24 September 2015
EMA/CHMP/524152/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Edistride

dapagliflozin

On 24 September 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Edistride, intended for the treatment of type 2 diabetes mellitus. The applicant for this medicinal product is AstraZeneca AB.

Edistride will be available as 5 mg and 10 mg film-coated tablets. The active substance of Edistride is dapagliflozin, an oral blood glucose-lowering medicine (ATC code: A10BX09). Dapagliflozin is a competitive, reversible, selective and orally active inhibitor of sodium-glucose co-transporter 2 (SGLT2). It improves fasting and post-prandial plasma glucose levels by reducing renal glucose re-absorption leading to urinary glucose excretion.

The benefits with Edistride are its ability to lower blood glucose by increasing urinary glucose excretion. The most common side effects are hypoglycaemia (when used with a sulphonylurea or insulin), urinary tract infection, genital tract infection, dyslipidaemia, dysuria and polyuria.

The full indication is:

"Edistride is indicated in adults aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control as:

Monotherapy

When diet and exercise alone do not provide adequate glycaemic control in patients for whom use of metformin is considered inappropriate due to intolerance.

Add-on combination therapy

In combination with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control (see sections 4.4, 4.5 and 5.1 for available data on different combinations)."

[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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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.