

PATIENT INFORMATION LEAFLET
PARACETAMOL & CAFFEINE 500 mg/65 mg EFFERVESCENT TABLETS
(paracetamol and caffeine)

The name of this medicine is Paracetamol & Caffeine 500 mg/65 mg Effervescent Tablets, which will be referred to as Paracetamol & Caffeine Tablets throughout this leaflet.

Read all of this leaflet carefully because it contains important information for you.

- This medicine is available without prescription. However, you still need to use Paracetamol & Caffeine Tablets carefully to get the best results from them.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Paracetamol & Caffeine Tablets are and what they are used for
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3. How to take Paracetamol & Caffeine Tablets
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6. Further Information

1. WHAT PARACETAMOL & CAFFEINE TABLETS ARE AND WHAT THEY ARE USED FOR

The active ingredients in your tablets are paracetamol and caffeine. Paracetamol is an analgesic and an antipyretic; it works by relieving pain and reducing body temperature when you have a fever. Caffeine acts to further help the effectiveness of paracetamol.

Paracetamol & Caffeine Tablets are used to treat headache, migraine, backache, rheumatic and muscle pain, toothache and period pain. They also relieve discomfort in colds, influenza, sore throats and help reduce temperature.

2. BEFORE YOU TAKE PARACETAMOL & CAFFEINE TABLETS

Do not take Paracetamol & Caffeine Tablets if you:

- are **allergic (hypersensitive)** to paracetamol, caffeine, or to any of the other ingredients (these are listed in section 6, Further Information)
- are taking any other paracetamol-containing products
- are under 12 years of age.

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Take special care with Paracetamol & Caffeine Tablets

Before you take Paracetamol & Caffeine Tablets you should tell your doctor or pharmacist if you:

- have severe kidney disease
- have severe liver disease, including alcoholic liver disease
- have persistent headaches.

Taking other medicines

Talk to your doctor or pharmacist before taking this medicine if you are taking any prescribed medicine, in particular:

- metoclopramide or domperidone - for nausea (feeling sick) or vomiting (being sick)
- cholestyramine - used to treat high cholesterol.

If you take blood thinning medicines (anticoagulants e.g. warfarin) and you need to take a pain reliever on a daily basis, talk to your doctor because of the risk of bleeding.

You may still be able to take Paracetamol & Caffeine Tablets but your doctor or pharmacist will be able to advise you.

Taking your medicine with food and drink

Paracetamol & Caffeine Tablets should be dissolved in a glass of water and can be taken with or without a meal.

You should avoid drinking too much coffee, tea or fizzy drinks when taking these tablets.

Fertility, pregnancy and breast-feeding

Paracetamol-Caffeine is not recommended for use during pregnancy or breastfeeding. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

It is unlikely that Paracetamol & Caffeine Tablets will affect your ability to drive or operate machines.

Important information about some of the ingredients of Paracetamol & Caffeine Tablets

Each of these tablets contains 409 mg of **sodium**. This may interfere if you are on a low sodium diet.

This product also contains **aspartame** (a source of phenylalanine), which should not be given to anyone with **phenylketonuria**.

3. HOW TO TAKE PARACETAMOL & CAFFEINE TABLETS

For oral use. Dissolve tablets in at least half a glass of water before taking.


Adults, the elderly and children aged 16 to 18 years: One to two tablets every 4 to 6 hours when necessary up to a maximum of 8 tablets in 24 hours. (A reduced dose may be required in the elderly).

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Children 12 to 15 years: One tablet every 6 hours when necessary up to a maximum of 4 tablets in 24 hours.

Do not take more than the recommended dose.

Not recommended for children under 12 years of age.

Method of Administration

For oral administration only. These tablets should be dissolved in a glass of water before taking them. These tablets are meant to be dissolved first so don't try to swallow them whole.

If you take more Paracetamol & Caffeine Tablets 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.

Remember to take the pack and any remaining tablets with you. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Paracetamol & Caffeine Tablets can cause side effects although not everybody gets them. If you get any of the following symptoms after taking these tablets you **should stop taking them and contact your doctor or pharmacist immediately:**

- **any sudden wheeziness, difficulty in breathing or dizziness, swelling of the eyelids, face, lips or throat**
- **skin rash**
- **Allergic skin reactions (which can sometimes be severe and include peeling, blistering and lesions of the skin)**
- **Signs of caffeine sensitivity including**
- **Difficulty sleeping, dizziness, nervousness, restlessness, irritability, anxiety, palpitations.**
- **Headache stomach upset**
- **Yellowing of the skin or eyes, pale stools or upper abdominal pain (these may be signs of liver problems)**

Very rarely effects on the blood have been reported, resulting in:

- an increased tendency to bruise or bleed easily
- an increased susceptibility to infection.

Breathing problems are more likely if you have asthma and have experienced them before when you have taken other medicines such as aspirin or ibuprofen (non-steroidal) anti-inflammatory medicines.

Reporting of side effects

If you get any side effects, talk to your doctor or 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. By reporting side effects you can help provide more information on the safety of this medicine.

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5. HOW TO STORE PARACETAMOL & CAFFEINE TABLETS

Keep out of the sight and reach of children.

Do not take this medicine after the expiry date (EXP) stated. The expiry date refers to the last day of that month.

Store in the original package and protect from moisture.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Paracetamol & Caffeine Tablets contain:

The active ingredients are paracetamol and caffeine. Each tablet contains 500 mg of paracetamol and 65 mg of caffeine.

Other ingredients are: citric acid (anhydrous) (E330), povidone, saccharin sodium, sodium hydrogen carbonate (E500), sodium carbonate anhydrous, simeticone (E900), Polysorbate 80 (E433) and aspartame (E951).

What Paracetamol & Caffeine Tablets look like and contents of the pack:

Paracetamol & Caffeine Tablets are white to off-white coloured circular flat bevelled tablets plain on both sides. Your medicine is available in packs of 24 tablets.

Marketing Authorisation Holder:

Fannin (UK) Limited, 42-46 Booth Drive, Park Farm South, Wellingborough, Northamptonshire, NN8 6GT, UK.

Manufacturer responsible for batch release:

Kent Pharmaceuticals Limited, Crowbridge Road, Ashford, Kent, TN24 0GR, U.K.

Kent Pharmaceuticals Limited, Repton Road, Measham, DE12 7DT, U.K.

This information is available in alternative formats upon request.

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