18 May 2017
EMA/CHMP/293038/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Veltassa

patiromer

On 18 May 2017 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Veltassa, intended for the treatment of hyperkalaemia. The applicant for this medicinal product is Vifor Fresenius Medical Care Renal Pharma France.

Veltassa will be available as a powder for oral suspension (8.4 g, 16.8 g and 25.2 g). The active substance of Veltassa is patiromer (as patiromer sorbitex calcium), a non-absorbed, cation exchange polymer that contains a calcium-sorbitol complex (ATC code: V03AE09). Veltassa increases faecal potassium excretion by binding potassium in the lumen of the gastrointestinal tract, resulting in a reduction of serum potassium levels.

The benefit with Veltassa is its ability to lower serum potassium levels. The most common side effects are hypomagnesaemia, constipation, diarrhoea, abdominal pain and flatulence.

The full indication is: "treatment of hyperkalaemia in adult patients".

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.

[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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