

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS’ REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor’s prescription only

Metformin Inovamed

Tablets

Composition

Each tablet contains:

Metformin hydrochloride 850 mg

For information on inactive and allergenic ingredients in the preparation – see section 6 – “Further information”.

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed to treat you. 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 not sufficient to stabilize blood glucose levels.

• In adults, Metformin Inovamed is indicated as monotherapy or in combination with other oral anti-diabetic medicines or with insulin.

• In children from age 10 and adolescents, Metformin Inovamed is indicated as monotherapy or in combination with insulin.

A reduction in diabetes complications has been observed in overweight type 2 diabetic adult patients treated with metformin as first-line therapy after failed dietary changes.

Therapeutic group:

Blood glucose-lowering medicines. The active ingredient belongs to the biguanides group.

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

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

If you are an overweight adult, taking Metformin Inovamed in the long term also helps reduce the risk of diabetes-related complications. There is a link between Metformin Inovamed and stable body weight or moderate weight loss.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the additional ingredients contained in the medicine (see section 6 “Further information”).
- You are suffering from liver problems.
- You are suffering from severely impaired kidney function.
- You are suffering 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” accumulate in the blood, which may lead to diabetic pre-coma. The symptoms include: stomach pains, rapid and deep breathing, sleepiness or unusual fruity-smelling breath.
- You have lost too much fluid from your body (dehydration), e.g., due to severe/prolonged diarrhea, or persistent vomiting. Dehydration may lead to kidney problems, which can lead to risk of lactic acidosis (see “Special warnings regarding use of the medicine” section).
- You have a severe infection, such as an infection affecting your lungs/bronchial system/kidneys. Severe infections may cause kidney problems, which can lead risk of lactic acidosis (see “Special warnings regarding use of the medicine” section).
- You are suffering from severe heart failure, or have recently had a heart attack, you have severe problems in the blood circulation (such as shock) or have breathing difficulties. These conditions may cause a deficiency in oxygen supply to the tissues, which can lead to risk of lactic acidosis (see “Special warnings regarding use of the medicine” section).
- You consume large quantities of alcohol.

If one or more of the above conditions apply to you, consult the doctor before starting treatment with this medicine.

Special warnings regarding use of the medicine

Before treatment with Metformin Inovamed, tell the doctor if:

- You are due to undergo an examination, such as an X-ray or screening that requires the injection of an iodine-containing contrast agents into your blood.
- You are about to undergo major surgery.

Stop taking Metformin Inovamed for a certain period of time before and after the examination or the surgery. Your doctor will decide whether you need a different treatment during this period. It is important that you follow the doctor’s instructions precisely.

Additional special warnings

Risk of lactic acidosis

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

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

Stop taking Metformin Inovamed for a short period if you have a condition that can be related to dehydration (significant fluid loss), such as severe vomiting, diarrhea, fever, heat exposure or if fluid intake is less than usual. Consult the doctor for further instructions.

Stop taking Metformin Inovamed and refer to a doctor or a hospital emergency room immediately if you experience some of the symptoms of lactic acidosis, as this condition may lead to coma. Symptoms of lactic acidosis include:

- Vomiting
- Abdominal pain
- Muscle cramps
- Malaise with severe tiredness
- Breathing difficulties
- Reduced body temperature and pulse

Lactic acidosis is a medical emergency and requires treatment in a hospital.

If you have to undergo major surgery, stop taking Metformin Inovamed during and for some time after the procedure. Your doctor will decide when you should stop and when to resume Metformin Inovamed treatment.

Metformin Inovamed as monotherapy does not cause hypoglycemia (blood glucose level that is too low). However, if you take Metformin Inovamed together with other medicines to treat diabetes that can cause hypoglycemia (such as sulphonylurea, insulin, meglitinides), there is a risk of hypoglycemia. If you experience symptoms of hypoglycemia such as weakness, dizziness, increased sweating, rapid pulse, vision disorders or difficulty concentrating – drinking or eating food containing sugar usually helps in this situation.

Tests and follow-up

- Your doctor will perform routine blood glucose tests and will adjust the Metformin Inovamed dosage to your blood glucose levels. Be sure to speak to the 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 frequently if you are elderly and/or if you have worsening kidney function.

Drug interactions

If you have to receive an injection of an iodine-containing contrast agent into your blood, e.g., for an X-ray or screening, stop taking Metformin Inovamed before or during the injection. The doctor will decide when you should stop and when you should resume treatment with Metformin Inovamed.

