

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed without a doctor's prescription

Medipirin 100 mg Gastro-resistant tablets

Each tablet contains:

Acetylsalicylic acid 100 mg

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

Read this 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 this medicine according to the instructions in the section about dose in this leaflet. Consult your pharmacist if you need further information.

1. What is this medicine intended for?

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

Therapeutic group: anticoagulant, platelet aggregation inhibitor.

Medipirin 100 mg inhibits the aggregation of blood platelets and in this way prevents blood clots from developing.

2. Before using this medicine

Do not use this medicine if:

- you are sensitive (allergic) to acetylsalicylic acid, salicylates or any of the other ingredients of this medicine (see section 6 'Additional information' for a list of inactive ingredients)
- 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 ulcers in your stomach or intestines
- you have a pathologically increased tendency to bleed
- 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 the section 'Pregnancy and breastfeeding').

Special warnings about using this medicine

Before using Medipirin 100 mg tell your doctor if:

- you are sensitive to other pain-relief, anti-inflammatory or antirheumatic medicines or other allergy-triggering substances.
- you are also taking nonsteroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen or naproxen (medicines for pain, fever or inflammation). See section 'Medicines that weaken the effect of this medicine'.
- you have other allergies (with symptoms like skin reactions, itching, hives).
- you have bronchial asthma, hay fever (allergic rhinitis), swelling of the nasal mucosa (nasal polyps) or chronic respiratory tract diseases.
- you are undergoing concomitant treatment with anticoagulant medicines (such as coumarin derivatives or heparin, with the exception of low-dose heparin).
- you have a history of stomach or intestinal ulcers or a history of bleeding in your stomach or intestines.
- you have impaired liver function.
- you have impaired renal function or reduced blood flow in your heart and blood vessels (for example renal vascular disease, congestive heart failure, blood volume depletion, major surgery, blood poisoning or severe bleedings), because acetylsalicylic acid may further increase the risk of damage to your renal function and acute renal failure.
- you are about to have a surgery, including a minor surgery (such as a tooth extraction): there may be an increased tendency to bleed. Inform your doctor or dentist that you are taking Medipirin 100 mg.
- you know that you have severe glucose-6-phosphate dehydrogenase (G6PD) deficiency. Acetylsalicylic acid may induce accelerated breakdown or disintegration of 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 may under certain circumstances cause a gout attack in predisposed patients.
- If you cut or injure yourself, it may take longer than usual for the bleeding to stop. This has to do with the action of this medicine. Minor cuts and injuries (for example when shaving) are usually not a problem. In the event of unusual bleeding (at an unusual place or for an unusual length of time), consult your 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. For younger patients, consult a doctor. Do not use Medipirin 100 mg 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 illnesses 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 other medicines, including non-prescription medications and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:

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

- anticoagulants (such as coumarin, heparin) and thrombolytic medicines (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 of products that are applied topically or cortisone replacement therapy for Addison's disease): there is an increased risk of bleeding and ulcers in the stomach and intestines.
- alcohol: increased risk of ulcers and bleeding in the stomach and intestines.
- other pain-relief and anti-inflammatory medicines (nonsteroidal anti-inflammatory drugs) and antirheumatic medicines with salicylic acid: increased risk of bleeding and ulcers in the stomach and intestines.
- medicines for diabetes such as insulin, tolbutamide, glibenclamide (so called sulfonylureas) in combination with acetylsalicylic acid at high doses: blood sugar level may be reduced.
- digoxin (a medicine to strengthen the heart muscle contraction).
- methotrexate (used to treat cancer and certain rheumatic conditions).
- valproic acid (used to treat epilepsy).
- selective serotonin re-uptake inhibitors (SSRIs) used to treat depression: increased risk of bleeding in the stomach and intestines.

Medicines that weaken the effect of this medicine:

- certain medicines that increase the excretion of urine (diuretics: aldosterone antagonists such as spironolactone and canrenoate, and loop diuretics such as furosemide).
- certain medicines for hypertension (in particular Angiotensin Converting Enzyme (ACE) inhibitors).
- medicines for gout that promote 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 of Medipirin 100 mg on inhibition of platelet aggregation 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 acetylsalicylic acid to protect the heart.

Before using acetylsalicylic acid inform your doctor about other medicines you are taking. If you are using acetylsalicylic acid regularly, ask your doctor for advice before taking any other medicine (including over-the-counter medicines).

- Do not take Medipirin 100 mg with any of the medicines listed above unless explicitly instructed to do so by a doctor.

Use of this medicine and food

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

Using this medicine and alcohol consumption

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

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Last trimester

Do not take Medipirin 100 mg during the last 3 months of pregnancy as it could harm your unborn baby or cause problems at delivery. This medicine can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected. See also 'Do not use this medicine if'.

