Medication Guide
SEGLUROMET® [seg-LUR-oh-met]
(ertugliflozin and metformin hydrochloride)
tablets, for oral use

Read this Medication Guide carefully before you start taking SEGLUROMET 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 SEGLUROMET?
SEGLUROMET may cause serious side effects, including:
Lactic Acidosis. Metformin, one of the medicines in SEGLUROMET, can cause a rare but serious condition called lactic acidosis (a buildup of an acid in the blood) that can cause death. Lactic acidosis is a medical emergency and must be treated in the hospital.
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 very weak or tired
- you have trouble breathing
- you have stomach pains, nausea or vomiting
- you have a slow or irregular heartbeat
- you have unusual (not normal) muscle pain
- you have unusual sleepiness or sleep longer than usual
- you feel dizzy or lightheaded

Most people who have had lactic acidosis had other conditions that, in combination with 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 SEGLUROMET 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 a heart attack, severe infection, or stroke.

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 SEGLUROMET 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.** SEGLUROMET 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 SEGLUROMET 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

SEGLUROMET can have other serious side effects. See "What are the possible side effects of SEGLUROMET?"

What is SEGLUROMET?

- SEGLUROMET contains 2 prescription medicines called ertugliflozin (STEGLATRO®) and metformin hydrochloride. SEGLUROMET is used in adults with type 2 diabetes to improve blood sugar (glucose) along with diet and exercise.
- SEGLUROMET is not recommended to decrease blood sugar (glucose) in people with type 1 diabetes. It is not known if SEGLUROMET is safe and effective in children under 18 years of age.

Who should not take SEGLUROMET?

Do not take SEGLUROMET if you:

- have severe kidney problems, have end stage renal disease (ESRD) or are on dialysis.
- have a condition called metabolic acidosis or diabetic ketoacidosis (increased ketones in the blood or urine).
- are allergic to ertugliflozin, metformin, or any of the ingredients in SEGLUROMET. See the end of this Medication Guide for a list of ingredients in SEGLUROMET. Symptoms of a **serious** allergic reaction to SEGLUROMET 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 SEGLUROMET and call your healthcare provider right away or go to the nearest hospital emergency room.

Before you take SEGLUROMET, 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 the 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.
- have heart problems, including congestive heart failure.
- are going to have surgery. Your healthcare provider may stop your SEGLUROMET before you have surgery. Talk to your healthcare provider if you are having surgery about when to stop taking SEGLUROMET 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 SEGLUROMET.
- are going to get an injection of dye or contrast agents for an x-ray procedure. SEGLUROMET may need to be stopped for a short time. Talk to your healthcare provider about when you should stop SEGLUROMET and when you should start SEGLUROMET again. See **"What is the most important information I should know about SEGLUROMET?"**
- are pregnant or plan to become pregnant. SEGLUROMET may harm your unborn baby. If you become pregnant while taking SEGLUROMET, 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 a premenopausal woman (before the "change of life"), who does not have periods regularly or at all. Talk to your healthcare provider about birth control choices while taking SEGLUROMET if you are not planning to become pregnant since SEGLUROMET may increase your chance of becoming pregnant. Tell your healthcare provider right away if you become pregnant while taking SEGLUROMET.
- are breastfeeding or plan to breastfeed. It is not known if SEGLUROMET passes into your breast milk. You should not breastfeed if you take SEGLUROMET.

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

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

- Take SEGLUROMET by mouth 2 times a day with meals, exactly as your healthcare provider tells you to take it. Taking SEGLUROMET with meals may lower your chance of having an upset stomach.
- Your healthcare provider may tell you to take SEGLUROMET along with other diabetes medicines. Low blood sugar can happen more often when SEGLUROMET is taken with certain other diabetes medicines. See "**What are the possible side effects of SEGLUROMET?**"
- 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 SEGLUROMET at the same time. Talk with your healthcare provider if you have questions about a missed dose.
- If you take too much SEGLUROMET, 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.
- SEGLUROMET will cause your urine to test positive for glucose.
- Your healthcare provider may do certain blood tests before you start SEGLUROMET and during treatment as needed. Your healthcare provider may change your dose of SEGLUROMET based on the results of your blood tests.

What should I avoid while taking SEGLUROMET?

- 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 SEGLUROMET?
SEGLUROMET may cause serious side effects, including:
See "**What is the most important information I should know about SEGLUROMET?**"

- **Amputations. SEGLUROMET 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. Your healthcare provider may decide to stop your SEGLUROMET for a while if you have any of these signs or symptoms. Talk to your healthcare provider about proper foot care.

- **Dehydration. SEGLUROMET 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 SEGLUROMET.**

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.

- **Serious urinary tract infections.** Serious urinary tract infections that may lead to hospitalization have happened in people who are taking SEGLUROMET. Tell your healthcare provider 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.
- **Low blood sugar (hypoglycemia).** If you take SEGLUROMET 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 SEGLUROMET. Signs and symptoms of low blood sugar may include:
  - headache
  - confusion
  - hunger
  - shaking or feeling jittery
  - drowsiness
  - dizziness
  - fast heartbeat
  - weakness
  - sweating
  - irritability
- **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 one of the medicines in SEGLUROMET. 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 above 100.4ºF 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)
- **Vaginal yeast infection.** 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)**. 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:
  - redness, itching, or swelling of the penis
  - foul smelling discharge from the penis
  - rash of the penis
  - pain in the skin around your 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 medicine and your symptoms do not go away.

- **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} blood levels before. Your healthcare provider may do blood tests to check your vitamin B_{12} levels.
- **Serious allergic reaction.** If you have any symptoms of a serious allergic reaction, stop taking SEGLUROMET and call your healthcare provider right away or go to the nearest hospital emergency room. See "**Who should not take SEGLUROMET?**". 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 ertugliflozin include:

- vaginal yeast infections and yeast infections of the penis **(See "What is the most important information I should know about SEGLUROMET?")**
- changes in urination, including urgent need to urinate more often, in larger amounts, or at night

The most common side effects of metformin hydrochloride include:

- diarrhea
- nausea
- stomach discomfort
- vomiting
- gas
- headache
- indigestion
- weakness

These are not all the possible side effects of SEGLUROMET.
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 SEGLUROMET?

- Store SEGLUROMET at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep SEGLUROMET dry.

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

General information about the safe and effective use of SEGLUROMET.
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use SEGLUROMET for a condition for which it was not prescribed. Do not give SEGLUROMET 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 SEGLUROMET that is written for health professionals.
For more information about SEGLUROMET, go to www.segluromet.com or call 1-800-622-4477.

What are the ingredients in SEGLUROMET?
Active ingredients: ertugliflozin and metformin hydrochloride.
Inactive ingredients: povidone, microcrystalline cellulose, crospovidone, sodium lauryl sulfate, and magnesium stearate.
The tablet film coating contains the following inactive ingredients: hydroxypropyl methylcellulose, hydroxypropyl cellulose, titanium dioxide, iron oxide red, and carnauba wax.

Manufactured for: Merck Sharp & Dohme LLC

Rahway, NJ 07065, USA

For patent information, go to: www.msd.com/research/patent

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