

## Paracetamol 120mg/5ml Oral Suspension

**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 as your doctor or pharmacist have 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.
- You must talk to a doctor if you do not feel better or if you feel worse.

### 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.

- It is used for mild to moderate pain including headache, migraine, nerve pain, toothache, sore throat, period pains and general aches and pains.
- It is also used to relieve the symptoms of cold and flu
- It is also used to help reduce a fever (high temperature).

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

#### Do not take Paracetamol:

- If you are allergic to paracetamol or any of the other ingredients of this medicine (listed in section 6). An allergic reaction can include a rash, itching or shortness of breath.
- If you have a liver disorder

Speak to your doctor or pharmacist if any of these apply to you.

#### Warnings and precautions

Talk to your doctor or pharmacist before taking Paracetamol 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.

### Other medicines and Paracetamol:

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 nausea and vomiting)
- anticonvulsants (medicines used to treat epilepsy or fits)
- oral contraceptives "the pill".

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

### 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.

### Driving and using machines:

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

### Paracetamol Suspension contains methyl and propyl parahydroxybenzoate, sucrose and sorbitol.

- Methyl and propyl parahydroxybenzoates – some people are allergic to these (the allergy may happen some time after starting the medicine).
- Sucrose (3g per 5ml spoonful). This should be taken into account if you have diabetes.
- Sorbitol. If your doctor has told you that you cannot tolerate some sugars, see your doctor before taking this medicine.

## 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.

### Taking this medicine

#### Check the tables below to see how much medicine to use

- This medicine contains 120mg of paracetamol in one 5ml spoonful.
- Take this medicine by mouth only.
- Never give more medicine than shown in table.
- It is important to **shake the bottle** for at least 10 seconds before use.
- Always use the spoon supplied with the pack. Do not overfill the spoon.
- Do not give this medicine with any other paracetamol-containing product.

### How much to take

#### For the relief of fever after vaccination at 2, 3 and 4 months

One 2.5 mL spoonful (small end). This dose may be given up to 4 times a day starting at the time of vaccination. Do not give more than 4 doses in any 24 hour period. Leave at least 4 hours between doses. If your baby still needs this medicine two days after receiving the vaccine talk to your doctor or pharmacist.

Age: 2 – 3 months	Dose
<b>Pain and other causes of fever</b> - if your baby weighs over 4 kg and was born after 37 weeks	One 2.5mL spoonful (small end). If necessary, after 4-6 hours, give a second 2.5mL dose
<ul style="list-style-type: none"> <li>■ Do not give to babies less than 2 months of age</li> <li>■ Leave at least 4 hours between doses</li> <li>■ Do not give more than 2 doses. This is to ensure that fever that may be due to a serious infection is quickly diagnosed. If your child is still feverish after two doses, talk to your doctor or pharmacist.</li> </ul>	

Child's Age	How Much	How often (in 24 hours)
3 – 6 months	One 2.5 mL spoonful (small end)	4 times
6 – 24 months	One 5 mL spoonful (large end)	4 times
2 – 4 years	One 5.0 mL spoonful (large end) and one 2.5 mL spoonful (small end)	4 times
4 – 8 years	Two 5 mL spoonfuls (large end)	4 times
8 – 10 years	Three 5 mL spoonfuls (large end)	4 times
10 - 12 years	Four 5 mL spoonfuls (large end)	4 times
<ul style="list-style-type: none"> <li>■ Do not give more than 4 doses in any 24 hour period</li> <li>■ Leave at least 4 hours between doses</li> <li>■ Do not give this medicine to your child for more than 3 days without speaking to your doctor or pharmacist</li> </ul>		

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

- Immediate medical advice should be sought in the event of an overdose, even if your child seems well, because of the risk of 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.**

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 but if the right amount is taken over a short period of time there should be no problems.

## **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 Oral Suspension**

- Keep out of the sight and reach of children.
- Do not store above 25°C. Protect from light. Store in the original package.
- Do not use after the expiry date (month, year) on the label and carton. 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 Suspension if you notice anything wrong with the medicine. Talk to your pharmacist.

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

### **What Paracetamol Suspension contains**

The active substance is paracetamol.

The other ingredients are methyl and propyl parahydroxybenzoate (E218 and E216), propylene glycol (E1520), xanthan gum (E415), liquid sorbitol (E420), sucrose, mango flavour and purified water.

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

Paracetamol Suspension is a white to off-white liquid which smells of mango. It comes in a brown glass bottle holding 100ml or 500ml of suspension.

A 2.5ml/5ml double ended spoon is provided to measure the dose.

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

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