

Package leaflet: Information for the patients



Paracetamol 500mg Tablets

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 Tablets are and what they are used for
2. What you need to know before you take Paracetamol 500mg Tablets
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6. Contents of the pack and other information

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

Paracetamol relieves pain and brings down high temperatures (reduces fever).

Paracetamol 500mg Tablets are used for the relief of

- mild to moderate pain including headache, migraine, nerve pain (neuralgia), toothache, sore throat and period pains
- symptoms of rheumatic and muscular aches and pains, sciatica, back pain (lumbago), joint swelling and stiffness
- symptoms of colds and flu.

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

Do not take Paracetamol 500mg Tablets

- if you are allergic to paracetamol, sodium metabisulfite or any of the other ingredients listed in section 6.

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

Warnings and precautions

Talk to you pharmacist or doctor before taking if

- you suffer from severe liver or kidney disease, including alcoholic liver disease.

Other medicines and Paracetamol 500mg Tablets

Talk to your pharmacist or doctor before taking the tablets if you are taking any of the following:

- medicines for nausea or sickness, such as metoclopramide or domperidone.
- colestyramine for high cholesterol or high blood fats

- warfarin (or other medicines used to thin the blood and reduce the risk of clotting). The risk of bleeding may be increased if you take paracetamol daily over a long period of time. However you can take occasional doses of paracetamol.
- 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 500mg Tablets 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 or midwife if the pain and/or fever are not reduced or if you need to take the medicine more often.

You can take paracetamol while breastfeeding

Important information about some of the ingredients in this medicine

Paracetamol 500mg Tablets contain less than 1 mmol sodium (23 mg) per 2 tablets, that is to say essentially 'sodium-free'.

Sodium metabisulfite (E223) which may rarely cause severe hypersensitivity (allergic) reactions and bronchospasm (narrowing of the windpipe).

3. How to take Paracetamol 500mg Tablets

Swallow the tablets, preferably with a drink of water.

Age	How much	How often
Adults and children over 16 years	1 or 2 tablets	Every 4-6 hours, as required. Don't take more than 8 tablets (4 doses) in any 24 hours
Children 12 – 15 years	1 to 1½ tablets	Every 4-6 hours, as required. Don't take more than 6 tablets (4 doses) in any 24 hours
Children 10 – 12 years	1 tablet	Every 4-6 hours, as required. Don't take more than 4 tablets (4 doses) in any 24 hours
Children 6 – 10 years	Half a tablet	Every 4-6 hours, as required. Don't take more than 2 tablets (4 doses) in any 24 hours
<p>Do not give to children under 6 years. Do not take more often than every 4 hours. Do not take for more than 3 days unless instructed by your doctor.</p>		

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.

4. Possible side effects

Like all medicines, paracetamol can cause side effects, although not everybody gets them.

Side effects are rare with paracetamol.

Stop taking the tablets and contact your doctor immediately if you notice

- skin rashes or other signs of allergic reaction such as itching, swelling of the lips, tongue or throat, or difficulty in breathing
- unexpected bruising or bleeding, persistent tiredness, or increase in the number of

infections (e.g. sore throats) which you get. These are possible signs of changes in the blood

- 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
- 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 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 Tablets

There are no special storage requirements.

Do not use after the expiry date shown on the carton.

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

6. Contents of the pack and other information

What Paracetamol 500mg Tablets contain

The active ingredient is: Paracetamol 500mg per tablet.

Other ingredients are: Pregelatinised maize starch, sodium metabisulfite (E223) and magnesium stearate.

What Paracetamol 500mg Tablets look like and the contents of the pack

Paracetamol 500mg Tablets are white, capsule-shaped tablets with a break line on one side.

This pack contains 16 tablets.

Marketing Authorisation Holder:

Galpharm Healthcare Ltd., Wrafton, Braunton, Devon, EX33 2DL, United Kingdom.

Manufacturer:

Galpharm International Ltd., Elmhirst Park, Middle Field Road, Barnsley, South Yorkshire, S75 4LS, United Kingdom.

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Other formats

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

0800 198 5000 (UK only)

Please be ready to give the following information:

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