

## **Package leaflet: Information for the patient**

### **Forxiga 5 mg film-coated tablets Forxiga 10 mg film-coated tablets dapagliflozin**

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet:**

1. What Forxiga is and what it is used for
2. What you need to know before you take Forxiga
3. How to take Forxiga
4. Possible side effects
5. How to store Forxiga
6. Contents of the pack and other information

#### **1. What Forxiga is and what it is used for**

Forxiga contains the active substance dapagliflozin. It belongs to a group of medicines called “oral anti-diabetics”.

- These are medicines taken by mouth for diabetes.
- They work by lowering the amount of sugar (glucose) in your blood.

Forxiga is used for a type of diabetes called “type 2 diabetes mellitus” in adult patients (aged 18 years and older). “Type 2 diabetes mellitus” is the type of diabetes that usually starts when you are older. If you have type 2 diabetes, your pancreas does not make enough insulin or your body is not able to use the insulin it produces properly. This leads to a high level of sugar in your blood. Forxiga works by removing excess sugar from your body via your urine.

- Forxiga is used if your 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 to treat diabetes. This may be another medicine taken by mouth and/or insulin given by injection.

It is important to continue to follow the advice on diet and exercise given to you by your doctor, pharmacist or nurse.

## **2. What you need to know before you take Forxiga**

### **Do not take Forxiga:**

- if you are allergic to dapagliflozin or any of the other ingredients of this medicine (listed in section 6).

### **Warnings and precautions**

Talk to your doctor, pharmacist or nurse before taking Forxiga, and during treatment:

- if you have “type 1 diabetes” – the type that usually starts when you are young, and your body does not produce any insulin.
- if you experience 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 odour to your urine or sweat, contact a doctor or the nearest hospital straight away. These symptoms could be a sign of “diabetic ketoacidosis” – a problem you can get with diabetes because of increased levels of “ketone bodies” in your urine or blood, seen in tests. The risk of developing diabetic ketoacidosis may be increased with prolonged fasting, excessive alcohol consumption, dehydration, sudden reductions in insulin dose, or a higher need of insulin due to major surgery or serious illness.
- if you have a kidney problem – your doctor may ask you to take a different medicine.
- if you have a liver problem – your doctor may start you on a lower dose.
- if you have a history of serious heart disease or if you have had a stroke.
- if you are on medicines to lower your blood pressure (anti-hypertensives) and have a history of low blood pressure (hypotension). More information is given below in **Other medicines and Forxiga**.
- if 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, ‘Possible side effects’. Tell your doctor before you start taking Forxiga if you have any of these signs.
- if you have or develop nausea (feeling sick), 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 you are 75 years old or older, you should not start taking Forxiga.
- if you are taking another medicine for diabetes that contains “pioglitazone”, you should not start taking Forxiga.
- if you have an increase in the amount of red blood cells in your blood, seen in tests.

Like for all diabetic patients it is important to check your feet regularly and adhere to any other advice regarding foot care given by your health care professional.

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

### **Kidney function**

Your kidneys should be checked before you start taking and whilst you are on this medicine.

### **Urine glucose**

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

### **Children and adolescents**

Forxiga is not recommended for children and adolescents under 18 years of age, because it has not been studied in these patients.

### **Other medicines and Forxiga**

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines.

Especially tell your doctor:

- if you are taking a medicine used to remove water from the body (diuretic). Your doctor may ask you to stop taking Forxiga. Possible signs of losing too much fluid from your body are listed at the top of section 4 'Possible side effects'.
- if you are taking 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 (hypo-glycaemia).

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. 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 control your blood sugar 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 using machines**

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 can cause too low blood sugar levels (hypo-glycaemia), 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 taking Forxiga.

### **Forxiga contains lactose**

Forxiga contains lactose (milk sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

## **3. How to take Forxiga**

Always take this medicine exactly as your doctor has told you. Check with your doctor, pharmacist or nurse if you are not sure.

### **How much to take**

- The recommended dose is 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.

### **Taking this medicine**

- Swallow the tablet whole with half a glass of water.
- 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 medicine(s) to lower the amount of sugar in your blood. These may be medicine(s) by mouth or insulin given by injection. Remember to take these other medicine(s) as your doctor has told you. This will help get the best results for your health.

**Diet and exercise**

To control your diabetes, you still need to keep to diet and exercise, even when you are taking this medicine. So it is important to keep following the advice about diet and exercise from your doctor, pharmacist or nurse. In particular, if you are following a diabetic weight control diet, continue to follow it while you are taking Forxiga.

