

# Benylin Phlegm Cough Menthol

## 100mg/5ml Oral Solution

### Guaifenesin

**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 or nurse has 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 7 days.

#### What is in this leaflet:

1. What Benylin Phlegm Cough Menthol is and what it is used for.
2. What you need to know before you take Benylin Phlegm Cough Menthol.
3. How to take Benylin Phlegm Cough Menthol.
4. Possible side effects.
5. How to store Benylin Phlegm Cough Menthol
6. Contents of the pack and other information

#### 1. What the Benylin Phlegm Cough Menthol is and what is it used for

Benylin Phlegm Cough Menthol contains guaifenesin which is a type of medicine called an expectorant. It helps to relieve chesty (productive) coughs by loosening phlegm (mucus), making it easier to cough up and the cough more productive.

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

#### 2. What you need to know before you take Benylin Phlegm Cough Menthol

##### **X Do NOT take this medicine if you**

- If you are **allergic** to guaifenesin or 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 Menthol if you:

- have had a **cough** for more than 7 days or your cough recurs or is accompanied by a **fever, rash or persistent headache**.
- have a **persistent cough** that may be caused by **asthma**.
- have a cough which brings up a lot of **mucus** (phlegm).
- suffer from severe **liver or kidney problems**.
- are taking **alcohol**.

##### **Children:**

The safety and efficacy of Guaifenesin in children aged under 12 years has not yet been established

### Interference with laboratory tests

If you are undergoing urine tests it is important to tell the doctor or nurse you are taking, or have recently taken, this medicine as it can affect some results.

### Other medicines and Benylin Phlegm Cough Menthol

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicine.

It is not recommended that you take this medicine with other cough medicines intended to stop you from coughing (antitussives or cough suppressants) as they may interfere with the action of this medicine.

### Benylin Phlegm Cough Menthol with food and drink

You can take this medicine with or without food or drink.

### ! Pregnancy and 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. This medicine should not be used during pregnancy unless advised by a doctor.
- Do not take this medicine if you are breast-feeding until you speak with a doctor or pharmacist.

### ! Driving and using machines

Benylin Phlegm Cough Menthol is not expected to affect your ability to drive or operate machinery. However, if you do feel unwell, do not drive or use machinery.

### Benylin Phlegm Cough Menthol contains

- 4.7 vol % **ethanol** (alcohol), i.e. up to 400 mg per dose, equivalent to approximately 10 ml beer, 4 ml wine per 10 ml dose. 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 or kidney disease or epilepsy.
- **Ponceau 4R** (E124) - red colouring - may cause allergic reactions.
- 17.6mg **sodium** per 10 ml dose. This should be taken into consideration by those on a controlled sodium diet.
- **glucose and fructose**. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

## 3. How to take Benylin Phlegm Cough Menthol

Always take 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.

- This solution is for oral use only.
- **Do not use more than the stated dose shown.**

Age	Dose
<b>Adults and adolescents over 12 years</b>	<b>One 10ml dose 4 times a day</b> using the supplied measuring cup and appropriate graduation mark.
<b>Elderly</b>	As for adults
<b>Patients with liver or kidney problems</b>	Speak to a doctor or pharmacist
<ul style="list-style-type: none"> <li>▪ Do <b>NOT</b> take more than 4 doses (40ml) in 24 hours.</li> <li>▪ Contact a doctor if your symptoms worsen or do not improve within 7 days.</li> </ul>	

### **! If you take too more Benylin Phlegm Cough Menthol than you should**

If anyone has too much, contact a doctor or your nearest Accident and Emergency Department taking this leaflet and pack with you.

If you take too much of this medicine you may develop kidney stones.

#### Symptoms may include:

- Upset stomach, nausea and drowsiness.

### **! If you forget to take Benylin Phlegm Cough Menthol**

You should only take this medicine as required following the dosage instructions carefully. If you forget to take a dose, take the next dose when needed. **Do not** take a double dose to make up for the forgotten dose. **Do not** take more than 4 doses (40 ml) in 24 hours.

## **4. Possible side effects**

Like all medicines, Benylin Phlegm Cough Menthol can cause side effects, although not everybody gets them.

### **If you experience any of the following stop using the medicine and seek medical help immediately:**

- **Allergic reactions** including **skin rashes** (which may be severe and include blistering and peeling of the skin) and **itching**.

#### **Other 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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto: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 Menthol

- Keep this medicine out of the sight and reach of children.
- Do not store this medicine above 25°C.
- Keep the product in the original packaging (bottle in a carton) to protect from light. Do not use if bottle seal is broken when purchased.
- Do not use this medicine after the expiry date which is stated on the bottle and outer carton after 'EXP'. The expiry date refers to the last day of that month.
- Use within 4 weeks of opening.
- Do not throw away any medicines. 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 Phlegm Cough Menthol contains:

The active substance is guaifenesin. Each ml of oral solution contains 20mg of guaifenesin. Each 10ml of oral solution contains 200mg of guaifenesin.

**The other ingredients are:** Xanthan gum, sodium chloride, saccharin sodium, ammonium glycyrrhizate, citric acid, sodium citrate, macrogol glycerol hydroxystearate 40, levomenthol, raspberry flavor (includes ethanol, glucose and fructose), glycerol, macrogol 1500, propylene glycol, ethanol, purified water, sodium benzoate (E211), Ponceau 4R (E124), caramel (E150)(includes glucose).

*(For further information on some of the ingredients see Section 2).*

### What Benylin Phlegm Cough Menthol looks like and contents of the pack

Benylin Phlegm Cough Menthol is a clear to slightly opalescent red solution for oral use only. It is available in a 150 ml brown glass bottle fitted with a plastic child resistant cap. A dosing cup which measures a 10ml dose is included in this pack.

**Product authorisation holder:** McNeil Healthcare (Ireland) Ltd. Airton Road, Tallaght, Dublin 24, Ireland.

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

**This medicinal product is authorised in the Member States of the EEA under the following names:**

**Belgium/Luxembourg:** Bronchosedal Mucus Menthol 20 mg/ml siroop

**Bulgaria:** Хекспекторал Ментол 20 mg/ml перорален разтвор

**Estonia:** Sudafed Broncho Menthol

**Cyprus:** Benylin Mucus Cough Max Menthol flavour 100mg/5ml Oral Solution

**Czech Republic:** OlynMuco s příchutí mentholu 20 mg/ml

**Greece:** Hexacough

**Ireland:** Benylin Phlegm Cough Menthol 100 mg/5ml Oral Solution

**Italy:** Actigrip Tosse Mucolitico “Gusto Mentolo 20 mg/ml, Soluzione Orale”

**Latvia/Lithuania:** Actifed Menthol 20mg/ml Syrup

**Poland:** Sudafed Muco na kaszel mokry

**Romania:** Hexpectral Mentol 20mg/ml Soluție Orală

**Slovak Republic:** OlynMuco s príchuťou mentolu 20 mg/ml

**Slovenia:** Hexpectral z okusom mentola 20 mg/ml peroralna raztopina

**Spain:** Iniston Expectorante 20 mg/ml Solución Oral Sabor Menta

**United Kingdom:** Benylin Mucus Max Cough Menthol flavour 100mg/5ml oral solution

**This package leaflet was prepared April 2017**