**Package leaflet: Information for the patient**

**Robitussin Plus Oral Solution**

guaifenesin 100mg/5ml pseudoephedrine hydrochloride 30mg/5ml

**Read all of this leaflet carefully before you start taking 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 5 days.

**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. What you need to know before you take Robitussin Plus**

Do not use in combination with any other medication unless your pharmacist 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 medicines for the relief of colds and flu, congestion or blocked nose, stimulant drugs called amphetamines (sometimes used to treat attention deficit disorders), appetite suppressants or drugs called tricyclic antidepressants.

• 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, 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 renal (kidney) impairment.

• You are a child under 12 years of age.

• You are taking an antibiotic called linezolid.

**Warnings and precautions**

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

• You are taking medicines to control your blood pressure e.g. medicines called alpha or beta blockers.

• You are taking medicines to treat acute migraine headache e.g. medicines called ergotamine 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).

• You are pregnant or breast-feeding.

• You are taking other medications, even those not prescribed (including herbal medicines).

• You suffer from severe hepatic (liver) impairment.

• You are more than 60 years old, as there is increased possibility of unwanted effects.

In case of surgery, it is advisable to stop treatment at least 24 hours before.

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

**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, due to inflammation of the colon (ischemic colitis). If you develop these gastro-intestinal symptoms, stop taking Robitussin Plus 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. If you develop sudden loss of vision or decreased vision, such as a blind spot or persistent blurring, stop taking Robitussin Plus and contact your doctor or seek medical attention immediately. See section 4.

**Children**

Do not give this medicine to children under the age of 12 years.

**Other Medicines and Robitussin Plus** Tell your doctor or pharmacist if you are taking, have recently taken or might use any other medicines. See medicines listed above in “Do not take this medicine if:” and the “Warnings and precautions” sections.

**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, pharmacist or nurse for advice before taking this medicine. Taking Robitussin Plus is not recommended if you are pregnant.

Decreased milk production in nursing mothers has been reported with pseudoephedrine, a component of Robitussin Plus. Pseudoephedrine is excreted in human milk. If you are breast- feeding, taking Robitussin Plus is not recommended.

**Driving and using machines**

This product can cause dizziness as side effect which could affect your ability to drive or operate machinery.

**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

10ml. 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, (including the elderly) and children aged 12 years and over:**

Take 10 ml up to three times daily. The maximum daily dose is 30 ml in any 24 hours Do not exceed the stated dose. Do not take more frequently than every 4 hours. Do not use with other decongestant or expectorant products.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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.

**Children under 12 years:**

Do not use.

**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, difficulty in passing urine, unable to sleep, convulsions or shaking.

**4. Possible side effects**

Like all medicines, this 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:

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

• Brain swelling with usually temporary effects such as headache, changes in vision, reduced consciousness, and seizures (known as posterior reversible encephalopathy syndrome or PRES)

• 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.

• Sudden chest pain or discomfort accompanied by shortness of breath

• You have difficulty urinating. This is more likely to occur if you have an enlarged prostate gland

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**

**Common** (may affect up to 1 in 10 people)

• Feeling sick (nausea) or being sick (vomiting).

• Dizziness

• Feeling nervous

• Not being able to sleep

**Rare** (may affect up to 1 in 1,000 people)

• Hallucinations (particularly in children)

• Skin rashes or hives

• Increased blood pressure

• Abdominal discomfort

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

• Headache, feeling restless or overactive

• Feeling anxious or irritable

• 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)

• Tremor

**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](http://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. Contents of the pack and other 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.

**What Robitussin Plus looks like and contents of the pack:**

**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.

**Marketing Authorisation Holder**

Haleon Ireland Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland.

**Manufacturer**

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

This leaflet was least revised in January 2024.

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