

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 include a 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.

- If you suffer from kidney or liver problems (including Gilbert's syndrome) as the dose you need to take may need to be reduced

- If you have hepatitis
- If you suffer from Glucose-6-phosphatohydrogenase enzyme deficiency,
- If you suffer from haemolytic anaemia (a form of anaemia caused by a breakdown of red blood cells)
- If you are an alcoholic or are recovering from alcoholism
- If you suffer from asthma and are sensitive to aspirin
- If you are dehydrated or suffer from chronic malnutrition
- If you have gout
- If you suffer from hyperthyroidism
- If you have arrhythmia.

Do not use Paracetamol/Caffeine 500 mg/65 mg Tablets without a doctor's prescription if you have alcohol problems or a liver damage and do not use Paracetamol/Caffeine 500 mg/65 mg Tablets and alcohol concomitantly. The effect of alcohol is not enhanced by the addition of Paracetamol/Caffeine 500 mg/65 mg Tablets.

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

- Clozapine (used to treat e.g. schizophrenia)
- Beta-blockers such as atenolol, metoprolol, oxeprenolol or propranolol (used to treat high blood pressure and heart conditions)
- Disulfiram (used in the treatment of alcoholism)
- Fluvoxamine, monoamine oxidase inhibitors and lithium (used to treat anxiety, depression and other psychological conditions)
- Diazepam (used to treat anxiety or as a sedative)
- St John's wort (used to treat mild forms of depression)
- Phenylpropanolamine and ephedrine (decongestants) or theophylline (for asthma)
- Other medicines containing paracetamol
- Colestyramine (used to treat high cholesterol levels and reduce the amount of fat in the blood)
- Metoclopramide and domperidone (used to control feeling sick or being sick)
- Anticoagulants taken by mouth (used to prevent the blood from clotting)
- Dipyridamole (often used during hospital tests for heart conditions)
- Methoxsalen (used to treat the skin condition psoriasis)
- Carbamazepine, phenobarbitol, phenytoin, stiripentol and lamotrigine (used to treat epilepsy)
- Levothyroxine (used to treat thyroid conditions)
- Pipermidic acid (used to treat infections)
- Probenecid (used to treat gout)
- Salicylamide (used to treat fever or mild pain)

- Isoniazid (used to treat tuberculosis)
- Zidovudine (used to treat HIV)
- Mexiletine (used to treat heart arrhythmias)
- Chloramphenicol, ciprofloxacin, norfloxacin, enoxacin, rifampicin (antibiotics)
- Flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment and which may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used.

The results of tests on uric acid and blood sugar may be affected by paracetamol.

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

Talk to your doctor before taking Paracetamol/Caffeine 500 mg/65 mg Tablets if you are pregnant or are breastfeeding. The caffeine in Paracetamol/Caffeine 500 mg/65 mg Tablets may affect your child.

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.

- Do not exceed the stated dose.
- If you have a high fever, or if symptoms get worse or persist for longer than 3 days, consult your doctor.
- **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.**
- Always use the lowest effective dose to relieve your symptoms
- **Prolonged use, except under medical supervision may be harmful.**

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 8 tablets in 24 hours.
Do not take more than 4 tablets a day in the following situations, unless directed by your doctor: - Weight less than 50kg - Chronic alcoholism - Dehydration - Chronic malnutrition	
Do not give Paracetamol / Caffeine 500mg/65mg 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

Immediate medical advice should be sought in the event of an overdose, because of the risk of irreversible 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.

Rare (may affect up to 1 in 1,000 people): Oedema (abnormal accumulation of fluid under the skin), abnormal vision, simple skin rash or urticaria (dark red rash on the skin), haemorrhage (bleeding), abdominal pain, diarrhoea, nausea, vomiting, dizziness, fever, reduction of irritability or agitation (sedation), platelet disorders (clotting disorders), stem cell disorders (disorders of the blood forming cell in the bone marrow), abnormal liver function, liver failure, hepatic necrosis (death of liver cells), jaundice, overdose and poisoning, tremor, headache, depression, confusion, hallucinations, sweating, pruritus (itching), feeling lousy (malaise).

Very rare (may affect up to 1 in 10,000 people):

Other allergic reactions (skin rash), hepatotoxicity (damage caused to the liver), thrombocytopenia (reduction in blood platelets, which increases the risk of bleeding or bruising), leucopenia (frequent infections due to poorly functioning white blood cells or decrease in white blood cells), neutropenia (reduced neutrophil count in blood), agranulocytosis (severe decrease in white blood cells which may lead to severe infections), haemolytic anaemia (abnormal breakdown of red blood cells, which may cause weakness or pale skin), hypoglycaemia (low levels of glucose in the blood), cloudy urine and kidney disorders.

Not known frequency:

Irregular heartbeat, anaemia (decrease in red blood cells), problems with the way your kidneys work (kidney alteration), problems with the way your liver works (liver alteration), haematuria (blood in urine), anuresis (inability to urinate), gastrointestinal effects, vertigo. There have been cases of difficulty breathing, wheezing, coughing, and shortness of breath with paracetamol, but these are more likely in asthmatics sensitive to aspirin or other NSAIDs such as ibuprofen.

If you have taken this medicine for a long time, you may get a headache, feel tired, or feel sleepy for up to a week after you stop taking the tablets.

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 to HPRa Pharmacovigilance website: www.hpra.ie

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, 16, 24, 30, 32, 48, 60 and 90 tablets. Not all pack sizes may be marketed.

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