

Package leaflet: Information for the user
Paracetamol 250 mg/5 ml oral suspension
paracetamol

- This medicine brings down high temperatures (also called fever) and relieves pain.
- This medicine is for children over 6 years.
- **Do not give the medicine to children who are:**
 - Taking some other medicines. See section 2
 - Allergic to paracetamol or any of the other ingredients listed in section 6.
- **Follow the dosage instructions carefully.** Children of different ages need different amounts. These are shown in the tables. See section 3
- **Speak to your doctor** if anything in this list applies:
 - If a child is not getting better, or needs more medicine than shown in the table. See section 3
 - If a child gets a rash, breathing problems, diarrhoea or gets very tired. See section 3

Read all of this leaflet carefully before you start taking or give this medicine to your child because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.
- You must talk to a doctor if your child does not feel better or feels worse after 3 days.
- If your child gets any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Paracetamol Suspension is and what it is used for

Paracetamol 250 mg/5 ml oral suspension (referred to as Paracetamol Suspension) is used to relieve mild to moderate pain and/or bring down fever (high temperature) in many conditions including cold and flu, headache, toothache, earache, post immunisation fever, sore throat and other aches and pains.

2. What you need to know before giving Paracetamol Suspension to your child

This medicine is suitable for most people but a few people should not use it. If you have any questions, talk to your doctor or pharmacist.

Do not give your child Paracetamol Suspension

- If your child is allergic to paracetamol or any of the other ingredients of this medicine (listed in section 6).
- If your child has ever had a bad reaction to any of the ingredients.
- If your child is taking anything else with paracetamol in it.

If any of these applies, get advice from a doctor or pharmacist without using Paracetamol Suspension.

Warnings and precautions

Talk to your doctor or pharmacist before giving your child this medicine if:

- Your child has serious kidney or liver problems.
- Your child has an inherited intolerance to fructose or been diagnosed with an intolerance to some other sugars.

During treatment with Paracetamol Suspension, tell your doctor straight away if:

you have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin.

Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

If adults take this medicine

The following additional warnings are included in case an adult takes this medicine:

- 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 drink large amounts of alcohol, talk to your doctor before you take this medicine. You may be more susceptible to the side effects of Paracetamol Suspension.
- If necessary, the 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 or pharmacist 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 breast-feeding.

Children under 6 years old

Not recommended for children under 6 years old. Ask your pharmacist to recommend a suitable medicine.

Other medicines and Paracetamol Suspension

Tell your doctor or pharmacist if your child is taking, has recently taken or might take any other medicines. If you are not sure about the medicine your child is taking, show the bottle or pack to your pharmacist.

- metoclopramide or domperidone (used to treat nausea and vomiting)
- cholestyramine (used to treat high cholesterol)
- anticoagulants (medicines that thin the blood, such as warfarin)
- anticonvulsants (medicines to treat epilepsy)

If any of these apply to your child, talk to a doctor or pharmacist.

Please inform your doctor or pharmacist if you are taking:

- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

Paracetamol Suspension contains methyl hydroxybenzoate (E218) and propyl (E216) hydroxybenzoate

This medicine contains methyl hydroxybenzoate (E218) and propyl hydroxybenzoate (E216) which may cause allergic reactions (possibly delayed).

Paracetamol Suspension contains sorbitol liquid (E420)

This medicine contains 1800 mg sorbitol liquid in each 5 ml dose which is equivalent to 360mg/ml. 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. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

Paracetamol Suspension contains maltitol liquid (E965)

If you have been told by your doctor that you (or your child) have an intolerance to some sugars, contact your doctor before taking this medicinal product. It may have a mild laxative effect. The calorific value is 2.3 kcal/g of maltitol.

Paracetamol Suspension contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per 5 ml, that is to say essentially 'sodium-free'.

3. How to give Paracetamol Suspension to your child

Check the table to see how much medicine you should give to your child.

