



## **Patient package insert according to Pharmacists' Regulations (Preparations) – 1986**

This medicine can be sold without a physician's prescription

### **Micropirin® 75, 100, Enteric Coated Tablets**

Each enteric-coated tablet contains acetylsalicylic acid at a dosage of 75 or 100 mg, respectively.

Inactive ingredients and allergens in the medicine - see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of the medicine".

**Read this entire leaflet carefully before using the medicine.** This leaflet contains concise information about the medicine. If you have any further questions, ask the doctor or pharmacist.

Take this medicine according to the instructions in section 3 "How to use the medicine?" in this leaflet. Consult the pharmacist if you need additional information.

#### **1. What is the medicine intended for?**

The medicine is intended for primary prevention of coronary heart disease in patients at increased risk and secondary prevention of heart and brain disease caused by arterial thrombosis.

**Therapeutic group:** anticoagulant, platelet aggregation inhibitor.

**Micropirin** inhibits the aggregation of blood platelets and in this way prevents blood clots from developing.

#### **2. Before using the medicine**

**Do not use the medicine if:**

- You are hypersensitive (allergic) to the active ingredient (acetylsalicylic acid), salicylates or any of the other ingredients this medicine contains (see section 6).
- You have a history of reacting to certain medicines for pain, fever, or inflammation (salicylates or other nonsteroidal anti-inflammatory drugs) experienced as asthma attacks or other allergic reactions.
- You have acute gastric or intestinal ulcers.
- You have a tendency to disorders leading to bleeding.
- You have kidney or liver failure.
- You have severe heart failure which is not being adequately treated.
- You are concurrently taking a 15 mg dosage of methotrexate or more a week.
- You are in your last trimester of pregnancy and are taking a daily dosage above 150 mg (see section "Pregnancy, breastfeeding and fertility").

#### **Special warnings regarding the use of the medicine**

**Before the treatment with Micropirin, tell the doctor if:**

- You are sensitive to other pain-relief, anti-inflammatory or antirheumatic medicines or other allergenic substances.
- You are also taking nonsteroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen or naproxen (medicines to treat pain, fever or inflammation). (See section "Medicines that weaken the effect of this medicine").
- You have other allergies (with symptoms like skin reactions, itching or hives).
- You have bronchial asthma, hay fever (allergic rhinitis), swelling of the nasal mucosa (nasal polyps) or chronic respiratory tract diseases.
- You are already being treated with anticoagulant medicines (such as coumarin derivatives or heparin, with the exception of low-dose heparin).

- You have gastric or duodenal ulcers or a history of gastrointestinal bleeding.
- You have impaired liver function.
- You have impaired renal function or impaired function of the cardiovascular system (such as renal vascular disease, congestive heart failure, blood volume depletion, major surgery, sepsis or major hemorrhagic events), because acetylsalicylic acid may further increase the risk of damage to your renal function and acute renal failure.
- You are about to have surgery (including minor surgery such as dental extractions): there may be an increased tendency to bleed. Inform your doctor or dentist that you are taking **Micropirin**.
- You know that you have severe glucose-6-phosphate dehydrogenase (G6PD) deficiency. Acetylsalicylic acid may cause accelerated breakdown or disintegration of the red blood cells or a certain type of anemia. Factors that may increase the risk of this are for example: high dosage, fever, or acute infections.

### **Additional warnings**

- At low doses, acetylsalicylic acid reduces the excretion of uric acid. This condition may cause a gout attack in predisposed patients.
- If you get cut or injured, the bleeding may continue for longer than usual. This has to do with the action of this medicine. Minor cuts or injuries (for example when shaving) are generally not significant. If you experience unusual bleeding (at an unusual place or for an unusual length of time), consult the doctor.
- Do not take medicines containing acetylsalicylic acid for prolonged periods or at high doses without consulting a doctor.

### **Children and adolescents**

This medicine is intended for adults over the age of 18. Under this age, consult a doctor. Do not use **Micropirin** in children or adolescents with feverish illnesses unless instructed to do so by a doctor and other therapeutic measures have failed. Prolonged vomiting in conjunction with such an illness could be a sign of Reye's syndrome, a very rare but life-threatening disease which requires immediate medical attention.

