

Robitussin

DRY COUGH MEDICINE

6200000079513

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.

In this leaflet:

1. What Robitussin Dry Cough Medicine is and what it is used for
2. Before you take Robitussin Dry Cough Medicine
3. How to take Robitussin Dry Cough Medicine
4. Possible side effects
5. How to store Robitussin Dry Cough Medicine
6. Further information

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.

Talk to your pharmacist before taking this medicine if you:

- are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs.
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.

Taking this medicine regularly, particularly for a long time, can lead to addiction. Only use this medicine as described in the leaflet.

Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Speak to your doctor if you experience withdrawal symptoms.

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.
- 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 219.3 mg of alcohol (ethanol) in each 10 ml dose which is equivalent to 22 mg/ml (2.08% w/v). The amount in 10 ml of this medicine is equivalent to less than 6 ml beer or 3 ml wine. The amount of alcohol in this medicine will not have any noticeable effects. If you are addicted to alcohol, talk to your doctor or pharmacist before taking this medicine. The alcohol in this medicine should be taken into account if you are pregnant or breastfeeding or have liver disease or epilepsy.
- This medicine contains 12.0 mg sodium benzoate in each 10 ml dose which is equivalent to 1.2 mg/ml. Sodium Benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old). This medicine is not for use in babies and children under 12 years.
- 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 less than 1 mmol sodium (23 mg) per 10 ml, that is to say essentially 'sodium-free'.

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.
- Unknown frequency: dependence and addiction (see section "How do I know if I am addicted?").

Drug Withdrawal

When you stop taking Robitussin Dry Cough Medicine, you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

How do I know if I am addicted?

If you notice any of the following signs whilst taking Robitussin Dry Cough Medicine, it could be a sign that you have become addicted.

- You need to take the medicine for longer than advised
- You feel you need to use more than the recommended dose
- You are using the medicine for reasons other than those indicated
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again

If you notice any of these signs, it is important you talk to your doctor or pharmacist.

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:

GlaxoSmithKline Consumer Healthcare (UK) Trading Limited, Brentford, TW8 9GS, U.K.

The dosing cup is manufactured by:

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

The EU Authorised Representative is: GSK Consumer Healthcare (GMDT) Clocherane, Youghal Road, Dungarvan, Co. Waterford, 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 or comments about your medicine or any other GSK Consumer Healthcare products, ring our customer Careline or e-mail us at customer.relations@gsk.com

Trade marks are owned by or licensed to the GSK group of companies.

Leaflet prepared: May 2022

PL Number: 44673/0207

