ASPAR Paracetamol 500mg Capsules

Docment Information

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Package Leaflet: Information for the Patient





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 after 3 days.

What is in this leaflet

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



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

These capsules contain paracetamol and are used to relieve mild to moderate pain including headache, migraine and tension headache, toothache, back ache, rheumatic and muscle pains, period pains and sore throat.

Paracetamol is also an anti-pyretic used to reduce fever, aches and pains of colds and flu.



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

Do not take Paracetamol 500 mg capsules if you:

• are allergic to Paracetamol or any of the other ingredients listed in section 6.

Warnings and precautions

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

- Suffer from liver or kidney problems
- Suffer from alcohol dependency
- Suffer from non-serious arthritis and need to take painkillers every day
- 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).

Other medicines and Paracetamol 500 mg Capsules

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

- Blood thinning medicines such as Warfarin
- Metoclopramide and Domperidone (for sickness and digestive disorders)
- Colestyramine (to help control cholesterol levels)
- Any other paracetamol containing products
- Flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

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.

If necessary, Paracetamol 500 mg 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/midwife if the pain and/or fever are not reduced or if you need to take the medicine more often.



3. How to take Paracetamol 500 mg 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.

The recommended dose is:

Dosage in adults and the elderly: Take one or two capsules every four to six hours as needed. Do not take more than 8 capsules in 24 hours.

Dosage in children 12 to 15 years: Take one capsule every four to six hours as needed. Do not take more than 4 doses in 24 hours. Swallow the capsules with a glass of water.

When taking this medicine, it is important to remember the following:

• Do not give to children under 12 years unless told to by your doctor.

- Wait at least 4 hours between doses
- . Do not exceed the stated dose.
- Do not take other Paracetamol containing products whilst taking this medicine.
- Do not give for more than 3 days at a time unless your doctor tells you to.
- If your symptoms continue or your headache becomes persistent, see your doctor.

If you take more Paracetamol 500 mg 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. Take the container and any remaining tablets with you. Symptoms of overdose include loss of appetite (anorexia), nausea, diarrhoea, vomiting and abdominal pain.

If you forget to take Paracetamol 500 mg Capsules:

Do not take a double dose to make up for a forgotten dose.

If you stop taking Paracetamol 500 mg Capsules:

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



4. Possible side effects

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

Frequency "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).

Serious side effects

If you experience any of these symptoms after taking this medicine go to the nearest hospital immediately:

- Allergic reactions which may be severe such as skin rashes and itching sometimes with swelling of the mouth or face or shortness of breath
- · Skin rash or peeling, or mouth ulcers
- Difficulty breathing. These are more likely if you have experienced them before when taking other painkillers such as ibuprofen and aspirin.
- . Unexplained bruising or bleeding, throat and mouth ulcers or bleeding gums accompanied by tiredness and flu like symptoms
- Hepatitis inflammation of the liver.

Other side effects

- · Blood problems including anaemia
- Pancreatitis
- Very rare cases of serious skin reactions have been reported.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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 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 500 mg Capsules

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

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Store below 25°C. Store in the original packaging to protect from light and moisture.

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 500 mg Capsules contain

The active substance is paracetamol 500 mg

The other ingredients are: Potato Starch, Magnesium Stearate, Sodium Lauryl Sulphate, Gelatin, Erythrosine (E127), Patent Blue V (E131), Titanium Dioxide (E171) and Quinoline Yellow (E104).

What Paracetamol 500 mg Capsules looks like and contents of the pack

They are red and white hard gelatine capsules. Available in packs of 8, 12 and 16 capsules.

Marketing Authorisation Holder and Manufacturer

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