

FOR RECTAL ADMINISTRATION ONLY

Paracetamol 125mg Suppositories

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 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.
- **You must contact your child's doctor if your child's symptoms get worse or do not improve.**
- If your child gets any side effects after being given this medicine, please tell a doctor or pharmacist.

In this leaflet:

- 1. What Paracetamol Suppositories are and what they are used for**
- 2. Before you give Paracetamol Suppositories to your child**
- 3. How to give Paracetamol Suppositories to your child**
- 4. Possible side effects**
- 5. How to store Paracetamol Suppositories**
- 6. Further information**

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

Paracetamol 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). Paracetamol Suppositories are used to treat pain and high temperature (fever) in babies and children from the age of 1 year. They are used by children who find it difficult to take paracetamol as tablets or syrup.

2. Before you give Paracetamol 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".

Take special care with Paracetamol Suppositories

Check with your doctor or pharmacist before using these suppositories if

- Your child has liver or kidney problems.

Taking other medicines

Please tell your child's doctor or pharmacist if your child is taking, or has recently taken, 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 Paracetamol 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 Paracetamol 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.

3. How to administer Paracetamol Suppositories to your child

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 Paracetamol Suppositories to give your child

1 to 3 years: One suppository

4 to 6 years: Two suppositories

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 Paracetamol 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 Paracetamol Suppositories to your child

- Give them as soon as you remember, then go on as before.
- 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 too many Paracetamol Suppositories to your child

- Do not give your child more suppositories than stated in the section called "How many Paracetamol 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, Paracetamol Suppositories can cause side effects, although not everybody gets them.

The following side effects can happen with this medicine.

Common (affects more than 1 in 100 people)

- Redness or soreness in or around the back passage.

Rare (affects less than 1 in 1,000 people)

- Allergic reactions.
- 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.

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.

5. How to store Paracetamol Suppositories

- Keep this medicine out of the reach and sight of children.
- Do not store above 25°C.
- Do not remove the suppositories from the blister until immediately before use.
- 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.
- Return any unused suppositories to the pharmacist, unless your child's doctor has told you to keep them.

6. Further Information

- What Paracetamol Suppositories contain – The active substance is paracetamol. The other ingredients are hard fat, macrogol cetostearyl ether and glyceryl ricinoleate.
- What Paracetamol 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 125mg paracetamol.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation is held by Phoenix Labs, Suite 12 Bunkilla Plaza, Bracetown Business Park, Clonee, Co. Meath, Ireland.

Paracetamol Suppositories are manufactured by PPF Hasco-Lek S.A., 51-131 Wrocław, Poland

This medicinal product is authorized in the member states of the EEA under the following names:

UK Paracetamol 250mg Suppositories / Paracetamol 500mg Suppositories

Ireland Paracetamol 250mg Suppositories / Paracetamol 500mg Suppositories

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