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REPRESENTATION: ☒ Colours represented with a diagonal line have been modified to aid PDF approval.

MANUFACTURING SITE

ReferenceNOTC010

Security Code / ICFPPPO

TECHNICAL DETAILS

ComponentLeaflet

PlantDelpharm Orléans

Dimensions160 x 210 mm

Master DielineJJDEL\_00043\_V1

Date14-05-2020

Profile

Text Limit

Bleed

Fold/Technical

Perforation

Stamping Area

Coding (Silent Zone)

Print & Varnish Free

Print Free

Varnish Free

Seal Area

Tamper Evident Label Area

Braille Grid

Fonts used

Gotham-Bold

Gotham-Medium

Gotham-Ultra

Humanist 521 BT-Bold

Humanist 521 BT-Bold Italic

Humanist 521 BT-Roman

Minion Pro-Regular

Zapf Dingbats-Regular

Smallest Text Size

4.0pt

Ave. Text Size

7.5pt

Largest Text Size

21.5pt



FLAVOUR 100 MG/5 ML 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, 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 this medicine is and what it is used for.
2. What you need to know before you take this medicine.
3. How to take this medicine.
4. Possible side-effects.
5. How to store this medicine.
6. Contents of the pack and other information.

## What this medicine is and what it is used for

BENYLIN® Mucus Cough Max Menthol Flavour 100 mg/5 ml Oral Solution 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 this medicine

### X Do NOT take this medicine

- if you are **allergic** to guaifenesin or any of the ingredients of this medicine (listed in section 6).

### ! Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine 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 **liver or kidney problems**.
- are taking **alcohol**.

### ! Children

The safety and efficacy of guaifenesin in children aged under 12 years have 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.

### ! Taking other medicines

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.

### ! Taking 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

This medicine is not expected to affect your ability to drive or operate machinery. However, if you do feel unwell, do not drive or use machinery.

### ! Important information on some of the other ingredients in this medicine

- 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 diarrhoea.

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### 3 How to take this medicine

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   | Take <b>two 5 ml spoonfuls</b> (total of 10 ml) <b>4 times a day</b> |
| Elderly                                | As for adults                                                        |
| Children under 12 years                | <b>Do not give</b>                                                   |
| 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 7 days.

#### If you take too much of this medicine

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 medicine

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, this medicine 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:

- 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 the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App store.

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

### 5 How to store this medicine

- Keep this medicine out of the sight and reach of children.
- Do not store this medicine above 25°C.
- Store in the original container in order 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 to protect the environment.

### 6 Contents of the pack and other information

#### What this medicine contains:

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

The other ingredients are: Xanthan gum, sodium chloride, saccharin sodium, ammonium glycyrrhizate, citric acid, sodium citrate, macrogol glycerol hydroxystearate 40, levomenthol, raspberry flavour (includes ethanol), glycerol, macrogol 1500, propylene glycol (E1520), ethanol, purified water, sodium benzoate (E211), Ponceau 4R (E124), caramel (E150)

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

#### What this medicine looks like and contents of the pack

BENYLIN® Mucus Cough Max Menthol Flavour 100 mg/5 ml Oral Solution 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.

**Marketing Authorisation holder:** McNeil Products Ltd, High Wycombe, Buckinghamshire, HP12 4EG, UK.

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

**This package leaflet was revised in March 2023.**

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