

Package Insert in Accordance with the Pharmacists' Regulations (Preparations) -1986

This medicinal product is marketed without a doctor's prescription

Godamed 100 mg

Each tablet contains:

Acetyl salicylic acid 100 mg

For a list of excipients, see Chapter 6, 'Additional Information'.

Read the entire leaflet carefully before using the medicinal product. This leaflet includes concise information about this medicinal product. If you have any other questions, contact your doctor or pharmacist.

You should take this preparation according to the instructions in the dosing section of this leaflet. Consult your pharmacist if you need any other information.

1. What Is the Medicinal Product Intended for?

This medicinal product is intended for the primary prevention of coronary heart disease in high-risk patients and the secondary prevention of heart and brain diseases caused by arterial thrombosis.

Therapeutic group: Anticoagulants, platelet antiaggregants

Godamed 100 mg inhibits the aggregation of blood platelets and in this way prevents the formation of blood clots.

2. Before Using This Medicinal Product

Do not use this medicinal product if

You are sensitive (allergic) to acetylsalicylic acid (the active ingredient), salicylates, or any of the other ingredients of Godamed 100 mg (for a list of excipients, see Chapter 6, 'Additional Information').

You have experienced certain reactions to medicines for pain, fever or inflammation (salicylates or other non-steroidal anti-inflammatory medications) in the form of asthma attacks or other allergic reactions.

You have an acute gastric or intestinal ulcer.

You have a pathologically increased tendency to bleed.

You suffer from renal or liver failure.

You suffer from improperly treated acute heart failure.

You are taking 15 mg or more Methotrexate a week.

You are in your last trimester of pregnancy and are taking a daily dose of 150 mg or more (see 'Pregnancy, Breastfeeding, and Fertility').

Special warnings pertaining to the use of the medicinal product

Before treatment with Godamed 100 mg, tell your doctor if:

- You are sensitive (allergic) to other pain-relief, anti-inflammatory medicines, anti-rheumatic medicines, or other allergenic substances.
- You are also taking non-steroidal anti-inflammatory medicines (NSAIDs) such as Ibuprofen or Naproxen (analgesics and antipyretic or anti-inflammatory medicines). See Section 2, 'Preparations that Reduce the Effect of the Medicinal Product'.
- You suffer from other allergies (with symptoms such as skin reactions, itching, or hives).
- You suffer from bronchial asthma, hay fever (allergic rhinitis), swelling of the nasal mucus membrane (nasal polyps), or a chronic respiratory tract disease.
- You are already receiving treatment with anticoagulants (such as Coumarin derivatives or Heparin, except for low-dose Heparin).
- You have gastric or duodenal ulcers or a history of gastrointestinal bleeding.
- You suffer from impaired liver function.

- You suffer from impaired renal or cardiovascular function (such as a renal vascular disease, congestive heart failure, blood volume depletion, a major surgery sepsis, or significant bleeding events) because acetylsalicylic acid may further increase the risk of damage to your renal function and acute renal failure.
- You are about to undergo surgery, including a small surgical procedure (e.g., tooth extraction); bleeding predisposition may increase. Tell your doctor or dentist that you are taking Godamed 100 mg.
- You are known to have severe G6PD deficiency. Acetylsalicylic acid may accelerate the lysis or rupture of red blood cells or cause a certain type of anemia. Factors that may increase this risk include a high dose, fever, or acute infection.

Additional warnings:

- At low doses, acetylsalicylic acid reduces the excretion of uric acid. This condition may stimulate a Gout attack in predisposed patients.
- If you are cut or injured, bleeding may continue longer than usual. This is associated with the effect of the medicinal product. Minor cuts or mild injuries (for example while shaving) are usually insignificant. If you experience an unusual bleeding episode (at an atypical location or for an unusual duration), consult your doctor.
- Do not take medicines that contain acetylsalicylic acid for prolonged periods or at high doses without consulting your doctor.

