What is the most important information I should know about INVOKANA?
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:
  o have a history of amputation
  o have heart disease or are at risk for heart disease
  o have had blocked or narrowed blood vessels, usually in your leg
  o have damage to the nerves (neuropathy) in your leg
  o 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). Dehydration may cause you to feel dizzy, faint, lightheaded, or weak, especially when you stand up (orthostatic hypotension).
  You may be at higher risk of dehydration if you:
  o have low blood pressure
  o take medicines to lower your blood pressure, including diuretics (water pill)
  o are on a low sodium (salt) diet
  o have kidney problems
  o 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.
• **Vaginal yeast infection.** Women who take INVOKANA may get vaginal yeast infections. Symptoms of a vaginal yeast infection include:
  o vaginal odor
  o white or yellowish vaginal discharge (discharge may be lumpy or look like cottage cheese)
  o vaginal itching
• **Yeast infection of the penis (balanitis or balanoposthitis).** Men who take INVOKANA may get a yeast infection of the skin around the penis. Certain 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 of yeast infection of the penis include:
  o redness, itching, or swelling of the penis
  o foul smelling discharge from the penis
  o rash of the penis
  o 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. Your doctor may suggest you use an over-the-counter antifungal medicine. Talk to your doctor right away if you use an over-the-counter antifungal medication and your symptoms do not go away.

What is INVOKANA?
• INVOKANA is a prescription medicine used:
  o along with diet and exercise to lower blood sugar (glucose) in adults with type 2 diabetes.
  o 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.
• INVOKANA is not for people with type 1 diabetes.
• INVOKANA is not for people with diabetic ketoacidosis (increased ketones in blood or urine).
• It is not known if INVOKANA is safe and effective in children under 18 years of age.

Who should not take INVOKANA?
Do not take INVOKANA if you:
• are allergic to canagliflozin or any of the ingredients in INVOKANA. See the end of this Medication Guide for a list of ingredients in INVOKANA. Symptoms of allergic reaction to INVOKANA may include:
  o rash
  o raised red patches on your skin (hives)
  o swelling of the face, lips, mouth, tongue, and throat that may cause difficulty in breathing or swallowing
• have severe kidney problems or are on dialysis.

What should I tell my doctor before taking INVOKANA?
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 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 doctor may change your diet or your dose of INVOKANA.
- are going to have surgery.
- are eating less due to illness, surgery, or a change in your diet.
- have or have had problems with your pancreas, including pancreatitis or surgery on your pancreas.
- drink alcohol very often, or drink a lot of alcohol in the short-term (“binge” drinking).
- have ever had an allergic reaction to INVOKANA.
- have other medical conditions.
- are pregnant or plan to become pregnant. INVOKANA may harm your unborn baby. If you become pregnant while taking INVOKANA, tell your doctor as soon as possible. Talk with your doctor about the best way to control your blood sugar while you are pregnant.
- are breastfeeding or plan to breastfeed. INVOKANA may pass into your breast milk and may harm your baby. Talk with your doctor about the best way to feed your baby if you are taking INVOKANA. 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.

INVOKANA may affect the way other medicines work, and other medicines may affect how INVOKANA works. Especially tell your doctor if you take:

- diuretics (water pills)
- phenytoin or phenobarbital (used to control seizures)
- digoxin (Lanoxin®)* (used to treat heart problems)
- rifampin (used to treat or prevent tuberculosis)
- ritonavir (Norvir®, Kaletra®)* (used to treat HIV infection)

Ask your doctor or pharmacist for a list of these medicines if you are not sure if your medicine is listed above.

Know the medicines you take. Keep a list of them and show it to your doctor and pharmacist when you get a new medicine.

How should I take INVOKANA?

- Take INVOKANA by mouth 1 time each day exactly as your doctor tells you to take it.
- Your doctor will tell you how much INVOKANA to take and when to take it. Your doctor may change your dose if needed.
- It is best to take INVOKANA before the first meal of the day.
- Your doctor may tell you to take INVOKANA along with other diabetes medicines. Low blood sugar can happen more often when INVOKANA is taken with certain other diabetes medicines. See “What are the possible side effects of INVOKANA?”
- If you miss a dose, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose and take the medicine at the next regularly scheduled time. Do not take two doses of INVOKANA at the same time. Talk to your doctor if you have questions about a missed dose.
- If you take too much INVOKANA, call your doctor or go to the nearest hospital emergency room right away.
- When your body is under some types of stress, such as fever, trauma (such as a car accident), infection, or surgery, the amount of diabetes medicine you need may change. Tell your doctor right away if you have any of these conditions and follow your doctor’s instructions.
- Stay on your prescribed diet and exercise program while taking INVOKANA.
- Check your blood sugar as your doctor tells you to.
- INVOKANA will cause your urine to test positive for glucose.
- Your doctor may do certain blood tests before you start INVOKANA and during treatment as needed. Your doctor may change your dose of INVOKANA based on the results of your blood tests.
- Your doctor will check your diabetes with regular blood tests, including your blood sugar levels and your hemoglobin A1c.

What are the possible side effects of INVOKANA?

INVOKANA may cause serious side effects including:

See “What is the most important information I should know about INVOKANA?”

- ketoacidosis (increased ketones in your blood or urine). Ketoacidosis has happened in people who have type 1 diabetes or type 2 diabetes, during treatment with INVOKANA. Ketoacidosis is a serious condition, which may need
Active ingredient: canagliflozin
Inactive ingredients: croscarmellose sodium, hydroxypropyl cellulose, lactose anhydrous, magnesium stearate, and microcrystalline cellulose. In addition, the tablet coating contains iron oxide yellow E172 (100 mg tablet only), macrogol/PEG, polyvinyl alcohol, talc, and titanium dioxide.

What are the ingredients of INVOKANA?

For more information about INVOKANA, call 1-800-FDA-1088 or visit our website at www.invokana.com.