

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.
- 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 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 mild or moderate 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, 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 a rare hereditary problem of fructose intolerance.

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.

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).
- 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 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 amounts of ethanol (alcohol) less than 100 mg per dose. (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).
- **Hydrogenated glucose syrup (E965):** if your child has an intolerance to some sugars, contact your doctor before giving this medicine.
- **Amaranth (E123)** (colouring): may cause allergic reactions.

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

Babies over 2 months of age

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

- 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.

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

- 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:

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 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 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 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, hydrogenated glucose syrup (E965), saccharin sodium (E954), xanthan gum, amaranth (E123), 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 pink suspension with cherry odour and taste presented in either:

- 70 ml, 100 ml, 150 ml and 200 ml amber glass bottles with tamper evident and child resistant cap. A 2.5 ml/5 ml measuring spoon is provided.
- 500 ml, 1 litre and 2 litre amber glass bottles with pilfer-proof screw caps or in 500 ml, 1 litre and 2 litre HDPE bottles with tamper evident and child resistant cap.

Marketing Authorisation Holder:

Pinewood Laboratories Limited, Ballymacarby, Clonmel, Co. Tipperary, Ireland.
Product Licence Number: PL 04917/0009

Manufacturers:

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