

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

The medicine is dispensed with a doctor's prescription only

**Glimepiride Teva 1 mg**

**Tablets**

Active ingredient and quantity:

Each tablet contains:  
Glimepiride 1 mg

**Glimepiride Teva 3 mg**

**Tablets**

Active ingredient and quantity:

Each tablet contains:  
Glimepiride 3 mg

For information on inactive ingredients, see section 2 "Important information about some of the ingredients in the medicine" and section 6 – "Further Information".

**Read this 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. The medicine is not intended for children and adolescents under the age of 18.

If a side effect worsens or if a side effect not mentioned in this leaflet occurs, please refer to a doctor or pharmacist.

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

The medicine is intended for the treatment of type 2 diabetes.

**Therapeutic group:**

The active ingredient belongs to the sulfonylurea group – preparations that increase the amount of insulin released by the pancreas.

**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 sensitive to other derivatives of sulfonylurea or to sulfonamides. You may also develop an allergy to this medicine. Signs of an allergic reaction include skin reactions and severe effects, such as shortness of breath, decreased blood pressure or anaphylactic shock.
- This medicine is not intended to treat type 1 diabetes, severe or unstable diabetes, ketosis or acidosis as a complication of diabetes, or diabetic coma.

**Special warnings regarding use of the medicine**

- Glimepiride Teva, as with all medicines from the sulfonylurea group, may cause hypoglycemia (low blood sugar levels). This may affect alertness and concentration and cause dangerous conditions. Before taking this medicine - talk to the doctor or pharmacist about how to identify and act in this situation. For your information, signs of hypoglycemia can be concealed or may disappear in patients taking medicines from the sympatholytic group, such as beta-blockers, clonidine, guanethidine and reserpine.
- Cases of severe allergic reactions have been reported. The reaction may include the following signs: shortness of breath, decreased blood pressure or anaphylactic shock. If you suspect that you are suffering from an allergic reaction, stop treatment with the medicine immediately and refer to a doctor.
- With medicines from the sulfonylurea group, there is a risk of increased incidence of death from heart problems.

**⚠ Before treatment with Glimepiride Teva, tell the doctor if:**

- You have a known deficiency of the G6PD enzyme. In this case, use of sulfonylurea-containing preparations may cause hemolytic anemia.
- You suffer from weakness and/or malnutrition.
- You suffer from impaired function of the: kidneys, adrenal gland, thyroid, liver.

**⚠ Tests and follow-up**

During the treatment period, monitor blood glucose levels, glycosylated hemoglobin (hemoglobin A1C), glucose in urine, and blood tests should be carried out to monitor blood cell levels and liver functions.

