

Package leaflet: Information for the user

Paracetamol 500 mg tablets

Paracetamol

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 of treatment.

What is in this leaflet

1. What Paracetamol is and what it is used for
2. What you need to know before you take Paracetamol
3. How to take Paracetamol
4. Possible side effects
5. How to store Paracetamol
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1. What Paracetamol is and what it is used for

The active ingredient is paracetamol which is a painkiller. It also reduces your temperature when you have a fever.

Paracetamol is suitable for the relief of headache, tension headache, migraine, backache, rheumatic and muscle pain, and toothache and period pain.

It can also relieve sore throat and fever, aches and pains of colds and flu and is recommended for the relief of pain due to mild arthritis.

You must talk to a doctor if you do not feel better or if you feel worse after 3 days of treatment.

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

Do not take Paracetamol :

- If you are allergic to paracetamol or to any of the other ingredients of this medicine (listed in section 6).
- If you are taking other medicines containing paracetamol.

Warnings and precautions

During treatment with Paracetamol 500 mg tablets, tell your doctor straight away if:

If 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).

Talk to your doctor or pharmacist before taking Paracetamol:

- If you have liver or kidney disease, including alcoholic liver disease.
- If you suffer from mild arthritis and need to take painkillers every day.

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

Children and adolescents

Paracetamol 500 mg tablets is not recommended in children below 10 years of age.

Other medicines and Paracetamol

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).

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

In particular, inform your doctor if you are taking:

- metoclopramide or domperidone (for nausea [feeling sick] or vomiting [being sick]).
- colestyramine (to lower blood cholesterol).
- blood thinning medicines (anticoagulants such as warfarin) and you need to take a pain reliever on a daily basis, because of the risk of bleeding. But you can still take occasional doses of Paracetamol at the same time as anticoagulants.

Pregnancy and breast-feeding

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.

Talk to your doctor before taking Paracetamol if you are pregnant.
You can take this medicine whilst breast-feeding.

3. How to take Paracetamol

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:

Adults (including the elderly) and adolescents aged 16 years and over:

Swallow 1-2 tablets every 4 to 6 hours as needed.

Do not take more than 8 tablets in 24 hours.

Use in children and adolescents aged 10 to 15 years

Take 1 tablet every 4 to 6 hours, if you need to.

Do not give more than 4 tablets in 24 hours.

Do not take this medicine for more than 3 days at a time, unless your doctor tells you to.

- Do not take it more frequently than every 4 hours.
- Do not take more than the recommended dose.

Do not give to children under 10 years of age.

If you take more Paracetamol than you should

In case of overdose immediately contact your doctor, even if you feel well, because of the risk of delayed, serious liver damage.

If you forgot to take Paracetamol

Do not take a double dose to make up for a forgotten dose. Take the next dose at the usual time.

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

4. Possible side effects

Frequency “Not known” (frequency cannot be estimated from the available data): “A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2)”

Like all medicines, this medicine can cause side effects, although not everybody gets them. A small number of people have had side effects.

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 to occur if you have experienced them before when taking other painkillers such as ibuprofen and aspirin.
- Unexplained bruising or bleeding.
- Nausea, sudden weight loss or loss of appetite.
- Yellowing of the eyes and skin.

Reporting of side effects

If you do 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 or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting this side effects you can help provide more information on the safety of this medicine.

5. How to store Paracetamol

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

Do not use this medicine after the ‘EXP’ date shown on the pack. 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 contains

- The active ingredient is paracetamol. Each tablet contains 500 mg paracetamol.
- The other ingredients are: Pregelatinised maize starch, Magnesium stearate.

What Paracetamol looks like and contents of the pack

Paracetamol 500 mg tablets are white to off white capsule shaped uncoated tablets with breakline on one side and plain on the other side.

Packs of 10 tablets, 16 tablets, 30 tablets, 32 tablets, 50 tablets, 100 tablets.

Marketing Authorisation Holder and Batch Release site

Ipca Laboratories UK Ltd.

Unit 97-98, Silverbriar,

Sunderland Enterprise Park East,

Sunderland, SR5 2TQ, United Kingdom

Batch Release Site

Elara Pharmservices Limited

7 Grimes Gates,

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