# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

BENYLIN Chesty Coughs (Non-drowsy)
Benylin Mucus Cough

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml of product contains 100 mg guaifenesin and 1.1 mg levomenthol.

Each 5 ml also contains:

| | |
|---|---|
| Ethanol | 197 mg |
| Glucose | 3.5 g |
| Sucrose | 1 g |
| Sodium | 16.43 mg |
| Sodium benzoate (E 211) | 10 mg |
| Ponceau 4R (E 124) | 0.25 mg |

For the full list of excipients, see Section 6.1.

## 3. PHARMACEUTICAL FORM

Clear red syrup

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

BENYLIN Chesty Coughs (Non-drowsy) is indicated for the symptomatic relief of cough.

### 4.2 Posology and method of administration

**Adults and children aged 12 years and over:**
Oral. Two 5 ml spoonfuls four times a day.

**Children under 12 years:**

This product is contraindicated in children under the age of 12 years (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 Pharmacokinetics].

Do not exceed the stated dose.

Keep out of the sight and reach of children.

## 4.3 Contraindications

This product 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 12 years.

## 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.

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

Contains 3.5 g of glucose and 1 g of sucrose per 5 ml. 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.

This medicine contains 197 mg of alcohol (ethanol) in each 5 ml. The amount in 5 ml 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 medicinal product contains 16.43 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 10 mg sodium benzoate (E 211) in each 5 ml.

This product contains Ponceau 4R (E 124) red colouring which may cause allergic reactions.

## 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).

## 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). Insufficient information is available on the effects of administration of this product during human pregnancy. This product 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 this product, 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 or operate machinery.

## 4.8 Undesirable effects

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

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, including isolated reports

Not known (cannot be estimated from the available data)

ADRs are presented for 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** | **Incidence** | **Reported adverse event** |
|---|---|---|
| Immune System Disorders | Not known | Hypersensitivity reactions (hypersensitivity, pruritus and urticaria)<br>Rash |
| Gastrointestinal Disorders | Not known | Abdominal pain upper<br>Diarrhoea<br>Nausea<br>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 and signs**

The effects of acute toxicity from guaifenesin may include gastro-intestinal 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

Pharmacotherapeutic Group: Cough and cold preparations, Expectorants. ATC Code: R05CA10

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 in reflex 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, decongestant and antitussive 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.

Menthol is well absorbed from the gastrointestinal tract following oral 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.

Menthol is hydroxylated in the liver by microsomal enzymes to p-methane -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 this product, menthol or guaifenesin in hepatic or renal impairment.

**Pharmacokinetics in the Elderly**

There have been no specific studies in the use of this product, menthol or guaifenesin in the elderly.

## 5.3 Pre-clinical 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
Ponceau 4R (E124)
Concentrated raspberry essence double strength
Natural sweetness enhancer
Carbomer
Purified water

### 6.2. Incompatibilities

None known

### 6.3 Shelf life

3 years

### 6.4. Special precautions for storage

Do not store above 30°C.

### 6.5 Nature and contents of container

125, 150, 200 or 300ml amber glass bottles with a 2 piece or a 3 piece plastic child resistant, tamper evident closure fitted with a polyterephtalate ethylene faced aluminium/expanded polyethylene laminated wad

### 6.6 Special precautions for disposal

No special requirements.

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 15513/0056

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

15th December 1997

## 10 DATE OF REVISION OF THE TEXT

16/02/2022