**⚠ Drug interactions**

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

- a. Medicines that may increase the effect of Glimepiride Teva and cause hypoglycemia (decrease in blood sugar levels), such as:
  - Medicines to treat diabetes (oral medicines to treat diabetes, pramlintide acetate and insulin).
  - Medicines to treat gastrointestinal ulcers and acidity (H2 receptor antagonists).
  - Medicines to treat inflammation and pain (e.g., propoxyphene, non-steroidal anti-inflammatories, salicylates).
  - Medicines to treat fungal and bacterial infections (e.g., miconazole, fluconazole, tetracyclines, quinolones, sulfonamides, chloramphenicol).
  - Medicines to treat blood clotting problems (coumarin type).
  - Muscle-building medicines (anabolic steroids and androgens).
  - Hormone replacement therapy for men.
  - Medicines to treat depression (e.g., fluoxetine and medicines from the MAO enzyme inhibitor group).
  - Medicines for lowering blood fat levels (fibrates).
  - Medicines for lowering blood pressure (e.g., guanethidine and ACE inhibitors group).
  - Medicines to treat heart rhythm problems (e.g., disopyramide).
  - Medicines to treat gout (e.g., sulfipyrazone, probenecid).
  - Medicines to treat cancer (e.g., cyclophosphamide).
  - Medicines used to improve blood flow (pentoxifylline).
  - Muscle relaxants (e.g., phenylamidol).
- b. Medicines that may reduce the effect of Glimepiride Teva and cause an increase in blood glucose levels:
  - Medicines that contain female sex hormones (to treat endometriosis - danazol, oral contraceptives, hormone replacement therapy for women).
  - Medicines to treat hypertension from the thiazide group and other diuretics.
  - Medicines to treat hypothyroidism (levothyroxine).
  - Medicines to treat inflammations and allergies (corticosteroids).
  - Medicines to treat mental illness (atypical antipsychotics, phenothiazines).
  - Medicines used to increase heart rate, treat asthma, nasal congestion, cough and cold, for treating emergency medical conditions (sympathomimetics).
  - Medicines to treat high cholesterol levels (nicotinic acid).
  - Medicines to treat constipation (laxatives).
  - Medicines to treat epilepsy (phenytoin).
  - Medicines to treat epilepsy, nervousness and sleeping problems (barbiturates).
  - Medicines to treat high blood pressure or low blood sugar levels (diazoxide).
  - Medicines to treat different infections such as tuberculosis (isoniazid and rifampin), and HIV (from the protease inhibitor group).
  - Medicines given for treatment of especially low glucose levels (glucagon).
  - Growth hormones (e.g., somatropin).
  - Medicine to reduce cholesterol that binds bile salts in the intestine (colesevelam). To prevent this interaction, take Glimepiride Teva at least 4 hours before taking colesevelam (see section 3).
- c. Medicines that may increase or reduce the effect of Glimepiride Teva:
  - Sympatholytic medicines to treat blood pressure or heart failure (e.g., beta-blockers, clonidine, reserpine). Sympatholytic medicines may mask signs of hypoglycemia, therefore, have regular check-ups at the doctor if you are taking these medicines.

**⚠ Use of the medicine and food**

Take Glimepiride Teva with breakfast or with the first main meal of the day.

**⚠ Use of the medicine and alcohol consumption**

**Do not drink wines or alcoholic beverages during the course of treatment with the medicine.** Alcohol may increase or weaken the effect of the medicine on reduction of blood sugar levels.

**⚠ Pregnancy, breastfeeding and fertility**

If you are pregnant, are planning to become pregnant, are breastfeeding or planning to breastfeed, consult the doctor before using medicines. If you are breastfeeding, monitor the baby for signs of hypoglycemia (e.g., jitters, cyanosis, apnea, hypothermia, excessive sleeping, unwillingness to feed, seizures).

**⚠ Driving and operating machinery**

Do not drive or operate dangerous machinery when using the medicine, as use of this medicine may impair alertness.

**⚠ Important information about some of the ingredients in the medicine**

This medicine contains a sugar called lactose. If you have been told by the doctor that you have an intolerance to certain sugars, consult the doctor before taking this medicine.

This medicine contains less than 23 mg sodium per tablet and is therefore considered sodium-free.

**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 in regards to the preparation dosage and treatment regimen.

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

The usual starting dosage is 1 mg or 2 mg, once a day.

For elderly patients and patients with kidney function problems, the recommended starting dosage is 1 mg per day. Increasing the dosage of the medicine will only be done following instructions from the attending doctor. The maximum dosage is 8 mg, once a day.

If you are taking colesevelam (for reducing cholesterol by binding the bile salts in the intestine), take Glimepiride Teva at least 4 hours before taking colesevelam.

**Do not exceed the recommended dose.**

- Swallow the tablet with water.
- The tablet can be halved.
- Do not chew the tablet. There is no information regarding crushing.
- Take the tablet with breakfast or the first main meal of the day.

**If you accidentally took a higher dosage,** you may suffer from hypoglycemia.

Effects of hypoglycemia include: cold sweat, pale skin, persistent headache, increased appetite, tremor. Severe hypoglycemia may cause coma, seizures and neurological disturbances.

**If you 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 this medicine** at the required time, do not take a double dose. Take the next dose at the scheduled time and consult the doctor.

Adhere to 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 or pharmacist.

