

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Benylin Dual Action Night Cough & Congestion
Benylin Mucus Cough Night

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains Diphenhydramine hydrochloride 14 mg, Guaifenesin 100 mg and Levomenthol 1.1 mg.

Also contains:

Ethanol	196.62mg/5ml
Glucose	3498.7mg/5ml
Sucrose	1005.7mg/5ml
Ponceau 4R	0.25mg/5ml
Sodium	18.53mg/5ml
Sodium Benzoate	10mg/5ml

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

A clear red syrup with no insoluble matter.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

For the relief of cough (dry and/or chesty), associated congestive symptoms and aiding restful sleep.

4.2. Posology and method of administration

Posology

Adults and children aged 12 years and over:

Two 5 ml spoonfuls four times a day.

Or to aid sleep patients may start with two 5 ml spoonfuls at bedtime followed by two 5 ml spoonfuls every 6 hours.

Do not take more than 4 doses (1 dose = two 5 ml spoonfuls) in 24 hours.

Children under 12 years:

This medicine is contraindicated in children under the age of 12 years (see section 4.3).

Elderly (over 65 years):

As for adults.

Do not exceed the stated dose.

Keep out of the sight and reach of children.

Method of Administration

For oral use

4.3. Contraindications

This product is contraindicated in individuals with hypersensitivity to diphenhydramine, guaifenesin, levomenthol or to any of the excipients listed in section 6.1.

This product 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. This product should not be used to sedate a child.

Subjects with moderate to severe renal dysfunction or hepatic disease should exercise caution when using this product (see section 5.2).

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

Diphenhydramine may enhance the sedative effects of central nervous system depressants, including alcohol, opioid analgesics, antipsychotics, sedatives and tranquilizers. Patients should be advised while taking this product to avoid alcoholic beverages and consult a healthcare professional prior to taking with central nervous system depressants (see section 4.5).

Excitability may occur.

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

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

If symptoms persist or get worse, or if new symptoms occur, patients should stop use and consult a physician.

Do not take with a cough suppressant.

This product contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

This product contains 7 g glucose and 2 g sucrose per 10 ml dose. This should be taken into account in patients with diabetes mellitus. Patients with rare glucose-galactose malabsorption should not take this medicine.

This product contains Ponceau 4R (E124) red colouring which may cause allergic reactions.

This medicinal product contains 5 vol % ethanol (alcohol), i.e. up to 196.62 mg per 5ml dose, which is equivalent to less than 5 ml beer, 2 ml wine per 5 ml dose. The small amount of alcohol in this medicine will not have any noticeable effects.

This medicinal product contains 18.53 mg sodium per 5ml dose, equivalent to 1.853% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

This product contains 8.47 mg benzoic acid in 5ml dose.

The label contains the following statements:

May cause drowsiness. If affected, do not drive, cycle or operate machinery.

Do not use to sedate a child.

Talk to your doctor or pharmacist:

If you suffer from a chronic or persistent cough, if you have asthma, suffering from an acute asthmatic attack or where cough is accompanied by excessive secretions.

If your cough lasts for more than 5 days, comes back, or is accompanied by a fever, rash or persistent headache.

Avoid alcoholic drink. Do not use if bottle seal is broken when purchased. Keep bottle tightly closed. Do not store above 30°C. Keep out of the sight and reach of children. As with all medicines, if you are pregnant consult your doctor or pharmacist before taking this product.

4.5. Interactions 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, antipsychotics and alcohol.

Antimuscarinic drugs: May have an additive muscarinic action with other drugs such as atropine and some antidepressants. This may result in tachycardia, dry mouth, gastrointestinal disturbances (e.g. colic), urinary retention and headache.

MAOIs: This product should not be used in patients taking MAOIs or within 14 days of stopping treatment as there is a risk of serotonin syndrome.

Guaifenesin

Interference with diagnostic tests: 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-hydroxyindole acetic acid (5-HIAA) and vanillylmandelic acid (VMA).

4.6. Fertility, pregnancy and lactation

Insufficient information is available on the effects of administration of this product during human pregnancy. This product should not be used during pregnancy or lactation unless the potential benefit of treatment to the mother outweighs the possible risks to the developing foetus or breastfeeding infant.

Diphenhydramine

There are no adequate and well-controlled studies of diphenhydramine in pregnant or breast-feeding women. Diphenhydramine crosses the placenta and is excreted into breast milk, but levels have not been reported.

Guaifenesin

Guaifenesin is excreted in breast milk in small amounts with no effect expected on the infant.

Levomenthol

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

4.7 Effects on ability to drive and use machines

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

4.8. Undesirable effects

Adverse drug reactions (ADRs) identified during clinical trials and post-marketing experience with diphenhydramine, guaifenesin, levomenthol or the combination 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)

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'.

