

Paracetamol 250mg/5ml Oral Suspension

Read all of this leaflet carefully 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
- You must contact a doctor if your symptoms worsen or do not improve
- If any of these side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

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 use Paracetamol Oral Suspension
3. How to use 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 use Paracetamol Oral Suspension

Do not give this medicine to a child:

- If s/he is allergic to paracetamol or any of the ingredients listed in section 6. An allergic reaction can include a rash, itching or shortness of breath.
- If s/he has ever had a bad reaction to any of the ingredients.
- **If s/he has taken any other medicine that contains paracetamol.**

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

Warnings and precautions

Talk to your doctor or pharmacist before giving Paracetamol to a child:

- If s/he has kidney problems
- If s/he has liver problems
- If s/he has an inherited intolerance to fructose or been diagnosed with an intolerance to some other sugars.

Your child may be more at risk of the side effects of paracetamol.

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

During treatment with Paracetamol Oral 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).

Other medicines and Paracetamol:

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

If you are not sure about the medicine your child is taking, show the bottle or pack to your pharmacist. If any of these bullet points apply, **talk to a doctor or pharmacist**.

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

- 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. If this applies to you talk to a doctor before use.
- 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.
- this medicine should not affect your ability to drive or use machines.

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

Paracetamol Suspension contains tartrazine and carmoisine, methyl and propyl parahydroxybenzoate, sucrose, propylene glycol and sorbitol.

This medicine contains:

- Tartrazine and carmoisine (in the flavouring) – these may cause allergic reactions.
- Methyl and propyl parahydroxybenzoates – may cause allergic reactions (possibly delayed).
- Sucrose. Contains 2.5g of sucrose per 5ml spoonful. This should be taken into account if you have diabetes mellitus. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- Propylene glycol. This medicine contains 163.9mg propylene glycol per 5ml spoonful. If you are pregnant, 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.
- Sorbitol. This medicine contains 682.0mg sorbitol per 5ml spoonful. 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.
- This medicine contains less than 1mmol sodium per ml, that is to say essentially ‘sodium-free’.

3. How to use Paracetamol Oral Suspension

Use 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.

Using this medicine

Check the table below to see how much medicine to use

- This medicine contains 250mg of paracetamol in one 5ml spoonful.
- Take this medicine by mouth only.
- 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 spoon supplied with the pack. Do not overfill the spoon. Do not use the 1.25ml graduation marking on the spoon for dosing this product.
- Do not give this medicine with any other paracetamol-containing product.

How much to use

Age	How Much	How often (in 24 hours)
6 – 8 years	One 5 mL spoonful (large end)	4 times
8 – 10 years	One 5.0 mL spoonful (large end) and one 2.5 mL spoonful (small end)	4 times
10 – 12 years	Two 5 mL spoonfuls (large end)	4 times
12 – 16 years	Two to three 5 mL spoonfuls (large end)	4 times
Adults and children over 16 years	Two to four 5 mL spoonfuls (large end)	4 times
<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■ Do not give to children under the age of 6 years.		

Do not exceed the stated dose. You must see a doctor if your symptoms worsen or do not improve after 3 days.

If you use more paracetamol than you should (overdose):

- Immediate medical advice should be sought in the event of an overdose, even if you or your child seem 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), sweating, vomiting (being sick), loss of appetite and abdominal pain may occur.

If you forget to take this medicine:

Take the next dose when needed, provided that the last dose was taken at least 4 hours ago. 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 or your child have an allergic reaction to this medicine see a doctor straight away.

An allergic reaction may include:

- swelling of the face, tongue or throat, difficulty swallowing, unexplained wheezing, shortness of breath, rash or hives.

Continued overleaf

- 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.
- 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 use and seek medical help right away.

Frequency “Not known” (frequency cannot be estimated from the available data): A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2).

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

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 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 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, pineapple flavour (containing tartrazine (E102) and carmoisine (E122)), sweetness enhancer, sodium citrate 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 and pineapple.

It comes in a brown glass bottle holding 100ml or 500ml of suspension. The pack contains a 2.5ml/5ml double-ended measuring spoon to measure the dose correctly (do NOT use the 1.25ml graduation marking on the 2.5ml end of the spoon for dosing).

The Marketing Authorisation Holder and Manufacturer is:

Rosemont Pharmaceuticals Ltd, Yorkdale Industrial Park,
Braithwaite Street, Leeds, LS11 9XE, UK.

Tel: + 44 (0) 113 244 1400

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