

Robitussin Plus Oral Solution

Guaifenesin 100mg/5ml

Pseudoephedrine hydrochloride 30mg/5ml

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 Plus** 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.
- 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.
- You must contact a doctor or pharmacist if symptoms persist.

In this leaflet:

- 1 What Robitussin Plus is and what it is used for
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1 What Robitussin Plus is and what it is used for

Robitussin Plus 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 helps clear nasal congestion (a blocked or stuffy nose).

2 Before you take Robitussin Plus

- Do not use in combination with any other medication unless your doctor approves it.

Do not take this medicine if:

- You are allergic (hypersensitive) to guaifenesin or pseudoephedrine hydrochloride or any of the other ingredients of **Robitussin Plus**.
- You are taking a monoamine oxidase inhibitor (MAOI) or have done so in the last 14 days.
- You are taking other medicine for depression (e.g. tricyclic antidepressants).
- You are taking sympathomimetics (medicines used to treat nasal congestion that also contain for example pseudoephedrine, phenylephrine or phenylpropanolamine).
- You are taking cardiac glycosides (e.g. digoxin).
- You are taking any medicine for heart disease or to lower blood pressure.
- You are suffering from heart disease, acute ischaemia (arterial disease or thrombosis), high blood pressure (severe hypertension) or hypertension not controlled by your medication, an overactive thyroid gland, increased pressure in your eyes (glaucoma), diabetes, or have difficulty passing urine due to an enlarged prostate.

- You suffer from severe hepatic (liver) or impairment, or if you have severe acute (sudden) or chronic (long-term) kidney disease or kidney failure
- You are a child under 12 years of age.

Warnings and Precautions

Talk to your doctor before taking this medicine if:

- You are pregnant or breast-feeding.
- You are taking other medications, even those not prescribed (including herbal medicines).
- You have had a cough for a long time (as a result of smoking), or if you have asthma or emphysema.

Pregnancy, breast-feeding and fertility:

- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

After taking the medicine:

- If you develop a feverish generalised erythema (redness of the skin) associated with pustules, stop taking Robitussin Plus and contact your doctor or seek medical attention immediately. See section 4.
- Sudden abdominal pain or rectal bleeding may occur with Robitussin Plus Oral Solution, due to inflammation of the colon (ischemic colitis). If you develop these gastro-intestinal symptoms, stop taking Robitussin Plus Oral Solution and contact your doctor or seek medical attention immediately. See section 4.
- Reduction of blood flow to your optic nerve may occur with Robitussin Plus Oral Solution. If you develop sudden loss of vision or decreased vision, such as a blind spot or persistent blurring, stop taking Robitussin Plus Oral Solution 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 Plus 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 of Robitussin Plus:

- 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 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 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. This medicine is not for use in babies and children under 12 years.
- This medicine contains 230 mg of alcohol (ethanol) in each 10 ml dose which is equivalent to 23 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 small amount of alcohol in this medicine will not have any noticeable effects.
- This medicine contains 15.2 mg propylene glycol in each 10 ml which is equivalent to 1.5 mg/ml.

3 How to take Robitussin Plus

Adults, the elderly and children over 12 years:

Take 10ml three times daily.

Children under 12 years:

Do not use.

Do not exceed the stated dose.

If symptoms persist for more than 5 days or come back, or you experience symptoms unrelated to your original condition such as fever, rash or persistent headache, discontinue use and immediately consult your doctor or pharmacist.

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: dizziness, nausea, vomiting, rash, 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, convulsions or shaking.

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 consult 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** Robitussin Plus 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:

- severe headache with a sudden onset
 - feeling sick
 - vomiting
 - confusion
 - seizures changes in vision
- Allergic reactions. Symptoms could include itchy skin or rashes, difficulty breathing, faster heart rate, swelling of the face of 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 Plus. See section 2.

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:

Other side effects have been reported

Not known (frequency cannot be estimated from the available data):

- 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.
- Inflammation of the colon due to insufficient blood supply (ischemic colitis). The symptoms of this are abdominal pain and rectal bleeding.
- Reduced blood flow to the optic nerve (ischaemic optic neuropathy).

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 the HPRA Pharmacovigilance website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Robitussin Plus

- Do not use this medicine after the expiry date shown on the bottle label or carton.

- Do not store above 25°C. Do not refrigerate or freeze.
- 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 Further information

What Robitussin Plus contains:

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

Robitussin Plus also contains: Glycerol, carmellose sodium, disodium edetate, sodium benzoate (E211), sodium cyclamate, amaranth (E123), ethanol (96%) (alcohol 2.3% w/v), levomenthol, liquid maltitol (E965), sorbitol solution 70%, propylene glycol, natural cherry flavour (contains ethanol 96%), citric acid anhydrous, caramel (E150), acesulfame potassium and purified water.

Robitussin Plus is a pink coloured oral solution with a cherry flavour for oral administration. It is supplied in a bottle containing 100ml with a tamper evident seal.

Who makes and supplies this medicine:

The Product Authorisation holder for Robitussin Plus is: Haleon Ireland Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland.

This medicine is manufactured by: Haleon Italy Manufacturing S.r.l., Via Nettunense, 90, 04011 Aprilia (LT), Italy.

PA 678/154/001

Leaflet prepared: October 2024

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