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Steglatro (*ertugliflozin*)

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

What is Steglatro and what is it used for?

Steglatro is a medicine used to control blood glucose (sugar) levels in adults with type 2 diabetes together with diet and exercise.

Steglatro can be used in combination with other diabetes medicines or on its own in patients who cannot take metformin.

Steglatro contains the active substance ertugliflozin.

How is Steglatro used?

Steglatro is available as tablets (5 and 15mg). The patient should start with one 5 mg tablet once a day in the morning. If the patients' glucose level is still too high the dose can be increased to 15 mg once a day. For more information about using Steglatro, see the package leaflet or contact your doctor or pharmacist.

Steglatro can only be obtained with a prescription.

How does Steglatro 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 active substance in Steglatro, 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.

What benefits of Steglatro have been shown in studies?

Several studies in around 4,800 patients with type 2 diabetes have shown that ertugliflozin helps lower glucose levels on its own and in combination with other diabetes medicine.



The studies looked mainly at effects on levels of HbA1c (a measure of blood glucose) after 6 months or one year of treatment. At the start of the studies, patients' HbA1c was above 7 percentage points. The results were as follows:

- A study of ertugliflozin on its own, showed that levels of HbA1c (a measure of blood glucose) fell by between 0.8 points and 1 point in patients who took the medicine compared with a rise of 0.2 points in patients receiving placebo (a dummy treatment).
- A second study found that in patients taking a combination of ertugliflozin and metformin, HbA1c levels fell by around 0.8 points, compared with reductions of 0.03 when placebo was added to metformin.
- A third study found that a combination of ertugliflozin at a 15 mg dose with metformin was about as effective as a combination of metformin with another diabetes medicine, glimepiride. HbA1c levels fell by 0.6 points with ertugliflozin and 0.7 points with glimepiride. A lower dose of ertugliflozin 5 mg was less effective.
- A fourth study found that, in patients taking metformin, adding ertugliflozin was as effective as adding sitagliptin, another diabetes medicine, with HbA1c levels falling by around 1 point with both treatments. HbA1c levels fell by a further 0.5 points when both medicines were added to metformin.
- A fifth study found that adding ertugliflozin to a combination of sitagliptin and metformin was more effective than placebo. HbA1c levels fell by between 0.8 and 0.9 points when ertugliflozin was added, compared with a fall of 0.1 with placebo.
- A sixth study found that adding the combination of ertugliflozin and sitagliptin 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.
- A seventh study showed that ertugliflozin was not more effective than placebo in patients with moderate kidney impairment. The data from this study showed that the effect of ertugliflozin reduces when the kidneys do not work properly.

Finally, in addition to lowering glucose levels, studies showed that ertugliflozin can help patients reduce bodyweight.

What are the risks associated with Steglatro?

The most common side effects with Steglatro (which may affect more than 1 in 10 people) are fungal infections of the vagina and other infections of the female reproductive system. Rare cases of diabetic ketoacidosis, a serious condition where the patient has very high blood acid levels, may occur in up to 1 in 1,000 patients. For the full list of side effects and restrictions with Steglatro, see the package leaflet.

Why is Steglatro authorised in the EU?

Studies showed that Steglatro helps lower glucose levels on its own and in combination with other diabetes medicines. In addition, Steglatro can help some patients lose weight.

Steglatro is not as effective in patients with moderate kidney impairment and should therefore not be started in such patients.

The European Medicines Agency concluded that Steglatro'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 Steglatro?

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

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

Other information about Steglatro

Steglatro received a marketing authorisation valid throughout the EU on 21 March 2018.

Further information on Steglatro can be found on the Agency's website: [ema.europa.eu/Find/medicine/Human medicines/European public assessment reports](http://ema.europa.eu/Find/medicine/Human%20medicines/European%20public%20assessment%20reports).

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