

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 ingredients, 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 your ailment. Do not pass it on to others. It may harm them, even if it seems to you that their ailment 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 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.

Insulin is a hormone produced by the pancreas that enables absorption of glucose from the blood. In diabetes, the body does not produce enough insulin or is unable to use the insulin it produces, therefore blood glucose levels increase. Metformin Inovamed helps lower blood glucose levels to as normal a level as possible.

In overweight adults, taking Metformin Inovamed in the long term helps reduce the risk of diabetes-associated complications.

Therapeutic group:

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

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).
- you are suffering from impaired liver function.
- you are suffering from severely impaired kidney function.
- you have uncontrolled diabetes, for example, if you have severe hyperglycemia (high blood glucose levels), nausea, vomiting, diarrhea, sharp 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 can lead to diabetic pre-coma. The symptoms include: stomach pains, rapid and deep breathing, sleepiness and/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 cause kidney problems, which can lead to the development of lactic acidosis (see "Special warnings regarding use of the medicine" section).
- you have a severe infection, such as an infection affecting the lungs/respiratory system/kidneys. Severe infection may cause kidney problems, which can lead to the development of lactic acidosis (see "Special warnings regarding use of the medicine" section).
- you are suffering from severe heart failure, have recently had a heart attack, have severe problems in the blood circulation (such as shock) or have breathing difficulties. These conditions can cause a decrease in oxygen supply to the body tissues and therefore increase the risk of developing lactic acidosis (see "Special warnings regarding use of the medicine" section).
- you consume large quantities of alcohol.

Special warnings regarding use of the medicine:

Before starting and during the course of treatment with Metformin Inovamed, tell the doctor if:

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

In the situations listed above, stop taking Metformin Inovamed for a certain period of time before and after the examination or the surgery. Your doctor will decide when you should stop and when you should resume treatment with Metformin Inovamed. Your doctor will decide whether you need a different treatment during this period. It is important that you follow your doctor's instructions precisely.

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, prolonged alcohol consumption, during 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 any of the above conditions applies to you, talk to the doctor for further instructions.

Stop taking Metformin Inovamed for a short period if you have a condition suspected to be dehydration (losing a significant amount of fluid) such as multiple vomiting episodes, diarrhea, fever, heat exposure or if fluid intake is less than usual. Consult your doctor for further instructions.

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

- vomiting
- abdominal pain
- muscle cramps
- malaise with severe tiredness
- breathing difficulties
- reduced body temperature and heart rate

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

Metformin Inovamed on its own 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.

During treatment with Metformin Inovamed, the 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. Consult the doctor if you are suffering from impaired kidney function.

Children and adolescents

Limited data in children and adolescents showed that side effects were similar in nature and severity to those reported in adults.

Tests and follow up

- During the course of treatment, your doctor will perform routine tests to measure blood glucose and will adjust the Metformin Inovamed dosage to your blood glucose levels. Stay in regular contact with the doctor. This monitoring is particularly important when treating children and adolescents or the elderly.
- During the course of treatment with Metformin Inovamed, the doctor will perform kidney function tests at least once a year. In elderly patients and/or people suffering from decreased kidney function, it may be necessary to perform the tests more frequently.

Drug interactions

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 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 (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 affect the levels 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. Taking Metformin Inovamed concomitantly with other anti-diabetes medicine may increase the risk of hypoglycemia.

If you have to receive an injection of an iodine-containing contrast agent into your blood, e.g., for an X-ray, 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.

Use of the medicine and food

Take Metformin Inovamed with or 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 due to the increased risk of lactic acidosis (see "Special warnings regarding use of the medicine" section).

Pregnancy and breastfeeding

During pregnancy, you may need insulin to treat your diabetes.

If you are pregnant, think you are pregnant or are planning to become pregnant, consult the doctor and he will decide if it is necessary to change your treatment.

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

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 can 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 experience 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 medicine.

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.

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 2000 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 dose is 2550 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 dosage.

How to take Metformin Inovamed:

Take Metformin Inovamed with or 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 an overdose or if a child has accidentally swallowed the medicine

Overdose may cause lactic acidosis. The symptoms of lactic acidosis include: vomiting, abdominal pain with muscle cramps, malaise with severe tiredness and breathing difficulties. Additional symptoms include reduced body temperature and heart rate. **If you experience these symptoms, seek medical treatment immediately, since lactic acidosis may cause coma. Stop taking Metformin Inovamed immediately and contact the doctor or proceed to an emergency room immediately.**

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.

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 by the list of side effects. You may not suffer from any of them.

Metformin Inovamed may cause a very rare but very serious side effect (may affect up to 1 in 10,000 patients), called lactic acidosis (see section 2 "Special warnings regarding use of the medicine"). **If this effect occurs, stop treatment and refer to a doctor or proceed to a hospital immediately**, since lactic acidosis may cause coma.

Additional side effects:

Very common side effects (may affect more than 1 patient in 10):

- digestive system disturbances, such as nausea, vomiting, diarrhea, abdominal pain and lack of appetite. These effects most often occur at the beginning of the treatment. These effects can be alleviated by dividing up the dose during the course of the day and by taking the medicine with or immediately after food. **If the symptoms persist, discontinue treatment and refer to a doctor.**

Common side effects (may affect less than 1 patient in 10):

- changes in sense of taste.

Very rare side effects (may affect less than 1 patient in 10,000)

- abnormalities in liver function test or jaundice (liver inflammation that may cause tiredness, lack of appetite, weight loss, with or without yellowing of the skin or eyes). **If you experience these symptoms, stop taking Metformin Inovamed and refer to your doctor.**
- skin reaction, e.g., skin redness (erythema), itch or itchy rash (urticaria).
- low vitamin B₁₂ levels in the blood.

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 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 waste water 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 does the medicine look like and what are 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.

This leaflet was checked and approved by the Ministry of Health in August 2019

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