

**PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986**

The medicine is dispensed with a doctor's prescription only

# Metformin Inovamed Tablets

## Active ingredient

Each tablet contains:

Metformin hydrochloride 850 mg

Inactive ingredients and allergens in the preparation – see section 6 – “Additional information”.

**Read the entire leaflet carefully before using the medicine.** This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.

This medicine has been prescribed for your treatment. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

## 1. What is the medicine intended for?

The medicine is intended for treatment of type 2 diabetes mellitus, particularly in overweight patients, when dietary changes and exercise alone are insufficient for stabilizing blood glucose levels.

- In adults, Metformin Inovamed is indicated as monotherapy or in combination with other oral medicines for treatment of diabetes or with insulin.
- In children from 10 years of age and in adolescents, Metformin Inovamed is indicated as monotherapy or in combination with insulin.

A decrease in diabetes complications was observed in adult overweight patients with type 2 diabetes, who were treated with metformin as a first-line treatment following failure of dietary change.

## Therapeutic class:

Blood glucose lowering medicines. The active ingredient belongs to the biguanide class.

Insulin is a hormone produced by the pancreas, which causes the body to absorb glucose (sugar) from the blood. Your body uses glucose to produce energy or stores it for future use.

If you suffer from diabetes, your pancreas does not produce enough insulin or your body cannot properly utilize the insulin it produces. This causes a high level of glucose in the blood. Metformin Inovamed helps to lower the blood glucose level to as normal as possible.

If you are an overweight adult, taking Metformin Inovamed over a long period of time also helps in reducing the risk for complications associated with diabetes. There is a connection between Metformin Inovamed and stable body weight or moderate weight loss.

## 2. Before using the medicine

### Do not use this medicine if:

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| <ul style="list-style-type: none"><li>• You are sensitive (allergic) to the active ingredient (metformin) or to any of the other ingredients this medicine contains (see section 6 “Additional information”).</li><li>• You suffer from liver problems.</li><li>• You suffer from a severe impairment in kidney function.</li><li>• You suffer from uncontrolled diabetes, with, for example, severe hyperglycemia (high blood glucose levels), nausea, vomiting, diarrhea, rapid weight loss, lactic acidosis (see “Risk of lactic acidosis” below) or ketoacidosis. Ketoacidosis is a condition in which substances called “ketone bodies” build up in the blood, which may lead to diabetic pre-coma. Symptoms include: abdominal pain, rapid and deep breathing, drowsiness or abnormal fruity breath odor.</li><li>• You have lost too much body fluids (dehydration), e.g. as a result of severe/prolonged diarrhea or continuous vomiting. Dehydration may cause kidney problems, which may lead to a risk of lactic acidosis (see section “Special warnings regarding the use of the medicine”).</li><li>• You suffer from a severe infection, such as an infection that affects your lungs/bronchial system/kidney. Severe infections may cause kidney problems, which may lead to a risk of lactic acidosis (see section “Special warnings regarding the use of the medicine”).</li><li>• You suffer from severe heart failure or have recently had a heart attack, you suffer from severe circulatory problems (e.g., shock) or you suffer from breathing difficulties. These conditions may lead to a lack of oxygen supply to the tissues, which may lead to a risk of lactic acidosis (see section “Special warnings regarding the use of the medicine”).</li><li>• You consume large amounts of alcohol.</li></ul> <p>If one or more of the abovementioned conditions apply to you, consult the doctor before starting treatment with this medicine.</p> |
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### Special warnings regarding the use of the medicine

#### Before treatment with Metformin Inovamed, tell the doctor if:

- You are about to undergo a test, such as an X-ray or a scan, that requires the injection of iodine-containing contrast agents to your blood.
- You are about to undergo a major surgery.

You must stop taking Metformin Inovamed for a certain period of time before and after the test or surgery. Your doctor will decide if you need another treatment during this time. It is important that you follow the doctor's orders precisely.

### Additional special warnings

#### Risk of lactic acidosis

Metformin Inovamed may cause a very rare but also very severe side effect called lactic acidosis, especially if your kidneys are not functioning properly. The risk of developing lactic acidosis also increases in the following cases: uncontrolled diabetes, serious infections, prolonged fasting, excessive alcohol consumption, dehydration (see details below), liver problems and any medical condition in which oxygen supply to body organs is reduced (such as acute and severe heart disease).

If one or more of the abovementioned conditions apply to you, consult the doctor for further instructions.

**Stop taking Metformin Inovamed for a short period of time if you suffer from a condition that may be related to dehydration (significant loss of fluids),** such as severe vomiting, diarrhea, fever, exposure to heat or if your fluid intake is lower than usual. Consult with the doctor for further instructions. **Stop taking Metformin Inovamed and immediately refer to a doctor or to a hospital emergency room if you experience some of the symptoms of lactic acidosis,** since this condition may lead to a coma. The symptoms of lactic acidosis include:

- Vomiting
- Abdominal pain
- Muscle cramps
- General malaise accompanied by severe fatigue
- Difficulty breathing
- Reduced body temperature and heart rate

Lactic acidosis is a medical emergency which necessitates hospital treatment. Consult with the doctor as soon as possible for further instructions if:

- You suffer from an inherited genetic disease that affects the mitochondria (components of energy production in the cells), such as MELAS syndrome (brain injury [mitochondrial encephalopathy], muscle injury [myopathy],

lactic acidosis and stroke-like events) or maternally inherited diabetes and deafness (MIDD).

