

Medication Guide
STEGLATRO™ (steh-GLA-troh)
(ertugliflozin)
tablets, for oral use

Read this Medication Guide carefully before you start taking STEGLATRO and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment.

What is the most important information I should know about STEGLATRO?

STEGLATRO may cause serious side effects, including:

- **Dehydration.** STEGLATRO 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).

You may be at risk of dehydration if you:

- have low blood pressure
- take medicines to lower your blood pressure, including water pills (diuretics)
- have kidney problems
- are on a low sodium (salt) diet
- 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 STEGLATRO may get vaginal yeast infections. Symptoms of a vaginal yeast infection include:

- 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).** Men who take STEGLATRO 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 your penis. Other symptoms of yeast infection of the penis include:

- redness, itching, or swelling of the penis
- rash of the penis
- foul smelling discharge from the penis
- pain in the skin around your 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 medicine and your symptoms do not go away.

What is STEGLATRO?

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

Do not take STEGLATRO if you:

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

Before you take STEGLATRO, tell your doctor about all of your medical conditions, including if you:

- have type 1 diabetes or have had diabetic ketoacidosis.
- have kidney problems.
- have liver problems.
- have or have had problems with your pancreas, including pancreatitis or surgery on your pancreas.
- have a history of urinary tract infections or problems with urination.
- are eating less due to illness, surgery, or a change in your diet.
- have a history of amputation.
- have had blocked or narrowed blood vessels, usually in the leg.
- have damage to the nerves (neuropathy) in your leg.
- have had diabetic foot ulcers or sores.
- are going to have surgery.
- drink alcohol very often, or drink a lot of alcohol in the short term (“binge” drinking).
- are pregnant or plan to become pregnant. STEGLATRO may harm your unborn baby. If you become pregnant while taking STEGLATRO, your doctor may switch you to a different medicine to control your blood sugar. Talk to your doctor 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 STEGLATRO passes into your breast milk. You should not breastfeed if you take STEGLATRO.

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

How should I take STEGLATRO?

- Take STEGLATRO exactly as your doctor tells you to take it.
- Take STEGLATRO by mouth 1 time in the morning each day, with or without food.
- Your doctor 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 STEGLATRO at the same time.
- Your doctor may tell you to take STEGLATRO along with other diabetes medicines. Low blood sugar can happen more often when STEGLATRO is taken with certain other diabetes medicines. See “What are the possible side effects of STEGLATRO?”.
- Stay on your prescribed diet and exercise program while taking STEGLATRO.
- Check your blood sugar as your doctor tells you to.
- Your doctor will check your diabetes with regular blood tests, including your blood sugar levels and your HbA1c.
- Talk to your doctor about how to prevent, recognize and manage low blood sugar (hypoglycemia), high blood sugar (hyperglycemia), complications of diabetes.
- Your doctor will do blood tests to check how well your kidneys are working before and during your treatment with STEGLATRO.
- 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.
- When taking STEGLATRO, you may have sugar in your urine, which will show up on a urine test.
- If you take too much STEGLATRO, call your doctor or go to the nearest hospital emergency room

right away.

What are the possible side effects of STEGLATRO?

STEGLATRO may cause serious side effects, including:

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

- **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 STEGLATRO. Ketoacidosis is a serious condition, which may need to be treated in a hospital. Ketoacidosis may lead to death. **Ketoacidosis can happen even if your blood sugar is less than 250 mg/dL. Stop taking STEGLATRO and call your doctor right away if you get any of the following symptoms:**
 - nausea
 - vomiting
 - stomach-area (abdominal) pain
 - tiredness
 - trouble breathing

If you get any of these symptoms during treatment with STEGLATRO, if possible check for ketones in your urine, even if your blood sugar is less than 250 mg/dL.

- **kidney problems.** Sudden kidney injury has happened to people treated with STEGLATRO. Talk to your doctor right away if you:
 - reduce the amount of food or liquid you drink, for example, if you are sick or cannot eat or
 - you start to lose liquids from your body, for example, from vomiting, diarrhea, or being in the sun too long
- **serious urinary tract infections.** Serious urinary tract infections that may lead to hospitalization have happened in people who are taking STEGLATRO. Tell your doctor if you have any signs or symptoms of a urinary tract infection such as a burning feeling when passing urine, a need to urinate often, the need to urinate right away, pain in the lower part of your stomach (pelvis), or blood in the urine. Sometimes people may also have a fever, back pain, nausea, or vomiting.
- **amputations. STEGLATRO may increase your risk of lower limb amputations. Amputations mainly involve removal of the toe.**

You may be at a higher risk of lower limb amputation if you:

- have a history of amputation
- 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

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 STEGLATRO for a while if you have any of these signs or symptoms. Talk to your doctor about proper foot care.

- **low blood sugar (hypoglycemia).** If you take STEGLATRO 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 or insulin may need to be lowered while you take STEGLATRO. Signs and symptoms of low blood sugar may include:
 - headache
 - drowsiness
 - hunger
 - irritability
 - dizziness
 - confusion
 - sweating
 - feeling jittery or shaky
 - weakness
 - fast heartbeat
- **a rare but serious bacterial infection that causes damage to the tissue under the skin (necrotizing fasciitis) in the area between and around the anus and genitals (perineum).** Necrotizing fasciitis of the perineum has happened in women and men who take medicines that lower blood sugar in the same way as STEGLATRO. Necrotizing fasciitis of the perineum may lead to hospitalization, may require multiple surgeries, and may lead to death. **Seek medical attention immediately if you have 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)
- **increased fats in your blood (bad cholesterol or LDL).**

The most common side effects of STEGLATRO include:

- vaginal yeast infections and yeast infections of the penis (**See “What is the most important information I should know about STEGLATRO?”**)
- 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 STEGLATRO.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

How should I store STEGLATRO?

- Store STEGLATRO at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep STEGLATRO dry.
- Store blister packs of STEGLATRO in the original package.

Keep STEGLATRO and all medicines out of the reach of children.

General information about the safe and effective use of STEGLATRO.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use STEGLATRO for a condition for which it was not prescribed. Do not give STEGLATRO to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or doctor for information about STEGLATRO that is written for health professionals. For more information about STEGLATRO, go to www.steglatro.com or call 1-800-622-4477.

What are the ingredients in STEGLATRO?

Active ingredient: ertugliflozin.

Inactive ingredients: microcrystalline cellulose, lactose monohydrate, sodium starch glycolate, and magnesium stearate. The tablet film coating contains the following inactive ingredients: hypromellose, lactose monohydrate, macrogol, triacetin, titanium dioxide, and iron oxide red.

Manufactured for: Merck Sharp & Dohme Corp., a subsidiary of
 **MERCK & CO., INC.**, Whitehouse Station, NJ 08889, USA

For patent information, go to: www.merck.com/product/patent/home.html.
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This Medication Guide has been approved by the U.S. Food and Drug Administration.

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