EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 June 2019
EMA/CHMP/365313/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Edistride

dapagliflozin

On 27 June 2019, 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 Edistride. The marketing authorisation holder for this medicinal product is AstraZeneca AB.

The CHMP adopted a change to the existing indication in type 2 diabetes as follows:[2]

> "Edistride is indicated in adults for the treatment of insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise ~~to improve glycaemic control~~
>
> - as monotherapy when metformin is considered inappropriate due to intolerance.
> - in addition to other medicinal products for the treatment of type 2 diabetes.
>
> For ~~clinical~~ study results with respect to **combination of therapies, effects on glycaemic control and cardiovascular events, and the** populations studied, ~~effects on glycaemic control and combinations with other medicinal products~~ see sections 4.4, 4.5 and 5.1."

For information, the full indication for Edistride will therefore read as follows:[3]

> "Type 2 diabetes mellitus
>
> Edistride is indicated in adults for the treatment of insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise
>
> - as monotherapy when metformin is considered inappropriate due to intolerance.
> - in addition to other medicinal products for the treatment of type 2 diabetes.
>
> For study results with respect to combination of therapies, effects on glycaemic control and cardiovascular events, and the populations studied, see sections 4.4, 4.5 and 5.1.

[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 shown in bold; removed text as strikethrough
[3] The text cited for the full indication is for the 5mg strength. The 10 mg strength is not indicated for type 1 diabetes

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Type 1 diabetes mellitus

Edistride is indicated in adults for the treatment of insufficiently controlled type 1 diabetes mellitus as an adjunct to insulin in patients with BMI ≥ 27 kg/m^2, when insulin alone does not provide adequate glycaemic control despite optimal insulin therapy."

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.