

Package leaflet: Information for the patient

Paracetamol 500 mg 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.

What is in this leaflet

1. What Paracetamol 500mg Capsules are and what they are used for
2. What you need to know before you take Paracetamol 500mg Capsules
3. How to take Paracetamol 500mg Capsules
4. Possible side effects
5. How to store Paracetamol 500mg Capsules
6. Contents of the pack and other information

1. What Paracetamol 500mg Capsules are and what they are used for

This medicine contains

- **paracetamol** which is a pain reliever (analgesic) and helps reduce your temperature when you have a fever.

These capsules are for the relief of mild to moderate pain including headache, migraine, toothache, nerve pain, sore throat and period pains.

They are also for the symptomatic relief of sprains and strains, rheumatic pains, sciatica, lumbago, fibrositis, muscular aches and pains, joint swelling and stiffness, flu, feverishness and feverish colds.

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

Do not take this medicine if you

- are **allergic** to paracetamol or any of the other ingredients.

Warnings and precautions

Talk to your doctor or pharmacist before taking Paracetamol 500mg Capsules, if you

- are breastfeeding
- suffer from kidney or liver problems, including alcoholic liver disease
- are alcohol dependent.

Pregnancy and breast-feeding

If necessary, Paracetamol 500mg 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.

Other medicines and Paracetamol 500mg Capsules

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

- to treat high cholesterol levels which reduce the amount of fat in the blood such as colestyramine
- to control feeling sick or being sick such as metoclopramide or domperidone
- like carbamazepine, a medicine used to treat epilepsy and bipolar disorder
- called anti-coagulants, which are used to thin the blood such as warfarin or other coumarins - you may take occasional doses of paracetamol but should consult your doctor if you need to take it on a regular basis
- 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.

Please turn over ➔

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

Information about some of the ingredients in this medicine

Sodium: This medicinal product contains less than 1 mmol (23 mg) per 2 capsules, that is to say essentially sodium-free.

3. How to take Paracetamol 500mg Capsules

Swallow the capsules whole with water. Do not chew.

Adults, the elderly and children over 16 years

2 capsules to be taken every 4 to 6 hours, as required. Do not take more than 4 doses (8 capsules) in any 24 hour period.

Children aged 12 to 15 years

1 capsule to be taken every 4 to 6 hours, as required. Do not take more than 4 doses (4 capsules) in any 24 hour period.

Do not give to children under 12 years.

Do not take more often than every 4 hours. Do not take for more than 3 days unless instructed by your doctor.

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

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. Go to your nearest hospital casualty department. Take your medicine and this leaflet with you.

4. Possible side effects

Most people do not have any side effects while taking this medicine. However, if you experience any of the following side effects, or anything else unusual happens, stop taking the medicine immediately, and see your doctor or pharmacist.

Rare side effects are

- allergic reactions such as skin rash
- mouth sores
- fever
- difficulty breathing
- you may become more prone to bleeding, bruising, fever and infections, such as sore throat and ulcers, due to changes in your blood
- nausea, sudden weight loss, loss of appetite and yellowing of the eyes and skin.

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 at: www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Paracetamol 500mg Capsules

Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date printed on the pack.

Do not store above 25°C.

6. Contents of the pack and other information

What Paracetamol 500mg Capsules contain

Each blue / white capsule contains the active ingredient: paracetamol 500mg.

The other ingredients are: maize starch, croscarmellose sodium, sodium laurilsulfate and magnesium stearate. The capsule shell is made of gelatin and contains the colours titanium dioxide (E171), indigo carmine (E132) and erythrosine (E127).

This product is available in pack sizes of 16 and 32 capsules.

The Marketing Authorisation holder and manufacturer is Wrafton Laboratories Limited, Braunton, Devon, EX33 2DL, UK.

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