

Give your kidneys the attention they deserve—talk to your doctor

With type 2 diabetes, one of the most important ways you can help take care of your kidneys is by **communicating with your doctor**. If you need a little help with topics to talk about, **look at the questions on the next page and bring this guide with you to your next appointment**. Check off the most relevant topics, add questions of your own, and be sure to take notes!

WHAT IS INVOKANA®?

- INVOKANA® (canagliflozin) is a prescription medicine used:
 - o along with diet and exercise to lower blood sugar (glucose) in adults with type 2 diabetes
 - to reduce the risk of major cardiovascular events such as heart attack, stroke, or death in adults with type 2 diabetes who have known cardiovascular disease
 - to reduce the risk of end-stage kidney disease (ESKD), worsening of kidney function, cardiovascular death, and hospitalization for heart failure in adults with type 2 diabetes mellitus and diabetic kidney disease (nephropathy) with a certain amount of protein in the urine
- INVOKANA® is not for people with type 1 diabetes. It may increase their risk of diabetic ketoacidosis (increased ketones in blood or urine).
- INVOKANA® is not used to lower blood sugar (glucose) in adults with type 2 diabetes with severe kidney problems.
- It is not known if INVOKANA® is safe and effective in children under 18 years of age.

IMPORTANT SAFETY INFORMATION

INVOKANA® can cause important side effects, including:

• Amputations. INVOKANA® may increase your risk of lower-limb amputations. Amputations mainly involve removal of the toe or part of the foot; however, amputations involving the leg, below and above the knee, have also occurred. Some people had more than one amputation, some on both sides of the body. You may be at a higher risk of lower-limb amputation if you: have a history of amputation, have heart disease or are at risk for heart disease, have had blocked or narrowed blood vessels (usually

Please read additional Important Safety Information on following pages and read full <u>Product Information</u> and <u>Medication Guide</u> for INVOKANA®.



How can having type 2 diabetes impact my kidneys?
How do I know if I have, or am at risk of having, diabetic kidney disease? How common is it in people with type 2 diabetes?
What is an eGFR number? What does it suggest about my health?
How often is kidney function typically screened?
Should I see a specialist for my kidneys (eg, nephrologist) if I have type 2 diabetes? If so, when?
How can INVOKANA® help people with diabetic kidney disease and type 2 diabetes?
How is INVOKANA® different from other types of medications I am taking / have tried for my type 2 diabetes?
How does INVOKANA® work?
What are the side effects of INVOKANA®?
What are some lifestyle changes to consider to help manage type 2 diabetes and my kidney health?

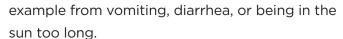
IMPORTANT SAFETY INFORMATION (CONT'D)

in leg), have damage to the nerves (neuropathy) in the leg, or have had diabetic foot ulcers or sores. Call your doctor right away if you have new pain or tenderness, any sores, ulcers, or infections in your leg or foot. Your doctor may decide to stop your INVOKANA® for a while if you have any of these signs or symptoms. Talk to your doctor about proper foot care.

 Dehydration. INVOKANA® can cause some people to become dehydrated (the loss of too much body water), which may cause you to feel dizzy, faint, lightheaded, or weak, especially when you stand up (orthostatic hypotension). There have function in people with type 2 diabetes who are taking INVOKANA. You may be at higher risk of dehydration if you take medicines to lower your blood pressure (including diuretics [water pills]), are on a low sodium (salt) diet, have kidney problems, or are 65 years of age or older. Talk to your doctor about what you can do to prevent dehydration including how much fluid you should drink on a daily basis. Call your healthcare provider right away if you reduce the amount of food or liquid you drink, for example if you cannot eat or you start to lose liquids from your body, for

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IMPORTANT SAFETY INFORMATION (CONT'D)



- Ketoacidosis (increased ketones in your blood or urine). Ketoacidosis has happened in people who have type 1 or type 2 diabetes, during treatment with INVOKANA®. Ketoacidosis has also happened in people with diabetes who were sick or who had surgery during treatment with INVOKANA®. Ketoacidosis is a serious condition. which may need to be treated in a hospital. Ketoacidosis may lead to death. **Ketoacidosis** can happen with INVOKANA® even if your blood sugar is less than 250 mg/dL. Stop taking INVOKANA® and call your doctor right away if you get any of the following symptoms: nausea, vomiting, stomach-area pain, tiredness, or trouble breathing. If you get any of these symptoms during treatment with INVOKANA®, if possible, check for ketones in your urine, even if your blood sugar is less than 250 mg/dL.
- Vaginal yeast infection. Symptoms of a vaginal yeast infection include: vaginal odor, white or yellowish vaginal discharge (discharge may be lumpy or look like cottage cheese), or vaginal itching.
- Yeast infection of the skin around the penis
 (balanitis or balanoposthitis). Swelling of an
 uncircumcised penis may develop that makes it
 difficult to pull back the skin around the tip of
 the penis. Other symptoms include: redness,
 itching, or swelling of the penis; rash of the penis;
 foul-smelling discharge from the penis; or pain
 in the skin around penis.

