

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

The medicine is dispensed without a doctor's prescription

ACAMOL® FOCUS

Caplets

Composition

Each caplet contains:

Acetylsalicylic acid	250 mg
Paracetamol	250 mg
Caffeine anhydrous	65 mg

For a list of 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.

This medicine is administered without a doctor's prescription and is intended for adults and children from age 12 and up. Take the medicine properly. Consult a pharmacist if you need further information.

This medicine is usually not intended for adolescents and children below the age of 12 years.

Refer to a doctor if the fever persists for more than 3 days or if there was no pain relief within 5 days, despite use of the medicine.

1. WHAT IS THE MEDICINE INTENDED FOR?

Pain reliever in conditions such as: migraine, headache, sinusitis, cold, muscle pain, menstrual pains, toothaches, mild arthritic pains and pains accompanied by fever.

Therapeutic group:

Analgesic in different conditions, including antipyretic.

2. BEFORE USING THE MEDICINE

Do not use this medicine:

- when you are pregnant or breastfeeding.
- if there is a known sensitivity to any of its ingredients or to other non-steroidal anti-inflammatories.
- if you are suffering from a bleeding peptic ulcer, hemorrhages, hemophilia, gout, stomach problems (active peptic ulcer) or from asthma in combination with nasal polyps.
- in children and adolescents up to 20 years of age for diseases accompanied by fever such as: flu or chickenpox (due to fear of Reye's syndrome).
- if after taking an analgesic or fever-reducing medicine, you have ever suffered from the following effects: urticaria (rash with swelling), swelling of the face, asthma, shock.

Special warnings regarding use of this medicine

- If you have previously developed skin side effects as a result of taking paracetamol-containing preparations, do not take paracetamol-containing preparations so that severe skin effects will not recur.
- If you or your child are sensitive to any food or medicine, inform the doctor before taking this medicine.
- 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.
 - other medicines which affect liver function are taken.
- Do not use this medicine frequently without consulting a doctor.
- Do not take other fever reducers and pain relievers or cold medicines without consulting a doctor or pharmacist to prevent overdose or paracetamol poisoning.
- Do not take additional medicines from the "Acamol family" and/or additional paracetamol-containing preparations.
- Avoid taking a high dosage (within the recommended limit) of this medicine when fasting.
- Do not drink wines or alcoholic beverages during the course of treatment with this medicine.
- This preparation contains aspirin, which, like other preparations belonging to the non-steroidal anti-inflammatory drugs (NSAIDs) group, may increase the risk of gastric hemorrhage, especially in the following cases:
In people concomitantly taking blood thinners, steroids and other NSAIDs, upon prolonged use of the preparation and when consuming alcohol.
- Limit caffeine consumption during the course of treatment.
- This preparation may interfere with blood sugar test results.
- Do not take this medicine 7 days before any surgery.

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

- a liver disease or impaired liver function
- impaired kidney function
- alcoholism
- jaundice
- impaired heart and/or blood vessel function (e.g., arrhythmias, hypertension)
- the respiratory system (e.g., asthma)
- nasal polyps
- the digestive system (e.g., ulcer)
- the blood system (e.g., coagulation, etc.)
- daily headaches, a headache that is different or more severe than usual, or if the headache is caused by an injury, cough or bending down
- if you are above the age of 50 and experience a headache for the first time and/or if your headache is accompanied by vomiting, fever and/or a stiff neck.

If you are taking, or have recently taken, other medicines including non-prescription medicines and food supplements and vitamins, tell the doctor or pharmacist. Especially inform the doctor or pharmacist if you are taking medicine from the following groups or have just finished treatment with the medicine:

