

FLAT DIMENSION = 130 x 560mm
FOLDED DIMENSION = 130 x 35mm

30mm

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Paracetamol/Caffeine 500 mg/65 mg Tablets (Paracetamol & 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 pharmacist has 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 all the possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if your symptoms worsen or do not improve within 3 days for fever and 5 days for pain.

What is in this leaflet

1. What Paracetamol/Caffeine 500 mg/65 mg Tablets are and what they are used for
2. What do you need to know before you take Paracetamol/Caffeine 500 mg/65 mg Tablets
3. How to take Paracetamol/Caffeine 500 mg/65 mg Tablets
4. Possible side effects
5. How to store Paracetamol/Caffeine 500 mg/65 mg Tablets
6. Contents of the pack and other information

1. What Paracetamol/Caffeine 500 mg/65 mg Tablets are and what are they used for

The name of your medicine is Paracetamol/Caffeine 500 mg/65 mg Tablets. It is a combination of two medicines called caffeine and paracetamol. The tablets contain two active ingredients. Paracetamol is a pain reliever

(analgesic) and helps to reduce your temperature when you have a fever. Caffeine helps to increase the pain relief from paracetamol and makes you more alert.

This medicine is for symptomatic treatment of mild to moderate pain and fever in conditions such as headache, toothache and period pains.

2. What you need to know before you take Paracetamol/Caffeine 500 mg/65 mg tablets

Important things you should know about Paracetamol/Caffeine 500 mg/65 mg Tablets

- Do not take this medicine with other paracetamol containing medicines.
- Excessive intake of caffeine (e.g. coffee, tea and some canned drinks) should be avoided while taking this product.
- Consult your doctor if your headaches or other symptoms persist.

Do not take Paracetamol/Caffeine 500 mg/65 mg Tablets

- if you are under 16 years of age.
- if you are allergic (hypersensitive) to paracetamol, caffeine or any of the other ingredients in your medicine (listed in Section 6). Signs of an allergic reaction includes rash and breathing problems. There can also be swelling of the legs, arms, face, throat or tongue
- if you are taking other paracetamol containing medicine.

Warnings and Precautions

Talk to your doctor or pharmacist before taking Paracetamol /Caffeine 500 mg/65 mg Tablets.

During treatment with this medicine, tell your doctor straight away if:

- you have liver problems
- you are underweight
- 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).

Use in children

Do not give this medicine to children under 16 years of age.

Other medicines and Paracetamol/Caffeine 500 mg/65 mg Tablets

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

While taking Paracetamol/Caffeine 500 mg/65 mg Tablets you should not take any other medicines which contain paracetamol.

This includes some painkillers, cough and cold remedies. It also includes a wide range of other medicines available from your doctor and more widely in shops.

Do not take Paracetamol/Caffeine 500 mg/65 mg Tablets, and tell your doctor, if you are taking

- metoclopramide or domperidone (for nausea [feeling sick] or vomiting [being sick])
- colestyramine (to lower blood cholesterol).
- If you take blood thinning drugs (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.
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2)
But you can still take occasional doses of this medicine at the same time as anticoagulants.
- This product is not recommended if you are taking lithium.

Paracetamol/Caffeine 500 mg/65 mg Tablets with food, drinks and alcohol

This medicine contains caffeine, which is also found in tea, coffee, chocolate and some fizzy drinks

such as cola. Taking too much caffeine can cause difficulty sleeping, shaking or a thumping sensation in the chest (palpitations).

You should limit drinking tea, coffee, chocolate or fizzy drinks containing caffeine if you are taking this medicine.

Do not drink alcohol whilst taking this medication.

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. The caffeine in Paracetamol / Caffeine 500mg/65mg Tablets may affect your child.

If necessary, paracetamol can be used during pregnancy. You should use the lowest possible dose that reduces your pain and/or your fever and use it for the shortest time possible. Contact your doctor or midwife if the pain and/or fever are not reduced or if you need to take the medicine more often.

