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

This medicine is to be supplied upon physician's prescription only

STEGLATRO 5 MG
STEGLATRO 15 MG
FILM-COATED TABLET

Each Steglatro 5 mg film-coated tablet contains:
5 mg ertugliflozin (as ertugliflozin L-pyroglutamic acid)

Each Steglatro 15 mg film-coated tablet contains:
15 mg ertugliflozin (as ertugliflozin L-pyroglutamic acid)

For a list of inactive ingredients see section 6 "Further information". See also section 2.8 "Important information about some of the ingredients of the medicine".

Read this leaflet carefully in its entirety 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 ailment is similar.

1. WHAT THE MEDICINE IS INTENDED FOR?

Steglatro is intended, in addition to diet and exercise, to improve the control of sugar levels in the blood in adults aged 18 years and older with type 2 diabetes: as a single treatment in patients which can't receive treatment with metformin or as an addition to other medicines which are intended for the use in diabetes.

Therapeutic group:
Steglatro contains the active substance ertugliflozin.
Steglatro is a member of a group of medicines called sodium glucose co-transporter-2 (SGLT2) inhibitors.

How Steglatro works
Ertugliflozin works by blocking the SGLT2 protein in your kidneys. This causes blood sugar to be removed in your urine.

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 THE MEDICINE

2.1 Do not use the medicine if:

- you are allergic to the active ingredient ertugliflozin or any of the other ingredients of this medicine (listed in section 6 "Further information").

2.2 Special warnings regarding use of the medicine
Before and during the treatment with Steglatro tell the doctor if:

- you have kidney problems.
- you have or have had yeast infections of the vagina or penis.
- you have ever had serious heart disease or if you have had a stroke.
- you have type 1 diabetes. Steglatro should not be used to treat this condition.
- you take other diabetes medicines; you are more likely to get low blood sugar with certain medicines.
- you 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.
- you 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.
- you have had a lower limb amputation.

It is important to check your feet regularly and adhere to any other advice regarding foot care and adequate hydration given by your healthcare professional. You should notify your doctor immediately if you notice any wounds or discolouration, or if you experience any tenderness or pain in your feet. Some studies indicate that taking ertugliflozin may have contributed to an increase in cases of lower limb amputation (mainly of the toe).

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 and around your anus and genitals, 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 this medicine works, your urine will test positive for sugar (glucose) while you are on this medicine.

2.3 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.

2.4 Interactions with other medicines
If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, you should tell the doctor or pharmacist. In particular, tell your doctor if you are taking:

- medicines which increase urine production (diuretics).

- other medicines that lower the sugar in your blood, such as insulin or medicines that increase insulin release from the pancreas.

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

2.5 Use of the medicine and food
You can take your tablet with or without food.

2.6 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 Steglatro can 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. Do not use Steglatro if you are pregnant.

It is not known if Steglatro passes into breast milk. Talk with your doctor about the best way to feed your baby if you take Steglatro. Do not use Steglatro if you are breast-feeding.

2.7 Driving and using machines
This medicine has no or negligible influence on the ability to drive and use machines. 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 and change in vision, and may affect your ability to drive and use machines. Do not drive or use any tools or machines if you feel dizzy while taking Steglatro.

2.8 Important information about some of the ingredients of the medicine
Steglatro contains lactose (milk sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation 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 of the preparation.
The dosage and treatment regimen will be determined by the doctor only.

How much to take
- The starting dose of Steglatro is one 5-mg tablet each day. Your doctor will decide whether to increase your dose to 15 mg.
- Your doctor will prescribe the right dose for you. Do not change your dose unless your doctor has told you to.

Do not exceed the recommended dose.

- **Method of administration:** swallowing
- Swallow the tablet;
- Crushing/ splitting/ chewing:
  To make the swallowing easier, it is possible, if needed, to split or crush the tablet for immediate use. The two halves need to be taken immediately after the splitting.
- 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 Steglatro.

If you have accidentally taken a higher dose
If you take too much Steglatro, talk to a doctor or pharmacist straight away.
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 the medicine
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 recommended by the doctor.
Even if there is an improvement in your health, do not discontinue use of this medicine before consulting your doctor.

If you stop taking this medicine
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 the dose <u>each time</u> you take a medicine. Wear glasses if you need them.

If you have further questions on the use of the medicine, consult with a doctor or a pharmacist.

4. SIDE EFFECTS

As with any medicine, the use of Steglatro 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.

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

Diabetic ketoacidosis (rare side effect, which may appear in 1-10 users out of 10, 000)

These are the signs of diabetic ketoacidosis (see also section 2.2 “Special warnings regarding use of the medicine”):
- 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 Steglatro.

Necrotising fasciitis of the perineum or Fournier’s gangrene (not known, cannot be estimated from the available data)
A serious soft tissue infection of the genitals or the area between and around your anus and genitals (see section 2.2 “Special warnings regarding use of the medicine” for symptoms).

If you notice any of the side effects above, contact a doctor or the nearest hospital straight away.

Contact your doctor as soon as possible if you notice the following side effects:
Dehydration (losing too much water from your body; common side effect, which 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

If you notice any of the side effects above, contact your doctor as soon as possible.

Other side effects when taking Steglatro:
Very common side effects (may appear in more than 1 user out of 10)
- 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)

Uncommon side effects (may appear in 1-10 users out of 1,000)
- blood tests may show changes related to kidney function (such as ‘creatinine’)
- painful urination

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.

Side effects can be reported to the Ministry of Health by using the link "Adverse Drug Reactions Report" at the home page of the Ministry of Health's web site (www.health.gov.il) which refers to the online side effects reporting form, or by using the link: /https://sideeffects.health.gov.il

5. HOW TO STORE THE MEDICINE

- 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.
- Medicines should not be disposed of via wastewater or household waste. Ask the pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

Do not use this medicine if the packaging is damaged or shows signs of tampering.

6. FURTHER INFORMATION

In addition to the active ingredient the medicine also contains:

- Tablet core:
  microcrystalline cellulose, lactose monohydrate (see section 2), sodium starch glycolate (Type A), magnesium stearate.
- Film coating:
  HPMC – 2910/hypromellose 6 cP, titanium dioxide, lactose monohydrate (see section 2), macrogol/PEG 3350, triacetin, iron oxide red.

What the medicine looks like and contents of the pack:

- Steglatro 5 mg film-coated tablets (tablets) are pink, 6.4 x 6.6 mm, triangular-shaped, embossed with “701” on one side and plain on the other side.
- Steglatro 15 mg film-coated tablets (tablets) are red, 9.0 x 9.4 mm, triangular-shaped, embossed with “702” on one side and plain on the other side.

Pack sizes:
Steglatro is available in Alu/PVC/PA/Alu blisters. 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.

Marketing authorization holder:
Merck Sharp & Dohme (Israel-1996) Company Ltd., P.O.Box 7121, Petah-Tikva 49170.

Manufacturer:
Merck Sharp & Dohme Corp., New-Jersey, USA.

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Drug registration no. listed in the official Registry of the Ministry of Health:
Steglatro 5 mg: 161-72-35636
Steglatro 15 mg: 161-73-35637