

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1 NAME OF THE MEDICINAL PRODUCT**

Benylin Chesty Coughs (Original)

### **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each 5 ml contains:

Diphenhydramine hydrochloride	14.0 mg
L-menthol	2.0 mg

Each 5ml also contains:

Sucrose	1 g
Liquid glucose	3.5 g
Ethanol	197 mg
Ponceau 4R (E 124)	0.25 mg
Sodium	16.62 mg
Benzyl alcohol	0.22 mg
Sodium benzoate (E 211)	10 mg

For a full list of excipients, see section 6.1.

### **3 PHARMACEUTICAL FORM**

Syrup.

A clear red syrup

### **4 CLINICAL PARTICULARS**

#### **4.1 Therapeutic indications**

BENYLIN CHESTY COUGHS (ORIGINAL) is indicated for the relief of cough and associated congestive symptoms.

#### **4.2 Posology and method of administration**

For oral use

**Adults and Children aged 12 years and over:**

One 10 ml dose of syrup 4 times a day.

Maximum daily dose: 40 ml syrup.

**Children under 12 years:**

BENYLIN CHESTY COUGHS (ORIGINAL) is contraindicated in children under the age of 12 years (see section 4.3).

**The Elderly:**

As for adults above (see Pharmacokinetics - The elderly).

Hepatic dysfunction

Caution should be exercised if moderate to severe hepatic dysfunction is present (see Pharmacokinetics - Hepatic dysfunction).

Renal dysfunction

It may be prudent to increase the dosage interval in subjects with moderate to severe renal failure (see Pharmacokinetics - Renal dysfunction).

Do not exceed the stated dose.

Keep out of the sight and reach of children.

**4.3 Contraindications**

BENYLIN CHESTY COUGHS (ORIGINAL) is contraindicated in individuals with known hypersensitivity to Diphenhydramine or L-menthol or to any of the excipients listed in section 6.1.

BENYLIN CHESTY COUGHS (ORIGINAL) should not be administered to patients currently receiving monoamine oxidase inhibitors (MAOIs) or within 14 days of stopping treatment (see section 4.5).

Not to be used in children under the age of 12 years.

**4.4 Special warnings and precautions for use**

This product may cause drowsiness. If affected individuals should not drive or operate machinery.

This product should not be used to sedate a child.

Diphenhydramine may enhance the sedative effects of central nervous system depressants including alcohol, sedatives, opioid analgesics, antipsychotics and tranquilizers. Alcoholic beverages should be avoided while taking this medicine (see section 4.5).

Do not use with any other product containing diphenhydramine, including topical formulations used on large areas of skin.

Subjects with hepatic disease or moderate to severe renal dysfunction should exercise caution when using this product (see Pharmacokinetics - Renal/Hepatic Dysfunction).

Patients with the following conditions should be advised to consult a physician before using this medicine:

- A chronic or persistent cough such as occurs with chronic bronchitis or emphysema, acute or chronic asthma, or where cough is accompanied by excessive secretions
- Susceptibility to angle-closure glaucoma
- Prostatic hypertrophy and/or urinary retention

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

This medicine contains 16.62 mg sodium (main component of cooking/table salt) in each 5 ml. This is equivalent to 0.83% of the recommended maximum daily dietary intake of sodium for an adult.

This medicine contains 0.22 mg benzyl alcohol in each 5ml. Benzyl alcohol may cause allergic reactions.

Ask your doctor or pharmacist for advice if you are pregnant or breast feeding. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called “metabolic acidosis”). High volumes should be used with caution and only if necessary, especially in subjects with liver or kidney impairment because of the risk of accumulation and toxicity (metabolic acidosis).

This medicine contains 10 mg sodium benzoate (E 211) in each 5 ml.

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.

## **4.5 Interaction with other medicinal products and other forms of interaction**

### **Diphenhydramine**

**CNS depressants:** may enhance the sedative effects of CNS depressants including barbiturates, hypnotics, opioid analgesics, anxiolytic sedatives, antipsychotics and alcohol. .

**Antimuscarinic drugs:** may have an additive muscarinic action with other drugs, such as atropine and some antidepressants.

