Paracetamol 500 mg Caplets

Read all of this leaflet carefully because it contains important information for you.
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.

- Keep this leaflet, you may need to read it again
- Ask your pharmacist if you need more information or advice
- You must contact a pharmacist or doctor if your symptoms worsen or do not improve after 3 days
- If any of the side effects get serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist, see section 4

What this medicine is for
This medicine contains Paracetamol which belongs to a group of medicines called analgesics and antipyretics, which act to relieve mild to moderate pain and reduce fever. It can be used to relieve headache, including migraine and tension headache, neuralgia, toothache, sore throat, period pain, rheumatic aches and pains, fever and the symptoms of colds and flu.

Before you take this medicine
This medicine can be taken by adults and children aged 10 years and over. However, some people should not take this medicine or should seek the advice of their pharmacist or doctor first.

X Do not take:
- If you are allergic to paracetamol or any of the other ingredients

! Tell your doctor before you take this medicine if you:
- Are suffering from liver problems including liver problems due to excessive alcohol consumption
- Suffer from Gilbert’s syndrome (mild jaundice)
- Are suffering from kidney problems
- Are suffering from dehydration and chronic malnutrition
- Suffer from asthma and are sensitive to aspirin
- Are taking any other paracetamol containing medicines
- Have a fever that does not improve after taking this medicine
- Have glucose-6-phosphate dehydrogenase deficiency (enzyme deficiency)
- Have hemolytic anemia (abnormal breakdown of red blood cells)

Other medicines and Paracetamol Caplets
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

The following medicines can affect paracetamol:
- Blood thinning drugs (anti-coagulants e.g. warfarin). The effect of anti-coagulants may be increased by prolonged regular use of paracetamol with an increased risk of bleeding, however occasional doses have no significant effect
- Colestyramine to lower blood cholesterol
- Metoclopramide and domperidone (to treat nausea and vomiting)
- Probenecid (medicine used to treat high levels of uric acid in the blood stream (gout))
- Medicine to treat fever or mild pain (aspirin, salicyamide)
- Barbiturates and tricyclic antidepressants (to treat depression)
- Medicines used to treat epilepsy (lamotrigine)
- Medicines to treat tuberculosis (isoniazid)

**Effects of paracetamol on laboratory tests**
Uric acid and blood sugar tests may be affected.

**Paracetamol Caplets with food and drink**
This medicine may be taken with or without food.

**Pregnancy, breast-feeding and fertility**
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Small amounts of paracetamol pass into breast milk. This medicine may be taken, as instructed in the section 'How to take this medicine', by mothers who are breastfeeding.

**Driving and using machines**
Paracetamol is not known to cause any effects on the ability to drive and use machines.

**Paracetamol Caplets contain sodium metabisulfite**
- Paracetamol caplets contain sodium metabisulfite which may rarely cause severe hypersensitivity reactions and bronchospasm (breathing difficulties).

**✔ How to take this medicine**
Check the foil is not broken before use. If it is, do not take that caplet.

<table>
<thead>
<tr>
<th>Age</th>
<th>How many to take</th>
<th>How often to take</th>
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<tbody>
<tr>
<td>Adults, the elderly and children 16 years and over</td>
<td>One to two</td>
<td>Every 4 to 6 hours, if you need to.</td>
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<td></td>
<td></td>
<td><strong>Don't take more than 8 caplets in any 24 hours.</strong></td>
</tr>
<tr>
<td>Children of 10 to 15 years</td>
<td>One</td>
<td>Every 4 to 6 hours, if you need to.</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Don't take more than 4 caplets in any 24 hours.</strong></td>
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</table>

Swallow each caplet with water.
The break-line is only there to help you break the tablet if you have difficulty swallowing it whole.

**Do not give to children under 10 years of age.**
Do not give to children for more than 3 days, unless your doctor tells you to.
Do not take more than the amount recommended above.
If you do not get better, talk to your doctor.

**! If you take too many caplets:** 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.

**Possible side effects**
Like all medicines, paracetamol can cause side effects, although not everybody gets them.
- very rare cases of serious skin reactions have been reported
- accumulation of fluid in the larynx including an itchy rash, throat swelling (severe allergic reaction)
- swelling on the face, mouth, hands (angioedema)

You should stop taking this medicine and see your doctor immediately if you experience symptoms like:
- serious skin disease causing rash, skin peeling and sores
- severe blistering and peeling of the skin

**Rare (may affect up to 1 in 1,000 people):**
Oedema (abnormal accumulation of fluid under the skin), abnormal vision, simple skin rash or urticaria (dark red rash on the skin), haemorrhage (bleeding), abdominal pain, diarrhoea, nausea, vomiting, dizziness, fever, reduction of irritability or agitation (sedation), platelet disorders (clotting disorders), stem cell disorders (disorders of the blood forming cell in the bone marrow), abnormal liver function, liver failure, hepatic necrosis (death of liver cells), jaundice, overdose and poisoning, tremor, headache, depression, confusion, hallucinations, sweating, pruritus (itching), feeling lousy (malaise).

**Very rare (may affect up to 1 in 10,000 people):** hepatotoxicity (damage caused to the liver), thrombocytopenia (reduction in blood platelets, which increases the risk of bleeding or bruising), leucopenia (frequent infections due to poorly functioning white blood cells or decrease in white blood cells), neutropenia (reduced neutrophil count in blood), agranulocytosis (severe decrease in white blood cells which may lead to severe infections), hemolytic anemia (abnormal breakdown of red blood cells, which may cause weakness or pale skin), hypoglycemia (low levels of glucose in the blood), cloudy urine and kidney disorders.

**Other adverse reactions** of paracetamol whose frequency cannot be estimated from available data are: anaemia (decrease in red blood cells), problems with the way your kidneys work (kidney alteration), problems with the way your liver works (liver alteration), haematuria (blood in urine), anuresis (inability to urinate), gastrointestinal effects, vertigo. There have been cases of difficulty breathing, wheezing, coughing, and shortness of breath with paracetamol, but these are more likely in asthmatics sensitive to aspirin or other NSAIDs such as ibuprofen.

**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](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

**How to store this medicine**
Do not store above 25°C.
Store in the original package in order to protect from moisture.
Keep this medicine in a safe place out of the sight and reach of children, preferably in a locked cupboard.
Use by the date on the end flap of the carton.
What is in this medicine
Each tablet contains Paracetamol 500 mg, which is the active ingredient.
As well as the active ingredient, the tablets also contain pregelatinised maize starch, sodium metabisulfite (E223), magnesium stearate.
The pack contains 16 or 32 white, capsule shaped tablets with a break-line on one side.

Who makes this medicine
Manufactured for The Boots Company PLC Nottingham NG2 3AA by the Marketing Authorisation holder Bristol Laboratories Ltd Unit 3 Canalside Northbridge Road Berkhamsted Hertfordshire HP4 1EG
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If you would like any further information about this medicine, please contact The Boots Company PLC Nottingham NG2 3AA