



PARACETAMOL
Oral Solution 120mg/5ml

Please read all of this leaflet carefully before you take this medicine or give it to a child.

- Keep this leaflet. You may need to read it again
- If you need more information or advice, please ask your doctor or pharmacist
- You must contact your doctor if your child's symptoms get worse or do not improve
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Paralink Paracetamol Oral Solution is and what it is used for
2. Before you give Paralink Paracetamol Oral Solution to your child
3. How to give Paralink Paracetamol Oral Solution
4. Possible side effects
5. How to store Paralink Paracetamol Oral Solution
6. Further information.

1. What Paralink Paracetamol Oral Solution is and what it is used for

Paralink Paracetamol Oral Solution 120mg/5ml is a strawberry flavoured, colourless, sugar-free solution which contains paracetamol as the active ingredient.

Paralink Paracetamol Oral Solution 120mg/5ml is used for the treatment of mild to moderate pain and to relieve symptoms of colds and flu. It is also used to lower a high temperature (fever), including fever following a child's immunisation.

It is suitable for children aged from 2 months.

2. Before you give Paralink Paracetamol Oral Solution to your child

DO NOT GIVE Paralink Paracetamol Oral Solution to your child if:

- Your child is allergic to paracetamol or to any of the other ingredients listed (see ingredients list in section 6)
- Your child has a 'hereditary fructose intolerance', a condition where some sugars can't be broken down
- Your child is taking any other paracetamol containing medicines.

TAKE SPECIAL CARE, speak to your doctor or pharmacist before using Paralink Paracetamol Oral Solution if:

- Your child has kidney or liver problems.

Taking other medicines:

Paralink Paracetamol Oral Solution can affect some other medicines your child may be taking. Always tell your doctor or pharmacist about all the medicines you are giving to your child. This means medicines you have bought yourself as well as those you have on prescription from your doctor.

Make sure your pharmacist knows if your child is taking or has recently taken any other medicines including:

- metoclopramide and domperidone used to treat feeling and being sick (nausea and vomiting)
- colestyramine, used to treat high cholesterol
- drugs that thin the blood (anticoagulants) such as warfarin
- drugs to treat epilepsy (anticonvulsants)
- oral contraceptives (the 'pill')
- other paracetamol containing medicines.

Other special warnings:

- Contains Paracetamol. Do not give with any other paracetamol containing products
- Immediate medical advice should be sought in the event of an overdose, because of the risk of irreversible liver damage
- Prolonged use, without medical supervision, can be harmful
- If symptoms persist, consult your doctor
- Do not exceed the stated dose.

If adults take this medicine:

The following warnings also apply if you are an adult taking this medicine:

- If you drink large amounts of alcohol, you may be more prone to the side effects of paracetamol, and the dangerous effects of a paracetamol overdose
- Ask your doctor or pharmacist for advice before taking this medicine if you are pregnant, think you might be pregnant or are breast feeding
- If necessary, Paralink Paracetamol Oral Solution can be used during pregnancy. 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 or midwife if the pain and/or fever are not reduced or if you need to take the medicine more often
- You can use this medicine while you are taking oral contraceptives ('the pill'), but it may not work as well on your pain or fever.

Important information about some of the ingredients

- Contains propylene glycol which may cause alcohol-like effects
- Contains sorbitol (E420) and maltitol (E965). If your child has an intolerance to some sugars, contact your doctor before giving this medicine
- Sorbitol may have a mild laxative effect; the calorific value of sorbitol is 2.6Kcal/g
- Contains the preservatives ethyl (E214), propyl (E216) and methyl (E218) parahydroxybenzoate which may cause allergic reactions which could be possibly delayed.

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3. How to give Paralink Paracetamol Oral Solution

Check the tables below to see how much of the medicine to use.

- For oral use only
- Never give more medicine than shown in the table
- Always use the syringe supplied with the pack
- Do not give with any other paracetamol-containing products.

Age	Dose	
For post-vaccination fever for babies aged between 2 – 3 months	2.5ml If necessary, after 4 – 6 hours, give a second 2.5ml 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• Leave at least 4 hours between doses• If further doses are needed, talk to your doctor or pharmacist		
Child's Age	How Much	How often (in 24 hours)
3 – 6 months	2.5ml	4 times
6 – 24 months	5ml	4 times
2 – 4 years	7.5ml	4 times
4 – 6 years	10ml	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 anyone has taken too much Paralink Paracetamol Oral Solution:

Immediate medical advice should be sought in the event of an overdose, because of the risk of irreversible liver damage.

Take your medicine or the pack with you so that the doctor knows what you have taken.

If you forget to give a dose of Paralink Paracetamol Oral Solution:

If you have missed a dose, don't worry; give the next dose when needed, provided that the last dose was given at least 4 hours ago. **Do not give a double dose (2 doses at the same time) to make up for a missed dose.**

If you are not sure how to give this medicine and would like further information, then please contact your doctor or pharmacist as soon as possible.

4. Possible side effects

Like all medicines Paralink Paracetamol Oral Solution may sometimes cause side effects, although, these don't affect everyone and are usually mild.

STOP giving Paralink Paracetamol Oral Solution and seek immediate medical help if you notice the following rare but serious symptoms:

- Severe allergic (hypersensitivity) reactions including skin rash. Very rare cases of serious skin reactions have been reported
- Unexpected bruising or bleeding, sore throat, infections or fever, pale skin and weakness or breathlessness. These can be a sign of severe blood disorders (thrombocytopenia and agranulocytosis).

Other side effects may include:

- Liver problems which may cause yellowing of the skin or whites of the eyes (jaundice)
- Kidney problems

Reporting of side effects

If your child gets 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 Paralink Paracetamol Oral Solution

Keep out of the reach and sight of children.

Do not use this medicine after the expiry date (EXP) shown on the carton or label. The expiry date refers to the last day of the month. Store below 25°C. Do not refrigerate. Store in the original container in order to protect from light. 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

Ingredients

Each 5ml of Paralink Paracetamol Oral Solution contains 120mg of the active ingredient paracetamol. The other ingredients are sorbitol (E420), liquid maltitol (E965), propylene glycol, macrogol 4000, glycerol, potassium sorbate, ethyl parahydroxybenzoate (E214), methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), citric acid, neohesperidin-dihydrochalcone, saccharin sodium, strawberry flavour and purified water.

What the medicine looks like

Paralink Paracetamol Oral Solution is a colourless, sugar free oral solution with a strawberry odour and taste. This medicine is available in pack sizes of 60ml and 100ml. Not all pack sizes may be available.

PA holder and manufacturer

Rice Steele Manufacturing Ltd, Cookstown Industrial Estate, Tallaght, Dublin 24, Ireland.

Product authorisation number

PA 95/7/1

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