

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

The medicine is dispensed with a doctor's prescription only

Dapagliflozin Teva 5 mg Film-coated tablets

Composition

Each tablet contains: Dapagliflozin 5 mg

Dapagliflozin Teva 10 mg Film-coated tablets

Composition

Each tablet contains: Dapagliflozin 10 mg

For information regarding inactive ingredients and allergens, 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 illness is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Type 2 diabetes

Dapagliflozin Teva is given for the treatment of type 2 diabetes in adults (aged 18 and above), when the diabetes is insufficiently controlled and in combination with diet and exercise

- As a single treatment in case of metformin intolerance.
- In addition to other medicines for the treatment of type 2 diabetes.

Heart failure

Dapagliflozin Teva is given for the treatment of symptomatic chronic heart failure in adults.

Chronic kidney disease

Dapagliflozin Teva for the treatment of adults with chronic kidney disease.

Therapeutic class

SGLT2 (sodium-glucose co-transporter 2) inhibitors.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients this medicine contains (see details in section 6).

Special warnings regarding the use of the medicine

Refer to the doctor or to the nearest hospital immediately

Diabetic ketoacidosis:

- If you suffer from diabetes and you experience nausea or vomiting, abdominal pain, increased thirst, deep and rapid breathing, confusion, unusual drowsiness or tiredness, sweet breath odor, sweet or metallic taste in the mouth, change in your urine or sweat odor or rapid weight loss.
- The above symptoms may be a sign of diabetic ketoacidosis – a rare but serious, sometimes life-threatening problem, which can occur in diabetic patients as a result of high levels of ketones in the urine or blood (seen in lab tests).
- The risk of developing diabetic ketoacidosis may increase in cases of prolonged fasting, excessive alcohol consumption, dehydration, sudden reduction in insulin dosage, or increased insulin need due to serious illness or surgery.
- When you are treated with Dapagliflozin Teva, diabetic ketoacidosis may occur even if your blood sugar level is normal.

If you suspect that you have diabetic ketoacidosis, immediately refer to the doctor or to the nearest hospital and stop using the medicine.

Necrotising fasciitis of the perineum:

- Refer to the doctor immediately if you develop a combination of the following symptoms: pain, tenderness, redness or swelling in the genital area or in the area between the genitals and the anus, accompanied by fever or general malaise. These symptoms may be a sign of a rare but serious, and even life-threatening infection called Fournier's gangrene/necrotising fasciitis of the perineum. This infection destroys the tissue under the skin and has to be treated immediately.

Before treatment with Dapagliflozin Teva, tell your doctor, pharmacist or nurse if:

- You have type 1 diabetes – the type that usually starts at a young age. Do not use Dapagliflozin Teva for treatment of this condition.
- You suffer from diabetes and from a kidney problem – the doctor may instruct you to take a different or an additional medicine for treatment of blood sugar level.
- You suffer from a liver function problem – the doctor may instruct you to start with a lower dosage.
- You are receiving medicinal treatment for lowering blood pressure, and you have a history of low blood pressure. See additional information below in the section "If you are taking, or have recently taken, other medicines...".
- You suffer from very high levels of glucose in the blood, which may lead to dehydration (loss of too much body fluid). Possible signs of dehydration are listed in section 4 "Side effects". Before starting treatment with Dapagliflozin Teva, please inform your doctor if you have one or more of these signs.
- You have or develop nausea, vomiting or fever, or if you are not able to eat or drink. These conditions may lead to dehydration. The doctor may instruct you to stop taking Dapagliflozin Teva until recovery, in order to prevent dehydration.
- You often suffer from urinary tract infections. If any of the above is relevant to you or if you are uncertain about them, refer to the doctor, pharmacist or nurse before using Dapagliflozin Teva.

Diabetes and foot care

If you suffer from diabetes, it is important to check your feet regularly and follow the additional medical recommendations given to you regarding foot care.

Sugar (glucose) in the urine

While taking the medicine, a urine test will be positive for sugar (glucose) due to the way Dapagliflozin Teva works.

