

## Information for the user



### 6 Years Plus Paracetamol 250mg/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

#### **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, headache, earache, sore throat and other pains. It can also be used to relieve the symptoms of colds and flu and to reduce fever.

#### **Before you give this medicine**

This medicine can be given to children from the age of 6 years 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 6 years**
- **If your child is allergic to or has ever had a bad reaction** to any of the ingredients in this medicine (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 in this medicine:**

This medicine contains 1.1 g of sorbitol in each 5 ml dose, which is equivalent to 220 mg/ml. Sorbitol may cause gastrointestinal discomfort and have a mild laxative effect. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

Methyl hydroxybenzoate (E218) may cause allergic reactions (possibly delayed).

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. 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 17.8 mg of propylene glycol per 5 ml dose.

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

If you drink large amounts of alcohol, talk to your doctor before you take this medicine. You may be more open to the side-effects of paracetamol. If this applies to you, talk to a doctor before use.

You can use this medicine while you are taking oral contraceptives ('the pill'), but it may not work so well on your pain or fever.

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

**Pregnancy and breastfeeding:** **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. Ask your doctor or pharmacist for advice before taking this medicine if you are breastfeeding.

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

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

Do not give anything else containing paracetamol while giving this medicine.

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 not sure about the medicine your child is taking show the bottle or pack 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**

For oral use only

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

#### **! Do not give anything else containing paracetamol while giving this medicine.**

Check the table 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.

Age	How much	How often
6 years up to 8 years	5 ml	Up to 4 times in any 24 hours. <b>Leave at least 4 hours</b> between doses.
8 years up to 10 years	7.5 ml (5 ml + 2.5 ml)	
10 years up to 12 years	10 ml (5 ml + 5 ml)	
12 years up to 16 years	10 ml to 15 ml (Two to three 5 ml doses)	
Adults and children of 16 years and over	10 ml to 20 ml (Two to four 5 ml doses)	
<b>Don't give more than 4 times in any 24 hours</b>		

Do not give to children under 6 years. Ask your Pharmacist to recommend a suitable product.

Do not give more than the amount recommended above.

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.

Do not give this medicine to your child for more than 3 days, unless your doctor or pharmacist tells you to.

If your child does not get better, talk to their doctor.

If you are not sure 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 straight away. Do not give this medicine until you get medical advice.

### **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 you give too much or if anyone has too much of the medicine:** Talk to a doctor at once if your child (or an adult) takes too much of this medicine even if they seem well. This is because too much paracetamol can cause delayed, serious liver damage.

**! If you forget to give this 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:**

- Allergic reactions including difficulty in breathing, swelling of the face, neck, tongue or throat, unexplained wheezing, shortness of breath, rash or hives (severe allergic reactions)
- Very rare cases of serious skin reactions have been reported. This may include skin reddening, rash, 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, and getting more, infections such as colds. This may be a sign of very rare changes in the blood

### If you take this medicine for a long time

This medicine is NOT intended for 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. If you notice any side-effects not included 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 at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard), 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 250 mg, which is the active ingredient.

As well as the active ingredient, the suspension also contains purified water, sorbitol (E420), glycerol (E422), microcrystalline cellulose, carmellose sodium, methyl hydroxybenzoate (E218), acesulfame potassium, hyetellose, strawberry flavour (containing benzyl alcohol and propylene glycol (E1520)) and cream flavour (containing propylene glycol (E1520)).

The pack contains 70 ml or 80 ml of an off white, strawberry-flavoured syrupy suspension. Not all pack sizes may be marketed.

## 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: Boots 6 Years Plus Paracetamol 250 mg/5 ml Oral Suspension

Reference number: 00014/0860

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

Artwork Reference Number: WBA-6025