

PACKAGE LEAFLET: INFORMATION FOR THE USER

Paracetamol Suppositories 120mg

Paracetamol

Read all of this leaflet carefully before you start giving your child this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, nurse or pharmacist.
- This medicine has been prescribed for your child. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

In this leaflet:

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

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

The active ingredient Paracetamol is a medicine with pain relieving properties.

Paracetamol Suppositories are used:

- for the relief of mild to moderate pain
- for the relief of a high temperature (fever)
- if you are unable to take Paracetamol orally e.g. after an operation or if you are feeling or being sick.

2. Before you use Paracetamol Suppositories

You should not give Paracetamol Suppositories to your child if:

- your child is allergic (hypersensitive) to Paracetamol or to any of the ingredients listed in section 6 of this leaflet

If this applies to your child please tell your doctor before taking this medicine.

Take special care with Paracetamol Suppositories if:

- your child suffers from severe liver or kidney problems

If your child's symptoms persist you should consult your doctor.

Do not use Paracetamol Suppositories with other medicines that contain Paracetamol.

Do not exceed the recommended dose.

During treatment with Paracetamol 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).

Taking other medicines

Please tell your doctor, nurse or pharmacist if your child is taking, or has recently taken, any other medicine including medicines obtained without prescription.

Please tell your doctor if your child is taking any of the following medicines:

- medicines used to thin your blood (anticoagulants) e.g. warfarin
- medicines used to stop you feeling or being sick such as metoclopramide and domperidone
- colestyramine, a medicine used to prevent coronary heart disease and diarrhoea caused by certain disorders

If you have any doubts as to whether Paracetamol Suppositories are suitable for your child please consult your doctor. 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).

Pregnancy and breast-feeding

If necessary, Paracetamol Suppositories 120mg 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.

3. How to use Paracetamol Suppositories

Always use Paracetamol Suppositories exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

1. If your child needs to empty their bowels this should be done before inserting the suppository.
2. Wash hands before opening individual packaging. If the suppository is too soft, it may be chilled in the refrigerator or under cold running water before unwrapping.
3. To remove a suppository, tear one from the strip along the perforations then peel it from the plastic wrapping by grasping the two halves of the wrapping at the tip of the suppository and pulling them gently apart. The tip should be moistened with a little cold water to aid insertion.



4. Using your index finger or middle finger, whichever you find easier, gently push the suppository into the rectum (back passage), making sure the rounded end of the suppository is inserted first.
5. The suppository should be inserted as far as possible, pushing the end of the suppository sideways to ensure contact with the wall of the bowel.

How much to use

The usual dose for children aged 1-5 years (around 10-18kg) is 1 or 2 suppositories every 4 to 6 hours up to a maximum of 4 doses in 24 hours.

The dose should be based on age and weight i.e. 1 year (10 kg)- (120mg) 1 suppository, 5 years (18 kg)- (240mg) 2 suppositories. You must not exceed the stated dose.

If you use more Paracetamol Suppositories than you should

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.

If these suppositories are swallowed contact your doctor or nearest casualty unit immediately taking the carton, any leftover suppositories and this leaflet with you.

4. Possible Side Effects

Like all medicines Paracetamol Suppositories can cause side effects, although not everybody gets them.

Side effects that may occur include:

- A skin rash. 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)”.

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 via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

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

5. How to Store Paracetamol Suppositories

Keep out of the reach and sight of children.

Do not use Paracetamol Suppositories after the expiry date on the carton label. The expiry date refers to the last day of that month.

Do not store above 25°C.

Do not use if the strip containing the suppositories is damaged.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further Information

What Paracetamol Suppositories contain

The active ingredient is Paracetamol 120mg

The other ingredients are Adeps solidus and Macrogol stearate

What Paracetamol Suppositories look like and contents of the pack:

Paracetamol Suppositories are smooth, white suppositories supplied in a plastic cavity in strips of 5. Each pack contains 10 suppositories.

Marketing Authorisation Holder

Phoenix Healthcare Limited

Suite 12, Bunkilla Plaza, Bracetown Business Park, Clonee, County Meath, Ireland

Manufacturer

Phoenix Healthcare Limited

Unit 31, 2nd Avenue, Cookstown Industrial Estate, Tallaght, Dublin 24, Ireland

Product Licence Number: PL 42727/0001

This leaflet was last approved in: March 2025