

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 doctor 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:

- **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 doctor 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 doctor 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.

- **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).

You may be at risk of dehydration if you:

- have low blood pressure
- take medicines to lower your blood pressure, including water pills (diuretics)
- have kidney problems
- are on a low sodium (salt) diet
- are 65 years of age or older

Talk to your doctor about what you can do to prevent dehydration including how much fluid you should drink on a daily basis.

- **Vaginal yeast infection.** Women who take STEGLUJAN may get vaginal yeast infections.

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).** Men who take STEGLUJAN may get a yeast infection of the skin around the penis. Certain men who are not circumcised may have swelling of the penis that makes it difficult to pull back the skin around the tip of your 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 doctor about what to do if you get symptoms of a yeast infection of the vagina or penis. Your doctor may suggest you use an over-the-counter antifungal medicine. Talk to your doctor 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 doctor if you have ever had heart failure or have problems with your kidneys. Contact your doctor 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 diabetes medicines called ertugliflozin (STEGLATRO™) and sitagliptin (JANUVIA®). STEGLUJAN can be used along with diet and exercise to lower blood sugar in adults with type 2 diabetes.
- STEGLUJAN is not for people with type 1 diabetes.
- STEGLUJAN is not for people with diabetic ketoacidosis (increased ketones in your blood or urine).
- 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.

Do not take STEGLUJAN if you:

- have severe kidney problems 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.

Before you take STEGLUJAN, tell your doctor about all of your medical conditions, including if you:

- have type 1 diabetes or have had diabetic ketoacidosis.
- have kidney problems.
- have liver problems.
- have or have had problems with your pancreas, including pancreatitis or surgery on your pancreas.
- have a history of urinary tract infections or problems with urination.
- are eating less due to illness, surgery, or a change in your diet.
- 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.
- are going to have surgery.
- drink alcohol very often, or drink a lot of alcohol in the short term (“binge” drinking).
- are pregnant or plan to become pregnant. STEGLUJAN may harm your unborn baby. If you become pregnant while taking STEGLUJAN, your doctor may switch you to a different medicine to control your blood sugar. Talk to your doctor about the best way to control your blood sugar if you plan to become pregnant or while you are pregnant.
Pregnancy Registry: If you take STEGLUJAN at any time during your pregnancy, talk with your doctor about how you can join the STEGLUJAN pregnancy registry. The purpose of this registry is to collect information about the health of you and your baby. You can enroll in this registry by calling 1-800-986-8999.
- 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 doctor about all of the medicines you take, including prescription and over-the-counter

medicines, vitamins, and herbal supplements.

How should I take STEGLUJAN?

- Take STEGLUJAN exactly as your doctor tells you to take it.
- Take STEGLUJAN by mouth 1 time in the morning each day, with or without food.
- Your doctor may change your dose if needed.
- 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.
- Your doctor 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?”.
- Stay on your prescribed diet and exercise program while taking STEGLUJAN.
- Check your blood sugar as your doctor tells you to.
- Your doctor will check your diabetes with regular blood tests, including your blood sugar levels and your HbA1c.
- Talk to your doctor about how to prevent, recognize and manage low blood sugar (hypoglycemia), high blood sugar (hyperglycemia), complications of diabetes.
- Your doctor will do blood tests to check how well your kidneys are working before and during your treatment with STEGLUJAN.
- 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 doctor right away if you have any of these conditions and follow your doctor’s instructions.
- When taking STEGLUJAN, you may have sugar in your urine, which will show up on a urine test.
- If you take too much STEGLUJAN, call your doctor or go to the nearest hospital emergency room right away.

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?**”

- **ketoacidosis (increased ketones in your blood or urine).** Ketoacidosis has happened in people who have **type 1 diabetes or type 2 diabetes** during treatment with STEGLUJAN. Ketoacidosis is a serious condition, which may need to be treated in a hospital. Ketoacidosis may lead to death. **Ketoacidosis can happen even if your blood sugar is less than 250 mg/dL. Stop taking STEGLUJAN and call your doctor right away if you get any of the following symptoms:**
 - nausea
 - vomiting
 - stomach area (abdominal) pain
 - tiredness
 - trouble breathing

If you get any of these symptoms during treatment with STEGLUJAN, if possible check for ketones in your urine, even if your blood sugar is less than 250 mg/dL.

- **kidney problems (sometimes requiring dialysis).** Sudden kidney injury has happened to people treated with STEGLUJAN. Talk to your doctor 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 doctor 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.

- **amputations.** STEGLUJAN may increase your risk of lower limb amputations. Amputations mainly involve removal of the toe.

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 doctor right away if you have new pain or tenderness, any sores, ulcers, or infections in your leg or foot. Your doctor may decide to stop your STEGLUJAN for a while if you have any of these signs or symptoms. Talk to your doctor about proper foot care.

- **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
 - dizziness
 - weakness
 - drowsiness
 - confusion
 - fast heartbeat
 - hunger
 - sweating
 - irritability
 - feeling jittery or shaky
- **increased fats in your blood (bad cholesterol or LDL).**
- **serious allergic reactions.** If you have any symptoms of a serious allergic reaction, stop taking STEGLUJAN and call your doctor right away. See **“Do not take STEGLUJAN if you:”**. Your doctor 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 doctor 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 doctor right away if you develop blisters or the breakdown of the outer layer of your skin (erosion). Your doctor 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 doctor for medical advice about side effects. You may report side effects to the 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.
- Store blister packs of STEGLUJAN in the original package.

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 doctor 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, and magnesium stearate.

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

Manufactured for: Merck Sharp & Dohme Corp., a subsidiary of
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This Medication Guide has been approved by the U.S. Food and Drug Administration.

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