Package leaflet: Information for the patient

Steglatro® 5 mg film-coated tablets
Steglatro® 15 mg film-coated tablets
ertugliflozin

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Steglatro is and what it is used for
2. What you need to know before you take Steglatro
3. How to take Steglatro
4. Possible side effects
5. How to store Steglatro
6. Contents of the pack and other information

1. What Steglatro is and what it is used for

What Steglatro is
Steglatro contains the active substance ertugliflozin.

Steglatro is a member of a group of medicines called sodium glucose co-transporter-2 (SGLT2) inhibitors.

What Steglatro is used for
- Steglatro lowers blood sugar levels in adult patients (aged 18 years and older) with type 2 diabetes.
- Steglatro can be used alone or with some other medicines that lower blood sugar.
- You need to keep following your food and exercise plan while taking Steglatro.

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. What you need to know before you take Steglatro

Do not take Steglatro
- if you are allergic to ertugliflozin or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor, pharmacist, or nurse before and while taking Steglatro 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 type 1 diabetes. Steglatro 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.
- 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.
- 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 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 this medicine works, your urine will test positive for sugar (glucose) while you are on this medicine.

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.

Other medicines and Steglatro
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, tell your doctor:
- if you are taking medicines which increase urine production (diuretics).
- if you are taking 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.

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.

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.

Steglatro contains lactose
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.

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

3. How to take Steglatro

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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.

Taking this medicine
- Swallow the tablet; if you have difficulties with swallowing, the tablet can be broken or crushed.
- 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 take more Steglatro than you should
If you take too much Steglatro, talk to a doctor or pharmacist straight away.

If you forget to take Steglatro
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.

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

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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

Diabetic ketoacidosis (rare, may affect up to 1 in 1,000 people)

These are the signs of diabetic ketoacidosis (see also section "Warnings and precautions"):
- 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 the genitals and the anus (see section "Warnings and precautions" 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, may affect up to 1 in 10 people)
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)
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
- vaginal yeast infection (thrush)

Common
- 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 (may affect up to 1 in 100 people)
- blood tests may show changes related to kidney function (such as 'creatinine')
- painful urination

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Steglatro

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister and the carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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

Do not throw away any 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. Contents of the pack and other information

What Steglatro contains

- The active substance is ertugliflozin.
  - 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).
- The other ingredients are:
  - Tablet core: microcrystalline cellulose (E460), lactose monohydrate (see section 2), sodium starch glycolate (Type A), magnesium stearate (E470b).
  - Film coating: hypromellose 2910/6 (E464), lactose monohydrate (see section 2), macrogol 3350 (E1521), triacetin (E1518), titanium dioxide (E171), iron oxide red (E172).

What Steglatro looks like and contents of the pack

- Steglatro 5 mg film-coated tablets (tablets) are pink, 6.4 x 6.6 mm, triangular-shaped, 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, with "702" on one side and plain on the other side.

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 Authorisation Holder and Manufacturer

Marketing Authorisation Holder in Great Britain: Merck Sharp & Dohme (UK) Limited, 120 Moorgate, London EC2M 6UR, UK

Marketing Authorisation Holder in UK (Northern Ireland): Merck Sharp & Dohme B.V., Waarderweg 39, 2031 BN Haarlem, The Netherlands

Manufacturer
Schering-Plough Labo NV, Industriepark 30 - Zone A, 2220 Heist-op-den-Berg, Belgium

For any information about this medicine, please contact:

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This leaflet was last revised in April 2021.

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.

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