25 January 2018
EMA/CHMP/12820/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Steglatro

ertugliflozin

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 Steglatro, intended for the treatment of type 2 diabetes. The applicant for this medicinal product is Merck Sharp & Dohme Limited.

Steglatro will be available as 5 mg and 15 mg film-coated tablets. The active substance of Steglatro is ertugliflozin, a blood glucose lowering agent (ATC code: A10BK04). 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.

The benefit with Steglatro is its ability to lower blood glucose. The most common side effects are vulvovaginal mycotic infection and other female genital mycotic infections. Serious diabetic ketoacidosis occurs rarely.

The full indication is:

"Steglatro 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:

- as monotherapy in patients for whom the use of metformin is considered inappropriate due to intolerance or contraindications;
- in addition to other medicinal products for the treatment of diabetes.

(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.

[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

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