

## Package leaflet: Information for the user



Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If your child get any side-effects, talk to your doctor or pharmacist. This includes any possible side-effects not listed in this leaflet. *See section 4.*
- You must talk to a doctor if you do not feel better or if you feel worse after a few days.

### What is in this leaflet

1. What Benylin Children's Cough Syrup is and what it is used for
2. What you need to know before you take Benylin Children's Cough Syrup
3. How to use Benylin Children's Cough Syrup
4. Possible side-effects
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## 1 What Benylin Children's Cough Syrup is and what it is used for

Benylin Children's Chesty Coughs Syrup is a medicine which is used to help relieve chesty coughs in children. It contains guaifenesin (an expectorant) to help loosen mucus (phlegm) from the lungs and make it easier to cough up. The medicine is for use in children aged 6-12 years.

## 2 What you need to know before you use Benylin Children's Cough Syrup

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 use Benylin Children's Cough Syrup ...

- If your child has ever had a **bad reaction** to this product or any of the ingredients. See section 6 for full list of ingredients.
- If your child is taking **any other cough and cold medicine**.
- If your child is aged under 6 years.

If any of these applies, **get advice from a doctor or pharmacist without using Benylin Children's Cough Syrup.**

### ! Warnings and precautions

**! Talk to your doctor or pharmacist before using Benylin children's ...**

- If your child suffers from **liver or kidney problems**.
- If your child has had a **cough** for a few weeks that may be caused by **asthma**, or a cough which brings up a lot of mucus (phlegm).
- If your child has a cough that tends to recur or is accompanied by a fever, rash or persistent headache.

If any of these apply now or in the past, **talk to a doctor or pharmacist.**

### ! Pregnancy and Breastfeeding

The following advice is included in case an older child or adult is taking the medicine.

- If you are pregnant or breast-feeding or not taking contraceptive measures, only use this medicine on the advice of your doctor.

**! Benylin Children's Cough Syrup contains sorbitol, sodium, propylene glycol (E1520), sodium benzoate, ethanol and benzyl alcohol**

- 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 14.9 mg sodium in each 5 ml dose. This is equivalent to 0.75% of the recommended maximum daily dietary intake of sodium for an adult.
- This medicine contains 0.1mg propylene glycol in each 5ml dose.

- This medicine contains 15 mg sodium benzoate in each 5 ml dose.

- This medicine contains 0.00025mg of alcohol (ethanol) in each 5ml which is equivalent to 0.00005 mg/ml. The amount in 5 ml is equivalent to less than 1ml beer or 1 ml wine.

The small amount of alcohol in this medicine will not have any noticeable effects.

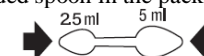
- This medicine contains 0.05 mg benzyl alcohol in each 5 ml dose which is equivalent to 0.01 mg per ml. Benzyl alcohol may cause allergic reactions. This medicine must be used with caution in patients with renal or hepatic impairment, or in patients who are pregnant or breast-feeding, because of the risk of accumulation and toxicity (metabolic acidosis).

## 3 How to use Benylin Children's Cough Syrup

**Check the tables that follow to see how much medicine to take**

- Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- 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 old

This medicine is not recommended for children under 6 years old.

### ! Children 6 – 12 years

Age	Dose
Children 6 – 12 years	Give two 5ml spoonfuls every 6 to 8 hours. Do not give more than eight 5ml spoonfuls in one day.
■ 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 anyone has too much**

If anyone has taken too much contact a doctor or pharmacist immediately.

If you take too much of this product you may develop kidney stones

### **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. **Do not** give a double dose.

## **4 Possible side-effects**

Like all medicines, this medicine can have side-effects, although not everybody gets them.

### **! If you experience 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**.

#### **Mild effects that may occur include:**

- Nausea or vomiting.
- Stomach pain and diarrhoea.

### **Reporting of side-effects**

If your child gets 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](http://www.hpra.ie).

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

## **5 How to store Benylin Children's Cough Syrup**

Do not store this product above 25°C.

Store in the original package.

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

Do not use this medicine after the expiry date on the packaging. The expiry date refers to the last day of that month.

■ Do not use if bottle seal is broken when purchased.

Keep bottle tightly closed in order to protect from moisture.

Do not throw away any medicine 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 Benylin Children's Cough Syrup contains**

The active substance is Guaifenesin.

The other ingredients are: Glycerol, sorbitol, liquid (non-crystallising) (E420), carmellose sodium, sodium citrate, sodium saccharin, sodium benzoate (E211), citric acid monohydrate, strawberry flavour (containing benzyl alcohol, ethanol and propylene glycol (E1520)) and water.

### **What the Benylin Children's Cough Syrup looks like and the contents of the pack**

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

### **Marketing Authorisation holder and Manufacturer**

**Product Authorisation Holder:** Johnson & Johnson (Ireland) Ltd., Airton Road, Tallaght, Dublin 24, Ireland.

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

**This leaflet was revised February 2021**

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