**If you take more Forxiga than you should**

If you take more Forxiga tablets than you should, talk to a doctor or go to a hospital immediately. Take the medicine pack with you.

**If you forget to take Forxiga**

What to do if you forget to take a tablet 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.

**If you stop taking Forxiga**

Do not stop taking Forxiga without talking to your doctor first. Your blood sugar may increase without this medicine.

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

**4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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

- loss of too much fluid from your body (dehydration), seen uncommonly.

These are signs of dehydration:

- very dry or sticky mouth, feeling very thirsty
- feeling very sleepy or tired
- passing little or no water (urine)
- fast heart beat.

- urinary tract infection, seen commonly.

These are signs of a severe infection of the urinary tract:

- fever and/or chills
- burning sensation when passing water (urinating)
- pain in your back or side.

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

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

- diabetic ketoacidosis, seen rarely (may affect up to 1 in 1,000 people)

These are the signs of diabetic ketoacidosis (see also section 2 Warnings and precautions):

- 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 odour to your urine or sweat.

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

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

Very common (may affect more than 1 in 10 people)

- low blood sugar levels (hypo-glycaemia) - when taking this medicine with a sulphonylurea or insulin

These are the signs of low blood sugar:

- 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 and what to do if you get any of the signs above.

**Other side effects when taking Forxiga:**

Common (may affect up to 1 in 10 people)

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

Uncommon (may affect up to 1 in 100 people)

- thirst
- constipation
- awakening from sleep at night to pass urine
- dry mouth
- weight decreased
- changes in laboratory blood tests (for example creatinine or urea)
- decrease in kidney function

**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

**United Kingdom**

Yellow Card Scheme

Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

**Ireland**

HPRA Pharmacovigilance  
Earlsfort Terrace  
IRL - Dublin 2  
Tel: +353 1 6764971  
Fax: +353 1 6762517  
Website: [www.hpra.ie](http://www.hpra.ie)  
e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

## **Malta**

ADR Reporting

Website: [www.medicinesauthority.gov.mt/adrportal](http://www.medicinesauthority.gov.mt/adrportal)

### **5. How to store Forxiga**

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date, which is stated on the blister or carton after 'EXP'. The expiry date refers to the last day of that month.
- This medicine does not require any special storage conditions.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

### **6. Contents of the pack and other information**

#### **What Forxiga contains**

- The active substance is dapagliflozin.  
Each Forxiga 5 mg film-coated tablet (tablet) contains dapagliflozin propanediol monohydrate equivalent to 5 mg dapagliflozin.  
Each Forxiga 10 mg film-coated tablet (tablet) contains dapagliflozin propanediol monohydrate equivalent to 10 mg dapagliflozin.
- The other ingredients are:
  - tablet core: microcrystalline cellulose (E460i), anhydrous lactose (see section 2 'Forxiga contains lactose'), crospovidone (E1202), silicon dioxide (E551), magnesium stearate (E470b).
  - film-coating: polyvinyl alcohol (E1203), titanium dioxide (E171), macrogol 3350, talc (E553b), yellow iron oxide (E172).

#### **What Forxiga looks like and contents of the pack**

- Forxiga 5 mg film-coated tablets are yellow and round with diameter of 0.7 cm. They have "5" on one side and "1427" on the other side.
- Forxiga 10 mg film-coated tablets are yellow and diamond-shaped approximately 1.1 x 0.8 cm diagonally. They have "10" on one side and "1428" on the other side.

Forxiga 5 mg tablets and Forxiga 10 mg tablets are available in aluminium blisters in pack sizes of 14, 28 or 98 film-coated tablets in non-perforated calendar blisters and 30x1 or 90x1 film-coated tablets in perforated unit dose blisters.

Not all pack sizes may be marketed in your country.

#### **Marketing Authorisation Holder**

AstraZeneca AB  
SE-151 85 Södertälje  
Sweden

**Manufacturer**

AstraZeneca UK Limited  
Silk Road Business Park  
Macclesfield  
SK10 2NA  
United Kingdom

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

**United Kingdom**

AstraZeneca UK Ltd  
Tel: +44 1582 836 836

**Ireland**

AstraZeneca Pharmaceuticals (Ireland) Ltd  
Tel: +353 1609 7100

**Malta**

Associated Drug Co. Ltd  
Tel: + 356 2277 8000

**This leaflet was last revised in 04/2017**

**Other sources of information**

Detailed information on this medicine is available on the European Medicines Agency web site:  
<http://www.ema.europa.eu>

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