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 Dry Coughs Night Syrup (diphenhydramine hydrochloride, dextromethorphan hydrobromide, levomenthol) Product Information

Presentation:
Clear red syrup containing 14 mg diphenhydramine hydrochloride, 6.5 mg dextromethorphan hydrobromide, and 2 mg levomenthol per 5ml. Each 5 ml also contains ethanol 196 mg, glucose 3.5 g, sucrose 1 g, Ponceau 4R (E124) 0.25 mg, sodium 16.7 mg, benzyl alcohol 0.48 mg, propylene glycol 2.61 mg, sodium benzoate (E211) 10 mg.

Uses:
For night time relief of persistent, dry, irritating cough and aiding restful sleep.

Dosage:
Adults and children over 12 years: two 5 ml spoonfuls at bedtime followed by two 5 ml spoonfuls every 6 hours (or two 5 ml spoonfuls 4 times a day). Do not take more than 4 doses in 24 hours. Please take note that one dose is equal to two 5 ml spoonfuls.

Contraindications:
This product is contraindicated for use in children under 12 years of age and in individuals with known hypersensitivity to diphenhydramine, dextromethorphan, levomenthol or to any of the product's excipients. Dextromethorphan-containing products should not be used by individuals who are either currently taking, or who have taken monoamine oxidase inhibitors (MAOIs) within the preceding 14 days. Patients taking serotonin reuptake inhibitors (SSRIs), drugs which impair metabolism of serotonin (including MAOIs), and CYP2D6 inhibitors, should not use this product. Concomitant use of dextromethorphan has been reported to induce a potentially life-threatening condition called serotonin syndrome, which includes mental-status changes, autonomic instability, neuromuscular abnormalities, and/or gastrointestinal symptoms. Discontinue this medicine immediately if serotonin syndrome is suspected. Dextromethorphan should not be given to patients in, or at risk of developing respiratory failure. This product contains 3.5 g glucose and 1 g sucrose per 5 ml; therefore, patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption, or sucrase-isomaltase insufficiency should not take this medicine. It also contains Ponceau 4R (E124) red colouring and 0.48 mg benzyl alcohol per 5 ml, both of which may cause allergic reactions.

Precautions:
May cause drowsiness. This should not be used to sedate a child. Patients with the following conditions should not use this product, unless directed by a physician:

acute or chronic asthma, a persistent or chronic cough such as occurs with chronic bronchitis or emphysema, or where cough is accompanied by excessive secretions. This product should not be taken with any other cough and cold medicines.
Diphenhydramine should be used with caution by individuals with susceptibility to angle-closure or with prostatic hypertrophy, urinary retention. Use with caution in moderate to severe renal impairment or hepatic dysfunction. It may also enhance the sedative effects of central nervous system depressants including alcohol, opioid analgesics, antipsychotics, sedatives, and tranquilizers. Do not use with any other product containing diphenhydramine including topical formulations used on large areas of skin.
Use of dextromethorphan with alcohol or other CNS depressants may increase the effects on the CNS and cause toxicity in relatively smaller doses. Fatal cases of dextromethorphan overdose have been reported very rarely. Caution should be exercised in atopic children due to histamine release. Serotonergic effects, including the development of a potentially life-threatening serotonin syndrome, have been reported for dextromethorphan with concomitant administration of serotonergic agents, such as selective serotonin re-uptake inhibitors (SSRIs), drugs which impair metabolism of serotonin (including monoamine oxidase inhibitors (MAOIs)) and CYP2D6 inhibitors. If serotonin syndrome is suspected, treatment with this medicine should be discontinued. Caution should be exercised in patients who are slow metabolizers of CYP2D6 or use CYP2D6 inhibitors.
Drug dependence, tolerance and potential for abuse for all patients, prolonged use of this product may lead to drug dependence (addiction), even at therapeutic doses. The risks are increased in individuals with current or past history of substance misuse disorder (including alcohol misuse) or mental health disorder (e.g., major depression). Drug withdrawal syndrome is characterised by some or all of the following: restlessness, lacrimation, rhinorrhoea, yawning, perspiration, chills, myalgia, mydriasis and palpitations. Other symptoms may also develop including irritability, anxiety, hyperkinesia, tremor, weakness, insomnia, anorexia, abdominal cramps, nausea, vomiting, diarrhoea, increased blood pressure, increased respiratory rate or heart rate.
Caution due to the following excipients:

- This product contains 16.7 mg sodium per 5 ml, equivalent to 0.835% of the WHO recommended maximum daily intake of 2 g sodium for an adult.
- This product contains 3.5 g glucose and 1 g sucrose per 5 ml; which should be taken into account in patients with diabetes mellitus.
- This medicine contains 10 mg sodium benzoate (E211) in each 5 ml.
- This medicine contains 2.61 mg propylene glycol in each 5 ml.
- This medicine contains 0.48 mg benzyl alcohol in each 5 ml. Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding, or if you have a liver or kidney disease.
- This medicine contains 196 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.

Pregnancy and Lactation:
This medicine should not be used during pregnancy or lactation unless the potential benefit of treatment to the mother outweighs the possible risk to the developing foetus or breastfeeding infant. There are no adequate and well-controlled studies in pregnant or breast-feeding women. It is not known whether dextromethorphan or its metabolites are excreted in breast milk or cross the placenta. However,

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. There are no adequate and well-controlled studies in pregnant women for menthol; however, menthol is excreted in breast milk.

Side effects:

Very common: somnolence

Common: dizziness, headache, paradoxical stimulation, psychomotor impairment, blurred vision, increased viscosity of bronchial secretion, dry mouth, gastrointestinal disorder, urinary retention, asthenia

Uncommon: confusional state, insomnia, irritability, nervousness, tinnitus, rash

Rare: blood disorder, hypersensitivity, depression, sleep disorder, extrapyramidal disorder, seizure, tremor, arrhythmia, palpitations, hypotension, liver disorder

Not known: agitation, drug dependence, hallucination, paraesthesia, tachycardia, chest discomfort, nasal dryness, respiratory depression, abdominal pain, diarrhoea, nausea, vomiting, angioedema, pruritus, urticaria, dysuria, drug withdrawal syndrome

Please refer to Summary of Product Characteristics for detailed information.

RRP (ex-VAT): 150 ml, £6.66

Legal category: P.

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

PL Number: PL 15513/0053.

Date of prep: 14 MAY 2025