

Paracetamol 500 mg Capsules

RelonChem

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

What is in this leaflet

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

Paracetamol 500 mg Capsules contain the active ingredient paracetamol and are used for the relief of mild to moderate pain, including:

- rheumatic and muscular pain
- backache, toothache
- neuralgia (severe nerve pain), period pain
- migraine, headache
- fevers, colds, sore throat and influenza.

You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

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

Do not take Paracetamol 500 mg Capsules if you are:

- allergic (hypersensitive) to paracetamol or any of the other ingredients in the product (*listed in Section 6 on, 'What Paracetamol 500 mg Capsules contain'*). Signs of an allergic reaction include a rash and breathing problems. There can also be swelling of the legs, arms, face, throat or tongue.

Children

Paracetamol 500 mg Capsules must not be given to children under 10 years of age.

Do not take paracetamol if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking paracetamol.

Warnings and precautions

Talk to a pharmacist or your doctor before taking this medicine if:

- you have severe kidney or liver problems
- you have a liver problem caused by alcohol
- 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).

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking this medicine.

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. This includes medicines obtained without prescription, including herbal medicines. This is because paracetamol can affect the way some other medicines work. Also, some other medicines can affect the way paracetamol works.

While taking Paracetamol 500 mg Capsules you should not take any other medicines which contain paracetamol.

This includes some painkillers and cough and cold remedies. It also includes a wide range of other medicines available from your doctor and more widely in shops.

Please inform your doctor or pharmacist if you are taking:

- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

Tell your doctor if you are taking any of the following medicines:

- medicines used to thin the blood such as warfarin
- metoclopramide or domperidone - used to stop you feeling sick (nausea) or being sick (vomiting)
- Cholestyramine - for lowering blood cholesterol levels.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking paracetamol.

Taking Paracetamol 500 mg Capsules with alcohol

You should not drink whilst taking these capsules. Drinking alcohol with paracetamol can increase your chances of getting side effects.

Pregnancy and breast-feeding

Talk to your doctor before taking these capsules if:

- you are pregnant, think you may be pregnant or plan to get pregnant
- you are breast-feeding or planning to breast-feed.

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.

Driving and using machines

Paracetamol 500 mg Capsules are not expected to affect your ability to drive or operate machinery.

3. How to take Paracetamol 500 mg Capsules

Always take this medicine exactly as described in this leaflet or as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- **Do not take more than the recommended dose**
- **If you need to use this medicine for more than three days at a time, see your doctor.**

Adults and children over 16 years:

Take one or two capsules every 4 to 6 hours, up to a maximum of eight capsules in any 24 hour period.

Children 10 to 15 years of age:

Take one capsule up to 4 times a day, every 4-6 hours when necessary. Maximum dose of four capsules in any 24 hour period.

This medicine is not recommended in children under 10 years of age.

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

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.
- Remember to take any remaining capsules and the pack with you. This is so the doctor knows what you have taken.

If you forget to take Paracetamol 500 mg Capsules

If you forget to take a dose at the right time, take it as soon as you remember. However, do not take a double dose to make up for a forgotten dose. Remember to leave at least 4 hours between doses.

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. The following side effects may happen with this medicine:

Stop taking Paracetamol 500 mg Capsules and see a doctor or go to a hospital straight away if:

- you get swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing. You could also notice an itchy, lumpy rash (hives) or nettle rash (urticaria). This may mean you are having an **allergic reaction** to paracetamol
- you get serious skin reactions. Very rare cases have been reported.

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)".

Tell your doctor or pharmacist if any of the following side effects gets serious or lasts longer than a few days:

- you get infections or bruise more easily than usual. This could be because of a blood problem (such as agranulocytosis, neutropenia or thrombocytopenia). This side effect has only happened in a few people taking paracetamol.

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.yellowcard.mhra.gov.uk" 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 Paracetamol 500 mg Capsules after the expiry date which is stated on the package. The expiry date refers to the last day of that month. Store in the original package.

Do not store above 25°C.

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. Each Capsule contains 500 mg of paracetamol.

The **other** ingredients are starch 1500, magnesium stearate, sodium lauryl sulphate.

The capsule shell is opaque red/white gelatin 100 mg, containing colours such as erythrosine (E127), patent blue V (E131), titanium dioxide (E171) and quinoline yellow (E104).

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

Paracetamol 500 mg Capsules are clean, oblong shaped red and white capsules. They are supplied in: cartons containing blister strips of 8, 16 and 32 capsules. Not all pack sizes may be marketed.

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