

## MEDICATION GUIDE

### Dapagliflozin ('dap" a gli floe zin) tablets, for oral use

#### What is the most important information I should know about Dapagliflozin?

##### Dapagliflozin 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 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 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.

- o nausea
- o vomiting
- o stomach area (abdominal) pain
- o tiredness
- o trouble breathing
- o ketones in your urine or blood
- **Dehydration. Dapagliflozin 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.** You may be at a higher risk of dehydration if you:
  - o take medicines to lower your blood pressure, including water pills (diuretics)
  - o are on a low salt diet
  - o have kidney problems
  - o 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 dapagliflozin 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).** Swelling of an uncircumcised penis may develop 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 the penis

Talk to your healthcare provider about what to do if you get symptoms of a yeast infection of the vagina or penis. Your healthcare provider may suggest you use an over-the-counter antifungal medicine. Talk to your healthcare provider right away if you use an over-the-counter antifungal medication and your symptoms do not go away.

#### What is Dapagliflozin?

- Dapagliflozin is a prescription medicine used:
  - o 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.
  - o along with diet and exercise to improve blood sugar (glucose) control in adults with type 2 diabetes.
- Dapagliflozin is not for use to improve blood sugar (glucose) control in people with type 1 diabetes.
- Dapagliflozin is 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 is 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?

##### Do not take Dapagliflozin if you:

- are allergic to dapagliflozin or any of the ingredients in dapagliflozin. See the end of this Medication Guide for a list of ingredients in dapagliflozin. Symptoms of a **serious** allergic reaction to dapagliflozin may include:
  - o rash
  - o raised red patches on your skin (hives)
  - o 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 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?

##### Before you take Dapagliflozin, 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 before you have surgery. Talk to your healthcare provider if you are having surgery about when to stop taking dapagliflozin 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 may harm your unborn baby. If you become pregnant while taking dapagliflozin, 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.

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

