Paracetamol Plus Caplets

Paracetamol, Caffeine

PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you If you are taking any of the following 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
- caffeine which helps to increase the pain relief from paracetamol and makes you

These tablets are for the relief of mild to moderate pain including headache, migraine, toothache, nerve pain, sore throat and period pains. They are also for symptomatic relief of sprains, strains, rheumatic pain, sciatica, lumbago, fibrositis, muscular aches and pains, joint swelling and stiffness, flu, feverishness and feverish colds.

2. Is this medicine suitable for you?

Do not take this medicine if you:

- are allergic to paracetamol, caffeine or any of the other ingredients
- have high blood pressure or are taking any medication for high blood pressure, such as beta blockers
- your heart beat is too fast, too slow or irregular
- are recovering from alcoholism and are taking the medicine disulfiram
- are taking any medication to treat anxiety. this includes antidepressants (e.g. lithium carbonate or monoamine oxidase inhibitors), anxiolytics or sedatives (e.g. diazepam)
- are currently taking the medicine ephedrine (a decongestant) or theophylline, which is used to treat asthma
- are pregnant or breastfeeding.

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

 suffer from kidney or liver problems, including alcoholic liver disease.

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
- · medicines used during hospital tests for heart conditions such as adenosine and dipyridamole
- medicines used to treat the skin condition psoriasis, such as methoxsalen
- medicines to treat epilepsy, such as
- medicines used to treat thyroid conditions, such as levothyroxine
- medicines used to treat infections, such as I pipemidic acid.

Contains paracetamol.

Do not take anything else containing paracetamol while taking this medicine

Taking this medicine with food and drink:

Each tablet contains 65 mg of caffeine and up to 8 tablets (or 520 mg of caffeine) may be taken per day. If you are also consuming other medicines or food that contains caffeine (coffee, tea, cola drinks, chocolate) you may have a high caffeine intake and might have difficulty sleeping, start shaking and/or have an uncomfortable feeling in the chest. You should avoid too much caffeine in drinks like coffee and tea.

Although the amount of caffeine in a drink of coffee and tea depends on how they are made, you can use the table below as a quide to the amount of caffeine contained within certain foods and drinks:

Food	Amount*	Caffeine content
Filter coffee	100 ml	50 - 100 mg
Instant coffee	100 ml	20 - 73 mg
Tea	100 ml	20 - 73 mg
Cola drink	100 ml	Up to 20 mg
Chocolate	100 g	5 - 20 mg
Your medicine	1 tablet	65 mg

*100 ml is a small cup / glass.

Maximum recommended caffeine intake per day: 520 mg.

3. How to take this medicine

Swallow the tablets whole with water. Do not chew.

Adults, the elderly and children over 12 **years:** 2 tablets every 4 hours as required. Do not take more than 4 doses (8 tablets) in any 24 hour period.

Do not take more often than every 4 hours.

Do not give to children under 12 years.

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

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.

If your symptoms continue or your headache becomes persistent, see your doctor.

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.

Stop taking the medicine and tell your doctor if you experience:

- allergic reactions which may be severe such as skin rash, or itching, sometimes with shortness of breath or swelling of the mouth, lips, tongue, throat or face.
- breathing problems. These are more likely if you have experienced them before when taking other painkillers such as aspirin or ibuprofen (non-steroidal anti-inflammatories)
- severe rash or peeling of the skin which may be accompanied by mouth ulcers.

Paracetamol side effects: Rare side effects are:

- other allergic reactions (e.g. skin rash). yellowing of the skin or eyes, pale stools or
- upper abdominal pain (these may be signs of liver problems)

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

Caffeine side effects:

If you do not take more than the recommended 520 mg of caffeine per day side effects are unlikely, but you must remember to take into account caffeine from coffee, tea, other medicines, etc. Some

people are more sensitive to caffeine and can get side effects at lower doses, especially if they have never had caffeine before or have not had caffeine for some time.

Side effects may include tremor, insomnia, nervousness, irritability, anxiety, headache, tinnitus (ringing in the ears), and stomach complaints (e.g. nausea, vomiting and diarrhoea), dizziness and restlessness. You may also notice palpitations, changes in heartbeat, an increased need to pass water, and rapid breathing.

If you experience any caffeine-related side effects, stop taking all medicines containing caffeine, including this medicine and stop consuming food that contains caffeine (coffee, tea, cola drinks, and chocolate).

If you stop taking caffeine after regular use:

There are some people who may experience unwanted side effects when they stop taking tablets or foods containing caffeine after regular use. The most common effect is headache but also tiredness and feeling less alert can occur. These effects are temporary and may last up to a week but to minimise these effects it is best to gradually reduce caffeine intake.

Reporting of side effects

Also you can help to make sure that medicines remain as safe as possible by reporting any unwanted side effects via the internet at www.mhra.gov.uk/yellowcard. Alternatively you can call Freephone 0808 100 3352 (available from 10 a.m. to 2 p.m. Mondays to Fridays) or fill in a paper form available from your local pharmacy. You can also report any unwanted side effects to the marketing authorisation holder by email to pharmacist@perrigouk.com.

5. How to store your medicine Keep all medicines out of the sight and reach of children.

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

6. What is in this medicine?

Each tablet contains the active ingredients: paracetamol 500 mg and caffeine 65 mg.

The other ingredients are: povidone, maize starch, methylcellulose, talc, calcium stearate and purified water.

This product is available in a pack size of 16

7. Who makes this medicine?

The Marketing Authorisation holder and manufacturer is Wrafton Laboratories Limited, Braunton, Devon, EX33 2DL, UK.

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