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Canagliflozin

pronounced as (kan" a gli floe' zin)

Why is this medication prescribed?

Canagliflozin is used along with diet and exercise, and sometimes with other medications, to lower blood sugar levels in people with type 2 diabetes (condition in which blood sugar is too high because the body does not produce or use insulin normally). Canagliflozin is also used to reduce the risk of stroke, heart attack, or death in people who have type 2 diabetes along with heart and blood vessel disease. Canagliflozin is also used to reduce the risk of end-stage kidney disease, worsening of kidney function, needing to be hospitalized for heart failure, and cardiovascular death in people who have type 2 diabetes along with severe kidney disease. Canagliflozin is in a class of medications called sodium-glucose co-transporter 2 (SGLT2) inhibitors. It lowers blood sugar by causing the kidneys to get rid of more glucose in the urine. Canagliflozin is not used to treat type 1 diabetes (condition in which the body does not produce insulin and, therefore, cannot control the amount of sugar in the blood).

Over time, people who have diabetes and high blood sugar can develop serious or life-threatening complications, including heart disease, stroke, kidney problems, nerve damage, and eye problems. Taking medication(s), making lifestyle changes (e.g., diet, exercise, quitting smoking), and regularly checking your blood sugar may help to manage your diabetes and improve your health. This therapy may also decrease your chances of having a heart attack, stroke, or other diabetes-related complications such as kidney failure, nerve damage (numb, cold legs or feet; decreased sexual ability in men and women), eye problems, including changes or loss of vision, or gum disease. Your doctor and other healthcare providers will talk to you about the best way to manage your diabetes.

How should this medicine be used?

Canagliflozin comes as a tablet to take by mouth. It is usually taken once a day before breakfast or the first main meal of the day. Take canagliflozin at around the same time every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take canagliflozin exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Your doctor may start you on a low dose of canagliflozin and gradually increase your dose.

Canagliflozin controls type 2 diabetes but does not cure it. Continue to take canagliflozin even if you feel well. Do not stop taking canagliflozin without talking to your doctor.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking canagliflozin,

- tell your doctor and pharmacist if you are allergic (rash, hives, swelling of your face, lips, tongue, or throat, or difficulty breathing) to canagliflozin, any other medications, or any of the ingredients in canagliflozin tablets. Ask your pharmacist or check the Medication Guide for a list of the ingredients.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention any of the following: angiotensin-converting enzyme (ACE) inhibitors such as benazepril (Lotensin, in Lotrel), captopril, enalapril (Vasotec, in Vaseretic), fosinopril, lisinopril (in Zestoretic), moexipril (Univasc, in Uniretic), perindopril (Aceon, in Prestalia), quinapril (Accupril, in Accuretic, in Quinaretic), ramipril (Altace), and trandolapril (Mavik, in Tarka); angiotensin receptor blockers such as azilsartan (Edarbi, in Edarbyclor), candesartan (Atacand, in Atacand HCT), eprosartan (Teveten), irbesartan (Avapro, in Avalide), losartan (Cozaar, in Hyzaar), olmesartan (Benicar, in Azor, in Benicar HCT, in Tribenzor), telmisartan (Micardis, in Micardis HCT, in Twynsta), and valsartan (Diovan, in Diovan HCT, in Exforge); digoxin (Lanoxin); diuretics ('water pills'); insulin; other medications for diabetes; phenobarbital; phenytoin (Dilantin, Phenytek); rifampin (Rifadin, Rimactane, in Rifamate, in Rifater); and ritonavir (Norvir, in Kaletra). Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- tell your doctor if you are on dialysis. Your doctor may tell you not to take canagliflozin.
- tell your doctor if you regularly drink alcohol or sometimes drink large amounts of alcohol in a short time (binge drinking), or are on a low sodium diet. Also, tell your doctor if you have ever had an amputation, or have ever had heart disease, peripheral vascular disease (narrowing of blood vessels in feet, legs, or arms causing numbness, pain, or coldness in that part of the body), neuropathy (nerve damage that causes tingling, numbness, and pain, usually in your hands and feet), foot ulcers or sores, low blood pressure, urinary tract infections, or urinary problems, pancreatic disease including pancreatitis (swelling of the pancreas) or have had surgery on your pancreas, yeast infections in the genital area, osteoporosis (a condition in which the bones become thin and weak and break easily), kidney or liver disease. If you are male, tell your doctor if you have never been circumcised. Tell your doctor if you are eating less due to illness, surgery, or a change in your diet or if you are unable to eat or drink normally due to nausea, vomiting, diarrhea, or if you become dehydrated from being in the sun too long.
- tell your doctor if you are pregnant, plan to become pregnant, or are breastfeeding. Do not breastfeed while you are taking canagliflozin. If you become pregnant while taking canagliflozin, call your doctor.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking canagliflozin.
- alcohol may cause a change in blood sugar. Ask your doctor about the safe use of alcoholic beverages while you are taking canagliflozin.
- you should know that canagliflozin may cause dizziness, lightheadedness, and fainting when you get up too quickly from a lying position. If you have this problem, call your doctor. This problem is more common when you first start taking canagliflozin. To avoid this problem, get out of bed slowly, resting your feet on the floor for a few minutes before standing up.
- ask your doctor what to do if you get sick, develop an infection or fever, experience unusual stress, or are injured. These conditions can affect your blood sugar and the amount of canagliflozin you may

