



## Cough Medicine Syrup

diphenhydramine hydrochloride 14mg/5ml,  
levomenthol 1.1mg/5ml

- This medicine can be used to relieve coughing and for the relief of allergic conditions and reactions.
- This medicine is for use by adults and children aged 12 years and over.
- **Do not use 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. Ask your pharmacist if you need more information or advice.

Go to see your doctor if your symptoms worsen or do not improve after a few days.

## What the medicine is for

Benylin Cough Medicine is a medicine which is used to relieve coughing and for the relief of allergic conditions and reactions. The liquid contains diphenhydramine 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 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.

### **X Do not use this medicine...**

- If you have ever had a **bad reaction** to any of the ingredients.

If any of these apply to you, **get advice from a doctor or pharmacist without using Benylin Cough Medicine.**

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

- If you suffer from **liver or kidney problems**
- If you suffer from a **persistent cough** that may be caused by smoking, asthma or emphysema, or a cough which brings up a lot of mucus (phlegm).
- 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 suffer from a respiratory condition, e.g. emphysema, bronchitis or bronchial asthma.
- If you are taking **alcohol**.
- If you have an **intolerance to some sugars**.
- If you suffer from **epilepsy**.
- 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 any **other medicines**, including:
  - other products containing **diphenhydramine** (even used on the skin).
  - **anticholinergic drugs** e.g.
  - **antidepressants** (drugs to treat **mood disorders**).
  - **atropine** (used to treat some **eye conditions** and occasionally **bowel conditions**).
  - **CNS depressants** e.g.
  - **sedatives** (drugs used to relax muscles or decrease anxiety).
  - **opioid analgesics** (painkillers)
  - **aniticonvulants**
  - **antidepressants**
  - **antihistamines** (used to treat allergies)

- **antiemetics** (used to treat nausea and vomiting)
- **antipsychotics**
- **hypnotics**

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**

- Do not use this medicine if you are pregnant or breast-feeding.

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

- This medicine may cause drowsiness. If affected, do not drive or operate machinery. Avoid alcoholic drink.

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

- 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. 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 dose, equivalent to 5 ml beer, 2 ml wine per 5 ml. 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.
- Ponceau 4R (E124) may cause allergic reactions. These reactions are more common in people who are allergic to aspirin.
- This medicinal product contains 16.61 mg sodium per 5 ml. To be taken in consideration by patients on a controlled sodium diet.

turn over ►

### 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.

### 3 How to take this medicine continued

#### **i** Children under 12 years

Benylin Cough Medicine is not recommended for children under 12 years old.

#### **i** Adults and children 12 years and over

Age	Dose
Adults and children over 12 years	Take <b>one or two 5 ml spoonfuls</b> three or four times a day.

- If symptoms persist, talk to your doctor or pharmacist.

#### **!** If anyone has too much

If anyone has too much, contact your doctor or pharmacist immediately.

#### **!** If you forget to take the medicine

You should only take this medicine as required following the dosage instructions above carefully. If you forget to take a dose, take the next dose when needed. **Do not** take a double dose.

### 4 Possible side-effects

Benylin Cough Medicine can have side-effects, like all medicines, although these don't affect everyone and are usually mild.

**If you experience any of the following, stop using the medicine and seek immediate help:**

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

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

- Difficulty passing water.
- Low blood pressure.
- Palpitations.
- Faster heart rhythm.
- Chest discomfort.
- Convulsions.

**Other effects which may occur include:**

- Confusion, hallucinations, agitation, nervousness, irritability.
- Drowsiness, dizziness, blurred vision.
- Shaking, tingling or numbness.
- Restlessness or excitement.
- Inability to sleep or trouble sleeping.
- Headache.
- Poor coordination.
- Ringing in ears.
- Constipation, diarrhoea.
- Dry mouth, nose and throat.
- Feeling sick, vomiting.
- Indigestion.
- Unusual tiredness or weakness.

#### **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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL-Dublin 2; Tel: +353 1 676 4971; Fax: +353 1 676 2517 Website: [www.hpra.ie](http://www.hpra.ie); Email: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).

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

### 5 Storing this medicine

Do not store above 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.

Keep the medicine tightly closed in the original container.

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 Cough Medicine are:** 14 mg Diphenhydramine hydrochloride and 1.1 mg Levomenthol.

**Other ingredients are:** Liquid glucose, sucrose, ethanol, glycerol, sodium citrate, saccharin sodium, citric acid monohydrate, sodium benzoate (E211), caramel T12 (E150), raspberry flavour, Ponceau 4R (E124) and water.

#### **What the medicine looks like**

Benylin Cough Medicine is a clear red syrup, available in 125 ml glass bottles.

**Product Authorisation holder:** McNeil Healthcare (Ireland) Ltd., Airtown Road, Tallaght, Dublin 24, Ireland.

**Manufacturer:** Famar Orleans, 5 avenue de Concorde, 45071 Orleans, Cedex 2, France.

**This leaflet was revised June 2015.**

Benylin is a registered trade mark.

**McNeil**  
Healthcare (Ireland) Ltd.

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## Orleans - Artworks Center

Client	JNJ		
Change request #	CRD <b>XXXX</b>		
Product	BENYLIN COUGH MEDICINE 125ML IE		
Component #	F310XXX		
ATW version	8.0		
Component type	Rolled Leaflet		
Dimensions	160 x 210 mm		
Drawing #	NOTC010		
Safety code type & #	Datamatrix F310XXX		
Client code	15-0247		
Main font type	Humanist 521 BT		
Minimum font size	7,5 pts		
Colours			
Recto 1	Verso 1	Recto 2	Verso 2
PMS 2735	PMS 2735		
PMS 485	PMS 485		
A print out of this artwork should not be used for exact colour matching but to check if the layout, spelling, text and colour references are correct. Please check thoroughly.			