

## **Package leaflet: Information for the user**

### **Robitussin Chesty Cough 100 mg / 5 ml Oral Solution**

Guaifenesin

**Read all of this leaflet carefully before you start taking 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 have 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section.
- You must talk to a doctor if you do not feel better or if you feel worse after 5 days .

#### **What is in this leaflet**

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

#### **1. What Robitussin Chesty Cough is and what it is used for**

Robitussin Chesty Cough contains the active ingredient guaifenesin. This active ingredient belongs to a group of medicines called cough expectorants. Robitussin Chesty Cough helps loosen phlegm (mucus) to make your cough more productive and relieve chest congestion.

#### **2. What you need to know before you take Robitussin Chesty Cough**

**Do not take Robitussin Chesty Cough if** you are allergic to guaifenesin or any of the other ingredients of this medicine. Please see section 6 for a full list of the ingredients.

- Do not give this medicine to children under 12 years of age..

#### **Warnings and precautions**

Talk to your doctor, pharmacist or nurse before taking Robitussin Chesty Cough if:

- you have had a cough for a long time (as a result of smoking), or if you have asthma or emphysema
- you have severe kidney and/or severe liver problems.

A doctor or healthcare professional should be sought if cough lasts more than 5 days, comes back, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.

#### **Other medicines and Robitussin Chesty Cough**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This product should not be taken with any other cough and cold medicine.

#### **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 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**

Robitussin Chesty Cough has no known effects on the ability to drive or operate machinery.

**Robitussin Chesty Cough contains amaranth, sorbitol, maltitol, sodium benzoate, alcohol, propylene glycol and sodium:**

This medicine contains sorbitol and maltitol which are sources of fructose. If you have been told by your doctor that you have 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 take or receive this medicine.

This medicine contains 2675 mg sorbitol per 10 ml dose which is equivalent to 267.5 mg/ml. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

This medicine contains 12.0 mg sodium benzoate in each 10 ml dose which is equivalent to 1.2 mg/ml.).

This medicine contains 230 mg of alcohol (ethanol 96%) in each 10 ml dose which is equivalent to 23 mg/ml (2.30% w/v). The amount in 10 ml of this medicine is equivalent to less than 6 ml beer or 3 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

This medicine contains 15.2 mg propylene glycol in each 10 ml which is equivalent to 1.5 mg/ml.

This medicine contains 23.9 mg sodium (main component of cooking/table salt) in each 10 ml. This is equivalent to 1% of the recommended maximum daily dietary intake of sodium for an adult.

### **3. How to take Robitussin Chesty Cough**

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.

For oral use.

**Adults, the elderly and children over 12 years of age:**

The recommended dose is 10 ml up to four times daily. Do not take more than 4 doses in 24 hours. Do not exceed the stated dose.

**Use in children under 12 years:**

Do not use this medicine in children under 12 years.

If symptoms persist for more than 5 days or come back, or you experience symptoms unrelated to your original condition, such as fever, rash or persistent headache, discontinue use and immediately consult your doctor or pharmacist.

**If you take more Robitussin Chesty Cough than you should:**

If you take too much of this medicine, consult your doctor or hospital immediately. Bring any remaining medicine with you to show the doctor.

Signs and symptoms that you have taken too much medicine are: nausea and vomiting. Taking large amounts of guaifenesin may cause kidney stones.

**If you forget to take Robitussin Chesty Cough**

Do not take a double dose to make up for a forgotten dose.

### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. If you experience any of the side effects mentioned below, stop taking this medicine immediately and consult your doctor:

- Allergic reactions: Symptoms may include difficulty breathing, swelling of the face, lips, mouth, tongue or throat, rash, hives (urticaria) or itching.

**Frequency not known (cannot be estimated from the available data).**

- Other possible side effects: Feeling sick (nausea), being sick (vomiting), or stomach discomfort.

**Frequency not known (cannot be estimated from the available data).**

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. 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](http://www.hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store Robitussin Chesty Cough**

Do not use this medicine after the expiry date shown on the bottle label and carton after EXP.

Do not store above 25°C.

Keep out of the sight and reach of children.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

### **6. Contents of the pack and other information**

#### **What Robitussin Chesty Cough contains:**

- The active substance is guaifenesin. Each 5 ml contains 100 mg of the active substance.
- The other excipients are: Glycerol, carmellose sodium, sodium benzoate (E211), sodium cyclamate, ethanol (96%) 2.3% w/v, levomenthol, liquid maltitol (E965), propylene glycol, natural flavouring substances, citric acid anhydrous, caramel (E150), natural cherry flavor (contains ethanol 96%), liquid sorbitol non-crystallising (E420), acesulfame potassium and purified water.

#### **What Robitussin Chesty Cough looks like and contents of the pack**

Robitussin Chesty Cough is a deep russet coloured oral solution with a cherry flavour for oral administration.

It is supplied in a 100 ml bottle or a 200 ml bottle with a tamper evident seal.

Not all pack sizes

may be marketed.

#### **Marketing Authorisation Holder and Manufacturer**

**Marketing Authorisation holder** Haleon Ireland Limited, Clocherane, Dungarvan, Co. Waterford, Ireland.

#### **Manufacturer**

Doppel Farmaceutici S.r.l., Via Martiri delle Foibe 1, 29016 Cortemaggiore (Piacenza), Italy.

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