

Steglujan™ 5 mg/100 mg film-coated tablets

Steglujan™ 15 mg/100 mg film-coated tablets

ertugliflozin/sitagliptin

▼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, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

- What Steglujan is and what it is used for
- What you need to know before you take Steglujan
- How to take Steglujan
- Possible side effects
- How to store Steglujan
- Contents of the pack and other information

1. What Steglujan is and what it is used for

What Steglujan is

Steglujan contains two active substances, ertugliflozin and sitagliptin.

- 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.

What Steglujan is used for

- Steglujan lowers blood sugar levels in adult patients (aged 18 years and older) with type 2 diabetes.
- Steglujan can be used instead of taking both ertugliflozin and sitagliptin as separate tablets.
- Steglujan 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 Steglujan.

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. What you need to know before you take Steglujan

Do not take Steglujan:

- if you are allergic to ertugliflozin or sitagliptin 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 Steglujan 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.
- 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).

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.

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 Steglujan

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 amount of sugar in your blood, such as insulin or medicines that increase insulin release from the pancreas.
- if you are taking digoxin (a medicine used to treat irregular heart beat 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.

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.

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.

3. How to take Steglujan

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 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.
- 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 Steglujan.

If you take more Steglujan than you should

If you take too much Steglujan, talk to a doctor or pharmacist straight away.

If you forget 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.

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.

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.

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.

If you notice any of the serious side effects above, stop taking this medicine and contact a doctor straight away.

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 Steglujan.

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 include:

Very common

- vaginal yeast infection (thrush)
- low blood sugar

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)
- 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 (may affect up to 1 in 100 people)

- blood tests may show changes related to kidney function (such as ‘creatinine’)
- painful urination
- stomach ache
- diarrhoea
- drowsiness
- dry mouth
- dizziness
- itching

Rare

- reduced number of platelets

Not known (frequency cannot be estimated from the available data)

- kidney problems (sometimes requiring dialysis)
- joint pain
- muscle pain
- back pain
- interstitial lung disease
- bullous pemphigoid (a type of skin blister)

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. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Steglujan

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.

Don't store above 30° C, store in the original package.

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. Contents of the pack and other information

What Steglujan contains

- The active substances are ertugliflozin and sitagliptin.
 - Each Steglujan 5 mg/100 mg film-coated tablet contains 5 mg of ertugliflozin (as ertugliflozin L-pyroglutamic acid) and 100 mg sitagliptin (as sitagliptin phosphate monohydrate).
 - Each Steglujan 15 mg/100 mg film-coated tablet contains 15 mg of ertugliflozin (as ertugliflozin L-pyroglutamic acid) and 100 mg sitagliptin (as sitagliptin phosphate monohydrate).
- The other ingredients are:
 - Tablet core: microcrystalline cellulose , calcium hydrogen phosphate (anhydrous), croscarmellose sodium, sodium stearyl fumarate , magnesium stearate .
 - Tablet coat: hypromellose , hydroxypropyl cellulose, titanium dioxide , iron oxide red, iron oxide yellow, iron oxide black, carnauba wax.

What Steglujan looks like and contents of the pack

- Steglujan 5 mg/100 mg film-coated tablets (tablets) are beige, almond-shaped, film-coated tablets debossed with “554” on one side and plain on the other side.
- Steglujan 15 mg/100 mg film-coated tablets (tablets) are brown, almond-shaped, film-coated tablets debossed with “555” on one side and plain on the other side.

Steglujan is available in Alu/PVC/PA/Alu blisters. The pack sizes are 14 (2x7), 28, 30, 84, 90 and 98 film-coated tablets in non-perforated blisters and 30x1 or 30 (3x10) film-coated tablets in perforated unit dose blisters.

Not all strengths and pack sizes may be marketed.

Manufacturer and Release Site:

Schering-Plough Labo NV

Industriepark 30

Heist-op-den-Berg

B-2220

Belgium

Marketing Authorization holder:

Merck Sharp & Dohme B.V.

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This leaflet was last revised in May 2019.

(THIS IS A MEDICAMENT) <p>-Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you. -Follow strictly the doctor's prescription, the method of use, and the instructions of the pharmacist who sold the medicament. -The doctor and the pharmacist are experts in medicine, its benefits and risks. -Do not by yourself interrupt the period of treatment prescribed for you. -Do not repeat the same prescription without consulting your doctor.</p> <p>Keep medicament out of reach of children Council of Arab Health Ministers Union of Arab Pharmacists</p>
