

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 Chesty Coughs (Original) (diphenhydramine hydrochloride, levomenthol) Product Information

Presentation:

Red syrup containing 14mg diphenhydramine hydrochloride and 2mg levomenthol per 5ml. sucrose 1 g, liquid glucose 3.5 g, ethanol 197 mg, Ponceau 4R (E 124) 0.25 mg, sodium 16.62 mg, benzyl alcohol 0.22 mg, sodium benzoate (E 211) 10 mg.

Uses:

Relief of cough and associated congestive symptoms.

Dosage:

Adults and Children aged 12 years and over: One 10 ml dose of syrup 4 times a day. Maximum daily dose: 40 ml syrup.

Contraindications:

Known hypersensitivity to diphenhydramine, L-menthol or to any of the excipients listed within the Summary of Product Characteristics (SmPC). BENYLIN CHESTY COUGHS (ORIGINAL) should not be administered to patients currently receiving monoamine oxidase inhibitors (MAOIs) or within 14 days of stopping treatment. Not to be used in children under the age of 12 years.

Precautions:

May cause drowsiness, if affected, do not drive or operate machinery. This product should not be used to sedate a child. Patients with the following conditions should consult a physician before using this medicine: A chronic or persistent cough such as occurs with chronic bronchitis or emphysema, acute or chronic asthma, or where cough is accompanied by excessive secretions, susceptibility to angle-closure glaucoma, prostatic hypertrophy and/or, urinary retention. Contains 3.5 g of glucose and 1 g of sucrose per 5 ml. This should be taken into account in patients with diabetes mellitus. Patients with hepatic disease or moderate to severe renal dysfunction should exercise caution when using this product. Alcoholic beverages should be avoided while taking this medicine. May potentiate effects of alcohol, opioid analgesics, antipsychotics, antihistamines and other CNS depressants. May enhance the effects of anticholinergics. Do not use with any other product containing diphenhydramine. This product contains Ponceau 4R (E124) red colouring which may cause allergic reactions. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine. This medicine contains 0.22 mg benzyl alcohol in each 5 ml. Benzyl alcohol may cause allergic reactions. This medicine contains 10 mg sodium benzoate (E 211) in each 5 ml. This medicine contains 197 mg of alcohol (ethanol) in each 5 ml. The amount in 5 ml of this medicine is equivalent to less than

5 ml beer or 2 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects. Please consult the SmPC for further precautions.

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 foetus or breastfeeding infant. '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. 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: dizziness, headache, paradoxical stimulation, psychomotor impairment, thickened respiratory tract secretions, dry mouth, nausea vomiting, asthenia, vision blurred

Uncommon: irritability hallucination nervousness, agitation, paraesthesia, sedation, tinnitus, tachycardia, chest discomfort, nasal dryness, pruritus, urticaria.

Rare: blood disorders, confusional state, convulsion, depression, extrapyramidal effects, tremor, arrhythmia palpitations, hypotension, liver dysfunction

Please refer to Summary of Product Characteristics for detailed information.

RRP (ex-VAT): 150ml £6.66; 300ml £9.91

Legal category: P.

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

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