**MAOIs:** Not be used in patients taking MAOIs or within 14 days of stopping treatment as there is a risk of serotonin syndrome.

### **Menthol**

There are no known drug interactions associated with menthol.

## **4.6 Fertility, pregnancy and lactation**

This product should not be used during pregnancy or breastfeeding unless the potential benefit of treatment to the mother outweighs the possible risks to the developing fetus or breastfeeding infant.

### **Diphenhydramine**

#### **Pregnancy**

Diphenhydramine has been in widespread use for many years without any apparent ill consequence. Diphenhydramine is known to cross the placenta and, therefore, should only be used during pregnancy if considered essential by a doctor.

#### **Breastfeeding**

Diphenhydramine is excreted into human breast milk, but levels have not been reported. Although the levels are not thought to be sufficiently high enough after therapeutic doses to affect the infant, the use of diphenhydramine during breastfeeding is not recommended.

### **Menthol**

There are no adequate and well-controlled studies in pregnant women for menthol. Menthol is excreted in breast milk; when 100 mg of menthol was ingested, there was up to 5.87 ug/L of menthol in breast milk.

## **4.7. Effects on Ability to Drive and Use Machines**

This product may cause drowsiness. If affected, the patient should not drive or operate machinery.

## 4.8 Undesirable effects

### Diphenhydramine

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

Very common	$\geq 1/10$
Common	$\geq 1/100$ and $< 1/10$
Uncommon	$\geq 1/1,000$ and $< 1/100$
Rare	$\geq 1/10,000$ and $< 1/1,000$
Very rare	$< 1/10,000$
Not known	(cannot be estimated from the available data)

System Organ Class (SOC)	Frequency*	Adverse Drug Reaction
Blood and Lymphatic System Disorders	Rare	Blood disorders
Immune System Disorders	Rare	Hypersensitivity reactions
Psychiatric Disorders	Uncommon	Irritability Hallucination Nervousness
	Rare	Confusional state
Nervous System Disorders	Very common	Somnolence (usually diminishes within a few days)
	Common	Dizziness Headache Paradoxical stimulation Psychomotor impairment
	Uncommon	Agitation Paraesthesia Sedation
	Rare	Convulsion Depression Extrapyramidal effects Insomnia Tremor
Eye Disorders	Common	Vision blurred
Ear and Labyrinth Disorders	Uncommon	Tinnitus
Cardiac Disorders	Uncommon	Tachycardia
	Rare	Arrhythmia Palpitations
Vascular Disorders	Rare	Hypotension
Respiratory, Thoracic and Mediastinal Disorders	Common	Thickened respiratory tract secretions
	Uncommon	Chest discomfort Nasal dryness
Gastrointestinal Disorders	Common	Dry mouth Nausea Vomiting
Hepatobiliary Disorders	Rare	Liver dysfunction

<b>System Organ Class (SOC)</b>	<b>Frequency*</b>	<b>Adverse Drug Reaction</b>
Skin and Subcutaneous Tissue Disorders	Uncommon	Pruritus Rash Urticaria
Renal and Urinary Disorders	Common	Urinary retention
General Disorders and Administration site conditions	Common	Asthenia

(\*) Frequency category based on clinical trials with single-ingredient diphenhydramine

### **Menthol**

Adverse reactions to menthol at the low concentration present in BENYLIN CHESTY COUGHS (ORIGINAL) are not anticipated.

### **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](http://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**

#### **Diphenhydramine**

#### **Mild to Moderate Symptoms:**

Drowsiness, anticholinergic syndrome (mydriasis, flushing, fever, dry mouth, urinary retention, decreased bowel sounds), tachycardia, mild hypertension, nausea and vomiting are common after overdose. Agitation, confusion and hallucinations may develop after moderate poisoning.

#### **Severe Symptoms:**

Effects may include delirium, psychosis, seizures, coma, hypotension, QRS widening, and ventricular dysrhythmias (including torsades de pointes), but are generally only reported in adults after large ingestions. Rhabdomyolysis and renal failure may rarely develop in patients with prolonged agitation, coma or seizure. Death may occur as a result of respiratory failure or circulatory collapse.

