

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 do not feel better or if you 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
- have high blood pressure (hypertension)
- have diabetes
- have an enlarged prostate
- 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
- are taking tricyclic antidepressants such as imipramine, amitriptyline
- suffer from kidney or liver problems, including alcoholic liver disease
- have pheochromocytoma.

Warnings and precautions

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

- are pregnant or breast-feeding
- have a very bad cough or asthma. See your doctor if your cough lasts for more than 5 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

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
- medicines to treat heart or circulatory problems, or to lower blood pressure, (e.g. digoxin, guanethidine, reserpine, methyl dopa)
- medicines to treat migraine (e.g. ergotamine and methysergide)
- 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 changes 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 taking 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

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking this medicine and tell your doctor or pharmacist immediately if you experience:

- Allergic reactions with swelling of the mouth, lips, tongue, throat or face which may make it difficult to breathe (anaphylaxis, angioedema)
- Severe skin reactions can include ulcers, blistering or peeling of the skin (Steven-Johnsons syndrome or toxic epidermal necrolysis)
- Breathing problems and wheezing. These are more likely if you have experienced them before when taking other painkillers such as ibuprofen or aspirin
- Unexplained bruising or bleeding (caused by low platelets in the blood)
- Recurring fevers or infections (caused by low white blood cells which increases the likelihood of infections)
- Severe stomach discomfort (caused by inflammation of the pancreas)
- Liver problems, which may appear as jaundice (yellowing of the eyes and skin), nausea and abdominal pain (hepatic dysfunction)
- Unusually fast pulse rate or a sensation of an unusually fast or irregular heartbeat (tachycardia, palpitations).

The following side effects may also occur. Tell your doctor or pharmacist if you get them.

- Difficulty passing water (the frequency is unknown but is more likely to occur in men with an enlarged prostate)
- Less serious allergic reaction including rashes, dermatitis or urticaria (hives)
- Headache, dizziness, insomnia (problems sleeping)
- Nausea (feeling sick), vomiting, stomach discomfort, diarrhoea
- Nervousness, irritability, restlessness, excitability
- Increased blood pressure.
- Visual disturbances. This is rare but is more likely in those with glaucoma.

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 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 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.

PL 12063/0105

Text revised: January 2023.

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

Artwork Reference: D1U73QAJ6