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Segluromet (*ertugliflozin / metformin hydrochloride*)

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

What is Segluromet and what is it used for?

Segluromet 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 glucose levels are not well controlled with the highest dose of metformin they can take
- patients on the highest dose of metformin they can take who are also taking another diabetes medicine
- patients who are already taking ertugliflozin and metformin as separate tablets.

Segluromet contains two active substances, ertugliflozin and metformin.

How is Segluromet used?

Segluromet is available as tablets in 4 strengths of ertugliflozin and metformin (2.5 mg/850 mg, 2.5 mg/1,000 mg, 7.5 mg/850 mg and 7.5 mg/1,000 mg).

The strength of Segluromet tablet to use depends on how well the patient's glucose levels are controlled. The dose is one tablet twice a day with food.

The doctor will check how well the patient's kidneys are working before treatment and once a year during treatment. The dose of Segluromet may be reduced or it may be stopped if the kidneys are not working well enough. Treatment will not be started if the kidney function is poor.

For more information about using Segluromet, see the package leaflet or contact your doctor or pharmacist. Segluromet can only be obtained with a prescription.

How does Segluromet 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.

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The two active substances in Segluromet, ertugliflozin and metformin, 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.

Metformin, on the other hand, works mainly by blocking glucose production in the body and by reducing the absorption of glucose in the gut.

What benefits of Segluromet have been shown in studies?

Four main studies in over 3,600 patients with type 2 diabetes have shown that adding ertugliflozin to metformin helps lower glucose levels when metformin is not working well enough. 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:

- The first 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 (a dummy treatment) was added to metformin.
- A second study found that adding ertugliflozin to a combination of sitagliptin (another diabetes medicine) and metformin was more effective than placebo. HbA1c levels fell by between 0.8 and 0.9 percentage points when ertugliflozin was added, compared with a fall of 0.1 with placebo
- 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. In this study, 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.
- The fourth study found that, in patients taking metformin, adding ertugliflozin was as effective as adding sitagliptin 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.

Finally, in addition to lowering glucose levels, studies showed that adding ertugliflozin to metformin helped patients reduce bodyweight.

What are the risks associated with Segluromet?

The most common side effects with Segluromet (which may affect more than 1 in 10 people) are fungal infections of the vagina and other infections of the female reproductive system and problems with the gut such as nausea, vomiting, diarrhoea, abdominal pain and loss of appetite. For the full list of side effects of Segluromet, see the package leaflet.

Segluromet must not be used in patients with uncontrolled diabetes with severe symptoms that lead to high acid levels in the blood. It must also not be used in patients with severe kidney problems or certain heart, circulatory, breathing or liver problems and in patients who drink alcohol to excess. For the full list of restrictions, see the package leaflet.

Why is Segluromet authorised in the EU?

Studies showed that Segluromet can help lower glucose levels in patients whose metformin treatment is not working well enough, including those taking another diabetes medicine in addition to metformin. Segluromet can also 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 Segluromet'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 Segluromet?

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

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

Other information about Segluromet

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

Further information on Segluromet 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.