### **Drug interactions**

**If you are taking, or have recently taken medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.** Especially if you are taking:

Medicines that increase the effect of the medicine to the extent that there is an increased risk of side effects:

- Anticoagulants (such as coumarin, heparin) and medicines that dissolve blood clots: acetylsalicylic acid can increase the risk of bleeding if taken before treatment with thrombolytic agents. Pay attention to external and internal signs of bleeding (such as bruising) if you are undergoing such treatment.
- Other platelet aggregation inhibitors (medicines that inhibit the clumping together of blood platelets) such as ticlopidine, clopidogrel: increased risk of bleeding.
- Medicines containing cortisone or cortisone-like substances (with the exception those that are used for local treatment or cortisone replacement therapy for Addison's disease): the risk for gastrointestinal bleeding and ulcers is increased.
- Alcohol: increased risk of gastrointestinal ulcers and bleeding.
- Other pain-relief and anti-inflammatory medicines (nonsteroidal anti-inflammatory drugs) and antirheumatic medicines with salicylic acid: increased risk of gastrointestinal ulcers and bleeding.
- Medicines for diabetes such as insulin, tolbutamide, glibenclamide (so called sulfonylureas) in combination with acetylsalicylic acid at high doses: blood glucose level may be reduced.
- Digoxin (a medicine to strengthen the heart muscle contraction).

- Methotrexate (used to treat cancer and certain rheumatic disorders).
- Valproic acid (used to treat epilepsy).
- SSRI (selective serotonin re-uptake inhibitors) medicines for the treatment of depression: increased risk of gastrointestinal ulcers and bleeding.

Medicines that weaken the effect of this medicine:

- Certain medicines that increase the excretion of urine (diuretics: aldosterone antagonists such as spironolactone, canrenoate, loop diuretics such as furosemide).
- Certain medicines for hypertension (in particular Angiotensin Converting Enzyme (ACE) inhibitors).
- Medicines for gout that increase the excretion of uric acid (such as probenecid, benzbromarone).
- Some nonsteroidal anti-inflammatory drugs (NSAIDs) (with the exception of acetylsalicylic acid) such as ibuprofen and naproxen: reduced effect on inhibition of platelet agglutination and clotting; may reduce the protective effect this medicine has against heart attacks and stroke.
- Metamizole (a medicine used to reduce pain and fever): may reduce the effect of acetylsalicylic acid on platelet aggregation when both medicines are taken together. Therefore, this combination should be used with caution in patients taking low-dose aspirin to protect the heart.

Before using acetylsalicylic acid inform the doctor about other medicines you are taking. If you are using acetylsalicylic acid regularly, consult your doctor before taking any other medicine, including non-prescription medicines.

Do not take **Micropirin** with any of the medicines listed above unless explicitly instructed to do so by a doctor.

### **Use of the medicine and food**

Swallow the tablet whole with plenty of water, at least 30 minutes before a meal.

### **Use of the medicine and alcohol consumption**

Do not consume alcohol while you are taking acetylsalicylic acid treatment.

### **Pregnancy, breastfeeding and fertility**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult a doctor or pharmacist before using this medicine.

#### Pregnancy

In the first and second trimester of pregnancy, **Micropirin** should only be taken if prescribed by a doctor.

In the last trimester of pregnancy, acetylsalicylic acid, the active ingredient in **Micropirin**, must not be taken at a dosage of more than 150 mg per day, due to an increased risk of complications for the mother and child before and during the delivery (this includes an increased risk of miscarriage and certain birth defects; see also "Do not use the medicine if"). During the last trimester of pregnancy, doses of up to 150 mg of **Micropirin** per day may only be taken if prescribed by your doctor.

#### Breastfeeding

Small amounts of acetylsalicylic acid and its metabolites pass into breast milk. No negative effects on the infant have been reported to date, so you do not have to stop breastfeeding if your daily dose is not greater than 150 mg. However, if you are taking higher doses (more than 150 mg daily), stop breastfeeding.

### **Driving and using machines**

No special precautions are necessary.

### **Important information about some of the ingredients of the medicine**

This medicine contains lactose. If you have been told by a doctor that you have an intolerance to certain sugars, consult your doctor before starting treatment with this medicine.

### **3. How to use the medicine?**

Check with your doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.

The usual recommended dosage is: One tablet a day.

**Do not exceed the recommended dose.**

#### **Treatment duration**

**Micropirin** is intended for long-term use. Your doctor will decide on the length of the treatment.

#### **Method of administration**

- Swallow the tablet whole with plenty of water, at least 30 minutes before a meal.
- Do not split, break or chew the tablet, because the medicine has an enteric (protective) coating.
- Do not keep the medicine in your mouth for longer than it takes to swallow it.

#### **If you have accidentally taken a higher dosage**

Dizziness and ringing in the ears, particularly in children and elderly patients, may be signs of serious poisoning. Inform your doctor immediately if you suspect you have overdosed. Your doctor will decide on the necessary measures to be taken depending on the severity of the overdose.

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

#### **If you forgot to take the medicine**

If you forgot to take this medicine at the designated time, continue to take a dose as recommended above under "How to use the medicine?", or as prescribed by the doctor, but never take a double dose to make up for a forgotten dose!