**If you stop taking the medicine**

Blood sugar levels may not be balanced and your illness may worsen. Continue taking the medicine until your doctor instructs you to stop treatment.

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

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

**4. SIDE EFFECTS**

As with any medicine, use of Glimepiride Teva 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.

**Discontinue use and refer immediately to a doctor or proceed to a hospital emergency room if you suffer from the following effects:**

- Hypoglycemia
- Worsening of allergic skin reactions and worsening of an allergic reaction that can be manifested by shortness of breath, a drop in blood pressure or anaphylactic shock.
- Hemolytic anemia in patients with or without a G6PD enzyme deficiency.

**Refer to the doctor as soon as possible if you suffer from the following effects:**

- Impaired liver function (accompanied by an increased level of bile salts and jaundice) and inflammation of the liver that may develop into liver failure.
- Photosensitivity reactions, allergic vasculitis, skin irritation or rash.
- Decreased white blood cell counts, decreased platelet levels (including extreme cases, such as platelet counts below 10,000/µl or skin rash).
- Low blood sodium levels (hyponatremia).

Additional side effects: dizziness, fatigue or weakness, headaches, nausea, weight gain, change in sense of taste, hair loss.

**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 following Drug Treatment" found on the Ministry of Health homepage ([www.health.gov.il](http://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 without explicit instruction from 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 at a temperature below 25°C.**
- Do not discard medicines in the wastewater or waste bin. Ask the pharmacist how to dispose of medicines that are no longer in use. These measures will help to protect the environment.

**6. FURTHER INFORMATION**

**In addition to the active ingredient, Glimepiride Teva 1 mg, 2 mg, 3 mg, 4 mg tablets also contain:**

Lactose monohydrate, sodium starch glycolate, microcrystalline cellulose, povidone, magnesium stearate and the following coloring substances:  
Glimepiride Teva 1 mg – iron oxide red (E172)  
Glimepiride Teva 2 mg – iron oxide yellow (E172) and indigo carmine aluminium lake (E132)  
Glimepiride Teva 3 mg – iron oxide yellow (E172)  
Glimepiride Teva 4 mg – indigo carmine aluminium lake (E132)

**What the medicine looks like and contents of the package:**

**Glimepiride Teva 1 mg** – Mottled pink, round tablet, bisected on both sides. One side of the tablet is debossed with "9" on one side of the score line and "3" on the other side of the score line. The second side of the tablet is debossed with "72" on one side of the score line and "54" on the other side of the score line.

**Glimepiride Teva 2 mg** – Mottled green, round tablet, bisected on both sides. One side of the tablet is debossed with "9" on one side of the score line and "3" on the other side of the score line. The second side of the tablet is debossed with "72" on one side of the score line and "55" on the other side of the score line.

**Glimepiride Teva 3 mg** – Light yellow to yellow, round tablet, bisected on both sides. One side of the tablet is debossed with "G" on one side of the score line and "3" on the other side of the score line.

**Glimepiride Teva 4 mg** – Mottled light blue, round tablet, bisected on both sides. One side of the tablet is debossed with "9" on one side of the score line and "3" on the other side of the score line. The second side of the tablet is debossed with "72" on one side of the score line and "56" on the other side of the score line.

The medicine is marketed in packages of 30 tablets.

**Name of License Holder and its Address:**

Abic Marketing Ltd., P.O.B. 8077, Netanya.

**Name of Manufacturer and its Address:**

Teva Pharmaceutical Industries Private Limited Company, Debrecen, Hungary.

This leaflet does not contain all the information about the preparation. If you have any question or you are uncertain about something, please refer to a doctor.

This leaflet was checked and approved by the Ministry of Health in December 2013 and updated in July 2019 in accordance with the Ministry of Health guidelines.

**Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:**

Glimepiride Teva 1 mg: 151.15.33843

Glimepiride Teva 2 mg: 151.16.33859

Glimepiride Teva 3 mg: 151.17.33870

Glimepiride Teva 4 mg: 151.18.33871