PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

FORXIGA 5 film-coated tablets

FORXIGA 10 film-coated tablets

Dapagliflozin

Contains sugar:

25 mg lactose anhydrous per 5 mg tablet

50 mg lactose anhydrous per 10 mg tablet

DO NOT TAKE FORXIGA IF YOU HAVE TYPE 1 DIABETES MELLITUS.

FORXIGA MUST NOT BE USED FOR THE TREATMENT OF ANY OTHER CONDITIONS EXCEPT FOR THE TREATMENT OF TYPE 2 DIABETES MELLITUS, HEART FAILURE AND CHRONIC KIDNEY DISEASE.

There have been reports of metabolic acidosis, including ketoacidosis, in patients taking FORXIGA.

Metabolic acidosis is an imbalance of acids in your blood, shown on blood tests. It is a serious and sometimes fatal condition that requires hospitalisation. Risk factors for metabolic acidosis include sudden decrease of your insulin dose, prolonged fasting from food and drink, or increasing your insulin dose due to major surgery or serious illness, or alcohol abuse. Caution is advised when using FORXIGA if you have these conditions. Diabetic ketoacidosis is a type of metabolic acidosis. Diabetic ketoacidosis is an increase of ketone bodies in your blood or urine, shown on blood or urine tests. Risk factors for

diabetic ketoacidosis include pancreatic conditions, such as inflammation of the pancreas or previous pancreatic surgery. Do not take FORXIGA if you have these conditions.

Metabolic acidosis, including diabetic ketoacidosis, may occur in patients with type 2 diabetes mellitus with normal (blood glucose test result below 14 mmol/L) or high blood sugar levels who are treated with FORXIGA.
Contact a doctor or the nearest hospital immediately if you have the following symptoms even if your blood sugar levels are normal: nausea, vomiting, abdominal pain, fatigue, thirst, passing of large volumes of urine, shortness of breath and confusion. These symptoms could be a sign of metabolic or diabetic ketoacidosis.

Read all of this leaflet carefully before you start taking FORXIGA.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse, or other health care provider
- FORXIGA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

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 "sodium glucose co-transporter-2 (SGLT2) inhibitors". They work by blocking the SGLT2 protein in your kidney. By blocking this protein, blood sugar (glucose), salt (sodium) and water are removed from your body via the urine.

- FORXIGA is used if your type 2 diabetes cannot be controlled with diet and exercise. Your doctor may ask you to take FORXIGA alone or with another diabetes medicine. It is important to keep following the advice about diet and exercise given to you by your doctor, nurse or pharmacist.
- FORXIGA is used for prevention and treatment of heart failure (when your heart does not pump enough blood that your body needs).
- FORXIGA is also used in patients with chronic kidney disease (reduced kidney function).

2. What you need to know before you take FORXIGA

Do not take FORXIGA:

- if you are allergic (hypersensitive) to dapagliflozin or any of the other ingredients of FORXIGA (listed in section 6). If you are not sure, talk to your doctor or pharmacist before taking **FORXIGA**.
- 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 are pregnant or plan to become pregnant. Talk with your doctor about the best way to control your blood sugar while you are pregnant.
- if you are breastfeeding. Talk to your doctor if you would like to breastfeed.
- if you have a history of inflammation of your pancreas or pancreatic surgery.

Warnings and precautions

Take special care with FORXIGA:

- if you are going to have surgery.
- if you are eating less due to illness or surgery, or you are dieting.
- if you have or have had problems with your pancreas.
- if you drink large amounts of alcohol, either every day or only from time to time.
- if you develop any of the following symptoms, which may be signs of ketoacidosis: nausea, vomiting, stomach-area (abdominal) pain, tiredness, difficulty breathing, increased levels of "ketone bodies" in your urine or blood. If this happens to you, contact a doctor or the nearest hospital immediately.
- if you have a mild kidney disease, your doctor will want to monitor your kidney function on an ongoing basis.
- if you often get infections of your urinary tract.
- if you are allergic to any other medicine used to lower the amount of sugar in your blood.

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

Children and adolescents

FORXIGA is not recommended for children and young people under 18 years.

Other medicines and FORXIGA

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor if:

- you are taking ketoconazole (medicine for fungal infections).
- you are taking a water pill (diuretic) – you may be more likely to lose fluid from your body (get

dehydrated). Your doctor may change your dose. Possible signs of losing too much fluid from your body are listed in section 4.

- you are taking other medicines that lower the amount of sugar in your blood – such as insulin or a “sulfonylurea” medicine. Your doctor may want to lower your dose of these other medicines, to stop you from getting low blood sugar (hypoglycaemia).
- you are taking lithium (medicine to treat mood disorders) because FORXIGA can lower the amount of lithium in your blood.

