

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

The medicine is dispensed without a doctor's prescription

ACAMOL® Tablets ACAMOL® Caplets

Composition

Each tablet/caplet contains:
Paracetamol 500 mg

For information on the inactive ingredients in the preparations, see section 6 – "Further Information".

Read the 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 administered without a doctor's prescription and is intended for adults and children aged 6 years and older. Take the medicine in accordance with section 3 in this leaflet. Consult a pharmacist if you need further information.

Refer to a 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 relief of pain and fever of different etiologies such as headache, toothache, colds, influenza, rheumatic pain and menstrual pain.

Therapeutic group:

Analgesic and antipyretic.

2. BEFORE USING THE MEDICINE

Do not use the 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 you have developed skin side effects in the past as a result of taking preparations containing paracetamol, do not take 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.
 - Alcoholic beverages are consumed during the course of treatment.
 - Other medicines which affect liver function, are taken.
- Do not use this medicine frequently without consulting a doctor.
- Do not take other antipyretics and analgesics or cold medicines without consulting a doctor or pharmacist to prevent overdose or paracetamol poisoning.
- Do not take other medicines from the "Acamol family" and/or other paracetamol-containing preparations.
- Avoid taking a high dosage (within the recommended limit) of this medicine when fasting.

Tell the doctor before commencing treatment if you are suffering, or have suffered in the past, from:

- Sensitivity to any food or medicine
- A liver disease or impaired liver function
- Impaired kidney function
- Alcoholism
- Jaundice
- If you are pregnant or breastfeeding

Drug interactions

If you are taking, or if you have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially if you are taking:

- Anticoagulants, such as warfarin.
- Preparations which stimulate production of liver enzymes (e.g., rifampicin, barbiturates).
- Antiepileptics – phenytoin, carbamazepine.
- Non-steroidal anti-inflammatory drugs.
- Metoclopramide or domperidone (for treatment of nausea, vomiting and other digestive problems).
- Chloramphenicol (antibiotic).
- Probenecid (for treatment of gout).
- Cholestyramine (to reduce excessive blood fats).
- Flucloxacillin (antibiotic), due to the serious risk of disturbances in the blood and fluids (High anion gap metabolic acidosis) which requires urgent treatment and may occur especially in cases of serious kidney damage, sepsis (a condition in which bacteria and their toxins are present in the blood and lead to organ damage), malnutrition, chronic alcoholism and conditions in which the maximum daily dose of paracetamol is used.

Use of paracetamol and alcohol consumption

Do not consume alcohol during the course of treatment with paracetamol due to increased risk of liver damage.

Pregnancy and breastfeeding

Pregnancy

If you are pregnant or breastfeeding, consult a doctor before commencing treatment with the medicine.

Take the lowest dose that is most effective for you in relieving pain and/or lowering fever, for the shortest possible time. Consult the doctor if there is no relief of pain or fever or if you need to take the medicine more often.

Breastfeeding

Small amounts of paracetamol pass into the breast milk. Consult the doctor before use.

Driving and operating machinery

Paracetamol does not affect the ability to drive or operate machinery.

Use in children

This medicine is intended for adults and children over the age of 6 years; see section 3.

Parents must report to the attending doctor any side effects and any additional information being given to the child.

3. HOW SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are uncertain regarding the dosage and treatment regimen for the preparation.

The usual dosage, unless otherwise instructed by the doctor:

Adults and children aged 12 years and over:

1-2 tablets/caplets every 4-6 hours, as needed.

Do not exceed a dosage of 8 tablets/caplets per day.

Children aged 9-12 years:

½-1 tablet/caplet every 4-6 hours, as needed. Do not exceed a dosage of 4 tablets/caplets in a day (2 grams in a day).

Children aged 6-9 years:

½ tablet/caplet every 4-6 hours, as needed. Do not exceed a dosage of 3 tablets/caplets in a day (1.5 grams in a day).

Do not give a tablet/caplet to children under 6 years of age.

Do not exceed the recommended dose.

Refer to a 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.

Directions for use

Do not chew or crush! The tablets/caplets can be halved on the score line.

Swallow the medicine with a small amount of water.

If you took an overdose or if a child has accidentally swallowed the medicine, refer immediately 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 could be nausea and vomiting, diarrhea, loss of appetite, abdominal pain, flatulence, excessive sweating, pain or sensitivity 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 a doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Acamol may cause side effects such as dizziness in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Side effects may be more serious in elderly people.

Serious side effects:

Stop treatment and refer to a doctor immediately:

- If acute 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.
- If, in rare cases, acute skin diseases appear, whose signs can be: redness, rash, blisters, widespread skin injury. Acute skin side effects may appear even if you have taken preparations containing the active ingredient paracetamol in the past with no problem. If skin side effects appear, stop treatment and refer to the doctor immediately.
- If signs of changes in the blood system appear, such as: bleeding, bruising easily, prolonged fatigue, development of inflammations more easily (such as a sore throat) as a result of a severe reduction in the white blood cells count.
- If shortness of breath occurs (rare).
- If breathing problems appear. It is more likely that that this will happen if you experienced breathing problems in the past when taking other painkillers such as ibuprofen and aspirin.
- If nausea, sudden weight loss, loss of appetite and yellowing of the whites of the eyes and skin appear.

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) 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 in a dry place, below 25°C.**

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Acamol tablets:

Pregelatinized starch, povidone, stearic acid.

Acamol caplets:

Pregelatinized starch, povidone, stearic acid, hydroxypropyl methylcellulose, polyethylene glycol.

What the medicine looks like and the contents of the package:

Acamol tablets:

A round white-cream-colored tablet with a score line on one side.

Acamol tablets in a blister (tray) pack contains 20 tablets.

Acamol caplets:

An oblong white-cream-colored tablet with a score line on one side.

Acamol caplets in a blister (tray) pack contains 7, 10, 14, 16, 20, 21, 42 caplets.

Acamol caplets in a bottle contains 16, 50 caplets.

Not all package sizes may be marketed.

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 November 2023 according to MOH guidelines.

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

Acamol tablets: 020.16.20534.00
Acamol caplets: 128.74.25337.08

teva ACAM TAB CAPL PL SH 281123