SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

BENYLIN CHILDREN'S NIGHT COUGHS

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains:

Diphenhydramine Hydrochloride	7.0 mg
Levomenthol	0.55 mg

Each 5ml also contains:

Sorbitol (E 420)	2.53 g
Ethanol	197 mg
Sodium	16.47 mg
Sodium benzoate (E 211)	25 mg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

A clear colourless syrup with no insoluble matter.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

BENYLIN CHILDREN'S NIGHT COUGHS is indicated for the relief of cough and its congestive symptoms, runny nose and sneezing, and in the treatment of hay fever and other allergic conditions affecting the upper respiratory tract. It is specially formulated for children and contains no artificial dyes or sucrose.

4.2 Posology and method of administration

Route of Administration: Oral

Children under 6 years:

BENYLIN CHILDREN'S NIGHT COUGHS is contraindicated in children under the age of 6 years (see section 4.3).

Children 6 to 12 years:

Two 5 ml spoonfuls every 6 hours

No more than four doses should be given in any 24 hours.

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

Do not exceed the stated dose.

Keep out of the sight and reach of children.

4.3 Contraindications

BENYLIN CHILDREN'S NIGHT COUGHS is contraindicated in individuals with known hypersensitivity to the Diphenhydramine or Levomenthol or to any of the excipients listed in section 6.1.

BENYLIN CHILDREN'S NIGHT COUGHS 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 6 years.

4.4 Special warnings and precautions for use

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

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.

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

The product may cause drowsiness. This product should not be used to sedate a child.

A dose of 10 ml of this medicine administered to a child 6 years of age and weighing 21 kg would result in exposure to 18.8 mg/kg of ethanol which may cause a rise in blood alcohol concentration (BAC) of about 3.13 mg/100 ml (see Appendix 1 of report EMA/CHMP/43486/2018).

For comparison, for an adult drinking a glass of wine or 500 ml of beer, the BAC is likely to be about 50 mg/100 ml.

Co-administration with medicines containing e.g., propylene glycol or ethanol may lead to accumulation of ethanol and induce adverse effects, in particular in young children with low or immature metabolic capacity.

This medicine contains 16.47 mg sodium (main component of cooking/table salt) in each 5 ml. This is equivalent to 0.82% of the recommended maximum daily dietary intake of sodium for an adult.

This product contains 2.53 g sorbitol in each 5 ml. 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 problems of fructose intolerance (HFI) should not take/be given this medicinal product**.**

Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

This medicine contains 25 mg sodium benzoate (E 211) in each 5 ml.

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 to 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.

Breast-feeding
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 breast-feeding 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 preparation may cause drowsiness, dizziness or blurred vision. 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 ≥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)

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
Skin and Subcutaneous	Uncommon	Pruritus Rash

System Organ Class (SOC)	Frequency*	Adverse Drug Reaction
Tissue Disorders		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 CHILDREN'S NIGHT COUGHS 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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Signs and Symptoms

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. In addition to supportive care, the intravenous use of Physostigmine may be efficacious in antagonising severe anticholinergic symptoms.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Diphenhydramine is a potent antihistamine and antitussive with anticholinergic properties. Recent experiments have shown that the antitussive action is discrete from H_1-receptor blockade and is located in the brain stem.

Menthol has mild local anaesthetic and decongestant properties.

5.2 Pharmacokinetic Properties

Diphenhydramine is well absorbed from the gastrointestinal tract. Peak serum levels are reached at between 2-2.5 hours after an oral dose. Duration of activity is between 4 - 8 hours. The drug is widely distributed throughout the body, including the CNS, and some 78% are bound to plasma proteins. Estimates of the volume of distribution lie in the range 3.3 - 6.8 l/kg.

Diphenhydramine experiences extensive first-pass metabolism, undergoing two successive N-Demethylations; the resultant amine is then oxidised to a carboxylic acid. Values for plasma clearance 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.

Pharmacokinetic studies in elderly subjects indicate no major differences in drug distribution or elimination compared with younger adults.

Menthol: After absorption, menthol is conjugated in the liver and excreted both in urine and bile as the glucuronide.

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 adminstration 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 Pre-clinical Safety Data

Not applicable

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium benzoate
Citric acid monohydrate
Sodium citrate
Saccharin sodium
Sodium carboxymethylcellulose 7MXF
Glycerol
Sorbitol 70% (non crystalline)
Concentrated raspberry essence (Ethanol, Propylene Glycol E1520)
Ethanol 96%
Purified water

6.2 Incompatibilities

None known

6.3 Shelf Life

Unopened: 36 months
Opened: Discard the bottle 4 months after opening, even if there is syrup remaining.

6.4 Special Precautions for Storage

Store below 30°C

6.5 Nature and contents of container

125.000 ml, 30.000 ml Round amber glass bottles with roll-on-pilfer-proof (ROPP) aluminium caps containing melinex-faced pulpboard wad
or
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 PET 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 15513/0044

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date Granted: 16 June 1997

10 DATE OF REVISION OF THE TEXT

22/06/2023