SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

BENYLIN Children's Chesty Coughs
Calcough Six Plus

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

BENYLIN Children's Chesty Coughs contains 50 mg guaifenesin in each 5 ml.

Each 5ml also contains:

Sorbitol liquid (non-crystallising)	2.525 g/5ml
Sodium Citrate	28.5 mg/5ml
Sodium Saccharin	20.5 mg/5ml
Sodium Benzoate	15 mg/5ml
Carmellose Sodium	48 mg/5ml
Benzyl alcohol	0.05 mg/5ml

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Syrup

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

BENYLIN Children's Chesty Coughs is an expectorant for the symptomatic relief of acute productive (chesty) coughs.

4.2. Posology and method of administration

Posology
Adults and children aged 12 years and over:

Not applicable.

Children aged 6 to 12 years:

10 ml syrup four times daily.
Maximum daily dose: 40 ml syrup (400 mg guaifenesin)

Not to be used for more than 5 days without the advice of a doctor. Parents and carers should seek medical attention if the child's condition deteriorates during treatment.

Children under 6 years:
Benylin Children's Chesty Coughs is contraindicated in children under the age of 6 years (see section 4.3).

Method of administration
For oral use

Do not exceed the stated dose.

Keep out of the sight and reach of children.

4.3 Contraindications

BENYLIN Children's Chesty Coughs is contraindicated in individuals with known hypersensitivity to the product, or any of its components.

Not to be used in children under the age of 6 years.

4.4 Special warnings and precautions for use

Ask a doctor before use if your child suffers from chronic cough, if he/she has asthma or is suffering from an acute asthma attack.

Stop use and ask a healthcare professional if your child's cough lasts for more than 5 days, comes back, or is accompanied by a fever, rash or persistent headache.

Do not give with a cough suppressant.

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

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.

This medicine contains 5.05g sorbitol in each 10 ml dose.
The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account. The content of sorbitol in medicinal products for oral use may affect the bioavailability of

other medicinal products for oral use administered concomitantly. Patients with hereditary fructose intolerance (HFI) should not take/be given this medicinal product. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

This medicinal product contains 33.04 mg sodium per 10 ml dose, equivalent to 1.65% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

This medicine contains 25.2 mg benzoate salt in each 10 ml dose.

This medicine contains 0.1 mg benzyl alcohol in each 10 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 Coughs 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 Coughs 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 breastfed 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

Guaifenesin has no or negligible influence on the ability to drive or operate machinery.

4.8 Undesirable effects

The safety of guaifenesin is based on available data from clinical trials and adverse drug reactions (ADRs) identified during post-marketing experience.

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 Clinical Trials, Epidemiology studies and Post-Marketing Experience with Guaifenesin. Frequency Category estimated from Clinical Trials or Epidemiology Studies

Body system (SOC)	**Incidence**	**Adverse Event Preferred Term**
Immune system disorders	Not known	Hypersensitivity reactions (hypersensitivity, pruritus and urticaria) Rash
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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9. Overdose

Symptoms

The effects of acute toxicity from guaifenesin may include gastrointestinal 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: Expectorants, 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.

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 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 Coughs 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 has 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 has the potential to impair fertility.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol

Sorbitol liquid (non-crystallising)
Sodium citrate
Citric acid monohydrate
Sodium saccharin
Sodium benzoate
Carmellose Sodium
Strawberry flavour (containing benzyl alcohol)
Purified water

6.2. Incompatibilities

None known.

6.3 Shelf life

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

6.4. Special precautions for storage

Do not store above 25°C. Store in the original package.

6.5. Nature and contents of container

BENYLIN Children's Chesty Coughs is stored in 125 ml, 300 ml or 30 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
a 2 piece plastic child resistant, tamper evident closure fitted with a PVDC wad.

Not all pack sizes may be marketed.

6.6. Instruction for use and handling (, and disposal)

Any unused product or waste material should be disposed of in accordance with local requirements

7 MARKETING AUTHORISATION HOLDER

McNeil Products Limited
50 – 100 Holmers Farm Way
High Wycombe
Buckinghamshire
HP12 4EG
UK

8. MARKETING AUTHORISATION NUMBER

PL 15513/0052

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

07/09/2001

10 DATE OF REVISION OF THE TEXT

26/10/2022