

# 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:
  - along with diet and exercise to lower blood sugar (glucose) in adults and children aged 10 years and older 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 recommended to decrease blood sugar (glucose) in people with type 1 diabetes.
- INVOKANA® is not recommended to decrease blood sugar (glucose) in people with type 2 diabetes with severe kidney problems.
- It is not known if INVOKANA® is safe and effective in children under 10 years of age.

### **IMPORTANT SAFETY INFORMATION**

#### INVOKANA® can cause serious side effects, including:

• Diabetic ketoacidosis (increased ketones in your blood or urine) in people with type 1 diabetes mellitus and other ketoacidosis. INVOKANA® can cause ketoacidosis that can be life-threatening and may lead to death. Ketoacidosis is a serious condition which needs to be treated in a hospital. People with type 1 diabetes have a high risk of getting ketoacidosis. People with type 2 diabetes or pancreas problems also have an increased risk of getting ketoacidosis. Ketoacidosis can also happen in people who: are sick, cannot eat or drink as usual, skip meals, are on a diet high in fat and low in carbohydrates (ketogenic diet), take less than the usual amount of insulin or miss insulin doses, drink too much alcohol, have a loss of too much fluid from the body (volume depletion), or who have surgery or a procedure that requires not having food for a long time (prolonged fasting). Ketoacidosis can happen even if your blood sugar is less than 250 mg/dL. Your healthcare provider may ask you to periodically check ketones in your urine or blood.

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



Canagliflozin) tablet
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)**

- Stop taking INVOKANA<sup>®</sup> and call your healthcare provider or get medical help right away if you get any of the following. If possible, check for ketones in your urine or blood, even if your blood sugar is less than 250 mg/dL:
  - Nausea
  - vomiting
  - stomach-area
     (abdominal) pain
- tiredness
- trouble breathing
- ketones in your urine or blood
- 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 in leg), have damage to the nerves (neuropathy) in the leg, or have had diabetic foot ulcers or sores. Call your healthcare provider right away if you have new pain or tenderness, any sores, ulcers, or infections in your leg or foot. Your healthcare provider may decide to stop your INVOKANA® for a while if you have any of these signs or symptoms. Talk to your healthcare provider about proper foot care.

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#### IMPORTANT SAFETY INFORMATION (CONT'D)



- Dehydration. INVOKANA<sup>®</sup> 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 been reports of sudden worsening of kidney function in people with type 2 diabetes who are taking INVOKANA<sup>®</sup>. You may be at higher risk of dehydration if you take medicines to lower your blood pressure (including diuretics [water pill]), are on a low sodium (salt) diet, have kidney problems, or are 65 years of age or older. Talk to your healthcare provider 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 example from vomiting, diarrhea, or being in the sun too long.
- Vaginal yeast infection. Women who take INVOKANA® may get vaginal yeast infections. Yeast infections can be a serious but common side effect of INVOKANA®. 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). Men who take INVOKANA® may get a yeast infection of the skin around the penis. Men who are not circumcised may have swelling of the penis 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; foulsmelling discharge from the penis; or pain in the skin around penis.

Talk to your healthcare provider 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<sup>®</sup>. Symptoms of allergic reaction to INVOKANA<sup>®</sup> 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

#### Before taking INVOKANA®, tell your healthcare

provider if you: have type 1 diabetes or have had diabetic ketoacidosis; have a decrease in your insulin dose; have a serious infection; have a history of infection of the vagina or penis; have a history of amputation; have had blocked or narrowed blood vessels (usually in your 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 [your healthcare provider may change your diet or your dose of INVOKANA<sup>®</sup>]; are going to have surgery or a procedure that requires not having food for a long time (prolonged fasting) [your healthcare provider may stop your INVOKANA® before you have surgery; talk to your healthcare provider 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; are dehydrated; 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 healthcare provider 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 healthcare provider right away. INVOKANA® may pass into your breast milk and may harm your baby. Do not breastfeed while taking INVOKANA®.

**Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

INVOKANA® may affect the way other medicines work, and other medicines may affect how INVOKANA® works.

#### Possible Side Effects of INVOKANA®

# INVOKANA<sup>®</sup> may cause serious side effects, including:

• Serious Urinary Tract Infections: may lead to hospitalization and have happened in people taking INVOKANA®. Tell your healthcare provider if you

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#### IMPORTANT SAFETY INFORMATION (CONT'D)

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<sup>®</sup>. 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<sup>®</sup> and call your healthcare provider 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 healthcare provider 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.

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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 <u>Medication</u> <u>Guide</u> for INVOKANA<sup>®</sup>.

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