

Patient leaflet in accordance with the Pharmacists'

Regulations (Preparations) - 1986

This medicine is dispensed without a doctor's prescription

AVCAMOL 250 mg Granules in personal packs

Composition

Each personal pack contains:
Paracetamol 250 mg

For information about inactive ingredients and allergens in the medicine, see section 2 under '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 children aged 4 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 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 relief of pain and reduction of fever.

Therapeutic group: analgesic and antipyretic.

2. Before using this medicine

Do not use this medicine if:

- There is a known sensitivity to paracetamol or to any of the other ingredients in this medicine (see section 6).

Special warnings about using 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 fever reducers or pain relievers 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.

Tell your doctor before starting treatment 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 breast-feeding

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. Particularly 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)

Using paracetamol and alcohol consumption

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

Pregnancy and breast-feeding

Pregnancy

If you are pregnant, 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.

Breast-feeding

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
Each personal pack of Avcamol 250 mg contains:

- 0.1 mg sucrose: if you have been told by your doctor that you are sensitive to some sugars, consult your doctor before taking this medicine.
- Sodium: this medicine contains less than 23 mg of sodium per dose, and is therefore considered sodium free.
- 601 mg sorbitol: Sorbitol is the source of fructose. If you are sensitive to some sugars or if you have hereditary fructose intolerance (HFI), consult with your doctor before use. Sorbitol may cause stomachache and diarrhoea.
- 3 mg sucralose.
- Flavouring: vanilla flavour and strawberry flavour.

Use in children

This medicine is intended for children aged 4 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.

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:

1-2 personal packs of Avcamol 250 mg, every 4-6 hours, as needed.

Do not take more than 8 personal packs a day (2 grams of paracetamol).

Children aged 4-8 years:

One personal pack of Avcamol 250 mg every 4-6 hours, as needed. Do not take more than 4 personal packs a day (1 gram of paracetamol).

Do not exceed the recommended dose.

Contact your doctor if fever lasts for more than 3 days or if the 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 250 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 contact 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 despite taking an overdose, immediate treatment is essential, **due to the risk of developing severe liver damage.** Taking an overdose may cause the following symptoms: nausea and vomiting, diarrhoea, loss of appetite, abdominal pain, bloating, increased sweating, pain or tenderness in the upper abdomen. 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

Like with all medicines, using Avcamol 250 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 severe 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. Severe skin side effects may appear even if you have taken medicines that contain the active ingredient paracetamol without suffering from side effects. 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, development of infections more easily as a result of a severe decline in the number of white blood cells.
- If shortness of breath appears (rare).

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 of Drug Treatment' 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! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- **Store below 25°C in the original package to protect against light and humidity.**

6. Additional information

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

Sorbitol, talc, basic butylated methacrylate polymer, strawberry flavour, vanilla flavour, magnesium oxide light, sodium carmellose, sucralose, magnesium stearate, hypromellose, stearic acid, sodium dodecyl sulfate, titanium dioxide, simeticone.

What the medicine looks like and contents of the pack:

An Avcamol 250 mg pack contains personal aluminium packs (sachets). Each personal pack contains white or almost white granules.

The medicine is approved for marketing in the following sizes: 2, 3, 8, 10, 20, 24, 40 personal packs. Not all pack sizes may be marketed.

Manufacturer and Registration holder's name and address:

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

This leaflet was revised in February 2022 according to MOH guidelines.

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

148.51.33446