

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE  
PATIENT MEDICATION INFORMATION**

** Segluromet™**

ertugliflozin and metformin hydrochloride tablets

Read this carefully before you start taking **Segluromet™** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Segluromet™**.

**Serious Warnings and Precautions**

**Lactic Acidosis**

**Lactic acidosis** is a rare but serious buildup of acid in the blood. It can cause death. It must be treated in the hospital. Segluromet™ contains a drug called metformin hydrochloride. If you build up too much metformin in your blood you are at risk for lactic acidosis.

Alcohol increases the risk of lactic acidosis caused by metformin. Do not ‘binge’ drink or drink alcohol often when you are taking Segluromet™.

**Diabetic Ketoacidosis**

**Diabetic ketoacidosis (DKA)** can happen while you are taking Segluromet™. It is a serious and life-threatening condition. Some cases of **DKA** can lead to death. It needs urgent hospital care. **DKA** can happen to diabetic patients with normal or high blood sugar levels. In **DKA** your body produces high levels of blood acids called ketones. It occurs when your body can't produce enough insulin.

Seek medical attention and **stop taking Segluromet™ right away** if you have any of the **DKA** symptoms. Do this even if your blood sugar levels are normal. The symptoms of **DKA** are: difficult breathing, nausea, vomiting, stomach pain, and loss of appetite. Confusion, thirst, unusual fatigue, sleepiness or tiredness, along with a sweet or metallic taste in the mouth or sweet smelling breath can be noticed. You may have a different odour to your urine or sweat.

Do not use Segluromet™ if you have type 1 diabetes. It is a disease where your body does not produce any insulin.

Do not use Segluromet™ if you have a history of **DKA**.

### **What is Segluromet™ used for?**

Segluromet™ is used with diet and exercise. It is used to improve blood sugar levels in adults with type 2 diabetes.

Segluromet™ can be used:

- when blood sugar is not controlled on metformin, or
- when blood sugar is already controlled on ertugliflozin and metformin, as individual drugs, or
- with sitagliptin, when blood sugar is not controlled on metformin and sitagliptin.

### **How does Segluromet™ work?**

Segluromet™ is a tablet. It contains two medicines. They are ertugliflozin and metformin hydrochloride. They work together to reduce the amount of sugar in your blood.

- ertugliflozin helps remove sugar from the body through the urine.
- metformin helps to lower the amount of sugar made by the liver.

### **What are the ingredients in Segluromet™?**

- Medicinal ingredients: **ertugliflozin** (in the form of ertugliflozin co-crystallized with L-pyroglutamic acid) and **metformin hydrochloride**
- Non-medicinal ingredients: carnauba wax, crospovidone, hydroxypropyl cellulose, hypromellose, iron oxide red, magnesium stearate, microcrystalline cellulose, povidone, sodium lauryl sulfate and titanium dioxide.

### **Segluromet™ comes in the following dosage forms:**

Tablets: 2.5 mg/500 mg, 2.5 mg/1000 mg, 7.5 mg/500 mg, 7.5 mg/1000 mg of ertugliflozin / metformin hydrochloride.

### **Do not use Segluromet™ if you:**

- Are allergic to any of its ingredients;
- Have kidney disease;
- Have liver problems;
- Are experiencing a loss of fluids from the body for any reason (severe dehydration). This could be due to excess heat exposure, vomiting or diarrhea. It can be due to reduced drinking with illness or fasting;
- Drink alcohol very often, or drink a lot of alcohol in the short term (“binge” drinking);
- Have severe heart problems or heart failure;
- Have a lack of oxygen in the blood. This is called hypoxemia. This can happen when you have conditions that affect your heart or breathing;
- Have a severe infection, are experiencing trauma, are about to have surgery, or are recovering from surgery;
- Have severe **dehydration** or shock;
- Are pregnant or planning to become pregnant. It is not known if Segluromet™ may harm your unborn baby. If you are pregnant, talk with your doctor about the best way to control your blood sugar while you are pregnant;

- Are breast-feeding or plan to breast-feed. It is not known if Segluromet™ passes into breast milk. Talk with your doctor if you would like to breast-feed;
- Are going to receive an injection of dye or a contrast agent for an x-ray procedure. Talk to your physician or pharmacist about when to stop Segluromet™ and when to start again.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Segluromet™. Talk about any health conditions or problems you may have, including if you:**

