

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

The medicine is dispensed with a doctor's prescription only

**Pioglitazone Teva 15 mg  
Pioglitazone Teva 30 mg  
Pioglitazone Teva 45 mg  
Tablets**

**Composition:**

Each tablet of Pioglitazone Teva 15 mg contains:

Pioglitazone (as hydrochloride) 15 mg

Each tablet of Pioglitazone Teva 30 mg contains:

Pioglitazone (as hydrochloride) 30 mg

Each tablet of Pioglitazone Teva 45 mg contains:

Pioglitazone (as hydrochloride) 45 mg

For information regarding inactive ingredients and allergens in the preparation see section 2 – "Important information about some of the ingredients of the medicine" and 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.

The medicine is not intended for children and adolescents under the age of 18 years.

**1. WHAT IS THE MEDICINE INTENDED FOR?**

The medicine is intended for the treatment of type 2 diabetes (non-insulin dependent) in patients whose blood sugar level cannot be controlled by treatment with metformin alone. Pioglitazone Teva is given as monotherapy in patients who are unable to take metformin, and whose blood sugar level cannot be controlled by diet or exercise. Likewise, Pioglitazone Teva may also be given in combination with other medicines for treatment of diabetes (such as: metformin, sulphonylurea or insulin) in cases of inadequate control of the blood sugar level.

Pioglitazone Teva helps control blood sugar level by improving the response of the body cells to the insulin produced in the body.

**Therapeutic class:**

The medicine belongs to the group of thiazolidinediones for treatment of diabetes.

**2. BEFORE USING THE MEDICINE**

**Do not use the medicine if:**

- There is a known sensitivity to pioglitazone or to any of the ingredients of the medicine listed in section 6.
- You suffer or have suffered in the past from heart failure.
- You suffer from a liver disease.
- You suffer from diabetic ketoacidosis, a complication of diabetes that leads to rapid weight loss, nausea or vomiting.
- You suffer or have suffered in the past from bladder cancer.
- You have blood in the urine that the doctor has not yet diagnosed.

**Special warnings regarding the use of the medicine:**

**Before using Pioglitazone Teva, inform the doctor if:**

- You have a known sensitivity to lactose, since the preparation contains lactose.
- You suffer from fluid retention in the body or from heart failure, particularly in people above 75 years of age. If you are taking anti-inflammatory medicines that may also cause fluid retention and swelling, you should consult the doctor.
- You suffer from an eye disease typical of diabetics, called macular edema (swelling of the back part of the eye).
- You suffer from polycystic ovary syndrome, as Pioglitazone Teva may cause ovulation and increase the chance of becoming pregnant. In order to avoid an unplanned pregnancy, it is recommended to use contraceptive preparations.
- You suffer from a liver or heart problem. Before starting treatment with Pioglitazone Teva, blood tests should be performed to assess liver function. It may be necessary to repeat the tests during the treatment. In certain people who have suffered from diabetes over many years as well as from heart diseases or stroke, and who have taken pioglitazone and insulin, heart failure has developed. Inform the doctor as soon as possible if you experience signs of heart failure, such as: unusual shortness of breath or sharp increase in body weight or localized edema (swelling).

**Warnings:**

- If you are taking other medicines for diabetes, you should take precautionary measures to prevent the development of a situation of low blood sugar level (hypoglycemia).
- Blood tests should be performed at a frequency that will be determined by the attending doctor, as there may be a reduction in blood count (anemia).
- In patients treated with this medicine, particularly in women, a high number of bone fractures has been observed. Consult with the doctor.

**Children and adolescents:**

This medicine is not recommended for children and adolescents under the age of 18 years.

**Tests and follow-up:**

- Routine blood tests should be performed while using Pioglitazone Teva in order to monitor liver function.

- Monitor your body weight at regular intervals. If there is an increase in body weight, consult the doctor.

**Drug interactions:**

**If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist.**

**In particular, inform the doctor if you are taking the following medicines:**

- Gemfibrozil (to lower cholesterol)
- Rifampicin (for treatment of tuberculosis and other infections)

If you are taking any of these medicines, your blood sugar levels should be checked in order to estimate the appropriate dosage of Pioglitazone Teva.

**Use of the medicine and food:**

Pioglitazone Teva may be taken with or without food. Swallow the tablets with a glass of water.

**Pregnancy and breastfeeding:**

If you are pregnant, think you are pregnant or are planning a pregnancy, breastfeeding or planning to breastfeed, inform the doctor. He may recommend that you stop using the medicine.

**Driving and operating machinery:**

The medicine does not impair the ability to drive or operate machinery, but be cautious if you experience vision impairment during treatment.

**Important information about some of the ingredients of the medicine:**

This medicine contains **lactose**. Lactose is a type of sugar. If you have been told by your doctor that you have an intolerance to certain sugars, consult your doctor before taking this medicine.

**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 about the dosage and how to use the preparation.

The dosage is according to the doctor's instructions only.

This medicine should be used at set intervals as determined by the treating doctor.

**Dosage:**

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

The generally accepted directions for use are as follows:

One tablet of Pioglitazone Teva 15 mg or 30 mg once daily.

If necessary, the doctor will increase the dosage to a maximum of 45 mg once daily.

