

Package Leaflet: Information for the user
Paramed Max Strength Cold & Flu Day & Night Capsules
Paracetamol, Phenylephrine, Caffeine

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
- **phenylephrine** which is a decongestant to reduce swelling in the passages of the nose to help you breathe more easily.

The Day capsules also contain:

- **caffeine**

These capsules are used for the relief of the symptoms of colds and flu, including aches and pains, sore throat, headache, nasal congestion (blocked nose) and feverishness (high temperature). The Day capsules can also relieve tiredness and drowsiness.

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

Do not take this medicine if you:

- are **allergic** to paracetamol, caffeine, phenylephrine or any of the other ingredients
- have a serious heart condition or cardiovascular disorder(s)
- have high blood pressure (hypertension)

- medicines to lower blood pressure, treat heart or circulatory problems such as beta blockers (e.g. atenolol)
 - have severe hepatic impairment
 - have severe renal impairment
 - have an overactive thyroid
 - have an enlarged prostate
 - have diabetes
 - have pheochromocytoma
 - have glaucoma, including closed angle glaucoma
 - 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 tricyclic antidepressants such as imipramine, amitriptyline
- are taking medicines belonging to a group called sympathomimetic amines such as dopamine, epinephrine

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 circulatory disorders such as a condition called Raynaud's Phenomenon, which results from poor circulation in the fingers and toes.
- if you are dehydrated
- difficulty passing urine
- have a blood condition called Haemolytic anaemia
- have genetic conditions such as Gilbert's syndrome or Glucose-6-phosphate dehydrogenase deficiency
- have Glutathione deficiency
- **During treatment with this medicine tell your doctor straight away if:**
- you have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting)

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 used to treat gout such as probenecid
- medicines to treat irregular heartbeats (arrhythmias) e.g. digoxin

- ergot alkaloids (drugs to treat severe headaches) other decongestant drugs such as ephedrine or xylometazoline
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (metabolic acidosis) that must have urgent treatment (See section 2)

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.

Information about some of the ingredients in this medicine

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

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, you should not take this medicine.

3. How to take this medicine

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

Swallow the capsules whole with water. Do not chew.

Adults, the elderly and children aged 16 years and over:

2 day capsules every 4 to 6 hours during the daytime, as required, followed by 2 night capsules at bedtime. 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 longer than 3 days, unless advised by your doctor.

The Day time capsules contain caffeine which may disrupt sleep if taken at night.

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 the medicine immediately and see your doctor or pharmacist.

Rare side effects are:

- allergic reactions such as skin rash
- fast, slow or irregular heartbeat (palpitations)
- eye disorders such as dilated pupils, acute angle closure glaucoma, most likely to occur in those with closed angle glaucoma.

Very rare side effects are:

- blood and lymphatic system disorders such as leukopenia, neutropenia and pancytopenia
- a severe allergic reaction known as anaphylaxis
- problems with your liver
- skin issues such as rashes, severe itching, sweating, hives
- purpura (small blood vessels leak blood under the skin)
- bronchospasm (muscles in your chest tighten)
- angioedema (swelling of the skin caused by build-up of fluid.)
- toxic epidermal necrolysis
- stevens-Johnson syndrome (rare condition arising from over reaction of the immune system)
- kidney and urinary disorders

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

- tingling and coolness of the skin
- difficulty sleeping (insomnia) (*Day capsule only*)
- nausea (feeling sick) (*Day capsule only*)
- problems or pain passing urine. This is most likely to occur in men with enlarged prostate gland.
- feeling nervous (*Day capsule only*)
- feeling dizzy (*Day capsule only*)
- a rise in blood pressure
- headache
- stomach disorders (nausea, vomiting, diarrhoea)
- A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist. 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 this medicine

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date printed on the pack.

Do not store above 25°C.

6. Contents of the pack and other information

What this medicine contains**Day Capsules:**

The active ingredients are paracetamol, phenylephrine hydrochloride and Caffeine.

Each Day capsule contains paracetamol 500 mg, caffeine 25 mg and phenylephrine hydrochloride 6.1 mg.

The other ingredients in the Day capsules 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), titanium dioxide (E171), patent blue V (E131) and erythrosine (E127).

Night Capsules:

The active ingredients are paracetamol and phenylephrine hydrochloride.

Each Night capsule contains paracetamol 500 mg and phenylephrine hydrochloride 6.1 mg.

The other ingredients in the Night capsules are: maize starch, croscarmellose sodium, sodium laurilsulfate, magnesium stearate and talc. The capsule shell is made of gelatin and contains the colours titanium dioxide (E171), erythrosine (E127) and indigo carmine (E132).

What this medicine looks like and contents of the pack

The pack contains 12 red and yellow coloured day capsules as well as 4 dark blue and light blue coloured night capsules.

Marketing Authorisation Holder & Manufacturer:

Wrafton Laboratories Limited, Braunton, Devon EX33 2DL, UK.

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