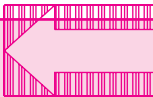


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PATIENT INFORMATION LEAFLET JUNIOR PARAPAEDED PARACETAMOL ORAL SUSPENSION 120 mg/5 ml Paracetamol 120 mg/5 ml

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 Junior Parapaed Paracetamol Oral Suspension 120 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
5. How to store Paracetamol Suspension
6. Further information

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

Junior Parapaed Paracetamol Oral Suspension 120 mg/5 ml ("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*).

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.

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).

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

This medicine is intended for use in children.

Ask your doctor or pharmacist for advice before taking any medicines during pregnancy or breast-feeding.

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:** Each 5 ml dose contains 75 mg of Ethanol (alcohol) equivalent to 1.8 ml beer and 0.7 ml wine. 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.
- **Maltitol Liquid (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. Calorific value 2.3 kcal/g maltitol. Each 5 ml contains 4.25 g of maltitol liquid.
- **Amaranth (E123)** (colouring): may cause allergic reactions.

3. HOW TO GIVE PARACETAMOL SUSPENSION TO YOUR CHILD

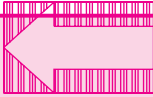
Check the tables overleaf to see how much of the medicine to use

- 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

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- Do not overfill the spoon
- Always use the spoon supplied with the pack
- Do not give with any other paracetamol-containing products

| Age: 2-3 months | Dose |
|--|---|
| For post-vaccination fever for babies aged between 2 - 3 months if your baby weighs over 4 kg and was born after 37 weeks | One 2.5 ml spoonful (small end) 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.• Leave at least 4 hours between doses.• Do not give more than 2 doses unless your doctor or pharmacist has advised otherwise. 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 | One 2.5 ml spoonful (small end) | 4 times |
| 6 - 24 months | One 5 ml spoonful (large end) | 4 times |
| 2 - 4 years | One 5 ml spoonful (large end) and one 2.5 ml spoonful (small end) | 4 times |
| 4 - 6 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 | | |

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.

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, Earlsfort Terrace, IRL - Dublin 2; Tel:

+353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; e-mail: medsafety@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 the sight and reach of children. Do not store above 25°C. Store in the original container to protect from moisture/light. 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 (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 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, Ballymacarby, Clonmel, Co. Tipperary, Ireland.

Product Licence Number: PA 281/2/1

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