

This 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 information about inactive ingredients and allergens, 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.

Take the medicine according to the instructions in section 3 - 'How to use this medicine'. Consult your pharmacist if you need additional information. Refer to the doctor if signs of the ailment (symptoms) worsen or do not improve after 5 days of pain treatment or after 3 days of treatment of pain accompanied by fever (see section 3 - 'How to use this medicine').

### 1. What is this medicine intended for?

The medicine is intended for temporary relief of headaches, mild to moderate pain associated with migraine headache, pain of menstrual discomfort and pain accompanied by fever.

### Therapeutic group:

**Acetylsalicylic acid** - non-steroidal anti-inflammatory drug (NSAIDs)

**Paracetamol** - analgesic and antipyretic

**Caffeine** - xanthine alkaloid, central nervous system stimulant

### 2. Before using this medicine

**Do not use this medicine if:**

- You are sensitive (allergic) to the active ingredients or any of the other ingredients in this medicine (see details in section 6). **Symptoms of an allergic reaction** may include asthma, wheezing or shortness of breath, skin rash or hives, swelling of the face or tongue, runny nose. If you are not sure, ask your doctor or pharmacist.
- You had an allergic reaction in the past to other medicines used to treat pain, inflammation or fever, such as diclofenac or ibuprofen.
- You have a stomach or intestinal ulcer, or if you have a history of peptic ulceration.
- You have observed blood in the stool or black stool (symptoms of bleeding or perforations in the digestive tract).
- You have hemophilia or other blood disorders.
- You have severe problems in the heart, liver and kidneys.
- You are taking more than 15 mg of methotrexate per week (see the 'Drug interactions' section).
- You are in the last three months of pregnancy (see the 'Pregnancy, breastfeeding and fertility' section).

### Special warnings about using this medicine

**Before treatment with Acamol Focus, tell your doctor if:**

- You have not been diagnosed with migraines in the past, since potentially severe conditions that are related to the brain or the nervous system should be ruled out before treatment.
- You have a migraine so acute that it necessitates bed rest, or if you have a headache that is different from your usual migraines, or if the migraine headaches are accompanied by vomiting.
- You started to have headaches after or due to a head injury, exertion, cough or bending over.
- You have chronic headaches (fifteen days or more in one month for more than three months), or if you have experienced your first headache after the age of 50.
- You are suffering from a hereditary condition called G6PD (Glucose-6-Phosphate Dehydrogenase) deficiency, which affects the red blood cells and may cause anemia, jaundice or spleen enlargement upon exposure to certain types of food and to medicines such as certain anti-inflammatory medicines (e.g. acetylsalicylic acid (aspirin)), or cause other illnesses.
- You had problems in the digestive system such as gastric ulcer, bleeding or black stool in the past. You had abdominal discomfort or heartburn after taking analgesics or anti-inflammatory medicines.
- You are suffering from bleeding disorders or abnormal vaginal bleeding that differs from your menstrual period (e.g., an unusually heavy and prolonged menstrual period).
- You have recently undergone a surgical operation (including minor ones such as dental surgery), or will undergo one within the next seven days.
- You have adult asthma, hay fever (allergic rhinitis), nasal polyps, chronic respiratory disease or you are developing allergic symptoms (such as skin reactions, itching, urticaria).
- You have gout, diabetes, overactive thyroid, arrhythmias, uncontrolled hypertension, impaired kidney or liver function.
- You are addicted to alcohol (see the 'Using this medicine and alcohol consumption' section).
- You are taking other medicines that contain acetylsalicylic acid (aspirin) or paracetamol, or other medicines, since certain medicines may interfere with Acamol Focus and cause side effects (see the 'Drug interactions' section).
- You are at risk of being dehydrated (e.g. due to vomiting, diarrhea, or before or after a major surgery).
- You are less than 18 years old. There is a possible association between acetylsalicylic acid (aspirin) and Reye's Syndrome when the medicine is given to children and adolescents. Reye's Syndrome is a rare syndrome which affects the brain and the liver and can be fatal. For that reason, Acamol Focus should not be used in adolescents and children under 18 years old without an explicit instruction from the doctor.
- You have or have had jaundice.

### Additional warnings:

As with any type of headache analgesics, taking Acamol Focus too often (i.e. more than ten days per month for this medicine) with concurrent chronic headaches (fifteen days or more per month), for more than three months, could worsen your headache or migraine. If you think this might be the case, refer to your doctor. You may have to stop taking Acamol Focus to resolve this problem.

Acamol Focus may reduce the symptoms of infection (e.g. headache, high body temperature) and may therefore make it more difficult to detect. If you are feeling unwell and need to see a doctor, remember to inform them that you are taking Acamol Focus.

### Children and adolescents

Acamol Focus is not intended for children and adolescents under the age of 12.

### Tests and follow-up

Acamol Focus may affect the results of laboratory tests. If you have been asked to have blood, urine or other lab tests, remember to tell that you are taking Acamol Focus.

