DRY COUGHS NIGHT SYRUP

Diphenhydramine, Dextromethorphan, Levomenthol

- This medicine is used to help provide night time relief of dry, irritating coughs and aid a restful sleep.
- This medicine is for use by adults and children aged 12 years and over.
- **Do not take this medicine:**
  - There are some people who should not use this medicine. *To find out if you are one of them see section 2* ▶
  - If you have ever had a **bad reaction** to any of the ingredients. *For the list of ingredients see section 6* ▶
- **Speak to your doctor:**
  - If you suffer from any of the conditions mentioned in section 2. *See section 2* ▶
  - If you are taking any other medicines. *See section 2* ▶
- **Follow the dosage instructions carefully.** *See section 3* ▶

Now read this whole leaflet carefully before you use this medicine. Keep the leaflet: you might need it again.

1 What the medicine is for

Benylin Dry Coughs NIGHT Syrup is a medicine which is used to help provide night time relief of dry, irritating coughs and aid a restful sleep. The liquid contains diphenhydramine hydrochloride which is an antihistamine that helps relieve coughing and dry secretions in the nose and chest, dextromethorphan hydrobromide which is an antitussive to help stop coughing and levomenthol which helps you breathe more easily by relieving congestion.

The medicine is for use in adults and children aged 12 years and over.

2 Before taking this medicine

This medicine is suitable for most people but a few people should not use it. If you are in any doubt, talk to your doctor or pharmacist.

Taking this medicine regularly, particularly for a long time, can lead to addiction. Only use this medicine as described in the leaflet. Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Speak to your doctor if you experience withdrawal symptoms.

X Do not use this medicine…

- If you have ever had a **bad reaction** to diphenhydramine, dextromethorphan, levomenthol or any of the ingredients of this medicine (listed in section 6).
- If you suffer from **lung disease**.
- If you are taking, or have taken in the last two weeks, **drugs for depression** known as Monoamine Oxidase Inhibitors (MAOIs).
- If you are taking selective serotonin re-uptake inhibitors (used to treat **depression** and **anxiety** such as fluoxetine, paroxetine and sertraline).
- For children under 12 years old.

If any of these apply to you, **get advice from a doctor or pharmacist without using Benylin Dry Coughs NIGHT Syrup.**

⚠ Talk to your doctor or pharmacist…

- If you suffer from **liver** or **kidney** problems.
- If you have **bronchitis**, **emphysema** or **asthma** or have had a **cough for a few weeks** or **a cough with a lot of mucus (phlegm).**
- If your child is prone to developing certain allergic reactions (e.g. **atopic reactions**).
- If you have difficulty with passing water or **prostate problems** (which may mean you need to pass water more often).
- If you are **susceptible to glaucoma** (increased pressure in the eye).
- If you are taking any other **cough and cold medicines**.
- If you are using any other medicines containing **diphenhydramine**, including those used on large areas of the skin.
- If you are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs.
- If you have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- If you have been told by your doctor that you are a **slow metabolizer of CYP2D6**.
- If you are taking medicines such as certain antidepressants or antipsychotics this medicine may interact with these medicines and you may experience mental status changes (e.g. agitation, hallucinations, coma), and other effects such as body temperature above 38°C, increase in heart rate, unstable blood pressure, and exaggeration of reflexes, muscular rigidity, lack of coordination and/or gastrointestinal symptoms (e.g nausea, vomiting, diarrhoea).
- If you are taking any **other medicines**, including:
  - *Antihistamines* (drugs used to treat the symptoms of **allergic reactions**).
  - *Tricyclic antidepressants* (drugs to treat **mood disorders**).
  - *Anticholinergic drugs* (drugs used to treat **cramps** and **spasms** such as *atropine*)
  - *Tranquillisers* (drugs used to **relax muscles** or **decrease anxiety**).
  - *Hypnotics* (**sleeping tablets** including barbiturates).
  - Certain **drugs for depression** such as norepinephrine-dopamine reuptake inhibitors (NDRIs), which include bupropion.
  - *Sedatives* (drugs used to treat **anxiety** and **tension**).
  - *Antipsychotics* (drugs used to treat **mood disorders** such as haloperidol, thioridazine, perphenazine).

turn over ▶

- *Anti-arrhythmic agents* (drugs used to treat an **irregular heartbeat** such as amiodarone, propafenone, quinidine and flecainide).
- *Calcimimetic agents* (drugs used to treat **secondary hyperparathyroidism**, elevated parathyroid hormone levels such as cinacalcet).
- *Antifungals* (terbinafine).
- *Opioid analgesics* (drugs used to **relieve pain** e.g. codeine, tramadol, morphine, methadone).

If you are not sure about any of the medicines you are taking, show the bottle or pack to your pharmacist.

If any of these bullet points apply to you now or in the past, **talk to a doctor or pharmacist.**

If you are pregnant or breast-feeding

- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

- This medicine may cause drowsiness. If affected, do not operate machinery. **Avoid alcoholic drink**.
- This medicine can affect your ability to drive. Do not drive whilst taking this medicine until you know how this medicine affects you. It may be an offence to drive when taking this medicine if your ability to drive safely is affected. Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

There is further information for patients who are intending to drive in the UK - go to www.gov.uk/drug-driving-law.