- If Pioglitazone Teva is taken in combination with other medicines for treatment of diabetes (such as: insulin, chlorpropamide, glibenclamide, gliclazide, tolbutamide), the doctor will determine whether a lower dosage of the medicines is required.
- The attending doctor will perform tests to assess the effectiveness of the treatment with Pioglitazone Teva, 3 to 6 months after starting treatment.
- If you are on a special diet for diabetics, persist with it while taking Pioglitazone Teva.

**Do not exceed the recommended dose.**

**Method of administration:**

Swallow the medicine with a glass of water. Do not halve the tablets in the absence of a score line.

There is no information regarding crushing.

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

**Effects of overdose:**

Blood sugar levels could fall excessively. The blood sugar level can be increased by eating sugar. The patient is recommended to carry with him food that contains sugar (such as: candies, sweets, cookies or sweetened juice).

**If you forgot to take this medicine** at the required time, take the next dose at the regular time. Do not take two doses together to compensate for the forgotten dose.

**Follow the treatment as recommended by the doctor,** even if your health condition improves. Do not stop the treatment without consulting the doctor or pharmacist.

**If you stop taking the medicine:**

Pioglitazone Teva should be taken every day for it to work properly. If you stop taking Pioglitazone Teva, your blood sugar level will increase. Consult your doctor before discontinuing this treatment.

**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 use of the medicine, consult the doctor or the pharmacist.**

**4. SIDE EFFECTS**

As with any medicine, using Pioglitazone 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.

- Heart failure can occur frequently (appears in 1-10 users out of 100) in patients taking pioglitazone in combination with insulin. Typical symptoms are unusual shortness of breath or a sharp increase in weight or localized swelling (edema). If you experience any of these effects, especially if you are over 65 years of age, seek medical help immediately.

- Bladder cancer may occur infrequently (appears in 1-10 users out of 1,000) in patients taking pioglitazone. Signs and symptoms include blood in the urine, pain while urinating or a sudden urgency in urination. If you experience any of these effects, consult the doctor as soon as possible.

- Localized swelling (edema) may occur very frequently (appears in more than one user

out of 10) in patients taking Pioglitazone Teva in combination with insulin. If you suffer from this effect, consult the doctor as soon as possible.

- Bone fractures have been reported frequently (appear in 1-10 users out of 100) in women taking pioglitazone, and at an unknown frequency in men taking pioglitazone. Whenever this side effect occurs, consult the doctor as soon as possible.

- Blurred vision due to swelling (or fluids) at the back part of the eye (unknown frequency). If you experience this effect for the first time, consult the doctor as soon as possible. If you suffer from blurred vision and the symptoms worsen, refer to the doctor as soon as possible.

- Allergic reactions (unknown frequency): if you experience a serious allergic reaction, including skin allergy (hives) which can be accompanied by itching and swelling of the face, lips, tongue or throat that may cause difficulty breathing or swallowing, stop taking the medicine and consult the doctor as soon as possible.

**Additional side effects:**

**Common side effects – effects that occur in 1-10 users out of 100:**

- Respiratory tract infections
- Visual disturbances
- Weight gain
- Loss of sensation

**Uncommon side effects – effects that occur in 1-10 users out of 1,000:**

- Inflammation of the sinuses (sinusitis)
- Insomnia

**Side effects with unknown frequency (effects whose frequency has not yet been determined):**

- Increased liver enzymes
- Allergic reactions

**Possible side effects when taking Pioglitazone Teva in combination with other medicines for treatment of diabetes:**

**Very common side effects – effects that occur in more than one user out of ten:**

- Decreased blood sugar levels (hypoglycemia)

**Common side effects – effects that occur in 1-10 users out of 100:**

- Headache
- Dizziness
- Joint pain
- Impotence
- Back pain
- Shortness of breath
- Slight decrease in red blood cell count
- Flatulence

**Uncommon side effects – effects that occur in 1-10 users out of 1,000:**

- Sugar or protein in the urine
- Increase in enzyme levels
- A sensation of loss of balance (vertigo)
- Sweating
- Tiredness
- Increased appetite

**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](http://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 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 appearing on the package. The expiry date refers to the last day of that month.

**Storage conditions:**

Store below 30°C.

**6. ADDITIONAL INFORMATION**

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

Lactose monohydrate, hydroxypropylcellulose, carmellose calcium, magnesium stearate.

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

**Pioglitazone Teva 15 mg:** white, round, flat tablet, with "TZ15" appearing on one side.

**Pioglitazone Teva 30 mg:** white, round, flat tablet, with "TZ30" appearing on one side.

**Pioglitazone Teva 45 mg:** white, round, flat tablet, with "TZ45" appearing on one side.

Quantity in the package: 14, 28, 30, 50, 56, 80, 90, 98 or 112 tablets.

Not all package sizes may be marketed.

**Name and address of the manufacturer and marketing authorization holder:**

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

The leaflet was revised in May 2023 in accordance with the Ministry of Health guidelines.

**Registration number of the medicine in the national drug registry of the Ministry of Health:**

Pioglitazone Teva 15 mg: 165.40.36343

Pioglitazone Teva 30 mg: 165.41.36344

Pioglitazone Teva 45 mg: 165.42.36345