First and second trimesters

Do not take Medipirin 100 mg during the first and second trimesters of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose possible for the shortest time possible should be used. From 20 weeks of pregnancy, Medipirin 100 mg can cause kidney problems in your unborn baby if taken for more than a few days, which can lead to low levels of the amniotic fluid that surrounds the baby (oligohydramnios), or to a narrowing of one of the blood vessels (ductus arteriosus) in your unborn baby's heart. This effect may occur very soon after starting Medipirin 100 mg treatment and is usually reversible once treatment is stopped. In the event of a diagnosis of a low level of amniotic fluid or narrowing of blood vessels in your unborn baby's heart, stop taking Medipirin 100 mg immediately. If you need treatment for longer than a few days, your doctor may recommend closer monitoring (with an emphasis on amount of amniotic fluid and the blood vessels in the unborn baby's heart).

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 as long as 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 this medicine

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

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:

One tablet a day.

Do not exceed the recommended dose.

Treatment duration:

Medipirin 100 mg is intended for long-term use. Your doctor will decide on the length of the treatment.

How to take it:

- Swallow the tablets whole with plenty of water, at least 30 minutes before a meal.
- Do not split, chew or break the tablets because the medicine has a gastric (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 dose

Dizziness and ringing in the ears, particularly in children and elderly patients, may be signs of a serious poisoning.

Tell your doctor immediately if you suspect an overdose. 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 some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine

If you forget to take this medicine at the scheduled time, continue taking the medicine as described in section 3 'How to use this medicine?', above, or as prescribed by your doctor but never take two doses together to make up for a missed dose.

If you stop taking this medicine

Do not stop taking Medipirin 100 mg without first consulting your doctor.

Do not take medicines in the dark! Check the label and dose each time you take a 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 **Medipirin 100 mg** may cause side effects in some of the users. Do not be alarmed by this list of side effects; you may not experience any of them.

If you experience any of the side effects listed below, stop taking Medipirin 100 mg and inform your doctor. This is so that your doctor will be able to evaluate the severity of the side effect and decide what to do.

Stop using Medipirin 100 mg at the first signs of hypersensitivity (see below under 'Rare side effects').

Common side effects (effects that occur in up to 1 in 10 users):

- Stomach and intestinal problems such as heartburn, nausea and vomiting, stomach pain, and diarrhea
- minor blood loss from the stomach and intestines.

Uncommon side effects (effects that occur in up to 1 in 100 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)).
- bleeding from the stomach or intestines. Long-term use of Medipirin 100 mg may cause anemia (due to iron deficiency) as a result of occult blood loss from the stomach or intestines.
- ulcers in the stomach or intestines, which in very rare cases can lead to perforation.

- inflammation in the stomach and intestines.

If you notice black stools or if you vomit blood (signs of serious bleeding in the stomach), you must inform your doctor immediately (see also 'Countermeasures', below).

Rare side effects (effects that occur in up to 1 in 1,000 users):

- hypersensitivity reactions of the skin, the respiratory system, the stomach and intestines 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, anaphylactic shock (a severe, acute allergic reaction), swelling of the face, tongue, and throat (angioedema).

Very rare side effects (effects that occur in up to 1 in 10,000 users):

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

Side effects whose exact frequency is unknown:

- Headache, dizziness, confusion, impaired hearing or 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 dose').
- There are reports of severe bleeding such as bleeding in the brain (particularly in patients with uncontrolled hypertension and/or patients taking anticoagulant treatment at the same time). In these rare to very rare reports 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 causing a blockage.

Countermeasures:

Stop taking Medipirin 100 mg if you experience any of the side effects listed above and tell your doctor. Your doctor will then evaluate the severity of the side effect and decide on any necessary measures.

Stop taking Medipirin 100 mg permanently at the first sign of a hypersensitivity reaction.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not listed in this leaflet, consult your doctor.

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) 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 this 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 below 25°C.

6. Additional information

In addition to the active ingredient, the medicine also contains the following inactive ingredients:

Lactose monohydrate, microcrystalline cellulose, methacrylic acid-ethylacrylate copolymer (1:1) dispersion 30%, potato starch, talc, colloidal anhydrous silica, triacetin,.

What Medipirin 100 mg looks like and the contents of the pack

Medipirin 100 mg gastro-resistant tablets are white film-coated tablets, round and biconvex, without break-score.

Pack sizes:

Tablets are packaged in blister trays and are available in packs of 30 or 100 tablets.

Not all pack sizes may be marketed.

Registration holder's name and address: A.L. Medi-Market Ltd., 3 Hakatif street, Emek Hefer Industrial Park, 3877701

Manufacturer's name and address: G.L. Pharma GmbH, Schlossplatz 1 , 8502 Lannach, Austria

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Registration number of the medicine in the Ministry of Health's National Drug Registry: 168-90-36092-00