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 illness is similar.

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.

Insulin is a hormone produced by the pancreas, which enables the absorption of glucose from the blood. In a state of diabetes, the body does not produce enough insulin or cannot utilize the insulin it produces, which leads to elevated blood glucose levels. Metformin Teva helps to lower blood glucose levels to as normal levels as possible.

In overweight adults, taking Metformin Teva as a long-term treatment helps reduce the risk for complications associated with diabetes.

Therapeutic class

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

2. Before using the medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the additional ingredients the medicine contains (see section 6).
- You suffer from hepatic impairment.
- You suffer from a severe impairment in kidney function.
- Your diabetes is uncontrolled, for example, if you have severe hyperglycemia (high blood glucose levels), nausea, vomiting, diarrhea, acute 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, which may lead to diabetic pre-coma. Symptoms include: abdominal pain, deep and rapid breathing, drowsiness and/or abnormal fruity breath odor.
- You have lost too much fluids (dehydration), e.g, as a result of severe/ prolonged diarrhea or continuous vomiting. Dehydration may cause kidney problems, which may lead to the development of lactic acidosis (see section "Special warnings regarding the use of the medicine").
- You have a severe infection such as an infection that affects the lungs/ respiratory system/kidneys. A severe infection may cause kidney problems, which may lead to the development of lactic acidosis (see section "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 reduced oxygen supply to body tissues, and therefore they increase the risk for developing lactic acidosis (see section "Special warnings regarding the use of the medicine").
- You consume large amounts of alcohol.

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, which requires the injection of an iodine-containing contrast agent into your blood.
- You are about to undergo a major surgery.

In the abovementioned cases, you should stop taking Metformin Teva for a certain period of time before and after the test or surgery. Your doctor will decide when you should stop and when you should renew the treatment with Metformin Teva. Your doctor will decide if you need an alternative treatment during this time. It is important that you follow the doctor's orders exactly.

Risk for lactic acidosis

Metformin Teva may cause a very rare but also very severe side effect called lactic acidosis, especially if your kidney function is impaired. The risk for developing lactic acidosis also increases in the following conditions: uncontrolled diabetes, serious infections, prolonged fasting, prolonged alcohol consumption, dehydration (see details below), liver problems and any other medical condition in which oxygen supply to body organs is reduced (such as acute and severe heart disease).

If any of the abovementioned conditions applies to you, consult with your doctor for further instructions.

Stop taking Metformin Teva for a short period of time if you are in a situation where dehydration (loss of a significant amount of fluids) is suspected, such as: lots of vomiting, diarrhea, fever, exposure to heat or when your fluid intake is lower than usual. Consult with your doctor for further instructions.

Stop taking Metformin Teva and immediately refer to a doctor or emergency room if you experience symptoms of lactic acidosis, since lactic acidosis may lead to a coma. The symptoms of lactic acidosis include:

- Vomiting
- Abdominal pain
- Muscle cramps
- Malaise accompanied by severe fatigue
- Breathing difficulties
- Reduced body temperature and heart rate

Lactic acidosis is a medical emergency which necessitates hospital treatment.

Metformin Teva alone 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.

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. Consult the doctor if you have kidney impairment.

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.

Tests and follow-up

- During treatment, your doctor will regularly check your blood glucose levels and will adjust the dosage of Metformin Teva to your blood glucose levels. You should maintain constant contact with the doctor. This monitoring is particularly important when treating children and adolescents or the elderly.
- During treatment with Metformin Teva, your doctor will perform kidney function tests at least once a year. In the elderly and/or in people with impaired kidney function, it might be necessary to perform the tests more often.

Drug-drug interactions

If you are taking or have recently taken other medicines including non-prescription medicines and food supplements, tell the doctor or the pharmacist. You may require more frequent monitoring of your blood glucose levels and kidney function, or the doctor may adjust your dosage of Metformin Teva, 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 (ACE inhibitors and 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 affect 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. Taking Metformin Teva concomitantly with other anti-diabetic medicines may increase the risk for hypoglycemia.

If you need to receive an injection of an iodine-containing contrast agent into your blood, e.g., for an x-ray, you should stop taking Metformin Teva before or close to the time of injection. Your doctor will decide when you should stop and when you should renew the treatment with Metformin Teva.

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 due to an increase in the risk for lactic acidosis (see section "Special warnings regarding the use of the medicine").

Pregnancy and breastfeeding

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

Consult with the doctor if you are pregnant, think you are pregnant or plan to become pregnant, so that he will decide if your treatment should be changed.

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

Driving and operating machinery

Metformin Teva alone does not cause hypoglycemia (a blood glucose level that is too low); thus, the medicine is not expected 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 difficulty concentrating. Do not drive or operate machinery if you experience 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.

Children from 10 years of age and adolescents:

The initial dosage is usually 500 mg or 850 mg (one tablet) once a day. The maximum daily dose is 2000 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 (one tablet) 2-3 times per day. The maximum daily dose is 2550 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 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.

The tablet should be swallowed 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 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 an overdose of this medicine or if a child accidentally swallowed this medicine

An overdose may cause lactic acidosis. The symptoms of lactic acidosis include: vomiting, abdominal pain with muscle cramps, malaise accompanied by severe fatigue and difficulty breathing. Additional 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 Teva immediately and contact the doctor or go to an emergency room immediately.**

If you forgot to take the medicine at the required time, do not take a double dose to compensate for a forgotten dose. Take the next dose at the scheduled time.

Follow the treatment as recommended by 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 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 (may affect less than 1 in 10,000 users) but also very severe, called lactic acidosis (see section 2 - "Special warnings regarding the use of the medicine"). **If this effect occurs, stop the treatment and refer immediately to a doctor or hospital,** since lactic acidosis may lead to a coma.

Additional side effects

Very common side effects - may affect more than 1 in 10 users

- Gastrointestinal disturbances such as: nausea, vomiting, diarrhea, abdominal pain and lack of appetite. These effects usually occur at the beginning of the treatment. 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 persist, stop the treatment and refer to the doctor.**

Common side effects - may affect less than 1 in 10 users

- Altered sense of taste

Very rare side effects - may affect less than 1 in 10,000 users

- Abnormalities in liver function tests or jaundice (inflammation of the liver which 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 Teva and refer to your doctor.**
- A skin reaction, such as redness of the skin (erythema), itching or an itchy rash (hives).
- Low levels of vitamin B12 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 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 under 25°C.**
- Medicines should not be disposed of via wastewater or household waste. Ask your 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, elongated tablet. The tablet is debossed with "93" on one side and "49" on the other.

Each package contains 30 tablets in blister packs.

Manufacturer and license holder

Teva Pharmaceutical Industries Ltd., P.O. box 3190, Petah Tikva.

This leaflet was revised in October 2020.

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

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