

MEDICATION GUIDE

Dapagliflozin (dap' a gli floe' zin)

Tablets, for oral use

What is the most important information I should know about dapagliflozin tablets?

Dapagliflozin tablets can cause serious side effects, including:

- **Diabetic ketoacidosis (increased ketones in your blood or urine) in people with type 1 diabetes and other ketoacidosis.** Dapagliflozin tablets 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. 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.

Stop taking dapagliflozin tablets 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
- tiredness
- vomiting
- trouble breathing
- stomach area (abdominal) pain
- ketones in your urine or blood

- **Dehydration.** Dapagliflozin tablets can cause some people to become dehydrated (the loss of body water and salt). Dehydration may cause you to feel dizzy, faint, lightheaded, or weak, especially when you stand up (orthostatic hypotension). There have been reports of sudden kidney injury in people with Type 2 diabetes who are taking dapagliflozin tablets. You may be at a higher risk of dehydration if you:

- take medicines to lower your blood pressure, including water pills (diuretics)
- are on a low salt diet
- have kidney problems
- 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.

- **Genital and urinary tract infections.** Dapagliflozin tablets can cause serious infections in your genital area or urinary tract that could require hospitalization. **A rare but serious bacterial infection called necrotizing fasciitis can cause damage to the tissue under the skin in the area between and around the anus and genitals (perineum).** This infection may require hospitalization, multiple surgeries, and could lead to death. **Seek medical attention immediately if you have a 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
- redness of skin (erythema)

Also tell your healthcare provider if you have any of these signs or symptoms of urinary tract infections or yeast infections:

○ Urinary tract infection:

- burning feeling when you urinate
- need to urinate often or right away
- pain in the lower part of your stomach (pelvis)
- blood in your urine

You may also have a fever, back pain, nausea, or vomiting.

○ Vaginal yeast infection:

- vaginal odor
- white or yellowish vaginal discharge (discharge may be lumpy or look like cottage cheese)
- vaginal itching

- **Yeast infection of the penis (balanitis or balanoposthitis):** If you are uncircumcised, swelling may make it difficult to pull back the skin around the tip of your penis. Other symptoms include:

- redness, itching, or swelling of the penis
- rash on the penis
- bad smelling discharge from the penis
- pain in the skin around the penis

Talk to your healthcare provider about what to do if you get symptoms of a yeast infection. They may suggest you use an over-the-counter antifungal medicine. Contact your healthcare provider right away if your symptoms do not improve after using an over-the-counter antifungal medicine.

What is dapagliflozin tablet?

- Dapagliflozin tablet is a prescription medicine used:
 - to reduce the risk of hospitalization for heart failure in adults with type 2 diabetes who also have known cardiovascular disease or multiple cardiovascular risk factors.
 - along with diet and exercise to improve blood sugar (glucose) control in adults with type 2 diabetes.

- Dapagliflozin tablets are not for use to improve blood sugar (glucose) control in people with type 1 diabetes.
- Dapagliflozin tablets are not for use to improve blood sugar (glucose) control in people with type 2 diabetes who have moderate to severe kidney problems, because it may not work.
- It is not known if dapagliflozin tablets are safe and effective to lower blood sugar (glucose) in children younger than 10 years of age with type 2 diabetes.

Who should not take dapagliflozin tablets?

Do not take dapagliflozin tablets if you:

- are allergic to dapagliflozin or any of the ingredients in dapagliflozin tablets. See the end of this Medication Guide for a list of ingredients in dapagliflozin tablets. Symptoms of a **serious** allergic reaction to dapagliflozin tablets may include:
 - rash
 - raised red patches on your skin (hives)
 - swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing

If you have any of these symptoms, stop taking dapagliflozin tablets and contact your healthcare provider or go to the nearest hospital emergency room right away.

What should I tell my healthcare provider before taking dapagliflozin tablets?

