

Package leaflet: Information for the user
Robitussin Mucus Cough and Congestion Relief 20mg, 6mg/ml Oral Solution,
Guaifenesin and Pseudoephedrine

Read all of this leaflet carefully before you start to take this medicine because it contains important information for you

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See Section 4.
- You must talk to a doctor if you do not feel better or if you feel worse 7 days.

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1. What Robitussin Mucus Cough and Congestion Relief is and what it is used for

This medicine contains the active ingredients guaifenesin and pseudoephedrine hydrochloride. Guaifenesin belongs to a group of medicines called cough expectorants and works by changing an unproductive cough to a cough that is more productive and less frequent. Pseudoephedrine hydrochloride belongs to a group of medicines called nasal decongestants and works by providing symptomatic relief of the common cold.

2. What you need to know before you take Robitussin Mucus Cough and Congestion Relief

Do not take this medicine if:

- You are allergic (hypersensitive) to guaifenesin or pseudoephedrine hydrochloride or any of the other ingredients in this medicine.
- You have very high blood pressure (severe hypertension) or hypertension not controlled by your medication.
- If you have severe acute (sudden) or chronic (long-term) kidney disease or kidney failure.
- If you have heart disease, an overactive thyroid gland, increased pressure in your eyes (glaucoma), diabetes, an enlarged prostate gland, phaeochromocytoma or have difficulty passing urine.
- You are taking a monoamine oxidase inhibitor (MAOI) medicine for depressive illness, such as Moclobemide, or have done so in the last 14 days.
- You are taking medicines to control your blood pressure e.g. medicines called alpha or beta blockers.
- You are taking any other sympathomimetic decongestants, decongestant or expectorant products, or the oxazolidinone class of antibiotics.
- You are under the age of 12.
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Take special care with Robitussin Mucus Cough and Congestion Relief:

Check with your doctor before use if:

- You are taking medicines to treat acute migraine headache e.g. medicines called ergotamin or methysergide.
- You have diabetes (too much sugar in your blood), hyperthyroidism, prostate gland enlargement, glaucoma, psychosis (severe mental health problem in which the person loses contact with reality and is unable to think and judge clearly) or high blood pressure, irregular heart beat and phaeochromocytoma (a rare tumour of the adrenal glands which sit above the kidneys).
- You have a chronic cough, asthma or are suffering from an asthma attack, chronic bronchitis or emphysema (disease of the lungs).

In case of surgery, it is advisable to stop treatment at least several days before.

The pseudoephedrine content in this product may induce a positive reaction during antidoping control tests.

Taking other medicines:

Talk to your doctor or pharmacist before taking this medicine if:

- You are taking digoxin, used to treat some heart conditions.
- You are taking medicines to reduce blood pressure.
- You are taking a medicine for depression (e.g. a tricyclic anti-depressant such as amitriptyline).

Pregnancy and breastfeeding

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

Driving and using machines

Users should be aware that this product can cause dizziness as side effect which could affect your ability to drive or operate machinery.

After taking the medicine:

If you develop a feverish generalised erythema (redness of the skin) associated with pustules, stop taking Robitussin Mucus Cough and Congestion Relief and contact your doctor or seek medical attention immediately. See Section 4.

Sudden abdominal pain or rectal bleeding may occur with Robitussin Mucus Cough and Congestion Relief, due to inflammation of the colon (ischemic colitis). If you develop these gastro-intestinal symptoms, stop taking Robitussin Mucus Cough and Congestion Relief and contact your doctor or seek medical attention immediately. See Section 4.

Reduction of blood flow to your optic nerve may occur with Robitussin Mucus Cough and Congestion Relief. If you develop sudden loss of vision, stop taking Robitussin Mucus Cough and Congestion Relief and contact your doctor or seek medical attention immediately. See Section 4.

Cases of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) have been reported following use of medicines containing pseudoephedrine. PRES and RCVS are rare conditions that can involve reduced blood supply to the brain. Stop using Robitussin Mucus Cough and Congestion Relief immediately and seek immediate medical assistance if you develop symptoms that may be signs of PRES or RCVS (see section 4 "Possible side effects" for symptoms)

Important information about some of the ingredients in this medicine:

- This product contains amarant (E123), which may cause allergic reactions.
- This medicine contains sorbitol and maltitol which are sources of fructose. If you have been told 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 27.5 mg sodium (main component of cooking/table salt) in each 10 ml. This is equivalent to 1.4 % of the recommended maximum daily dietary intake of sodium for an adult.
- 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 242 mg of alcohol (ethanol) in each 10 ml dose which is equivalent to 24 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 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 15.2 mg propylene glycol in each 10 ml which is equivalent to 1.5 mg/ml. Use of this medicine in newborn babies (up to 4 weeks old) can cause harm if given with other medicines that contain propylene glycol or alcohol. This medicine should not be used in babies or children under 12 years old.
- 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.

