



PACKAGE LEAFLET: INFORMATION FOR THE PATIENT Paracetamol 500 mg hard capsules

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 have 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 effect, 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

1. What Paracetamol 500 mg hard capsules are and what is it used for
2. What you need to know before you take Paracetamol 500 mg hard capsules
3. How to take Paracetamol 500 mg hard capsules
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1. What Paracetamol 500 mg hard capsules are and what it is used for

Paracetamol 500mg hard capsules contain the active ingredient paracetamol and are used for the relief of mild to moderate pain, including:

- rheumatic and muscular pain
- backache, toothache
- neuralgia (severe nerve pain), period pain
- migraine, headache
- fevers, colds and flu
- mild arthritis.

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

DO NOT take Paracetamol 500 mg hard capsules if you are:

- allergic (hypersensitive) to paracetamol, other pain relievers or any of the other ingredients in the product (see Section 6 on 'What Paracetamol 500mg hard capsules contain') Signs of an allergic reaction including a rash and breathing problems. there can also be swelling of the legs, arms, face, throat or tongue.
- if you are **taking any other prescription or non-prescription medicines containing paracetamol** to treat pain, fever, symptoms of cold and flu, or to aid sleep.

Warnings and precautions:

Talk to your doctor or pharmacist or nurse before taking Paracetamol 500mg hard capsules if you:

- suffer from mild arthritis and need to take painkillers every day.
- have kidney or liver problems.
- underweight or malnourished.
- are an alcoholic.
- have a severe infection as this may increase the risk of metabolic acidosis.

Signs of metabolic acidosis include:

- deep, rapid, difficult breathing
- feeling sick (nausea), being sick (vomiting)
- loss of appetite

Contact a doctor immediately 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 not sure if any of the above apply to you, talk to your doctor or pharmacist before taking this medicine.

During treatment with Paracetamol, 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).

Other medicines and Paracetamol 500 mg hard capsules

Tell your doctor or Pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without prescription, including herbal medicines.

This is because paracetamol can affect the way some other medicines work. Also some other medicines can affect the way paracetamol works.

While taking paracetamol 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.

- Anything else containing paracetamol (see 'DO NOT take paracetamol 500mg hard capsules')
- 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 at the same time as anticoagulants.
- Cholestyramine (reduces blood cholesterol level)
- Metoclopramide and domperidone (for nausea [feeling sick] or vomiting [being sick]) or colestyramine (to lower blood cholesterol).
- Flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

Please talk to your doctor if you take blood thinning drugs (anticoagulants e.g. 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 500 mg hard capsules at the same time as anticoagulants.

Taking Paracetamol 500mg hard capsules with alcohol

You should not drink whilst taking these capsules. Taking alcohol with paracetamol can increase your chances of getting side effects.

Pregnancy and Breast-Feeding

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant, planning to become pregnant or breast-feeding.

If necessary, Paracetamol 500 mg hard capsules 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 or midwife if the pain and/or fever are not reduced or if you need to take the medicine more often. You can take this product whilst breastfeeding.

Driving and using machines Paracetamol 500mg hard capsules are not expected to affect your ability to drive or operate machinery.

Paracetamol 500mg hard capsules contains Sodium

This medicine contains less than 1 mmol (23 mg) of sodium per capsule, that is to say it is essentially 'sodium-free'.

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3. How to take Paracetamol 500 mg hard capsules

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. Swallow each hard capsules with a drink of water.

Adults and children aged 16 years and over:

Take one or two capsules every 4 to 6 hours as needed.
Do not take more than 8 capsules in 24 hours.

Children aged 10-15 years:

Give 1 capsule every 4 to 6 hours as needed. Do not give more than 4 capsules in 24 hours.
Do not give more than 3 days at a time unless your doctor tells you to.
Do not take more frequently than every 4 hours.
Do not take more than the recommended dose.

Do not give to children under 10 years.

Warning: Do not take more medicine than the label tells you to. If you do not get better, talk to your doctor. Contains paracetamol. Do not take anything else containing paracetamol while taking this medicine.

If you take more Paracetamol 500 mg hard capsules than you should

It is extremely important to follow the dosage instructions that have been given to you. Do not change your dose without discussing it with your doctor first.

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.

Symptoms of overdose include pallor (paleness of skin), nausea, vomiting, anorexia and stomach pain.

If you accidentally take more than the recommended dose, or know someone who has, contact your doctor or nearest hospital casualty immediately. Take any remaining medicine and this leaflet with you if possible.

If you forget to take Paracetamol 500 mg hard capsules

If you miss a dose, take it as soon as you remember. NEVER take a double dose to make up for the dose you have forgotten.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although 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.

The following have also been reported:

Blood doesn't clot well, which may result in easy bruising or bleeding. A severe reduction in the number of white blood cells, which makes infections more likely.

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)

Reporting of side effects

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme. Website at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

5. How to store Paracetamol 500 mg hard capsules

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 and the vial after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 to protect the environment.

6. Contents of the pack and other information

What Paracetamol 500 mg hard capsules contain

The active substance is Paracetamol 500mg.

The other ingredients are:

Capsules content: Maize starch, talc, magnesium stearate.

Capsules shell: Iron oxide red, titanium dioxide (E171), gelatin, sodium lauryl sulfate and water.

Printing Ink: Shellac (E904), black Iron Oxide (E172), and Potassium hydroxide (E525).

What Paracetamol 500mg hard capsules look like and contents of the pack

Paracetamol 500mg hard capsules are hard gelatin capsules (size 0) with a red opaque cap and a white opaque body, imprinted with 'PCC' on cap and '500' on body with black ink filled with white to off-white granular powder.

Paracetamol 500mg hard capsules are available in child resistant blister packs containing white opaque PVC and aluminium lidding foil.

Pack size of 10 and 16 hard capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Manufacturer

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