Before you take dapagliflozin tablets, 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 liver problems.
- have a history of urinary tract infections or problems with urination.
- are on a low sodium (salt) diet. Your healthcare provider may ask you to change your diet.
- are going to have surgery. Your healthcare provider may stop your dapagliflozin tablets before you have surgery. Talk to your healthcare provider if you are having surgery about when to stop taking dapagliflozin tablets and when to start it again.
- are eating less or there is a change in your diet.
- are dehydrated.
- 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).
- are pregnant or plan to become pregnant. Dapagliflozin tablets may harm your unborn baby. If you become pregnant while taking dapagliflozin tablets, your healthcare provider may switch you to a different medicine to control your blood sugar. Talk to your healthcare provider about the best way to control your blood sugar if you plan to become pregnant or while you are pregnant.
- are breastfeeding or plan to breastfeed. It is not known if dapagliflozin passes into your breast milk. You should not breastfeed if you take dapagliflozin tablets.

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

Dapagliflozin tablets may affect the way other medicines work, and other medicines may affect how dapagliflozin tablets works.

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

How should I take dapagliflozin tablets?

- Take dapagliflozin tablets exactly as your healthcare provider tells you to take it.
- Take dapagliflozin tablets by mouth 1 time each day, with or without food.
- Your healthcare provider will tell you how much dapagliflozin tablets to take and when to take it. Your healthcare provider may change your dose if needed.
- 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 2 doses of dapagliflozin tablets at the same time. Talk with your healthcare provider if you have questions about a missed dose.
- If you take too much dapagliflozin tablets, call your healthcare provider or Poison Help line at 1-800-222-1222, or go to the nearest emergency room right away.
- If you have diabetes:
 - 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 healthcare provider right away if you have any of these conditions and follow your healthcare provider's instructions.

○ Your healthcare provider may tell you to take dapagliflozin tablets along with other diabetes medicines. Low blood sugar can happen more often when dapagliflozin tablets is taken with certain other diabetes medicines. See “What are the possible side effects of dapagliflozin tablets?” ● Dapagliflozin tablets will cause your urine to test positive for glucose. ● Your healthcare provider may do certain blood tests before you start dapagliflozin tablets and during treatment as needed. Your healthcare provider may change your dose of dapagliflozin tablets based on the results of your blood tests.
What are the possible side effects of Dapagliflozin tablets? Dapagliflozin tablets may cause serious side effects, including: See “What is the most important information I should know about dapagliflozin tablets?”. ● Low blood sugar (hypoglycemia) in patients with diabetes mellitus. If you take dapagliflozin tablets 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 dapagliflozin tablets. Signs and symptoms of low blood sugar may include: ○ headache ○ confusion ○ hunger ○ shaking or feeling jittery ○ drowsiness ○ dizziness ○ fast heartbeat ○ weakness ○ sweating ○ irritability ● Serious allergic reaction. If you have any symptoms of a serious allergic reaction, stop taking dapagliflozin tablets and call your healthcare provider right away or go to the nearest hospital emergency room. See “Who should not take dapagliflozin tablets?”. Your healthcare provider may give you a medicine for your allergic reaction and prescribe a different medicine for your diabetes. The most common side effects of dapagliflozin tablets include: ● vaginal yeast infections and yeast infections of the penis ● stuffy or runny nose and sore throat ● 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 dapagliflozin tablets. For more information, ask your healthcare provider or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.
How should I store dapagliflozin tablets? ● Store dapagliflozin tablets at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F) [see USP Controlled Room Temperature]. ● Bottle of 30's and 90's count of dapagliflozin tablets come in a child-resistant package. ● Keep dapagliflozin tablets and all medicines out of the reach of children.
General information about the safe and effective use of dapagliflozin tablets Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use dapagliflozin tablets for a condition for which it is not prescribed. Do not give dapagliflozin tablets to other people, even if they have the same symptoms you have. It may harm them. This Medication Guide summarizes the most important information about dapagliflozin tablets. If you would like more information, talk to your healthcare provider. You can ask your pharmacist or healthcare provider for information about dapagliflozin tablets that is written for healthcare professionals. For more information about dapagliflozin tablets call 1-866-210-9797.
What are the ingredients in dapagliflozin tablets? Active ingredient: dapagliflozin. Inactive ingredients: anhydrous lactose, colloidal silicon dioxide, croscopovidone, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate and microcrystalline cellulose. In addition, the film coating contains the following inactive ingredients: iron oxide yellow, polyethylene glycol, polyvinyl alcohol, talc and titanium dioxide. Manufactured by: Alembic Pharmaceuticals Limited (Formulation Division), Panelav 389350, Gujarat, India Manufactured for: Alembic Pharmaceuticals, Inc. Bedminster, NJ 07921, USA

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