- Anticoagulants, e.g., warfarin or clopidogrel
- Preparations which stimulate production of enzymes in the liver (e.g., rifampicin, barbiturates)
- Antiepileptics – phenytoin, carbamazepine
- Non-steroidal anti-inflammatory drugs
- Metoclopramide or domperidone (for treatment of nausea, vomiting and other digestive problems)
- Chloramphenicol (antibiotic)
- Probenecid (to treat gout)
- Cholestyramine (to reduce excessive blood fats)
- Methotrexate
- Antidiabetic agents
- Zidovudine (for AIDS)
- Other analgesics and anti-inflammatories
- Medicines that affect urinary acidity
- Corticosteroids
- Antihypertensives (such as ACE inhibitors)
- Antidepressants or anxiolytics (such as SSRIs)
- Antacids

- Medicines to treat asthma (e.g., theophylline)
- Diuretics (such as furosemide)
- Do not take this medicine together with other paracetamol-containing preparations

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

Do not use this medicine when you are pregnant or breastfeeding. See section 2.

Use in children

This medicine is not usually intended for adolescents and children below the age of 12 years.

3. HOW SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are unsure.

Recommended dosage unless otherwise instructed by the doctor:

Adults and children over 12 years of age: 2 caplets every 6 hours.

Do not take more than 8 caplets in any 24 hours.

Do not take the medicine for more than 48 hours for migraine.

Do not exceed the recommended dose.

This medicine is not usually intended for adolescents and children below the age of 12 years.

Refer to a doctor if the fever persists for more than 3 days or if there was no pain relief within 5 days.

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! Swallow the medicine with a full glass of water.

Take the medicine after a meal.

Do not lie down for 15-30 minutes after taking the medicine.

Do not halve or crush the medicine.

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 feel well, immediate treatment is essential, **due to risk of developing severe liver damage.** Side effects can be nausea and vomiting, diarrhea, loss of appetite, abdominal pain, flatulence, 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.

4. SIDE EFFECTS

As with any medicine, use of Acamol® Focus may cause side effects such as irritations or dizziness in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Severe side effects

Discontinue treatment and refer to a doctor immediately:

- if severe allergic reactions occur, such as rash and itching, redness, swelling of the face, lips, tongue, throat and/or limbs, which may cause difficulty breathing or swallowing.
- In rare cases, paracetamol may cause occurrence of severe skin diseases, whose signs can include: redness, rash, blisters, widespread skin damage. Severe skin side effects may occur even if you took in the past preparations containing paracetamol as the active ingredient without any problem.
- If skin side effects occur, discontinue treatment and refer to a doctor immediately.
- if signs of changes in the blood system occur, such as: bleeding, bruises, development of inflammations more easily.
- if signs of bloody or black stool, increased weakness or tiredness, strong stomach pain, dizziness, fainting, severe vomiting containing blood or resembling coffee grounds occur.
- if signs of tremor, restlessness, anxiety, tinnitus, hearing problems, changes in heart-rate, convulsions, loss of appetite, increased sweating, dark urine, changes in urination, yellowing of eyes and/or skin occur.

Other side effects

Nausea, stomach irritation, abdominal pain, heartburn, mild abdominal pain, nervousness, insomnia.

If any of the side effects worsen, or if you are suffering from a side effect not mentioned in this leaflet, consult the doctor immediately.

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach of children and/or infants to avoid poisoning. Do not induce vomiting without explicit instruction from 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 dry place, below 25°C.

Can be used up to 6 months after first opening the container, but not beyond the expiry date.

Leave the desiccant inside the container and close the container tightly after each use.

Even if stored according to their recommended conditions, medicines may be kept for a limited period only. Please note the expiry date of the preparation! In any case of doubt, consult the pharmacist who dispensed this medicine to you.

Do not store different medications in the same package.

6. FURTHER INFORMATION

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

Microcrystalline cellulose, stearic acid, crospovidone, silicon dioxide, pregelatinized starch, povidone, hydroxypropyl methylcellulose, FD&C red #40, FD&C yellow #6, polyethylene glycol 400, titanium dioxide, polysorbate 80, purified water.

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

Red, bioconvex caplets, with a desiccant, in a white, plastic container.

Manufacturer and License holder:

Teva Pharmaceutical Industries Ltd., P.O.B. 3190, Petah-Tiqva.

This leaflet was checked and approved by the Ministry of Health on 30/9/2013.

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

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