

## **Paracetamol 500mg Capsules, hard Paracetamol**

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

This medicine is available without prescription, but you still need to take Paracetamol 500mg capsules, hard carefully to get the best results from them.

- 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, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

### **What is in this leaflet:**

1. What Paracetamol 500mg Capsules, hard are and what they are used for
2. What you need to know before you take Paracetamol 500mg capsules, hard
3. How to take Paracetamol 500mg capsules, hard
4. Possible side effects
5. How to store Paracetamol 500mg capsules, hard
6. Contents of the pack and other information

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

Paracetamol 500mg capsules, hard 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 and are recommended for the relief of pain due to mild arthritis.

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 500mg capsules, hard**

#### **DO NOT take paracetamol 500mg Capsules, hard:**

- 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 any other medicines containing paracetamol.

#### **Warnings and precautions**

Consult your doctor before taking these capsules if you:

- Suffer from mild arthritis and need to take painkillers every day.
- Have kidney or liver problems.
- Are underweight or malnourished
- Regularly drink alcohol
- Have severe infection as this may increase the risk of **metabolic acidosis**,

Signs of metabolic acidosis include:

- deep, rapid, difficult breathing
- feeling sick (nausea) being sick (vomiting)
- loss of appetite

**Contact a doctor immediately** if you get a combination of these symptoms. You may need to avoid using this product altogether or limit the amount of paracetamol that you take.

## Children

Do not give to children under 10 years.

### Other medicines and Paracetamol 500mg capsules, hard

Talk to your doctor or pharmacist before taking these capsules if you are taking any prescribed medicines; particularly **metoclopramide** or **domperidone** (for **nausea** [feeling sick] or **vomiting** [being sick]) or **colestyramine** (to lower **blood cholesterol**). If you take **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 capsules at the same time as anticoagulants.

### Taking Paracetamol 500mg Capsules, hard with food and drink

Avoid alcoholic drinks whilst taking these capsules.

### Pregnancy and Breast Feeding

**Talk to your healthcare professional** before taking Paracetamol capsules if you are **pregnant**. You can take this product whilst **breast feeding**

If necessary, paracetamol 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 or 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 500mg capsules, hard

**Adults and children aged 16 years and over:**

**Swallow 1-2 capsules every 4 to 6 hours as needed.**

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

**Children aged 10 -15 years:**

**Give 1 capsule every 4 to 6 hours as needed. Do not give more than 4 capsules in 24 hours.**

**Do not give for more than 3 days at a time unless your doctor tells you to.**

**Do not take more frequently than every 4 hours.**

**Do not take more than the recommended dose**

**Do not give to children under 10 years.**

### If you take more Paracetamol 500mg Capsules, hard 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 your symptoms continue or your headache becomes persistent, **see your doctor**.

### If you forget to take Paracetamol 500mg Capsules, hard

If you forget to take your capsules(s), take the next dose as normal.

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

## 4. Possible side effects

Like all medicines, Paracetamol 500mg Capsules, hard can have side effects, but not everybody gets them. A small number of people have had side effects. Very rare cases of serious skin reactions have been reported

**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 or 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**.

### **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 500mg capsules**

Keep out of the sight and reach of children

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

Do not use Paracetamol 500mg Capsule, hard after the expiry date shown on the package. The expiry date refers to the last day of that month.

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

### **6. Contents of the pack and other information**

#### **What Paracetamol 500mg Capsules, hard contain**

The **active** substance is paracetamol 500mg.

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

The capsule shell is opaque pink/white hard gelatin containing colours iron oxide red (E172) and titanium dioxide (E171).

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

Paracetamol 500mg Capsules, hard are clean, oblong shaped pink and white capsules.

They are supplied in cartons containing child resistant blister packs containing opaque PVC and aluminium/PET/paper as the lidding foil.

Pack sizes available on prescription: 56,60,84,96 or 100 capsules in a carton.

Pack size available from the pharmacy: 32 capsules in a carton)

Note: All pack sizes may not be marketed

#### **Marketing Authorisation Holder**

Somex Pharma

Ilford, Essex

IG3 8BS.UK

#### **Manufacturer**

Somex Pharma

Ilford, Essex

IG3 8RA.UK

**This leaflet was last revised in 05/2024**