

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

The medicine is dispensed without a doctor's prescription

Acamol® Teva Tablets Acamol® Teva Caplets

Composition

Each tablet/caplet contains:
Paracetamol 500 mg

For information on inactive and allergenic ingredients, see section 2 "Important information about some of the ingredients in the medicine" and 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 intended for adults and children from the age of 6 years and above.

Take the medicine in accordance with the instructions in section 3 of 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 to relieve pain and reduce fever of different etiologies such as headaches, toothache, cold, influenza, rheumatic pain and menstrual pain.

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 contained in the medicine – see section 6 "Further Information".

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 higher than recommended dosage or for a prolonged period.
 - alcoholic beverages are consumed during the course of treatment.
 - other medicines that affect liver function are being 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.

Before starting treatment, tell the doctor 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

While using the medicine, tell your doctor immediately if:

you are suffering from a severe illness, including severe renal impairment or sepsis (a condition in which bacteria and their toxins circulate in the blood and lead to organ damage), malnutrition, chronic alcoholism, or if you are also taking flucloxacillin (antibiotic). A serious condition called metabolic acidosis (a blood and body fluid abnormality) has been reported in patients in situations when they took paracetamol at the recommended dosage for a prolonged period or when they took paracetamol together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep and rapid breathing, drowsiness, nausea and vomiting.

Drug interactions

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

- Anticoagulants, e.g., 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 digestion problems).
- Chloramphenicol (antibiotic).
- Probenecid (for treatment of gout).
- Cholestyramine (to reduce excessive blood fats).
- Flucloxacillin (antibiotic), due to serious risk of blood and body fluid disturbances (this disturbance is called metabolic acidosis) which requires urgent treatment (see section 2).

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 effective for you in relieving pain and/or lowering fever, for the shortest possible amount of time. Consult the doctor if there is no relief of the pain or fever or if you need to take the medicine more frequently.

Breastfeeding

Small amounts of paracetamol pass into breast milk. Consult a 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 all side effects and any additional medicine being given to the child.

Important information about some of the ingredients in the medicine

This medicine contains less than 23 mg sodium per tablet/caplet and is therefore considered "sodium-free".

3. HOW SHOULD YOU USE THE MEDICINE?

Consult with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the medicine.

Unless instructed otherwise by the doctor, the recommended dosage is usually:

Adults and children from the age of 12 years and above: 1-2 tablets/caplets every 4-6 hours, as needed.

Do not exceed a dosage of 8 tablets/caplets per day (4 gram 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 per day (2 gram per day).

Children aged 6-9 years: ½ tablet/caplet every 4-6 hours, as needed.

Do not exceed a dosage of 3 tablets/caplets per day (1.5 gram per 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 unless explicitly instructed to do so by the doctor! Even if you feel well, immediate treatment is essential, **due to the risk of development of severe liver damage.** Side effects can include nausea and vomiting, diarrhea, loss of appetite, abdominal pains, swelling, increased 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 Teva 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 severe in the elderly.

Severe side effects:

Stop treatment and refer to a doctor immediately:

- If serious allergic reactions occur, such as rash and itching, swelling of the limbs, face, lips, tongue, throat, which may cause difficulty breathing or swallowing.
- If, in rare cases, severe skin diseases appear, whose signs can be: redness, rash, blisters, widespread skin damage. Severe skin side effects may appear even if you have taken preparations containing the active ingredient paracetamol in the past without a problem. If skin side effects appear, stop the treatment and refer to a doctor immediately.
- If signs of changes in the blood system develop, such as: bleeding, easy bruising (hematomas), prolonged fatigue, development of inflammations (e.g., sore throat) more easily as a result of a severe decrease in the number of white blood cells.
- If shortness of breath occurs (rare).
- If breathing problems occur. It is more likely that they will occur if you have previously experienced breathing problems when taking other painkillers, such as ibuprofen and aspirin.
- If you develop nausea, sudden weight loss, loss of appetite and yellowing of the eyes and skin.
- If a severe condition called metabolic acidosis, which can make the blood more acidic, occurs in patients with serious illness using this medicine (see section 2). The frequency of this side effect is unknown (the frequency cannot be estimated from the available data).

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 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 following link:

<https://sideeffects.health.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a 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 Teva Tablets:

Microcrystalline cellulose, Maize starch, Povidone, Croscarmellose sodium, Talc, Silica colloidal anhydrous, Magnesium stearate.

Acamol Teva Caplets:

Microcrystalline cellulose, Maize starch, Povidone, Croscarmellose sodium, Talc, Silica colloidal anhydrous, Magnesium stearate.

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

Acamol Teva Tablets: A round white tablet with a score line on one side.

Acamol Teva Tablets in a blister pack (trays) containing 10, 20, 30, 60 tablets.

Not all package sizes may be marketed.

Acamol Teva Caplets: An oblong white tablet (caplet) with a score line on both sides.

Acamol Teva Caplets in a blister pack (trays) containing 20, 30, 40, 50, 60, 70 caplets.

Acamol Teva Caplets in a bottle containing 50 caplets.

Not all package sizes may be marketed.

Name of Manufacturer and License Holder and Address:

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

This leaflet was revised in June 2025.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
Acamol Teva Tablets 176.60.36645
Acamol Teva Caplets 176.61.37219

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