

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 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
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6. Further information

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

Paracetamol 250 mg/5 ml Oral Suspension ("Paracetamol Suspension") contains paracetamol to relieve pain and reduce high temperatures. Paracetamol Suspension can be used in children over 6 years and adults for the treatment of mild or moderate pain and feverishness associated with toothache, headache, earache, sore throat, post immunisation fever, colds and flu and other aches and pains.

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, or alcohol.

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).
- has kidney or liver problems.
- has an intolerance to some sugars.

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

Take special care with Paracetamol Suspension

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

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)
- are used to prevent pregnancy (e.g. oral steroid contraceptives)
- contain 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.

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 and fever.

The effects of alcohol may be increased whilst taking Paracetamol Suspension

Avoid alcohol when taking this medicine.

Pregnancy and breast-feeding

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

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

Important information about some of the ingredients of Paracetamol Suspension

Paracetamol 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.
- **Hydrogenated glucose syrup (E965):** If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. May have a mild laxative effect. Each 5 ml spoonful of this product contains 3.93 g of hydrogenated glucose syrup. Calorific value 2.3 kcal/g hydrogenated glucose syrup.

3. HOW TO GIVE PARACETAMOL 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
- Do not overfill the spoon
- Always use the spoon supplied with the pack
- Do not give anything else containing paracetamol while giving this medicine
- For short term use only.

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

- 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.

Speak to your doctor:

- If your child needs more than the doses shown in the table, or if fever doesn't go away within 3 days speak to your doctor straight away.
- If you are not sure of the cause of your child's illness or if it is accompanied by a rash, breathing difficulties, diarrhoea or excessive tiredness or lethargy, speak to your doctor straight away. Do not give this medicine until you get medical advice.

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** give 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 the 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 very rare side effects that may affect 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: This medicine is not intended for 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.

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 250 mg.
- The **other ingredients** are: ethanol, sorbitan monooleate, glycerol (E422), microcrystalline cellulose and carmellose sodium, hydrogenated glucose syrup (E965), saccharin sodium (E954), xanthan gum, strawberry 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 strawberry odour and taste presented in 70 ml and 80 ml amber glass bottles with a child resistant cap. 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, Ballymacarby, Clonmel, Co. Tipperary, Ireland.

Product Licence Number: PL 04917/0081

Manufacturers:

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

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