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Steglujan (*ertugliflozin / sitagliptin*)

An overview of Steglujan and why it is authorised in the EU

What is Steglujan and what is it used for?

Steglujan is a medicine used to control blood glucose (sugar) levels in adults with type 2 diabetes. It is used together with diet and exercise in the following patients:

- patients whose blood glucose levels are not satisfactorily controlled with the diabetes medicines metformin and/or a sulphonylurea, in combination with either ertugliflozin or sitagliptin;
- patients who are already taking ertugliflozin and sitagliptin as separate tablets.

Steglujan contains the active substances ertugliflozin and sitagliptin.

How is Steglujan used?

Steglujan is available as tablets in 2 strengths of ertugliflozin and sitagliptin (5 mg/100 mg and 15 mg/100 mg) and can only be obtained with a prescription.

The recommended starting dose is one 5 mg/100 mg tablet taken once a day. In patients whose blood sugar needs further control, the dose can be increased to one 15 mg/100 mg tablet once a day.

For more information about using Steglujan, see the package leaflet or contact your doctor or pharmacist.

How does Steglujan work?

Type 2 diabetes is a disease in which the body does not make enough insulin to control the level of glucose in the blood or when the body is unable to use insulin effectively. The result is a high level of glucose in the blood. The two active substances in Steglujan work in different ways to lower glucose levels:

Ertugliflozin helps to lower blood glucose by making the patient pass out glucose in the urine. It does this by blocking a protein in the kidneys (called SGLT2) that normally takes glucose back into the blood from the kidneys.

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Sitagliptin blocks the breakdown of incretin hormones in the body. These hormones stimulate the pancreas to produce insulin. Prolonging the action of incretin hormones makes the pancreas produce more insulin when blood glucose levels are high. Sitagliptin also reduces the amount of glucose made by the liver, by increasing insulin levels and decreasing the levels of the hormone glucagon.

Together, these actions reduce blood glucose levels and help to control type 2 diabetes.

What benefits of Steglujan have been shown in studies?

Three main studies, involving 1,987 patients showed that Steglujan was effective at lowering blood glucose levels in patients with type 2 diabetes, as measured by the decrease in blood levels of HbA1c (a measure of blood glucose) after 6 months of treatment. At the start of the studies, patients' HbA1c was above 7.0%. In addition, the results indicated that treatment with Steglujan was associated with a beneficial reduction in body weight.

The first study, in patients who were all taking metformin, compared the combination of ertugliflozin and sitagliptin with ertugliflozin or sitagliptin on their own. Treatment with the combination of ertugliflozin and sitagliptin lowered HbA1c levels by up to 1.5 percentage points, compared with reductions of up to 1.1 for ertugliflozin and for sitagliptin on their own.

The second study found that adding ertugliflozin to a combination of sitagliptin and metformin was more effective than placebo (a dummy treatment). HbA1c levels fell by between 0.8 and 0.9 points, compared with a fall of 0.1 with placebo.

The third study compared Steglujan with placebo in patients who were not taking other diabetes medicines and in whom diet and exercise were not enough to control their blood sugar levels. This study found that adding Steglujan to diet and exercise was much more effective than placebo, with HbA1c levels falling by between 1.6 and 1.7 points with the combination of ertugliflozin and sitagliptin compared with a fall of 0.4 points with placebo.

What are the risks associated with Steglujan?

The most common side effects with Steglujan (which may affect more than 1 in 10 people) are fungal infections of the vagina and other infections of the female reproductive system.

For the full list of side effects and restrictions with Steglujan, see the package leaflet.

Why is Steglujan authorised in the EU?

Steglujan was shown to be effective at controlling blood glucose levels. Treatment with Steglujan also led to weight loss, which is considered beneficial in patients with diabetes. The benefits of Steglujan were lower in patients with kidney problems. Regarding safety, this was considered in line with that of other medicines of the same class.

The European Medicines Agency decided that Steglujan's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Steglujan?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Steglujan have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Steglujan is continuously monitored. Side effects reported with Steglujan are carefully evaluated and any necessary action taken to protect patients.

Other information about Steglujan

Steglujan received a marketing authorisation valid throughout the EU on 23 March 2018.

Further information on Steglujan can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports.

This overview was last updated in 04-2018.