Information for the user

FOR RECTAL ADMINISTRATION ONLY

Paralink 250mg Suppositories

Read all of this leaflet carefully before you give this medicine to your child because it contains important information for you and your child. This medicine is available without prescription. However, you still need to use it 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.
- If your child gets any side effects talk to your child's 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 if your child feels worse.**

What is in this leaflet:

1. What Paralink Suppositories are and what are they used for
2. What you need to know before you give Paralink Suppositories to your child
3. How to use Paralink Suppositories
4. Possible side effects
5. How to store Paralink Suppositories
6. Contents of the pack and other information

1. What Paralink Suppositories are and what they are used for

Paralink Suppositories contain a medicine called paracetamol. Paracetamol is one of a group of medicines called pain-killers (analgesics). A suppository is a small, torpedo-shaped medicine which is inserted into the back passage (rectum).Paralink Suppositories are used to treat pain and high temperature (fever) in children from the age of 6 years. They are used by children who find it difficult to take paracetamol as tablets or syrup.

2. What you need to know before you give Paralink Suppositories to your child

Do not give your child these suppositories if:

- They are allergic to paracetamol or the other main ingredient which is called "hard fat".

Warnings and Precautions

Talk to your child's doctor or pharmacist before using these suppositories:

- If your child has liver or kidney problems

During treatment with Paralink Suppositories, tell your doctor straight away:

If your child has severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or your child suffers from malnutrition, chronic alcoholism or if they 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 Suppositories
Please tell your child's doctor or pharmacist if your child is taking, has recently taken or might take, any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because the suppositories can affect the way some medicines work and some medicines can have an effect on Paralink Suppositories. In particular, tell your child's doctor or pharmacist if your child is taking any of the following:

- Other medicines that contain paracetamol - **do not give your child Paralink Suppositories at the same time**
- Barbiturates (a type of sedative)
- Medicines for epilepsy or fits (also called "anti-convulsants")
- Medicines such as warfarin for treating blood clots
- Do not give your child alcohol, or any medicines containing alcohol whilst they are being given these suppositories.
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called high anion gap metabolic acidosis) that must have urgent treatment (see Section 2)

3. How to use Paralink Suppositories

This medicine is for rectal use only.
If your child's doctor or pharmacist has told you how to use this medicine, do exactly as they have told you. Otherwise follow the instructions below. If you do not understand the instructions, or are not sure, ask the doctor or pharmacist.

How many Paralink Suppositories to give your child
Children aged 6 to 9 years (20 - 30kg) - one 250 mg suppository
Children aged 10 to 12 years (30 - 40kg) - one to two 250 mg suppositories

The dosage should be based on your child's age and weight.
These doses may be repeated up to a maximum of 4 times in 24 hours.
Suppositories should not be given more often than every 4 hours.

If you are not sure how many suppositories to give your child, don't guess, ask your child's doctor or a pharmacist. Do not give your child this medicine for more than 3 days, without speaking to your child's doctor.
Do not give your child more suppositories than stated above.

How to use Paralink Suppositories

1. Your child's bowels need to be empty when you give them this medicine. If your child needs to go to the toilet, make sure they do so before you give them the suppository.
2. You may find it easier to give your child the suppository if they are lying on their front or side. Do whichever is more comfortable for your child.
3. Wash your hands. Then peel the wrapping apart to remove the suppository. Do not break the suppository before use.
4. Gently push the suppository into your child's back passage, pointed end first. Then wash your hands.
5. Try to keep your child still for a minute or two.
6. If your child needs to be given another suppository remove another one from the wrapper. Then insert it into your child's back passage as before. Once again you should try to keep your child still for a minute or two. Then wash your hands.

If you forget to give Paralink Suppositories to your child

- If you forget to give your child a dose of Paralink Suppositories, give them as soon as you remember.
- However, if it is almost time for the next dose, skip the missed dose.
- **Do not give your child a double dose (two doses at the same time} next time, to make up for a forgotten dose.**

If you give more Paralink Suppositories to your child than you should

- Do not give your child more suppositories than stated in the section called "How many Paralink Suppositories to give your child"
- **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**

4. Possible side effects

Like all medicines, Paralink Suppositories can cause side effects, although not everybody gets them. The following side effects can happen with this medicine.

Common (may affect up to 1 in 10 people)

- Redness or soreness in or around the back passage.

Rare (may affect up to 1 in 1,000 people)

- Allergic reactions such as swelling of the face, lips, tongue or throat.
- Skin problems, such as a rash or itching.
- Blood problems. If these happen, your child may bruise or bleed more easily, get infection more easily, or get a high temperature (fever) and ulcers in the mouth and throat.
- Liver problems.

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)

If your child gets any of the side effects mentioned above or gets any side effects not mentioned in this leaflet, talk to your child's doctor or pharmacist.

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.
HPRA Pharmacovigilance
Website: www.hpra.ie

5. How to store Paralink Suppositories

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C and keep the blister strips in the outer carton.
- Do not use this medicine after the expiry date which is stated on the carton and blister. The expiry date refers to the last day of that month.
- Do not throw away any medicines via wastewater or household waste. These measures will help protect the environment. Ask your doctor or pharmacist how to throw away medicines, unless your child's doctor has told you to keep them.

6. Contents of the pack and other information

What Paralink Suppositories contain - The active substance is paracetamol. The other ingredients are hard fat, macrogol cetostearyl ether and glyceryl ricinoleate.

What Paralink Suppositories look like and the contents of the pack - A suppository is a small, torpedo shaped medicine which is inserted into the back passage (rectum). Each pack contains 10 white suppositories, each containing 250mg paracetamol.

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