

Medication Guide
STEGLUJAN® [STEG-loo-jan]
(ertugliflozin and sitagliptin)
tablets, for oral use

Read this Medication Guide carefully before you start taking STEGLUJAN 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 STEGLUJAN?

STEGLUJAN may cause serious side effects, including:

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

- **Inflammation of the pancreas (pancreatitis)** which may be severe and lead to death. Certain medical problems make you more likely to get pancreatitis.

Before you start taking STEGLUJAN, tell your healthcare provider if you have ever had:

- pancreatitis
- a history of alcoholism
- kidney problems
- stones in your gallbladder (gallstones)
- high blood triglyceride levels

Stop taking STEGLUJAN and call your healthcare provider right away if you have pain in your stomach area (abdomen) that is severe and will not go away. The pain may be felt going from your abdomen through to your back. The pain may happen with or without vomiting. These may be symptoms of pancreatitis.

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

- **Dehydration. STEGLUJAN 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 STEGLUJAN.

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.

• **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
- rash of the penis
- foul smelling discharge from 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.

• **Heart failure.** Heart failure means your heart does not pump blood well enough.

Before you start taking STEGLUJAN, tell your healthcare provider if you have ever had heart failure or have problems with your kidneys. Contact your healthcare provider right away if you have any of the following symptoms:

- increasing shortness of breath or trouble breathing, especially when you lie down
- swelling or fluid retention, especially in the feet, ankles or legs
- an unusually fast increase in weight
- unusual tiredness

These may be symptoms of heart failure.

What is STEGLUJAN?

STEGLUJAN contains 2 prescription medicines called ertugliflozin (STEGLATRO®) and sitagliptin (JANUVIA®). STEGLUJAN is used in adults with type 2 diabetes to improve blood sugar (glucose) along with diet and exercise.

- STEGLUJAN is not recommended to decrease blood sugar (glucose) in people with type 1 diabetes.
- If you have had pancreatitis (inflammation of the pancreas) in the past, it is not known if you have a higher chance of getting pancreatitis while you take STEGLUJAN.
- It is not known if STEGLUJAN is safe and effective in children under 18 years of age.

Who should not take STEGLUJAN?

Do not take STEGLUJAN if you:

- have severe kidney problems, end stage renal disease (ESRD), or are on dialysis.
- are allergic to ertugliflozin, sitagliptin, or any of the ingredients in STEGLUJAN. See the end of this Medication Guide for a list of ingredients in STEGLUJAN. Symptoms of a **serious** allergic

reaction to STEGLUJAN 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 STEGLUJAN and call your healthcare provider right away or go to the nearest hospital emergency room.

Before you take STEGLUJAN, 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 STEGLUJAN before you have surgery. Talk to your healthcare provider if you are having surgery about when to stop taking STEGLUJAN 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 STEGLUJAN.
- are pregnant or plan to become pregnant. STEGLUJAN may harm your unborn baby. If you become pregnant while taking STEGLUJAN, 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 STEGLUJAN passes into your breast milk. You should not breastfeed if you take STEGLUJAN.

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

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

- Take STEGLUJAN 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 STEGLUJAN along with other diabetes medicines. Low blood sugar can happen more often when STEGLUJAN is taken with certain other diabetes medicines. See **“What are the possible side effects of STEGLUJAN?”**.
- 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 STEGLUJAN at the same time. Talk with your healthcare provider if you have questions about a missed dose.
- If you take too much STEGLUJAN, 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.
- STEGLUJAN will cause your urine to test positive for glucose.
- Your healthcare provider may do certain blood tests before you start STEGLUJAN and during treatment as needed. Your healthcare provider may change your dose of STEGLUJAN based on the results of your blood tests.

What are the possible side effects of STEGLUJAN?

STEGLUJAN may cause serious side effects, including:

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

- **Kidney problems (sometimes requiring dialysis).** Sudden kidney injury has happened to people treated with STEGLUJAN. Talk to 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 STEGLUJAN. 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 STEGLUJAN 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 STEGLUJAN. Signs and symptoms of low blood sugar may include:

○ headache	○ drowsiness	○ weakness
○ confusion	○ dizziness	○ sweating
○ hunger	○ fast heartbeat	○ irritability
○ shaking or feeling jittery		
- **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 STEGLUJAN. 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 100.4°F 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)
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- **Serious allergic reactions.** If you have any symptoms of a serious allergic reaction, stop taking STEGLUJAN and call your healthcare provider right away or go to the nearest hospital emergency room. See **“Who should not take STEGLUJAN?”**. Your healthcare provider may give you a medicine for your allergic reaction and prescribe a different medicine for your diabetes.
- **Joint pain.** Some people who take medicines called DPP-4 inhibitors, one of the medicines in STEGLUJAN, may develop joint pain that can be severe. Call your healthcare provider if you have severe joint pain.
- **Skin reaction.** Some people who take medicines called DPP-4 inhibitors, one of the medicines in STEGLUJAN, may develop a skin reaction called bullous pemphigoid that can require treatment in a hospital. Tell your healthcare provider right away if you develop blisters or the breakdown of the outer layer of your skin (erosion). Your healthcare provider may tell you to stop taking STEGLUJAN.

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 STEGLUJAN?”**)
- changes in urination, including urgent need to urinate more often, in larger amounts, or at night.

The most common side effects of sitagliptin include:

- upper respiratory infection
- stuffy or runny nose and sore throat
- headache
- stomach upset and diarrhea

STEGLUJAN may have other side effects including swelling of the hands or legs. Swelling of the hands and legs can happen when sitagliptin, one of the medicines in STEGLUJAN, is used with rosiglitazone (Avandia®). Rosiglitazone is another type of diabetes medicine.

These are not all the possible side effects of STEGLUJAN.

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 STEGLUJAN?

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

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

General information about the safe and effective use of STEGLUJAN.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use STEGLUJAN for a condition for which it was not prescribed. Do not give STEGLUJAN 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 STEGLUJAN that is written for health professionals.

For more information about STEGLUJAN, go to www.steglujan.com or call 1-800-622-4477.

What are the ingredients in STEGLUJAN?

Active ingredients: ertugliflozin and sitagliptin.

Inactive ingredients: microcrystalline cellulose, dibasic calcium phosphate anhydrous, croscarmellose sodium, sodium stearyl fumarate, magnesium stearate, and propyl gallate.

The tablet film coating contains the following inactive ingredients: hypromellose, hydroxypropyl cellulose, titanium dioxide, iron oxide red, iron oxide yellow, ferrousferric oxide/black iron oxide, and carnauba wax.

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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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