System Organ Class (SOC)	Frequency	Adverse Drug Reaction (Preferred Term)
Blood and Lymphatic System	Rare	Blood disorder ¹
Immune System Disorders	Rare	Hypersensitivity ^{1,2}
	Not known	Angioedema ¹
Psychiatric Disorders	Uncommon	Agitation ¹ Insomnia ¹ Irritability ¹ Nervousness ¹
	Rare	Confusional state ¹ Depression ¹ Sleep disorder ¹
	Not known	Hallucination ¹
Nervous System Disorders	Very common	Somnolence (usually diminishes within a few days)* Sedation ¹
	Common	Dizziness* Headache ¹ Paradoxical stimulation Psychomotor impairment ¹
	Rare	Convulsion ¹ Extrapyramidal disorder ¹ Tremor ¹
	Not known	Coordination abnormal ¹ Paraesthesia ¹
Eye Disorders	Common	Blurred Vision ¹
Ear and Labyrinth Disorders	Uncommon	Tinnitus ¹
Cardiac Disorders	Rare	Arrhythmia ¹ Palpitations ¹
	Not known	Tachycardia ¹

Vascular Disorders	Rare	Hypotension ¹
Respiratory, Thoracic and Mediastinal Disorders	Common	Dry throat ¹ Increased viscosity of bronchial secretion ¹
	Not known	Nasal dryness ¹
Gastrointestinal Disorders	Common	Dry mouth* Gastrointestinal disorder ¹
	Not known	Abdominal discomfort ² Abdominal pain upper ² Constipation ¹ Diarrhoea ^{1,2} Dyspepsia ¹ Nausea ^{1,2} Vomiting ^{1,2}
Hepatobiliary Disorders	Rare	Liver Disorder ¹
Skin and Subcutaneous Tissue Disorders	Uncommon	Rash ^{1,2}
	Not known	Erythema ¹ Pruritus ^{1,2} Urticaria ^{1,2}
Renal and Urinary Disorders	Common	Urinary retention ¹
	Not known	Dysuria ¹
General Disorders and Administration Site Conditions	Common	Asthenia*
	Not known	Chest discomfort

* Frequency category based on clinical trials with single-ingredient diphenhydramine.

¹ Associated with diphenhydramine

² Associated with guaifenesin

Levomenthol

Adverse reactions to levomenthol at the low concentration present in the product 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

Diphenhydramine

Following overdose in adults, moderate symptoms have been associated with ingestions of greater than 300-500 mg and serious symptoms associated with doses greater than 1 g diphenhydramine.

Young children may be more sensitive to the effects of overdose.

Mild to Moderate Symptoms:

Somnolence, anticholinergic syndrome (mydriasis, flushing, fever, tachycardia, dry mouth, urinary retention, decreased bowel sounds, agitation confusion and hallucinations), mild hypertension, nausea and vomiting are common after overdose.

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.

Guaifenesin

Somnolence may be associated with guaifenesin overdose.
When taken in excess, guaifenesin may cause renal calculi.

Levomenthol

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

Treatment

Gastric lavage in the conscious patient and intensive supportive therapy where necessary, as with cases of overdose with antihistaminic drugs.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Other cough suppressants and expectorants
ATC code: R05FB

Diphenhydramine is a potent antihistamine and antitussive with anticholinergic and sedative properties. Recent experiments have shown that the antitussive action is discrete from H₁-receptor blockade and is located in the brain stem.

Guaifenesin is reported to reduce the viscosity of tenacious sputum and is used as an expectorant.

Levomenthol has mild local anaesthetic and decongestant properties.

5.2 Pharmacokinetic properties

Diphenhydramine is well absorbed in the gastro-intestinal 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% is 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.

Guaifenesin is readily absorbed after oral administration. It is rapidly metabolised by oxidation to β -(2-methoxy-phenoxy) lactic acid. About 40% of a dose is excreted as this metabolite in the urine in 3 hours.

After absorption Levomenthol is conjugated in the liver and excreted both in the 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 dependant 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

There are no pre-clinical data of relevance to the prescriber which are additional to those already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium benzoate (E211)
Sucrose
Glucose liquid
Glycerol
Citric acid monohydrate
Sodium citrate
Saccharin sodium
Ethanol 96%
Caramel (E150d)

Ponceau 4R (E124)
Concentrated raspberry essence
Natural sweetness enhancer
Carbomer
Purified water

6.2. Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25°C. Do not refrigerate or freeze.

6.5 Nature and contents of container

125, 150 or 300 ml amber glass bottles with a 2 piece plastic child resistant, tamper evident closure fitted with a polyterephthalate 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

United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 15513/0050

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

16 June 1997 / 27 July 2001

10 DATE OF REVISION OF THE TEXT

25/01/2024