Children and adolescents:

This medicinal product is intended for people over 18 years of age. For younger patients, consult your doctor. Do not use Godamed 100 mg in children or adolescents with feverish illnesses unless ordered to by the doctor once other therapies have failed. Continuous vomiting concomitantly with this disease may be a sign of Reye's Syndrome, which is a very rare and life-threatening disease that requires immediate medical care.

Drug interactions:

If you are taking or have recently taken other medicines, including over-the-counter medicines and nutritional supplements, tell this to your doctor or pharmacist. This is particularly important if you are taking:

Preparations that increase the effect of this medicinal product or that may increase the risk of side effects:

- Anticoagulants (such as Coumarin or Heparin) and thrombolytics: Acetylsalicylic acid may increase the risk of bleeding if taken before thrombolytic therapy. Pay attention to external and internal signs of bleeding (such as bruises) if you are receiving such treatment.
- Other platelet antiaggregants such as Ticlopidine or Clopidogrel: Increased risk of bleeding.
- Corticosteroids: preparations that contain Cortisone or Cortisone-like preparations (other than those used for topical therapy or Cortisone replacement therapy for Addison's disease): An increased risk of gastrointestinal side effects.
- Alcohol: An increased risk of gastrointestinal ulcers and bleeding.
- Other analgesics and anti-inflammatory medicines (non-steroidal anti-inflammatory medicines) and other anti-rheumatic medicines in general: An increased risk of gastrointestinal ulcers and bleeding.
- Antidiabetic medicines: Blood glucose level may decrease.
- Digoxin, which increases myocardial contractility.
- Methotrexate, which is used to treat cancer and certain rheumatic disorders.
- Valproic acid, which is used to treat epilepsy.
- SSRIs, which are used to treat depression: An increased risk of gastrointestinal bleeding.

Preparations that Reduce the Effect of this Medicinal Product:

- Medicines that increase the excretion of urine (diuretics: Aldosterone antagonists, such as Spironolactone, Canrenoate, and loop diuretics such as Furosemide).
- Certain medicines for hypertension (particularly ACE inhibitors).
- Medicines for Gout that increase the excretion of uric acid (such as Probenecid and Benzbromarone).

- Some non-steroidal anti-inflammatory medicines (NSAIDs) (except for salicylic acid) such as Ibuprofen and Naproxen: A reduced inhibitory effect on platelet aggregation and coagulation: May reduce the protection offered by the medicinal product against heart attack and stroke.
- Metamizole (a medicine to reduce pain and fever): May reduce the effect of acetylsalicylic acid on platelet aggregation when both medicines are taken concomitantly. This combination should therefore be used carefully in patients who are taking a low dose of Godamed 100 mg to prevent cardiac events.

Before using acetylsalicylic acid, tell your doctor about the other medicines you are taking. If you regularly use acetylsalicylic acid, consult your doctor before taking other medicines, including over-the-counter medicines.

- Do not take Godamed 100 mg with one of the above medicines if you are not explicitly instructed to do this by your doctor.

Medicine intake and alcohol consumption

Do not consume alcohol as long as you are receiving treatment with acetylsalicylic acid.

Pregnancy, breastfeeding, and fertility

If you are pregnant or breastfeeding, or if you suspect you are pregnant or intend to become pregnant, consult your doctor or pharmacist before using this medicine.

Pregnancy

In the first and second trimester of pregnancy, Godamed 100 mg should only be taken if prescribed by your doctor.

During the last trimester of pregnancy, do not take acetylsalicylic acid, the active ingredient of Godamed 100 mg, at a dose of more than 150 mg per day due to the increased risk of complications to the mother and the child before and during birth (including an increased risk of miscarriage and certain birth defects; see also the section '**Do Not Use This Medicinal Product If:**'). During the third trimester of pregnancy, Godamed 100 mg can only be taken at a dose of up to 150 mg per day only if prescribed by your doctor.

Breastfeeding

Small quantities of acetylsalicylic acid and its metabolites pass into breast milk. No effects on babies have been reported so there is no need to discontinue breastfeeding if the daily dose does not exceed 150 mg. Still, breastfeeding should be discontinued when higher doses are used (above 150 mg daily).

