



PATIENT INFORMATION LEAFLET
PARACETAMOL 250 mg/5 ml ORAL SUSPENSION
Paracetamol 250 mg/5 ml

Read all of this leaflet carefully because it contains important information for you and your child.

This medicine is available without prescription; however, you still need to give Paracetamol 250 mg/5 ml Oral Suspension 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 see a doctor if your child's symptoms worsen or do not improve after 3 days.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Paracetamol Oral Suspension is and what it is used for
2. Before you give Paracetamol Oral Suspension to your child
3. How to give Paracetamol Oral Suspension to your child
4. Possible side effects
5. How to store Paracetamol Oral Suspension
6. Further information

1. WHAT PARACETAMOL ORAL SUSPENSION IS AND WHAT IT IS USED FOR

Paracetamol 250 mg/5 ml Oral Suspension ("Paracetamol Oral Suspension") contains paracetamol to relieve pain and reduce high temperatures. Paracetamol Oral Suspension can be used in children and adults for the treatment of mild or moderate pain and feverishness associated with teething, toothache, headache, colds and flu. It is suitable for adults who have difficulty swallowing tablets.

2. BEFORE YOU GIVE PARACETAMOL ORAL SUSPENSION TO YOUR CHILD

DO NOT give Paracetamol Oral Suspension if your child is taking any other paracetamol-containing products, other flu, cold, cough or decongestant products, or alcohol.

DO NOT give Paracetamol Oral Suspension to your child if he/she:

- is allergic (hypersensitive) to paracetamol, or any of the other ingredients of Paracetamol Oral Suspension (see Section 6 and end of Section 2).
- has kidney or liver problems

If you are not sure about any of the above, please consult your doctor.

Take special care with Paracetamol Oral Suspension

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

During treatment with Paracetamol, 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).

Taking other medicines

Tell your doctor or pharmacist if your child is taking, or has recently taken, any other medicine, even those obtained without a prescription, but especially medicines which:

- are to treat 'flu' or a cold, containing paracetamol and/or a decongestant
- thin the blood (e.g. warfarin)
- control nausea and vomiting (e.g. domperidone or metoclopramide)
- reduce levels of cholesterol and other fats in the blood (e.g. colestyramine)
- treat epilepsy (e.g. anti-convulsants)
- have been prescribed by your doctor to improve sleep (e.g. barbiturates), or for anxiety or depression (e.g. tricyclic antidepressants)
- are used to prevent pregnancy (e.g. oral steroidal contraceptives)
- contain flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

The effects of alcohol may be increased whilst taking Paracetamol Oral Suspension

Avoid alcohol when taking this medicine.

Pregnancy and breast-feeding

If necessary, Paracetamol Oral Suspension can be used during pregnancy. Ask your doctor or pharmacist for advice before taking any medicines during pregnancy or breast-feeding. 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.

Driving and using machines

Paracetamol Oral Suspension is not expected to affect your ability to drive or operate machinery.

Important information about some of the ingredients of Paracetamol Oral Suspension

Paracetamol Oral Suspension contains:

- **Ethanol:** This medicinal product contains up to 0.15 g per 5 ml dose of ethanol (alcohol), equivalent to 3.6 ml beer or 1.5 ml wine per 5 ml dose. Harmful for those suffering from alcoholism. To be taken into account in pregnant or breast-feeding women, children and high-risk groups such as patients with liver disease, or epilepsy.
- **Liquid maltitol (E965):** if your child has an intolerance to some sugars, contact your doctor before giving this medicine.

3. HOW TO GIVE PARACETAMOL ORAL SUSPENSION TO YOUR CHILD

Check the table overleaf to see how much of the medicine to use

- For oral use only
- It is important to **shake the bottle** for at least 10 seconds before use
- Never give more medicine than shown in the table

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- Do not overfill the spoon
- Always use the spoon supplied with the pack
- Do not give anything else containing paracetamol while giving this medicine

Child's Age	How Much	How often (in 24 hours)
6 - 8 years	One 5 ml spoonful (large end)	4 times
8 - 10 years	One 5 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
<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 your child does not get better, talk to your doctor • Do not give to children under the age of 6 years. 		

Children aged 12-16 years: Two - three 5 ml spoonfuls (large end) up to 4 times a day

Adults and children over 16 years: Two - four 5 ml spoonfuls (large end) up to 4 times a day.

If your child takes more of this medicine than they 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 can cause delayed, serious liver damage.

If you forget to give this medicine:

If you miss a dose give it as soon as you remember and take any remaining doses for that day at evenly spaced times. Do not take a double dose to make up for the missed dose.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Paracetamol Oral Suspension can cause side effects although not everybody gets them.

You or your child may notice the following:

- **rash, itchy skin, swelling of the lips, eyes, tongue, or difficulty in breathing, which may be signs of an allergic reaction. STOP giving Paracetamol Oral Suspension to your child immediately.**
- blood disorders

Very rare cases of serious skin reactions have been reported.

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)".

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. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE PARACETAMOL ORAL SUSPENSION

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

Do not store above 25°C. Store in the original container. Keep the container in the outer carton.

Do not use this medicine after the expiry date which is stated on the label and/or carton. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Paracetamol Oral Suspension contains

Each 5 ml of Paracetamol Oral Suspension contains:

- The **active ingredient**: paracetamol 250 mg.
- The **other ingredients** are: ethanol, sorbitan monooleate, glycerol (E422), microcrystalline cellulose and carmellose sodium, liquid maltitol (E965), saccharin sodium (E954), xanthan gum, orange flavour, sodium benzoate (E211), citric acid monohydrate, polysorbate 80 and purified water (see end of Section 2 for further information).

What Paracetamol Oral Suspension looks like and contents of the pack:

Paracetamol Oral Suspension is a cream to brown oral suspension with orange odour and taste presented in 70 ml, 100 ml, 150 ml and 200 ml amber glass bottles with pilfer-proof screw caps. A 2.5 ml/5 ml measuring spoon is provided. This medicinal product is a colour free and sugar free product.

Marketing Authorisation Holder:

Pinewood Laboratories Limited, Ballymacarbry, Clonmel, Co. Tipperary, Ireland.

Product Licence Number: PL 04917/0029

Manufacturers:

Pinewood Laboratories Limited, Ballymacarbry, Clonmel, Co. Tipperary, Ireland or
CP Pharmaceuticals Ltd., Ash Road North, Wrexham, LL13 9UF.

Date of revision: January 2025