



# Children's Night Coughs

Diphenhydramine & Levomenthol

6 Years +

- 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 your child has ever had a **bad reaction** to this product or any of the ingredients.
- If your child is taking, or has taken in the last two weeks, **drugs for depression** known as Monoamine Oxidase Inhibitors (MAOIs).
- If your child is aged under 6 years old.
- To make your child sleepy.

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) or **prostate problems** (which may mean they need to pass water more often).
- If your child has a **persistent cough** such as occurs with **bronchitis** or **emphysema**; has **asthma**; is suffering from an asthma attack; or has a **cough that produces a lot of mucus (phlegm)**.
- If your child may have **glaucoma** (increased pressure in the eye).
- If your child is taking any other medicines containing **diphenhydramine** including any creams, ointments or gels.
- 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.:
    - **Sleeping tablets** including *barbiturates*.
    - *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 delusions, hallucinations or confused thoughts*).
    - alcohol.

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:

- 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.

### ! 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 2.53 g sorbitol in each 5 ml. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.
- This medicine contains 197 mg of alcohol (ethanol) in each 5 ml. The amount in 5 ml of this medicine is equivalent to 5 ml beer or 2 ml wine. The amount of alcohol in this medicine is not likely to have an effect in adults and adolescents, and its effects in children are not likely to be noticeable. It may have some effects in younger children, for example feeling sleepy. The alcohol in this medicine may alter the effects of other medicines. Talk to your doctor or pharmacist if you are taking other medicines. If you are pregnant or breast-feeding, talk to your doctor or pharmacist before taking this medicine. If you are addicted to alcohol, talk to your doctor or pharmacist before taking this medicine.

turn over ►

- This medicine contains 16.47 mg sodium (main component of cooking/table salt) in each 5 ml. This is equivalent to 0.82% of the recommended maximum daily dietary intake of sodium for an adult.
- This medicine contains 25 mg sodium benzoate (E 211) in each 5 ml.

## 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.

### **!** 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.

### **!** 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

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

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

- Allergic reactions including skin rashes (which may be severe and include blistering and peeling of the skin) and itching.

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

- Difficulty passing urine.
- Fits or seizures.

**Other effects that may occur include:**

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

- Drowsiness

**Common (may affect up to 1 in 10 people)**

- Dizziness or unusual weakness
- Stimulation or slowness in movement or speech
- Headache, thickened mucus or blurred vision
- Dry mouth, nausea or vomiting

**Uncommon (may affect up to 1 in 100 people)**

- Irritability, hallucinations, nervousness, agitation or sedation
- Pins & needles (paraesthesia)
- Ringing in the ears (tinnitus)
- A fast heartbeat, low blood pressure or chest discomfort
- Dry nose

**Rare (may affect up to 1 in 1,000 people)**

- Blood disorders
- Confusion, depression, involuntary movements, shakiness (tremor) or difficulty sleeping
- Irregular heartbeat or increased awareness of the heartbeat (palpitations).
- Liver problems

**Reporting of side-effects**

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 directly via the Yellow Card Scheme at [www.mhra.gov.uk/yellowcard](http://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

Store below 30°C.

Keep the product out of the sight and reach 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 (E420), glycerol, ethanol, sodium carboxymethylcellulose, sodium citrate, citric acid monohydrate, sodium benzoate (E211), sodium saccharin, raspberry essence (ethanol, propylene glycol (E 1520)) 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, High Wycombe, Buckinghamshire, HP12 4EG, UK.

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

**This leaflet was revised in January 2022.**

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.

McNeil Products Limited 2022 ©

