

**Patient Package Leaflet in Accordance With
the Pharmacists' Regulations (Preparations) – 1986**

The medicine is dispensed with a doctor's prescription only

Forxiga® 5 mg

Forxiga® 10 mg

Film coated tablets

Film coated tablets

Composition:

Each tablet contains:

Each tablet contains:

Dapagliflozin 5 mg

Dapagliflozin 10 mg

For inactive ingredients please see section 2: "Important information regarding some of the medicine ingredients" and Section 6: 'Further Information'.

Read this leaflet carefully in its entirety before using the medicine.

Keep this leaflet, you may need it again.

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.

1. WHAT IS THE MEDICINE INTENDED FOR?

Type 2 diabetes mellitus

Forxiga is used to treat type 2 diabetes mellitus in adults (aged 18 years and older), when the diabetes cannot be controlled with other medicines for diabetes, diet and exercise.

Your doctor may ask you to take Forxiga on its own, if you are intolerant to metformin, or together with other medicines including insulin.

During treatment with Forxiga, it is important to integrate diet and exercise according to the advice of your doctor/medical team.

Heart failure

Forxiga is used to treat symptomatic chronic heart failure in adults.

Chronic kidney disease

Forxiga is used to reduce the risk of sustained eGFR decline, end-stage kidney disease, cardiovascular death, and hospitalization for heart failure in adults with chronic kidney disease at risk of progression.

Limitations of Use

Forxiga is not recommended for the treatment of chronic kidney disease in patients with polycystic kidney disease or patients requiring or with a recent history of immunosuppressive therapy for kidney disease. Forxiga is not expected to be effective in these populations.

Therapeutic group

Selective, reversible and competitor inhibitor of the glucose transporter SGLT2 in the kidney, that inhibits the reabsorption of the glucose and cause significant excretion of glucose in the urine.

2. BEFORE USING THE MEDICINE

X Do not use Forxiga if:

- you are hypersensitive to the active ingredient dapagliflozin or any of the other ingredients of this medicine (see section 6 “Further Information” below).
- you are on dialysis.

I Special warnings regarding use of Forxiga

Refer to your doctor immediately if you develop a combination of the following symptoms: pain, tenderness, redness, or swelling of the genitals or the area between the genitals and the anus with fever or feeling generally unwell. These symptoms could be a sign of a rare but serious or even life-threatening infection, called necrotising fasciitis of the perineum or Fournier’s gangrene which destroys the tissue under the skin and must be treated immediately.

Before treatment with Forxiga, tell the doctor, the pharmacist or the nurse if:

- you have “type 1 diabetes” (the type of diabetes where your body does not produce any insulin). Forxiga should not be used in patients with type 1 diabetes mellitus.
- you are going to have surgery.
- you are eating less due to illness or surgery, or you are dieting.
- you drink alcohol very frequently or you drink large amounts of alcohol in a short time.
- If you have diabetes and you develop any of the following symptoms, which may be signs of ketoacidosis: nausea, vomiting, stomach-area (abdominal) pain, excessive thirst, unusual sleepiness or tiredness, trouble breathing, breathing difficulties, loss of appetite, rapid weight loss, confusion, acetone odor of breath, typical taste in the mouth and a different odor to your urine/sweat. If you have any of these signs, stop use of the medicine and immediately refer to your doctor or to the nearest hospital.

- you have increased levels of ketone bodies in your urine or blood, seen in tests. This is a sign of diabetic ketoacidosis – a rare and sometimes life-threatening problem you can get with diabetes. Ketoacidosis risk factors: prolonged fasting, sudden reductions in insulin dose or a higher need of insulin due to serious illness or surgery, dehydration, and excessive alcohol consumption.
- When you are treated with Forxiga, diabetic ketoacidosis can occur even if your blood sugar is normal.
- you have diabetes and a kidney problem – your doctor may ask you to take a different medicine or additional medicine to control your blood sugar level.
- you have a liver problem - your doctor may start you on a lower dose.
- you are on medicines to lower your blood pressure and have a history of low blood pressure. More information is given below under ‘If you are taking, or have recently taken other medicines [...]’.
- you have very high levels of glucose in your blood which may make you dehydrated (lose too much body fluid). Possible signs of dehydration are listed at the top of section 4, ‘Side Effects’. Tell your doctor before you start taking Forxiga if you have any of these signs.
- you have or develop nausea, vomiting or fever or if you are not able to eat or drink. These conditions can cause dehydration. Your doctor may ask you to stop taking Forxiga until you recover to prevent dehydration.
- if you often get infections of the urinary tract.

