16 September 2021
EMA/CHMP/526207/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Segluromet

ertugliflozin / metformin hydrochloride

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 Segluromet. The marketing authorisation holder for this medicinal product is Merck Sharp & Dohme B.V.

The CHMP adopted an extension to the existing indication as follows:[2]

Segluromet is indicated in adults **for the treatment of** ~~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~~ **insufficiently** controlled on their maximally tolerated dose of metformin alone
- **in combination with** ~~in patients on their maximally tolerated doses of metformin in addition to~~ other medicinal products for the treatment of diabetes **in patients insufficiently controlled with metformin and these products**
- in patients already being treated with the combination of ertugliflozin and metformin as separate tablets.

~~(~~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:

Segluromet is indicated in adults for the treatment of type 2 diabetes mellitus as an adjunct to diet and exercise:

- in patients insufficiently controlled on their maximally tolerated dose of metformin alone
- in combination with other medicinal products for the treatment of diabetes in patients insufficiently controlled with metformin and these products

[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
[2] New text in bold, removed text as strikethrough

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- in patients already being treated with the combination of ertugliflozin and metformin as separate tablets.

For study results with respect to combinations of therapies, effects on glycaemic control, cardiovascular events and the population 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 the marketing authorisation has been granted by the European Commission.