

Robitussin[®]

DRY COUGH MEDICINE

SUB-IINS-00098

Dextromethorphan Hydrobromide
7.5 mg per 5 ml

Liquid for Oral Administration

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

This medicine is available without prescription. However, you will still need to use this medicine carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after 7 days.
- If any of the side effects gets 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
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1. What Robitussin Dry Cough Medicine is and what it is used for

The active ingredient dextromethorphan belongs to a group of medicines called cough suppressants that work by providing relief from persistent dry irritant coughs.

2. 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 in this medicine.
- You are currently taking a prescription monoamine oxidase inhibitor (MAOI), used to treat depression and Parkinson's disease or have taken this medicine in the last 14 days.
- You are currently taking a selective serotonin reuptake inhibitor (SSRI), used to treat depression and anxiety or have taken this medicine in the last 14 days.
- You are currently taking any other medication for depression, psychiatric, or emotional conditions, or Parkinson's disease or have done so in the last 14 days.

Take special care and talk to your doctor before taking this medicine if:

- You have had a cough for a long time or if you have asthma or suffer from serious asthma attacks, or if your cough is accompanied by a fever, rash, or persistent headache.
- You have liver problems.

This medicine 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.

Pregnancy and breastfeeding

Talk to your doctor before taking this medicine if you are pregnant or breastfeeding.

Driving and using machines

The medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you.
- It may be an offence to drive when taking this medicine.
- However, you would not be committing an offence if:
 - The medicine has been taken to treat a medical problem and
 - You have taken it according to the information provided with the medicine and
 - It was not affecting your ability to drive safely

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

Details regarding a new driving offence concerning driving after drugs have been taken in the UK may be found here: <https://www.gov.uk/drug-driving-law>

Taking other medicines

Do not take if you are taking any of the following medicines, or have done so in the last 14 days:

- A prescription monoamine oxidase inhibitor (MAOI), used to treat depression and Parkinson's disease.
- A selective serotonin reuptake inhibitor (SSRI), used to treat depression and anxiety.
- Any other medication for depression, psychiatric, or emotional conditions, or Parkinson's disease.

If you are not sure if your prescription medicine contains one of these drugs, ask a doctor or pharmacist before taking this product.

Talk to your doctor or pharmacist if you are taking:

- Quinidine or Amiodarone (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.
- 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).

Important information about some of the ingredients of this medicine:

- This medicine contains amaranth (E123), which may cause allergic reactions.
- If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine as it contains sorbitol and maltitol.
- This medicinal product contains 2.5 % v/v alcohol (ethanol) (196 mg per 10 ml dose). This is equivalent to approximately 1.6 ml wine per dose which can be harmful for those suffering from alcoholism and should be taken into account if you are pregnant or breastfeeding or have liver disease or epilepsy.

3. How to take Robitussin Dry Cough Medicine

For oral use only.

Adults, the elderly and children over 12 years: Take 10 ml up to four times daily, as required.

Children under 12 years: Do not use.

Use the dosing cup provided with the pack.

Do not exceed the stated dose.

Stop using this medicine and ask a healthcare professional if you have had a cough for **more than 7 days** or if you have any other symptoms which might be related to your cough, for example 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 any remaining medicine with you 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, Robitussin Dry Cough Medicine can cause side effects, although not everybody gets them.

Side effects with dextromethorphan hydrobromide are rare. However, susceptible individuals may experience unwanted side effects.

If any of the side effects gets serious or you experience any other side effects, **STOP** taking this medicine immediately and consult your doctor:

- Allergic reactions. Symptoms could include itchy skin or rashes, difficulty breathing, faster heart rate, swelling of the face or the throat.
- Stomach upset.
- Dizziness, drowsiness, mental confusion.

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, 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 Robitussin Dry Cough Medicine

- Do not use this medicine after the expiry date shown on the top end of the carton.
- Store below 25°C.
- Keep out of the sight and reach of children.

6. Further 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, sodium carboxymethyl cellulose, sodium benzoate, disodium edetate, maltitol (E965), ethanol, citric acid anhydrous, amaranth (E123), caramel (E150), levomenthol, cherry/grenadine flavour, sorbitol solution 70%, sodium cyclamate, acesulfame potassium salt, purified water.

Robitussin Dry Cough Medicine is a liquid, supplied in a 100 ml bottle or 250 ml bottle.

Not all pack sizes may be marketed.

Who makes and supplies this medicine:

The Marketing Authorisation holder for Robitussin Dry Cough Medicine is:
Pfizer Consumer Healthcare Ltd, Ramsgate Road, Sandwich, Kent, CT13 9NJ, UK.

The dosing cup is manufactured by:

Humphrey Cosburn Plastics, 89 Union Street, Toronto, Ontario, M6N 3N2, Canada.

The EU Authorised Representative is: Pfizer Healthcare Ireland

This medicine is manufactured by:

Wyeth Pharmaceuticals, New Lane, Havant, Hampshire, PO9 2NG, United Kingdom.
Pfizer Consumer Manufacturing Italy S.r.l., Via Nettunense, 90, 04011 Aprilia (LT), Italy

If you have any queries, comments about this medicine or require information in large print or CD please contact the Careline by phone or write to:

Careline, Pfizer Consumer Healthcare Ltd, Walton Oaks, Surrey, KT20 7NS, UK.

or carelineUK@pfizer.com

Leaflet prepared: October 2019

PL Number: 00165/0100

MA111/00402



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- Supplier to generate the code -

DATAMATRIX CODE with at least 12 cells
of a minimum of 0.25mm (9.84mils),
PRINTED IN BLACK, WITH AT LEAST
1 MM QUIET AREA ON ALL SIDES

DATA MATRIX VALUE = TBD