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:
Red syrup containing 14mg Diphenhydramine hydrochloride, 6.5mg Dextromethorphan hydrobromide and 2mg Levomenthol per 5ml. Each 5ml 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. Do not take more than 4 doses in 24 hours.

Contraindications:
Use in children under 12 years. Contraindicated in individuals with known hypersensitivity to diphenhydramine, dextromethorphan, levomenthol or to any of the excipients listed. Dextromethorphan should not be used in patients taking monoamine oxidase inhibitors (MAOIs), or within 14 days of stopping MAOI treatment. There is a risk of serotonin syndrome with the concomitant use of dextromethorphan and MAOIs and the concomitant use of these medications may cause a rise in blood pressure and/or hypertensive crisis. Patients taking serotonin reuptake inhibitors. Patients in or at risk of developing respiratory failure.

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.
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 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. 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 in patients who are slow metabolizers of CYP2D6 or use CYP2D6 inhibitors.
Use of dextromethorphan with alcohol or other CNS depressants may increase the effects on the CNS and cause toxicity in relatively smaller doses. Diphenhydramine may enhance the sedative effects of central nervous system depressants including alcohol, opioid analgesics, antipsychotics, sedatives, and tranquilizers.
Caution in atopic children due to histamine release. Do not use with any other product containing diphenhydramine including topical formulations used on large areas of skin.
This product should not be taken with any other cough and cold medicines.
Caution due to the following excipients:

- This product contains Ponceau 4R (E124) red colouring which may cause allergic reactions.
- 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 5ml. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine. This 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. Benzyl alcohol may cause allergic reactions. Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding. Ask your doctor or pharmacist for advice 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.

See SPC for further precautions.

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.
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
Very rare:
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

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, UK
PL Number: 15513/0053.
Date of preparation: 12 June 2023