



## Non-Drowsy Dry Coughs Syrup

dextromethorphan hydrobromide 7.5 mg/ 5 ml

- This medicine is used to help relieve dry, irritating coughs.
- 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.

## 1 What the medicine is for

Benylin Dry Coughs Non-Drowsy is a medicine which is used to help relieve dry, irritating coughs. The liquid contains dextromethorphan hydrobromide which is an antitussive to help stop persistent coughing.

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 you are taking, or have taken in the last two weeks, **drugs for depression** known as Monoamine Oxidase Inhibitors (MAOIs).
- If you are under 12 years old.

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

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

- If you suffer from **liver or kidney problems.**
- If you have a **persistent cough** such as occurs with asthma or produces a lot of mucus (phlegm).
- If 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 any **other medicines.**
- 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 fungus** (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 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, only use this medicine on the advice of your doctor.

### ! Some of the ingredients can cause problems

- This medicine contains sucrose, sorbitol 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 2.38 g glucose per dose. Contains 1.6 g sucrose. This should be taken into account in patients with diabetes mellitus.
- This medicinal product contains 6 vol% ethanol (alcohol), i.e. up to 240 mg per dose, equivalent to 6 ml beer, 2.5 ml wine per dose. This can be harmful for those suffering 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 glycerol, which can cause headache and may upset the stomach when taken in large doses. It is important not to take more than the recommended dose.
- Each 5ml of product contains approximately 0.2 g of sorbitol, which can cause stomach upset and diarrhoea when taken in large doses.
- This medicinal product contains sodium benzoate, which may irritate the skin, eyes and mucosal surfaces.
- The product contains 4.4 mg of sodium per 5ml dose. To be taken into consideration by patients on a sodium controlled diet.

## 3 How to take this medicine

**Check the tables below to see how much medicine to take.**

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

### i Children under 12 years

This product is not recommended for children under 12 years old.

turn over ►

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

Age	Dose
Adults and children over 12 years	Take <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.

## **3** How to take this medicine *continued*

### **!** 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

Benlyn Dry Coughs Non-Drowsy 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 medical help:**

- Allergic reactions: signs of allergy include rash (such as hives), itching and or swollen face or neck.

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

- Upset stomach or diarrhoea.
- Nausea or vomiting.
- Dizziness.

- Restlessness, confusion or excitation.
- Sleepiness.
- Difficulty sleeping (insomnia).
- Shortness of breath or difficulty breathing.

## **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 this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label 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 ingredient in 5 ml of Benlyn Dry Coughs Non-Drowsy is:** 7.5 mg Dextromethorphan hydrobromide.

**Other ingredients are:** Sorbitol solution (70%) E420, glycerol, sucrose, liquid glucose, citric acid monohydrate, sodium benzoate (E211), caramel, saccharin sodium, imitation peach flavour, levomenthol, ethanol (96% v/v), carbomer and purified water.

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

Benlyn Dry Coughs Non-Drowsy is a pale brown coloured, peach flavoured syrup, available in 125 ml glass bottles.

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

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

**This leaflet was revised December 2016.**

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**McNeil**  
Healthcare (Ireland) Ltd.

LN50XX01  
16-0648

## Orleans - Artworks Center

Client	JNJ		
Change request #	CRD 0XXX		
Product	BENYLIN DRY COUGHS NON DROWSY 125ML IE		
Component #	LN50XX01		
Old component #	F310461		
ATW version	10.0		
Component type	Rolled Leaflet		
Dimensions	160 x 210 mm		
Drawing #	NOTC010		
Safety code type & #	Datamatrix LN50XX01		
Client code	16-0648		
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		
CYAN	CYAN		
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.			