

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

Read this package insert carefully in its entirety before using this medicine

The format of this leaflet was determined by the Ministry of Health and its content was checked and approved by it in February 2012

This medicine is dispensed without need of a doctor's prescription.

You must use it correctly.
Consult the pharmacist if you need further information.

Refer to the doctor if symptoms of your illness get worse or do not improve after three days.

ACETOSAL 300 mg Tablets

Composition: Each tablet contains:
Acetylsalicylic Acid 300 mg

Inactive ingredients: Starch, Aerosil

Therapeutic group: Non-steroidal anti-inflammatory drugs (NSAIDs).

Indication: Relief of pain and reduction of fever, treatment of non-infectious inflammatory processes (anti-rheumatic).
(Treatment of rheumatic conditions, according to doctor's instructions only).

When should the preparation not be used?

Do not use this medicine if you are breastfeeding.

Do not use during the third trimester of pregnancy.

Do not use this medicine if there is a known sensitivity to any of its ingredients or to other non-steroidal anti-inflammatory drugs or salicylates. Do not use if there is a history of asthma caused by exposure to salicylates or other substances with similar action, particularly non-steroidal anti-inflammatory drugs. Do not use the preparation if you have ever had an allergic reaction when taking any analgesic. Do not take concomitantly with other non-steroidal anti-inflammatory drugs.

If you have just undergone or are about to undergo heart surgery.

Do not use this medicine in children and adolescents up to 20 years of age for diseases accompanied by fever such as influenza or chickenpox, for fear of Reye's syndrome.

Do not use this medicine in patients with asthma associated with nasal polyps.

Do not use this medicine in patients who are suffering or have suffered from ulcer of the stomach or intestine, dyspepsia, bleeding, in hemophilia patients, coagulation or platelet function disorders - thrombocytopenia (too few platelets). Avoid concomitant use with anticoagulants.

In case of kidney failure, liver failure or severe heart failure.

Do not take this medicine without consulting a doctor before starting treatment:

If you are pregnant. If you are suffering, or have suffered in the past, from impaired function of: the respiratory system (e.g., asthma, chronic respiratory tract infections, hay fever or nasal polyps), the heart and/or vascular system, the liver, the kidney/urinary tract, the digestive system (history of gastrointestinal ulcers or bleeding), the blood system (such as coagulation disorders) heartburn, hypertension.

Do not use this medicine if you are suffering, or have suffered in the past, from a stomach problem, such as: heartburn, abdominal pain or peptic ulcer, heart and kidney diseases. If you are taking diuretics, if you are above 60 years of age, if taking a medicine from this group or any other analgesics in the past caused severe side effects. If you are suffering, or have suffered in the past, from: anemia, dehydration, gout, impaired liver function, lupus. In children or adolescents for viral infectious diseases with or without fever.

If you suffer from allergies (skin reactions, itching, urticaria).

Warnings: Do not use this medicine in children and adolescents without consulting your doctor.

Do not use this medicine frequently and for more than 3 consecutive days without consulting the doctor.

If you are sensitive to any type of food or medicine, inform your doctor before commencing treatment with this medicine. During prolonged treatment with this medicine or treatment at high dosages, the following tests should be performed: blood, liver and kidney function. Inform your doctor, or discontinue use if the medicine was not taken according to the doctor's instructions, 5 days before surgical intervention, dental surgery or treatment. If you consume 3 or more alcoholic drinks a day, consult a doctor about whether you should take this medicine or use another preparation for relief of pain and/or reduction of fever, since acetylsalicylic acid in combination with alcohol may cause bleeding in the stomach. Taking this preparation may cause bleeding in the stomach, especially if: you are past 60 years of age, you are taking other non-steroidal anti-inflammatory drugs, you consume more than 3 alcoholic drinks a day. Taking this preparation at higher than recommended dosage or for longer than 10 days may increase the risk of stroke or heart attack and bleeding in the stomach. Do not use this preparation for 6 weeks after chickenpox vaccination. Prolonged intake of analgesics can cause headache. Regular intake of analgesics, especially concomitantly with different kinds of analgesics, may harm the kidneys.