- are older than 65 years of age;
- are older than 80 years old of age. The doctor needs to check how well your kidneys work before you start on Segluromet™;
- have kidney problems;
  - You have a higher chance of having **Kidney problems**, if you:
    - are dehydrated or suffer from excessive vomiting, diarrhea, or sweating;
    - are not eating and drinking as per your normal diet. For example you are fasting or ill.
    - have existing kidney issues;
    - have heart failure;
    - take or change other medications such as a diuretic, blood pressure pill or an NSAID;
    - are over 65 years old.
- have heart failure or heart disease;
- have low blood pressure;
- are taking a high blood pressure medicine;
- are taking a diuretic medicine also known as water pills. They are used to remove excess water from the body;
- often get urinary tract infections;
- have an increased chance of developing **DKA**, if you:
  - are dehydrated or suffer from excessive vomiting, diarrhea, or sweating;
  - are on a very low carbohydrate diet;
  - drink a lot of alcohol;
  - have/have had problems with your pancreas. This includes pancreatitis or surgery on your pancreas;
  - are hospitalized for major surgery, serious infection, or sudden serious medical illness;
  - have a history of **DKA**.
- have vitamin B<sub>12</sub> deficiency or anemia;
- have hypothyroidism (low levels of thyroid hormones);
- are at increased risk for a possible **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. This feels like tingling or numb hands and feet;
  - have had diabetic foot ulcers or sores;
  - have a lower limb infection;
  - are dehydrated. Staying well hydrated and doing regular foot care may help you avoid amputations. Ask your doctor for advice on these topics.

**Other warnings you should know about:**

- You have a higher chance of getting **lactic acidosis** if you:
  - have severe kidney problems;  
Your kidneys can be affected by certain x-ray tests that use injected dye. Segluromet™ is usually stopped before and for two days after such a test. Your doctor should discuss this with you;
  - drink a lot of alcohol (very often or short-term “binge” drinking);
  - get **dehydration** (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 don’t drink enough fluids;
  - have surgery. Talk with your doctor before any surgery if you must restrict what you eat and drink. In these cases, Segluromet™ should be stopped for 2 days before the surgery. Wait until you are eating and drinking again before you restart Segluromet™. Your doctor should discuss this with you;
  - have a heart attack, severe infection, or stroke;
  - take other medications.
- Segluromet™ is not recommended for use in patients under 18 years of age.
- Segluromet™ may cause higher levels of bad cholesterol, called LDL. This is a type of fat in your blood.
- Segluromet™ increases the chance of getting a yeast infection of the penis or vagina. This is more likely in people who have had yeast infections in the past. It is also more common in uncircumcised men. In rare instances, phimosis (when the foreskin of the penis cannot be pulled back past the glans) was reported and sometimes circumcision was performed.
- Segluromet™ may cause abnormal kidney function or **kidney problems**.

**Driving and using machines:** Segluromet™ may cause you to feel dizzy, weak or lightheaded. Do not drive or use machines until you know how the medicine affects you.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements, or alternative medicines.**

If you start any new medicine, tell your healthcare professional.

**The following may interact with Segluromet™:**

- Nifedipine (used to treat high blood pressure and chest pain).
- Cationic drugs (e.g., amiloride, digoxin, morphine, procainamide, quinidine, quinine, ranitidine, triamterene, trimethoprim and vancomycin).
- Certain “blood thinners” (phenprocoumon or other Vitamin K anticoagulants).
- Diuretics, known as water pills. They are used to remove excess water from the body.
- Medicines to lower your blood pressure.
- Other drugs that tend to produce high blood sugar (hyperglycemia) and may lead to a loss of blood sugar control. Some example of drugs that can increase the blood sugar include:
  - Thiazide and other diuretics (water pills)
  - Corticosteroids (used to treat joint pain and swelling)

- Phenothiazines (used to treat schizophrenia)
- Thyroid products
- Estrogens or estrogens plus progestogen
- Oral contraceptives (birth control pills)
- Phenytoin (used to treat epilepsy)
- Nicotinic Acid
- Sympathomimetics (used for heart problems)
- Calcium channel blocking drugs (used for high blood pressure)
- Isoniazid (used to treat tuberculosis)
- Beta-2-agonists (used to treat breathing problems)
- ACE inhibitor drugs (may lower blood glucose)
- Carbonic anhydrase inhibitors

Tell your healthcare professional if you take medicines to lower your blood sugar. Examples are glyburide, gliclazide, glimepiride (sulfonylureas) or insulin. If you take Segluromet™ with any of these drugs it can increase the risk of low blood sugar. This is called **hypoglycemia**. Segluromet™ is not approved for use with these drugs.

**How to take Segluromet™:**

- 2 times a day
- by mouth
- with a meal to lower your chance of an upset stomach

**Usual Adult dose:** 1 tablet twice a day.

Your doctor will individualize your starting dose of Segluromet™ based on your current treatment regimen. Take Segluromet™ exactly as your physician has prescribed.

Your doctor may adjust your dose, if needed to further control your blood sugar level.

**Overdose:**

If you think you have taken too much Segluromet™, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

**Missed Dose:**

- If you miss a dose, take it as soon as you remember. If you do not remember until it is time for your next dose, skip the missed dose and go back to your regular schedule.
- Do not take 2 doses of Segluromet™ at the same time.

