Patient Information Leaflet



Paracetamol 500 mg tablets

Please 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 doctor or 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.

What is in this leaflet

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1. What Paracetamol Tablets are and what they are used for

Paracetamol is an analgesic (pain killer) and an antipyretic (helps to reduce body temperature when you have a fever).

This medicine is used for the relief of headache, migraine, neuralgia and rheumatic aches and pains. Also for the relief of symptoms of colds and influenza.

2. What you need to know before you take Paracetamol Tablets Do not take Paracetamol Tablets if:

• you are allergic to paracetamol or any of the other ingredients of this medicine (listed in section 6).

Do not take anything else containing paracetamol while taking this medicine.

Warnings and precautions

Talk to your doctor or pharmacist before taking Paracetamol Tablets if:

- you suffer from any liver or kidney problems
- you suffer from alcohol dependence
- you suffer from asthma and are sensitive to aspirin
- you have a depleted level of glutathione (an antioxidant) in your body.

Other medicines and Paracetamol Tablets

Tell your doctor or pharmacist before taking these tablets if you are taking, have recently taken or might take any other medicines, including any medicines you have bought yourself, particularly any of the following:

- anticoagulants to thin the blood e.g. warfarin
- colestyramine (to lower cholesterol levels)
- metoclopramide or domperidone (for feeling sick or being sick)

- imatinib or busulfan (treatments for cancer/leukaemia)
- 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
- carbamazepine, phenytoin, phenobarbital, primidone (for epilepsy), rifampicin (antibiotic for infections), and also St. John's wort (hypericum perforatum) as the risk of liver damage is greater when these are taken in combination with the maximum recommended doses of paracetamol.

Paracetamol with alcohol

Avoid drinking alcohol while you are taking this medicine as together they can affect your liver function.

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 Tablets can be used during pregnancy and while breast-feeding, but you should use the lowest possible dose that reduces your pain and/or your fever and use it for the shortest time possible.

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 Tablets

The tablets should be swallowed with a drink of water. The tablet can be divided into equal doses.

Dose

Unless instructed otherwise by your doctor:

Age	Dose	How often
Adults, the elderly and	1 or 2 tablets	Every 4 – 6 hours.
children 16 years and over		Do not take more than 4
Children 12 – 15 years	1 to 1 ¹ / ₂ tablets	doses in any 24 hour period.
Children 10 – 12 years	1 tablet	
Children 6 – 10 years	1/2 tablet	
Children under 6 years	Not recommended	

Do not take more medicine than the label tells you to. If you do not get better, talk to your doctor.

If you take more Paracetamol 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 Tablets

Do NOT take a double dose to make up for the missed dose.

4. Possible side effects

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

If any of the following very rare side effects occur (may affect up to 1 in 10,000 people), STOP taking the tablets and contact your doctor IMMEDIATELY:

- 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 or aspirin
- unexplained bruising or bleeding (may be signs of a problem with your blood)
- feeling sick, sudden weight loss, loss of appetite and yellowing of the eyes and skin (may be signs of a problem with your liver function).

Very rare cases of serious skin reactions have been reported.

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 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 carton. The expiry date refers to the last day of that month.

Keep this medicine in the original package and protect from heat, light and moisture. 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 Tablets contain

Paracetamol 500mg Tablets contain paracetamol 500mg as the active substance. They also contain the following other ingredients: maize starch, povidone, pregelatinized maize starch, sodium starch glycollate and magnesium stearate.

What Paracetamol Tablets looks like and contents of the pack

Paracetamol Tablets are white capsule shaped tablets, plain on one side and with a breakline on the other side.

This medicine is available in pack sizes of 16, 24, 32, 100, 500, or 1000 tablets. (Not all pack sizes may be marketed).

Marketing Authorisation Holder and Manufacturer

Crescent Pharma Limited, Units 3 & 4, Quidhampton Business Units, Polhampton Lane, Overton, Hants, RG25 3ED, UK

This leaflet was last revised in September 2022.

Artwork reference: WBA-3593 R3