Drug Interactions: If you are taking another drug concomitantly or if you have just finished treatment with another medicine, including non-prescription medicines and nutritional supplements, inform the attending doctor, in order to prevent hazards or lack of efficacy arising from drug interactions. This is especially

important for medicines belonging to the following groups: anti-nausea medicines (metoclopramide, domperidone), anticoagulants, anti-diabetics, steroids, ascorbic acid (Vitamin C), medicines for treatment of gout (probenecid, sulfinpyrazone, phenylbutazone), medicines for treating glaucoma (acetazolamide), medicines for treating epilepsy (valproic acid, phenytoin), methotrexate, diuretics (furosemide, spironolactone), antibiotics (for the tetracycline group, vancomycin, additional medicines with analgesic and anti-inflammatory action, other salicylates or non-steroidal anti-inflammatory drugs, medicines for treating acquired immunodeficiency syndrome (zidovudine), medicines which change urine pH (antacids, citrate, carbonic anhydrase inhibitor), mifepristone, chickenpox vaccine, anti-hypertensives (ACE inhibitors - such as ramipril, enalapril, captopril and calcium channel blockers), SSRI antidepressants (such as fluoxetine), cyclosporin, tacrolimus, digoxin, lithium, nicotinic acid, ginkgo biloba (food supplement).

Side Effects: In addition to the desired effect of the medicine, adverse reactions may occur during the course of taking this medicine, such as: mild abdominal pain and heartburn, nausea and vomiting. These side effects usually disappear within a short time following the period of adaptation to the medicine. However, if they continue or disturb you, consult your doctor.

Effects that require special attention:

Nausea, dizziness, weakness (rare): stop treatment and contact the doctor.
Hyperproduction of gastric mucosa (rare): stop treatment and contact the doctor.

Rare side effects: Severe bleeding such as cerebral hemorrhage (especially in patients with uncontrolled hypertension and/or under treatment with anticoagulants): stop treatment and contact the doctor. Increased risk of bleeding, e.g., bleeding after surgery, hemorrhages, nose bleeds, skin bleeding, urogenital bleeding, bleeding gums: stop treatment and contact the doctor. Bloody or black stools or bloody vomit (rare), clinical and laboratory anemia manifested by weakness, paleness, reduced blood flow to the tissues: stop treatment and contact the doctor immediately. Gastrointestinal inflammation and ulcers (rare), which under some circumstances are accompanied by hemorrhages and perforation of the intestinal wall (very rare), temporarily impaired liver function and elevation of liver enzymes (very rare), gastrointestinal inflammation (rare): stop treatment and contact the doctor immediately. Multisystem allergic reaction that includes reactions such as: rash, urticaria, edema, pruritis, a drop in blood pressure, attacks of breathing difficulties, runny nose, nasal congestion, swelling of the face, tongue and pharynx (angioedema), severe skin reactions (rare), and in rare cases a severe reaction including anaphylactic shock: stop treatment and contact the doctor immediately. Dizziness, tinnitus, headache, hearing disruption, mental confusion - can be signs of overdose: stop

treatment and contact the doctor.

If you feel faint, stop treatment and contact the doctor immediately.

In the event that you experience side effects not mentioned in this leaflet, or if there is a change in your general health, consult your doctor immediately.

Adverse reactions and drug interactions in children: Parents must inform the attending doctor about any side effects, as well as any additional medicine being taken by the child. See above for details of special warnings.

Recommended dosage unless otherwise prescribed by your doctor: Before first use of the medicine - consult the doctor.

For pain relief and reducing fever:

Children and adolescents: Do not use without consulting your doctor.

Adults: 1-2 tablets every 4-6 hours.

Do not exceed the recommended dosage.

If there is no improvement in your condition within 3 days, notify your doctor (unless given by the doctor for treatment of rheumatic conditions).

Treatment of rheumatic conditions: according to the doctor's instructions.

If you forget to take this medicine at the specified time, take the dose as soon as you remember, but never take a double dose to compensate for a missed one.

Directions for Use: Do not chew! Swallow the medicine with a full cup of water. Take the medicine with or after a meal. Do not keep this medicine in your mouth longer than the time required for swallowing it. Do not lie down for 15-30 minutes after taking the medicine.

Avoid Poisoning!

This medicine, and all other medicines, must be stored in a safe place out of the reach of children and/or infants, to avoid poisoning.

If you have taken an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you.

Do not induce vomiting unless explicitly instructed to do so by a doctor! This medicine has been prescribed for the treatment of your ailment, in another patient it may cause harm. **Do not give this medicine to your relatives, neighbors or acquaintances.**

Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them.

Storage: Store at a temperature below 25°C. Even if kept in their original container and stored as recommended, medicines may be kept for a limited period only. Please note the expiry date of the medicine! In case of doubt, consult the pharmacist who dispensed the medicine to you. Do not store different medications in the same package.

Licence Number: 020 68 20911 00

Manufacturer: Rekah Pharmaceutical Industry Ltd., 30 Hamelacha St., Holon.