



Dry Coughs Syrup

Diphenhydramine hydrochloride 14 mg/5ml

Levomethol 2 mg/5ml

Dextromethorphan hydrobromide 6.5 mg/5ml

- 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 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.**

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.

I What the medicine is for

Benylin Dry Coughs is a medicine which is used to help relieve dry, irritating coughs. 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 levomethol which helps you breathe more easily by relieving congestion.

The medicine is for use in adults and children aged 12 years and over.



2 What you need to know 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 take 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 have a persistent cough such as occurs with smoking, asthma or emphysema, or produces a lot of mucus (phlegm).
- If you have an inherited intolerance to fructose or related conditions.

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

⚠ Talk to your doctor or pharmacist...

- If you suffer from **liver or kidney problems.**
- If you have an enlarged prostate (difficulty passing water or needing to pass water often).
- If you have narrow-angle glaucoma (increased pressure in the eye).
- If you have a persistent cough such as occurs with smoking, emphysema or asthma, have asthma, are suffering from an asthma attack, or a cough that produces a lot of mucus (phlegm).
- 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 any **other medicines**, including:
 - **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.:
 - **hypnotics** (**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, methadone).
- **antipsychotics** (drugs used to treat **mood disorders** such as haloperidol, thioridazine, perphenazine).
- barbiturates (a kind of **sleeping tablet**).
- anticonvulsants (drugs to treat **epilepsy**).
- anti-emetics (used to treat **nausea and vomiting**).
- diphenhydramine (an antihistamine) including products used on the skin.
- 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.
- **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).

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.**

⚠ 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.

⚠ 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 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 dose. Contains 1 g sucrose per dose. 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. 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. These reactions are most common in people who are allergic to aspirin.
- 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.

i Children under 12 years

Benlyn Dry Coughs is not recommended for children under 12 years old.

i Adults and children 12 years and over

Age	Dose
Children under 12 years	Not Recommended
Adults and children over 12 years	Take two 5ml spoonfuls three or four times a day. Maximum daily dose: 40 ml syrup

- 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

If you forget to take a dose, take the next dose when needed. **Do not** take a double dose.

4 Possible side-effects

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

- Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing.

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

- A fast heartbeat or an increased awareness of the heartbeat (palpitations).

Other effects which may occur include:

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

Common (may affect up to 1 in 10 people)

- Dry mouth or throat.
- Dizziness.
- Unusual weakness.

Uncommon (may affect up to 1 in 100 people)

- Confusion, difficulty sleeping, irritability, nervousness or agitation.
- Rash.
- A persistent noise in the ears.

Other effects which may occur but it is unknown how often

- Hallucinations, fits, difficulty performing tasks, restlessness, tremors, headache or pins and needles.
- Low blood pressure.
- Blurred vision.
- Chest discomfort.
- Upset stomach, stomach pain or discomfort, nausea, vomiting, constipation, diarrhoea or indigestion.
- Dry nose.
- Itching or itchy rash.
- Difficulty in/or pain when passing urine.

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: +35316764971; Fax: +35316762517

Website: www.hpra.ie;

Email: medsafety@hpra.ie

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

5 How to store this medicine

Keep this medicine tightly closed and store in the original container.

Keep this medicine out of the sight and reach of children.

Do not store above 30°C.

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 Contents of the pack and other information

What's in this medicine?

The active ingredients in 5 ml of Benlyn Dry Coughs 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

Benlyn Dry Coughs is a clear red syrup, available in 125 ml glass bottles.

Product Licence 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 December 2016.

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McNeil
Healthcare (Ireland) Ltd.

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Orleans - Artworks Center

Client	JNJ		
Change request #	CRD 0XXX		
Product	BENYLIN DRY COUGHS SYRUP 125ML IE		
Component #	LN50XX01		
Old component #	F310469		
ATW version	8.1		
Component type	Rolled Leaflet		
Dimensions	160 x 210 mm		
Drawing #	NOTC010		
Safety code type & #	Datamatrix LN50XX01		
Client code	16-065?		
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		
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.			