### 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:

- Any other medicine that contains paracetamol, acetylsalicylic acid (aspirin) or any other analgesic/antipyretic.
- Medicines used to prevent blood clotting such as oral anticoagulants (e.g. warfarin), heparin, thrombolytics (e.g. streptokinase) or other antiplatelets (ticlopidine, clopidogrel, cilostazol).
- Corticosteroids (used for relieving inflammation).
- Barbiturates and benzodiazepines (for treatment of anxiety and insomnia).
- Lithium, SSRIs (Selective Serotonin Reuptake Inhibitors) or fluvoxamine (for treatment of depression).
- Sulfonylurea and insulin (for treatment of diabetes).
- Methotrexate (for treatment of certain types of cancer, arthritis or psoriasis).
- Certain medicines for treating infections (e.g. rifampicin, isoniazid, chloramphenicol, ciprofloxacin or piperimic acid).
- Levothyroxine (for treatment of hypothyroidism (underactive thyroid)).
- Metoclopramide (for treatment of nausea and vomiting).
- Medicines for treatment of epilepsy.
- Medicines for treatment of hypertension and heart failure.
- Diuretics (for increasing urine production and reducing excessive fluids).
- Medicines for treatment of gout.
- Oral contraceptives.
- Zidovudine (for treatment of human immunodeficiency virus).
- Medicines for treatment of slow gastric emptying, such as propantheline.
- Clozapine (for treatment of schizophrenia).
- Sympathomimetic medicines (for raising blood pressure or treating nasal congestion).
- Anti-allergy medicines (for treatment or relief of allergies).
- Theophylline (for treatment of asthma).
- Terbinafine (for treatment of fungal infections).
- Cimetidine (for treatment of heartburn and peptic ulcers).
- Disulfiram (for treatment of alcohol dependence).
- Nicotine (for smoking cessation).
- Cholestyramine (for treatment of high cholesterol levels).

### Using this medicine and food

The recommended dose of this medicine contains an amount of caffeine similar to that in a cup of coffee. While using this medicine, limit your intake of caffeine-containing medicines, foods and beverages, because too much caffeine may cause nervousness, irritability, sleeplessness, and occasionally, rapid heartbeat.

### Using this medicine and alcohol consumption

Refrain from alcohol consumption during treatment with this medicine. If you are consuming three or more alcoholic beverages a day, ask your doctor whether you should take this medicine or other medicines for relieving pain/lowering fever. Paracetamol and acetylsalicylic acid (aspirin) may damage the liver and cause stomach bleeding.

### Pregnancy, breastfeeding and fertility

- If you are pregnant, think you might be pregnant or are planning to become pregnant, inform your doctor and do not take Acamol Focus.
- It is especially important not to take Acamol Focus during the last three months of the pregnancy, since it may harm the fetus or cause problems during labor.
- Acamol Focus is not recommended while breastfeeding.
- Consult with your doctor or pharmacist before taking any medicine.
- Acamol Focus belongs to a group of medicines (NSAIDs) which may impair women's fertility. This effect is reversible when the medicine is stopped.
- This medicine has the potential side effect of kidney damage to the unborn baby and insufficient amniotic fluid as of Week 20 of the pregnancy. It is recommended that you avoid use of NSAIDs as of Week 20 of pregnancy and consult with a healthcare professional if necessary.

**Driving and using machines:** Taking Acamol Focus has no known effect on your ability to drive and use machines.

If you notice side effects such as dizziness or drowsiness, you should avoid driving and using machines.

Tell your doctor as soon as possible.

### Important information about some of this medicine's ingredients:

Acamol Focus contains Allura Red and Sunset Yellow FCF that may cause allergic reactions.

### 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.

The recommended dosage is usually:

#### For treatment of migraine-related headaches:

Adults: 2 caplets. If the medicine was taken for a migraine with no improvement, or if it became worse after one dose, consult your doctor. Children under 18 years of age: Consult your doctor.

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

#### For headaches, pain of menstrual discomfort and pain accompanied by fever:

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

Pain relief may be felt within 15 minutes of taking the dose.

Do not take more than 8 caplets in 24 hours.

#### Do not exceed the recommended dose.

Do not use this medicine for more than 5 days for pain or 3 days for pain with fever without consulting the doctor.

#### Elderly:

There is no special dosage recommendation. If you have low body weight, you should seek the advice of your doctor or a pharmacist.

The medicine should be swallowed whole with a full glass of water.

Do not split or crush the medicine.

There is no information about splitting/crushing/chewing.

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

Acamol Focus caplets contain acetylsalicylic acid (aspirin), paracetamol and caffeine. Do not take more than the recommended dosage and do not take other medicines that may contain these ingredients or other ingredients used for treatment of pain, inflammation or high fever (non-steroidal anti-inflammatory drugs) while using Acamol Focus.

Refrain from taking a high dose (within the recommended limit) of this medicine while fasting.

**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.

Immediate medical treatment is critical, due to the possible risk of irreversible damage to the liver on account of the paracetamol. Do not wait for the appearance of symptoms, since in the beginning the overdose may not cause noticeable symptoms.