Children and adolescents

No information is available regarding the safety and efficacy of using this preparation in children and adolescents.

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. Especially if you are taking:

- Diuretics, for removing fluids from the body.
- Other medicines for lowering blood sugar levels, such as insulin or medicines from the sulfonylurea group. The doctor may instruct you to reduce the dosage of these medicines, to prevent you from reaching low blood sugar levels (hypoglycemia).
- Lithium, since Dapagliflozin Teva may lower the levels of lithium in your blood.

Use of the medicine and food

The medicine may be taken with or without food.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you might be pregnant or are planning to become pregnant, refer to the doctor or pharmacist before taking this medicine.

You should stop taking the medicine if you are pregnant, since the medicine is not recommended in the second and third trimesters of pregnancy. Consult the doctor regarding the best method of treating and balancing your blood sugar level during pregnancy.

If you are breastfeeding or planning to breastfeed, consult the doctor before taking the medicine.

Do not use Dapagliflozin Teva if you are breastfeeding. It is unknown whether the medicine is excreted into breastmilk.

Driving and operating machinery

The medicine Dapagliflozin Teva has no effect or negligible effect on the ability to drive and operate machinery. Taking the medicine with other medicines (medicines from the sulfonylurea group or insulin), may lead to a too low level of blood sugar (hypoglycemia), which can cause signs such as shaking, sweating or changes in vision, and may affect the ability to drive and operate machinery. Do not drive or operate machinery or equipment if you feel dizzy while taking Dapagliflozin Teva.

Important information about some of the ingredients of the medicine

Sodium – this medicine contains less than 1 mmol of sodium (23 mg) per tablet, and is therefore considered sodium-free.

Lactose – if you have been told by the doctor that you have an intolerance to sugars, consult the doctor before taking this medicine.

3. HOW SHOULD YOU USE THE MEDICINE?

- Always use 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 and treatment regimen will be determined only by the doctor.

The accepted dosage

- The generally accepted dosage is one tablet of 10 mg once a day.
- The doctor may instruct you to take one tablet of 5 mg if you have impaired liver function.
- The doctor will prescribe the appropriate dosage for you.

Do not exceed the recommended dose.

Method of use

- Swallow the tablet whole with half a glass of water.
- No information is available regarding crushing/halving/chewing.
- The tablet may be taken with or without food.
- The tablet can be taken at any time during the day, however, try to take the tablet at the same time each day. This will help you remember to take the medicine.

The doctor can also prescribe you other medicines in addition to Dapagliflozin Teva. Remember to also take the other medicine the doctor has prescribed. Taking your medicines regularly will help your health.

Diet and exercise

Diet and exercise can help your body balance your blood sugar level. If you have diabetes, it is important to adhere to any diet and exercise plan recommended by your doctor while taking Dapagliflozin Teva.

If you accidentally took a higher dosage of Dapagliflozin Teva

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

If you forgot to take Dapagliflozin Teva

If you forgot to take a tablet at the required time, check how much time is left until the next dose:

- If there are 12 hours or more left until the next dose, take the Dapagliflozin Teva dose shortly after you remember, and then take the next dose at the usual time.
- If there are less than 12 hours left until the next dose, do not take the forgotten dose. Take the next dose at the usual time.
- Do not take a double dose of Dapagliflozin Teva in order to compensate for a forgotten dose.

Follow the treatment as recommended by the doctor.

If you stop taking Dapagliflozin Teva

Do not stop treatment with Dapagliflozin Teva without consulting with the doctor. If you have diabetes, your blood sugar level may increase without the medicine.

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 Dapagliflozin 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.

