

## **Robitussin Dry Cough 7.5mg/5ml Oral Solution**

### **Dextromethorphan Hydrobromide**

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

This medicine is available without prescription. However, you still need to use **Robitussin Dry Cough** medicine carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your doctor or pharmacist if you need more information or advice.
- You must contact a doctor or pharmacist if your symptoms worsen, do not improve after 7 days or are accompanied by fever, rash or persistent headaches
- If any of the side effects get serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

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### **1 What Robitussin Dry Cough medicine is and what it is used for**

**Robitussin Dry Cough** medicine contains the active ingredient dextromethorphan hydrobromide. This active ingredient belongs to a group of medicines called cough suppressants that work by providing relief from persistent dry irritant coughs.

### **2 What you need to know before you take Robitussin Dry Cough medicine**

#### **Do not take this medicine if:**

- You are allergic (hypersensitive) to dextromethorphan hydrobromide or any of the other ingredients of **Robitussin Dry Cough** medicine (list in section 6).
- You have a chest infection, worsening asthma or severe respiratory problems.
- You are taking a selective serotonin reuptake inhibitor (SSRI).
- You are taking fluoxetine or a prescription monoamine oxidase inhibitor (MAOI), usually used to treat depression, or have taken either medicine within the last 14 days.

#### **Talk to your doctor before taking this medicine if:**

- You have had a cough for a long time or if you have asthma or are suffering from an asthma attack, or if your cough is accompanied by a fever, rash, or persistent headache.
- Your cough produces too much phlegm (mucus), lasts or is chronic, such as occurs with smoking, asthma or emphysema.
- You have liver or severe kidney problems.
- You are pregnant or breast-feeding.

**Robitussin Dry Cough** contains dextromethorphan which can cause dependency. It should be used with care.

Particular caution is advised if you are an adolescent or have had drug dependency in the past. This medicine can lead to dependence. Therefore the treatment should be of short duration.

Do not drink alcohol (wine, beer, spirits) whilst taking this medicine.

**Children:** Do not give this medicine to children under 12 because the potential benefits are not greater than the risks.

### **Taking other medicines**

#### **Talk to your doctor or pharmacist if you are taking:**

- Amiodarone, quinidine, flecainide or propafenone (or any other medicines which are used to treat heart conditions)
- Terbinafine, used to treat fungal infections
- Cinacalcet, used to treat an overactive parathyroid gland
- Methadone, used for severe pain
- Bupropion, used for smoking cessation; or
- any other medication for depression, psychiatric or emotional conditions, or Parkinson's disease such as haloperidol, perphenazine and thioridazine.

• If you are taking medicines such as certain antidepressants or antipsychotics. **Robitussin Dry Cough** Medicine may interact with these medicines and you may experience mental status changes (e.g. agitation, hallucinations, coma), and other effects such as body temperature above 38°C, increase in heart rate, unstable blood pressure, and exaggeration of reflexes, muscular rigidity, lack of coordination and/or gastrointestinal symptoms (e.g. nausea, vomiting, diarrhoea).

Do not take this medicine if you are taking a prescription monoamine oxidase inhibitor (MAOI) or a selective serotonin reuptake inhibitor (SSRI) eg. sertraline or have taken either medicine within the last 14 days.

#### **Important information about some of the ingredients of Robitussin Dry Cough medicine:**

- This product contains amaranth (E123), which may cause allergic reactions.
- 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 2094 mg sorbitol per 10 ml dose which is equivalent to 209.4 mg/ml. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.
- This medicine contains 208 mg of alcohol (ethanol 96%) in each 10 ml dose which is equivalent to 21 mg/ml (2.08% w/v).
- The amount in 10 ml of this medicine is equivalent to less than 6 ml beer or 3ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.
- This medicine contains 12.0 mg sodium benzoate in each 10 ml dose which is equivalent to 1.2 mg/ml.

This medicine is not for use in babies and children under 12 years.

- This medicine contains less than 1 mmol sodium (23 mg) per 10 ml, that is to say essentially 'sodium-free'.

**Pregnancy and breast-feeding:** If you are pregnant, breast-feeding or think you may be pregnant, ask your doctor for advice before taking this medicine.

**Driving and using machines:** This product may cause drowsiness or dizziness. If affected, do not drive or operate machinery.

### **3 How to take Robitussin Dry Cough medicine**

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

Take 10 ml three or four times daily using the dosing cup provided.

#### **Children under 12 years:**

Do not use.

Do not exceed the stated dose. Should not be used with other cough and cold medicines.

Stop use and ask a healthcare professional if your cough lasts for more than 7 days, comes back, or is accompanied by a fever, rash, or persistent headache.

#### **If you take more medicine than you should**

If you take too much of this medicine, consult your doctor or hospital immediately. Bring the remaining medicine to show the doctor. If you take more **Robitussin Dry Cough** Medicine than you should, you may experience the following symptoms: nausea and vomiting, involuntary muscle contractions, agitation, confusion, somnolence, disturbances in consciousness, involuntary and rapid eye movements, cardiac disorders (rapid heart beating), coordination disorders, psychosis with visual hallucinations, and hyperexcitability. Other symptoms in case of massive overdose may be : coma, severe breathing problems, and convulsions. Contact your doctor or hospital straight away if you experience any of the above symptoms.

#### **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, such as skin rash or itching, sometimes with breathing problems or swelling of the lips, tongue, throat or face (rare).
- Stomach upset, nausea, vomiting, abdominal discomfort (uncommon).
- Drowsiness, dizziness (uncommon).

#### **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 Dry Cough medicine**

- Do not use this medicine after the expiry date shown on the bottle and carton.
- 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 Dry Cough medicine contains:**

Each 5 ml contains 7.5 mg of the active substance dextromethorphan hydrobromide. **Robitussin Dry Cough** medicine also contains: Glycerol, carmellose sodium, sodium benzoate, disodium edetate, maltitol liquid, ethanol (96%) (alcohol 2.08% w/v), citric acid anhydrous, amaranth (E123), caramel (E150), levomenthol, cherry / grenadine flavour (contains ethanol 96%), sorbitol, liquid (non-crystallising) 70% (E420), sodium cyclamate, acesulfame potassium, purified water. **Robitussin Dry Cough** is an 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. Notall pack sizes may be marketed.

##### **Who makes and supplies this medicine:**

##### **The Product Authorisation holder for Robitussin Dry Cough medicine is:**

Haleon Ireland Limited,

12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland.

**This medicine is manufactured by:** Doppel Farmaceutici S.r.l., Via Martiri delle Foibe 1, 29016  
Cortemaggiore (Piacenza) , Italy.

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