

Package leaflet: Information for the user

(Boots logo)

Paracetamol 500 mg Hard Capsules

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 500 mg Hard Capsules are and what they are used for

This medicine contains Paracetamol which belongs to a group of medicines called analgesics and antipyretics to relieve mild to moderate pain and reduce fever.

It can be used to relieve headaches, earache, rheumatic or muscular pain, back pain, toothache, period pain and the symptoms of cold and flu.

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

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

This medicine is available without prescription to treat minor conditions. However, you still need to take it carefully to get the best results from it

This medicine can be taken by adults and children aged 12 years and over. However, some people should not take this medicine or should seek the advice of their pharmacist or doctor first.

Do not take Paracetamol 500 mg Hard Capsules:

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

Warnings and precautions

Talk to your pharmacist or doctor before taking Paracetamol 500 mg Hard Capsules:

- If you have kidney problems.
- If you have liver problems (including a disease caused by drinking alcohol).

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 prescribed by your doctor and medicine you have bought for yourself, including herbal and homeopathic remedies.

Take care if you are taking any of the following medicines:

- Flucloxacillin (antibiotic), due to 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.
- Domperidone or metoclopramide for feeling sick or being sick (may increase the pain relief effect of paracetamol).
- Colestyramine for reducing blood fat levels (may reduce the pain relief effect of paracetamol).
- Warfarin or other blood thinners – if you take warfarin you can take occasional amounts of this medicine, but talk to your doctor first before you take it on a regular basis.
- Barbiturates (for epilepsy) or tricyclic antidepressants (may keep paracetamol in your body for longer).
- Oral contraceptives or other medicines for epilepsy (may reduce the pain relief effect of paracetamol).

If you are unsure about interactions with any other medicines, talk to your doctor or pharmacist.

Paracetamol 500 mg Hard Capsules with alcohol

Do not drink alcohol (wine, beer, spirits) whilst taking this medicine.

Pregnancy and 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 fever and use it for the shortest time possible. Contact your doctor if the pain and/or fever are not reduced or if you need to take the medicine more often.

You can take this medicine if you are breast-feeding.

Important information about some of the other ingredients of Paracetamol 500 mg Hard Capsules

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

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.

Check the foil is not broken before use. If it is, do not take that capsule.

Swallow each capsule whole with water.

The recommended dose is:

Adults and children aged 16 years and over: Take one or two capsules every 4 to 6 hours if you need to, up to a maximum of 8 capsules in 24 hours.

Children aged 12 to 15 years: Take one capsule every 4 to 6 hours if you need to, up to a maximum of 4 capsules in 24 hours.

Do not exceed the stated dose.

Consult your doctor if there is no improvement.

Prolonged use except on your doctor's advice may be harmful.

This product should only be used when clearly necessary.

If you take more Paracetamol 500 mg Hard Capsules than you should

Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of irreversible liver damage. Go to your nearest hospital casualty department.

Take your medicine and this leaflet with you.

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.

! If you get any of these serious side effects, stop taking the capsules. See a doctor at once:

- Difficulty in breathing, swelling of the face, neck, tongue or throat (severe allergic reactions).
- Very rare cases of serious skin reactions have been reported. This may include peeling, blistering and lesions of the skin.

If you get any of the following side effects see your pharmacist or doctor:

- Other allergic reactions (e.g. skin rash).
- Unusual bruising, or infections such as sore throats – this may be a sign of very rare changes in the blood.

If any side effect becomes severe, or you notice any side effects 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 via 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 500 mg Hard Capsules

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

Do not store above 30°C. Store in the original package, in order to protect from moisture.

Do not use this medicine after the expiry date which is stated on the blister and carton. 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 500 mg Hard Capsules contain

- The active substance is paracetamol

- The other ingredients are sodium starch glycolate, magnesium stearate, sodium laurilsulfate. The capsule shell contains gelatin, indigo carmine (E132), titanium dioxide (E171).

What Paracetamol 500 mg Hard Capsules look like and contents of the pack

The pack contains 12 or 24 hard capsules with a blue cap and white body.

Marketing Authorisation Holder

Taw Pharma (Ireland) Ltd,
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Dublin 2,
Dublin,
Ireland,
D02 Y940.

Manufacturer

Famar AVE,
Anthoussa Attiki 15349,
Greece.

For any information about this medicine, please contact the Marketing Authorisation Holder.

This leaflet was last revised in July 2022.

Other formats

To request a copy of this leaflet in Braille, large print or audio please call:

1890 708091 (ROI only)

and ask for Boots Medical Information.

Please be ready to give the following information:

Product Name: Paracetamol 500 mg Hard Capsules

Reference Number: PA 23081/001/001