

PART III: CONSUMER INFORMATION

Pr **FORXIGA**®

dapagliflozin tablets

(as dapagliflozin propanediol monohydrate)

Read this carefully before you start taking FORXIGA and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about FORXIGA.

ABOUT THIS MEDICATION

WHAT THE MEDICATION IS USED FOR:

FORXIGA is used along with diet and exercise to improve blood sugar levels in adults with type 2 diabetes. FORXIGA can be used:

- alone, if you cannot take metformin,
- with metformin,
- with a sulfonylurea,
- with metformin and a sulfonylurea,
- with sitagliptin (with or without metformin),
- with insulin (with or without metformin).

WHAT IT DOES:

FORXIGA removes excess sugar from the body through the urine.

WHEN IT SHOULD NOT BE USED:

Do not take FORXIGA if you:

- are allergic to dapagliflozin or any of the nonmedicinal ingredients listed below.
- have type 1 diabetes (a disease in which your body does not produce any insulin).
- have diabetic ketoacidosis (DKA, a complication of diabetes) or a history of DKA.
- have severe kidney problems or you are on dialysis.
- have severe liver disease.
- have bladder cancer.
- take pioglitazone, a drug to reduce the amount of sugar in the blood.
- are pregnant or planning to become pregnant; it is not known if FORXIGA will harm your unborn baby. Talk with your doctor about the best way to control your blood sugar while you are pregnant.
- are breast-feeding or plan to breast-feed; it is not known if FORXIGA will pass into your breast milk. Talk to your doctor if you would like to breast-feed.

WHAT THE MEDICINAL INGREDIENT IS:

Dapagliflozin (as dapagliflozin propanediol monohydrate).

WHAT THE NONMEDICINAL INGREDIENTS ARE:

Anhydrous lactose, crospovidone, magnesium stearate, microcrystalline cellulose, silicon dioxide. In addition, the film coating contains the following inactive ingredients: polyethylene glycol, polyvinyl alcohol, talc, titanium dioxide and yellow iron oxide.

WHAT DOSAGE FORMS IT COMES IN:

Tablets 5 mg and 10 mg.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

- Diabetic ketoacidosis (DKA), is a serious and life-threatening condition that requires urgent hospitalization. DKA has been reported in patients with type 2 diabetes mellitus (T2DM) with normal or high blood sugar levels who are treated with FORXIGA and other sodium-glucose co-transporter 2 (SGLT2) inhibitors. Some cases of DKA have led to death.
- Seek medical attention right away and **stop taking FORXIGA immediately** if you have any of the following symptoms (even if your blood sugar levels are normal): difficulty breathing, nausea, vomiting, stomach pain, loss of appetite, confusion, feeling very thirsty, feeling unusually tired, a sweet smell to the breath, a sweet or metallic taste in the mouth, or a different odour to urine or sweat.

Do not use FORXIGA if you have:

- DKA or a history of DKA
- type 1 diabetes.

BEFORE you use FORXIGA talk to your doctor or pharmacist if you:

- have type 1 diabetes (your body does not produce any insulin). FORXIGA should not be used in patients with type 1 diabetes.
- have an increased chance of developing DKA, including if you:
 - are dehydrated or suffer from excessive vomiting, diarrhea, or sweating;
 - are on a very low carbohydrate diet;
 - drink a lot of alcohol;
 - have/have had problems with your pancreas, including pancreatitis or surgery on your pancreas;
 - are hospitalized for major surgery, serious infection or serious medical illness;
 - have a history of diabetic ketoacidosis (DKA).
- are older than 65 years of age
- have or have had any kidney problems
- have or have had any cases of liver disease
- have heart disease or low blood pressure

- are taking a medicine for high blood pressure or taking a water pill (used to remove excess water from the body)
- are taking medicines to lower your blood sugar such as glyburide, gliclazide or glimepiride (sulfonylureas) or insulin. Taking FORXIGA with any of these medicines can increase the risk of having low blood sugar (hypoglycemia)
- have a history of bladder cancer
- have intolerance to some milk sugars. FORXIGA tablets contain lactose
- often get urinary tract infections

FORXIGA is not recommended for use in patients under 18 years of age.

FORXIGA will cause your urine to test positive for sugar (glucose).

FORXIGA may cause changes in the amount of cholesterol or fats in your blood.

FORXIGA increases the chance of getting a yeast infection of the penis or vagina. This is more likely in people who have had yeast infections in the past.

FORXIGA may cause abnormal kidney function. Your doctor will do blood tests to monitor how well your kidneys are working while you are taking FORXIGA.

Driving and using machines: FORXIGA may cause dizziness or lightheadedness. Do not drive or use machines until you know how the medicine affects you.