- You experience any of the following symptoms after starting treatment with metformin: seizures, decreased cognitive abilities, difficulties in body movements, symptoms that indicate nerve damage (such as pain or loss of sensation), migraine and deafness.

If you need to undergo a major surgery, you must stop taking Metformin Inovamed during and for a certain period after the procedure. Your doctor will decide when you should stop and when you should restart the treatment with Metformin Inovamed.

Metformin Inovamed as a monotherapy does not cause hypoglycemia (a blood glucose level that is too low). However, if you are taking Metformin Inovamed together with other anti-diabetic medicines that can cause hypoglycemia (such as sulfonylurea, insulin, meglitinides), there is a risk of hypoglycemia. If you experience symptoms of hypoglycemia, such as weakness, dizziness, increased sweating, rapid heartbeat, visual disturbances or difficulty concentrating – drinking or eating sugar-containing food usually helps in this situation.

#### Tests and follow-up

- Your doctor will perform regular blood glucose tests and will adjust the dosage of Metformin Inovamed to your blood glucose levels. Make sure to speak with your doctor regularly. This monitoring is particularly important when treating children and adolescents or the elderly.
- During treatment with Metformin Inovamed, your doctor will check your kidney function at least once a year, or more often if you are elderly and/or if your kidney function is worsening.

#### Drug interactions

If you need to receive an injection of an iodine-containing contrast agent into your blood, e.g., for an X-ray or a scan, you should stop taking Metformin Inovamed before or at the time of injection. Your doctor will decide when you should stop and when you should restart the treatment with Metformin Inovamed.

**If you are taking, have recently taken, or if you may take other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.** You may require more frequent monitoring of your blood glucose levels and kidney function or the doctor may adjust your dosage of Metformin Inovamed. Tell your doctor or pharmacist especially if you are taking:

- Medicines that increase urine output (diuretics).
- Medicines for treatment of pain and inflammation (NSAIDs and COX-2 inhibitors, such as ibuprofen and celecoxib).
- Certain medicines for treatment of hypertension (angiotensin converting enzyme [ACE] inhibitors, angiotensin-II receptor blockers).
- Beta-2 receptor agonists such as salbutamol or terbutaline (for treatment of asthma).
- Corticosteroids (for treatment of various conditions, such as treatment of severe skin inflammation or asthma).
- Medicines that may change the level of Metformin Inovamed in your blood, especially in case of impaired kidney function (such as verapamil, rifampicin, cimetidine, dolutegravir, ranolazine, trimethoprim, vandetanib, isavuconazole, crizotinib, olaparib).
- Other anti-diabetic medicines.

#### Use of the medicine and food

Metformin Inovamed should be taken with or right after a meal, to prevent side effects in the digestive system.

#### Use of the medicine and alcohol consumption

Avoid excessive consumption of alcohol during treatment with Metformin Inovamed, as there may be an increase in the risk of lactic acidosis (see section “Special warnings regarding the use of the medicine”).

#### Pregnancy and breastfeeding

Tell your doctor if you are pregnant, think you are pregnant or are planning to become pregnant, so that he may decide whether your treatment or the monitoring of your blood glucose levels should be changed.

Metformin Inovamed is not recommended if you are breastfeeding or planning to breastfeed.

#### Driving and operating machinery

Metformin Inovamed alone does not cause hypoglycemia (a blood glucose level that is too low); therefore, the medicine is not supposed to affect your ability to drive or operate machinery.

However, you should be careful if you are taking Metformin Inovamed together with other anti-diabetic medicines which may cause hypoglycemia (such as sulfonylurea, insulin, meglitinides). Symptoms of hypoglycemia include weakness, dizziness, increased sweating, fast heartbeat, visual disturbances or difficulty concentrating. Do not drive or operate machinery if you start feeling these symptoms.

## 3. How should you use the medicine?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the medicine.

The dosage and treatment regimen will be determined by the doctor only.

Metformin Inovamed does not replace a healthy lifestyle. You should follow the dietary guidelines recommended by the doctor, and exercise regularly.

#### The usual dosage is:

**Children from 10 years of age and adolescents:**

The initial dosage is usually 500 mg or 850 mg once a day. The maximum daily dose is 2,000 mg per day divided into 2 or 3 doses. Treatment of children 10-12 years of age is recommended only if explicitly instructed by the doctor, since experience in this age group is limited.

**Adults:**

The accepted initial dosage is usually 500 mg or 850 mg 2-3 times per day.

The maximum daily dose is 2,550 mg per day, divided into 3 doses.

If you have impaired kidney function, your doctor may prescribe you a lower dosage.

If you are also being treated with insulin, your doctor will instruct you how to start treatment with Metformin Inovamed.