Driving and using machinery

There is no need to take special precautions.

3. How Should This Medicinal Product Be Used?

Consult your doctor or pharmacist if you are unsure of the dose or the treatment with this preparation.

The recommended daily dose is usually:

One tablet a day.

Do not exceed the recommended dose.

- The tablet can be swallowed intact with plenty of fluids (preferably - a glass of water) after a meal.
It can also be dissolved in the mouth or chewed and then swallowed. The tablet can also be split in half or crushed.
- Do not take the medicinal product on an empty stomach.

Treatment duration:

Godamed 100 mg is intended for long-term use. The treating doctor should determine the treatment duration.

If you have accidentally taken a higher dose

Dizziness and tinnitus can be signs of severe poisoning, particularly in children and elderly patients. Inform the doctor immediately if you are worried that you have taken an overdose. The doctor will decide on the necessary measures based on the overdose you have taken.

If you have taken an overdose or if a child or someone else has taken the medicinal product, contact a doctor or visit the hospital's emergency room immediately and bring with you the package of the medicinal product.

If you have forgotten to take the medicinal product

If you have forgotten to take this medicinal product as scheduled, take the tablet immediately as outlined above in Section 3, '**How Should This Medicinal Product Be Used?**' or as prescribed by your doctor. Do not ever take two doses together to compensate for a missed dose! .

If you stop taking this medicinal product

Do not stop taking Godamed 100 mg without consulting the doctor.

Do not take medicines in the dark! Inspect the label and the dose every time you take a medicine.

Wear glasses if you need to.

If you have any other questions about the use of this medicinal product, consult the doctor or the pharmacist.

4. Side Effects

Like all medicines, using Godamed 100 mg may cause side effects in some users. Do not be alarmed when reading the list of side effects. You might not suffer from any of them.

If you experience any of the side effects listed above, stop taking Godamed 100 mg and inform your doctor so they can assess the severity of the side effects and decide on the course of action.

Discontinue the use of Godamed 100 mg immediately upon the onset of the first signs of hypersensitivity (see below the list of rare side effects).

Common side effects (effects that appear in one of every 10 users at most):

- Heartburn
- Nausea, vomiting, abdominal pain
- Diarrhea
- Mild blood loss in the gastrointestinal tract

Uncommon side effects (effects that appear in one of every 100 users at most):

- Skin reactions [very rare cases may involve an eruption of severe skin rash involving the mucosa with fever (Erythema exsudativum multiforme)]
- Bleeding in the gastrointestinal tract: Prolonged use of Godamed 100 mg may cause anemia (due to iron deficiency) as a result of occult blood loss in the gastrointestinal tract. Severe bleeding in the gastrointestinal tract can lead to black stool or make you vomit blood.
- Gastrointestinal ulcers, which can rarely lead to perforation.
- Inflammation in the gastrointestinal tract.
- Contact your doctor immediately if you notice black tarry stool or if you vomit blood (signs of severe bleeding in the gastrointestinal tract; see 'Countermeasures' below).

Rare side effects (effects that appear in one of every 1,000 users at most):

- Hypersensitivity reactions in the skin, in the respiratory system, in the gastrointestinal tract, and in the cardiovascular system, particularly in asthmatic patients. The signs can include the following: Hypotension, episodes of breathing difficulties, inflammation of the nasal mucosa, stuffy nose, allergic reactions (shock), swelling of the face, tongue, and throat (angioedema).

Very rare side effects (effects that appear in one of every 10,000 users at most):

- Elevated liver values.
- Impaired renal function and acute renal failure.
- Reduced blood sugar levels (hypoglycemia).

- At low doses, acetylsalicylic acid reduces the excretion of uric acid. This condition may stimulate a Gout attack in predisposed patients.

