

Adverse events should be reported. Reporting forms and information can be found at <https://yellowcard.mhra.gov.uk/>

Adverse events should also be reported to McNeil Products Limited on freephone 0800 238 9999.

Benylin Mucus Cough Night (Guaifenesin, Levomenthol, Diphenhydramine) Product Information

Presentation:

A clear red syrup with no insoluble matter containing 100 mg Guaifenesin, 1.1 mg Levomenthol and 14 mg Diphenhydramine per 5 ml. Also contains 196.62 mg Ethanol, 3498.7 mg Glucose, 1005.7 mg Sucrose, 0.25 mg Ponceau 4R, 18.53 mg Sodium and 10 mg Sodium Benzoate per 5ml.

Uses:

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

Dosage:

Adults, the elderly and children over 12 years: 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.

Contraindications:

Children under 12 years. Known hypersensitivity to diphenhydramine, guaifenesin, levomenthol, or any of the product's excipients. Not for use in patients currently receiving monoamine oxidase inhibitors (MAOIs) within 14 days of stopping treatment.

Precautions:

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.

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. Excitability may occur. Patients with the following conditions should be advised to consult a physician before using this product: Acute or chronic bronchial asthma, persistent or chronic cough such as occurs with smoking, asthma chronic bronchitis or emphysema or where cough is accompanied by excessive secretions, susceptibility to narrow angle-closure glaucoma, prostatic enlargement (hyperplasia/hypertrophy) with 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.

Caution regarding the following excipients:

- 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 product contains 5 vol % ethanol (alcohol), i.e. up to 196.6 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.

See SPC for further precautions.

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.

Side effects:

Very common: Somnolence (usually diminishes within a few days), Sedation.

Common: Dizziness, Headache, Paradoxical stimulation, Psychomotor impairment, Blurred vision, Dry throat, Increased viscosity of bronchial secretion, Dry mouth, Gastrointestinal disorder, Urinary retention, Asthenia.

Uncommon: Agitation, Insomnia, Irritability, Nervousness, Tinnitus, Rashes.

Rare: Blood disorder, Hypersensitivity, Confusional state, Depression, Sleep disorder, Convulsion, Extrapyrarnidal disorder, Tremor, Arrhythmia, Palpitations, Hypotension, Liver disorder.

Not known: Angioedema, Hallucination, Coordination abnormal, Paraesthesia, Tachycardia, Nasal dryness, Abdominal discomfort, Abdominal pain upper, Constipation, Diarrhoea, Dyspepsia, Nausea, Vomiting, Erythema, Pruritus, Urticaria, Dysuria, Chest discomfort.

RRP (ex-VAT): 150ml £7.57

Legal category: P

PL Holder: McNeil Products Limited 50 – 100 Holmers Farm Way High Wycombe Buckinghamshire HP12 4EG United Kingdom

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