Do not halve the Metformin Inovamed tablet. When a dosage of 500 mg is required, you should find a preparation containing 850 mg of metformin that can be halved (to obtain a dosage of 425 mg), which may serve as an alternative to a tablet containing 500 mg.

#### Do not exceed the recommended dose.

#### How to take Metformin Inovamed:

Metformin Inovamed should be taken with or right after a meal, to prevent side effects in the digestive system.

Swallow the tablet with a glass of water.

- If you are taking one dose per day, take it in the morning (with breakfast).
- If you are taking the medicine twice per day, take it in the morning (with breakfast) and in the evening (with dinner).
- If you are taking the medicine 3 times per day, take it in the morning (with breakfast), at lunchtime (with lunch) and in the evening (with dinner).

#### Crushing/halving/chewing:

Do not crush or chew the tablets.

No information is available regarding halving.

If after a while you think the effect of Metformin Inovamed is too strong or too weak, consult with the doctor.

#### If you accidentally took a higher dosage

If you took an overdose, you may suffer from lactic acidosis. The symptoms of lactic acidosis are not specific, such as vomiting, abdominal pain with muscle cramps, general malaise accompanied by severe fatigue and breathing difficulties. Other symptoms include reduced body temperature and heart rate.

**If you experience these symptoms, seek medical attention immediately, since lactic acidosis may lead to a coma. Stop taking Metformin Inovamed immediately and refer immediately to a doctor or to a hospital emergency room.**

If you took an overdose or if a child accidentally swallowed this medicine, go to the doctor or to a hospital emergency room immediately and take the package of the medicine with you.

#### If you forgot to take the medicine

If you forgot to take the medicine at the scheduled time, do not take a double dose to compensate for a forgotten dose. Take the next dose at the usual time. Follow the treatment as recommended by the doctor. Even if there is an improvement in your health condition, do not stop treatment with the medicine without consulting the doctor.

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

**If you have any other questions regarding the use of the medicine, consult the doctor or the pharmacist.**

## 4. Side effects

As with any medicine, using Metformin Inovamed 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.

Metformin Inovamed may cause a side effect which is very rare (an effect that appears in less than one user out of 10,000) but very serious, called lactic acidosis (see section 2 – “Special warnings regarding the use of the medicine”). **If this effect occurs, stop taking Metformin Inovamed and refer immediately to a doctor or to a hospital,** since lactic acidosis may lead to a coma.

#### Additional side effects:

#### Very common side effects (effects that occur in more than one user out of ten):

- Digestive disturbances such as nausea, vomiting, diarrhea, abdominal pain and loss of appetite. These side effects usually occur at the beginning of the treatment with Metformin Inovamed. These effects can be alleviated by dividing the dosage throughout the day and by taking Metformin Inovamed with or right after a meal. **If the symptoms continue, stop taking Metformin Inovamed and consult the doctor.**

#### Common side effects (effects that occur in 1-10 users out of 100):

- Changes in the sense of taste.
- Decreased or low levels of vitamin B12 in the blood (the symptoms may include extreme fatigue, painful and red tongue [tongue inflammation – glossitis], “pins and needles” sensation [paresthesia] or pale or yellow skin). Your doctor may perform several tests in order to find out the cause of the symptoms, as some of them may also be caused by diabetes or by other unrelated health problems.

#### Very rare side effects (effects that occur in less than one user out of 10,000):

- Lactic acidosis. A very rare but very serious complication, especially if your kidneys are not functioning properly. The symptoms of lactic acidosis are not specific (see in section 2 “Special warnings regarding the use of the medicine”).
- Abnormalities in liver function tests or jaundice (inflammation of the liver which may cause tiredness, loss of appetite, weight loss with or without yellowing of the skin or the white of the eyes). **If you experience these symptoms, stop taking Metformin Inovamed and refer to your doctor.**
- Skin reactions, such as redness of the skin (erythema), itching or itchy rash (hives).

#### Children and adolescents

Limited data regarding children and adolescents have shown side effects similar in nature and severity to those reported in adults.

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

#### Reporting side effects

Side effects may be reported to the Ministry of Health by clicking on the link “Report side effects due to medicinal treatment” found on the Ministry of Health website homepage ([www.health.gov.il](http://www.health.gov.il)), which will direct you to the online form for reporting side effects, or by entering the following link: <https://sideeffects.health.gov.il>

## 5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- **Store below 25°C.**
- Do not discard medicines via wastewater or the trash. Ask your pharmacist how to destroy medicines no longer in use. These measures will help protect the environment.

## 6. Additional information

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

Hypromellose, povidone (K-90), magnesium stearate, macrogol 400, macrogol 6000.

**What does the medicine look like and what are the contents of the package?**

A white, biconvex, round, film-coated tablet, debossed with 'A' on one side and with '61' on the other side.

The tablets are packed in blisters inside a cardboard box containing 30 tablets.

**Manufacturer:** Aurobindo Pharma Ltd., Hyderabad, India.

**License holder and importer:** Inovamed Ltd., P.O. Box 62, Even Yehuda.

Revised in August 2025.

**Registration number of the medicine in the national drug registry of the Ministry of Health:** 162-59-35148.