

Package leaflet: Information for the user



PHLEGM COUGH SYRUP

Guaifenesin 100mg/5ml
Levomenthol 1.1mg/5ml

Read all of this leaflet carefully before you start taking 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 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 take Benylin Phlegm Cough Syrup
4. Possible side-effects
5. How to store Benylin Phlegm Cough Syrup
6. Contents of the pack and other information



I What Benylin Phlegm Cough Syrup is and what is it used for

Benylin Phlegm Cough 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 take 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 take 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 breast-feeding

- If you are pregnant or breast-feeding, or not taking contraceptive measures, ask your doctor or pharmacist for advice before taking this medicine.

! Benylin Phlegm Cough Syrup contains sucrose, liquid glucose, ethanol, Ponceau 4R (E124) and sodium

- 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. This product contains 3.49 g glucose per 5 ml. Contains 1 g of sucrose per 5 ml. 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 5 ml, 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.
- This medicinal product contains 16.42 mg sodium per 5 ml. To be taken into consideration by patients on a controlled sodium diet.

3 How to take Benylin Phlegm Cough Syrup

Check the table below to see how much medicine to take.

- Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.
- For oral use only.
- Do not use more than the stated dose shown.

turn over ►

i Children under 12 years

This medicine is not recommended for children under 12 years.

i 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 symptoms persist, talk to your doctor or pharmacist.

! If you take more Benylin Phlegm Cough Syrup than you should

If anyone has too much, contact your doctor or 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** take a double dose.

4 Possible side-effects

Like all medicines, this medicine can cause side-effects, although not everyone gets them.

If you experience any of the following stop using the 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 or 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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@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.

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 (E150), carbomer, raspberry essence, natural sweetness enhancer and water.

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

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

Marketing Authorisation Holder and Manufacturer

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.

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

This leaflet was last revised in January 2016.

Benylin is a registered trade mark.

McNeil
Healthcare (Ireland) Ltd.

LN0000101
16-0006

Orleans - Artworks Center

Client	JNJ		
Change request #	CRD XXXX		
Product	BENYLIN PHLEGM COUGH SYRUP 125ML IE		
Component #	LN0000101		
Old component #	F310386		
ATW version	3.0		
Component type	Rolled Leaflet		
Dimensions	160 x 210 mm		
Drawing #	NOTC010		
Safety code type & #	Datamatrix LN0000101		
Client code	16-0006		
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		
PMS 349	PMS 349		

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.