

## Paracetamol Adult 500mg/5ml Oral Suspension

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

### 1. What Paracetamol Oral Suspension 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 Suspension. It is used for mild to moderate pain when you cannot take other paracetamol formulations such as a lower strength liquid paracetamol, effervescent tablets or tablets.

### 2. What you need to know before you take Paracetamol Oral Suspension

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

- had an allergic reaction to paracetamol or any of the ingredients listed in section 6. An allergic reaction can include a rash, itching or shortness of breath
- **taken any other products that contain paracetamol**
- 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.

#### Warning and precautions

Talk to your doctor or pharmacist before taking this medicine if you:

- have kidney problems
- have liver problems, including those due to drinking too much alcohol
- suffer from a condition known as Gilberts syndrome
- are taking other medicines that affect the liver
- suffer from glucose-6-phosphate dehydrogenase deficiency (enzyme deficiency)
- suffer from haemolytic anaemia (a reduction in the red blood cells which can make the skin pale yellow and cause weakness or breathlessness)
- suffer from reduced glutathione levels
- are malnourished, dehydrated or weigh less than 50 kg
- are elderly.

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.

Medicines containing paracetamol should only be used for a few days without advice from your doctor or dentist.

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If you have a high fever, signs of a secondary infection or if symptoms persist for more than three days, consult your doctor.

Prolonged use of paracetamol, especially in combination with other pain killing medicinal products, may cause kidney problems.

### **Other medicines and Paracetamol**

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 nausea and vomiting)
- chloramphenicol (used to treat infections)
- 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.

### **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**

If you are pregnant, planning to become pregnant or are breast-feeding, talk to your doctor or pharmacist before taking this medicine.

If necessary, Paracetamol 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**

This medicine should not affect your ability to drive or use machines.

### **Paracetamol Oral Suspension contains methyl and propyl parahydroxybenzoate, propylene glycol and liquid maltitol**

Paracetamol Oral Suspension contains:

- Methyl and propyl parahydroxybenzoates – may cause allergic reactions (possibly delayed).
- Propylene glycol. This medicine contains 112.2mg propylene glycol per 5ml spoonful. If you are pregnant or breast-feeding or if you suffer from a liver or kidney disease, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.
- Liquid maltitol (2.05g per 5ml dose). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- This medicine contains less than 1mmol sodium per ml, that is to say essentially 'sodium-free'.

## **3. How to take Paracetamol Oral Suspension**

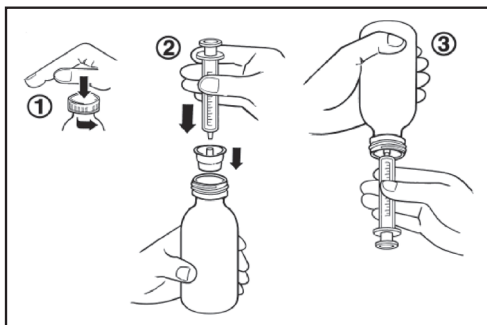
Take this medicine as your doctor or pharmacist has told you. Look on the label and ask your doctor or pharmacist if you are not sure.

### **How to take**

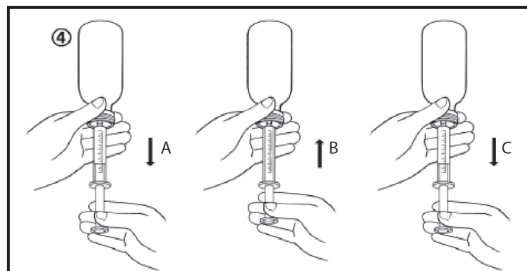
- This medicine contains 500mg of paracetamol in one 5ml dose.
- Take this medicine by mouth only.
- Shake the bottle for at least 10 seconds before use.
- Always use the syringe supplied with the pack.

### 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):

- Immediate medical advice should be sought in the event of an overdose, even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage. Phone your doctor or go to your nearest accident and emergency department straight away.
- 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.**

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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. Symptoms could include skin reddening, blisters or rash.
- rarely, a severe reduction in the number of white blood cells, which makes infections more likely
- other rare side effects like shortness of breath.

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

- skin rash
- occasionally the blood does not clot well, which may result in easy bruising or bleeding

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

If any of the side effects gets serious, or if you notice any side effects not mentioned in this leaflet, please tell your doctor or pharmacist.

### **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: [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 Oral Suspension**

- Keep out of the sight and reach of children.
- Do not store above 25°C. Do not refrigerate or freeze. Store in the original package.
- Do not use 1 month after you first open it. Take it back to the pharmacy.
- Do not use after the expiry date (month, year) on the label. 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 Suspension if you notice anything wrong with the medicine. Talk to your pharmacist.

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

### **What Paracetamol Oral Suspension contains**

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

The other ingredients are methyl and propyl parahydroxybenzoate (E218 and E216), propylene glycol (E1520), liquid maltitol (E965), saccharin sodium, acesulfame potassium (E950), sodium dihydrogen phosphate dihydrate, disodium hydrogen phosphate dihydrate, magnesium aluminium silicate, masking flavour, strawberry flavour and purified water.

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

Paracetamol Oral Suspension is a pink-brown liquid which smells of strawberry. It comes in a brown glass bottle holding 150ml of oral suspension with a 5ml purple syringe and an adaptor

### **The Marketing Authorisation Holder and Manufacturer is**

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