PACKAGE LEAFLET: INFORMATION FOR THE USER

Benylin Mucus Cough Honey & Lemon 100mg / 5ml Syrup 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 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 one week

What is in this leaflet:

1. What Benylin Mucus Cough Honey & Lemon 100mg/ 5ml Syrup is and what it is used for.

2. What you need to know before you take this Benylin Mucus Cough Honey & Lemon 100mg / 5ml Syrup

- 3. How to take Benylin Mucus Cough Honey & Lemon 100mg / 5ml Syrup.
- 4. Possible side effects.
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- 6. Contents of the pack and other information

1. What Benylin Mucus Cough Honey & Lemon 100mg / 5ml Syrup is and what is it used for

Benylin Mucus Cough Honey & Lemon 100mg / 5ml Syrup 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. This is a non-drowsy formulation. The medicine is for use in adults and adolescents aged 12 years and over.

2. What you need to know before you take this Benylin Mucus Cough Honey & Lemon 100mg / 5ml Syrup

Do not take this Benylin Mucus Cough Honey & Lemon 100mg / 5ml Syrup 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 Honey & Lemon 100mg / 5ml Syrup if you:

- have had a cough for more than one week 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.

Other medicines and Benylin Mucus Cough Honey & Lemon 100mg/ 5ml Syrup

Always tell your doctor or pharmacist if you are taking, have recently taken, or might take

any other medicine, including medicines obtained without a prescription. 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. Some urine tests may be affected if taken within 24 hours of taking this medicine. Tell the doctor or nurse taking the urine sample that you are taking this medicine.

Benylin Mucus Cough Honey & Lemon 100mg / 5ml Syrup with food and drink

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

Pregnancy breast-feeding and fertility

If you are pregnant or think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this Benylin Mucus Cough Honey & Lemon 100mg / 5ml Syrup. This medicine is not recommended in pregnancy. Do not take this medicine if you are breast-feeding until you speak with a doctor or pharmacist.

Driving and using machines

It is not expected that this product will affect your ability to drive or operate machinery. However, if you do feel unwell, do not drive or use machinery.

Benylin Mucus Cough Honey & Lemon 100mg / 5ml Syrup contains:

• This medicine contains 393 mg of alcohol (ethanol) in each 10 ml dose which is equivalent to 39.3 mg/ml. The amount in 10 ml of this medicine is equivalent to less than 10 ml beer or 4 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

• 41.1 mg sodium (main component of cooking/table salt) in each 10 ml dose. This is equivalent to 2.054% of the recommended maximum daily dietary intake of sodium for an adult.

• approximately 2 g of sucrose and 7 g of glucose in each 10 ml dose.. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine. This should be taken into account in patients with diabetes mellitus. Sucrose and glucose may be harmful to the teeth.

- 20 mg of sodium benzoate in each 10 ml dose.
- 57.7 mg propylene glycol in each 10 ml dose.

3. How to take this Benylin Mucus Cough Honey & Lemon 100mg / 5ml Syrup

Always take this Benylin Mucus Cough Honey & Lemon 100mg / 5ml Syrup 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 syrup is for oral use only. **Do not use more than the stated dose shown.**

Age	Dose
Adults and adolescents of 12 years and over	Take 10 ml (two 5 ml spoonfuls) four times a day
Children under 12 years	Do not give
Patients with liver or kidney problems	Speak to a doctor or pharmacist

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

If you take more Benylin Mucus Cough Honey & Lemon 100mg / 5ml Syrup 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 this Benylin Mucus Cough Honey & Lemon 100mg / 5ml Syrup

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 Honey & Lemon 100mg / 5ml Syrup can cause side effects, although not everybody gets them.

If you experience any of the following stop using the Benylin Mucus Cough Honey & Lemon 100mg / 5ml Syrup 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 adverse reactions (or side effects) that may occur include (frequency not known):

- Stomach pain
- Nausea
- Vomiting
- Diarrhoea
- Upset stomach

Reporting of side effects

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, website: <u>www.hpra.ie</u>.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store this Benylin Mucus Cough Honey & Lemon 100mg / 5ml Syrup

Keep the product out of the sight and reach of children Store in the original bottle in order to protect from light. Do not use if bottle seal is broken when purchased. Do not use this product after the expiry date which is stated on the bottle and outer carton. The expiry date is the last day in the month indicated. Use within 6 months 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 Honey & Lemon 100mg / 5ml Syrup contains:

The active substance is: Guaifenesin. This product contains 100 mg guaifenesin in each 5 ml.

The other ingredients are: Sodium citrate, citric acid monohydrate, carbomer, glycerol, ethanol, glucose, sucrose, sucralose, sodium benzoate (E211), caramel (E150), flavours: honey, lemon, cooling, levomenthol, tingling, hot mix, enhancer and bitterness blocker and water.

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

What Benylin Mucus Cough Honey & Lemon 100mg / 5ml Syrup looks like and contents of the pack

Benylin Mucus Cough Honey & Lemon 100mg / 5ml Syrup is a yellow brown coloured syrup for oral use only.

It is available in a 150 ml brown glass bottle fitted with a plastic child resistant cap. Not all pack sizes will be marketed.

Please retain the carton.

Marketing authorisation holder: JNTL Consumer Health I (Ireland) Ltd., Block 5, High Street, Tallaght, Dublin 24, Ireland

Manufacturer: Delpharm Orleans, 5 avenue de Concyr, Orleans Cedex 2, 45071, France. and Johnson & Johnson Consumer NV/SA, Michel De Braeystraat 52, 2000 Antwerpen, Belgium

This medicine is authorised in the member states of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

MS	Name
Belgium	Bronchosedal Mucus Honing & Citroen 20 mg/ml siroop
Cyprus	Benylin Mucus Cough Honey & Lemon Flavour 20 mg/ml
Denmark	Benysine
Greece	Hexacough Warm Honey and Lemon
Ireland	Benylin Mucus Cough Honey & Lemon 100mg / 5ml Syrup
Luxembourg	Bronchosedal Mucus Miel & Citron 20 mg/ml sirop
Norway	Benysine
Sweden	Nipenesin 20 mg/ml sirap

United Kingdom (Northern Ireland)	Benylin Mucus Cough Max Honey & Lemon Flavour 100 mg/5 ml Syrup
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This package leaflet was last revised in March 2024