Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Benylin Mucus Cough Menthol 100 mg/5 ml oral solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

This product contains 20 mg guaifenesin in each ml (100mg in 5ml).

Excipient(s) with known effect:

Ethanol 39.7mg/ml
Ponceau 4R (E124) 0.05mg/ml
Macrogol glycerol hydroxystearate 40 3 mg/ml
Sodium benzoate (E211) 1 mg/ml
Propylene glycol (E1520) 200.35 mg/ml

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral solution
Clear to slightly opalescent red liquid

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Benylin Mucus Cough Menthol is indicated to help loosen phlegm and thin bronchial secretions associated with productive cough, for use in adults and adolescents over 12 years.

4.2 Posology and method of administration

Posology

Adults and adolescents over 12 years:

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

Paediatric population
The safety and efficacy of Benylin Mucus Cough Menthol in children aged under 12 years have not yet been established.

No data are available

The 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 ofadministration:

Oral

4.3 Contraindications

Hypersensitivity to active substance 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 7 days, 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.

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

This medicinal product may contain very trace amounts of glucose.

Patients with rare glucose galactose malabsorption should not take this medicine.

This medicinal product contains 381 mg of alcohol (ethanol) in each 10 ml dose which is equivalent to 38.1 mg/ml. The amount in 10 ml of this medicine is equivalent to 9.5 ml beer or 3.8 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

This product contains Ponceau 4R (E124) red colouring which may cause allergic reactions.

This medicinal product contains less than 1 mmol sodium (23 mg) per 10 ml dose, that is to say essentially 'sodium-free'.

This medicinal product contains 2003.5 mg propylene glycol in each 10 ml dose. While propylene glycol has not been shown to cause reproductive or developmental toxicity in animals or humans, it may reach the foetus and was found in milk. As a consequence, administration of propylene glycol to pregnant or lactating patients should be considered on a case by case basis. Medical monitoring is required in patients with impaired renal or hepatic functions because various adverse events attributed to propylene glycol have been reported such as renal dysfunction (acute tubular necrosis), acute renal failure and liver dysfunction.
This medicinal product contains macrogol glycerol hydroxystearate 40. It may cause stomach upset and diarrhoea.

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 which revealed 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 Cough Menthol 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 Cough Menthol 100 mg/ 5 ml Oral Solution 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

Guaifenesin 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 Disorder	Not Known	Hypersensitivity reactions including pruritus and urticaria Rash Anaphylactic reaction
Gastrointestinal Disorders	Not Known	Gastrointestinal discomfort, nausea and 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 and signs

The symptoms and signs of overdose may include gastro-intestinal discomfort, 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:
Guaifenesin 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

There is no information available on the pharmacokinetics of guaifenesin in special populations.

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 C_{max} was approximately 1.4 ug/ml, with t_{max} 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

Xanthan gum

Sodium chloride
Saccharin sodium
Ammonium glycyrrhizate
Sodium benzoate (E211)
Citric acid
Sodium citrate
Macrogol glycerol hydroxystearate 40
Levomenthol
Raspberry flavour F2126 (includes ethanol)
Caramel (E150)
Ponceau 4R (E124)
Glycerol
Macrogol 1500
Propylene glycol (E1520)
Ethanol 96%
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years
In-use: 4 weeks

6.4 Special precautions for storage

Do not store above 25°C
Store in the original container to protect from light.

6.5 Nature and contents of container

Type III, Amber glass bottle, containing 150 ml, fitted with:

A plastic child resistant cap fitted with a PET-faced wad.

A plastic dosing cup marked with a 10ml graduation is included in this pack.

6.6 Special precautions for disposal

No special requirements.

Any unused medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 7th October 2011

Date of last renewal: 6th April 2015

10 DATE OF REVISION OF THE TEXT

May 2025