

## Information for the user



# Paracetamol 120mg/5ml Oral Suspension

**Read all of this leaflet carefully because it contains important information for you.**

This medicine is available without prescription to treat minor conditions. However, you still need to give it carefully to get the best results from it.

- Keep this leaflet, you may need to read it again
- Ask your pharmacist if you need more information or advice
- You must contact a pharmacist or doctor if your child's symptoms worsen or do not improve after 3 days
- The leaflet is written in terms of giving this medicine to your child, but if you are an adult who is intending to take this medicine yourself the information in this leaflet will apply to you as well
- **Follow the dosage instructions carefully.** Children of different ages need different amounts. These are shown in the tables on the back of the leaflet.

## What this medicine is for

This medicine contains Paracetamol which belongs to a group of medicines called analgesics and antipyretics, which act to relieve pain and reduce fever.

It can be used to relieve mild to moderate pain including toothache, teething pain, headache and other pains. It can also be used to relieve the symptoms of colds and flu and to reduce fever, including fever after vaccination at 2 months of age.

## Before you give this medicine

This medicine can be given to children from the age of 2 months and over. However, some children should not be given this medicine or you should seek the advice of their pharmacist or doctor first.

### **X Do not give:**

- **If your child is under 2 months**
- **If your child is between 2-3 months old** and is taking this medicine **for pain or other causes of fever** and:
  - weighs less than 4 kg or
  - was born before 37 weeks
- **If your child is allergic** to any of the ingredients (see "What is in this medicine")
- **If your child is taking anything else with paracetamol in it**

### **! Talk to your pharmacist or doctor:**

- If your child has liver or kidney problems
- If your child takes any other medicines (see "If your child takes other medicines")

## Other important information

### **Information about some of the ingredients:**

This medicine contains 0.8 g sorbitol and 1.3 g maltitol per 5 ml spoonful. This provides 5 kcal per 5 ml spoonful. If your child has been told by a doctor that they have an intolerance to some sugars, contact their doctor before taking this medicinal product.

Methyl hydroxybenzoate (E218) may cause allergic reactions (possibly delayed). The colour carmoisine (E122) may cause allergic reactions.

This medicine contains less than 1 mmol sodium (23mg) per 5 ml dose, that is to say

essentially 'sodium-free'.

This medicine contains 0.06 mg of benzyl alcohol in each 5 ml dose. Benzyl alcohol may cause allergic reactions. Do not use for more than a week in young children (less than 3 years old), unless advised by your doctor or pharmacist.

Ask your doctor or pharmacist for advice if you are pregnant or breastfeeding, or have liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").

This medicine contains 12 mg of propylene glycol in each 5 ml dose.

This medicine contains 11.5 mg benzoate salt in each 5 ml dose.

### **Information for adults intending to take this medicine**

This medicine may be harmful if you are dependant on alcohol or have alcoholic liver disease. Do not drink alcohol (wine, beer, spirits) whilst taking this medicine.

Oral contraceptives may reduce the pain relief obtained with this medicine.

If you are elderly your doctor or pharmacist may advise you to take the medicine less regularly or leave longer between doses. In this case follow their instructions.

Pregnancy and breastfeeding: Do not take this medicine unless your pharmacist or doctor tells you to. **If necessary**, this medicine 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.

### **If your child takes other medicines**

#### **! This medicine contains paracetamol.**

Do not give with any other paracetamol-containing products.

Before you give this medicine, make sure that you tell your pharmacist about ANY other medicines you might be giving your child at the same time, particularly the following:

- Domperidone or metoclopramide (for feeling sick or being sick)
- Colestyramine (to reduce blood fat levels)
- Medicines to thin the blood (e.g. warfarin)
- Medicines for epilepsy (e.g. barbiturates)
- Medicines for depression (e.g. tricyclic antidepressants)
- 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.

If you are unsure about interactions with any other medicines, talk to your pharmacist. This includes medicines prescribed by your doctor and medicine you have bought for your child, including herbal and homeopathic remedies.

### **✓ How to give this medicine**

Check the cap seal is not broken before first use. If it is, do not give the medicine.

#### **! Do not give this medicine with any other paracetamol-containing product.**

Check the tables on the back of the leaflet to see how much of the medicine to give to your child. Never give more medicine than shown in the table.

It is important to **shake the bottle** for at least 10 seconds before use.

Always use the syringe supplied with the pack. The syringe can be used to measure 2.5 ml or 5 ml by drawing the liquid to the correct mark on the syringe.

Give this medicine to your child to swallow.