- For oral use only.
- Always use the double sided measuring spoon supplied with the pack.
- It is important to shake the bottle for at least 10 seconds before use.
- Do not give more medicine than the label tells you to.
- If your child does not get better, talk to your doctor.
- Do not give anything else containing paracetamol while giving this medicine.

How to use the measuring spoon

- Shake the bottle for at least 10 seconds and remove the cap.
- Open the bottle and pour the oral suspension in measuring spoon 2.5 ml or 5 ml as appropriate (see table for the correct dose).
- Place the spoon in child's mouth and administer the dose.
- After use, close the bottle and wipe out bottle's neck clean.
- Wash and dry the measuring spoon after each use.

Dosage

Child's Age	How much - up to 4 times a day
Children under 6 years	Not recommended for children under 6 years old. Ask your pharmacists to recommend a suitable product
6-8 years	5 ml
8-10 years	7.5 ml (5 ml+2.5 ml)
10-12 years	10 ml (5 ml+5 ml)
12-16 years	10 - 15 ml (Two to three 5 ml doses)
Adults and children over 16 years	10 - 20 ml (Two to four 5 ml doses)
<ul style="list-style-type: none">• 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.	

Talk to your doctor:

- If your child needs more than the doses shown in the table, or if fever doesn't go away, talk to your doctor as soon as possible.
- 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 Paracetamol Suspension until you get medical advice.

If you or your child take more Paracetamol Suspension than you should

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 Suspension can cause delayed, serious liver damage. The symptoms of overdose may include pale skin, nausea, sweating, feeling of discomfort or uneasiness, vomiting, loss of appetite and abdominal pain.

If you forget to give Paracetamol Suspension to your child

Give the next dose when needed, provided that the last dose was given at least 4 hours ago. **Do not** give a double dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them and they are usually mild.

Tell your doctor as soon as possible if you notice any of these:

- allergic reactions including swelling of the face, tongue or throat, difficulty swallowing, unexplained wheezing, shortness of breath, rash or hives.
- becoming unusually tired, unexpected bruising or bleeding and getting more infections (such as colds) than usual. These are very rare effects in people taking Paracetamol Suspension.
- very rare cases of serious skin reactions have been reported. Symptoms may include: skin reddening, blisters, rash. If skin reactions occur or existing skin symptoms worsen, stop using this medicine and seek medical help right away.
- A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2): Frequency "Not known" (frequency cannot be estimated from the available data)

If your child shows any of these signs, **stop giving Paracetamol Suspension and talk to a doctor right away.**

Long term use: People who use medicines containing Paracetamol Suspension every day for a long time (several months or more) could get certain side-effects, including liver and kidney damage. People taking Paracetamol Suspension 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 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 Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in Google Play Store 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 Suspension

Keep this medicine out of the sight and reach of children.

Do not store above 25°C.

Store in the original package.

Do not use after the end of the month shown as an expiry date on the packaging.

Once the bottle has been opened, this medicine should be used within 60 days.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Paracetamol Suspension contains

- The active substance is paracetamol. Each 5 ml of suspension contains 250 mg of paracetamol.
- The other ingredients are: maltitol liquid (E965), sorbitol liquid (E420), glycerol (E422), MCC and carmellose sodium, xanthum gum, polysorbate 80, methyl hydroxybenzoate (E218), propyl hydroxybenzoate (E216), acesulfame potassium, sodium saccharin, strawberry flavour 502301T, Strawberry 054267A, sodium hydroxide, citric acid monohydrate & purified water.

What Paracetamol Suspension looks like and contents of the pack

Paracetamol Suspension is off-white to brownish coloured suspension with strawberry flavour.

Amber PET bottle with a white opaque polypropylene, child-resistant closure fitted with EPE liner and tamper evident ring.

Pack size: 100 ml, 200 ml and 500 ml. Double ended measuring spoon (2.5 ml and 5 ml) is supplied with this product.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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