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PACKAGE LEAFLET: INFORMATION FOR THE USER

Paracetamol 125mg Suppositories

Paracetamol

Read all of this leaflet carefully before your child starts using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your child's doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your child's pharmacist if you need more information or advice.
- If your child gets any side effects, talk to a doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must contact a doctor if your child does not feel better or if your child feels worse after 3 days.
- The product is called Paracetamol 125mg Suppositories but will be referred to as Paracetamol Suppositories throughout this leaflet.

What is in this leaflet

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

1. WHAT PARACETAMOL SUPPOSITORIES ARE AND WHAT THEY ARE USED FOR

Paracetamol Suppositories contain a medicine called paracetamol. This belongs to 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 children from 1 to 5 years of age. They can be used in children who find it difficult to take paracetamol as tablets or syrup.

You must talk to a doctor if your child does not feel better or if your child feels worse after 3 days.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE PARACETAMOL SUPPOSITORIES

Do not give Paracetamol Suppositories to your child:

- if your child is allergic to paracetamol, soya, peanuts or any of the other ingredients of this medicine (listed in Section 6).

Warnings and precautions

Talk to a doctor or pharmacist before using Paracetamol Suppositories.

Take special care with the use of Paracetamol Suppositories and talk to your child's pharmacist or doctor if:

- your child has problems with their liver or kidneys.

Other medicines and Paracetamol Suppositories

Tell your child's doctor or pharmacist if your child is taking, has recently taken or might take any other medicines. This is because Paracetamol Suppositories can have an effect on the way some medicines work and some medicines can have an effect on how Paracetamol Suppositories work.

In particular tell your child's doctor or pharmacist if your child is taking any of the following:

- Other medicines containing paracetamol – **do not give your child Paracetamol Suppositories at the same time.**
- Medicines to treat nausea (feeling sick) and vomiting (being sick), such as metoclopramide and domperidone.
- Colestyramine, used to reduce the level of cholesterol (fat) in the blood.
- Medicines called anticoagulants, such as warfarin, used for treating blood clots or "thinning the blood".
- Medicines called anticonvulsants used for treating epilepsy or fits (e.g. phenytoin, carbamazepine).
- The antibiotic rifampicin.
- Flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment and which may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used.

3. HOW TO USE PARACETAMOL SUPPOSITORIES

This medicine is for rectal use only. Always use this medicine exactly as described in this leaflet or as your child's doctor or pharmacist have told you. Check with your child's doctor or pharmacist if you are not sure.

The recommended dose is:

Age	Number of suppositories	Minimum length of time between doses	Maximum number of suppositories in 24 hours
1 year (up to 10kg)	1	4 – 6 hours	4
Over 1 year to 5 years (10-20kg)	1 or 2	4 – 6 hours	4 - 8

Do not give your child more suppositories than stated above.

How to use the suppositories:

- 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 that they do it before you give them the suppository.
- It may be easier to give your child the suppository if they are lying on their front or side on a bed.
- Wash your hands. Then peel the wrapping apart to take out the suppository. Do not break the suppository before use.
- Gently push the suppository into your child's back passage with the pointed end first. To make it easier to give the suppository you may warm it slightly between your hands beforehand.
- Try to keep your child still for a minute or two and then wash your hands.
- If you need to give another suppository, then follow the above procedure again.

If you have given more Paracetamol Suppositories to your child than you should

- Talk to a doctor at once if your child takes too much of this medicine even if they seem well. This is because too much paracetamol can cause delayed, serious liver damage.

If you forget to give Paracetamol Suppositories to your child

Do not give a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medication, ask your child's doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop giving Paracetamol Suppositories to your child immediately and call your child's doctor if you notice your child has any signs of allergic reaction.

Signs of an allergic reaction include a rash, swallowing or breathing problems, swelling of the lips, face, throat or tongue. The following side effects can happen with this medicine.

Common side effects (affects more than 1 in 100 people taking this medicine):

- Redness or soreness in and around the back passage.

Rare side effects (affects less than 1 in 1000 people taking this medicine):

- Blood problems. If these happen, your child may bruise or bleed more easily than usual, be more susceptible to infections, or get a high temperature (fever) and ulcers in the mouth and throat.
- Liver problems. Symptoms may include jaundice (yellowing of the skin or whites of the eyes).

Reporting of side effects

If your child gets any side effects, talk to a doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly, via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE PARACETAMOL SUPPOSITORIES

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and on the blister strip. The expiry date refers to the last day of that month. Do not store over 30°C.

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 Paracetamol Suppositories contain

The active substance is paracetamol. Each suppository contains 125mg of paracetamol.

The other ingredients are hydrogenated fat and soyabean lecithin.

What Paracetamol Suppositories look like and contents of the pack

Cream coloured, torpedo shaped suppository, available in packs of 10 suppositories.

Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder: Amdeepcha Limited, 85 Yarmouth Road, Blofield, Norwich, Norfolk, NR13 4LQ, UK.

Manufacturer: Dr. Pflieger Arzneimittel GmbH, Dr. Robert Pflieger Strasse 12, Bamberg, D-96052, Germany.

This package leaflet was last revised in April 2022