

Pack Copy Specification	PGP Tablets - Leaflet
Marketing Authorisation number	PA 1120/1/1

Benylin Phlegm Cough & Cold Multi-Relief Tablets
Paracetamol 250 mg, Guaifenesin 100 mg, Phenylephrine Hydrochloride 5 mg

PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you take this medicine because it contains important information you need to know.

This medicine is available without prescription, however, you still need to use this product carefully to get the best results from it. Keep this leaflet as you may need to read it again. Ask your pharmacist if you need more information or advice.

1. What is this medicine and what is it used for?

This medicine contains:

- **paracetamol** which is a pain reliever (analgesic) and helps reduce your temperature when you have a fever
- **guaifenesin** which is an expectorant to help loosen phlegm
- **phenylephrine** which is a decongestant to reduce swelling in the passages of the nose to help you breathe more easily.

These tablets are used for the relief of symptoms of colds and flu, including aches and pains, headache, blocked nose, sore throat, chills and chesty coughs.

2. Is this medicine suitable for you?

Do not take this medicine if you:

- are **allergic** to paracetamol, guaifenesin, phenylephrine or any of the other ingredients
- have a serious heart condition or cardiovascular disorder(s)
- have high blood pressure (hypertension)
- have diabetes
- have an overactive thyroid
- have glaucoma
- have difficulty passing urine, an enlarged prostate or other prostate problems
- have phaeochromocytoma (a rare tumour of adrenal gland tissue)
- suffer from liver or kidney problems
- have porphyria, which is a type of blood disorder that causes skin or nervous system problems
- are pregnant or breastfeeding
- are taking tricyclic antidepressants such as imipramine or amitriptyline
- are taking antidepressant drugs called monoamine oxidase inhibitors (MAOI's), or have taken them within the last 14 days - these are medicines such as phenelzine, isocarboxazid and tranylcypromine

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- are currently taking other decongestant drugs (e.g. ephedrine and xylometazoline) or stimulants (e.g. dexamfetamine).

Please see your doctor or pharmacist before taking this medicine if you:

- suffer from alcoholic liver disease or alcohol dependence
- have circulatory disorders such as a condition called Raynaud's Phenomenon, which results from poor circulation in the fingers and toes
- have angina
- suffer from chronic cough or asthma.

If you are taking any of the following medicines please see your doctor:

- medicines to treat high cholesterol levels which reduce the amount of fat in the blood such as colestyramine
- medicines to control feeling sick or being sick such as metoclopramide or domperidone
- medicines called anti-coagulants, which are used to thin the blood such as warfarin or other coumarins - you may take occasional doses of paracetamol but should consult your doctor if you need to take it on a regular basis
- barbiturates (for epilepsy or to help you sleep), such as phenobarbitones
- medicines to treat migraine (e.g. ergotamine and methysergide)
- medicines to treat heart or circulatory problems, or to lower blood pressure, (e.g. digoxin, guanethidine, reserpine, methyl dopa)
- beta blockers (e.g. atenolol) or vasodilators (e.g. hydralazine)
- phenothiazines used as sedatives (e.g. chlorpromazine, pericyazine and fluphenazine)
- if you are going to have a general anaesthetic as this may cause changes in heart rhythm.

Contains paracetamol.

Do not take with any other paracetamol-containing products.

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.

Other important information:

Do not drink alcohol (beer, wine, spirits etc) while taking this product.

If you **are taking medication**, or **are under medical care**, consult your doctor before using this medicine. Do not take with other flu, cold or decongestant products or cough suppressants.

Long term use of this product is not recommended.

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Driving and using machines

If this medicine makes you feel dizzy, tired or sleepy do not drive or operate machinery.

3. How to take this medicine

For oral use. Swallow the tablets whole with water. Do not chew.

For all indications:

Adults, the elderly and children aged 12 years and over: Two tablets every 4-6 hours when necessary to a maximum of 4 doses in 24 hours.

Children under 12 years:

Not to be used unless recommended by a doctor.

Dosage should not be continued for longer than 3 days without consulting a doctor.

Do not exceed the stated dose. If your symptoms persist or worsen, you must see a doctor or pharmacist.

Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage. Go to your nearest hospital casualty department. Take your medicine and this leaflet with you.

4. Possible side effects

Most people do not have any side effects while taking this medicine. However, if you experience any of the following side effects, or anything else unusual happens, stop taking the medicine immediately, and see your doctor or pharmacist:

- allergic reactions which may be severe such as skin rash, peeling of the skin, itching, swollen red areas of the skin, sometimes with shortness of breath or swelling of the mouth, lips, tongue, throat or face.
Very rare cases of serious skin reactions have been reported.
- breathing problems, these are more likely if you have experienced them before when taking other painkillers such as aspirin or ibuprofen.
- stomach pain, stomach upsets, nausea, vomiting, diarrhoea
- tingling or coolness of the skin
- a faster or slower heart beat
- difficulty sleeping (insomnia)
- nervousness or tremors
- a rise in blood pressure with headache, and irregular heartbeat (palpitations)
- restlessness
- dizziness, headache

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- anxiety, irritability, excitability
- problems or pain passing water
- hallucinations
- eye disorders
- pins and needles and cold feelings in your extremities.

You may become more prone to bleeding, bruising, fever and infections such as sore throat and ulcers, due to changes in your blood.

If you have previously experienced an allergic reaction (hypersensitivity) when taking decongestants, appetite suppressants and stimulants, you may be at increased risk of developing an allergic reaction when taking this product.

Reporting of side effects

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store your medicine

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister foil. The expiry date refers to the last day of the month.

Do not store above 25°C.

6. What is in this medicine?

Each white, capsule-shaped tablet contains the active ingredients: paracetamol 250 mg, guaifenesin 100 mg and phenylephrine hydrochloride 5 mg.

The other ingredients are: microcrystalline cellulose, stearic acid, povidone, hypromellose and polyethylene glycol.

This product is available in pack sizes of 8, 10, 12, 16, 20 or 24 tablets, although not all pack sizes may be marketed.

7. Who makes this medicine?

The Marketing Authorisation holder and manufacturer is Wrafton Laboratories Limited (trading as Perrigo), Braunton, Devon, EX33 2DL, UK.

Marketed by McNeil Healthcare (Ireland) Ltd. Airton Road, Tallaght, Dublin 24, Ireland. PA 1120/1/1

Benylin is a registered trademark.

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This medicinal product is authorised in the Member States of the EEA under the following names:

United Kingdom: Perrigo Paracetamol, Guaifenesin, Phenylephrine Hydrochloride 250mg/100 mg/5 mg Tablets;

Ireland: Benylin Phlegm Cough & Cold Multi-Relief Tablets.

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