**Babies over 2 months in age****For the relief of fever after vaccination at 2, 3 and 4 months**

2.5ml. 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. **Do not give to babies less than 2 months of age.**

**For other causes of fever and pain:**

Child's age	How much	
2-3 months	2.5 ml – usually once, if necessary, after 4-6 hours, a second 2.5 ml dose may be given	
<b>Do not give to babies less than 2 months of age.</b> Only give if your baby weighs over 4 kg and was born after 37 weeks. Do not give more than 2 doses. Leave at least 4 hours between 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.		
Child's age	How much	How often (in 24 hours)
3-6 months	2.5 ml	4 times
6-24 months	5 ml	4 times
2-4 years	7.5 ml	4 times
4-6 years	10 ml	4 times
Do not give more than 4 doses in any 24 hour period. Leave at least 4 hours between doses. Do not give this medicine to your child for more than 3 days without speaking to your doctor or pharmacist.		

Do not give more than the amount recommended above.

If symptoms do not go away talk to your doctor.

**Directions for using the syringe:**

1. **Shake the bottle** for at least 10 seconds before use.
2. Push the syringe firmly into the plug (hole) in the neck of the bottle.
3. To fill the syringe, turn the bottle upside down. Whilst holding the syringe in place, gently pull the plunger down drawing the medicine to the correct mark (2.5 ml or 5 ml) on the syringe.
4. Turn the bottle the right way up, and then gently twist the syringe to remove from the bottle plug.
5. Place the end of the syringe into the child's mouth, normally to the side of the mouth between the gums and cheek. Press the plunger down to slowly and gently release the medicine.
6. If the table above advises you to give more than 5 ml of the medicine, repeat steps 2 to 5 to give your child the correct amount of medicine.

After use replace the cap on the top of the bottle tightly. Store all medicines out of the sight

and reach of children.

Wash the syringe in warm water and allow to dry.

If your child needs more than the doses shown in the table, or if fever doesn't go away speak to your doctor as soon as possible.

If you are unsure of the cause of your child's illness or it is accompanied by a rash, breathing difficulties, diarrhoea or excessive tiredness or lethargy, speak to your doctor and do not give this medicine until you get medical advice.

- ! **If you give too much or if anyone accidentally swallows some of the medicine:** Talk to a doctor at once if your child takes too much of this medicine even if they seem well. This is because too much paracetamol can cause delayed, serious liver damage. Go to your nearest hospital casualty department. Take the medicine and this leaflet with you.
- ! If you forget to give the medicine: Give the next dose when needed, provided that the last dose was given at least 4 hours ago. **Do not** give a double dose.

### **Possible side effects**

Most people will not have problems, but some may get some.

**If your child gets any of these serious side effects, stop giving the medicine. See a doctor at once:**

- Difficulty in breathing or swallowing, unexplained wheezing, swelling of the face, neck, tongue or throat (severe allergic reactions)
- Very rare cases of serious skin reactions have been reported. This may include peeling, blistering and lesions of the skin. If skin reactions occur or existing skin symptoms worsen, stop use and seek medical help right away.
- Becoming unusually tired, unusual bruising or bleeding, or getting more infections such as colds or sore throats. This may be a sign of very rare changes in the blood.

**If your child gets any of the following or any side effects not listed in this leaflet, see your pharmacist or doctor.**

- Other allergic reactions (e.g. skin rash)

**Long term use:** People who use medicines containing paracetamol every day for a long time (several months or more) could get certain side-effects, including liver and kidney damage. People taking paracetamol in the usual way for shorter periods have not had these problems, but liver function tests may be affected.

### **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 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.

### **How to store this medicine**

Do not store above 25°C. Store in the original package. Keep the lid tightly closed.

Keep this medicine in a safe place out of the sight and reach of children, preferably in a locked cupboard.

Use by the date on the end flap of the carton or on the label edge. After this date return any unused product to your nearest pharmacy for safe disposal.

## **What is in this medicine**

Each 5 ml of oral suspension contains Paracetamol 120 mg, which is the active ingredient. As well as the active ingredient, the suspension also contains purified water, maltitol liquid (E965), sorbitol (E420), glycerol (E422), microcrystalline cellulose, carmellose sodium, methyl hydroxybenzoate (E218), hyetellose, carmoisine (E122), strawberry flavours and sugar flavour.

The pack contains 100 ml or 200 ml of a pink strawberry-flavoured syrupy suspension.

## **Who makes this medicine**

Manufactured for the Marketing Authorisation holder The Boots Company PLC Nottingham NG2 3AA by BCM Ltd Nottingham NG2 3AA.

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If you would like any further information about this medicine, please contact The Boots Company PLC Nottingham NG2 3AA

## **Other formats**

To request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK only)

Please be ready to give the following information:

Product name: Paracetamol 120mg/5ml Oral Suspension (100ml)

Reference number: 00014/0638

Product name: Paracetamol 120mg/5ml Oral Suspension (200ml)

Reference number: 00014/0660

This is a service provided by the Royal National Institute of Blind People.

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