PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS REGULATIONS (PREPARATIONS) 1986

This medicine is marketed upon physician's prescription only

STEGLUJAN® 5/100 MG TABLETS
STEGLUJAN® 15/100 MG TABLETS
FILM-COATED TABLET

Each **STEGLUJAN 5/100 MG** film-coated tablet contains:
5 mg ertugliflozin (as ertugliflozin L-pyroglutamic acid) and 100 mg sitagliptin (as sitagliptin phosphate monohydrate).

Each **STEGLUJAN 15/100 MG** film-coated tablet contains:
15 mg ertugliflozin (as ertugliflozin L-pyroglutamic acid) and 100 mg sitagliptin (as sitagliptin phosphate monohydrate).

For the list of inactive ingredients see section 6 “FURTHER INFORMATION”. See also section 2.9 “Important information about some of the ingredients of the medicine”.

Read the entire leaflet carefully before using the medicine.
- This leaflet contains concise information about the medicine. If you have any further questions, refer to the doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. WHAT STEGLUJAN IS INTENDED FOR?
STEGLUJAN is indicated in adults aged 18 years and older with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control:
- when metformin and/or a sulphonylurea (SU) and one of the monocomponents of **STEGLUJAN** do not provide adequate glycaemic control
- in patients already being treated with the combination of ertugliflozin and sitagliptin as separate tablets.

Therapeutic group:
- Ertugliflozin belongs to a group of medicines called sodium glucose co-transporter-2 (SGLT2) inhibitors.
- Sitagliptin belongs to a group of medicines called DPP-4 (dipeptidyl peptidase-4) inhibitors.

How STEGLUJAN works
- Ertugliflozin works by blocking the SGLT2 protein in your kidneys. This causes blood sugar to be removed in your urine.
- Sitagliptin helps to increase the levels of insulin produced after a meal. It also lowers the amount of sugar made by your body.

What is type 2 diabetes?
Type 2 diabetes is a condition in which your body does not make enough insulin or the insulin that your body produces does not work as well as it should. Your body can also make too much sugar. When this happens, sugar (glucose) builds up in the blood. This can lead to serious medical problems, like heart disease, kidney disease, blindness and poor circulation.

2. BEFORE USING STEGLUJAN

2.1 Do not use STEGLUJAN if:

you are allergic to ertugliflozin or sitagliptin or any of the other ingredients of this medicine (listed in section 6).

2.2 Special warnings regarding use of STEGLUJAN

Before starting treatment with STEGLUJAN tell the doctor if you:

- have kidney problems.
- have or have had yeast infections of the vagina or penis.
- have ever had serious heart disease or if you have had a stroke.
- have or have had a disease of the pancreas (such as pancreatitis).
- have type 1 diabetes. **STEGLUJAN** should not be used to treat this condition.
- take other diabetes medicines: you are more likely to get low blood sugar with certain medicines.
- might be at risk of dehydration (for example, if you are taking medicines that increase urine production [diuretics] or lower blood pressure or if you are over 65 years old). Ask about ways to prevent dehydration.
- have or have had gallstones, alcohol dependence or very high levels of triglycerides (a form of fat) in your blood. These medical conditions can increase your chance of getting pancreatitis (see section 4).
- experience rapid weight loss, feeling sick or being sick, stomach pain, excessive thirst, fast and deep breathing, confusion, unusual sleepiness or tiredness, a sweet smell to your breath, a sweet or metallic taste in your mouth or a different odour to your urine or sweat contact a doctor or the nearest hospital straight away. These symptoms could be a sign of “diabetic ketoacidosis” – a problem you can get with diabetes because of increased levels of “ketone bodies” in your urine or blood, seen in tests. The risk of developing diabetic ketoacidosis may be increased with prolonged fasting, excessive alcohol consumption, dehydration, sudden reductions in insulin dose, or a higher need of insulin due to major surgery or serious illness.

It is important to check your feet regularly and adhere to any other advice regarding foot care given by your healthcare professional.

Cases of inflammation of the pancreas (pancreatitis) have been reported in patients receiving sitagliptin (see section 4).

Talk to your doctor immediately if you develop a combination of symptoms of pain, tenderness, redness, or swelling of the genitals or the area between the genitals and the anus with fever or feeling generally unwell. These symptoms could be a sign of a rare but serious or even life-threatening infection, called necrotising fasciitis of the perineum or Fournier’s gangrene which destroys the tissue under the skin. Fournier’s gangrene has to be treated immediately.

When this medicine is used in combination with insulin or medicines that increase insulin release from the pancreas, low blood sugar (hypoglycaemia) can occur. Your doctor may reduce the dose of your insulin or other medicine.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

Urine glucose

Because of how **STEGLUJAN** works, your urine will test positive for sugar (glucose) while you are on this medicine.

