



**PHLEGM
COUGH
PLUS
DECONGESTANT
SYRUP**

Guaifenesin 100mg/5ml
Pseudoephedrine Hydrochloride 30mg/5ml

- This medicine is used to relieve chesty coughs and help clear the stuffy, blocked up feeling in your nose and sinuses and reduce catarrh without causing drowsiness.
- This medicine is for use by adults and children aged 12 years and over.
- **Do not take this medicine:**
 - There are some people who should not take this medicine. *To find out if you are one of them see section 2* ▶
 - If you have ever had a **bad reaction** to any of the ingredients. *For the list of ingredients see section 6* ▶
- **Speak to your doctor:**
 - If you suffer from any of the conditions mentioned in section 2. See section 2 ▶
 - If you are taking any **other medicines**. See section 2 ▶
- **Follow the dosage instructions carefully.** These are shown in the table. 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 symptoms worsen or do not improve after a few days.

I What the medicine is and what it is used for

Benylin Phlegm Cough Plus Decongestant is a medicine which is used to relieve chesty coughs, help clear the stuffy, blocked up feeling in your nose and sinuses and reduce catarrh. The syrup contains pseudoephedrine hydrochloride, which is a decongestant that relieves nasal and sinus congestion and guaifenesin, which is an

expectorant that helps to loosen the mucus in your throat and chest.

This medicine is for use by adults and children aged 12 years and over.

2 What you need to know before you take this medicine

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 this medicine...

- If you have ever had a **bad reaction** (e.g. rash, swelling of face and throat, difficulty breathing) to any of the ingredients.
- If you have **very high blood pressure** or **severe heart disease**.
- If you are taking, or have taken in the last two weeks, **drugs for depression** known as Monoamine Oxidase Inhibitors (MAOIs).
- If you have had a **cough** for a few weeks, or a cough which brings up any blood or a lot of mucus that may be caused by **asthma** or **emphysema**.
- For a child under 12 years old.

If any of these apply to you, **get advice from a doctor or pharmacist without taking Benylin Phlegm Cough Plus Decongestant.**

! Talk to your doctor or pharmacist...

- If you have **liver or kidney problems**.
- If you have **high blood pressure** or **heart disease**.
- If you have **diabetes** or have been diagnosed with an **intolerance to some sugars**.
- If you have an **overactive thyroid gland**.
- If you have **glaucoma** (increased pressure in the eye).
- If you have **prostate problems** (difficulty with passing water or needing to pass water often).
- If you have **emphysema, chronic bronchitis** or **asthma**.
- If your **cough** keeps re-occurring or you have a **cough** with a **fever, rash** or **headache**.

- If you are taking any **other medicines**, including:
 - **Antihypertensives** (drugs used to treat **high blood pressure** such as guanethidine, methyldopa, alpha and beta blockers, debrisoquine, bretylium and betanidine).
 - The antibacterial agent, furazolidone.
 - Decongestants, appetite suppressants, stimulants or sedatives.
 - **Tricyclic antidepressants** (used to treat **mood disorders**).

If you are not sure about any of the medicines you are taking, show the bottle or pack to your pharmacist.

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

! If you are pregnant or breast-feeding

- If you are pregnant, or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

! Some of the ingredients can cause problems

- This medicine contains glycerol, which can cause headaches and may also upset the stomach when taken in large doses.
- This medicine contains 5% v/v ethanol (alcohol), which is up to 190 mg per 5 ml, equal to 5 ml beer or 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.
- This medicine contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- Methyl hydroxybenzoate and propyl hydroxybenzoate may cause allergic reactions such as skin rash; this may happen after a few days.
- The colourings Ponceau 4R (E124) and Sunset Yellow (E110) in this medicine may cause allergic reactions.

turn over ▶

3 How to take this medicine

i Check the table that follows to see how much medicine to take.

- For oral use only.
- Always **shake the bottle** thoroughly before use.
- Do not use more than the stated dose shown in the table.
- Do not overfill the spoon.

There is a double-ended spoon in the pack.



i Children under 12 years

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

i Adults and children aged 12 years and over

Age	Dose
Adults and children aged 12 years and over	Two large 5 ml spoonfuls every 4 - 6 hours, up to 4 times a day
<ul style="list-style-type: none">■ Leave at least 4 hours between doses.■ Do not give more than 4 doses in 24 hours.■ If symptoms persist talk to your doctor.	

! If anyone has too much

If anyone has too much, contact your doctor or pharmacist immediately.

! If you forget to take the medicine

If you forget to take a dose, take the next dose when needed provided that the last dose was taken at least 4 hours ago. **Do not** take a double dose.

4 Possible side-effects

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

If you experience any of the following stop using the medicine and seek immediate medical help:

- Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing.

If you experience any of the following, stop using this medicine and talk to your doctor:

- Hallucinations.
- Allergic reactions including skin rashes such as hives (which may be severe and include blistering and peeling of the skin) and itching.
- A fast or irregular or change in heartbeat or an increased awareness of the heartbeat (palpitations, tachycardia, arrhythmia).
- Trouble passing water (especially men with prostate problems).
- Restlessness or sleep disturbances.

Other effects which may occur include:

Common (may affect up to 1 in 10 people)

- Difficulty sleeping, nervousness or dizziness.
- Dry mouth or nausea.

Other effects which may occur but it is unknown how often

- Agitation, anxiety, feeling jittery or feelings of extreme happiness.
- Headache, extreme restlessness, tremors or muscle spasms.
- Stomach pain, diarrhoea or vomiting.
- Skin rashes.
- Pain when passing water.
- An increase in blood pressure.

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 How to store this medicine

Do not store above 25°C.

Do not refrigerate.

Keep the product out of the sight and reach of children.

Keep the container in the outer carton in order to protect from light.

Do not use after the end of the month shown as an expiry date on the packaging.

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 Contents of the pack and other information

What's in this medicine?

The active ingredients in Benylin Phlegm Cough Plus Decongestant are: 100 mg Guaifenesin and 30 mg Pseudoephedrine hydrochloride in each 5 ml spoonful.

Other ingredients are: Sucrose, glycerol, methyl hydroxybenzoate (E218), propyl hydroxybenzoate (E216), ethanol (alcohol), Ponceau 4R (E124), flavouring (wild cherry and menthol), Sunset Yellow (E110) and purified water.

What the medicine looks like

Benylin Phlegm Cough Plus Decongestant is a clear orange-red cherry flavoured liquid available in 100 ml glass bottle.

The Product Authorisation holder: McNeil Healthcare (Ireland) Limited, Airtown Road, Tallaght, Dublin 24, Ireland.

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

This leaflet was revised September 2015.

Benylin is a registered trade mark.

McNeil
Healthcare (Ireland) Ltd.

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Client	JNJ		
Change request #	CRD XXXX		
Product	BENYLIN PHLEGM COUGH + DECONGESTANT 100ML IE		
Component #	F310XXX		
ATW version	3.2		
Component type	Rolled Leaflet		
Dimensions	160 x 210 mm		
Drawing #	NOTC010		
Safety code type & #	Datamatrix F310XXX		
Client code	15-0112		
Main font type	Humanist 521 BT		
Minimum font size	7,5 pts		
Colours			
Recto 1	Verso 1	Recto 2	Verso 2
PMS 349	PMS 349		
PMS 485	PMS 485		
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