Some of the ingredients can cause problems

- This medicine contains 1 g sucrose and 3.5 g liquid glucose per 5 ml. If you have been told by your doctor that you have an intolerance to some sugars contact your doctor before taking this medicinal product. This should be taken into account in patients with diabetes mellitus.
- 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.
- The red colouring Ponceau 4R (E124) in this medicine may cause allergic reactions.
- 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, or have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").
- 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 16.7 mg sodium (main component of cooking/table salt) in each 5 ml. This is equivalent to 0.835 % of the recommended maximum daily dietary intake of sodium for an adult.

3 How to take this medicine

Check the table that follows to see how much medicine to take.

- For oral use only.
- Do not take more medicine than the label tells you to.
- Do not use to sedate a child.

Children under 12 years

Do not give to children under 12 years old.

Adults and children aged 12 years and over

Age	Dose
Adults and children aged 12 years and over	Take **two 5 ml spoonfuls** at bedtime followed by **two 5 ml spoonfuls** every 6 hours or **two 5 ml spoonfuls** four times a day.

- Do not take more than 4 doses in 24 hours.
- If symptoms persist or worsen, talk to your doctor or pharmacist.

If you take more than you should

If anyone has too much contact a doctor or your nearest Accident and Emergency Department (Casualty) taking this leaflet and pack with you.

If you take more of this medicine than you should, you may experience the following symptoms: nausea and vomiting, involuntary muscle contractions, agitation, confusion, somnolence, disturbances in consciousness, involuntary and rapid eye movements, cardiac disorders (rapid heart beating), coordination disorders, psychosis with visual hallucinations, and hyperexcitability. Also, other types of hallucinations, psychotic disorders, seizures, clumsiness, dizziness, speech problems, lack of energy, high blood pressure, tremor, or constricted or dilated pupils.

Other symptoms in case of massive overdose may be: coma, severe breathing problems, and convulsions.

Contact your doctor or hospital straight away if you experience any of the above symptoms.

If you forget to take the medicine

If you forget to take a dose, take the next dose when needed provided that the last dose was taken at least 4 hours ago. **Do not** take a double dose.

turn over ▶

Drug Withdrawal

When you stop taking this medicine, you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

How do I know if I am addicted?

If you notice any of the following signs whilst taking this medicine, it could be a sign that you have become addicted.

- You need to take the medicine for longer than advised
- You feel you need to use more than the recommended dose
- You are using the medicine for reasons other than those indicated
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again.

If you notice any of these signs, it is important you talk to your doctor or pharmacist.

4 Possible side-effects

Like all medicines, this medicine can cause side-effects, although not everybody gets them.

If you experience any of the following stop using this medicine and seek immediate medical help:

- Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing.
- Allergic reactions including skin rashes such as hives (which may be severe and include blistering or peeling of the skin) and itching.
- Hallucinations or fits.

If you experience any of the following stop using this medicine and talk to your doctor:

- Sleep disturbances.
- A fast or irregular heartbeat or an increased awareness of the heartbeat (palpitations).
- Trouble passing water (especially in men with prostate problems).

Other effects which may occur include:

Very common (may affect more than 1 in 10 people)

- Drowsiness

Common (may affect up to 1 in 10 people)

- Dependence and addiction (see section "How do I know if I am addicted?")
- Dizziness or headache
- Difficulty performing tasks
- Blurred vision
- Thickened mucus or dry mouth
- Upset stomach
- Unusual weakness

Uncommon (may affect up to 1 in 100 people)

- Difficulty sleeping
- Feeling confused, irritated or nervous
- Tinnitus (a persistent noise in the ears)

Rare (may affect up to 1 in 1000 people)

- Depression
- Tremor, shakiness or slurred speech or low blood pressure

Other effects which may occur but it is not known how often

- Tingling or numbness of the hands or feet (pins and needles)
- Chest discomfort or shallow breathing
- Dry nose
- Stomach pain, diarrhoea, nausea or vomiting
- Pain when passing water
- Feeling agitated

If you get any side-effects talk to your doctor, pharmacist or nurse. This includes any possible side-effects not listed in this leaflet. You can also report side-effects in the UK directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side-effects, you can help provide more information on the safety of this medicine.

5 Storing this medicine

Do not store this product above 30°C.

Store in the original container.

Keep this medicine out of the sight and reach of children.

Discard this medicine 4 months after first opening the bottle.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Further information

What's in this medicine?

The active ingredients in 5 ml of Benylin Dry Coughs NIGHT Syrup are:14 mg Diphenhydramine hydrochloride, 6.5 mg Dextromethorphan hydrobromide and 2 mg Levomenthol.

Other ingredients are: Liquid glucose, sucrose, ethanol, glycerol, sodium citrate, saccharin sodium, citric acid monohydrate, sodium benzoate (E211), caramel (E150), raspberry flavour (benzyl alcohol, propylene glycol, ethanol), carbomer, Ponceau 4R (E124) and water.

What the medicine looks like

Benylin Dry Coughs NIGHT Syrup is a clear red syrup, darkening on ageing to brown syrup, available in 150 ml glass bottles.

Marketing Authorisation Holder:
McNeil Products Ltd.,
1 Station Hill Square,
Station Hill, Reading,
RG1 1LN, UK.

Manufacturer: Delpharm Orléans, 5 avenue de Concyr, 45071 Orleans, Cedex 2, France.

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