If any of the above applies to you or you are not sure, talk to your doctor, pharmacist or nurse before taking Forxiga.

Diabetes and foot care

If you have diabetes, it is important to check your feet regularly and adhere to any other advice regarding foot care given by your health care professional.

Urine glucose

Because of how Forxiga works, your urine will test positive for sugar (glucose) while you are on this medicine.

Children and adolescents

No information regarding the safety and efficacy of this medicinal product in children and adolescents is available.

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 inform the doctor or pharmacist if you are taking:

- a medicine used to remove water from the body (diuretic).
- other medicines that lower the amount of sugar in your blood such as insulin or a “sulphonylurea” medicine. Your doctor may want to lower the dose of these other medicines, to prevent you from getting low blood sugar levels (hypoglycemia).
- lithium because Forxiga can lower the amount of lithium in your blood.

Use of the medicine and food

You can take this medicine with or without food.

Pregnancy and breastfeeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to become pregnant, refer to your doctor before taking Forxiga.

You should stop taking this medicine if you become pregnant, since it is not recommended during the second and third trimesters of pregnancy. Talk to your doctor about the best way to treat and control your blood sugar level while you are pregnant.

Talk to your doctor if you would like to or are breast-feeding before taking this medicine.

Do not use Forxiga if you are breast-feeding. It is not known if this medicine passes into human breast milk.

Driving and operating machinery

Forxiga has no or negligible influence on the ability to drive and use machines. Taking this medicine with other medicines called sulphonylureas or with insulin might cause too low blood sugar levels (hypoglycemia), which may cause symptoms such as shaking, sweating and change in vision, and may affect your ability to drive and use machines. Do not drive or use any tools or machines, if you feel dizzy while taking Forxiga.

Important information regarding some of the medicine ingredients

Forxiga contains lactose

The tablets contain lactose which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine (Lactose content - see section 6 'Further information').

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 or manner of treatment with the medicine.
- The dosage and course of treatment will be determined only by the doctor.

The usual dosage

- The recommended dose is usually one 10 mg tablet each day.
- Your doctor may start you on a 5 mg dose if you have a liver problem.
- Your doctor will prescribe the strength that is right for you.

Do not exceed the recommended dosage.

Method of use

- Swallow the tablet whole with half a glass of water.
- There is no data regarding crushing, halving or chewing the tablet.

- You can take your tablet with or without food.
- You can take the tablet at any time of the day. However, try to take it at the same time each day. This will help you to remember to take it.

Your doctor may prescribe Forxiga together with other medicines. Remember to take these other medicines as your doctor has told you. This will help get the best results for your health.

Diet and exercise

Diet and exercise can help your body to balance its blood sugar better. If you have diabetes, it is important to stay on any diet and exercise program recommended by your doctor while taking Forxiga.

If you accidentally take a higher dose of Forxiga

If you take more Forxiga tablets than you should, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and take the medicine pack with you.

If you forget to take Forxiga

If you forgot to take the medicine at the scheduled time, it depends on how long it is until your next dose.

- If it is 12 hours or more until your next dose, take a dose of Forxiga as soon as you remember. Then take your next dose at the usual time.
- If it is less than 12 hours until your next dose, skip the missed dose. Then take your next dose at the usual time.
- Do not take a double dose of Forxiga to make up for a forgotten dose.

Take Forxiga as recommended by your doctor.

If you stop taking Forxiga

Do not stop taking Forxiga without talking to your doctor first. If you have diabetes, your blood sugar level may increase without this medicine.

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

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Forxiga may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not suffer from any of them.

Contact a doctor or the nearest hospital straight away if you have any of the following side effects:

- **angioedema**, very rare side effect (may affect up to 1 in 10,000 patients).
signs of angioedema:
 - swelling of the face, tongue or throat
 - difficulties swallowing
 - hives and breathing problems

- **Diabetic ketoacidosis in people with diabetes mellitus**, rare side effect (may affect up to 1 in 1,000 patients). These are the signs of diabetic ketoacidosis (see also section 2 “Special warnings regarding use of Forxiga”):
 - increased levels of “ketone bodies” in your urine or blood
 - rapid weight loss
 - feeling sick or being sick
 - stomach pain
 - excessive thirst
 - fast and deep breathing
 - confusion
 - unusual sleepiness or tiredness
 - a sweet smell to your breath, a sweet or metallic taste in your mouth or a different odor to your urine or sweat.

