

Amdeepcha

Paraserts 250mg Suppositories

Leaflet

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PACKAGE LEAFLET: INFORMATION FOR THE USER Paraserts 250mg Suppositories

Paracetamol

Read all of this leaflet carefully before you give your child 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 talk to a doctor if your child does not feel better or if your child feels worse after 3 days.
- The product is called Paraserts 250mg Suppositories but will be referred to as Paraserts throughout this leaflet.

What is in this leaflet

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

1. WHAT PARASERTS ARE AND WHAT THEY ARE USED FOR

Paraserts 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). Paraserts are used to treat pain and high temperature (fever) in children from 6 to 12 years of age e.g. headache, toothache, earache, sore throat, and aches and pains associated with colds and influenza. They can be used in children having difficulty taking paracetamol as tablets, capsules or syrup such as when nausea and/or vomiting is present.

You must talk to a doctor or pharmacist 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 PARASERTS

Do not give Paraserts 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).
- taking any other medicines containing paracetamol.

If you are not sure of the cause of your child's illness or it is accompanied by a rash, breathing difficulties, diarrhoea or excessive tiredness or lethargy, speak to your doctor straight away. Do not give Paraserts until you get medical advice.

Warnings and precautions

During treatment with Paraserts, tell your child's 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 your child is 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).

Before giving Paraserts, talk to your child's pharmacist or doctor if:

- your child has problems with their liver or kidneys.
- your child is taking any of the following:
 - 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 (called metabolic acidosis) that must have urgent treatment (see section 2).

If you are not sure what medicine your child is taking, show the bottle or pack to your pharmacist.

3. HOW TO USE PARASERTS

This medicine is for rectal use only. Do not put the suppository in your mouth or swallow it. If the suppository is swallowed accidentally, tell your child's doctor straight away or contact your nearest Accident and Emergency Department.

Always give this medicine exactly as described in this leaflet. Check with your child's doctor or pharmacist if you are not sure. If you switch between oral and rectal paracetamol forms, leave at least 4 - 6 hours between doses, and never give these suppositories at the same time as oral liquids or tablets containing paracetamol.

This product is suitable for children aged 6 to 12 years.

Age	Number of suppositories	Minimum length of time between doses	Maximum number of suppositories in 24 hours
6 to 9 years	1	4 - 6 hours	4
10 to 12 years	1 or 2	4 - 6 hours	4 - 8

Do not give your child more suppositories than stated above.

This product is not suitable for use in children under 6 years of age.

Consult your child's doctor if symptoms get worse or do not improve within 3 days.

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.

1. Wash your hands.
2. Peel the wrapping apart to take out the suppository. Do not break the suppository before use as the whole suppository should be administered.
3. It may be easier to give your child the suppository if they are lying on their front or side on a bed.
4. 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.
5. Try to keep your child still for a minute or two and then wash your hands.

If you need to give a second suppository, then follow steps 1 to 5 again.

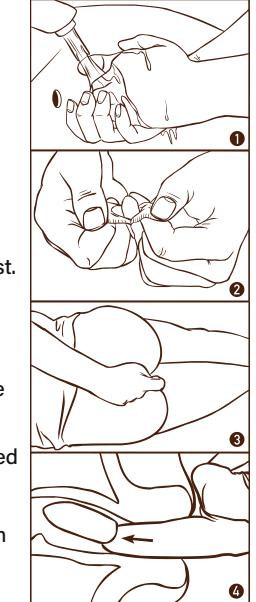
If your child vomits after having a suppository there is no need to give them another dose because of this. The suppository will still work normally as it is absorbed in the rectum. If your child vomits after having taken oral paracetamol, it is possible they may have absorbed some of it. A suppository should not be administered until 4-6 hours has elapsed from the time the initial oral dose was given.

If you have given more Paraserts than you should

Talk to a doctor at once if you give your child 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 Paraserts to your child

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



4. POSSIBLE SIDE EFFECTS

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

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

Signs of an allergic reaction include a rash, hives, swallowing problems, difficulty breathing or wheezing, swelling of the lips, face, throat or tongue.

The following side effects can happen with this medicine.

Common side effects (may affect up to 1 in 10 people):

- Mild redness or irritation around the rectum may occur. If symptoms persist for more than a few days after stopping use, consult your doctor.

Very rare side effects (may affect up to 1 in 10,000 people):

- Very rare cases of serious skin reactions have been reported. Symptoms may include skin reddening, blisters, rash. If skin reactions occur or existing skin symptoms worsen, stop use and seek medical help right away.

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).
- 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.

Long term use: People who use medicines containing paracetamol every day for a long time (several months or more) could get certain side-effects, including liver damage. People taking paracetamol in the usual way for shorter periods have not had these problems, but liver function tests may be affected. If you notice any side effect not included in this leaflet, please tell your child's doctor or pharmacist.

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 PARASERTS

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 Paraserts contain

The active substance is paracetamol. Each suppository contains 250mg of paracetamol. The other ingredients are hydrogenated fat and soyabean lecithin.

What Paraserts 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. Pfleger Arzneimittel GmbH, Dr. Robert Pfleger Strasse 12, Bamberg, D-96052, Germany.

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