

## Package leaflet: Information for the user

### Paracetamol 500mg/5ml Oral Solution

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

#### Contains Paracetamol

**Do not** take any other paracetamol containing products.

**Do not** exceed the stated dose.

**Immediate** medical advice should be sought in the event of overdose, because of the risk of irreversible liver damage.

#### What is in this leaflet

1. What Paracetamol Oral Solution is and what it is used for
2. Before you take Paracetamol Oral Solution
3. How to take Paracetamol Oral Solution
4. Possible side effects
5. How to store Paracetamol Oral Solution
6. Contents of the pack and other information

#### 1. What Paracetamol Oral Solution is and what it is used for

Paracetamol belongs to a group of medicines called pain-killers or analgesics. This medicine is a higher strength Paracetamol Oral Solution. It is used for mild to moderate pain when you cannot take other paracetamol formulations such as lower strength liquid paracetamol, effervescent tablets or tablets.

#### 2. Before you take Paracetamol Oral Solution

##### Do not take this medicine if you have:

- had an allergic reaction to paracetamol or any of the other ingredients listed in section 6. An allergic reaction can include a rash, itching or shortness of breath
- a liver disorder

This medicine should not be given to children or adolescents under the age of 16 years.

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.

##### Take special care with this medicine if you have:

- kidney problems
- liver problems, including those due to drinking too much alcohol.

You may be more at risk of the side effects of paracetamol. Speak to your doctor or pharmacist if any of these apply to you.

#### Taking other medicines

You must not take **any other medicines that contain paracetamol** while you are taking this medicine.

Tell your doctor if you are taking any of these medicines:

- barbiturates (sleeping tablets)
- tricyclic antidepressants (such as amitriptyline)

- colestyramine (used to treat high cholesterol)
- warfarin (used to thin the blood and prevent clotting)
- zidovudine (used in HIV infections and AIDS)
- domperidone and metoclopramide (used to treat and vomiting)
- 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.

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

### **Taking Paracetamol Oral Suspension with food and drink**

Do not drink alcohol while taking paracetamol. This is because taking alcohol and paracetamol together can increase the risk of liver damage.

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

**Pregnancy:** If necessary, Paracetamol Oral Solution 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.

**Breast-feeding:** If you are breast-feeding, ask your doctor or pharmacist for advice before taking this medicine.

### **Driving and using machines**

This medicine should not affect your ability to drive or operate machinery.

### **Important information about some of the ingredients in Paracetamol Oral Solution**

This medicine contains:

- Methyl and propylparahydroxybenzoates (E216 and E218), - some people are allergic to these (the allergy may happen some time after starting the medicine).
- Sunset yellow (E110), an azo colouring agent which may cause allergic reactions

## **3. How to take Paracetamol 500mg/5ml Oral Solution**

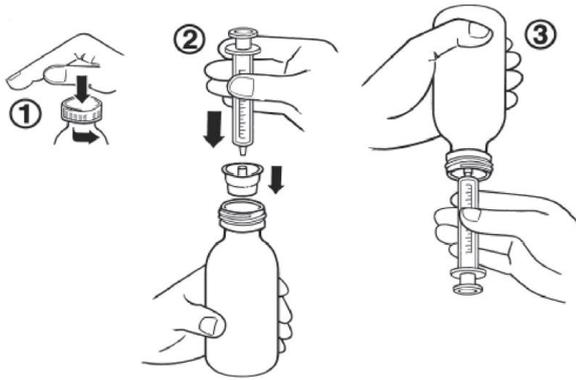
Take this medicine as your doctor or pharmacist has told you. Look on the label and ask your doctor or pharmacist if you are not sure.

### **How to take**

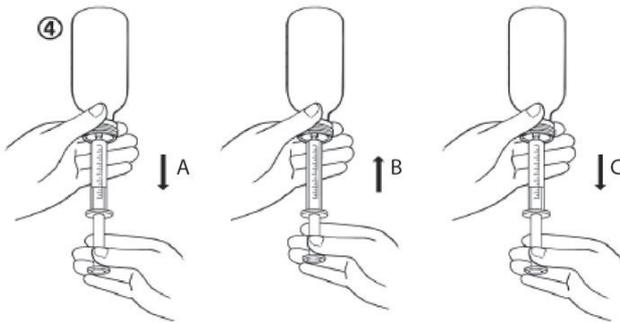
- This medicine contains 500mg of paracetamol in one 5ml dose.
- Take this medicine by mouth only.
- Shake the bottle for at least 10 seconds before use.
- Always use the syringe supplied with the pack.