**What are possible side effects from using Segluromet™?**

These are not all the possible side effects you may have when taking Segluromet™. If you experience any side effects not listed here, contact your healthcare professional.

**Side effects may include:**

- Unusual thirst
- Vaginal itching
- You feel generally well and have changes in your urination. These include the need to urinate more often, in larger amounts, or at night
- Headache
- **Gastrointestinal symptoms:** Diarrhea, nausea, vomiting. Abdominal bloating, gas and loss of appetite. Severe vomiting and diarrhea can lead to **dehydration**.
- Change in taste or a metallic taste
- Skin reactions such as redness, itching, and hives
- Liver problems

Segluromet™ will cause your urine to test positive for sugar (glucose). You should use a different way to monitor your diabetes.

Segluromet™ can cause abnormal blood test results. Your doctor may do blood tests before you start Segluromet™ and while you take it. They may check your blood sugar, blood fat levels, liver and thyroid function, amount of Vitamin B<sub>12</sub> and red blood cells in your blood and how well your kidneys are working. Your doctor will decide when to perform blood tests and will interpret the results.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>VERY COMMON</b>			
<b>Genital infections –Vaginal yeast infection:</b> severe itching, burning, soreness, irritation and a whitish-grey cottage cheese-like discharge.	X		
<b>COMMON</b>			
<b>Volume depletion (dehydration, loss of fluids from your body):</b> dry or sticky mouth, headache, dizziness, urinating less often than normal, thirst.		X	
<b>Low blood sugar (hypoglycemia):</b> shaking, sweating, rapid heartbeat, change in vision, hunger, headache and change in mood.		X	
<b>Genital infections – Yeast infection of the penis:</b> red, swollen, itchy head of the penis; thick, lumpy discharge under foreskin with an unpleasant odour; difficulty retracting foreskin, pain when passing urine or during sex.	X		
<b>UNCOMMON</b>			
<b>Urinary tract infection:</b> burning sensation when passing urine, pain in the pelvis or mid-back pain, increased need to urinate.		X	
<b>Acute kidney infection:</b> painful, urgent or frequent urination, lower back (flank) pain, fever or chills,			X

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
cloudy or foul smelling urine, blood in your urine.			
<b>Kidney problems:</b> you feel unwell and you have any change in the amount, frequency or colour (pale or dark) of your urine.		X	
<b>Low blood pressure:</b> dizziness, fainting, lightheadedness, which may occur when you go from sitting to standing up and when you start on Segluromet™.		X	
<b>Possible need for lower limb amputation:</b> on the feet, toes or legs, new pain or tenderness in a specific bone with redness; non-healing sores or ulcers; brownish/black cold skin.		X	
<b>RARE</b>			
<b>Diabetic ketoacidosis (DKA):</b> difficulty breathing, nausea, vomiting, stomach pain, loss of appetite, confusion, thirst, unusual fatigue, sleepiness or tiredness, a sweet or metallic taste in the mouth, sweet smelling breath, or different odour to urine or sweat.			X
<b>Encephalopathy</b> (disease of the brain that severely alters thinking): muscle weakness in one area, poor decision-making or concentration, involuntary twitching, trembling, difficulty speaking or swallowing, seizures.			X
<b>Lowering of TSH level in patients with low thyroid function.</b> Signs of low thyroid function are: fatigue, feeling cold, dry skin, poor memory and concentration, weight gain.		X	
<b>VERY RARE</b>			
<b>Lactic acidosis:</b> Malaise or a feeling of general discomfort, uneasiness or pain. Feel very weak or tired. Somnolence, sleepiness, drowsiness or an increasing strong desire for sleep. You can have low blood pressure, feel dizzy or lightheaded. Feel cold in your hands or feet. A slow or irregular heartbeat, trouble breathing. Unusual muscle pain. Stomach pain with nausea, vomiting, or diarrhea.			X
<b>Vitamin B<sub>12</sub> deficiency (decreased Vitamin B<sub>12</sub> levels in the blood):</b> fatigue, shortness of breath, tingling or numbness of the fingers or toes, difficulty walking properly, irritability, confusion, tender calves.		X	
<b>Hepatitis or Liver disorder:</b> Yellow of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite.		X	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

## Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### Storage:

Store at 15°C to 30°C. Protect from moisture.

Keep out of reach and sight of children.

### If you want more information about Segluromet™:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website or the Merck Canada website [www.merck.ca](http://www.merck.ca) or by calling Merck Canada at 1-800-567-2594.

To report an adverse event related to Segluromet™, please contact 1-800-567-2594.

This leaflet was prepared by Merck Canada Inc.

Last Revised: May 28, 2018

™ Merck Sharp & Dohme Corp. Used under license.

© 2018 Merck Canada Inc. All rights reserved.