

# Robitussin

## MUCUS COUGH AND CONGESTION RELIEF

20mg, 6mg/ml Oral Solution

PAA159305

### Guaifenesin and Pseudoephedrine

#### 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 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 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 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. 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 are suffering from heart disease, an overactive thyroid gland, increased pressure in your eyes (glaucoma), diabetes, an enlarged prostate gland 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.

Take special care and talk to your doctor or pharmacist 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.

##### 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 another decongestant product (e.g. sympathomimetics such as phenylephrine).
- You are taking a medicine to control the symptoms of asthma (e.g. an inhaled beta-agonist such as Salbutamol).
- 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.

##### 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.

##### Important information about some of the ingredients in this 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 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, 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.** 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, 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:

- Allergic reactions. Symptoms could include itchy skin or rashes, difficulty breathing, faster heart rate, swelling of the face or throat.
- 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)

#### 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.
- Skin rashes or hives.
- An increased blood pressure.
- Difficulty passing urine.

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](http://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. Further 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: 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:

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.

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