#### **If you stop taking the medicine**

Do not stop taking the medicine without consulting your doctor.

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

**If you have further questions on the use of this medicine, consult the doctor or pharmacist.**

### **4. Side effects**

Like any medicine, the use of **Micropirin** 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.

**If you experience any of the side effects listed below, stop taking Micropirin and inform the doctor so that the doctor will be able to evaluate the severity of the side effect and decide what to do.**

**Stop using Micropirin at the first signs of hypersensitivity (see below under Rare side effects).**

**Common side effects** (effects that occur in 1-10 in 100 users):

- Heartburn

- Nausea and vomiting, stomach ache
- Diarrhea
- Minor blood loss from the gastrointestinal tract

**Uncommon side effects** (effects that occur in 1-10 in 1,000 users):

- Skin reactions (in very rare cases there may be a severe eruption of skin rash involving the mucous membranes and fever (Erythema exsudativum multiforme)).
- Gastrointestinal bleeding. Prolonged use of **Micropirin** may cause anemia (due to iron deficiency) as a result of occult blood loss from the gastrointestinal tract. Severe bleeding in the gastrointestinal tract may be experienced as black stools or vomiting blood.
- Gastrointestinal ulcers which in very rare cases can lead to perforation.
- Gastrointestinal inflammation.

If you notice black stools or bloody vomit (signs of serious bleeding in the stomach, see "Countermeasures", below), refer immediately to the doctor.

**Rare side effects** (effects that occur in 1-10 in 10,000 users):

- Hypersensitivity reactions of the skin, the respiratory system, the gastrointestinal tract and cardiovascular system, particularly in patients with asthma. Symptoms could be: drop in blood pressure, attacks of difficult breathing, inflammation of nasal mucosa, stuffy nose, allergic reactions, swelling of the face, tongue, and throat (angioedema).

**Very rare side effects** (effects that occur in less than 1 in 10,000 users):

- Elevated liver values.
- Renal impairment and acute renal failure.
- Reduced blood sugar levels (hypoglycemia).
- At low doses acetylsalicylic acid reduces the excretion of uric acid. This condition may cause a gout attack in predisposed patients.

**Side effects with unknown frequency** (effects for which a frequency has not yet been determined):

- Headache, dizziness, confusion, impaired hearing and tinnitus (ringing in your ears) can be signs of an overdose, especially in children and elderly patients (see "If you have accidentally taken a higher dosage").
- There have been reports of severe bleeding such as bleeding in the brain (particularly in patients with uncontrolled hypertension and/or combined treatment with anticoagulants). These are rare to very rare reports, in which some of the cases were life-threatening.
- Accelerated breakdown or disintegration of red blood cells and a certain type of anemia in patients with severe glucose-6-phosphate dehydrogenase (G6PD) deficiency.
- Bleeding: nosebleeds, bleeding gums, skin bleeding or bleeding from the urinary tract and genitals, possibly with prolongation of the bleeding time. This effect can persist for 4 to 8 days after use.
- If there is pre-existing damage to the intestinal mucosa, membranes may form in the intestinal cavity possibly with subsequent constriction.

#### Countermeasures:

Stop taking **Micropirin** if you experience any of the side effects listed above, and inform the doctor, who will decide what should be done, depending on the severity of the side effect. Stop taking **Micropirin** permanently at the first sign of a hypersensitivity reaction.

**If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect which is not mentioned in this leaflet, consult the doctor.**

Side effects can be reported to the Ministry of Health by clicking the link

"דיווח על תופעות לוואי עקב טיפול תרופתי" found on the homepage of the Ministry of Health website ([www.health.gov.il](http://www.health.gov.il)) directing to the online form for reporting side effects or via the link: <https://sideeffects.health.gov.il>

## **5. How to store the medicine?**

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (תאריך תפוגה) stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Store below 25°C.
- Do not throw away any medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Additional information**

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

Lactose monohydrate, corn starch, microcrystalline cellulose, stearic acid, methacrylic acid copolymer 30%, silica colloidal anhydrous, talc, triethyl citrate.

**Micropirin 100** also contains yellow iron oxide.

### **What the medicine looks like and what the package contains:**

**Micropirin 75:** White, round film-coated tablets.

Approved package sizes: 14, 20, 28, 30, 50 tablets.

**Micropirin 100:** Yellow, round film-coated tablets.

Approved package sizes: 10, 14, 28, 30 tablets.

Not all package sizes may be marketed.

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### **Drug registration number at the national drug registry of the Ministry of Health:**

**Micropirin 75:** 067-43-27307-00

**Micropirin 100:** 103-93-28861-01

**Manufacturer and registration holder:** Dexcel Ltd., 1 Dexcel St., Or Akiva 3060000, Israel