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Package leaflet: Information for the user

PARACETAMOL 500MG CAPSULES

(paracetamol)

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, pharmacist or nurse 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, pharmacist or nurse. 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 after three days.

What is in this leaflet

1. What Paracetamol Capsules is and what it is 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 is and what it is used for

Paracetamol capsules are used for the relief of headache, tension headache, migraine, backache, rheumatic and muscle pain, toothache and period pain. They also relieve sore throat and the fever, aches and pains of colds and flu. The active ingredient is paracetamol which is a painkiller and also reduces your temperature when you have a fever.

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

Do not take this medicine if you:

- are allergic to paracetamol or any other ingredients of this medicine (listed in section 6)
- are taking any other prescription or non-prescription medicines containing paracetamol to treat pain, fever, symptoms of cold and flu, or to aid sleep.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking this medicine if you:

- are suffering from liver problems including liver problems due to excessive alcohol consumption
- if you suffer from mild arthritis
- are suffering from Gilbert's syndrome (mild jaundice)
- are suffering from kidney problems
- are suffering from dehydration and chronic malnutrition (underweight)
- 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 haemolytic anemia (abnormal breakdown of red blood cells).

During treatment with Paracetamol, tell your doctor straight away if:

- you have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting), loss of appetite.

Other medicines and paracetamol

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. The following medicines can affect paracetamol:

- Drugs to thin the blood (anti-coagulant drugs e.g. Warfarin, other coumarins)
- Medicines used to relieve sickness (e.g. Metoclopramide, Domperidone)
- Medicines used to treat high cholesterol (Cholestyramine)
- 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)
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2.).

Effects of paracetamol on laboratory tests

Uric acid and blood sugar tests may be affected.

Paracetamol capsules with food and drink

This medicine may be taken with or without food.

Pregnancy and breast-feeding

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.

If necessary, paracetamol 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.

Small amounts of paracetamol may pass into breast milk. This medicine may be taken, as instructed (see section 3), by mothers who are breast-feeding.

Driving and using machines

Paracetamol has no influence on the ability to drive and use machines.

Important Information about some of the ingredients of Paracetamol Capsules

The capsule shell contains propyl parahydroxybenzoate (E216) and methyl parahydroxy- benzoate (E218) which may cause allergic reactions (possibly delayed).

Information on sodium content

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

3. How to take Paracetamol Capsules

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.

- If your symptoms continue or your headache becomes persistent, see your doctor.
- The capsules should be swallowed whole with a drink of water.

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SAME SIZE ARTWORK
560 x 130 mm
Front

560mm

10mm

Adults, the elderly and children aged 16 years and over: Swallow 2 capsules every 4 hours as needed.

- Do not take more than 8 capsules in 24 hours.

Children aged 12-15 years: Take 1 capsule every 4-6 hours as needed.

- Do not take more than 4 capsules in 24 hours.

Do not take more frequently than every 4 hours.

Do not take more than the recommended dose.

Do not give to children under 12 years.

DO NOT EXCEED THE STATED DOSE.

If you take more Paracetamol capsules than you should

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 of Paracetamol capsules

If necessary, take the missed dose when you remember, however, if it is almost time for your next dose, skip the missed dose and then take your next dose when it is due.

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

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

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
- breathing problems. These are more likely if you have experienced them before when taking other painkillers such as ibuprofen and aspirin
- unexplained bruising or bleeding
- Nausea, sudden weight loss, loss of appetite and yellowing of the eyes and 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.

Not Known (frequency cannot be estimated from the available data): A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2)

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 Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. 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 store above 25°C. Store in the original package.
- Do not use the capsules after the expiry date printed on the pack (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 capsules contain

- The active substance is Paracetamol.
- The other ingredients are: pregelatinised maize starch, magnesium stearate and sodium laurilsulfate.
- The capsule shell contains: titanium dioxide (E171), erythrosine (E127), quinoline yellow (E104), patent blue V (E131), gelatin, methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216).

What Paracetamol capsules look like and contents of the pack

- They are red cap and white body hard gelatin capsules, containing white free flowing powder.
- This medicine is available in packs containing 6, 8, 10, 12, 16, 20, 24, 30 or 32 capsules.
- Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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