

PATIENT INFORMATION LEAFLET
SIX PLUS PARAPAED PARACETAMOL ORAL SUSPENSION 250 mg/5 ml
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 Six Plus Parapaed Paracetamol Oral Suspension 250 mg/5 ml 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

Six Plus Parapaed Paracetamol Oral Suspension 250 mg/5 ml ("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 teething, toothache, headache, colds and flu. It is suitable for diabetics and adults who have difficulty swallowing tablets or who are sensitive to Ibuprofen or Aspirin.

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*).

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

Take special care with Paracetamol Suspension

- if you have kidney or liver problems
- if you suffer from alcohol dependence
- as prolonged use except under medical supervision can be harmful.

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. 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 following information is included in case an adult is taking this product:

- You can use Paracetamol Suspension while you are taking oral contraceptives ('the pill') but it may not be as effective 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.
- **Liquid Maltitol (E965):** if you or your child have an intolerance to some sugars, contact your doctor before giving this medicine. May have a mild laxative effect. Calorific value 2.3 kcal/g maltitol.

3. HOW TO GIVE PARACETAMOL SUSPENSION TO YOUR CHILD

Check the table below 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 with any other paracetamol-containing products

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 symptoms persist, please consult 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.

DO NOT EXCEED THE STATED DOSE

If your child takes more of this medicine than they should:

If your child takes too much of this medicine, or if they take other paracetamol-containing medicines by mistake, you should take them to your doctor or hospital **immediately, even if they feel well**, because of the risk of 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:

Uncommon (>1/1000, <1/100)

- kidney problems

Very Rare (<1/10,000)

- 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
- liver disorders

- pancreas 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 HPRA Pharmacovigilance, Website: www.hpra.ie. 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 to protect from moisture/light. 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, 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 Suspension looks like and contents of the pack:

Paracetamol Suspension is a cream/white to brown suspension with an orange flavour and odour presented in 70 ml, 100 ml, 140 ml, 150 ml and 200 ml amber glass bottles with pilfer-proof screw caps. A 2.5 ml/5 ml measuring spoon is provided.

Dispensing packs of 500 ml, 1 Litre and 2 Litre are only available to pharmacists. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

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

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