

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

 **Steglujan™**

ertugliflozin and sitagliptin tablets

Read this carefully before you start taking Steglujan™ 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 Steglujan™.

Serious Warnings and Precautions

Diabetic ketoacidosis (DKA) can happen while you are taking Steglujan™. 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 cannot produce enough insulin.

Seek medical help and **stop taking Steglujan™ 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 Steglujan™ if you have type 1 diabetes. It is a disease where your body does not produce any insulin.

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

What is Steglujan™ used for?

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

Steglujan™ can be used:

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

How does Steglujan™ work?

Steglujan is a tablet. It contains two medicines. They are ertugliflozin and sitagliptin. They work together to reduce the amount of sugar in your blood.

- Ertugliflozin helps remove sugar from the body through the urine.
- Sitagliptin helps to increase your insulin when your blood sugar is high. This is especially true after a meal.

What are the ingredients in Steglujan™?

- Medicinal ingredients: **ertugliflozin** (in the form of ertugliflozin co-crystallized with L-pyroglutamic acid) and **sitagliptin** phosphate.
- Non-medicinal ingredients: carnauba wax, croscarmellose sodium, dibasic calcium phosphate anhydrous, ferrousferic oxide/black iron oxide, hydroxypropyl cellulose, hypromellose, iron oxide red, iron oxide yellow, magnesium stearate, microcrystalline cellulose, sodium stearyl fumarate, and titanium dioxide.

Steglujan™ comes in the following dosage forms:

Tablets: 5 mg/100 mg, 15 mg/100 mg of ertugliflozin/sitagliptin (as sitagliptin phosphate).

Do not use Steglujan™ if you:

- Are allergic to any of its ingredients.
- Have severe or end-stage kidney disease or are on dialysis. If you have moderate kidney problems, talk to your health care professional before you take Steglujan™.
- Have severe liver disease.
- Are experiencing a loss of fluids from the body for any reason. This could be due to excess heat exposure, vomiting, diarrhea or dehydration. It can be due to reduced drinking with illness or fasting.
- Are pregnant or planning to become pregnant. It is not known if Steglujan™ 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 Steglujan™ passes into breast milk. Talk with your doctor if you would like to breast-feed.

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

- are older than 65 years of age;
- have any kidney problems;
- have liver problems;
- have heart failure or heart disease;
- have or have had pancreatitis (inflammation of the pancreas)
- have risk factors for **pancreatitis** such as:
 - gallstones. These are solid particles that form in the gall bladder.
 - a history of alcoholism,
 - high triglyceride levels.

Pancreatitis can be severe and lead to death.

- have low blood pressure;
- had an organ transplant;
- have human immunodeficiency syndrome (HIV);
- are taking 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**
- 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:

- Steglujan™ is not recommended for use in patients under 18 years of age.
- Steglujan™ may cause higher levels of bad cholesterol, called LDL (a type of fat in your blood).
- Steglujan™ 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.
- Steglujan™ may cause abnormal kidney function.
- **Serious skin reactions** can occur. These skin reactions are called **Stevens-Johnson syndrome** and **bullous pemphigoid**. They can happen after the first dose or up to 3 months on the drug. You may need treatment in a hospital. You may need to see a dermatologist to diagnose and treat these skin reactions.

Driving and using machines: Steglujan™ 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 Steglujan™:

- diuretics, known as water pills. They are used to remove excess water from the body.
- medicines to lower your blood pressure.

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

How to take Steglujan™:

Follow the directions given to you by your doctor.

- once a day in the morning;
- by mouth;
- with or without food.

Usual Adult Dose: 1 tablet a day.

The usual starting dose is one 5 mg ertugliflozin/100 mg sitagliptin tablet each day. Your doctor may increase your dose to one 15 mg ertugliflozin/100 mg sitagliptin tablet to further control your blood sugar level.

Overdose:

If you think you have taken too much Steglujan™, 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 Steglujan™ on the same day.

What are possible side effects from using Steglujan™?

These are not all the possible side effects you may have when taking Steglujan™. 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
- Sore throat
- Stuffy or runny nose

Additional side effects have been reported:

- Vomiting
- Constipation
- Headache
- Joint pain
- Muscle aches
- Arm or leg pain
- Back pain
- Itching
- Blisters

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

Steglujan™ can cause abnormal blood test results. Your doctor may do blood tests before you start Steglujan™ and while you take it. They may check your blood sugar, blood fat levels, liver function, amount of 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	
VERY COMMON			
Genital infections – Vaginal yeast infection: severe itching, burning, soreness, irritation and a whitish-grey cottage cheese-like discharge.	X		
COMMON			
Volume depletion (dehydration, loss of fluids from your body): dry or sticky mouth, headache, dizziness, urinating less often than normal, thirst.		X	
Low blood sugar (hypoglycemia): shaking, sweating, rapid heartbeat, change in vision, hunger, headache and change in mood.		X	
Genital infections – Yeast infection of the penis: 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		
UNCOMMON			
Urinary tract infection: burning sensation when passing urine, pain in the pelvis or mid-back pain, increased need to urinate.		X	
Acute kidney infection: painful, urgent or frequent urination, lower back (flank) pain, fever or chills, cloudy or foul smelling urine, blood in your urine.			X
Kidney problems: you feel unwell and you have any change in the amount, frequency or colour (pale or dark) of your urine.		X	
Low blood pressure: dizziness, fainting, lightheadedness which may occur when you go from lying to sitting to standing up and when you start on Steglujan™.		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	
Possible need for lower limb amputation: 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	
RARE			
Diabetic ketoacidosis (DKA): 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
Pancreatitis: prolonged severe stomach pain and possible vomiting.			X
Allergic reactions: including rash, hives, and swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing.			X
Serious skin reactions including Stevens-Johnson syndrome, Bullous Pemphigoid: blisters or break down of skin.		X	
Acute kidney failure (sometimes requiring dialysis): nausea, loss of appetite and weakness, pass little or no urine, breathlessness			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 Steglujan™:

- 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 or by calling Merck Canada at 1-800-567-2594

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

This leaflet was prepared by Merck Canada Inc.

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