2.3 Tests and follow-up

Your doctor will do blood tests to check how well your kidneys are working before and during your treament with **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 hemoglobin A1C.

2.4 Children and adolescents
Children and adolescents below 18 years should not take this medicine. It is not known if this medicine is safe and effective when used in children and adolescents under 18 years of age.

2.5 Interactions with other medicines
If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially if you are taking:
- medicines which increase urine production (diuretics).
- other medicines that lower the amount of sugar in your blood, such as insulin or medicines that increase insulin release from the pancreas.
- digoxin (a medicine used to treat irregular heartbeat and other heart problems). The level of digoxin in your blood may need to be checked if you are taking it with **STEGLUJAN**.

If any of the above apply to you (or you are not sure), tell your doctor.

2.6 Using this medicine and food
You can take your tablet with or without food.

2.7 Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

It is not known if **STEGLUJAN** can harm your unborn baby. You should not take this medicine during pregnancy.

It is not known if this medicine passes into breast milk. Talk with your doctor about the best way to feed your baby if you take **STEGLUJAN**. You should not use this medicine if you are breast-feeding or plan to breast-feed.

2.8 Driving and using machines
This medicine has no or negligible influence on the ability to drive and use machines. However, dizziness and drowsiness have been reported with sitagliptin, which may affect your ability to drive or use machines. Do not drive or use any tools or machines if you feel dizzy while taking **STEGLUJAN**.

Taking this medicine in combination with insulin or medicines that increase insulin release from the pancreas can cause blood sugar levels to drop too low (hypoglycaemia), which may cause symptoms such as shaking, sweating or changes in vision and may affect your ability to drive and use machines.

2.9 Important information about some of the ingredients of the medicine
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

3. HOW TO USE STEGLUJAN?
Always use **STEGLUJAN** according to the doctor's instructions. You should check with the doctor or pharmacist if you are not sure regarding the dosage and treatment regimen.
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The dosage and treatment regimen will be determined by the doctor only.

The recommended dose of **STEGLUJAN** is one tablet once a day.
The dose of **STEGLUJAN** that you take will depend on your condition and the amount of ertugliflozin and sitagliptin needed to control your blood sugar.

Do not exceed the recommended dose.

Method of administration
- Swallow the tablet; if you have difficulties with swallowing, you can split, chew, brake or crush the tablet for immediate use.
- Take one tablet every morning. Try to take it at the same time; this will help you remember to take it.
- You can take your tablet with or without food.
- You need to keep following your food and exercise plan while taking **STEGLUJAN**.

If you have accidentally taken a higher dose than you should
If you have taken an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or to a hospital emergency room and bring the package of the medicine with you.

If you have forgotten to take STEGLUJAN
If you forget a dose, take it as soon as you remember. However, if it is nearly time for your next dose, skip the missed dose and go back to your regular schedule. Do not take a double dose (two doses on the same day) to make up for a forgotten dose.
Adhere to the treatment regimen as recommended by the doctor.

If you stop taking STEGLUJAN
Do not stop taking this medicine without talking to your doctor. Your blood sugar levels may increase if you stop the medicine.

Do not take medicines in the dark! Check the label and dose <u>each time</u> you take a medicine. Wear glasses if you need them.
If you have any further questions regarding the use of the medicine, consult with a doctor or a pharmacist.

4. SIDE EFFECTS
As with any medicine, **STEGLUJAN** may cause side effects in some users.
Do not be alarmed by reading the list of side effects, you may not suffer from any of them.

Stop taking STEGLUJAN and contact a doctor straight away if you notice any of the following serious side effects:
- Severe and persistent pain in the abdomen (stomach area) which might reach through to your back with or without nausea and vomiting, as these could be signs of an inflamed pancreas (pancreatitis).
- A serious allergic reaction (frequency not known), including rash, hives, blisters on the skin/peeling skin and swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing. Your doctor may prescribe a medicine to treat your allergic reaction and a different medicine for your diabetes.

Contact a doctor or the nearest hospital straight away if you have any of the following serious side effects:

Diabetic ketoacidosis (rare side effect, may appear in 1-10 users out of 10,000)
These are the signs of diabetic ketoacidosis (see also section “Special warnings about using **STEGLUJAN**”):
- increased levels of “ketone bodies” in your urine or blood
- rapid weight loss
- feeling sick or being sick
- stomach pain
- excessive thirst

- fast and deep breathing
- confusion
- unusual sleepiness or tiredness
- a sweet smell to your breath, a sweet or metallic taste in your mouth or a different odour to your urine or sweat

This may occur regardless of blood glucose level. Your doctor may decide to temporarily or permanently stop your treatment with **STEGLUJAN**.

Necrotising fasciitis of the perineum or Fournier's gangrene (frequency not known , the frequency of this effect has not been established yet)
A serious soft tissue infection of the genitals or the area between the genitals and the anus (see section "Special warnings about using **STEGLUJAN**" for symptoms).

