

Package leaflet: Information for the patient
Paracetamol 500 mg Capsules, hard
 paracetamol

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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?

1. What Paracetamol capsules are and what they are used for
2. What you need to know before you take Paracetamol capsules
3. How to take Paracetamol capsules
4. Possible side effects
5. How to store Paracetamol capsules
6. Contents of the pack and other information

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

The active ingredient is paracetamol which is a painkiller and also reduces your temperature when you have a fever. Paracetamol capsules are used for fast and effective relief of mild pain such as headaches, toothache, backache, muscle pains and period pain in adults, the elderly and children aged over 10 years. It also relieves sore throat and the feverishness, aches and pains of colds and flu. Paracetamol capsules also help relieve the mild to moderate pain of osteoarthritis in adults and the elderly (which has been diagnosed by a doctor).

2. What you need to know before you take Paracetamol capsules

Do not take Paracetamol capsules

- if you have ever had an allergic reaction to paracetamol or to any of the other ingredients (listed in Section 6).
- if you are taking any other medicines containing paracetamol.

Warnings and precautions

Talk to your doctor or pharmacist before taking

- If you have liver or kidney problems including alcoholic liver disease
- If you are underweight (less than 50 kg) or are malnourished
- If you use large quantities of alcohol regularly (alcoholism)
- If you suffer from severe dehydration
- If you are taking medicines that affect your liver
- If you are elderly
- If you have glutathione deficiency

(a metabolic disorder which may lead to difficulty in breakdown of paracetamol)

- If you have an enzyme deficiency called Glucose-6-phosphate dehydrogenase deficiency
- If you have haemolytic anaemia (abnormal breakdown of red blood cells).

If any of the above applies to you, you may need to reduce the amount of paracetamol that you take or avoid taking this medicinal product altogether.

If you have a severe infection, 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.

Children

Do not give this medicine to children aged under 10 years.

Other medicines and Paracetamol capsules

Talk to your doctor or pharmacist before taking these capsules if you are taking any prescribed medicines; particularly metoclopramide or domperidone (for nausea [feeling sick] or vomiting [being sick]); colestyramine (to lower blood cholesterol). 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. However you can still take occasional doses of Paracetamol capsules at the same time as anticoagulants.

Please inform your doctor or pharmacist if you are taking:

- 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 and breastfeeding

If necessary, Paracetamol capsules can be used during pregnancy. You should use the lowest possible dose for the shortest time possible. Contact your doctor if the pain and/or fever are not reduced. You can take this product whilst breastfeeding.

3. How to take Paracetamol capsules

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

Take 1-2 capsules every 4 to 6 hours as required. Do not take more than eight capsules in any 24 hours.

Do not take more than four capsules a day (2 g/day) in the following situations, unless directed by your doctor:

- Weight less than 50 kg
- Use of large quantities of alcohol regularly (alcoholism)
- Dehydration
- Malnutrition.

Children aged 10-15 years:

Give 1 capsule every 4 to 6 hours as required. Do not take more than 4 capsules in any 24 hours.

Do not give to children for more than 3 days without consulting a doctor.

Children under 10 years:

Do not give to children under 10 years of age.

Use in kidney or liver impairment:

If you have been diagnosed with kidney or liver problems, please consult your doctor or pharmacist. You may need to take a lower dose or increase the length of time between doses.

- **Contains paracetamol.**
- **Do not take more than the recommended dose.**
- **Do not take more frequently than every 4 hours.**
- **Do not take more than 4 doses in 24 hours.**
- **If symptoms persist consult your doctor.**
- **Prolonged use except under medical supervision may be harmful.**
- **Always use the lowest effective dose to relieve your symptoms.**

If you take too many capsules

Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage.

4. Possible side effects

Like all medicines Paracetamol capsules can have side effects, but not everybody gets them.

Very rare cases of serious skin reactions have been reported.

Stop taking this medicine and tell your doctor immediately if:

- you experience serious skin reactions, very rare cases of which have been reported.
- you experience allergic reactions such as skin rash or itching, sometimes with breathing problems or swelling of the lips, tongue, throat or face.
- you experience a severe skin rash or peeling of the skin which may be accompanied by mouth ulcers.
- you may have previously experienced breathing problems with aspirin or non-steroidal anti-inflammatories and experience a similar reaction to this product.
- you experience unexplained bruising or bleeding.

These reactions are very rare.

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 capsules

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

Do not use this medicine after the expiry date (EXP) which is stated on the outer carton and the blisters. The expiry date refers to the last day of that month. Do not store above 30°C. Store in the original package to protect from moisture. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Paracetamol capsules contains Active ingredient Each capsule contains 500 mg of Paracetamol.

The other ingredients are Mannitol, glycerol distearate, magnesium stearate. Composition of hard gelatin capsule shell - iron oxide yellow (E172), FD & C red 3 (E127), titanium dioxide (E171), sodium lauryl sulphate, polyethylene glycol, gelatin.

What Paracetamol capsules look like and contents of the pack

PVC-Aluminium thermoformed blister packs, containing 6, 12, 24, 48, 96 or 100 capsules.

Not all pack sizes may be marketed.

The hard capsules contain white to off-white crystalline powder filled in size '0' capsules with ivory colour body and ivory colour cap.

Marketing Authorisation Holder

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AZURE
 PHARMACEUTICALS

285 mm

36 mm

50 mm

130 mm

Space for Pharmacode

285 mm

130 mm

Auto-Cartonator PIL - Cutterguide

Dimension: 130 x 285 mm (Open Size) 130 x 36 mm (Folded Size)