

# **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. These are shown in the table. See section 3 ►

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

# I 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.

This medicine can lead to dependence. Therefore the treatment should be of short duration.

## X Do not use this medicine...

- If you have ever had a bad reaction to any of the ingredients.
- If you suffer from lung disease.
- If you have prostate problems. (Difficulty with passing water or needing to pass water often).
- If you have narrow-angle glaucoma (increased pressure in the eye).
- If you are taking, or have taken in the last two weeks, drugs for depression known as Monoamine Oxidase Inhibitors (MAOIs).
- 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.

### A Talk to your doctor or pharmacist...

- If you suffer from liver or kidney problems.
- If you are taking alcohol.
- If you have been told by your doctor that you have an intolerance to some sugars.
- If you have a history of drug abuse
- 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 staus 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:
  anticholinergic drugs e.g.
  - antihistamines (drugs used to treat allergies).
    antidebressants (drugs to treat mood disorders).
  - atropine (used to treat some eye conditions and occasionally bowel conditions).
- minor tranquillisers (drugs used to relax muscles or decrease anxiety).

- barbiturates (a kind of sleeping tablet).
- Certain drugs for depression such as selective serotonin reuptake inhibitors (SSRIs), which includes fluoxetine, paroxetine, sertraline and also norepinephrine-dopamine reuptake inhibitor (NDRI), which include bupropion.
- Antipsychotics (drugs used to treat mood disorders such as haloperidol, thioridazine, perphenazine).
- Anti-arrhythmic agents (drugs used to treat irregular heart beats such as amiodarone, propafenone, quinidine and flecainide).
- Calcimimetic (drugs used to treat secondary hyperparathyroidism, elevated parathyroid hormone levels such as cinacalcet).
- Anti fungals (terbinafine).
- Opioids (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 the bullet points apply to you now or in the past, **talk to a doctor or pharmacist**.

## A If you are pregnant or breast-feeding

 Ask your doctor or pharmacist for advice before taking this medicine if you are pregnant or breast-feeding.

### 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 <u>https://www.gov.uk/drug-driving-law</u>

# Some of the ingredients can cause problems

■ This medicine contains sodium benzoate, which can irritate the skin, eyes and mucous membranes. turn over ▶



- This medicine contains sucrose and liquid glucose. If you have been told by your doctor that you have an intolerance to some sugars contact your doctor before taking this medicinal product. Contains 3.5 g glucose per 5 ml. Contains 1 g sucrose per 5 ml. This should be taken into account in patients with diabetes mellitus.
- This medicinal product contains 5 vol % ethanol (alcohol), i.e. up to 200 mg per 5 ml, equivalent to 5 ml beer, 2 ml vine per 5 ml. This can be harmful for those suffering from alcoholism. The ethanol content should be taken into account in pregnant or breast-feeding women, children and high-risk groups such as patients with liver disease or epilepsy.
- Ponceau 4R (E124) may cause allergic reactions.
- This medicinal product contains 16.7 mg sodium per 5 ml. To be taken in consideration by patients on a controlled sodium diet.

## 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 than the stated dose shown.

## 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 <b>two 5 ml spoonfuls</b> at bedtime followed by <b>two 5 ml</b> <b>spoonfuls</b> every 6 hours or <b>two 5 ml spoonfuls</b> four times a day.

Do not take more than 4 doses in 24 hours.

If symptoms persist, talk to your doctor or pharmacist.

#### \Lambda 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, involuntarty and rapid eye movements, caridac disorders (rapid heart beating), coordination disorders, psychosis with visual hallucinations, and hyperexcitability. 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. **Do not** take a double dose.

## 4 Possible side-effects

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.

#### Mild effects which may occur include:

- Drowsiness, dizziness, blurred vision.
- Dry mouth, nose and throat.
- Upset stomach.
- Vomiting.
- Nausea.
- Problems with passing water.

If you experience 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 <u>www.mhra.</u> <u>gov.uk/yellow.card</u>.

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

The following details are applicable for Malta: ADR Reporting www.medicinesauthority.gov.mt/adrportal.

# 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.

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, carbomer, Ponceau 4R (E124) and water:

#### What the medicine looks like

Benylin Dry Coughs NIGHT Syrup is a clear red syrup, available in 150 ml glass bottles.

Marketing Authorisation Holder: McNeil Products Ltd, Maidenhead, Berkshire, SL6 3UG, UK.

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

This leaflet was revised October 2019. Benylin is a registered trade mark.



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