Side effects of unknown frequency:

- Headache, dizziness, confusion, impaired hearing, and tinnitus (ringing in the ears) can be signs of an overdose, particularly in children and elderly patients (see 'If you have accidentally taken a higher dose').
- Cases of severe bleeding have been reported, such as bleeding in the brain (particularly in patients with uncontrolled hypertension and/or on combination therapy with anticoagulants). These reports have been rare to very rare and some of the cases have been life-threatening.
- Accelerated lysis or rupture of red blood cells and a particular type of anemia in patients suffering from severe G6PD deficiency.
- Bleeding episodes: Bleeding from the nose, bleeding from the gums, bleeding in the skin, or bleeding in the urinary tract and reproductive organs; also, bleeding may continue further. This effect can persist 4 to 8 days after use.

Countermeasures:

- Stop taking Godamed 100 mg if you experience the above effects and inform your doctor so they can decide which measures should be taken based on the severity of the side effects.
- Stop taking Godamed 100 mg even if you only see one sign that indicates a hypersensitivity response. After that, Godamed 100 mg should never be taken again.

If you develop a side effect, if one of your side effects worsens, or if you have a side effects not mentioned in the leaflet, consult your doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting Side Effects and Drug-related Adverse Events" on the homepage of the Ministry of Health website (www.health.gov.il), which redirects to an online form for reporting side effects, or by clicking on the link: <https://sideeffects.health.gov.il/>

5. How Should the Medicinal Product Be Stored?

- **Prevent poisoning!** This medicinal product and any other medicinal product should be kept in a closed place out of the reach and sight of children and/or babies to prevent poisoning. Do not induce vomiting without explicit instructions from your doctor!
- Do not use the medicinal product after the expiration date (Exp. Date), which appears on the package.
The expiration date refers to the last day of the mentioned month.
- **Storage conditions:** Store under 25° C.
- Do not throw medicines into wastewater or the household trash. Ask the pharmacist how to dispose of medicines that are no longer used; these measures will help protect the environment.

6. Additional Information

In addition to the active substance, the medicinal product also contains the following excipients: Glycine, Maize starch, Powdered Cellulose, Lemon flavour (IFF no 15.81.4287), Saccharin sodium

- **What the medicinal product looks like and what the package content is:**
Godamed 100 mg is a white, rounded tablet with a break line that enables to split the dose into two equal parts each of which contains 50 mg of the active ingredient, acetylsalicylic acid.
- The tablets come in blister (strip) pack that contains 10, 20, 30, 40, or 50 tablets.
Not all package sizes are necessarily marketed.
- Registration holder and their address: Gramse Pharmaceuticals Ltd., POB 528, Yokne'am Ilit, 2069206.
- Name of the manufacturer and their address: Dr. Pflieger Arzneimittel GmbH, Bamberg, Germany
- Edited in January 2021 in accordance with the guidelines of the Ministry of Health.
- The medicinal product's registration number in the official drug registry at the Ministry of Health: 133-80-29716-00

GODAMED PIL 12012021

Table of leaflet updates	Updated chapters	Evidence of update	Comments
01 - 04 January 2021	Most of the leaflet was updated due to consistency with the generic product in Israel, Aspirin Cardio	The text was copied from the leaflet of Aspirin Cardio , which had been approved by the Ministry of Health on 16 April 2020, and changes were made in order to meet the required registration conditions.	

Obligation to use the consumer's leaflet

Name of the preparation: **GODAMED 100mg** 133-80-29716-00

I hereby declare that the leaflet has been examined twice, as part of which it has been read in its entirety. To the best of my knowledge, it contains no contradictions, typos, syntactic errors, or incorrect information and complies with the registration conditions that apply to preparations in Israel.

I hereby declare that the changes marked in this leaflet are the only changes that have been made. The submitted version of this leaflet has been copied from the leaflet of **Aspirin Cardio**, which had been edited in June 2020, and changes have been made to comply with the required registration conditions.

This leaflet was updated based on the circular of the Medicinal Drugs Registration Department number 587734819 dated 16 December 2019 titled 'Notification about Updates to Leaflets of Medical and Veterinary Preparations - Updated December 2019'



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David Wagner 04 January 2021
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