PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed without a doctor's prescription

ACAMOLi® BABY SUPPOSITORIES 80 mg

Composition
Each suppository contains:
Paracetamol 80 mg

For the list of inactive ingredients in the preparation, see section 6 – "Further Information".

Read this leaflet carefully in its entirety before using this medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.
This medicine is dispensed without a doctor's prescription and is intended for babies 3-11 months of age for reduction of fever and relief of pain. Refer to the doctor if the fever persists for more than 3 days or if the symptoms do not pass within 5 days despite use of the medicine.
Administer the medicine correctly. Consult a pharmacist if you need further information.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended for the relief of pain and reduction of fever.
For rectal use (anus).

Therapeutic group:
Analgesic and antipyretic.

2. BEFORE USING THE MEDICINE

☒ Do not use this medicine:
- if there is a known sensitivity to paracetamol or to any of the other ingredients of the medicine.

Special warnings regarding use of the medicine
- If the child has developed skin side effects in the past as a result of taking preparations containing paracetamol, do not administer preparations containing paracetamol, so that severe skin effects will not recur.
- The preparation contains paracetamol which may cause liver damage when:
  - given at a dosage higher than recommended or for a prolonged period.
  - consuming alcoholic beverages during the course of treatment.
  - taking additional medicines which affect liver function.
- Do not administer this medicine frequently without consulting a doctor.
- Do not take additional fever reducers and pain relievers or cold medicines without consulting a doctor or pharmacist, to prevent overdose or paracetamol poisoning.
- Do not take additional medicines from the Acamol "family" or other paracetamol-containing preparations.
- Avoid taking a high dosage (within the recommended limit) of this medicine when fasting.
- If the child is sensitive to any food or medicine, inform the doctor before administering the medicine.

❗ Consult the doctor before commencing treatment if you are suffering, or have suffered in the past, from:
- liver disease or impaired liver function
- impaired kidney function
- alcoholism
- jaundice
- If you are pregnant or breastfeeding

❗ If you are taking, or have recently taken, other medicines, including non-prescription medicines and food supplements and vitamins, tell the doctor or pharmacist. In particular, inform the doctor or pharmacist if you are taking a medicine from the following groups or if you have just finished treatment with the medicine:
- Anticoagulants, especially warfarin.
- Preparations that stimulate liver enzyme production (e.g., rifampicin, barbiturates).
- Medicines for epilepsy - phenytoin, carbamazepine.
- Non-steroidal anti-inflammatory preparations.
- Metoclopramide or domperidone (to treat nausea, vomiting and other digestion problems).
- Chloramphenicol (antibiotic).
- Probenecid (to treat gout).
- Cholestyramine (to reduce excessive blood fats).

❗ Use of paracetamol and alcohol consumption
During the course of treatment with paracetamol, do not consume alcohol due to increased risk of liver damage.

❗ Pregnancy and breastfeeding
If you are pregnant or breastfeeding, consult the doctor before commencing use of the medicine.

❗ Use in children
Parents must inform the attending doctor of any side effects as well as any other medicine being given to the child.
Do not give the child alcohol or alcohol-containing medicines during treatment with this medicine.

3. HOW SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are uncertain.
The dosage is determined according to the baby's weight; consult a doctor/pharmacist to determine the dosage appropriate for your baby's weight.

The usual dosage unless otherwise instructed by the doctor:
Babies 3-11 months of age: one suppository every 6 hours, up to 4 suppositories in 24 hours.
Wait at least 4 hours before administering another dose.

Refer to the doctor if the fever persists for more than 3 days or if the symptoms do not pass within 5 days despite use of the medicine.
Do not exceed the recommended dosage.
If the child accidentally received a double dose, consult the doctor immediately or proceed to an emergency room.

Directions for use
Note: If the suppository is too soft to allow insertion, it can be cooled by keeping it in a refrigerator for about 30 minutes, or by holding it under a stream of cold water before removing the wrapper.

1. How to insert the suppository: First, wash your hands well.
2. Opening instructions: Separate one suppository from the strip of suppositories. To remove the plastic wrapper, separate the tabs in the flat part of the plastic wrapper and pull sideways until the suppository comes out.
3. Lay the baby on his side, and gently insert the suppository deep into the anus with your finger.
4. Wash your hands well after inserting the suppository.

If you have taken an overdose or if a child has accidentally swallowed the medicine, immediately refer to a doctor or to a hospital emergency room and bring the package of the medicine with you. Do not induce vomiting without explicit instruction from the doctor!

Even if you feel well, immediate treatment is essential, **due to the risk of developing severe liver damage**. Side effects can be nausea and vomiting, diarrhea, loss of appetite, abdominal pain, flatulence, increased sweating, pain or tenderness in the upper abdomen, and they may not reflect the severity of the liver damage.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Acamoli suppositories may cause side effects, such as redness or soreness in the anal area, in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Severe side effects:
Stop treatment and refer to the doctor immediately:
- If severe allergic reactions occur, such as rash and itching, swelling of the face, lips, tongue, throat and/or limbs, which may cause difficulty breathing or swallowing.
- Paracetamol may, in rare cases, cause the appearance of severe skin diseases, whose signs can be: redness, rash, blisters, widespread skin damage.
  Severe skin side effects may occur even if you have taken preparations containing the active ingredient paracetamol in the past without any problem.
  If skin side effects occur, stop treatment and refer to the doctor immediately.
- If signs of changes in the blood system occur, such as: bleeding, bruises, developing inflammations more easily.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach of children and/or infants to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.
Do not use the medicine after the expiry date (Exp. Date) that appears on the package. The expiry date refers to the last day of that month.
Store below 25°C.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:
Witepsol W-35, Witepsol E-76

What the medicine looks like and the contents of the package:
Each package contains white-cream colored suppositories.

Manufacturer and License Holder:
Teva Pharmaceutical Industries Ltd., P.O.B. 3190, Petah-Tikva.

This leaflet was checked and approved by the Ministry of Health in November 2013.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
132.91.31113.00

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