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

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

Use of the medicine and food

Take Metformin Inovamed with or immediately 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 since there may be an increased risk of lactic acidosis (see “Special warnings regarding use of the medicine” section).

Pregnancy and breastfeeding

If you are pregnant, think you are pregnant or are planning to become pregnant, tell the doctor so he will decide if it is necessary to change your treatment or monitoring of your blood glucose levels.

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

Driving and operating machinery

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

However, exercise caution if you take Metformin Inovamed together with other medicines to treat diabetes that may cause hypoglycemia (such as sulphonylurea, insulin, meglitinides). Symptoms of hypoglycemia include weakness, dizziness, increased sweating, fast heartbeat, vision disorders or difficulty concentrating. Do not drive or operate machinery if you start experiencing these symptoms.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor’s instructions. Check with the doctor or pharmacist if you are uncertain regarding the dosage and treatment regimen of the preparation.

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

Metformin Inovamed is not a substitute for a healthy lifestyle. Follow the diet guidelines recommended by the doctor and make sure to exercise regularly.

The usual dosage is:

Children aged 10 years and above and adolescents:

The usual starting dosage is generally 500 mg or 850 mg (one tablet), once a day. The maximum daily dosage is 2,000 mg a day divided into 2 or 3 doses. Treatment of children aged 10-12 years is only recommended on explicit instruction from the doctor, as experience in this age group is limited.

Adults:

The usual starting dosage is generally 500 mg or 850 mg (one tablet), 2-3 times a day.

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

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

If you are also being treated with insulin, the 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, use a 850 mg metformin preparation which can be halved (to obtain a dosage of 425 mg), which can substitute a 500 mg tablet.

Do not exceed the recommended dose.

How to take Metformin Inovamed:

Take Metformin Inovamed with or immediately 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 a day, take it in the morning (with breakfast) and in the evening (with dinner).
- If you are taking the medicine 3 times a day, take it in the morning (with breakfast), in the afternoon (with lunch) and in the evening (with dinner).

Crushing/halving/chewing:

Do not halve, chew or crush the tablet.

If, after some time, you think the effect of Metformin Inovamed is too strong or too weak, consult the doctor.

If you accidentally took a higher dosage

If you accidentally 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, malaise with severe tiredness and breathing difficulties. Additional symptoms include reduced body temperature and pulse. **If you experience these symptoms, seek medical treatment immediately, since lactic acidosis may cause coma. Stop taking Metformin Inovamed immediately and contact a doctor immediately or proceed to a hospital emergency room.**

If you accidentally took an overdose or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring 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 the forgotten dose. Take the next dose at the usual time.

Adhere to the treatment regimen as recommended by the doctor. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

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

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

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

Additional side effects:

Very common side effects (effects that occur in more than 1 in 10 users):

- Digestive system disturbances, such as nausea, vomiting, diarrhea, abdominal pain and loss of appetite. These side effects most often occur at the beginning of the treatment with Metformin Inovamed. These effects can be alleviated by dividing up the dosage during the course of the day and by taking Metformin Inovamed with or immediately after a meal. **If the symptoms persist, stop taking Metformin Inovamed and consult the doctor.**
- Common side effects (effects that occur in 1-10 in 100 users):**
- Changes in sense of taste.
 - Reduction of or low blood vitamin B12 levels (symptoms may include extreme tiredness, sore and red tongue [tongue inflammation – glossitis], pins and needles sensation [paresthesia] or pale or yellow skin). Your doctor may perform several tests to identify the cause of the symptoms since some may be caused by diabetes or other unrelated health problems.

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

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

Children and adolescents

Limited data in children and adolescents showed that side effects were 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 the leaflet, consult with the doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- **Store in a dry place, below 25°C.**
- Do not dispose of medicines in the wastewater or waste bin. Ask the pharmacist how to dispose of medicines that are not in use. These measures will help protect the environment.

6. FURTHER INFORMATION

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

Hypromellose, Povidone (K-90), Magnesium stearate, Macrogol 400, Macrogol 6000.

What the medicine looks like and the contents of the package

A round, convex, white, film-coated tablet, with ‘A’ imprinted on one side and ‘61’ on the other side.

The tablets are packaged in blisters, in a carton box containing 30 tablets.

Manufacturer: Aurobindo Pharma Ltd., 2 Maitrivihar, Ameerpet, Hyderabad – 500038, India.

Registration holder and importer: Inovamed Ltd., 55 Be’er Ganim St., P.O.B. 55, Even Yehuda 40500.

Revised in June 2022 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 162-59-35148.