Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Benylin Phlegm Cough Syrup Guaifenesin 100 mg/5ml Levomenthol 1.1 mg/ 5ml Syrup

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 mls contains 100 mg guaifenesin and 1.1 mg levomenthol

Excipients with known effect: Each 5ml contains
Glucose liquid 3.5g
Sucrose 1g
Ponceau 4R (E124) 0.25mg
Sodium benzoate (E211) 10mg
Sodium 16.4mg
Ethanol 197mg
Propylene glycol (E1520) 1.07mg
Invert sugar 6.75mg

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Syrup.
Clear, red syrup having a characteristic odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Benylin Phlegm Cough Syrup is indicated for the symptomatic relief of productive cough.

4.2 Posology and method of administration

Adults and children over 12 years:
Oral.
Two 5 ml spoonfuls every 4 to 6 hours.
Do not give more than 4 doses in 24 hours.
Maximum daily dose 40ml.

Children under 12 years:
Not recommended. [See section 4.3].

The Elderly:
As for adults.

Hepatic/renal dysfunction
Experience with the use of this product suggests that normal adult dosage is appropriate for mild to moderate dysfunction. Caution should be exercised in severe hepatic and severe renal impairment. [See section 4.4].

4.3 Contraindications

This product is contraindicated in individuals with known hypersensitivity to the active substance or to any of the excipients.

Benylin Phlegm Cough Syrup should not be used in children under the age of 12 years.

4.4 Special warnings and precautions for use

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

Caution should be exercised when using the product in the presence of severe renal or severe hepatic impairment. [See section 4.2].

This medicinal product contains 3.5g glucose per 5ml, contains 1 g of sucrose per 5ml and 6.75mg invert sugar per 5ml. This should be taken into account in patients with diabetes mellitus.
Patients with rare hereditary problems of fructose intolerance, glucose galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine.

This medicine contains 197 mg of alcohol (ethanol) in each 5 ml dose. The amount in a 5 ml dose of this medicine is equivalent to less than 5 ml beer or 2 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.
This medicine contains Ponceau 4R (E124) which may cause allergic reactions.

This medicine contains 16.42 mg sodium per 5 ml equivalent to 0.82% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

This medicine contains 1.07mg propylene glycol in each 5ml dose.

This medicine contains 10mg sodium benzoate in each 5ml dose.

4.5 Interaction with other medicinal products and other forms of interaction

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

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 Phlegm Cough Syrup is not recommended during pregnancy and in women of childbearing potential not using contraception.

Breastfeeding
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 Phlegm Cough 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

Based on the pharmacodynamic profile of guaifenesin it is not expected that this product would interfere with the ability to drive or operate machinery.

4.8 Undesirable effects

Adverse drug reactions (ADRs identified during clinical trials and post-marketing experience with guaifenesin/menthol are included in the table below by System Organ Class (SOC). The frequencies are provided according to the following convention:

Very common ≥1/10
Common ≥1/100 and < 1/10

Uncommon ≥1/1,000 and <1/100
Rare ≥1/10,000 and <1/1,000
Very rare <1/10,000
Not known (cannot be estimated from the available data)

ADRs are presented by frequency category based on 1) incidence in adequately designed clinical trials or epidemiology studies, if available or 2) when incidence cannot be estimated, frequency is listed as 'Not known'

Body System (SOC)	**Frequency**	**Adverse Drug Reaction (Preferred Term)**
Immune System Disorders	Not known	Hypersensitivity (including Pruritus and Urticaria)
Gastrointestinal Disorders	Not known	Abdominal discomfort
	Not known	Abdominal pain upper
	Not known	Diarrhoea
	Not known	Nausea
	Not known	Vomiting
Skin and Subcutaneous Tissue Disorders	Not known	Rash

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

Guaifenesin
The symptoms and signs of overdose may include gastro-intestinal discomfort, nausea and somnolence. When taken in excess, Guaifenesin may cause renal calculi.

Menthol
Excessive use of menthol may lead to abdominal pain, vomiting, flushed face, dizziness, weakness, tachycardia, stupor, and ataxia

Treatment
Treatment should be symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: R05CA03

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.

Menthol has mild local anaesthetic and decongestant properties.

5.2 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 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 or menthol in humans.

Metabolism and elimination

Guaifenesin appears to undergo both oxidation and demethylation. Following an oral dose of 600 mg guaifenesin to 3 healthy male volunteers, the $t_{½}$ was approximately 1 hour and the drug was not detectable in the blood after approximately 8 hours.

Menthol is hydroxylated in the liver by microsomal enzymes to p-menthane -3, 8 diol. This is then conjugated with glucuronide and excreted both in urine and bile as the glucuronide.

Pharmacokinetics in Renal/Hepatic Impairment

There have been no specific studies of Benylin Phlegm Cough Syrup, menthol or guaifenesin in hepatic or renal impairment.

Pharmacokinetics in the Elderly

There have been no specific studies in the use of Benylin Phlegm Cough Syrup, menthol or guaifenesin in the elderly.

5.3 Preclinical safety data

Carcinogenicity

There is insufficient information available to determine whether guaifenesin or menthol have carcinogenic potential.

Mutagenicity

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

The results of a range of tests suggest that menthol does not have a mutagenic potential.

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

The results of a number of studies suggest that the administration of menthol does not produce any statistically significant teratogenic effects in rats, rabbits and mice.

Fertility

There is insufficient information available to determine whether guaifenesin or menthol have the potential to impair fertility.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium benzoate (E211)
Sucrose

Liquid Glucose
Glycerol
Citric acid monohydrate
Sodium citrate
Saccharin sodium
Ethanol 96%
Caramel T12 (E150) (containing glucose, sucrose and invert sugar)
Ponceau 4R (E124)
Concentrated raspberry essence double strength (containing propylene glycol and ethanol)
Natural sweetness enhancer
Carbomer
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 30°C. Keep bottle tightly closed in order to protect from moisture.

6.5 Nature and contents of container

Amber glass bottles (pharmacopoeial grade III) with an aluminium ROPP cap with melinex-faced pulpboard wad or with a 3 piece plastic child resistant, tamper evident closure fitted with a PE-Alu-PET or polyethylene/ expanded polyethylene laminated wad or with a plastic HDPE cap fitted with a PE-Alu-PET wad.

Pack sizes: 30 ml, 125 ml or 300 ml.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special 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

PA23490/031/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 8th September 2016

10 DATE OF REVISION OF THE TEXT

March 2024