## 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 the product or any of its constituents; with or within two weeks of receiving MAOIs.

## **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; may cause drowsiness – do not drive or operate machinery if affected. Product should not be used to sedate children. Alcohol or other potential sedating medicines or other cough and cold medicine should not be used concurrently with this product. Use with caution: hepatic or moderate to severe renal impairment or urinary retention; in patients with, or susceptible to, angle-closure glaucoma; symptomatic prostatic hypertrophy. Consult a doctor if child suffers from a chronic or persistent cough, asthma or where cough is accompanied by excessive secretions. See SPC for further details.

**Interactions:** This product may have an additive muscarinic action with antimuscarinics; may potentiate sedative effects of CNS depressants.

Pregnancy and lactation: Consult doctor before use.

## Side effects:

<u>Common</u>: Drowsiness, paradoxical stimulation, headache, psychomotor impairment, urinary retention, dry mouth, blurred vision, gastrointestinal disturbances, thickened respiratory tract secretions.

<u>Rare:</u> hypotension, extrapyramidal effects, dizziness, confusion, depression, sleep disturbances, 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, Foundation Park, Maidenhead, Berks, SL6 3UG.

PL Number: 15513/0044.

Date of preparation: 5 Mar 2010