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PACKAGE LEAFLET: INFORMATION FOR THE USER

PARACETAMOL 500 MG CAPLETS

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 have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.
- 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 Caplets are and what they are used for
2. What you need to know before you take Paracetamol Caplets
3. How to take Paracetamol Caplets
4. Possible side effects
5. How to store Paracetamol Caplets
6. Contents of the pack and other information

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

Paracetamol is an analgesic and an antipyretic which means it relieves pain and reduces high temperature (fever).

These caplets are used for the relief of:

- headache, tension headache, migraine, neuralgia (nerve pain), rheumatic and muscle pain, toothache and period pain.
- sore throat and fever, aches and pains of colds and flu.

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

Do not take these Caplets if you:

- are allergic to paracetamol or any other ingredients of this medicine (listed in Section 6)

- are taking any other paracetamol-containing products

Warnings and Precautions

Talk to your doctor or pharmacist before you take this medicine if you:

- Are suffering from liver problems including liver problems due to excessive alcohol consumption
- Have 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-phosphatedehydrogenase 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, Salicylamide)
- 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 (see section 3), 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).

3. How to take Paracetamol Caplets

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.

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

The breakline is only there to help you break the caplet if you have difficulty swallowing it whole.

The recommended dose is:

Adults, the elderly and children 16 years and over: Take one to two caplets every 4-6 hours, if you need to. **Do not take more than 8 caplets** in any 24 hours.

Children 10 to 15 years of age: Take one caplet every 4-6 hours, if you need to. **Do not take more than 4 caplets** in any 24 hours.

Do not take more often than every 4 hours.

Do not give to children for more than three days without seeing your doctor.

DO NOT GIVE TO CHILDREN UNDER 10 YEARS OF AGE.

XXXX

Paracetamol
500 mg Caplets
Insert Luton

SAME SIZE ARTWORK
430 x 130mm
Front

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

If you take more Paracetamol Caplets than you should

If you accidentally take more caplets than you should, tell your doctor immediately or go to the nearest hospital A & E (casualty) department. Take your medicine in its original packaging with you in order to enable the doctor to identify your medication easily.

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.

If you forget to take a dose

If necessary, take the missed dose when you remember and then leave at least 4 hours before taking the next dose.

DO NOT TAKE A DOUBLE DOSE TO MAKE UP FOR THE FORGOTTEN DOSE

4. Possible side effects

Like all medicines, this medicine 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.

The frequency using the following convention:

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

5. How to store Paracetamol Caplets

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C. Store in the original package in order to protect from moisture.
- Do not use the caplets after the expiry date printed on the carton or label (EXP.). 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 Caplets contain

- The active substance is Paracetamol.
- The other ingredients are: pregelatinised maize starch, sodium metabisulfite (E223) and magnesium stearate.

What Paracetamol Caplets looks like and contents of the pack

- The caplets are white capsule shaped with a breakline on one side.
- They are available in cartons containing 8, 12, 16, 24, 30, 32 or 100 caplets or containers of 16 and 1000 caplets for dispensing purposes.
- Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Name and address:

Bristol Laboratories Limited,
Unit 3, Canalside, Northbridge Road, Berkhamsted, Hertfordshire,
HP4 1EG, United Kingdom

Telephone: 0044 (0)1442 200922

Fax: 0044 (0)1442 873717

E-mail: info@bristol-labs.co.uk

Paracetamol 500 mg Caplets; PL 17907/0001

This leaflet was last revised in January 2017

To request a copy of this leaflet in Braille, large print or audio format, please contact the licence holder at the address (or telephone, fax, email) above.

V10 18-01-17 D1

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- are allergic to paracetamol or any other ingredients of this medicine (listed in Section 6)
- are taking any other paracetamol-containing products

Warnings and Precautions**Talk to your doctor or pharmacist before you take this medicine if you:**

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- Are suffering from kidney problems
- Are suffering from dehydration and chronic malnutrition
- Suffer from asthma and are sensitive to aspirin
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- Have a fever that does not improve after taking this medicine
- Have glucose-6-phosphatedehydrogenase deficiency (enzyme deficiency)
- Have hemolytic anemia (abnormal breakdown of red blood cells).

Other medicines and Paracetamol Caplets

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Uric acid and blood sugar tests may be affected.

Paracetamol Caplets with food and drink

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Paracetamol Caplets contain Sodium metabisulfite

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

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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.

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

The breakline is only there to help you break the caplet if you have difficulty swallowing it whole.

The recommended dose is:

Adults, the elderly and children 16 years and over: Take one to two caplets every 4-6 hours, if you need to. **Do not take more than 8 caplets in any 24 hours.**

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Do not take more often than every 4 hours.

Do not give to children for more than three days without seeing your doctor.

DO NOT GIVE TO CHILDREN UNDER 10 YEARS OF AGE.

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

XXXXXX

Paracetamol
500 mg Caplets
Insert Ipca

SAME SIZE ARTWORK
320 x 130mm
Front

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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.

If you forget to take a dose

If necessary, take the missed dose when you remember and then leave at least 4 hours before taking the next dose.

DO NOT TAKE A DOUBLE DOSE TO MAKE UP FOR THE FORGOTTEN DOSE**4. Possible side effects**

Like all medicines, this medicine 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:

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Rare (may affect up to 1 in 1,000 people):

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jaundice, overdose and poisoning, tremor, headache, depression, confusion, hallucinations, sweating, pruritus (itching), feeling lousy (malaise).

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Berkhamsted, Hertfordshire, HP4 1EG, United Kingdom

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Paracetamol 500 mg Caplets; PL 17907/0001

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V22 18-01-17 D0

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xxxxx

5mm

Paracetamol
500 mg Caplets
Insert lpa

SAME SIZE ARTWORK
270 x 160mm
Front

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