3. How to take Robitussin Mucus Cough and Congestion Relief

For oral use only.

Adults, (including the elderly) and children aged 12 years and over: Take 10 ml every 4-6 hours 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. Do not take more frequently than every 4 hours. Do not use with other decongestant or expectorant products.

Do not use for more than 7 days, without speaking to your doctor. No more than four doses should be taken in any 24 hours.

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, persistent headache or shortness of breath.

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.

Signs and symptoms that you have taken too much are: nausea, vomiting, a feeling your heart is beating too fast or too slow, palpitations, feeling anxious, irritable or nervous, feeling restless, increased blood pressure, difficulty in passing urine, unable to sleep, seizures (fits) or shaking.

If you forget to take your medicine:

Take a dose when you need to, provided the last dose was taken at least 4 hours ago. Do not take a double dose to make up for the one you have missed.

4. Possible side effects

Like all medicines, your medicine can cause side effects, although not everybody gets them. Side effects with guaifenesin or pseudoephedrine are rare. However, susceptible individuals may experience unwanted side effects. If you experience any of the following serious effects then **STOP** taking this medicine immediately and contact your doctor or pharmacist:

- Serious conditions affecting blood vessels in the brain known as posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS). Stop using this product immediately and seek urgent medical attention if you develop symptoms, that may be signs of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS). These include:
 - o severe headache with a sudden onset
 - o feeling sick
 - o vomiting
 - o confusion
 - o seizures changes in vision
- Allergic reactions. Symptoms could include anaphylaxis, itchy skin or rashes, difficulty breathing, faster heart rate, swelling of the face or throat, and feeling faint, which may lead to loss of consciousness.
- A feeling your heart is beating too fast or palpitations.
- Sudden onset of fever, reddening of the skin, or many small pustules (possible symptoms of Acute Generalized Exanthematous Pustulosis - AGEP) may occur within the first 2 days of treatment with Robitussin Mucus Cough and Congestion Relief. See Section 2.
- Inflammation of the colon due to insufficient blood supply (ischemic colitis). The symptoms of this are sudden abdominal pain or rectal bleeding.
- Reduced blood flow to the optic nerve (ischaemic optic neuropathy)
- Dry mouth
- Sudden chest pain or discomfort accompanied by shortness of breath
- Sudden and severe headache accompanied by a vomiting sensation or disturbance in vision
- You have difficulty urinating. This is more likely to occur if you have an enlarged prostate gland

Other possible side effects

- If any of the side effects below get serious or you experience any other side effects, stop taking this medicine immediately and consult your doctor:
- Feeling sick (nausea) or being sick (vomiting).
- Dizziness, headache, feeling restless or overactive.
- Feeling anxious, irritable or nervous.
- If you cannot sleep, or suffer from hallucinations (particularly in children).
- Skin rashes or hives.
- An increased blood pressure.
- Tremor

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 Mucus Cough and Congestion Relief

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

6. Contents of the pack and other information

What Robitussin Mucus Cough and Congestion Relief contains:

Each 5 ml contains 100 mg of the active substance guaifenesin and 30 mg of the active substance pseudoephedrine hydrochloride.

Robitussin Mucus Cough and Congestion Relief also contains: Glycerol, Carmellose Sodium, Disodium Edetate, Sodium Benzoate (E211), Sodium Cyclamate, Amaranth (E123), Ethanol (96%), Levomenthol, Maltitol (E965), Sorbitol Solution 70%, Natural Cherry Flavouring, Citric Acid Anhydrous, Caramel (E150), Acesulfame Potassium and Purified Water.

Robitussin Mucus Cough and Congestion Relief is a liquid, supplied in a 100 ml bottle.

Who makes and supplies this medicine:

The Marketing Authorisation holder for Robitussin Mucus Cough and Congestion Relief is: Haleon UK Trading Limited, The Heights, Weybridge, Surrey, KT13 0NY, U.K.

The dosing cup is manufactured by:

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

This medicine is manufactured by:

Wyeth Pharmaceuticals, New Lane, Havant, Hampshire, PO9 2NG, United Kingdom.

Haleon Italy Manufacturing S.r.l., Via Nettunense, 90, 04011 Aprilia (LT), Italy.

If you have any queries or comments about your medicine or any other Haleon products, ring our customer Careline or

e-mail us at mystory.gb@haleon.com

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