This may occur regardless of blood sugar (glucose) level. Your doctor may decide to temporarily or permanently stop your treatment with Forxiga.

- Infections of the genitals area (Fournier's gangrene/necrotising fasciitis of the perineum), a serious soft tissue infection of the genitals or the area between the genitals and the anus, seen very rarely.

Stop taking Forxiga and see a doctor as soon as possible if you notice any of the following serious side effects:

- **Urinary tract infection**, common side effect (may affect up to 1 in 10 patients). signs of a severe infection of the urinary tract:
 - fever and/or chills
 - burning sensation when urinating
 - pain in your back or side.

Although uncommon, if you see blood in your urine, tell your doctor immediately.

Contact your doctor as soon as possible if you have any of the following side effects:

- Very common side effects (may affect more than 1 in 10 patients): low blood sugar levels (hypoglycemia) - when taking this medicine with another drug from the sulphonylurea group or insulin, signs of low blood sugar level:
 - shaking, sweating, feeling very anxious, fast heart beat
 - feeling hungry, headache, change in vision
 - a change in your mood or feeling confused.

Your doctor will tell you how to treat low blood sugar levels (hypoglycemia) and what to do if you get any of the signs above.

Other side effects when taking Forxiga:

Common side effects (affects up to 1 in 10 patients):

- genital infection (thrush) of the penis or vagina (signs may include irritation, itching, unusual discharge or odor)
- back pain
- passing more urine than usual or needing to pass urine more often
- changes in the amount of cholesterol or fats in your blood (shown in tests)
- increase in the amount of red blood cells in your blood (shown in tests)
- decrease in creatinine renal clearance (shown in tests) in the beginning of treatment
- dizziness
- rash

Uncommon side effects (affects up to 1 in 100 patients):

- loss of too much fluid from your body (dehydration, signs may include: very dry or sticky mouth, passing little or no urine, fast heart beat).
- thirst
- constipation
- awakening from sleep at night to pass urine
- dry mouth
- weight decreased
- increases in creatinine (shown in laboratory blood tests) in the beginning of treatment
- increases in urea (shown in laboratory blood tests)

Very rare side effects (affects less than 1 in 10,000 patients):

- inflammation of the kidneys (tubulointerstitial nephritis)

If a side effect appears, if any of the side effects worsens or if you suffer from any 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 of Drug Treatment” found on the Ministry of Health homepage

(www.health.gov.it) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.it/>

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid Poisoning! This medicine, and any other medicine, should 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 unless explicitly instructed to do so by 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 30°C.

6. FURTHER INFORMATION

- In addition to the active ingredient, the medicine also contains:

Tablet:

microcrystalline cellulose (E460i), anhydrous lactose*, crospovidone (E1202), silicon dioxide (E551), magnesium stearate (E470b).

Film-coating:

polyvinyl alcohol (E1203), titanium dioxide (E171), macrogol 3350 (E1521), talc (E553b), yellow iron oxide (E172).

*Lactose content:

Forxiga 5 mg – each tablet contains 25 mg lactose

Forxiga 10 mg – each tablet contains 50 mg lactose

- What does the medicine look like and the content of the pack?

Forxiga 5 mg tablets - yellow and round with a diameter of 0.7 cm. On one side stamping of "5", and stamping of "1427" on the other side.

Forxiga 10 mg tablets - yellow and diamond-shaped, approximately 1.1 x 0.8 cm diagonally. On one side stamping of "10", and stamping of "1428" on the other side.

Forxiga 5 mg and Forxiga 10 mg are available in aluminium packs with possible pack sizes of 14, 28, 30, 90 or 98 tablets (not all pack sizes may be marketed).

Manufacturer:

AstraZeneca AB, Sodertalje, Sweden.

License holder:

AstraZeneca (Israel) Ltd.,

1 Atirei Yeda St., Kfar Saba 4464301.

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

Forxiga 5 mg: 152-57-34012-00

Forxiga 10 mg: 152-58-34013-00

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