

**PATIENT PACKAGE INSERT 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 the list of the inactive ingredients in the preparation, see section 6 – “Further Information”.

**Read this leaflet carefully in its entirety before using this 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 for the treatment of your ailment. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar.**

This medicine is not intended for children and adolescents.

## Warnings regarding lactic acidosis

Metformin Teva® may cause a very severe and rare complication called lactic acidosis (high mortality rate when left untreated), especially if your kidneys do not work properly. The risk for lactic acidosis increases when your diabetes is not controlled, if you are fasting for a long time or if you consume alcohol, in dehydration due to severe diarrhea or vomiting, if you suffer from liver problems or from any medical condition accompanied by a lack of oxygen supply to the body organs (such as acute and severe heart diseases).

It is important to comply with the medicinal treatment, to follow instructions for a proper diet and to comply with a regular exercise program because this may reduce the risk of lactic acidosis. Development of the disease may be without special symptoms. Symptoms of lactic acidosis include: vomiting, abdominal pain with muscle cramps, a general unwell feeling with severe fatigue and breathing difficulties. Additional symptoms include reduced body temperature and heart rate.

**If you experience these symptoms, stop taking the medicine immediately and refer to a doctor or emergency room immediately, since lactic acidosis may cause a coma.**

## Warnings regarding hypoglycemia

Metformin Teva® as a monotherapy does not cause hypoglycemia (low blood glucose levels). However, if you are taking Metformin Teva® in combination with other medicines for the treatment of diabetes that may cause hypoglycemia (e.g., medicines of the sulphonylurea group, insulin, meglitinides), there is a risk of developing hypoglycemia. If you experience symptoms of hypoglycemia, such as: weakness, tremor, dizziness, headache, increased sweating, hunger, fast heart rate, vision disturbances, or difficulty concentrating, it is recommended to eat or drink something that contains sugar.

If you experience the effects mentioned above, do not drive or use machinery.

## 1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended for the treatment of diabetes as a monotherapy or in combination with other medicines to treat diabetes.

## Therapeutic group:

The active ingredient belongs to the biguanide group.

## 2. BEFORE USING THE MEDICINE

### Do not use the medicine if:

- Do not use the medicine if you are breastfeeding.
- Do not use this medicine if there is a known sensitivity to metformin or to any of its other ingredients.
- Do not use the medicine if you suffer from impaired function of:
  - the kidney – severe renal disease or impaired function
  - the liver
  - the respiratory system – e.g., breathing difficulties
  - the heart – e.g., heart diseases, heart attack in the past. If you are being treated for acute heart failure or have recently had a heart attack, or have severe blood circulation problems (such as shock) or have breathing difficulties – this may lead to reduced oxygen supply to body tissues and to a risk of developing lactic acidosis. Do not use the medicine in case of severe and unstable heart failure.
- If you are in a state of unconsciousness (diabetic coma).
- If you are suffering from nausea and vomiting.
- If you have diabetic ketoacidosis – a dangerous condition in which ketone bodies build up in the blood; typical signs are abdominal pain, deep, rapid breathing, sleepiness, abnormal odor from the mouth.
- If you drink large quantities of alcohol.
- If you are suffering from a severe infection (e.g., an infection which affects the lungs/kidney) or if you have a fever.
- If you are suffering from dehydration (e.g., caused by severe diarrhea or vomiting several times in a row).
- If your diabetes is uncontrolled, such as if you have severe hyperglycemia (high blood sugar levels).
- If you experience rapid loss of body weight.
- If you are in a state of shock.
- If you have suffered in the past from lactic acidosis.
- If you have a blood clot in the lungs – signs include: cough, shortness of breath, chest pain and rapid heart rate.
- If you have inflammation of the pancreas – signs include: severe abdominal pain, generally with nausea and vomiting.

**Before treatment with Metformin Teva®, tell the doctor if:**

- if you are pregnant or are planning to become pregnant.
- if you are due to undergo an examination, such as an x-ray, which requires use of a contrast agent that contains iodine that is injected into your blood or if you are due to undergo major surgery or if you have undergone surgery or another traumatic event.

**Stop taking Metformin Teva® for a certain period of time before and after the examination (at least 48 hours) or surgery in accordance with the doctor's instructions.**

## Special warnings regarding use of the medicine:

- During the course of treatment with this medicine, kidney function tests should be performed at least once a year. (Elderly people/people with impaired kidney function are advised to have the test performed more frequently – every 3-6 months).
- In prolonged treatment with this medicine, annual tests for vitamin B<sub>12</sub> level should be performed to confirm that there is no reduction in the absorbance of the vitamin.
- If you are sensitive to any food or medicine, inform the doctor before taking the medicine.
- Be sure to visit the doctor at set time intervals to prevent situations of excessive increase in blood sugar level.
- If you have to undergo surgery or have been referred for a test that uses a contrast agent (such as an x-ray), inform the doctor that you are taking this medicine. It is recommended, upon consultation with the doctor, to stop taking the medicine before and after the test and to continue treatment only after a kidney function test.
- In patients with heart failure there is an increased risk of lack of oxygen and kidney failure. In patients with chronic, stable heart failure, regular heart and kidney function tests should be performed. Do not use the medicine in patients with severe and unstable heart failure (see section 2).

