09 November 2023
EMA/CHMP/331542/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Veltassa

patiromer

On 9 November 2023, 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 Veltassa. The marketing authorisation holder for this medicinal product is Vifor Fresenius Medical Care Renal Pharma France.

The CHMP adopted a new pharmaceutical form and strength (1g powder for oral suspension) together with a new indication in paediatric patients. For information, the full indication for Veltassa will be as follows:[2]

> Veltassa is indicated for the treatment of hyperkalaemia in adults **and adolescents aged 12 to 17 years**.

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.

[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**

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