

Package leaflet: Information for the user



Ultra Cold & Flu Relief All in One Capsules

(Paracetamol, Guaifenesin, Phenylephrine Hydrochloride)

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 have 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 don't feel better or feel worse after 3 days.

What is in this leaflet

1. What this medicine is and what it is used for
2. What you need to know before you take this medicine
3. How to take this medicine
4. Possible side effects
5. How to store this medicine
6. Contents of the pack and other information

1. What this medicine is and what it is 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 capsules are used for the relief of the symptoms of colds and flu and the pain and congestion of sinusitis, including aches and pains, headache, blocked nose and sore throat, chills and feverishness (high temperature). They can also loosen stubborn mucus (phlegm) and provide relief from chesty coughs.

2. What you need to know before you take this medicine

Do not take this medicine if you:

- are **allergic** to paracetamol, guaifenesin, phenylephrine or any of the other ingredients (listed in section 6)
- have a serious heart condition or cardiovascular disorder(s)
- have high blood pressure (hypertension)
- have an overactive thyroid

- have glaucoma, including closed angle glaucoma
- have difficulty passing urine
- 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 and isocarboxazid
- are taking beta-blocking drugs
- are currently taking other decongestant drugs or stimulants (e.g. ephedrine, amfetamines and xylometazoline).
- are taking a cough medicine called a cough suppressant.

Warnings and precautions

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

- are pregnant or breast-feeding
- suffer from kidney or liver problems, including alcoholic liver disease
- have diabetes
- have phaeochromocytoma
- have a very bad cough or asthma. See your doctor if your cough lasts for more than 3 days or comes back, or if you have a fever, rash or a headache which won't go away
- have circulatory disorders such as a condition called Raynaud's Phenomenon, which results from poor circulation in the fingers and toes
- have angina
- have an enlarged prostate gland, as this may cause more difficulty in passing urine
- have severe stomach or intestinal problems
- suffer with phenylketonuria, a rare, inherited metabolic disorder.

Other medicines and this medicine

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines especially:

- 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 phenobarbitone
- tricyclic antidepressants such as imipramine, amitriptyline
- medicines to treat heart or circulatory problems, or to lower blood pressure, (e.g. digoxin, guanethidine, reserpine, methyldopa)
- aspirin or other NSAIDs (non-steroidal anti-inflammatory drugs)
- medicines to treat migraine (e.g. ergotamine and methysergide)

- zidovudine as this might cause blood problems (low white blood cell count)
- 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 blood or urine tests as taking this medicine may affect the results
- if you are going to have a general anaesthetic, as this may cause change in heart rhythm.
- Flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment and which may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism and if the maximum daily doses of paracetamol are used.

Contains paracetamol.

Do not take anything else containing paracetamol while taking this medicine.

This medicine with food and alcohol

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

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 using this medicine.

Other important information:

- If you **are taking medication**, or **are under medical care**, consult your doctor before using this medicine
- **Long term use** of this product is not recommended.
- This medicine should only be used if you have all of the following symptoms – pain and/or fever, a blocked nose and a chesty cough
- Use medicines which will only treat the symptoms you have
- **Do not take** with other flu, cold or decongestant products
- This product could cause dizziness. If affected do not drive or operate machinery.

Information about some of the ingredients in this medicine

This medicine contains less than 1mmol sodium (23mg) per 2 capsules, that is to say essentially 'sodium-free'.

3. How to take this medicine

Swallow the capsules whole with water.

Do not chew.

Adults, the elderly and children 16 years and over: 2 capsules every 4 to 6 hours as required.

Leave at least 4 to 6 hours between doses.

Do not take more than 8 capsules (4 doses) in any 24 hour period.

Do not give to children under 16 years.

Do not take more medicine than the label tells you to. If you do not get better, talk to your doctor.

Do not take for more than 3 days, unless advised by your doctor.

If you take more of this medicine than you should

Talk to a doctor at once if you take too much of this medicine even if you feel well. This is because too much paracetamol can cause 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.

Rare side effects are:

- allergic reactions which may be severe such as a 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
- stomach upsets
- tingling and coolness of the skin
- a faster or slower heart beat
- difficulty sleeping (insomnia)
- nervousness, tremors, convulsions
- a rise in body temperature
- a rise in blood pressure with headache, vomiting (being sick) and irregular heart beat (palpitations).

More rarely, the following side effects can happen:

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

Very rare cases of serious skin reactions have been reported.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for the MHRA Yellow Card in 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 your medicine

Keep this medicine out 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 that month.

Do not store above 25°C.

6. Contents of the pack and other information

What this medicine contains

The active ingredients are paracetamol, guaifenesin and phenylephrine hydrochloride. Each hard capsule contains paracetamol 500 mg, guaifenesin 100 mg and phenylephrine hydrochloride 6.1 mg.

The other ingredients are: maize starch, croscarmellose sodium, sodium laurilsulfate, magnesium stearate and talc. The capsule shell is made of gelatin and contains the

colours quinoline yellow (E104), indigo carmine (E132), erythrosine (E127) and titanium dioxide (E171).

What this medicine looks like and contents of the pack

This medicine contains blue and green capsules, available in packs of 8 or 16 capsules. Not all pack sizes may be marketed.

Manufactured for The Boots Company PLC, Nottingham, NG2 3AA by the Marketing Authorisation holder Wrafton Laboratories Limited, Braunton, Devon, EX33 2DL, UK.

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If you would like any further information about this medicine, please contact the Boots Company PLC Nottingham NG2 3AA

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