26 January 2023
EMA/CHMP/30826/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Dapagliflozin Viatris

dapagliflozin

On 26 January 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Dapagliflozin Viatris, intended for the treatment of type 2 diabetes mellitus, heart failure and chronic kidney disease. The applicant for this medicinal product is Viatris Limited.

Dapagliflozin Viatris will be available as 5 mg and 10 mg film-coated tablets. The active substance of Dapagliflozin Viatris is dapagliflozin, a sodium-glucose cotransporter 2 (SGLT2) inhibitor (ATC code: A10BK01). SGLT2 is responsible for glucose reabsorption in the kidneys. By blocking the action of SGLT2, dapagliflozin reduces renal glucose reabsorption, resulting in urinary glucose excretion and reduced blood glucose levels.

Dapagliflozin Viatris is a generic of Forxiga, which has been authorised in the EU since 11 November 2012. Studies have demonstrated the satisfactory quality of Dapagliflozin Viatris, and its bioequivalence to the reference product Forxiga. A question and answer document on generic medicines can be found here.

The full indication is:

> Type 2 diabetes mellitus
>
> Dapagliflozin Viatris 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

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

Chronic kidney disease

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

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.