**If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.** In particular, inform the doctor or pharmacist if you are taking or plan to take:

- Anticoagulants
- Estrogens (female hormones), including oral contraceptives
- Diuretics (e.g., from the thiazide group, furosemide)
- Corticosteroids (e.g., to treat severe skin inflammation or asthma)
- Cimetidine, ranitidine (for gastric ulcer)
- Medicines to treat hypertension (e.g., ACE inhibitors, calcium channel blockers - e.g., nifedipine)
- Medicines to treat heart problems (e.g., digoxin, quinidine)
- Salbutamol or terbutaline (to treat asthma)
- Aspirin or other non-steroidal anti-inflammatory drugs (e.g., ibuprofen)
- Other medicines for the treatment of diabetes (e.g., insulin, sulphonylurea [glipizide, glimepiride], meglitinide)
- Antibiotics
- Medicines to lower blood lipids (e.g., nicotinic acid)
- Antipsychotics (e.g., phenothiazines)
- Thyroid hormones
- Adrenaline, danazol
- Phenytoin or tetracosactrin
- Isoniazid (for tuberculosis)
- Alcohol
- Vancomycin (antibiotic)
- Trimethoprim (antibacterial against infections)
- Contrast agents containing iodine (see section 2)

## Use of the medicine and food

Take the medicine with or immediately after a meal.

**Use of the medicine and alcohol consumption**  
Do not drink alcohol during the course of treatment with this medicine (or take other alcohol-containing medicines). Alcohol may increase the risk of lactic acidosis, especially if you suffer from liver problems or from malnutrition.

## Pregnancy and breastfeeding

Consult a doctor regarding use of the medicine if you are pregnant, think you are pregnant or are planning to become pregnant.

The medicine is not recommended if you are breastfeeding or are planning to breastfeed your baby.

## Use in children

This medicine is not intended for children and adolescents.

## Driving and use of machinery

Take caution if you are taking Metformin Teva® together with other medicines for the treatment of diabetes that may cause hypoglycemia – see warning at the beginning of this leaflet. Do not drive or operate machinery if you begin to feel symptoms of hypoglycemia.

## 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.

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

Take the medicine with or immediately after a meal, with a cup of water.

Do not change the dosage, dosing times or the diet associated with treatment on your own.

Do not halve, chew or crush the tablet.

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

**The usual dosage, unless instructed otherwise by the doctor is:**

### Adults:

The usual dosage of Metformin Teva® is generally one tablet, 1-3 times a day. The maximal dosage is 2550 mg per day, split into 3 doses.

If you are also taking insulin to treat diabetes, the attending doctor will instruct you how to start taking Metformin Teva®.

**Do not exceed the recommended dose.**

## Tests and follow-up:

- Blood tests should be performed regularly to check blood glucose level. Routine blood tests are particularly important in the elderly.
- During the course of treatment with this medicine, kidney function tests should be performed at least once a year. Elderly people and people with impaired kidney function are advised to have the test performed more frequently.

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

**Overdose may lead to a complication of lactic acidosis. Signs of lactic acidosis:** vomiting, abdominal pain with muscle cramps, general unwell feeling accompanied with severe fatigue and breathing difficulties. Additional symptoms include reduced body temperature and heart rate. Refer to a doctor or emergency room for immediate medical attention.

**If you forgot to take the medicine at the required time,** do not take a double dose. Take the next dose at the regular time.

**Adhere to the treatment as recommended by the doctor,** even if there is an improvement in your health. Do not discontinue the treatment without consulting the doctor or pharmacist. The symptoms from which you suffered may recur or worsen. 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 a doctor or pharmacist.

## 4. SIDE EFFECTS

As with any medicine, use of Metformin 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.

**Stop treatment and refer to a doctor immediately in the following cases:**

**Very rare side effects (affect less than one patient in 10,000 patients):**

- **Lactic acidosis** whose early signs are: vomiting, abdominal pain accompanied with muscle cramps, severe fatigue, general unwell feeling and breathing difficulties. This complication is very dangerous and may lead to a coma. **Stop taking the medicine immediately and refer to a doctor or emergency room immediately, since lactic acidosis may lead to a coma.**
- In case of abnormal liver function or if you have hepatic inflammation (inflammation may cause fatigue, lack of appetite, weight loss with or without yellowing of the skin and eyes).

### Additional side effects:

**Very common side effects (affect more than one patient in 10 patients):**

- Digestive system disturbances, such as nausea, vomiting, diarrhea, abdominal pain and lack of appetite. These effects usually occur at the beginning of treatment. These effects can be made milder by dividing the dose over the day as per the doctor's instruction, or by taking the medicine with or immediately after eating.

**If the symptoms continue, stop the treatment and refer to a doctor.**

**Common side effects (affect less than one patient in 10 patients):**

- Taste change.

**Very rare side effects (affect less than one patient in 10,000 patients):**

- Low blood B<sub>12</sub> levels.
- Skin reaction such as skin redness, itching or itchy rash.

**If any of the side effects occur, worsen, or if you are suffering from a side effect not mentioned in this leaflet, consult the doctor.**

## 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 of children and/or infants 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 in a dry place, below 25°C.**
- Do not discard medicines in the waste water or waste bin. Ask the pharmacist how to dispose of medicines no longer in use. These measures will help protect the environment.

## 6. FURTHER 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 the medicine looks like and the contents of the package:**

Each package contains 30 tablets. Metformin Teva® 850 mg: white, film-coated, oval-shaped tablet. The number “93” appears on one side of the tablet and “49” on the other side.

### Manufacturer and license holder:

Teva Pharmaceutical Industries Ltd., P.O.B. 3190, Petah Tikva 49131.

This leaflet was checked and approved by the Ministry of Health in March 2015.

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

130.25.30822

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