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Package Leaflet: Information for the user

Paracetamol and Caffeine 500mg / 65mg Tablets

Paracetamol and Caffeine

Please read right through this leaflet before you start using this medicine.

This medicine is available without prescription, but you still need to use Paracetamol and Caffeine 500mg / 65mg 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.
- 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 you feel worse after 3 days.
- Contains Paracetamol.

What is in this leaflet:

- 1. What Paracetamol and Caffeine 500mg / 65mg Tablets are and what they are used for
- 2. What you need to know before you take Paracetamol and Caffeine 500mg / 65mg Tablets
- 3. How to take Paracetamol and Caffeine 500mg / 65mg Tablets
- 4. Possible side effects
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1. What Paracetamol and Caffeine 500mg / 65mg Tablets are and what they are used for

Paracetamol and Caffeine 500mg / 65mg Tablets are suitable for the relief of headache, migraine, backache, rheumatic pain, and toothache and period pain.

They also relieve the fever, aches and pains of colds and flu. The tablets contain two active ingredients. Paracetamol is a painkiller and reduces your temperature when you have a fever. Caffeine acts to further help the effectiveness of paracetamol.

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

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

- if you have ever had an allergic reaction to paracetamol, caffeine or to any of the other ingredients (listed in Section 6)
- if you are taking any other prescription or nonprescription medicines containing paracetamol to treat pain, fever, symptoms of cold and flu, or to aid sleep.

Ask your doctor before you take this medicine:

- if you have liver or kidney problems
- if you are underweight or malnourished
- if you regularly drink alcohol
- If you have severe infection or 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)
- loss of appetite

During treatment with Paracetamol and Caffeine 500mg / 65mg Tablets, **tell your doctor straight away** if you get a combination of these symptoms. You may need to avoid using this product altogether or limit the amount of paracetamol that you take.

If you are taking other medicines

Talk to your doctor or pharmacist before taking these tablets if you are taking any prescribed medicines; particularly metoclopramide or domperidone (for nausea [feeling sick] or vomiting [being sick]) or cholestyramine (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. But you can still take occasional doses of Paracetamol and Caffeine 500mg / 65mg Tablets at the same time as anticoagulants. This product is not recommended if you are taking lithium.

Please inform your doctor or pharmacist if you are taking flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

Pharmacode Reading Direction

65mg Tablets

Pregnancy and breast feeding

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

Adults and children aged 16 years and over:

Swallow 2 tablets every 4 hours as needed. Do not take more than 8 tablets in 24 hours.

Children aged 12-15 years:

Swallow 1 tablet every 4 hours as needed.

- Do not give more than 4 tablets in 24 hours.
- Do not take more frequently than every 4 hours. Do not take more than the recommended dose.
- Do not give to children under 12 years.
- Avoid too much caffeine in drinks like coffee and tea.

High caffeine intake can cause difficulty sleeping, shaking and an uncomfortable feeling in the chest. If your symptoms continue or your headache becomes persistent, see your doctor.

If you take too many tablets 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.

4. Possible side effects

Like all medicines, Paracetamol and Caffeine 500mg/ 65mg Tablets can have side effects but not everybody gets them. A small number of people have had side effects. Very rare cases of serious skin reactions have been reported.

Stop taking the medicine and tell your doctor immediately 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
- Skin rash or peeling, or mouth ulcers
- Breathing problems. These are more likely if you have experienced them before when taking other painkillers such as ibuprofen and aspirin
- Unexplained bruising or bleeding
- Nausea, sudden weight loss, loss of appetite and yellowing of the eyes and skin.

Reporting of side effects

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

5. How to store Paracetamol and Caffeine 500mg 65mg Tablets

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date (EXP)

which is stated on the carton and blister. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment

This medicinal product does not require any special storage conditions

6. Contents of the pack and other information

Active ingredients: Each tablet contains Paracetamol 500 mg and Caffeine 65 mg.

Other ingredients: Microcrystalline Cellulose (PH101), Sodium Starch Glycolate (Type A), Povidone (PVP-K 30), Pregelatinized Starch, Croscarmellose sodium, Maize Starch, colloidal Anhydrous silica, Stearic Acid

This medicine is available in child resistant Alu-PVC - PVC white opaque film blister packs of 16's tablets

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Paracetamol and Caffeine 500mg / 65mg Tablets PL 43461/0116

This leaflet was revised in 05/2025.

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