MEDICATION GUIDE

Dapagliflozin (dap-a-gli-FLOE-zin) and Metformin Hydrochloride (met-FOR-min HYE-droe-KLOR-ide) Extended-Release Tablets, for oral use

What is the most important information I should know about dapagliflozin and metformin hydrochloride extended-release tablets? Dapagliflozin and metformin hydrochloride extended-release tablets can cause serious side effects, including:

- **Lactic Acidosis**. Metformin, one of the medicines in dapagliflozin and metformin hydrochloride extended-release tablets, can cause a rare but serious condition called lactic acidosis (a build-up of an acid in the blood) that can cause death. Lactic acidosis is a medical emergency and must be treated in the hospital.

Stop taking dapagliflozin and metformin hydrochloride extended-release tablets and call your healthcare provider right away if you have any of the following symptoms, which could be signs of lactic acidosis:

- you feel cold in your hands or feet
- you feel dizzy or lightheaded
- you have a slow or irregular heartbeat
- you feel very weak or tired
- you have unusual (not normal) muscle pain
- you have trouble breathing
- you feel unusual sleepiness or sleep longer than usual
- you have stomach pains, nausea or vomiting

Most people who have had lactic acidosis with metformin have other things that, combined with the metformin use, led to the lactic acidosis. Tell your healthcare provider if you have any of the following, because you have a higher chance for getting lactic acidosis with dapagliflozin and metformin hydrochloride extended-release tablets if you:

- have severe kidney problems or your kidneys are affected by certain x-ray tests that use injectable dye.
- have liver problems.
- drink alcohol very often or drink a lot of alcohol in the short-term ("binge" drinking).
- get dehydrated (lose a large amount of body fluids). This can happen if you are sick with a fever, vomiting, or diarrhea. Dehydration can also happen when you sweat a lot with activity or exercise and do not drink enough fluids.
- have surgery.
- have new or worsening symptoms of congestive heart failure such as shortness of breath or increased fluid or swelling of the legs.
- have a heart attack, severe infection, or stroke.
- are 65 years of age or older.
- have a genetically inherited disease affecting mitochondria (the energy-producing parts within cells) such as mitochondrial encephalomyopathy with lactic acidosis, and stroke-like episodes (MELAS) syndrome and maternally inherited diabetes and deafness (MIDD).

The best way to keep from having a problem with lactic acidosis from metformin is to tell your healthcare provider if you have any of the problems in the list above. Your healthcare provider may decide to stop your dapagliflozin and metformin hydrochloride extended-release tablets for a while if you have any of these things.\

- **Diabetic Ketoacidosis (increased ketones in your blood or urine) in people with type 1 diabetes and other ketoacidosis.** Dapagliflozin and metformin hydrochloride extended-release 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 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.

  Stop taking dapagliflozin and metformin hydrochloride extended-release 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
  - vomiting
  - stomach area (abdominal) pain
  - tiredness
  - trouble breathing
  - ketones in your urine or blood

- **Genital and urinary tract infections.** Dapagliflozin and metformin hydrochloride extended-release 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 (may be lumpy or look like cottage cheese)
  - vaginal itching
- **Yeast infection of the skin around 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 are dapagliflozin and metformin hydrochloride extended-release tablets?

- Dapagliflozin and metformin hydrochloride extended-release tablets are prescription medicine that contains 2 prescription medicines called dapagliflozin (FARXIGA) and metformin HCl.
- Dapagliflozin and metformin hydrochloride extended-release tablet can be used along with diet and exercise to improve blood sugar (glucose) in adults with type 2 diabetes.
- One of the medicines in dapagliflozin and metformin hydrochloride extended-release tablet, dapagliflozin (FARXIGA), can also be used in adults with type 2 diabetes who have:
  - chronic kidney disease and dapagliflozin is needed to reduce the risk of further worsening of your kidney disease, end-stage kidney disease (ESKD), death due to cardiovascular disease, and hospitalization for heart failure.
  - heart failure (when the heart cannot pump enough blood to the rest of your body) and dapagliflozin is needed to reduce the risk of cardiovascular death, hospitalization for heart failure and urgent heart failure visit.
  - known cardiovascular disease or multiple cardiovascular risk factors and dapagliflozin is needed to reduce the risk of hospitalization for heart failure.
- Dapagliflozin and metformin hydrochloride extended-release tablets are not for use to improve blood sugar (glucose) control in people with type 1 diabetes.
- Dapagliflozin and metformin hydrochloride extended-release tablets are only for use in people with type 2 diabetes mellitus, because it contains the prescription medicine metformin HCl.
- Dapagliflozin and metformin hydrochloride extended-release tablet is not for use for treatment of chronic kidney disease in people with certain genetic forms of polycystic kidney disease, or who are taking or have recently received immunosuppressive therapy to treat kidney disease. If you have these conditions, dapagliflozin and metformin hydrochloride extended-release tablet is not expected to work for treatment of chronic kidney disease.
- It is not known if dapagliflozin and metformin hydrochloride extended-release tablet is safe and effective to lower blood sugar (glucose) in children younger than 10 years of age with type 2 diabetes mellitus.
- It is not known if dapagliflozin and metformin hydrochloride extended-release tablets are safe and effective for treatment of heart failure or chronic kidney disease in children younger than 18 years of age.

