Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
This medicine is dispensed without a doctor's prescription

AVCAMOL 500 mg

Granules in personal packs

Composition
Each personal pack contains:
Paracetamol 500 mg

For information about inactive ingredients and allergens in the medicine, see section 2 - 'Important information about some of this medicine's ingredients', and section 6 - 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

The medicine is intended for adults and children aged 9 years and over. Take this medicine according to the instructions in the section about dose in this leaflet. Consult your pharmacist if you need further information.
Contact your doctor if fever lasts for more than 3 days or if the disease symptoms worsen or do not pass within 5 days, despite use of this medicine.

1. WHAT IS THIS MEDICINE INTENDED FOR?

This medicine is intended for reduction of fever and relief of pain due to various reasons, such as headaches, toothaches, cold, flu, rheumatic pain and menstrual cramps.

Therapeutic group: analgesic and antipyretic.

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- You are sensitive (allergic) to paracetamol or to any of the other ingredients that this medicine contains (see section 6).

Special warnings regarding use of this medicine
- If you previously developed skin side effects as a result of taking medicines containing paracetamol, do not take medicines containing paracetamol so that severe skin side effects will not recur.
- The medicine contains paracetamol, which may cause liver damage when:
  - Administered at a higher dosage than recommended or for a prolonged period
  - You drink alcoholic beverages during treatment
  - You take additional medicines that affect liver function
- Do not use this medicine frequently without consulting your doctor.
- Do not take additional antipyretics and analgesics or cold medicines without consulting with your doctor or pharmacist to prevent overdose or paracetamol poisoning.
- Do not take additional medicines from the "Acamol family" and/or other medicines containing paracetamol.
- Avoid taking a high dosage (even if within the recommended dosage range) of this medicine when fasting.

Before starting treatment with Avcamol, tell your doctor if you suffer or have previously suffered from:
- Sensitivity to any food or any medicine
- Liver disease or impaired liver function
- Impaired kidney function
- Alcoholism
- Jaundice
- If you are pregnant or breastfeeding

Children and adolescents
This medicine is intended for children aged 9 years and over, see section 3 – 'How to use this medicine?'.
Parents must inform the treating doctor about any side effects, as well as any additional medicine being given to the child.

Interactions with other medicines
If you are taking or have recently taken other medicines, including non-prescription medicines and dietary supplements, tell your doctor or pharmacist. Especially if you are taking:
- Medicines to prevent blood clots e.g., warfarin
- Medicines that accelerate production of liver enzymes (e.g. rifampicin, barbiturates)
- Medicines for epilepsy - phenytoin, carbamazepine
- Non-steroidal anti-inflammatory drugs
- Metoclopramide or domperidone (for treatment of nausea, vomiting and additional digestive problems)
- Chloramphenicol (antibiotic)
- Probenecid (to treat gout)
- Cholestyramine (to reduce excess lipids in the blood)
- Flucloxacillin (antibiotic). There is a risk of blood and body fluid disorders (high anion gap metabolic acidosis), a condition requiring urgent treatment. This may occur particularly in patients with severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood, leading to organ damage), malnutrition, chronic alcoholism, and upon use of the maximum daily dosage of paracetamol.

Using paracetamol and alcohol consumption
Do not consume alcohol during treatment with paracetamol due to increased risk of liver damage.

Pregnancy and breastfeeding
Pregnancy
If you are pregnant or breastfeeding, consult your doctor before starting use of this medicine.
Take the lowest possible dose effective for you to reduce your pain and/or fever, for the shortest time possible. Consult your doctor if your pain or fever is not relieved or if you need to take the medicine more often.
Breastfeeding
Small amounts of paracetamol pass into breast milk. Consult your doctor before use.

Driving and using machines
Paracetamol does not affect your ability to drive or operate machines.

Important information about some of this medicine's ingredients
- Contains 801 mg sorbitol per personal dose. Sorbitol is a source of fructose. If you have been told by your doctor that you have a sensitivity to certain sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic condition of inability to break down fructose, consult your doctor before use. Sorbitol may cause abdominal pain and diarrhoea.
- Contains sucrose. If you have been told by your doctor that you are sensitive to certain sugars, consult your doctor before taking this medicine.
- Contains sulphites. These may rarely cause a severe hypersensitivity reaction and bronchospasm (a spasm of bronchi in the lungs).
- Contains sodium: this medicine contains less than 23 mg of sodium per dose, and is therefore considered 'sodium free'.

