



14 October 2021
EMA/CHMP/589418/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Edistride dapagliflozin

On 14 October 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 Edistride. The marketing authorisation holder for this medicinal product is AstraZeneca AB.

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

Type 2 diabetes mellitus

Edistride is indicated in adults **and children aged 10 years and above** 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, cardiovascular and renal events, and the populations studied, see sections 4.4, 4.5 and 5.1.

Heart failure

Edistride is indicated in adults for the treatment of symptomatic chronic heart failure with reduced ejection fraction.

Chronic kidney disease

Edistride is indicated in adults for the treatment of chronic kidney disease.

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

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



(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.