



Package leaflet: Information for the patient

Paracetamol 500mg Tablets

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 doctor or 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 any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

What is in this leaflet

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1. WHAT PARACETAMOL 500MG TABLETS ARE AND WHAT THEY ARE USED FOR

These tablets contain paracetamol and are used to treat mild to moderate pain including headache, migraine, neuralgia, toothache, sore throat, period pain, flu, fever, aches and pains including muscle pains, backache and rheumatic aches and pains.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PARACETAMOL 500MG TABLETS

Do not take Paracetamol 500mg Tablets

- If you are allergic to Paracetamol or any of the other ingredients listed in section 6 (see section 4 – possible side effects).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Paracetamol 500mg Tablets if you:

- Suffer from liver or kidney problems
- Suffer from alcohol dependency
- Suffer from non-serious arthritis and need to take painkillers every day

Other medicines and Paracetamol 500mg Tablets

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

- Blood thinning medicines such as Warfarin
- Metoclopramide and Domperidone (for sickness and digestive disorders)
- Colestyramine (to help control cholesterol levels)
- Any other paracetamol containing products
- 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.

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.

If necessary, Paracetamol 500mg Tablets 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/midwife if the pain and/or fever are not reduced or if you need to take the medicine more often.

3. HOW TO TAKE PARACETAMOL 500MG TABLETS

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

The recommended dose is:

Dosage in adults, the elderly and children 16 years and over: Take one or two tablets every four to six hours as needed. Do not take more than 8 tablets in 24 hours.

Dosage in children 10 to 15 years: Take one tablet every four to six hours as needed. Do not take more than 4 tablets in 24 hours.

Do not give the tablets to children aged under 10 years unless told to by your doctor. Do not give for more than 3 days at a time unless your doctor tells you to.

When taking this medicine, it is important to remember the following:

- Wait at least 4 hours between doses
- Do not exceed the stated dose.
- Do not take other Paracetamol containing products whilst taking this medicine.
- If your symptoms continue or your headache becomes persistent, see your doctor.

If you take more Paracetamol 500mg 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. Take the container and any remaining tablets with you. Symptoms of overdose include loss of appetite (anorexia), nausea, diarrhoea, vomiting and abdominal pain.

If you forget to take Paracetamol 500mg Tablets:

Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

If you stop taking Paracetamol 500mg Tablets:

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

Serious side effects

If you experience any of these symptoms after taking this medicine go to the nearest hospital immediately:

- Allergic reactions which may be severe such as skin rashes and itching sometimes with swelling of the mouth or face or shortness of breath

- Skin rash or peeling, or mouth ulcers
- Difficulty breathing. These are more likely if you have experienced them before when taking other painkillers such as ibuprofen and aspirin.
- Unexplained bruising or bleeding, throat and mouth ulcers or bleeding gums accompanied by tiredness and flu like symptoms
- Hepatitis – inflammation of the liver.

Other side effects

- Blood problems which can lead to an increased risk of infection.

Very rare cases of serious skin reactions have been reported.

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.

5. HOW TO STORE PARACETAMOL 500MG TABLETS

Keep this medicine out of the sight and reach of children.

Store below 25°C. Store in the original packaging to protect from light and moisture.

Do not use this medicine after the expiry date which is stated on the carton after EXP. 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.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Paracetamol 500mg Tablets contain

The active substance is paracetamol 500mg.

The other ingredients are Potato Starch, Pregelatinised Starch, Magnesium Stearate, Talc and Colloidal Silica.

What Paracetamol 500mg Tablets looks like and contents of the pack

They are white flat circular bevel edged tablets embossed with a breakline and aP 500 on one side and plain on the reverse.

Available in packs of 8, 12 and 16 tablets (not all pack sizes may be marketed).

Marketing Authorisation Holder and Manufacturer

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This leaflet was last revised in January 2024.

Artwork Reference: PTT-BO/10