

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

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

Benylin Mucus 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 Mucus 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 Mucus 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 Mucus 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 Mucus 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 Mucus 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 Mucus Cough Menthol contains

- This medicinal product contains 381 mg of alcohol (ethanol) in each 10 ml dose which is equivalent to 38.1 mg/ml. The amount in 10 ml of this medicine is equivalent to 9.5 ml beer or 3.8 ml wine.
The small amount of alcohol in this medicine will not have any noticeable effects.
- **Ponceau 4R** (E124) - red colouring - may cause allergic reactions.
- This medicinal product contains less than 1 mmol sodium (23 mg) per 10 ml dose, that is to say essentially 'sodium-free' **Glucose**. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
- This medicinal product contains 10 mg of benzoate salt in each 10 ml dose.
- 2003.5 mg propylene glycol in each 10 ml dose. If you are pregnant or breast-feeding, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine. If you suffer from a liver or kidney disease, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.
- Macrogol glycerol hydroxystearate 40 May cause stomach upset and diarrhea

3. How to take Benylin Mucus 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
Adults and adolescents over 12 years	One 10ml dose 4 times a day using the supplied measuring cup and appropriate graduation mark.
Elderly	As for adults
Patients with liver or kidney problems	Speak to a doctor or pharmacist

- Do **NOT** take more than 4 doses (40ml) in 24 hours.
- Contact a doctor if your symptoms worsen or do not improve within 7 days.

! If you take too more Benylin Mucus 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 Mucus 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 Mucus 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**.
- Difficulty in breathing, swelling of the face, neck, tongue or throat (anaphylactic reaction).

Other effects that may occur include (frequency not known):

- 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 Mucus 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 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 Mucus 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 Mucus Cough Menthol looks like and contents of the pack

Benylin Mucus 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: JNTL Consumer Health I (Ireland) Ltd. Block 5, Hight Street, Tallaght, Dublin 24, Ireland.

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

This medicinal product is authorised in the Member States of the European Economic Area under the following names:

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

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

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

Spain: Iniston Mucosidad 20 mg/ml Solución Oral

Sweden: Nipenesin Mentol 20 mg/ml oral lösning

This package leaflet was last revised