Who should not take dapagliflozin and metformin hydrochloride extended-release tablets? Do not take dapagliflozin and metformin hydrochloride extended-release tablets if you:

- have severe kidney problems.
- are allergic to dapagliflozin, metformin HCl, or any of the ingredients in dapagliflozin and metformin hydrochloride extended-release tablets. See the end of this Medication Guide for a complete list of ingredients in dapagliflozin and metformin hydrochloride extended-release tablets. Symptoms of a **serious** allergic reaction to dapagliflozin and metformin

hydrochloride extended-release 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 and metformin hydrochloride extended-release tablets and contact your healthcare provider or go to the nearest hospital emergency room right away.

- have a condition called metabolic acidosis or diabetic ketoacidosis (increased ketones in your blood or urine).

What should I tell my healthcare provider before taking dapagliflozin and metformin hydrochloride extended-release tablets? Before you take dapagliflozin and metformin hydrochloride extended-release 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 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 ask you to change your diet.
- have heart problems, including congestive heart failure.
- are 65 years of age or older.
- are going to have surgery or a procedure that requires not having food for a long time (prolonged fasting). Your healthcare provider may stop dapagliflozin and metformin hydrochloride extended-release tablets before you have surgery. Talk to your healthcare provider if you are having surgery about when to stop taking dapagliflozin and metformin hydrochloride extended-release 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 going to get an injection of dye or contrast agents for an x-ray procedure. Dapagliflozin and metformin hydrochloride extended-release tablets may need to be stopped for a short time. Talk to your healthcare provider about when you should stop dapagliflozin and metformin hydrochloride extended-release tablets and when you should start dapagliflozin and metformin hydrochloride extended-release tablets again. See **"What is the most important information I should know about dapagliflozin and metformin hydrochloride extended-release tablets?"**
- have low levels of vitamin B_{12} in your blood.
- are pregnant or plan to become pregnant. Dapagliflozin and metformin hydrochloride extended-release tablets may harm your unborn baby. If you are pregnant or plan to become pregnant, talk to your healthcare provider about the best way to control your blood sugar.
- are breastfeeding or plan to breastfeed. It is not known if dapagliflozin and metformin hydrochloride passes into your breast milk. Talk with your healthcare provider about the

best way to feed your baby if you are taking dapagliflozin and metformin hydrochloride extended-release tablets. You should not breastfeed if you take dapagliflozin and metformin hydrochloride extended-release tablets.

- are a person who has not gone through menopause (premenopausal) who does not have periods regularly or at all. Dapagliflozin and metformin hydrochloride extended-release tablets can cause the release of an egg from an ovary in a person (ovulation). This can increase your chance of getting pregnant. Tell your healthcare provider right away if you become pregnant while taking dapagliflozin and metformin hydrochloride extended-release tablets.
- have a genetically inherited disease affecting mitochondria (the energy-producing parts within cells) such as MELAS syndrome and MIDD.

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

Dapagliflozin and metformin hydrochloride extended-release tablets may affect the way other medicines work and other medicines may affect the way dapagliflozin and metformin hydrochloride extended-release tablets works. Know the medicines you take. Keep a list of them and show it to your healthcare provider and pharmacist when you get a new medicine.

How should I take dapagliflozin and metformin hydrochloride extended-release tablets?

- Take dapagliflozin and metformin hydrochloride extended-release tablets exactly as your healthcare provider tells you to take it.
- Your healthcare provider will tell you how much dapagliflozin and metformin hydrochloride extended-release tablets to take and when to take it. Your healthcare provider may change your dose if needed.
- Take dapagliflozin and metformin hydrochloride extended-release tablets by mouth 1 time each day with meals to lower your chance of an upset stomach. Talk to your healthcare provider about the best time of day for you.
- Swallow dapagliflozin and metformin hydrochloride extended-release tablets whole. Do not crush, cut, or chew dapagliflozin and metformin hydrochloride extended-release tablets.
- You may sometimes pass a soft mass in your stools (bowel movement) that looks like dapagliflozin and metformin hydrochloride extended-release tablets.
- If you miss a dose of dapagliflozin and metformin hydrochloride extended-release tablets, 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 and metformin hydrochloride extended-release tablets at the same time. Talk with your healthcare provider if you have questions about a missed dose.

