

PATIENT INFORMATION LEAFLET
PARACETAMOL 120 mg/5 ml ORAL SUSPENSION
Paracetamol 120 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 120 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.
- Do not give your child this medicine for more than 3 days without speaking to your doctor.
- If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Paracetamol Suspension is and what it is used for
2. Before you give 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. Further information

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

Paracetamol 120 mg/5 ml Oral Suspension ("Paracetamol Suspension") contains paracetamol to relieve pain and reduce high temperatures. Paracetamol 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. BEFORE YOU GIVE PARACETAMOL SUSPENSION TO YOUR CHILD

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

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

- is allergic (hypersensitive) to paracetamol, or any of the other ingredients of Paracetamol Suspension (*see Section 6 and end of Section 2*)
- weighs less than 4 kg
- was born early before 37 weeks
- is less than 2 months old.

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

Take special care with Paracetamol Suspension if

- you do not get better, talk to your doctor
- your child has serious kidney or liver problems
- your child has an intolerance to some sugars.

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. Do NOT give with other paracetamol products.
- 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)
- contain flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

If **adults** take this medicine the following additional warnings apply, 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.

The effects of alcohol may be increased whilst taking Paracetamol Suspension. Avoid alcohol when taking this medicine.

Pregnancy and breast-feeding

This medicine is intended for use in children. If necessary, Paracetamol 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 Suspension is not expected to affect ability to drive or operate machinery.

Important information about some of the ingredients of Paracetamol 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, contact your doctor before giving this medicine.

3. HOW TO GIVE PARACETAMOL SUSPENSION TO YOUR CHILD

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

Consult a pharmacist or other healthcare professional before use in children under 2 months.

23LF02156PW

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.

Age 2-3 months	Dose
Pain and other causes of fever - if your baby weighs over 4 kg and was born after 37 weeks	2.5 ml If necessary, after 4-6 hours, give a second 2.5 ml dose
<ul style="list-style-type: none"> Do not give to babies less than 2 months of age 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 Leave at least 4 hours between doses 	

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 		

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:

Give the next dose when needed provided that the last dose was given at least 4 hours ago. Do not take a double dose to make up for the missed dose.

4. POSSIBLE SIDE EFFECTS

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

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

- allergic reactions** including swelling of face, tongue or throat, difficulty swallowing, unexplained wheezing, shortness of breath which may be accompanied by skin rash or hives.
- becoming unusually tired, unexpected bruising or bleeding and getting more infections (such as colds) than usual.

These are rare effects in people taking paracetamol. Very rare cases of serious skin reactions have been reported.

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

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.

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 SUSPENSION

Keep all medicines out of 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 Suspension contains

Each 5 ml of Paracetamol 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 Suspension looks like and contents of the pack:

Paracetamol Suspension is a cream to brown oral suspension with cherry odour and taste presented in 70 ml and 100 ml amber glass bottles with tamper evident child-resistant caps. A 2.5 ml/5 ml measuring spoon is provided. This medicinal product is a colour free and sugar free product. Do not use this product if the tamper evident seal of the cap has been broken or damaged.

Marketing Authorisation Holder:

Pinewood Laboratories Limited, Ballymacarbry, Clonmel, Co. Tipperary, Ireland.
Product Licence Number: PL 04917/0083

Manufacturers:

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

Date of revision: January 2025