3. HOW TO USE THIS MEDICINE?

Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

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

Children aged 9-12 years:
One personal pack of Avcamol 500 mg or one personal pack of Avcamol* 250 mg every 4-6 hours, as needed.
Do not take more than 4 personal packs of Avcamol 500 mg a day or 8 personal packs of Avcamol 250 mg a day (2 grams of paracetamol).
* There is a separate lower strength product containing 250 mg paracetamol - Avcamol 250 mg.

Adults and children aged 12 years and older:
1-2 personal packs of Avcamol 500 mg every 4-6 hours, as needed.
Do not take more than 8 personal packs a day (4 grams of paracetamol).

Do not take a partial dose from one personal pack, since accurate dosage cannot be obtained.

Do not exceed the recommended dose.

Contact your doctor if fever lasts for more than 3 days or if the disease symptoms worsen or do not pass within 5 days, despite use of this medicine.

Directions for use
Do not take with food. Open the personal pack of Avcamol 500 mg, empty its contents directly into the mouth, onto the tongue, and swallow.
There is no need for water.

If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you. Do not induce vomiting unless explicitly instructed to do so by a doctor. Even if you feel well, immediate treatment is essential, **due to the risk of developing severe liver damage.** Possible side effects are nausea and vomiting, diarrhoea, loss of appetite, abdominal pain, bloating, increased sweating, pain or tenderness in the upper abdomen, and they may not reflect the severity of liver damage.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.
If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, using Avcamol 500 mg may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.
The side effects may be more severe in the elderly.

Serious side effects:
Stop treatment and contact your doctor immediately:
- If acute allergic reactions appear such as swelling of the limbs, rash and itching, swelling of the face, lips, tongue and/or throat, which may cause difficulties breathing or swallowing.
- If, in rare cases, serious skin diseases appear, the signs of which may be redness, rash, blisters, or extensive skin damage. Acute skin side effects may appear even if you have previously taken medicines that contain the active ingredient paracetamol with no problem.
- If skin side effects appear, stop the treatment and contact your doctor immediately.
- If signs of changes in the blood system appear, such as bleeding, easily bruising, persistent tiredness, development of inflammations more easily (e.g. sore throat) as a result of a severe decline in the number of white blood cells.
- If shortness of breath appears (rare).
- If breathing problems occur. They are more likely to occur if you have previously experienced breathing problems while taking other analgesics such as ibuprofen and aspirin.
- If you experience nausea, sudden weight loss, loss of appetite and yellowing of the eyes and skin.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects
You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects due to Medicinal Treatment' found on the Ministry of Health home page (www.health.gov.il), which links to an online form for reporting side effects. You can also use this link: https://sideeffects.health.gov.il

5. HOW TO STORE THE MEDICINE?

- Prevent poisoning! This and all other medicines should 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 unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which appears on the package. The expiry date refers to the last day of that month.
- **Store below 25°C in the original package to protect from light and moisture.**

6. ADDITIONAL INFORMATION

In addition to the active ingredient, this medicine also contains:
Sorbitol, talc, basic butylated methacrylate polymer, strawberry flavour, magnesium oxide, vanilla flavour, sodium carboxymethyl cellulose, hypromellose, stearic acid, sodium lauryl sulphate, magnesium stearate, titanium dioxide, sucralose, N-2,3-trimethyl-2-isopropylbutanamide, simeticone.

What the medicine looks like and contents of the package:
An Avcamol 500 mg pack contains personal aluminium packs (sachets). Each personal pack contains white or almost white granules, capable of flowing with no agglomerates or clots with the odour of strawberry/vanilla.
The medicine is approved for marketing in the following sizes:
2,8,10,12,16,20,24,32,36,40,48,50 personal packs. Not all package sizes may be marketed.

Name and address of the manufacturer and license holder:
Teva Israel Ltd., 124 Dvora HaNevi'a St., Tel Aviv 6944020

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

Registration number of the medicine in the Ministry of Health's National Drug Registry:
148.53.33459