



25 January 2018
EMA/CHMP/12790/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Segluromet

ertugliflozin / metformin

On 25 January 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Segluromet, intended for the treatment of type 2 diabetes. The applicant for this medicinal product is Merck Sharp & Dohme Limited.

Segluromet is a fixed dose combination of ertugliflozin and metformin, two oral blood glucose lowering medicines (ATC code: A10BD23). It will be available as film-coated tablets (containing 2.5 mg ertugliflozin/1000 mg metformin; 2.5 mg/850 mg; 7.5 mg/1000 mg; and 7.5 mg/850 mg). Ertugliflozin works by blocking a protein in the kidney called the human sodium-glucose co-transporter-2 (SGLT2). This reduces glucose re-absorption in the kidney leading to glucose excretion in the urine. Metformin works by suppressing glucose production by the liver, by decreasing intestinal absorption of glucose, and by increasing peripheral glucose uptake and utilisation.

The benefit with Segluromet is its ability to lower blood glucose. The most common side effects are vulvovaginal mycotic infection and other female genital mycotic infections as well as gastrointestinal symptoms (nausea, vomiting, diarrhoea, abdominal pain and loss of appetite). Serious diabetic ketoacidosis occurs rarely.

The full indication is:

"Segluromet is indicated in adults aged 18 years and older with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control:

- in patients not adequately controlled on their maximally tolerated dose of metformin alone;
- in patients on their maximally tolerated doses of metformin in addition to other medicinal products for the treatment of diabetes;
- in patients already being treated with the combination of ertugliflozin and metformin as separate tablets.

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion



(For study results with respect to combinations and effects on glycaemic control, see sections 4.4, 4.5 and 5.1.)”

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.