



PATIENT INFORMATION LEAFLET
PARACETAMOL 120 mg/5 ml ORAL SUSPENSION
Paracetamol 120 mg/5 ml

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4
- You must talk to your doctor if you do not feel better or if you feel worse after 3 days.

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 120 mg/5 ml Oral Suspension ("Paracetamol Oral Suspension") contains paracetamol to relieve pain and reduce high temperatures. Paracetamol Oral Suspension can be used in babies and children for the treatment of pain and feverishness associated with teething, toothache, headache, colds and flu. It can also be used in babies who develop fever after vaccination.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE PARACETAMOL ORAL SUSPENSION

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

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.

Warnings and precautions

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).

Other medicines and Paracetamol Oral Suspension

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. cholestyramine)
- 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).
- 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 while taking this medicine.

Pregnancy and breast-feeding

This medicine is intended for use in children.

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

This medicine is intended for use in children. However, it should be noted that Paracetamol Oral Suspension is not expected to affect ability to drive or operate machinery.

Important information about some of the ingredients of Paracetamol Oral Suspension

Paracetamol Suspension contains:

- **Ethanol:** This medicinal product contains small quantities of ethanol (alcohol), less than 100 mg per 5 ml. (It contains up to 0.08 g of ethanol (alcohol) per 5 ml dose, equivalent to less than 2 ml beer or 1 ml wine per 5 ml dose).
- **Liquid Maltitol Syrup (E965):** if your child has an intolerance to some sugars including fructose, contact your doctor before giving this medicine.

3. HOW TO USE PARACETAMOL ORAL SUSPENSION

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

- For oral use only
- Never give more medicine than shown in the table
- Do not overfill the spoon
- Always use the spoon supplied with the pack
- Do not give anything else containing paracetamol while giving this medicine

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For the relief of fever after vaccination at 2, 3 and 4 months

2.5 ml. This dose may be given up to 4 times a day 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.

Children aged 3 months - 6 years:

Child's Age	How Much	How often (in 24 hours)
3 - 6 months	2.5 ml	4 times
6 - 24 months	5 ml	4 times
2 - 4 years	7.5 ml (5 ml + 2.5 ml)	4 times
4 - 6 years	10 ml (5 ml + 5 ml)	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 It is important to shake the bottle for at least 10 seconds before use.		

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. CONTENTS OF THE PACK AND OTHER INFORMATION**What Paracetamol Oral Suspension contains**

Each 5 ml of Paracetamol Oral Suspension contains:

- The **active ingredient**: paracetamol 120 mg.
- The **other ingredients** are: ethanol, sorbitan monooleate, glycerol (E422), magnesium aluminium silicate, liquid maltitol syrup (E965), saccharin sodium (E954), xanthan gum, cherry 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 cherry 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 04917/0028

Manufacturers:

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

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