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 0808 238 9999.

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

Presentation:
Syrup containing 7 mg diphenhydramine hydrochloride and 0.55mg levomenthol per 5 ml. Each 5 ml also contains the following excipients: sorbitol (E 420) 2.53g, ethanol 197 mg, sodium 16.47 mg, sodium benzoate (E 211) 25mg

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 to 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. Patients with hepatic disease or moderate to severe renal dysfunction should exercise caution when using this product. 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. 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 5ml. 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 this medicinal product. Sorbitol may cause gastrointestinal discomfort and mild laxative effect. This medicine contains 25 mg sodium benzoate in each 5 ml.

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.

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.

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.

Please refer to Summary of Product Characteristics for detailed information.

RRP (ex-VAT): 125 ml £4.66
Legal category: P.
PL Holder: McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG
PL Number: PL 15513/0044.
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