



## Children's Night Coughs

6 - 12 YEARS

diphenhydramine, levomenthol

- This medicine is used to help relieve the symptoms of cough and congestion and also for hayfever and other allergic conditions.
- This medicine is for use by children aged 6-12 years.
- **Do not give your child this medicine:**
  - There are some people who should not use this medicine. *To find out if your child is one of them see section 2 ▶*
  - If your child has ever had a **bad reaction** to any of the ingredients. *For the list of ingredients see section 6 ▶*
- **Speak to your doctor:**
  - If your child suffers from any of the conditions mentioned in section 2. *See section 2 ▶*
  - If your child is taking any other medicines. *See section 2 ▶*
- **Follow the dosage instructions carefully.** *See section 3 ▶*

Some children should not take this product. Follow the instructions shown in the table carefully.

**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 Children's Night Coughs is a medicine used to relieve the symptoms of cough and congestion. It also helps relieve runny nose and sneezing associated with hayfever and other allergies. The liquid contains diphenhydramine hydrochloride which is an antihistamine that helps relieve coughing and dry secretions in the nose and chest, and levomenthol which helps you breathe more easily by relieving congestion.

The medicine is for use in children aged 6 to 12 years.



## 2 Before giving your child this medicine

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

### **X** Do not give your child this medicine...

- If s/he has ever had a **bad reaction** to this product or any of the ingredients.
- If he suffers from **prostate problems** (difficulty with passing water or needing to pass water often).
- If s/he suffers from or has had **closed angle glaucoma** (increased pressure in the eye).
- If s/he is taking, or has taken in the last two weeks, **drugs for depression** known as Monoamine Oxidase Inhibitors (MAOIs).
- If s/he is taking **any other cough and cold medicine**.
- If s/he is aged under 6 years old.

If any of these apply, **get advice from a doctor or pharmacist without using Benylin Children's Night Coughs.**

### **!** Talk to your doctor or pharmacist...

- If your child suffers from **liver or kidney problems**.
- If your child has **difficulty passing water** (urinary retention).
- If your child has a **persistent cough** such as occurs with asthma, has **asthma**, is suffering from an **asthma attack** or a **cough that produces a lot of mucus (phlegm)**.
- If your child is taking any other medicines containing **codeine** (sometimes used as a pain killer).
- If you have been told by your doctor that your child has an **intolerance to some sugars**.
- If your child is taking **any other medicines**, including:
  - **Antimuscarinic / anticholinergic drugs** e.g.:
    - **tricyclic antidepressants** (drugs to treat **mood disorders**).
    - **atropine** (used to treat some **eye conditions** and occasionally **bowel conditions**).
  - **CNS depressants** e.g.:
    - **barbiturates** (a kind of **sleeping tablet**).
    - **minor tranquillisers** (drugs used to **relax muscles** or **decrease anxiety**).

- **opioid analgesics** (drugs used to **relieve pain** e.g. codeine, tramadol, morphine).
- **antipsychotics** (drugs used to treat **mood disorders**).

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

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

### **!** If you are pregnant or breast-feeding

The following advice is included in case an older child or adult is taking the medicine:

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

### **!** Special warnings about this medicine

- This product can make some people feel drowsy, dizzy or have blurred vision. Make sure that your child is not affected if he or she is going to do anything where they need to be alert. Be especially careful if the child is taking another medicine which may also cause drowsiness.
- If an older child or adult is taking the medicine remember that this product may cause drowsiness, dizziness or blurred vision. Do not drive or operate machinery if you are affected. Avoid alcoholic drink.

### **!** Some of the ingredients can cause problems

- This medicine contains sorbitol 70% (non crystalline). If you have been told by your doctor that your child has an intolerance to some sugars contact your doctor before taking this medicinal product.
- This medicinal product contains 5 vol % ethanol (alcohol), i.e. up to 200 mg per 5 ml, equivalent to 5 ml beer, 2 ml wine per 5 ml. This can be harmful for those suffering from alcoholism. To be taken into account in pregnant or breast-feeding women, children and high-risk groups such as patients with liver disease or epilepsy.
- This medicinal product contains 16.47 mg sodium per 5 ml. To be taken in consideration by patients on a controlled sodium diet.

turn over ▶

## 3 How to use this medicine

Check the table below to see how much medicine to take.

- For oral use only.
- Do not use more than the stated dose shown below.

### **i** Children under 6 years

Do not give to children under 6 years old.

### **i** Children 6 to 12 years

Age	Dose
Children 6 – 12 years	Two 5 ml spoonfuls every 6 hours

- Do not give more than 4 doses in 24 hours.
- Do not use for more than 5 days without the advice of a doctor.
- Do not use to sedate a child.
- If symptoms persist or worsen, talk to your doctor or pharmacist.

### **A** If anyone has too much

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

### **A** If you forget to give the medicine

You should only give this medicine as required following the dosage instructions above carefully. If you forget to give a dose, give the next dose when needed provided that the last dose was at least 6 hours ago. **Do not** give a double dose.

## 4 Possible side-effects

Benylin Children's Night Coughs can have side-effects, like all medicines, although these don't affect everyone and are usually mild.

**If your child experiences any of the following, stop using the medicine and seek immediate help:**

- Allergic reactions including skin rashes (which may be severe and include blistering and peeling of the skin) and itching.
- Rarely people can experience fits.
- Rarely abnormal blood test results for liver function.

**If your child experiences any of the following, stop using the medicine and talk to your doctor:**

- Rarely people can have an irregular heartbeat or an increased awareness of the heartbeat (palpitations).
- Sleep disturbances.

**Other effects that may occur include:**

- Commonly: drowsiness, including some difficulty performing tasks.
- Commonly: headache, upset stomach, difficulty in passing urine, stimulation, blurred vision, dry mouth, thickened mucus.
- Rarely: low blood pressure, tremor, shakiness, slurred speech, dizziness, confusion, depression.
- Rarely: blood disorders.

If your child experiences any side-effects not included in this leaflet, or you are not sure about anything, **talk to your doctor or pharmacist.**

## 5 Storing this medicine

Store below 30°C.

Keep the product out of the reach and sight of children.

Do not use your medicine after the date shown as an expiry date on the packaging.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6 Further information

**What's in this medicine?**

**The active ingredients in 5 ml of Benylin Children's Night Coughs are:** 7 mg Diphenhydramine hydrochloride and 0.55 mg Levomenthol.

**Other ingredients are:** Sorbitol solution, glycerol, ethanol, sodium carboxymethylcellulose, sodium citrate, citric acid monohydrate, sodium benzoate (E211), sodium saccharin, raspberry essence and purified water.

**What the medicine looks like**

Benylin Children's Night Coughs is a clear colourless syrup, available in 125 ml glass bottles.

**Product Licence 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 January 2010.**

Benylin is a registered trade mark.

## 7 Information about treating cough and cold in children

It's normal for children to get 8 or more colds in a year. Because colds are caused by viruses, not bacteria, antibiotics don't help.

Here are simple steps to help your child who has a cough or cold.

- **If they are hot/feverish:** Increase the amount of fluid your child normally drinks. Lower their temperature with a paracetamol or ibuprofen medicine which has doses for children.
- **For coughs:** Coughing serves a purpose, it helps clear phlegm and mucus. Give the child plenty of warm clear fluids to drink.
- **To help with breathing:** Plain saline nose drops / sprays can help with blocked noses.

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