INTERACTIONS WITH THIS MEDICATION

Talk to your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Drugs that may interact with FORXIGA include:

- medicines you take for diabetes, especially sulfonylurea medications or insulin. Low blood sugar (hypoglycemia) may occur if you already take another medication to treat diabetes. Discuss with doctor how much of each medicine to take.

PROPER USE OF THIS MEDICATION

Follow the directions given to you by your doctor.

Take FORXIGA:

- once a day
- at any time of the day
- by mouth
- with or without food

Swallow whole. Do not cut or divide tablets.

USUAL ADULT DOSE:

Recommended adult starting dose: one 5 mg tablet a day. Your doctor may increase your dose to one 10 mg tablet, if needed to further control your blood sugar level.

OVERDOSE:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

MISSED DOSE: If you miss a dose of FORXIGA, take it as soon as you remember. If you do not remember until it is almost time for your next dose, skip the missed dose and go back to your regular schedule. Do not take a double dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

These are not all the possible side effects you may feel when taking FORXIGA. If you experience any side effects not listed here, contact your healthcare professional. Please also see Warnings and Precautions.

Side effects may include:

- sore throat
- influenza
- constipation
- diarrhea
- nausea
- back pain
- pain in the arms, legs, hands or feet
- headache
- rash

If any of these affects you severely, tell your doctor or pharmacist.

FORXIGA can cause abnormal blood test results. Your doctor will decide when to perform blood tests. They may check kidney function, blood fat levels (Low Density Lipoprotein cholesterol or LDL-C) and amount of red blood cells in your blood (hematocrit).

Diabetic Ketoacidosis (DKA) is a serious medical condition normally seen at high blood sugar levels; however, it has also been seen at near normal blood sugar levels. Get medical help right away if you have any of the symptoms in the table below under DKA, even if your blood sugar levels are normal.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Frequency / Symptom / effect		Talk with your doctor or pharmacist		Get immediate medical help
		Only if severe	In all cases	
Common	Urinary tract infection: pain, difficulty or increased need to urinate		X	
	Yeast infection of vagina: severe itching, burning, soreness, irritation, and a whitish or whitish-gray cottage cheese-like discharge	X		
	Yeast infection of penis: red, swollen, itchy, head of penis; thick, lumpy discharge under foreskin; unpleasant odour; difficulty retracting foreskin; pain passing urine or during sex	X		
Uncommon	Volume depletion (loss of needed fluids from the body; dehydration): dry or sticky mouth, headache, dizziness or urinating less often than normal		X	
	Low blood pressure: dizziness, fainting, lightheadedness; may occur when you go from lying to sitting to standing up		X	

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Frequency / Symptom / effect		Talk with your doctor or pharmacist		Get immediate medical help
		Only if severe	In all cases	
Uncommon	Low blood sugar (hypoglycemia): shaking, sweating, rapid heartbeat, change in vision, hunger, headache and change in mood		X	
Rare	Diabetic ketoacidosis (DKA): difficulty breathing, nausea, vomiting, stomach pain, loss of appetite, confusion, feeling very thirsty, feeling unusual tiredness, a sweet smell to the breath, a sweet or metallic taste in the mouth, or a different odour to urine or sweat			X
	Kidney problems: any change in the amount, frequency or colour (pale or dark) of urine		X	
Very rare	Acute kidney infection: painful, urgent or frequent urination, lower back (flank) pain, fever or chills, cloudy or foul smelling urine, blood in your urine			X

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Frequency / Symptom / effect		Talk with your doctor or pharmacist		Get immediate medical help
		Only if severe	In all cases	
Very rare	Severe infection that spreads from urinary tract throughout body (sepsis): fever or low body temperature, chills, rapid breathing, rapid heartbeat, pain with urination, difficulty urinating, frequent urination			X
Very rare	Inflammation of the pancreas (pancreatitis): severe stomach pain that lasts and gets worse when you lie down, nausea, vomiting		X	

This is not a complete list of side effects. For any unexpected effects while taking FORXIGA, contact your doctor or pharmacist.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Call toll-free at 1-866-234-2345

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

HOW TO STORE IT

Store at room temperature (15-30 °C).

Keep FORXIGA well out of reach of children.

MORE INFORMATION

NOTE: This INFORMATION FOR THE CONSUMER leaflet provides you with the most current information at the time of printing.

The most current information, the Consumer Information Leaflet plus the full Product Monograph, prepared for health professionals can be found at: <http://www.astrazeneca.ca> or by contacting the sponsor, AstraZeneca Canada Inc. at: Customer Inquiries 1-800-668-6000, Renseignements 1-800-461-3787.

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