need.

What special dietary instructions should I follow?

Be sure to follow all exercise and dietary recommendations made by your doctor or dietitian. It is important to eat a healthful diet and exercise regularly.

Follow your doctor's instructions about drinking enough fluids throughout the day while you are on this medication.

What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

What side effects can this medication cause?

This medication may cause changes in your blood sugar. You should know the symptoms of low and high blood sugar and what to do if you have these symptoms.

Canagliflozin may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- urinating a lot, including at night
- increased thirst
- constipation
- dry mouth

Some side effects can be serious. If you experience any of these symptoms, call your doctor immediately:

- frequent, urgent, burning, or painful urination
- decrease in amount of urine
- urine that is cloudy, red, pink, or brown
- strong smelling urine
- pelvic or rectal pain
- (in women) vaginal odor, white or yellowish vaginal discharge (may be lumpy or look like cottage cheese), or vaginal itching
- (in men) redness, itching, or swelling of the penis; rash on the penis; foul smelling discharge from the penis; or pain in the skin around the penis
- feeling tired, weak, or uncomfortable; along with a fever and pain, tenderness, redness, and swelling of the genitals or the area between the genitals and the rectum

If you experience any of the following symptoms, stop taking canagliflozin and call your doctor immediately or get emergency medical treatment:

- rash
- hives
- itching
- difficulty swallowing
- swelling of the face, throat, tongue, lips, mouth, or eyes
- hoarseness

If you experience any of the following symptoms of ketoacidosis (a serious condition that may develop if high blood sugar is not treated), stop taking canagliflozin and call your doctor immediately or get emergency medical treatment. If possible, check for ketones in your urine if you have these symptoms, even if your blood sugar is less than 250 mg/dL:

- nausea
- vomiting
- stomach-area pain
- tiredness
- difficulty breathing

You should know that canagliflozin can increase the risk of having a lower limb (toe, foot, or leg) amputation. Your doctor will tell you how to take care of your legs and feet properly to help avoid infections and complications that could lead to an amputation. Follow the doctor's instructions carefully and call your doctor right away if you have any pain, tenderness, sores, ulcers, or swollen, warm, reddened area in your leg or foot, fever or chills, or other signs and symptoms of infection.

Canagliflozin may increase the chance of having a fracture (broken bone), particularly in the upper arms, wrists, or hands. Talk to your doctor about the risks of taking this medication.

Canagliflozin may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom).

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps

and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor will order a lab test before and during your treatment with canagliflozin to check how well your kidneys are working. Your blood sugar levels should be checked regularly to determine your response to canagliflozin. Your doctor will order other lab tests, including glycosylated hemoglobin (HbA1c), to check your response to canagliflozin. Your doctor will also tell you how to check your response to this medication by measuring your blood sugar levels at home. Follow these instructions carefully.

Before having any laboratory test, tell your doctor and the laboratory personnel that you are taking canagliflozin. Because of the way this medication works, your urine may test positive for glucose.

You should always wear a diabetic identification bracelet to be sure you get proper treatment in an emergency.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Invokana[®]

Brand names of combination products

- Invokamet[®] (containing Canagliflozin and Metformin)

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