

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

The medicine is dispensed
without a doctor's prescription

ACAMOLI®

SUPPOSITORIES 150 mg



Composition

Each suppository contains:

Paracetamol 150 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.

You must use the preparation according to the instructions in the dosage section of this leaflet. Consult a pharmacist if you need further information.

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.**

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 listed in section 6.

Special warnings regarding use of the medicine

- If the patient/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 medicines to reduce fever and relieve pain 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 patient is sensitive to any food or medicine, inform the doctor before administering the medicine.

Consult the doctor before commencing treatment if the patient is suffering, or has 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 and vitamins, tell the doctor or pharmacist. In particular, inform the doctor or pharmacist if the patient is taking a medicine from the following groups or if has just finished treatment with the medicine:

- Anticoagulants, such as warfarin.
- Preparations that stimulate liver enzyme production (e.g., rifampicin, barbiturates – an anesthetic).
- Medicines for epilepsy – phenytoin, carbamazepine.
- Non-steroidal anti-inflammatory preparations.
- Metoclopramide or domperidone (to treat nausea, vomiting and other digestive problems).
- Chloramphenicol, flucloxacillin (antibiotics).
- Probenecid (to treat gout and occasionally given in order to increase blood levels of penicillin).
- 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 an 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 regarding the dosage and treatment regimen of the medicine.

The dosage is determined by the weight of the child/patient, consult a doctor/pharmacist to determine the dosage appropriate for the child's/patient's weight.

This medicine is not usually intended for children and infants below the age of two, for them, it is recommended to use a liquid preparation.

The usual dosage unless otherwise instructed by the doctor:

Children up to 3 years of age: in accordance with the doctor's instruction.

Children 3-4 years of age: 1 suppository, 4-5 times per day.

Children 4-6 years of age: 1-2 suppositories, 4-5 times per 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 patient/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 approximately 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 patient/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 has taken an overdose or if a child has accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you. Do not induce vomiting without an 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 a 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 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 in 1,000 patients): Severe side effects, stop treatment and refer to the doctor immediately in the following cases:

- If severe allergic reactions occur, such as swelling of the face, lips, tongue, throat and/or limbs which may cause breathing or swallowing difficulties.
- If skin problems occur, such as rash or itching.
- If skin side effects occur – paracetamol may, in very 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 signs of changes in the blood system occur, such as: bleeding and bruising more easily, developing inflammations more easily, occurrence of high fever and blisters in the mouth and throat.
- If liver problems occur – you may be asked to perform blood tests to check liver function.

Common side effects (affect up to 1 patient out of 10 patients):

- Redness or pain at or around the insertion area of the suppository (in the anus).

If a side effect occurs, if one of the side effects worsens, or if you are suffering 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) 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 in order to avoid poisoning. Do not induce vomiting without an 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) packed with 12 or 18 white-cream-colored suppositories.

Name of Manufacturer and License Holder and its Address:

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

This leaflet was revised in May 2023 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
027.08.21691.00