If symptoms of overdose do appear, they may be:

- For acetylsalicylic acid (aspirin):** Dizziness, ringing in the ears, deafness, sweating, hyperventilation, high fever, nausea, vomiting, headache, confusion or restlessness, circulatory collapse or respiratory failure.
- For paracetamol:** Initial symptoms that may appear are nausea, vomiting, diarrhea, loss of appetite, pallor, drowsiness, sweating and later abdominal pain, bloating, pain or sensitivity in the upper stomach, which may not reflect the severity of the damage to the liver.
- For caffeine:** Anxiety, nervousness, restlessness, insomnia, excitement, muscle cramps, confusion, convulsions, hyperglycemia, tachycardia (rapid heartbeat) or cardiac arrhythmia.

**Even if these symptoms do not appear or if they resolve, it is vital to seek medical help immediately.**

**If you forgot to take the medicine,** take it as soon as you remember, but do not take a double dose to compensate for a forgotten dose.

Do not take more than 8 caplets in a 24-hour period.

**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 all medicines, using Acamol Focus may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.**

**Stop using the medicine and contact a doctor immediately if you experience one or more of these severe side effects:**

- An allergic reaction with swelling of the face, lips, mouth, tongue or throat. This may cause difficulty in swallowing, wheezing, breathing difficulties, and feeling of tightness in the chest (signs of asthma). You may also have a rash or itching, or you may faint.
- A skin rash (including hives, itching), skin redness, blisters in the lips, eyes or mouth, skin peeling, sores, mouth ulcers.

In rare cases, paracetamol may cause the appearance of acute skin diseases, the symptoms of which may be redness, rash, blisters, extensive skin damage. Acute skin side effects may appear even if you have taken medicines that contain the active ingredient paracetamol without any problems.

If skin side effects appear, stop treatment and contact your doctor immediately.

- If signs of changes in the blood system appear such as bleeding, bruises, development of inflammation more easily.
  - Stomach or intestinal bleeding, stomach or intestinal ulcer, which may be accompanied by acute abdominal pain, bloody or black stool or bloody vomit. As with treatment with all analgesics and antipyretics, this can happen at any time during the treatment, without prior history, and may be fatal. This side effect is especially severe in the elderly.
  - Yellowing of the skin or eyes (signs of liver failure).
  - Dizziness (signs of low blood pressure).
  - Irregular heartbeat.

### Additional side effects

The following side effects have been reported in 16 clinical trials conducted on more than 4,800 patients.

Tell your doctor if you notice any of the following side effects:

#### Common side effects – affect up to 1 in 10 users

- Nervousness, dizziness
- Nausea, abdominal discomfort

#### Uncommon side effects – affect up to 1 in 100 users

- Insomnia, tremor, numbness, headache
- Ringing in the ears
- Dry mouth, diarrhea, vomiting
- Tiredness, feeling of nervousness
- Increase in heart rate

#### Rare side effects – affect up to 1 in 1,000 users

- Sore throat, difficulty swallowing, numbness or tingling around the mouth, excessive saliva
- Decreased appetite, altered sense of taste
- Anxiety, euphoria, stress
- Attention disorders, memory loss, changes in coordination
- Pain sensation in the cheeks and forehead
- Eye pain, vision disturbances
- Hot flashes, problems in peripheral blood vessels (such as in the arms or legs)
- Nose bleeds, slow and shallow breathing, runny nose
- Burping, flatulence (gas)
- Excessive sweating, itching, itchy rash, increased skin sensitivity
- Muscle, bone or joint rigidity, neck pain, back pain, muscle cramps
- Weakness, chest discomfort

**Side effects with unknown frequency (effects whose frequency has not yet been determined)**

The following side effects have also been reported since the beginning of marketing of the medicine. In general, the frequency during post-marketing surveillance cannot be determined precisely, thus it is indicated as "unknown".

- Restlessness, general bad or abnormal feeling
- Somnolence, migraine
- Skin reddening, rash. Very rare cases of severe skin reactions have been reported.
- Palpitations, shortness of breath, sudden breathing difficulties, and feeling of tightness in the chest with wheezing or cough (asthma)
- Abdominal pain, abdominal discomfort after meals
- Liver enzyme elevation

**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](http://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) which is stated on the package. The expiry date refers to the last day of that month.

### Storage conditions

**Store in a dry place, below 25°C.**

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

**Leave the desiccant in the container and close the container tightly after each use.**

### 6. Additional information

**In addition to the active ingredients, this medicine also contains:**

Microcrystalline cellulose, stearic acid, crospovidone, silicon dioxide, pregelatinized starch, polyvidone, 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 contents of the pack:

Red, biconvex caplets

Package sizes: the package contains 30 or 50 caplets in a bottle with a desiccant. Not all pack sizes may be marketed.

#### Manufacturer and registration holder:

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

**This leaflet was revised in January 2022 according to MOH guidelines.**

**Registration number of the medicine in the Ministry of Health's National Drug Registry:** 131 35 30995