



Children's Dry Coughs Syrup

6 - 12 YEARS

Diphenhydramine hydrochloride 7 mg/5 ml
Levomethol 0.55 mg/5 ml

- 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.**
Children of different ages need different amounts. *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 child's symptoms worsen or do not improve after a few days.

I What the medicine is for

Benylin Children's Dry Coughs Syrup is a medicine used to relieve the symptoms of cough and congestion and also for hayfever and other allergic conditions. 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 s/he is taking **any other cough and cold medicine**.
- If s/he is under 6 years.

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

A Talk to your doctor or pharmacist...

- If your child suffers from **liver or kidney problems**.
- If your child has **narrow-angle glaucoma** (increased pressure in the eye).
- If your child suffers from a **respiratory condition**, e.g. emphysema, bronchitis or bronchial asthma.
- If you have been told by your doctor that your child has an **intolerance to some sugars**.
- If your child has taken alcohol.
- If your child is taking any **other medicines**, including:
 - other products containing **diphenhydramine**.
 - **anticholinergic drugs** e.g.
 - **antidepressants** (drugs to treat **mood disorders**).
 - **atropine** (used to treat some **eye conditions** and occasionally **bowel conditions**).
 - **sedatives** (drugs used to **relax muscles** or **decrease anxiety**).
- Consult a doctor or pharmacist before use in children aged 6 to 12 years.

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.**

A 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.

A 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.

A Some of the ingredients can cause problems

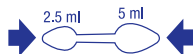
- This medicine contains sorbitol 70% (non crystalline) which can cause stomach upset and diarrhoea when taken in large doses.
- This medicinal product contains 5 vol % ethanol (alcohol), i.e. up to 200 mg per dose, equivalent to 5 ml beer, 2 ml wine per 5 ml. This can be harmful for those suffering from alcoholism. 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.
- This medicinal product contains glycerol, which can cause headaches and may also upset the stomach when taken in large doses. It is important not to take more than the recommend dose.
- This medicinal product contains sodium benzoate, which may irritate the skin, eyes and mucosal surfaces.

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.
- There is a double-ended spoon in this pack.



i Children under 6 years

Benlyn Children's Dry Coughs is not recommended for children under 6 years old.

i Children 6 to 12 years

Age	Dose
Children 6 – 12 years	Give two 5ml spoonfuls 3 to 4 times a day. Do not give more than 8 spoonfuls in one day.

- Maximum daily dose: 40ml.
- Do not give more than 4 doses in 24 hours.
- Use only when simple measures have failed to provide adequate relief.
- Do not give to a child under 12 years of age for more than 5 days without consulting your doctor.
- 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 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 4 to 6 hours ago. **Do not** give a double dose.

4 Possible side-effects

Benlyn Children's Dry Coughs Syrup 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 or 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 water.
- Low blood pressure.
- Palpitations, upset heart rhythm.
- Convulsions.

Other effects which may occur include:

- Unusual drowsiness or weakness, dizziness.
- Blurred vision, ringing in ear.
- Constipation, diarrhoea.
- Nausea, vomiting, heartburn.
- Tremors, pins & needles.
- Headache.
- Restlessness or excitation.
- Confusion, hallucinations, nervousness, irritability.
- Dry mouth, nose and throat.
- Difficulty sleeping.
- Rash, hives, itching.
- Uncomfortable chest.

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 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. The expiry date refers to the last day of that month.

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 Benlyn Children's Dry Coughs Syrup are:

7 mg Diphenhydramine hydrochloride and 0.55 mg Levomenthol.

Other ingredients are: Sorbitol (E420), glycerol, ethanol, sodium carboxymethylcellulose, sodium citrate, citric acid monohydrate, sodium benzoate (E211), sodium saccharin, raspberry essence and purified water.

What the medicine looks like

Benlyn Children's Dry Coughs Syrup is a clear colourless syrup, available in 125 ml glass bottles.

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

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

This leaflet was revised June 2015.

Benlyn is a registered trade mark.

McNeil
Healthcare (Ireland) Ltd.

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Orleans - Artworks Center

Client	JNJ		
Change request #	CRD XXXX		
Product	BENYLIN CHILDREN'S DRY COUGHS 125ML IE		
Component #	F310XXX		
ATW version	9.0		
Component type	Rolled Leaflet		
Dimensions	160 x 210 mm		
Drawing #	NOTC010		
Safety code type & #	Datamatrix F310XXX		
Client code	15-0246		
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.			