

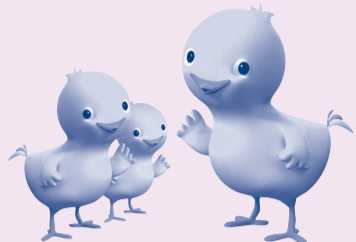
**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986**

The medicine is dispensed without a doctor's prescription

**ACAMOLI®**

**FORTE**

**SUPPOSITORIES 250 mg**



**Composition**

Each suppository contains:  
Paracetamol 250 mg

For the list of inactive and allergenic ingredients in the preparation, see section 6 – “Further Information”.

**Read the leaflet carefully in its entirety before using the 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 children 6 years of age and above for reduction of fever and relief of pain.
- The medicine can also be used in adults.
- **Refer to the doctor if the fever persists for more than 3 days or if the symptoms worsen or 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, detailed in section 6.

**Special warnings regarding use of the medicine**

- If the adult/child has developed skin side effects in the past as a result of taking preparations containing paracetamol, do not administer preparations containing paracetamol, so as not to cause serious skin effects again.
- 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 antipyretic and analgesic medicines 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 you or your child is sensitive to any food or medicine, inform the doctor before administering the medicine.

**Consult the doctor before commencing treatment if you or the patient is suffering, or suffered in the past, from:**

- liver disease or impaired liver function
- impaired kidney function
- alcoholism
- jaundice
- If the patient is pregnant or breastfeeding

**Drug interactions**

**If the patient is taking, or has recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.** In particular, inform the doctor or pharmacist if the patient is taking or has just finished treatment with a medicine from the following groups:

- Anticoagulants, such as warfarin.
- Preparations that stimulate production of enzymes in the liver (e.g., rifampicin, barbiturates - hypnotic).
- Medicines for epilepsy - phenytoin, carbamazepine.
- Non-steroidal anti-inflammatory preparations.
- Metoclopramide or domperidone (to treat nausea, vomiting and other digestive problems).
- Chloramphenicol, flucloxacillin (antibiotic).
- Probenecid (to treat gout and sometimes given to increase the levels of penicillin in the blood).
- 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 the patient is pregnant or breastfeeding, consult the doctor before commencing use of this 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 about the dosage and treatment regimen of the preparation.

**The dosage is determined by the child's weight; consult a doctor/pharmacist to determine the dosage appropriate for your child's weight.**

**The usual dosage unless otherwise instructed by the doctor:**

**Children up to 6 years of age:** only in accordance with the doctor's instruction.

**Children 6-12 years of age:** 1-2 suppositories, 4-5 times a day.

**Adults:** 2 suppositories, 4-5 times a day.

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 worsen or do not pass within 5 days despite use of the medicine.**

**Do not exceed the recommended dose.**

If the child/patient 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 storing it in a refrigerator for about 30 minutes, or by holding it under a stream of cold water before removing the wrapper.

1. **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.
2. **How to insert the suppository:** First, wash your hands well.
3. Lay the child 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 the patient took 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, bloating, 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 Acamol Forte Suppositories may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

**Rare side effects (affect up to 1 patient in 1,000)**

**Severe side effects, stop treatment and refer to the doctor immediately:**

- If severe allergic reactions occur, such as swelling of the face, lips, tongue, throat and/or limbs, which may cause difficulty breathing or swallowing.
- If skin problems occur, such as rash or itching.
- If skin side effects occur - paracetamol may very rarely cause severe skin diseases to occur, whose signs may be: redness, rash, blisters, widespread skin damage.  
Severe skin side effects may occur even if you have previously taken preparations containing the active ingredient paracetamol in the past without any problem.
- If signs of changes in the blood system occur, such as: bleeding and bruising that occur more easily, development of inflammations more easily, onset of high fever and blisters in the mouth and throat.
- If liver problems occur - you may be asked to perform blood tests to check your liver function.

**Common side effects (affect up to 1 patient in 10)**

- Redness or pain in or around the area where the suppository was inserted (in the anus).

**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.**

**Reporting side effects:**

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](http://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 and sight 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 a plastic tray (blister) in which 12 white-cream-colored suppositories are packaged.

**Name of Manufacturer and License Holder and Address:**

Teva Israel Ltd.,  
124 Dvora HaNevi'a St., Tel Aviv 6944020

**The leaflet was revised in March 2023 according to MOH guidelines.**

**Registration number of the medicine in the National Drug Registry of the Ministry of Health:**  
122.20.30214.00