Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Benylin Children's Chesty Cough 50mg/5ml Syrup

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains 50 mg guaifenesin.

Excipients with known effect:
Sorbitol liquid (E420) 2.525g per 5ml.
Benzyl alcohol 0.05mg per 5ml
Sodium benzoate (E211) 15mg per 5 ml
Sodium 14.9mg per 5ml
Propylene glycol (E1520) 0.1mg per 5ml
Ethanol 0.00025mg per 5ml

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Syrup
A colourless to slightly yellow, clear syrup.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Benylin Children's Chesty Coughis indicated for the symptomatic relief of productive coughs.

4.2 Posology and method of administration

Adults and children 12 years and over:

Not appropriate.

Children aged 6 to 12 years:

Oral. 10 ml three or four times daily
Maximum daily dose: 40 ml
Use only when simple measures have failed to provide adequate relief.
Use for more than five consecutive days is not recommended.

Children under 6 years:
Not recommended. [See Section 4.3]

4.3 Contraindications

Use in patients hypersensitive to the active ingredients.

Use in patients at risk of developing respiratory failure.

Use in children under 6 years of age is contraindicated.

4.4 Special warnings and precautions for use

BENYLIN Children's Chesty Coughs 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.

If cough tends to recur or is accompanied by a fever, rash or persistent headache, a physician should be consulted.

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

Patients with rare hereditary problems of fructose intolerance should not take this medicine.

Not more than 4 doses should be given in any 24 hours. Do not exceed the stated dose.

Do not take with any other cough and cold medicine.

Consult a pharmacist or other healthcare professional before use in children aged 6 to 12 years.

This medicine contains 2.525g sorbitol in each 5 ml dose. Patients with hereditary problems of fructose intolerance should not take this medicine.
Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

This medicinal product contains 14.9 mg sodium per 5 ml dose, equivalent to 0.75% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

This medicine contains 15 mg sodium benzoate in each 5 ml dose.

This medicine contains 0.1 mg propylene glycol in each 5ml.

This medicine contains 0.00025mg of alcohol (ethanol) in each 5ml which is equivalent to 0.00005 mg/ml. The amount in 5 ml is equivalent to less than 1ml beer or 1 ml wine.
The small amount of alcohol in this medicine will not have any noticeable effects.

This medicine contains 0.05 mg benzyl alcohol in each 5 ml dose. Benzyl alcohol may cause allergic reactions. This medicine must be used with caution in patients with renal or hepatic impairment, or in patients who are pregnant or breast-feeding, because of the risk of accumulation and toxicity (metabolic acidosis).

4.5 Interaction with other medicinal products and other forms of interaction

If urine is collected within 24 hours of a dose of Benylin Children's Chesty Cough 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

This product has been formulated specifically for children, and would therefore not normally be taken during 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 Children's Chesty Cough 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 Children's Chesty Coughs 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

It is not expected that this product would interfere with the ability to drive or operate machinery.

4.8 Undesirable effects

Adverse drug reactions identified during post-marketing experience with guaifenesin are included in the table below. 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 category is listed as 'Not known'.

Adverse Drug Reactions Identified During Post-Marketing Experience with Guaifenesin by Frequency Category Estimated from Clinical Trials or Epidemiology Studies:	
Body System (SOC) Adverse Event preferred term	Frequency Category
Immune System Disorders: Hypersensitivity reactions (Hypersensitivity, pruritus, and urticaria)	Not known
Rash	Not known
Gastrointestinal Disorders:	
Abdominal pain upper	Not known
Diarrhoea	Not known
Nausea	Not known
Vomiting	Not known

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 effects of acute toxicity from guaifenesin may include gastrointestinal discomfort, nausea and drowsiness. When taken in excess, guaifenesin may cause renal calculi.

Treatment

Treatment should be symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

Absorption

Guaifenesin is well absorbed from the gastro-intestinal tract following oral administration, although limited information regarding its pharmacokinetics is available. 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 t½ was approximately 1 hour and the drug was not detectable in the blood after approximately 8 hours.

Pharmacokinetics in Renal/Hepatic Impairment

There have been no specific studies of Benylin Children's Chesty Cough or guaifenesin in subjects with renal or hepatic impairment.
Caution is therefore recommended when administering this product to subjects with severe renal or hepatic impairment.

Pharmacokinetics in the Elderly

Not applicable.

5.3 Preclinical safety data

Mutagenicity

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

Carcinogenicity

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

Teratogenicity

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

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

Glycerol (E422)
Sorbitol, liquid (non-crystallising) (E420)
Sodium citrate (E331)
Citric acid monohydrate
Sodium saccharin

Sodium benzoate (E211)
Carmellose Sodium
Strawberry Flavour (containing benzyl alcohol, propylene glycol and ethanol)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened: 3 years.
Opened: Discard the bottle, 4 Months after first opening, even if there is syrup remaining.

6.4 Special precautions for storage

Do not store above 25°C.
Store in the original container.
Keep the container tightly closed in order to protect from moisture.

6.5 Nature and contents of container

30 ml, 125 ml and 300 ml amber glass bottles with a polyester wadded white aluminium ROPP cap or a 3 piece plastic child resistant, tamper evident closure fitted with a polyester faced wad or polyethylene/expanded polyethylene laminated wad, or 2 piece plastic child resistant, tamper evident closure fitted with a PVDC wad.

A spoon with a 5 ml and 2.5 ml measure is supplied with the pack.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Do not use if bottle seal is broken when purchased.

7 MARKETING AUTHORISATION HOLDER

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High Street
Tallaght
Dublin 24
D24 YK8N
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8 MARKETING AUTHORISATION NUMBER

PA23490/011/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 27 July 2008

10 DATE OF REVISION OF THE TEXT

March 2024