Refer to the doctor or the nearest hospital immediately if you notice any of the following side effects:

- **Angioedema** – a very rare side effect (may affect up to 1 in 10,000 patients).
Signs of angioedema:
 - Swelling of the face, tongue or throat
 - Difficulty swallowing
 - Hives and breathing difficulties
- **Diabetic ketoacidosis** – occurs rarely in patients with type 2 diabetes (occurs in 1-10 users out of 10,000). These are the signs of diabetic ketoacidosis (see also section 2 "Special warnings regarding the use of the medicine"):
 - High levels of ketones in the urine or blood
 - Nausea or vomiting
 - Abdominal pain
 - Increased thirst
 - Rapid and deep breathing
 - Confusion
 - Uncharacteristic tiredness or drowsiness

- Sweet breath odor, metallic or sweet taste in the mouth or a different odor to your urine or sweat
- Rapid weight loss

This effect may occur regardless of sugar (glucose) levels in your blood. The doctor may decide to temporarily or permanently stop the treatment with Dapagliflozin Teva.

- **Infections in the genital area (Fournier's gangrene/necrotising fasciitis of the perineum)** – a serious infection in the soft tissues of the genitals or the area between the genitals and the anus, a very rare effect.

Stop treatment with Dapagliflozin Teva and refer to the doctor as soon as possible if you notice any of the following serious side effects:

- **Urinary tract infection** – a common effect (an effect that occurs in 1-10 users out of 100).
Signs of a severe urinary tract infection:
 - Fever and/or chills
 - Burning sensation during urination
 - Pain in the back or in the sides of the bodyEven though this is an uncommon effect, if you notice blood in the urine, please inform the doctor immediately.

Refer to the doctor as soon as possible if you notice any of the following side effects:

- **Low blood sugar level (hypoglycemia)** – a side effect that occurs very commonly (effects that occur in more than one user out of ten) in patients with diabetes taking Dapagliflozin Teva together with an additional medicine from the sulfonylurea group or with insulin. Signs of low blood sugar level:
 - Tremor, sweating, feeling very anxious, fast heartbeat
 - Hunger sensation, headache, changes in vision
 - A change in your mood or a sense of confusion

The doctor will instruct you on how to treat a drop in blood sugar level (hypoglycemia) and what to do if the signs above appear.

Other side effects while using Dapagliflozin Teva:

Side effects that occur commonly (effects that affect 1-10 users out of 100):

- Genital infection (fungal) in the vagina or penis (the signs may include irritation, itch, unusual discharge or unusual odor)
- Back pain
- Passing more urine than usual or needing to urinate more frequently
- Change in the level of cholesterol or lipids in the blood (seen in blood tests)
- An increase in the amount of red blood cells in the blood (seen in blood tests)
- A decrease in the levels of creatinine renal clearance in the beginning of the treatment (seen in blood tests)
- Dizziness
- Rash

Uncommon side effects (effects that occur in 1-10 users out of 1,000):

- Excessive loss of fluids from the body (dehydration, the signs may include: excessive dryness or stickiness in the mouth, passing little urine or not passing urine, fast heartbeat)
- Thirst
- Constipation
- Urinating at night
- Dry mouth
- Weight loss
- Elevation of creatinine in the beginning of treatment (seen in blood tests)
- Elevation of urea levels (seen in blood tests)

Very rare side effects (effects that occur in less than 1 user out of 10,000):

- Kidney infection (tubulointerstitial nephritis)

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 the 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 below 25°C.**

Do not discard medicines in wastewater or domestic trash. Ask your pharmacist how to discard medicines you no longer use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

In addition to the active ingredient the medicine also contains:

Microcrystalline cellulose, anhydrous lactose, crospovidone, colloidal silicon dioxide, sodium stearyl fumarate, sodium lauryl sulfate, purified water, opadry II 85F32782 yellow (polyvinyl alcohol-part. hydrolyzed, polyethylene glycol, macrogol, titanium dioxide, talc, iron oxide yellow).

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

Dapagliflozin Teva 5 mg

A yellow, round tablet. One side is debossed with "TV" and the other side is debossed with "5D".

Dapagliflozin Teva 10 mg

A yellow, oval tablet. One side is debossed with "TV" and the other side is debossed with "1D". The package contains 30 tablets in a blister pack.

Name and address of the manufacturer and license holder:

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

The leaflet was revised in September 2024.

Registration numbers of the medicine in the national drug registry of the Ministry of Health:

Dapagliflozin Teva 5 mg: 175-85-37397-99

Dapagliflozin Teva 10 mg: 175-84-37398-99

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