Talk to your doctor about what to do if you get symptoms of a yeast infection of the vagina or penis.



Do not take INVOKANA® if you:

- are allergic to canagliflozin or any of the ingredients in INVOKANA®. Symptoms of allergic reaction to INVOKANA® may include: rash; raised red patches on your skin (hives); swelling of the face, lips, mouth, tongue, and throat that may cause difficulty in breathing or swallowing
- are on kidney dialysis

Before you take INVOKANA®, tell your doctor if you: have a history of amputation; have heart disease or are at risk for heart disease; have had blocked or narrowed blood vessels (usually in leg); have damage to the nerves (neuropathy) in your leg; have had diabetic foot ulcers or sores; have kidney problems; have liver problems; have a history of urinary tract infections or problems with urination; are on a low sodium (salt) diet; are going to have surgery (your doctor may stop your INVOKANA® before you have surgery; talk to your doctor if you are having surgery about when to stop taking INVOKANA® and when to start it again); are eating less or there is a change in diet; have or have had pancreas problems; drink alcohol very often (or drink a lot of alcohol in the short-term); or ever had an allergic reaction to INVOKANA®.

Tell your doctor if you are or plan to become pregnant, are breastfeeding, or plan to breastfeed. INVOKANA® may harm your unborn baby. If you become pregnant while taking INVOKANA®, tell your doctor right away. INVOKANA® may pass into your breast milk and may harm your baby. Do not breastfeed while taking INVOKANA®.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Especially tell your doctor if you take diuretics

(water pills), rifampin (used to treat or prevent

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IMPORTANT SAFETY INFORMATION (CONT'D)

tuberculosis), phenytoin or phenobarbital (used to control seizures), ritonavir (Norvir®, Kaletra®— used to treat HIV infection), or digoxin (Lanoxin®— used to treat heart problems).

Possible Side Effects of INVOKANA® INVOKANA® may cause serious side effects, including:

- Serious Urinary Tract Infections: may lead to hospitalization and have happened in people taking INVOKANA®. Tell your doctor if you have any signs or symptoms of a urinary tract infection such as: burning feeling while urinating, need to urinate often or right away, pain in the lower part of your stomach (pelvis), or blood in the urine. Some people may also have fever, back pain, nausea, or vomiting
- Low blood sugar (hypoglycemia). If you take INVOKANA® with another medicine that can cause low blood sugar, such as a sulfonylurea or insulin, your risk of getting low blood sugar is higher. The dose of your sulfonylurea medicine or insulin may need to be lowered while you take INVOKANA®. Signs and symptoms of low blood sugar may include: headache, drowsiness, weakness, dizziness, confusion, irritability, hunger, fast heartbeat, sweating, shaking, or feeling jittery
- A rare but serious bacterial infection that causes damage to the tissue under the skin (necrotizing fasciitis) in the area between and around the anus and genitals (perineum). Necrotizing fasciitis of the perineum has happened in people who take INVOKANA®. Necrotizing fasciitis of the perineum may lead to hospitalization, may require multiple surgeries, and may lead to death. Seek medical attention immediately if you have fever or you are feeling very weak, tired, or uncomfortable (malaise) and you develop any



- of the following symptoms in the area between and around your anus and genitals: pain or tenderness, swelling, or redness of the skin (erythema)
- Serious allergic reaction. If you have any symptoms of a serious allergic reaction, stop taking INVOKANA® and call your doctor right away or go to the nearest hospital emergency room
- Broken Bones (fractures): Bone fractures have been seen in patients taking INVOKANA®. Talk to your doctor about factors that may increase your risk of bone fracture

The most common side effects of INVOKANA® include: vaginal yeast infections and yeast infections of the penis; changes in urination, including urgent need to urinate more often, in larger amounts, or at night.

These are not all the possible side effects of INVOKANA®

Tell your doctor if you have any side effect that bothers you or that does not go away. **Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.** You may also report side effects to Janssen Scientific Affairs, LLC at 1-800-526-7736

Please read full <u>Product Information</u> and Medication Guide for INVOKANA®.

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