

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

The medicine is dispensed with a doctor's prescription only

Metformin Teva

Tablets

Composition

Each tablet contains:
Metformin hydrochloride 850 mg

For information about inactive ingredients 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 treatment of your illness. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar to yours.

1. WHAT IS THE MEDICINE INTENDED FOR?

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

- In adults, Metformin Teva 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 Teva 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 agents. 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, which leads to a high level of glucose in the blood. Metformin Teva helps to lower the blood glucose level to as normal a level as possible.

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

2. BEFORE USING THE MEDICINE Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient (metformin) or to any of the other ingredients this medicine contains (see section 6).
- You have liver problems.
- You suffer from a severe impairment in kidney function.
- You suffer from uncontrolled diabetes, with, for example: severe hyperglycemia (high blood glucose levels), nausea, vomiting, diarrhea, rapid weight loss, lactic acidosis (see "Risk for lactic acidosis" below) or ketoacidosis. Ketoacidosis is a condition in which substances called "ketone bodies" build up in the blood, and which may lead to diabetic pre-coma. Symptoms include: abdominal pain, deep and rapid breathing, drowsiness or abnormal rapid breath odor.
- You have lost too much body fluid (dehydration), for example: as a result of severe or prolonged diarrhea or continuous vomiting. Dehydration may cause kidney problems, which can increase the risk of lactic acidosis (see subsection "Special warnings regarding the use of the medicine").
- You suffer from a severe infection, such as an infection that affects the lungs/bronchial system/kidneys. Severe infections may cause kidney problems, which can increase the risk of lactic acidosis (see subsection "Special warnings regarding the use of the medicine").
- You have severe heart failure, have recently had a heart attack, have severe circulation problems (e.g., shock) or have 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 subsection "Special warnings regarding the use of the medicine").
- You consume large amounts of alcohol. If one or more of the abovementioned conditions applies to you, consult the doctor before starting treatment with this medicine.

Special warnings regarding the use of the medicine

Before and during treatment with Metformin Teva, inform the doctor if:

- You are about to undergo a test, such as an X-ray or a scan, that requires the injection of an iodine-containing contrast agent to your blood.
- You are about to undergo a major surgery. You must stop taking Metformin Teva for a certain period of time before and after the test or surgery. Your doctor will decide if you need an alternative treatment during this time. It is important that you follow the doctor's orders precisely.

Risk for lactic acidosis

Metformin Teva 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 applies to you, consult the doctor for further instructions.

Stop taking Metformin Teva for a short period of time if you suffer from a condition which may be related to dehydration (significant loss of fluids), such as: lots of vomiting, diarrhea, fever, exposure to heat or if you consume less fluids than usual. Consult with the doctor for further instructions.

Stop taking Metformin Teva 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
- Breathing difficulties
- Reduced heart rate and body temperature

Lactic acidosis is a medical emergency which necessitates hospital treatment.

If you need to undergo a major surgery, you must stop taking Metformin Teva 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 Teva.

Metformin Teva as a monotherapy does not cause hypoglycemia (a blood glucose level that is too low). However, if you are taking Metformin Teva together with other anti-diabetic medicines which 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 regularly test your blood glucose levels and determine the dosage of Metformin Teva accordingly. Make sure to speak with your doctor regularly. This monitoring is particularly important in children, adolescents and the elderly.
- During treatment with Metformin Teva, 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 Teva before or at the time of injection. Your doctor will decide when you should stop and when you should restart the treatment with Metformin Teva.

If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist. You may require more frequent monitoring of your blood glucose levels and kidney function, or your doctor may adjust your dosage of Metformin Teva. 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, celecoxib).
- Certain medicines for treatment of hypertension (angiotensin converting enzyme inhibitors [ACE], 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: severe skin inflammation or asthma).
- Medicines that may change your metformin blood levels, especially if your kidney function is impaired (such as: verapamil, rifampicin, cimetidine, dolutegravir, ranolazine, trimethoprim, vandetanib, isavuconazole, crizotinib, olaparib).
- Other anti-diabetic medicines.

Use of the medicine and food

Metformin Teva 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 Teva, as there may be an increase in the risk for lactic acidosis (see subsection "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 Teva is not recommended if you are breastfeeding or planning to breastfeed.

Driving and operating machinery

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

However, you should be careful if you are taking Metformin Teva together with other anti-diabetic medicines which may cause hypoglycemia (such as: sulfonylurea, insulin, meglitinides). Symptoms of hypoglycemia include weakness, dizziness, increased sweating, rapid heartbeat, visual disturbances or concentration difficulties. 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 only by the doctor.

Metformin Teva does not replace a healthy lifestyle. You should follow the dietary instructions advised 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 Teva.

The Metformin Teva 850 mg tablet should not be halved. When a dose of 500 mg is required, a medicine containing 850 mg of metformin which can be halved should be used (to obtain a dose of 425 mg), which may serve as an alternative for a 500 mg tablet.

Do not exceed the recommended dose.

How to take Metformin Teva

Metformin Teva 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).

How to take the medicine

Crushing/halving/chewing:

Do not halve, chew or crush the tablet.

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

If you accidentally took a higher dosage

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

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

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, 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 the 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 Teva may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

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

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

- Gastrointestinal disturbances such as: nausea, vomiting, diarrhea, abdominal pain and loss of appetite. These effects usually occur at the beginning of the treatment with Metformin Teva. These effects may be eased by dividing the dosage throughout the day and taking the medicine with or right after a meal.

If the symptoms continue, stop taking Metformin Teva and consult the doctor.

Common side effects (side 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), numbness sensation (paresthesia) or pale or yellow skin]. Your doctor may conduct 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 health problems.

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

- Lactic acidosis. A very rare but very severe complication, especially if your kidneys are not functioning properly. Symptoms of lactic acidosis are not specific (see in section 2 – "Special warnings regarding the use of the medicine" and at the beginning of this section).

- 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 Teva and refer to your doctor.**

- A skin reaction, such as: redness of the skin (erythema), itching or an itchy rash (hives).

Children and adolescents

Limited data regarding children and adolescents have demonstrated that side effects are similar in type 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 your 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), which will direct you to the online form for reporting side effects, or by clicking on 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 in a dry place, below 25°C.**
- Do not discard medicines in the wastewater or domestic trash. Ask the pharmacist how to dispose of medicines no longer in use. These measures will help to protect the environment.

6. ADDITIONAL INFORMATION

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

Povidone K-30, hypromellose, titanium dioxide, magnesium stearate, colloidal silicon anhydrous, polyethylene glycol

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

A white, film-coated, oval shaped tablet. The number "93" is debossed on one side of the tablet, and "49" is debossed on the other side.

Each package contains 30 tablets packed in blisters.

Name and address of the manufacturer and marketing authorization holder

Teva Israel Ltd., 124 Dvora HaNevi'a St., Tel Aviv 6944020

This leaflet was revised in August 2022 in accordance with the Ministry of Health guidelines.

Registration number of the medicine in the national drug registry of the Ministry of Health: 130 25 30822