount of alcohol in this medicine will not have any noticeable effects.

This medicinal product contains 41.1 mg sodium per 10 ml, equivalent to 2.054% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

This medicinal product contains 20 mg of sodium benzoate in each 10 ml dose.

This medicinal product contains 57.8 mg propylene glycol in each 10 ml dose.

4.5 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.

4.6 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). Benylin Mucus Honey & Lemon 100mg / 5ml 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
Benylin Mucus Honey & Lemon 100mg / 5ml 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.

4.7 Effects on ability to drive and use machines

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

4.8 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:

SOC	Frequency Category	Adverse Event Term
Immune System Disorders	Not Known	Hypersensitivity reactions including pruritus and 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 HPRA Pharmacovigilance, website: www.hpra.ie.

4.9 Overdose

Symptoms andsigns

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.

5 PHARMACOLOGICAL PROPERTIES

5.1 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.

5.2 Pharmacokinetic properties

SpecialPopulations

No information regarding guaifenesin's pharmacokinetics in special populations is available.

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

5.3 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium citrate
Citric acid monohydrate
Carbomer
Glycerol (E422)
Ethanol 96% Glucose, liquid Sucrose
Sucralose
Sodium benzoate (E211)

Flavours: Levomenthol
Bitterness blocking flavour 84E260
Honey flavour SN781458
Lemon flavour 557579CW8
Cooling flavour 539692T Tingling flavour 538723T

Hot mix flavour 538842T
Non-alcohol enhancer SC008414
(Flavours contain Propylene glycol (E1520) and other flavouring ingredients) Caramel (E150)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years
In-use: 6 months

6.4 Special precautions for storage

Store in the original bottle in order to protect from light.

6.5 Nature and contents of container

Type III, Amber glass bottle, containing 150ml or 300ml fitted with: A plastic child resistant cap fitted with a PET-faced wad.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

JNTL Consumer Health I (Ireland) Limited
Office 5, 6 And 7
Block 5
High Street
Tallaght
Dublin 24
D24 YK8N
Ireland

8 MARKETING AUTHORISATION NUMBER

PA23490/041/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 22nd March 2024

10 DATE OF REVISION OF THE TEXT