### **Measuring your dose:**

1. Open the bottle: press the cap and turn it anticlockwise (figure 1).
2. Insert the syringe adaptor into the bottle neck (figure 2).
3. Take the syringe and put it in the adaptor opening (figure 2).
4. Turn the bottle upside down (figure 3).



5. Fill the syringe with a small amount of solution by pulling the piston down (figure 4 A). Then push the piston upward in order to remove any possible bubbles (figure 4 B). Finally, pull the piston down to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor (figure 4 C).



6. Turn the bottle the right way up.
7. Remove the syringe from the adaptor. Put the end of the syringe into your mouth and push the piston slowly back in to take the medicine.
8. Wash the syringe with water and let it dry before you use it again.
9. Close the bottle with the plastic screw cap.

### How much to take

- **Adults and adolescents over 16:**  
500mg (5ml) to 1000mg (10ml) up to three to four times a day, as required. Maximum daily intake should not exceed 4g (40ml)

### How often to take

- Take a dose of this medicine every 4 to 6 hours when needed.
  - Do not take more than 4 doses in 24 hours.
- Do not exceed the stated dose.**

### If you take more paracetamol than you should (overdose:)

- 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
- There may be no symptoms during the first 24 hours although paleness, nausea (feeling sick), vomiting (being sick) and abdominal pain may occur.

### If you forget to take this medicine

Take the next dose when needed. Do not take a double dose to make up for a forgotten dose.

### 4. Possible side effects

Like all medicines, paracetamol can cause side effects, although not everybody gets them. The side effects below may sometimes happen:

**If you have an allergic reaction to this medicine see a doctor straight away.**

An allergic reaction may include:

- skin rash, flaking skin, boils, sore lips and mouth, swelling of the face, fever
- sudden wheezing, fluttering or tightness of the chest or collapse.

**If you get any of the following side effects, stop taking this medicine and see your doctor as soon as possible:**

- bruising more easily, sore throat or other signs of infection (these may be signs of a blood disorder)
- severe pain in the abdomen and back, with fever (high temperature), loss of appetite, nausea and vomiting (these may be signs of pancreas inflammation)
- very rare cases of serious skin reactions have been reported.

**Tell your doctor if you get any of these side effects:**

- skin rash

If paracetamol is taken for a long time, it may lead to liver and kidney problems.

### **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: [www.hpra.ie](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 Oral Solution**

- Keep out of the sight and reach of children.
- Store below 25°C. Do not refrigerate or freeze. Store in the original bottle.
- Do not use three months after you first open it. Take it back to the pharmacy.
- Do not use after the expiry date (month, year) on the carton and label after EXP. The expiry date refers to the last day of that month.
- If it is out of date or you no longer want it, take it back to the pharmacy.
- Do not use Paracetamol Oral Solution if you notice anything wrong with the medicine. Talk to your pharmacist.

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

### **What Paracetamol Oral Solution contains**

The active substance is paracetamol. Each 5ml contains 500mg paracetamol.

The other ingredients are propylene glycol (E1520), glycerol (E422), methyl and propylparahydroxybenzoates (E216 and E218), sunset yellow (E110), macrogol 400, citric acid monohydrate, sodium citrate, sucralose, peppermint flavour, and purified water.

### **What Paracetamol Oral Solution looks like and contents of the pack**

Paracetamol 500mg/5ml Oral Solution is a clear, amber solution.

It is available in an amber glass bottle with child proof cap packed in an outer box. A plastic dosing syringe (pipette) is also included to help measure the dose. Bottle sizes are 150ml, 200ml and 500ml. Not all pack sizes may be marketed.

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

Marketing Authorisation Holder: Pinewood Laboratories Limited, Ballymacarbry, Clonmel, Co. Tipperary, Ireland

Manufacturer: CP Pharmaceuticals Limited, Ash Road North, Wrexham, LL13 9UF

**This medicinal product is authorised in the Member States of the EEA under the following names:**  
Ireland: Paracetamol 500mg/5ml Oral Solution

**This leaflet was last revised in 04/2022.**