Pregnancy and breastfeeding

You should not take FORXIGA if you are pregnant or breastfeeding your baby. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking FORXIGA.

Driving and using machines

Taking FORXIGA with other medicines or insulin used to treat your diabetes can cause too low blood sugar levels (hypoglycaemia), 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. It is not always possible to predict to what extent FORXIGA may interfere with the daily activities of a patient.

You should ensure that you do not engage in the above activities until you are aware of the measure to which FORXIGA affects you.

FORXIGA contains lactose

If you have been told by your doctor that you have been an intolerance to some sugars, contact your doctor before taking FORXIGA.

3. How to take FORXIGA

Do not share medicines prescribed for you with any other person.

Always take FORXIGA exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How much to take

- The usual dose is one 10 mg tablet each day.
- Your doctor will prescribe the strength that is right for you.
- Your doctor will tell you how long your treatment with FORXIGA will last.
- Do not stop treatment early.
- If you have the impression that the effect of FORXIGA is too strong or too weak for you, tell your doctor or pharmacist.

Taking FORXIGA

- Swallow the tablet whole with some 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 medicines to lower the amount of sugar in your blood.

Diet and exercise

To control your diabetes, you still need to diet and exercise, even when you are taking FORXIGA. So, it is important to keep following the advice about diet and exercise from your health care

provider. In particular, if you are following a diabetic weight control diet, keep on with this while you are taking FORXIGA.

If you take more FORXIGA than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take FORXIGA

Take your missed dose as soon as you remember, if within a few hours after missing a dose. However, if it is nearly time for your next dose, skip the missed dose. Then take your next dose at the usual time.

Do not take a double dose to make up for forgotten individual doses.

If you stop taking FORXIGA

Do not stop taking FORXIGA without talking to your doctor first. If you have the impression that the effect of FORXIGA is too strong or too weak, talk to your doctor or pharmacist.

4. Possible side effects

Diabetic ketoacidosis (diabetic coma) and similar side effects may occur. Symptoms are nausea, vomiting, abdominal pain, fatigue, thirst, passing of large volumes of urine, shortness of breath and mental confusion. Urgent medical attention is required.

FORXIGA can have side effects.

Not all side effects reported for FORXIGA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking FORXIGA, please consult your

health care provider for advice.

If any of the following happens, stop taking FORXIGA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty 36in swallowing or breathing
- rash or itching
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to FORXIGA. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

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

These are signs of losing too much fluid from your body (volume depletion or dehydration).

- fever or chills
- burning sensation when passing water (urinating)
- pain in your back or side
- blood in your urine, although uncommon

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

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- low blood sugar levels (hypoglycaemia) - when taking FORXIGA with other medicine or insulin to treat your diabetes. These are signs of low blood sugar (hypoglycaemia):
  - shaking, sweating, feeling very anxious, fast heartbeat
  - 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 and what to do if you get any of the signs above.

- yeast infection (thrush) of your penis or vagina
- back pain
- passing more water (urine) than usual or needing to pass water more often
- high sugar levels (glucose) in urine (shown in tests)
- 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)
- infection of your bladder
- rash.

Less frequent side effects:

- awakening from sleep at night to pass urine
- change in amount of urea in blood (shown in tests)
- increase thirst and dry feeling of your mouth
- constipation
- itching of the genitals
- increase sweating
- tight foreskin which may cause difficulty urinating or inflammation of glans or foreskin

(phimosis).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of FORXIGA.

5. How to store FORXIGA

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 30 °C. Store in the original package.

Do not use FORXIGA after the expiry date stated on the container.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What FORXIGA contains:

- The active substance is dapagliflozin propanediol.
- The other ingredients are:

Tablet core: crospovidone, lactose anhydrous, magnesium stearate, microcrystalline cellulose, silicon dioxide.

Film-coating: polyvinyl alcohol, polyethylene glycol, talc, titanium dioxide, yellow iron oxide.

What FORXIGA looks like and contents of the pack

FORXIGA 5:

Yellow, biconvex, 0,7 cm diameter round, film-coated tablet with "5" debossed on one side and "1427" debossed on the other side.

FORXIGA 10:

Yellow, biconvex, approximately 1,1 x 0,8 cm diamond shaped, film-coated tablet with "10" debossed on one side and "1428" debossed on the other side.

Silver aluminium/aluminium foil blister packs of 14, 28, 30, 90 and 98 tablets packed in a carton.

Holder of certificate of registration:

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