

PATIENT INFORMATION LEAFLET

Paralink 180mg Suppositories Paracetamol

Please read all of this leaflet carefully before you give this medicine 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 Suppositories are and what they are used for
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1. What Paralink Suppositories are and what they are used for

Paralink Suppositories contain the active ingredient paracetamol. Paracetamol is a pain killer and can reduce high temperatures (fever). It provides effective relief of fever and pain associated with colds and flu, headaches, rheumatism and teething. Paralink Suppositories may also be used after an operation.

Paralink 180mg Suppositories can be used in children from 3 months to 6 years of age. It is a smooth, white, tapered cylindrical medicine which is inserted into the back passage (rectum) and is recommended for use in children who may find it difficult to take paracetamol by mouth.

2. Before you give Paralink Suppositories

Do not give Paralink 180mg Suppositories to your child if:

- Your child is allergic to paracetamol or to any of the other ingredients listed
- (see ingredients section)
- Your child is under 3 months of age
- Your child is taking any other paracetamol containing products.

You must be especially careful. Speak to your doctor or pharmacist before giving Paralink Suppositories if:

- Your child has kidney or liver problems.

Other special warnings:

- Contains paracetamol. Do not give with any other paracetamol containing products
- Immediate medical advice should be sought in the event of overdose, because of the risk of irreversible liver damage

- Do not exceed the stated dose
- If symptoms persist, consult your doctor
- Using Paralink 180mg Suppositories for a long period of time without medical supervision can be harmful to your child. **Do not give this medicine to your child for longer than 3 days without speaking to your doctor or pharmacist first.**

During treatment with Paralink 180mg Suppositories, 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).

If any of the above applies, please talk to a doctor or pharmacist before giving this medicine.

If adults use this medicine:

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

- If you drink large amounts of alcohol and/or have alcoholic liver disease, 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 180mg Suppositories 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
- Paralink Suppositories do not affect your ability to drive and operate machinery.

Taking other medicines:

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:

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

Do not give your child alcohol, or any medicines containing alcohol, while they are taking this medicine.

Please inform your doctor or pharmacist if you are taking:

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).

3. How to give Paralink 180mg Suppositories

Read this section carefully to see how many Paralink 180mg Suppositories to give.

- **Do not** give more of this medicine than shown overleaf
- **Do not** give Paralink 180mg Suppositories to children under 3 months of age
- Paralink Suppositories are for rectal use (back passage) only.

The usual dose is as follows:

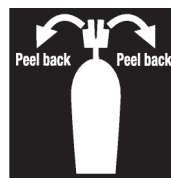
Age	Dose
3 months – 1 year (5 – 10kg)	½ Suppository
1 – 3 years (10 – 15kg)	1 Suppository
3 – 6 years (15 – 20kg)	1 ½ Suppositories

- **Leave at least 6 hours between doses or as directed by your doctor**
- **Do not give more than 4 doses in any 24 hours**
- **Do not give this medicine to your child for longer than 3 days without speaking to your doctor or pharmacist first**
- **Do not exceed the stated dose.**

Ask your doctor or pharmacist for advice if you are not sure how many suppositories to give to your child.

Instructions for use:

1. If your child needs to empty their bowels this should be done before inserting the suppository
2. You may find it easier to give your child the suppository if they are lying on their side or on their front. Do whatever is more comfortable for your child
3. Wash your hands
4. To remove a suppository, tear one from the strip along the perforations then peel it from the plastic wrapping by holding the two halves of the wrapping at the tip of the suppository and gently pulling them apart



5. If necessary moisten the tip, then gently push the suppository into your child's back passage (rectum) with the pointed end first
6. Wash your hands
7. Try to keep your child still for a minute or two
8. The process should be repeated if your child needs another suppository.

If anyone has given too many Paralink Suppositories:

Do not give more suppositories than stated in section 3, 'How to give Paralink Suppositories'.

Immediate medical advice should be sought in the event of an overdose, even if the child seems well, because of the risk of delayed, serious liver damage.

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

If you forget to give Paralink Suppositories to your child:

If you forget to give your child a dose of Paralink Suppositories, don't worry; give it to them as soon as you remember provided that the last dose was given at least 6 hours ago. **Do not give a double dose (2 doses at the same time) to make up for a missed dose.**

If your child's symptoms do not go away or if you are not sure how to give this medicine then please contact your doctor or pharmacist as soon as possible.

4. Possible side effects

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

Stop giving Paralink Suppositories and seek immediate medical help if you notice the following rare but serious symptoms:

- 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 can 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 HPRAs Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2

Tel: +353 I 6764971; Fax: +353 I 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 180mg suppositories

Keep out of the reach and sight of children.

Store below 25°C.

Do not use this medicine after the expiry date (EXP) shown on the carton or plastic strip. The expiry date refers to the last day of the month. If you have any medicines that are out of date, return them to your pharmacist for safe disposal.

6. Further Information

Ingredients

Each Paralink 180mg Suppository contains 180mg of the active ingredient paracetamol. The other ingredients are fat and macrogol stearate.

What the medicine looks like

Paralink Suppositories are white, tapered cylindrical suppositories packed in strips of five, with two strips (ten suppositories) per carton.

Product Authorisation Holder

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If you would like this leaflet in a different format, please contact the product authorisation holder at the above address.