16 September 2021
EMA/CHMP/513781/2021 Corr.[1]
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[2] (post authorisation)

Steglatro

ertugliflozin

On 16 September 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Steglatro. The marketing authorisation holder for this medicinal product is Merck Sharp & Dohme B.V.

The CHMP adopted an extension to an existing indication as follows:[3]

Steglatro is indicated **for the treatment of** adults ~~aged 18 years and older~~ with **insufficiently controlled** type 2 diabetes mellitus as an adjunct to diet and exercise ~~to improve glycaemic control~~:

- as monotherapy ~~in patients for whom the use~~ when 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 of **therapies,** ~~and~~ effects on glycaemic control, **cardiovascular events and the population studied,** see sections 4.4, 4.5 and 5.1.~~)~~

For information, the full indication is as follows:

Steglatro is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise:
- as monotherapy when 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 of therapies, effects on glycaemic control, cardiovascular events, and the populations studied, see sections 4.4, 4.5, and 5.1.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to

[1] 30 September 2021
[2] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion
[3] New text in bold, removed text as strikethrough

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the marketing authorisation has been granted by the European Commission.