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

The medicine is dispensed without a doctor's prescription

Avcamol 500 mg

Composition

Each personal pack contains:
Paracetamol 500 mg

For a list of the inactive ingredients in the preparation, see section 6 - "Further Information".

Read this 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.

The medicine is intended for adults and children from 6 years of age and above. You must take the medicine in the correct manner. Consult a pharmacist if you need further information.

Refer to the doctor if the fever lasts more than 3 days or if the symptoms do not pass within 5 days, despite use of the medicine.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended for the relief of pain and reduction of fever.

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).

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
 - consuming alcoholic beverages during the course of treatment
 - taking additional medicines which affect liver function
- Do not use this medicine frequently without consulting a doctor.
- Do not take additional fever reducers and pain relievers or cold medicines without consulting a doctor or pharmacist, to prevent paracetamol overdose or poisoning.
- Do not take additional medicines from the "Acamol family" and/or other paracetamol-containing preparations.
- Avoid taking a high dosage (even within the recommended dosage range) of this medicine when fasting.
- If you are sensitive to any food or medicine, inform the doctor before taking this medicine.

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

- liver disease or impaired liver function
- impaired kidney function
- alcoholism
- jaundice
- if you are pregnant or breastfeeding

If you are taking, or have recently taken, other medicines

including non-prescription medicines and food supplements and vitamins, tell the doctor or pharmacist. In particular, inform the doctor or pharmacist if you are taking a medicine from the following groups or if you have just finished treatment with the medicine:

- Anticoagulants, especially warfarin
- Preparations that accelerate production of liver enzymes (e.g., rifampicin, barbiturates)
- Medicines for epilepsy – phenytoin, carbamazepine
- Non-steroidal anti-inflammatory preparations
- Metoclopramide or domperidone (for treatment of nausea, vomiting and other digestive problems)
- Chloramphenicol (antibiotic)
- Probenecid (to treat gout)
- Cholestyramine (to reduce excessive blood fats)

Use of paracetamol and consumption of alcohol

During the course of treatment with paracetamol, do not consume alcohol due to the increased risk of liver damage.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, consult the doctor before commencing use of the medicine.

Use in children

This medicine is intended for adults and children from 6 years of age and above, see section 3.

Parents must inform the attending doctor about any side effects as well as any additional medicine being given to the child.

3. HOW SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are uncertain.

The usual dosage unless otherwise instructed by the doctor:

Adults and children 12 years of age and above:

1-2 personal packs of Avcamol 500 mg every 4-6 hours, as needed. Do not take more than 8 personal packs in 24 hours (4 grams paracetamol).

Children 6-12 years of age:

One personal pack of Avcamol 500 mg every 4-6 hours, as needed. Do not take more than 4 personal packs in 24 hours (2 grams paracetamol).

Do not exceed the recommended dose.

Refer to the doctor if the fever lasts more than 3 days or if the symptoms do not pass within 5 days, despite use of the medicine.

Directions for use

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

If you took an overdose or if a child accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you. Do not induce vomiting without explicit instruction from the doctor! Even if you are feeling well despite taking an overdose, immediate treatment is essential **due to the risk of developing severe liver damage.** Overdose may cause the following symptoms: nausea and vomiting, diarrhea, loss of appetite, abdominal pains, flatulence, increased sweating, pain or tenderness in the upper abdomen. 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.

4. SIDE EFFECTS

As with any medicine, use of Avcamol 500 mg may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Severe side effects:

Stop treatment and refer to the doctor immediately:

- If severe allergic reactions occur, 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.
- Paracetamol may, in rare cases, cause the appearance of severe skin diseases, whose signs can be: redness, rash, blisters or widespread skin damage. Severe skin side effects may occur even if you have not suffered from side effects when taking preparations containing the active ingredient paracetamol in the past. If skin side effects occur, stop treatment and refer to the doctor immediately.
- If signs of changes in the blood system occur, such as: bleeding, bruises, developing inflammations more easily.

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.

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine, and any other medicine, must be kept in a safe place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without explicit instruction from the 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 from light and humidity.

6. FURTHER INFORMATION

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

Sorbitol, talc, basic butylated methacrylate polymer, magnesium oxide light, sodium carmellose, hypromellose, stearic acid, sodium dodecyl sulphate, magnesium stearate, titanium dioxide, sucralose, N-2,3-trimethyl-2-isopropylbutanamide, simeticone.

Each personal pack of Avcamol 500 mg also contains:

Vanilla flavor, Strawberry flavor
Sucrose 0.14 mg
Sodium 0.53-0.68 mg
Sorbitol 801 mg
Sucralose 1.5 mg

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

Avcamol 500 mg packages contain aluminum stick packs. Each stick pack contains white to almost white granules.

The preparation is approved for marketing in the following sizes: 2, 8, 10, 12, 16, 20, 24, 32, 36, 40, 48, 50, 96 stick packs per package, but not all package sizes may actually be marketed.

Manufacturer:

Teva Pharmaceutical Industries Ltd., P.O.Box 3190 Petah-Tikva.

License Holder:

Abic Marketing Ltd., P.O.Box 8077, Netanya.

This leaflet was checked and approved by the Ministry of Health in October 2013.

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

148.53.33459

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