

## **PACKAGE LEAFLET – INFORMATION FOR THE USER**

### **Paracetamol 500mg Tablets (Paracetamol)**

**Read all of this leaflet carefully before you start taking this medicine.**

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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#### **1. WHAT ARE PARACETAMOL TABLETS AND WHAT ARE THEY USED FOR**

Paracetamol tablets belongs to a group of medicines called Analgesics and Antipyretics. It works by relieving pain and reducing high temperature and fever.

Paracetamol tablets are used for the relief of mild to moderate pain including headache, migraine, tension headaches, neuralgia (severe pain in nerves), backache, toothache, sore throat, period pain, symptomatic relief of sprains, strains, rheumatic pain, sciatica (low back pain and leg pain), lumbago (low back pain), fibrositis (muscle and connective tissue pain), muscular aches and pains, joint swelling and stiffness, influenza, feverishness and feverish colds. It may also be used for symptomatic relief of pain due to non-serious arthritis.

#### **2. BEFORE YOU TAKE PARACETAMOL TABLETS**

**Do not take Paracetamol tablets:**

- If you are allergic to paracetamol or any of the other ingredients of Paracetamol tablets (see section 6).
- If you are taking any other products that contain Paracetamol.
- If you are under 10 years of age.

**Take special care with Paracetamol Tablets**

**Before taking Paracetamol Tablets, Tell your doctor if:**

- you are suffering from liver or kidney disease, including non-cirrhotic alcoholic liver disease.

**Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including those medicines obtained without a prescription.

In particular, tell your doctor if you are taking any of the following medicines:

- Anticoagulants to thin your blood e.g. warfarin
- Some antibiotics e.g. chloramphenicol
- Medicines to control nausea and vomiting e.g. metoclopramide, domperidone
- Medicines to control high lipid levels e.g. colestyramine
- Flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment, and which may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used.

### **Pregnancy and breast-feeding**

Tell your doctor if you are pregnant or planning to become pregnant, or are breast-feeding.

Ask your doctor or pharmacist for advice before taking any other medicine.

If necessary, paracetamol tablets 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.

### **Driving and using machines**

Paracetamol tablets has no influence on the ability to drive and operate machinery.

*Consult your doctor if you are suffering from joint pain and need to take painkillers every day.*

## **3. HOW TO TAKE PARACETAMOL TABLETS**

**Always take Paracetamol Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.**

For oral administration and short term use only. Swallow the tablets with water.

### **Dosage**

Adults, Elderly and Children over 16 years:

Take 1-2 tablets up to four times a day as required. Do not take more than 8 tablets per day (24 hours)

**Children 10 – 15 years:**

1 tablet every 4 hours as required, to a maximum of 4 tablets in 24 hours.

**Leave at least 4 hours between doses.**

Do not take with any other paracetamol-containing products.

Do not give to children under 10 years of age.

Do not exceed the stated dose.

If symptoms persist for more than 3 days or get worse consult your doctor or pharmacist.

### **If you take more Paracetamol Tablets than you should**

**Immediate medical advice** should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage.

If you or someone else swallows several of these tablets all together, or you think a child has swallowed any of these tablets, contact your doctor or pharmacist or hospital emergency department immediately.

Always take any tablets left over with you, also the box and leaflet as this will allow easier identification of the tablets.

### **If you forget to take Paracetamol Tablets**

If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose, do not take the missed dose and just carry on as before. Do not take a double dose to make up for a forgotten dose.

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

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, paracetamol can cause side-effects, although not everybody gets them.

If you experience any of the following serious effects STOP taking this medicine immediately and contact your doctor or pharmacist:

Severe **allergic reactions** include:

- difficulty in breathing
- skin rash and itching
- swelling of the face and throat
- runny nose

### **Other possible side effects**

- Occasionally the blood does not clot well, which may result in easy bruising or bleeding.
- Rarely, a severe reduction in the number of white blood cells, which makes infections more likely.

Very rare cases of serious skin reactions have been reported

### **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](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 TABLETS**

### **Keep out of the sight and reach of children.**

Do not store above 25°C. Store in original package.

Do not use your tablets after the expiry date stated on the label or carton.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## **6. FURTHER INFORMATION**


### **What Paracetamol Tablet contains?**

The **Active** substance in your tablet is Paracetamol.

The **Other** ingredients are Maize Starch, Gelatin, Sodium Starch Glycollate, Magnesium Stearate, Purified Talc and Colloidal Anhydrous Silica.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially “sodium free”.

#### **What Paracetamol Tablet looks like and contents of the pack?**

Paracetamol Tablets are white, uncoated caplet with inscription  on one side and plain on the other side.

They are available in blister pack of 100 Tablets. Each Blister strip contains 10 Tablets.

#### **Marketing Authorisation Holder and Manufacturer**

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**This leaflet was last approved in 04/2022**

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