- If you take too much dapagliflozin and metformin hydrochloride extended-release tablets, call your healthcare provider or Poison Help line at 1-800-222-1222, 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 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 stop taking dapagliflozin and metformin hydrochloride extended-release tablets at least 3 days before any surgery or procedure that requires not having food or water for a long time (prolonged fasting).
- Your healthcare provider may tell you to take dapagliflozin and metformin hydrochloride extended-release tablets along with other diabetes medicines. Low blood sugar can happen more often when dapagliflozin and metformin hydrochloride extended-release tablets are taken with certain other diabetes medicines. See **"What are the possible side effects of dapagliflozin and metformin hydrochloride extended-release tablets?"**.
- Dapagliflozin and metformin hydrochloride extended-release tablets will cause your urine to test positive for glucose.
- Your healthcare provider may do certain blood tests before you start dapagliflozin and metformin hydrochloride extended-release tablets and during treatment as needed.
  Your healthcare provider may change your dose of dapagliflozin and metformin hydrochloride extended-release tablets based on the results of your blood tests.

What should I avoid while taking dapagliflozin and metformin hydrochloride extended-release tablets?

- Avoid drinking alcohol very often or drinking a lot of alcohol in a short period of time ("binge" drinking). It can increase your chances of getting serious side effects.

What are the possible side effects of dapagliflozin and metformin hydrochloride extended-release tablets? Dapagliflozin and metformin hydrochloride extended-release tablets may cause serious side effects including:

See "**What is the most important information I should know about dapagliflozin and metformin hydrochloride extended-release tablets?**"

- **Dehydration.** Dapagliflozin and metformin hydrochloride extended-release 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 mellitus who are taking dapagliflozin, a medicine in dapagliflozin and metformin hydrochloride extended-release 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.

- **Low blood sugar (hypoglycemia).** If you take dapagliflozin and metformin hydrochloride extended-release tablets with another medicine that can cause low blood sugar, such as sulfonylureas 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 and metformin hydrochloride extended-release 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 and metformin hydrochloride extended-release tablets and call your healthcare provider right away or go to the nearest hospital emergency room. See **"Who should not take dapagliflozin and metformin hydrochloride extended-release tablets?".** Your healthcare provider may give you a medicine for your allergic reaction and prescribe a different medicine for your diabetes.
- **Low vitamin B_{12} (vitamin B_{12} deficiency).** Using metformin for long periods of time may cause a decrease in the amount of vitamin B_{12} in your blood, especially if you have had low vitamin B_{12} levels before. Your healthcare provider may do blood tests to check your vitamin B_{12} levels.

The most common side effects of dapagliflozin and metformin hydrochloride extended-release tablets include:

- vaginal yeast infections
- diarrhea
- headache
- stuffy or runny nose and sore throat
- urinary tract infection

Tell your healthcare provider or pharmacist if you have any side effect that bothers you or does not go away.

These are not all of the possible side effects of dapagliflozin and metformin hydrochloride extended-release 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. You may also report side effect to Lupin Pharmaceuticals, Inc. at 1800-399-2561.

How should I store dapagliflozin and metformin hydrochloride extended-release tablets?

Store dapagliflozin and metformin hydrochloride extended-release tablets at room temperature between 68°F and 77°F (20°C and 25°C).

Keep dapagliflozin and metformin hydrochloride extended-release tablets and all medicines out of the reach of children.

General information about the safe and effective use of dapagliflozin and metformin hydrochloride extended-release tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use dapagliflozin and metformin hydrochloride extended-release tablets for a condition for which it is not prescribed. Do not give dapagliflozin and metformin hydrochloride extended-release 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 and metformin hydrochloride extended-release tablets. If you would like more information, talk to your healthcare provider. You can ask your pharmacist or healthcare provider for information about dapagliflozin and metformin hydrochloride extended-release tablets that is written for health professionals.

For more information, go to www.lupinpharmaceuticals.com or call 1-800-399-2561.

What are the ingredients in dapagliflozin and metformin hydrochloride extended-release tablets?

Active ingredients: dapagliflozin and metformin hydrochloride

Inactive ingredients: crospovidone, colloidal silicon dioxide, hypromellose, lactose monohydrate, microcrystalline cellulose, magnesium stearate, povidone, sodium carboxymethyl cellulose, sodium stearyl fumarate.

The film coatings contain the following inactive ingredients: polyvinyl alcohol, polyethylene glycol, talc, titanium dioxide. Additionally, the film coating for the dapagliflozin and metformin hydrochloride extended-release tablets 5 mg/500 mg tablets contains iron oxide red and iron oxide yellow. The film coating for the dapagliflozin and metformin hydrochloride extended-release tablets 5 mg/1000 mg contains iron oxide red and iron oxide black. The film coating for the dapagliflozin and metformin hydrochloride extended-release tablets 10 mg/500 mg contains iron oxide red and iron oxide yellow. The film coating for the dapagliflozin and metformin hydrochloride extended-release tablets 10 mg/1000 mg tablets contains D & C yellow #10 aluminum lake, FD & C yellow #6/ sunset yellow FCF aluminum lake, FD & C blue #2/ indigo carmine aluminum lake.

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