



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 June 2014
EMA/CHMP/204589/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Velphoro

mixture of polynuclear iron(III)-oxyhydroxide, sucrose, and starches

On 26 June 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Velphoro, chewable tablet 500 mg iron as sucroferric oxyhydroxide indicated for the control of serum phosphorus levels in adult chronic kidney disease (CKD) patients on haemodialysis (HD) or peritoneal dialysis (PD).

The applicant for this medicinal product is Vifor Fresenius Medical Care Renal Pharma France. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Velphoro is a mixture of polynuclear iron(III)-oxyhydroxide, sucrose, and starches also known as sucroferric oxyhydroxide, which is used for treatment of hyperphosphataemia; ATC code: V03AE05. Phosphate binding takes place by ligand exchange between hydroxyl groups and/or water and the phosphate ions throughout the physiological pH range of the gastrointestinal tract. Serum phosphorus levels are reduced as a consequence of the reduced dietary phosphate absorption.

The benefits with Velphoro are its ability to reduce serum phosphorus in patients on maintenance dialyses with an acceptable safety profile based on data up to one year. The most common side effects are abnormal product taste and gastrointestinal disorders. The vast majority of these gastrointestinal disorders occurred early during treatment and abated over time with continued dosing.

A pharmacovigilance plan for Velphoro chewable tablet will be implemented as part of the marketing authorisation.

The approved indication is to control serum phosphorus levels in adult chronic kidney disease (CKD) patients on haemodialysis (HD) or peritoneal dialysis (PD).

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.



The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Velphoro chewable tablet and therefore recommends the granting of the marketing authorisation.