



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.

1 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 your child is taking **any other cough and cold medicine.**
- If your child is taking, or has taken in the last two weeks, drugs for depression known as Monoamine Oxidase Inhibitors (MAOIs).
- 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.**

! 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 **asthma, a persistent cough** that may be caused by chronic bronchitis or emphysema, or a cough which brings up a lot of mucus (phlegm).
- 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 suffers from **epilepsy.**
- 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 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**).
 - *CNS depressants* e.g.
 - *sedatives* (drugs used to relax muscles or decrease anxiety).
 - *opioid analgesics* (painkillers)

- *anticonvulsants*
- *antidepressants*
- *antihistamines* (used to treat allergies)
- *antiemetics* (used to treat nausea and vomiting)
- *antipsychotics*
- *hypnotics*

- 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.**

! If you are pregnant or breastfeeding

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.

! 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.

! Benylin Children's Dry Coughs contains sorbitol (E240), sodium, propylene glycol (E1520), sodium benzoate (E211) and ethanol

- This medicine contains 2.525 g sorbitol in each 5 ml dose. Patients with hereditary problems of fructose intolerance should not take 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.

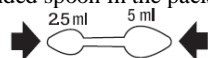
- This medicinal product contains 16.47 mg sodium per 5 ml. This is equivalent to 0.82% of the recommended maximum daily dietary intake of sodium for an adult.
- This medicine contains 1.07 mg propylene glycol in each 5ml.
- This medicinal product contains 25 mg sodium benzoate in each 5ml dose.

3 How to use 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

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



! Children under 6 years

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

! Children 6 – 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 a 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 this medicine and seek immediate help:

- **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 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, Website: www.hpra.ie.

By reporting side-effects you can help provide more information on the safety of this 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 the 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 70% (non-crystalline) (E420), glycerol, ethanol, carmellose sodium, sodium citrate, citric acid monohydrate, sodium benzoate (E211), saccharin sodium, concentrated raspberry essence (double strength) (containing propylene glycol (E1520) and ethanol) 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 Folder: Johnson & Johnson (Ireland) Ltd., Airtown Road, Tallaght, Dublin 24, Ireland.

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

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