In children, CNS excitation, including hallucinations and convulsions may appear; with larger doses, coma or cardiovascular collapse may follow.

## **Menthol**

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

## **Treatment**

Treatment of overdose should be symptomatic and supportive. The benefit of gastric decontamination is uncertain. Consider activated charcoal (charcoal dose: 50 g for adults; 1 g/kg for children) only if the patient presents within 1 hour of ingestion of a potentially toxic amount. Seizures may be controlled with Diazepam or Thiopental Sodium. The intravenous use of Physostigmine may be efficacious in antagonising severe anticholinergic symptoms.

# **5 PHARMACOLOGICAL PROPERTIES**

## **5.1 Pharmacodynamic properties**

Diphenhydramine possesses antitussive, antihistaminic and anticholinergic properties. Experiments have shown that the antitussive effect (resulting from an action on the brainstem) is discrete from its antihistaminic effect. The duration of activity of diphenhydramine is between 4 and 8 hours. Menthol has mild local anaesthetic and decongestant properties.

## **5.2. Pharmacokinetic Properties**

### **Absorption**

Diphenhydramine and menthol are well absorbed from the gut following oral administration. Peak serum levels of diphenhydramine following a 50 mg oral dose are reached at between 2 and 2.5 hours.

### **Distribution**

Diphenhydramine is widely distributed throughout the body, including the CNS. Following a 50 mg oral dose of diphenhydramine, the volume of distribution is in the range 3.3 - 6.8 l/kg, and it is some 78% bound to plasma proteins.

### **Metabolism and Elimination**

Diphenhydramine undergoes extensive first pass metabolism. Two successive N-demethylations occur, with the resultant amine being oxidised to a carboxylic acid. Values for plasma clearance of a 50 mg oral dose of diphenhydramine lie in the range 600-1300 ml/min and the terminal elimination half-life lies in the range 3.4 - 9.3 hours. Little unchanged drug is excreted in the urine. 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.

## **The Elderly**

Pharmacokinetic studies indicate no major differences in distribution or elimination of Diphenhydramine compared to younger adults.

## **Renal Dysfunction**

The results of a review on the use of Diphenhydramine in renal failure suggest that in moderate to severe renal failure, the dose interval should be extended by a period dependent on Glomerular filtration rate (GFR).

## **Hepatic Dysfunction**

After intravenous administration of 0.8 mg/kg Diphenhydramine, a prolonged half-life was noted in patients with chronic liver disease which correlated with the severity of the disease. However, the mean plasma clearance and apparent volume of distribution were not significantly affected.

### **5.3. Preclinical Safety Data**

#### **Mutagenicity**

The results of a range of tests suggest that neither diphenhydramine or menthol have mutagenic potential.

#### **Carcinogenicity**

There is insufficient information to determine the carcinogenic potential of diphenhydramine or menthol, although such effects have not been associated with these drugs in animal studies.

#### **Teratogenicity**

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

#### **Fertility**

There is insufficient information to determine whether diphenhydramine has the potential to impair fertility, although a diminished fertility rate has been observed in mice in one study.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Ammonium chloride  
Liquid glucose  
Sucrose  
Ethanol 96%  
Glycerol  
Sodium citrate  
Saccharin sodium  
Citric acid monohydrate  
Sodium benzoate (E 211)  
Caramel T12  
Raspberry flavour 503.850/T (benzyl alcohol, propylene glycol (E 1520), ethanol)  
Carbomer  
Ponceau 4R (E 124)  
Purified water

## **6.2. Incompatibilities**

None known

## **6.3 Shelf life**

Unopened: 2 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

## **6.5 Nature and contents of container**

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

## **6.6 Special precautions for disposal <and other handling>**

No special requirements.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required (these should be disposed

of in line with local requirements). These measures will help to protect the environment.

**7      MARKETING AUTHORISATION HOLDER**

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

**8.     MARKETING AUTHORISATION NUMBER(S)**

PL 15513/0048

**9.     DATE OF FIRST AUTHORISATION / RENEWAL OF THE  
AUTHORISATION**

21/03/2006

**10    DATE OF REVISION OF THE TEXT**

22/06/2023