**Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard**

**Adverse events should also be reported to McNeil Products Limited on 01344 864 042.**

## Benylin Children's Night Coughs (Diphenhydramine hydrochloride, Levomenthol) Product Information

**Presentation:** Syrup containing 7mg Diphenhydramine HCl and 0.55mg Levomenthol per 5ml.
**Uses:** Relief of cough and associated congestive symptoms, runny nose, sneezing, and treatment of hayfever and other allergic conditions affecting the upper respiratory tract.
**Dosage:** Children 6 - 12 years: 10ml every 6 hours.
**Contraindications:** Use in children under 6 years; hypersensitivity to Diphenhydramine or Levomenthol (or menthol) or to any of the excipients. BENYLIN CHILDREN'S NIGHT COUGHS should not be administered to patients currently receiving monoamine oxidase inhibitors (MAOIs) or within 14 days of stopping treatment.
**Precautions:**
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; Patients with the following conditions should be advised to consult a physician before using: 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. Do not use with any other product containing diphenhydramine, including topical formulations used on large areas of skin. The product may cause drowsiness. This product should not be used to sedate a child. This product contains sorbitol. Patients with hereditary problems of fructose intolerance (HFI) should not take this medicinal product. 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. This medicine contains 25 mg benzoate salt in each 5 ml. This preparation may cause drowsiness, dizziness or blurred vision. **See SPC for further precautions.**

**Interactions: 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.

**Pregnancy and lactation**: This product should not be used during pregnancy or breast-feeding unless the potential benefit of treatment to the mother outweighs the possible risks to the developing fetus or breastfeeding infant. 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. 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.

**Side effects:**

*Very Common*: Somnolence

*Common:* Asthenia, Nausea

Vomiting, Dizziness, paradoxical stimulation, headache, psychomotor impairment, urinary retention, dry mouth, blurred vision, , thickened respiratory tract secretions.

*Uncommon*: Irritability, Hallucination, Nervousness, Agitation, Paraesthesia, Sedation, Tinnitus, Tachycardia, Chest Discomfort, Nasal Dryness, Pruritus, Rash, Urticaria

*Rare:* hypotension, extrapyramidal effects, Confusional state, depression, insomnia, tremor, convulsions, palpitation, arrhythmia, hypersensitivity reactions, blood disorders and liver dysfunction.

**RRP (ex-VAT):** 125 ml £3.90;

**Legal category:** P.

**PL Holder:** McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK

**PL Number:** 15513/0044.

**Date of preparation:** 05 MAR 2021