

## PATIENT INFORMATION LEAFLET

### Paracetamol 500mg Film-coated tablets Paracetamol

**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 exactly as your 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.

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

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

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

**Paracetamol 500mg tablets are used for relief of headaches, including migraine and tension headaches, toothache, backache, rheumatic and muscle pains, neuralgia and period pain.** It also relieves sore throat and the feverishness, aches and pains of colds and flu. 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 Tablets**

##### **Do not take Paracetamol 500mg Tablets:**

- **if you are allergic** to paracetamol or to any of the ingredients of this medicine (listed in section 6).
- if you are **taking other medicines containing paracetamol.**

Warnings and precautions

##### **! Talk to your doctor or pharmacist before taking Paracetamol 500mg Tablets:**

- if you have **severe liver or kidney disease**, including **alcoholic liver disease**.
- if you are alcohol dependent
- if you are elderly or weigh less than 50kg

Prolonged use of any type of painkiller for headaches can make them worse. If this happens, talk to your doctor.

##### **! Other medicines and Paracetamol 500mg Tablets**

Talk to your doctor or pharmacist before taking these tablets if you are taking any prescribed medicines; particularly **metoclopramide** or **domperidone** (for **nausea** [feeling sick] or **vomiting** [being sick]); **cholestyramine** (to lower **blood cholesterol**); **Probenecid** (gout), **flucloxacillin** (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2),

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. However you can still take **occasional** doses of paracetamol tablets at the same time as anticoagulants.

**During treatment with Paracetamol 500mg Tablets, tell your doctor straight away if:**

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).

**! Pregnancy and breastfeeding**

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 500mg 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 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 Tablets**

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

The recommended dose is:

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

Swallow 1 to 2 tablets every 4 to 6 hours as required.

Do not take more than 8 tablets in any 24 hours.

**Children aged 10-15 years:**

Swallow 1 tablet every 4 to 6 hours as required. Do not take more than 4 tablets in any 24 hours.

**NOT SUITABLE FOR CHILDREN UNDER 10 YEARS.**

**! • Contains Paracetamol**

- **Do not take for more than three days without consulting your doctor.**
- **Do not take more than the recommended dose.**
- **This product should be used only when clearly necessary.**
- **If symptoms persist consult your doctor.**
- **Prolonged use except under medical supervision may be harmful.**

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

### **4. Possible side effects**

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

**Stop taking this medicine and tell your doctor immediately if:**

- you experience allergic reactions such as skin rash or itching or hives, sometimes with breathing problems or swelling of the lips, tongue, throat or face. These reactions are rare.
- you experience a severe skin rash or a serious skin reaction, such as peeling of the skin which may be accompanied by mouth ulcers.
- you may have previously experienced breathing problems with aspirin or non-steroidal anti-inflammatories, and experience a similar reaction to this product.
- you experience unexplained bruising or bleeding.
- you experience cloudy urine.

These reactions are very rare.

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: <http://www.hpra.ie>

By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store Paracetamol 500mg Tablets**

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

This medicine does not require any special storage conditions.

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

The active substance is paracetamol. Each tablet contains 500 mg paracetamol. The other ingredients are Pregelatinised maize starch, povidone, stearic acid, Hypromellose, polyethylene glycol and carnauba wax.

Paracetamol 500mg Tablets are white, capsule shaped, film-coated tablets marked with a breakline on one side.

Paracetamol 500mg Tablets are produced in packs of 16, 24 tablets. Not all pack sizes may be marketed.

**Marketing Authorisation holder** Chefaro Ireland DAC, The Sharp Building, Hogan Place, Dublin 2, Ireland and all enquiries should be sent to this address.

**Manufacturer:** Perrigo Supply Chain International DAC, The Sharp Building, Hogan Place, Dublin 2, Dublin, D02 TY74, Ireland

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