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

The medicine is dispensed without a doctor's prescription – for general sale

ACAMOL® Teva Caplets

Composition
Each caplet contains:
Paracetamol 500 mg

For information on the inactive and allergenic ingredients, see section 2 "Important information about some of the ingredients of 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 (for general sale) is given without a doctor's prescription and is intended for adults and children aged 12 years and older.

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 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 – see section 6 "Further Information".

Special warnings regarding use of the medicine

- **Do not take other medicines from the "Acamol family" and/or other paracetamol-containing preparations.**
- If you have developed skin side effects in the past as a result of taking paracetamol-containing preparations, do not take paracetamol-containing preparations, 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.
  - Taking other medicines that affect liver function.
- 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 overdosage or paracetamol poisoning.
- Avoid taking a high dosage (within the recommended limit) of this medicine when fasting.

Before beginning 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 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, e.g., warfarin • Preparations which stimulate production of liver enzymes (e.g., rifampicin, barbiturates) • Antiepileptics – phenytoin, carbamazepine • Non-steroidal anti-inflammatory preparations • Metoclopramide or domperidone (for treatment of nausea, vomiting and other digestive problems) • Chloramphenicol (an 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
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 a doctor before commencing treatment with the medicine.

Pregnancy
Take the lowest dose effective for you in relieving pain and/or lowering fever, for the shortest possible 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, for general sale, is intended for adults and children aged 12 years and older.
Parents should report to the attending doctor any side effects and any additional medicine being given to the child.

Important information about some of the ingredients of the medicine
This medicine contains less than 23 mg sodium in a caplet and is therefore considered sodium-free.

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 recommended dosage, unless otherwise instructed by the doctor, is generally:
Adults and children aged 12 years and older:
1-2 caplets every 4-6 hours, as needed.
Do not exceed a dosage of 8 caplets (4 gram) per day.
Do not exceed the recommended dose.
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.

Directions for use
There is no information regarding crushing and chewing. The 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 developing severe liver damage.** Side effects from an overdose can be: nausea and vomiting, diarrhea, loss of appetite, abdominal pain, bloating, 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 the 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 severe allergic reactions occur, such as a rash and itching, swelling of the face, lips, tongue, throat which may cause difficulty breathing or swallowing and/or swelling of the limbs • 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 with no problem. If skin side effects appear, stop the treatment and refer to the doctor immediately • If signs of changes in the blood system appear, such as: bleeding, easy bruising (hematomas), prolonged fatigue, development of inflammations more easily (such as a sore throat) as a result of a severe decrease in the number of white blood cells • If shortness of breath occurs (rare) • If breathing problems appear. It is more likely 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 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 (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 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, 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:
Microcrystalline cellulose, Maize starch, Povidone, Croscarmellose sodium, Talc, Silica colloidal anhydrouse, Magnesium stearate.

What the medicine looks like and the contents of the package:
An oblong white tablet (caplet) with a score line on both sides.
The caplets are packaged in a blister pack (tray) containing 10 caplets or in a bottle package containing 16 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 October 2025.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 176.61.37219

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