

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 give Paracetamol Oral Suspension to a child
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 give Paracetamol Oral Suspension to a child

Do not give Paracetamol to a child:

- If s/he is 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 s/he is taking anything else with paracetamol in it**
- If s/he is between 2-3 months old and is taking this medicine for other causes of pain and fever and:
 - weighs less than 4 kg or
 - was born before 37 weeks.

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.

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 (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.

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 have liver problems, including those due to drinking too much alcohol, you may be more open 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 methyl and propyl parahydroxybenzoate, sucrose, propylene glycol and sorbitol.

- Methyl and propyl parahydroxybenzoates – may cause allergic reactions (possibly delayed).
- Sucrose. Contains 3g 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 162.4mg propylene glycol per 5ml spoonful. If your child is less than 5 years old, talk to your doctor or pharmacist before giving them this medicine, in particular if they use other medicines that contain propylene glycol or alcohol. 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.

3. How to use Paracetamol Oral Suspension

Always give 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 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 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 give

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
Pain and other causes of fever - 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">■ Do not give to babies less than 2 months of age■ Leave at least 4 hours between doses■ 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.	

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">■ 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		

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

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

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 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 your child has 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 your child gets any of the following side effects, stop giving 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. Symptoms may include: skin reddening, blisters, rash. If skin reactions occur or existing skin symptoms worsen, stop use and seek medical help right away.

If paracetamol is taken for a long time (several months or more), 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 but liver function tests may be affected.

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 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.

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:

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This leaflet was last revised in 10/2022.