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 take 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 you 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 3 days.

What is in this leaflet

- 1. What Benylin Phlegm Cough Syrup is and what it is used for
- 2. What you need to know before you take Benylin Phlegm Cough Syrup
- 3. How to use Benylin Phlegm Cough Syrup
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1 What Benylin Phlegm Cough Syrup is and what it is used for

Benylin Phlegm Cough Syrup is a medicine which is used to help relieve chesty coughs.

It contains Guaifenesin (an expectorant) to help loosen mucus (phlegm) from the lungs and make it easier to cough up, and Levomenthol to help you breathe more easily by easing congestion.

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

2 What you need to know before you use Benylin Phlegm Cough Syrup

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 Benylin Phlegm Cough Syrup ...

■ If you are allergic to guaifenesin or levomenthol or to any of the other ingredients of this medicine (listed in section 6).

! Warnings and precautions

! Talk to your doctor or pharmacist before taking Benylin Phlegm Cough Syrup...

- If you suffer from **liver** or **kidney problems**.
- If you have been told by your doctor that you have an intolerance to some sugars.
- If you have had a **cough** for a few weeks that may be caused by **asthma**, or a cough which brings up a lot of mucus (phlegm).

! Other medicines and Benylin Phlegm Cough Syrup

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. If you are not sure about any of the medicines you are taking, show the bottle or pack to your pharmacist. Please tell your doctor that you are taking this product if you have a urine test.

! Pregnancy and Breastfeeding

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

! Benylin Phlegm Cough Syrup contains sucrose, liquid glucose, invert sugar, sodium benzoate, propylene glycol (E1520), ethanol, Ponceau 4R (E214) and sodium

- This medicine contains sucrose, liquid glucose and invert sugar. 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 5 ml, 1.0 g of sucrose per 5ml and 6.75mg invert sugar per 5ml. This should be taken into account in patients with diabetes mellitus.
- This medicine contains 197 mg of alcohol (ethanol) in each 5 ml dose. The amount in a 5 ml dose of this medicine is equivalent to less than 5 ml beer or 2 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects Ponceau 4R (E124) may cause allergic reactions.

- This medicinal product contains 16.42 mg sodium (main component of cooking/table salt) per 5 ml. This is equivalent to 0.82% of the recommended maximum daily dietary intake of sodium for an adult.
- This medicine contains 1.07mg propylene glycol in each 5ml dose.
- This medicine contains 10mg sodium benzoate in each 5ml dose.

3 How to take Benylin Phlegm Cough Syrup

Check the table below 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

pharmacist.

■ Do not take more than the stated dose shown below

! Children under 12 years old

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

! Adults and children 12 years and over

Age	Dose
Adults and children over 12 years	Take two 5 ml spoonfuls four times a day.
■ Do not give more than 4 doses in 24 hours.	

- ! If you take more Benylin Phlegm Cough Syrup than you should
 If anyone has too much contact a doctor or pharmacist

■ If symptoms persist, talk to your doctor or

in anyone has too much contact a doctor of pharmacist immediately.

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

If you forget to take Benylin Phlegm Cough Syrup

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** 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 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 How to store Benylin Phlegm Cough Syrup

Do not store this product above 30°C. Keep the product out of the sight and reach 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 the month.

Keep the bottle tightly closed to protect from moisture. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help to protect the environment. will help protect the environment.

6 Contents of the pack and other information

What Benylin Phlegm Cough Syrup contains:

The active substances are Guaifenesin and Levomenthol.

The other ingredients are: Sucrose, liquid glucose, ethanol, glycerol, sodium citrate, saccharin sodium, citric acid monohydrate, sodium benzoate (E211), Ponceau 4R (E124), caramel T12 (E150) (containing glucose, sucrose and invert sugar), carbomer, Concentrated raspberry

essence double strength (containing propylene glycol and ethanol), natural sweetness enhancer and purified water.

What the Benylin Phlegm Cough Syrup looks like and the contents of the pack

Benylin Phlegm Cough Syrup is a clear red syrup, available in 125 ml and 300ml glass bottles.

Marketing Authorisation holder and Manufacturer

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

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

For information in large print, tape, CD or Braille, telephone 1800220044.

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