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.

Skin reaction (frequency not known)
Some people who take medicines called DPP-4 inhibitors like sitagliptin 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**.

Contact your doctor as soon as possible if you notice the following side effects:

Urinary tract infection (very common side effect, may appear in more than 1 user out of 10)
The signs of urinary tract infection are:
- burning sensation when passing urine
- urine that appears cloudy
- pain in the pelvis or mid-back (when kidneys are infected)

Although uncommon, if you have fever or see blood in your urine, tell your doctor immediately.

Dehydration (losing too much water from your body; common side effect, may appear in 1-10 users out of 100)
Symptoms of dehydration include:
- dry mouth
- feeling dizzy, light-headed, or weak, especially when you stand up
- fainting

You may be more likely to get dehydrated if you:
- have kidney problems
- take medicines that increase your urine production (diuretics) or lower blood pressure
- are 65 years or older

Low blood sugar (hypoglycaemia; common side effect)
Your doctor will tell you how to treat low blood sugar and what to do if you have any of the symptoms or signs below. The doctor may lower the dose of your insulin or other diabetes medicine.

Signs and symptoms of low blood sugar may include:
- headache
- drowsiness
- irritability
- hunger
- dizziness
- confusion
- sweating
- feeling jittery
- weakness
- fast heart beat

Kidney problems (frequency not known)
Sometimes requiring dialysis.

Joint pain (frequency not known)
Some people who take medicines called DPP-4 inhibitors like sitagliptin, may develop joint pain that can be severe. Call your doctor if you have severe joint pain.

Other side effects include:
Very common side effect
- vaginal yeast infection (thrush)

Common side effects
- yeast infections of the penis
- changes in urination, including urgent need to urinate more often, in larger amounts, or at night
- thirst
- vaginal itching
- blood tests may show changes in the amount of urea in your blood
- blood tests may show changes in the amount of total and bad cholesterol (called LDL - a type of fat in your blood)
- blood tests may show changes in the amount of red blood cells in your blood (called haemoglobin)
- constipation
- flatulence
- swelling of the hands or legs
- flu
- headache
- upper respiratory infection
- stuffy or runny nose and sore throat
- osteoarthritis
- arm or leg pain
- nausea/vomiting

Uncommon side effects (may appear in 1-10 users out of 1000)
- blood tests may show changes related to kidney function (such as ‘creatinine’)
- stomach ache
- diarrhoea
- drowsiness

- dry mouth
- dizziness
- itching

Rare side effect
- reduced number of platelets

Frequency not known (the frequency of these effects has not been established yet)
- kidney problems (sometimes requiring dialysis)
- joint pain
- muscle pain
- back pain
- interstitial lung disease
- bullous pemphigoid (a type of skin blister)

If a side effect appears, if any of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: https://sideeffects.health.gov.il

5. HOW TO STORE STEGLUJAN?
- Avoid Poisoning! This medicine and any other medicine must be stored in a safe place out of the reach and sight of children and/or infants, in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the pack. The expiry date refers to the last day of the indicated month.
- **Storage conditions**:

Store below 30°C. Store in the original package in order to protect from moisture.
- Do not use this medicine if the packaging is damaged or shows signs of tampering.
- Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. FURTHER INFORMATION
In addition to the active ingredients STEGLUJAN also contains:
Tablet core: microcrystalline cellulose (E460), calcium hydrogen phosphate (anhydrous), sodium stearyl fumarate (E487), croscarmellose sodium, magnesium stearate (E470b).
Tablet coat: hypromellose (E464), hydroxypropyl cellulose (E463), titanium dioxide (E171), iron oxide yellow (E172), iron oxide red (E172), iron oxide black (E172), carnauba wax (E903).

What STEGLUJAN looks like and contents of the pack
- **STEGLUJAN 5/100 mg tablets** are beige, almond-shaped, film-coated tablets debossed with "554" on one side and plain on the other side.
- **STEGLUJAN 15/100 mg tablets** are brown, almond-shaped, film-coated tablets debossed with "555" on one side and plain on the other side.

Pack sizes:
The pack sizes are 14, 28, 30, 84, 90 and 98 film-coated tablets in non-perforated blisters and 30x1 film-coated tablets in perforated unit dose blisters.

Not all pack sizes may be marketed.

Registration holder's name and address:
Merck Sharp & Dohme (Israel-1996) Company Ltd., P.O. Box 7121, Petah-Tikva 49170.

Manufacturer's name and address: Merck Sharp & Dohme Corp., New Jersey, USA.

Revised in February 2022 according to MOHs guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry:
STEGLUJAN 5/100 mg tablets: 167-01-36006
STEGLUJAN 15/100 mg tablets: 167-02-36036