Due to the caffeine content of this product it should not be used if you are pregnant or breast feeding.

Driving and using machines

Do not drive or operate machinery if you feel dizzy or drowsy after taking Paracetamol/Caffeine 500 mg/65 mg Tablets

Information on sodium content

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

3. How to take Paracetamol/Caffeine 500 mg/65 mg tablets

Always take this medicine exactly as described in this leaflet as your doctor or pharmacist have told you to. Check with your doctor or pharmacist if you are not sure.

130mm

- **Do not take with other paracetamol containing medicines**
- **Avoid too much caffeine in drinks like coffee and tea. High caffeine intake can cause difficulty in sleeping, shaking and an uncomfortable feeling in the chest.**

Do not give to children under 16 years of age. The usual recommended dose is:

For short term use only.

Age	Dose and how often to take
Adults (16 years and over)	Two tablets up to four time daily. The dose should not be repeated more frequently than every 4 hours. Do not take more than 8 tablets in 24 hours.
Do not give Paracetamol/Caffeine 500 mg/65 mg Tablets 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. If fever persists for more than 3 days or pain for more than 5 days or gets worse or other symptoms appear, stop taking this medicine and consult a doctor.	

Use in children

Paracetamol/Caffeine 500 mg/65 mg Tablets should not be given to children under 16 years of age.

If you take more Paracetamol/Caffeine 500 mg/65 mg 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.

If you forget to take Paracetamol/Caffeine 500 mg/65 mg Tablets

If you forget to take a dose at the right time, take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose. Do not take a double dose to make up for the forgotten dose. Remember to leave at least 4 hours between doses.

4. Possible side effects

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

Taking a painkiller for headaches too often or for too long can make them worse.

Very rare cases of serious skin reactions have been reported.

Stop taking Paracetamol/Caffeine 500 mg/65 mg Tablets and see a doctor or go to a hospital straight away if you experience:

- Allergic reactions which may be severe such as skin rash and itching sometimes with swelling of the mouth or face or shortness of breath.
- Allergic skin reactions (which can sometimes be severe and include peeling, blistering and lesions of skin)
- Accumulation of fluid in the larynx including an itchy rash, throat swelling (severe allergic reaction).
- Breathing problems: These are more likely if you have asthma or have experienced them before when taking other painkillers such as ibuprofen and aspirin.
- Unexplained bruising and bleeding
- Nausea, sudden weight loss, loss of appetite and yellowing of the eyes and skin.
- Tremor, difficulty sleeping, dizziness, nervousness, restlessness, irritability, anxiety
- Headache, Fast or irregular heartbeat, rapid breathing
- Stomach upset.
- Not known: A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2)

If any side effects become severe, or you notice any side effect not listed here, please tell your pharmacist or doctor.

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 Website: 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 Paracetamol/Caffeine 500 mg/65 mg Tablets

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the packs. The expiry date refers to the last day of that month.
- This medicinal product does not require any special storage conditions.
- Do not throw away any medicines via wastewater or household waste. Ask the pharmacist how to throw away any medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Paracetamol/Caffeine 500 mg/65 mg Tablets contain

Each tablet contains 500 mg Paracetamol and 65 mg of Caffeine.

The other ingredients are: Povidone K30 (E1201), Povidone K90 (E1201), Potato starch, Pregelatinised maize starch, Purified Talc (E553b), Croscarmellose sodium, Stearic acid (E570) and Magnesium stearate.

What Paracetamol/Caffeine 500 mg/65 mg Tablets look like and contents of the pack

Paracetamol/Caffeine 500 mg/65 mg Tablets are white to off-white, capsule-shaped, biconvex tablets plain on both sides. These tablets are packaged in blister packs comprising of white opaque PVC/PVdC (20 micron/40 gsm) and with backing of foil, which are placed in an outer carton along with leaflet. These are available in the pack sizes of 4, 6, 12 and 16 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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Paracetamol/Caffeine 500 mg/65 mg Tablets; PL 17907/0305

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