



**PACKAGE LEAFLET: INFORMATION FOR THE PATIENT**

## Paracetamol 500 mg Capsules, hard

**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 or pharmacist.
- 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 or if you notice any side effects not listed in this leaflet, please talk to your doctor or pharmacist.

### 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
4. Possible side effects
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

The active ingredient is paracetamol which is a painkiller and also reduces your temperature when you have a fever. Paracetamol 500 mg 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.

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

#### Do not take Paracetamol 500 mg Capsules:

- If you have ever had an allergic reaction to paracetamol or to any of the other ingredients (listed in Section 6).
- If you are taking other medicines containing paracetamol.

#### Warnings and precautions

##### Talk to your doctor before taking Paracetamol 500 mg Capsules:

- if you have liver or kidney disease, including alcoholic liver disease.

During treatment with Paracetamol 500 mg Capsules, 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).

#### Other medicines and Paracetamol 500 mg Capsules

Please inform your doctor or pharmacist if you are taking:

- metoclopramide (for nausea [feeling sick] or vomiting [being sick]) or colestyramine (to lower blood cholesterol).
- blood thinning drugs (anticoagulants e.g. warfarin) and you need to take a pain reliever on a daily basis, talk to your doctor because of the risk of bleeding. But you can still take occasional doses of Paracetamol 500 mg Capsules at the same time as anticoagulants.
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

#### Pregnancy and breast feeding

Talk to your doctor before taking Paracetamol 500 mg Capsules if you are pregnant.

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 if the pain and/or fever are not reduced or if you need to take the medicine more often.

You can take this product whilst breast feeding.

#### Driving and using machines

The product is not expected to affect the ability to drive a car or operate machinery.

#### Sodium

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

### 3. How to take Paracetamol 500 mg Capsules

**Adults, the elderly and children 16 years and over:** One or two capsules every 4-6 hours up to a maximum of 8 capsules in 24 hours.

#### Children and adolescents

- Children 12-15 years: One capsule every 4-6 hours up to a maximum of 4 capsules in 24 hours.

**Use in children:** Paracetamol 500 mg Capsules should not be given to children under 12 years of age.

- Do not give for more than 3 days without consulting a doctor.
- Do not take more frequently than every 4 hours.
- Do not take more than the recommended dose.

#### If you take too many capsules

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 your symptoms continue or your headache becomes persistent, **see your doctor**.

Symptoms of overdose are observed after 2-3 days. The symptoms are loss of appetite, nausea, vomiting, pain in the abdomen, jaundice and discoloration of urine and stools. In severe cases, life-threatening liver injury may occur.

#### 4. Possible side effects

Like all medicines, Paracetamol 500 mg Capsules can have side effects but not everybody gets them. A small number of people have had side effects.

Stop taking the medicine and tell your doctor immediately if you experience:

- Allergic reactions which may be severe, such as skin rash and itching sometimes with swelling of the mouth or face or shortness of breath
- Skin rash, peeling, or mouth ulcers
- 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.

Very rare cases of serious skin reactions 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).

#### 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](http://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 out of the sight and reach of children.

Store in the original packaging.

Do not use after the expiration date as indicated on the package. The expiry date refers to the last day of the 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 500 mg Capsule contains

Each capsule contains: Paracetamol 500 mg.

Also contains:

Pregelatinised starch, magnesium stearate and sodium lauryl sulfate.

Shell content: Erythrosine (E 127), indigo carmine (E 132), titanium dioxide (E 171), gelatin and purified water.

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

Paracetamol 500 mg Capsules are red cap and white body hard gelatin Size "0" capsules filled with white to off white blend.

Paracetamol 500 mg Capsules are available in child-resistant blister packs of 16 and 32 capsules.

#### Marketing Authorisation Holder

Dawa Limited, 5 Sandridge Close, Harrow, Middlesex, HA1 1XD, UK.

#### Manufacturer

Drugsrus Limited, 5 Sandridge Close, Harrow, Middlesex, HA1 1XD, UK.

This leaflet was last revised on 05/2025.

Blind or partially sighted?  
Is this leaflet hard to see or read?  
Call 020 8423 2111 to obtain the  
leaflet in a format suitable for you.