

Package Leaflet: Information for the patient



PARACETAMOL

Oral Solution 120mg/5ml

Read all of this leaflet carefully before you start taking this medicine, or give it to a child, because it contains important information for you.

- Keep this leaflet. You may need to read it again
- Ask your pharmacist if you need more information or advice.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See Section 4.
- You must talk to a doctor if your child does not feel better or feels worse after 3 days.

What is in this leaflet:

1. What Paralink Paracetamol Oral Solution is and what it is used for
2. What you need to know 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. Contents of the pack and other 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. What you need to know 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.

Warnings and precautions

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

- Your child has kidney or liver problems.

During treatment with Paralink Paracetamol Oral Solution, tell your doctor straight away if:

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).

Other medicines and Paralink Paracetamol Oral Solution:

Paralink Paracetamol Oral Solution can affect some other medicines your child may be taking. 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.
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment (see section 2).

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.

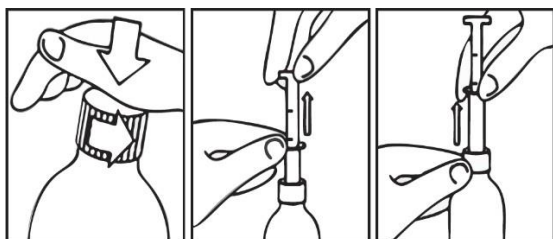
3. How to give Paralink Paracetamol Oral Solution

Always give this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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
- Do not give with any other paracetamol-containing products.
- Always use the syringe supplied with the pack

Instructions for use:



- Open bottle cap by twisting it and pushing downwards. Place syringe into bottle with the white syringe plunger closed.
- Pull the plunger towards you until the 2.5ml or the 5ml marking is level with the outer clear plastic rim.
- Press the plunger gently, into the child's mouth, to release a trickle. Do not squirt it out quickly. The child should be allowed time to swallow the medicine.
- The syringe should be washed, by hand, and air-dried after use.

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 you take or use more Paralink Paracetamol Oral Solution than you should:

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 forgotten dose.**

If you have any further questions on the use of this medicines, ask your doctor, pharmacist or nurse.

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4. Possible side effects

Like all medicines Paralink Paracetamol Oral Solution can cause side effects, although not everybody gets them 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

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 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 this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date (EXP) which is stated 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 to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Paralink Paracetamol Oral Solution contains

The active ingredient is paracetamol. Each 5mL contains 120mg of 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 Paralink Paracetamol Oral Solution looks like and contents of the pack

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.

Marketing Authorisation Holder Phoenix Healthcare Limited,

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Manufacturer

Phoenix Healthcare Limited,

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Product authorisation number

PA1721/006/001

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