

**Patient information leaflet for BENYLIN WET COUGH****PATIENT INFORMATION LEAFLET****SCHEDULING STATUS****S0****Benylin Wet Cough liquid****Guaifenesin 200 mg per 10 mL**

**Contains sweeteners: Each 10 mL contains 16 mg saccharin sodium and 13 mg sodium cyclamate.**

**Contains sugar alcohol: Each 10 mL contains 4,015 g sorbitol.**

**Read all of this leaflet carefully because it contains important information for you.**

Benylin Wet Cough is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use Benylin Wet Cough carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Benylin Wet Cough with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see your doctor if your symptoms worsen or do not improve after 7 days.

**What is in this leaflet**

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

**1. What Benylin Wet Cough is and what it is used for**

Benylin Wet Cough contains guaifenesin (an expectorant) to help loosen mucus (phlegm) from the lungs and make it easier to cough up.

## **2. What you need to know before you use Benylin Wet Cough**

### **Do not use Benylin Wet Cough**

- If you or your child is hypersensitive (allergic) to guaifenesin or any of the other ingredients of Benylin Wet Cough (see **What Benylin Wet Cough contains**).
- If you are pregnant or breastfeeding (see **Pregnancy, breastfeeding and fertility**).
- If you or your child has acute porphyria.

Benylin Wet Cough is not recommended for use in children under the age of 4 years.

### **Warnings and precautions**

#### **Take special care with Benylin Wet Cough**

- If you suffer from liver or kidney problems.
- If you or your child have a persistent or chronic cough accompanied by excessive, mucus (phlegm). You should only use Benylin Wet Cough under the advice and supervision of your doctor.
- Consult your doctor if your or your child's cough persists for more than one week, tends to recur or is accompanied by high fever, rash or persistent headache.

### **Children**

Benylin Wet Cough should not be used in children below 4 years of age (see **Do not use Benylin Wet Cough**).

### **Other medicines and Benylin Wet Cough**

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

Benylin Wet Cough may interfere with certain laboratory test results.

### **Benylin Wet Cough with food, drink and alcohol**

See section 3.

### **Pregnancy, breastfeeding and fertility**

Do not use Benylin Wet Cough if you are pregnant or breastfeeding your baby (see **Do not use Benylin Wet Cough**).

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using Benylin Wet Cough.

### **Driving and using machines**

Benylin Wet Cough may cause side effects, such as drowsiness or dizziness. Do not drive a vehicle, operate machinery or do anything else that requires your attention until you know how Benylin Wet Cough affects you.

### **Benylin Wet Cough contains sorbitol and sodium benzoate**

Benylin Wet Cough contains sorbitol. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

Sorbitol is a source of fructose. If your doctor has told you that you or your child has an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you or your child take Benylin Wet Cough.

Benylin Wet Cough contains sodium benzoate which may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

### **Benylin Wet Cough contains sodium**

Benylin Wet Cough contains 57 mg sodium (main component of cooking/table salt) in each 10 mL. This is equivalent to 2,85 % of the recommended maximum daily dietary intake of sodium for an adult.

### **3. How to use Benylin Wet Cough**

Do not share medicines prescribed for you or your child with any other person.

For oral use only.

**DO NOT USE MORE THAN THE RECOMMENDED DOSE.**

Shake the bottle before use.

#### **Adults and children over 12 years:**

Two to four medicine measures (10 mL – 20 mL) every 4 hours.

#### **Children 6 – 12 years old:**

One to two medicine measures (5 mL – 10 mL) every 4 hours.

#### **Children 4 to under 6 years:**

Half to one medicine measures (2,5 mL – 5 mL) every 4 hours.

#### **Children under 4 years of age:**

Do not give Benylin Wet Cough to children younger than 4 years.

Benylin Wet Cough can be taken with or without food.

If you have the impression that the effect of Benylin Wet Cough is too strong or too weak, tell your doctor or pharmacist.

**If you use more Benylin Wet Cough than you should**

Signs of too much Benylin Wet Cough can include nausea (feeling sick), vomiting (being sick), severe abdominal pain and drowsiness.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

**If you forget to take a dose of Benylin Wet Cough**

If you forget to take or give a dose, take or give the next dose when needed provided that the last dose was at least 4 hours ago. Do not take or give a double dose to make up for the forgotten individual doses.

**4. Possible side effects**

Benylin Wet Cough can have side effects.

Not all side effects reported for Benylin Wet Cough are included in this leaflet. Should your or your child's general health worsen or if you experience any untoward effects while using Benylin Wet Cough, please consult your health care provider for advice.

If any of the following happens, stop using Benylin Wet Cough and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash, hives or itching;
- fainting.

These are all very serious side effects. If you or your child have them, you may have had a serious allergic reaction to Benylin Wet Cough. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

*Side effects occurring less frequently:*

- headache or dizziness;
- drowsiness;
- diarrhoea, nausea (feeling sick), vomiting (being sick), pain in your stomach.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

### **Reporting of side effects**

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reactions Reporting Form**”, found online under SAHPRA’s publications:

<http://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of Benylin Wet Cough.

For further information, please contact the Johnson & Johnson call centre on 0860 410032 (landline).

### **5. How to store Benylin Wet Cough**

- Store at or below 25 °C.
- Store all medicines out of reach of children.
- Keep well closed and store in a cool place.
- Keep the container in the outer carton.
- Do not use after the expiry date printed on the label / carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage

systems (e.g. toilets).

## 6. Contents of the pack and other information

### What Benylin Wet Cough contains

Each 10 mL contains:

Guaifenesin                      200 mg

The other ingredients are citric acid (E330), glycerine (E422), L- menthol (flavourant), polyethylene glycol (E521), propylene glycol (E1520), purified water, saccharin sodium (E954), sodium benzoate, sodium carboxymethyl cellulose, sodium citrate (E331), sodium cyclamate (E952(iv)), sorbitol (E420) and strawberry flavour.

Preservative: sodium benzoate 0,1 % *m/v*.

Alcohol and colourant free.

### What Benylin Wet Cough looks like and contents of the pack

A clear, colourless to straw-coloured, syrupy liquid with a strawberry odour and taste.

Amber glass bottles of 50 mL, 100 mL and 200 mL with a plastic measuring cup.

### Holder of certificate of registration

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