

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 healthcare provider 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:

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

- **Amputations. STEGLATRO may increase your risk of lower limb amputations.**

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 healthcare provider right away if you have new pain or tenderness, any sores, ulcers, or infections in your leg or foot. Talk to your healthcare provider about proper foot care.

- **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). There have been reports of sudden worsening of kidney function in people who are taking STEGLATRO.**

You may be at risk of dehydration if you:

- take medicines to lower your blood pressure, including water pills (diuretics)
- are on a low sodium (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 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.

- **Genital and urinary tract infections.** STEGLATRO 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 urineYou 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 is STEGLATRO?

- STEGLATRO is a prescription medicine used in adults with type 2 diabetes to improve blood sugar (glucose) control along with diet and exercise.
- STEGLATRO is not recommended to decrease blood sugar (glucose) in people with type 1 diabetes.
- It is not known if STEGLATRO is safe and effective in children under 18 years of age.

Who should not take STEGLATRO?

Do not take STEGLATRO if you:

- 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

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

Before you take STEGLATRO, tell your healthcare provider about all of your medical conditions, including 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 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.
- 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 change your diet or your dose.
- are going to have surgery. Your healthcare provider may stop your STEGLATRO before you have surgery. Talk to your healthcare provider if you are having surgery about when to stop taking STEGLATRO 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).
- have ever had an allergic reaction to STEGLATRO.
- are pregnant or plan to become pregnant. STEGLATRO may harm your unborn baby. If you become pregnant while taking STEGLATRO, 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 STEGLATRO passes into your breast milk. You should not breastfeed if you take STEGLATRO.

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

STEGLATRO may affect the way other medicines work, and other medicines may affect how STEGLATRO 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 STEGLATRO?

- Take STEGLATRO by mouth 1 time in the morning each day, with or without food, exactly as your healthcare provider tells you to take it.
- Your healthcare provider 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?”**.
- 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. Talk with your healthcare provider if you have questions about a missed dose.
- If you take too much STEGLATRO, call your healthcare provider 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.
- STEGLATRO will cause your urine to test positive for glucose.
- Your healthcare provider may do certain blood tests before you start STEGLATRO and during treatment as needed. Your healthcare provider may change your dose of STEGLATRO based on the results of your blood tests.

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?”**

- **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
 - weakness
 - confusion
 - dizziness
 - sweating
 - hunger
 - fast heartbeat
 - irritability
 - shaking or feeling jittery
- **Serious allergic reaction.** If you have any symptoms of a serious allergic reaction, stop taking STEGLATRO and call your healthcare provider right away or go to the nearest hospital emergency room. See **“Who should not take STEGLATRO?”**. 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 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 healthcare provider for medical advice about side effects. You may report side effects to 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.

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 healthcare provider 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.

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

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