

## Velphoro<sup>®</sup> (sucroferric oxyhydroxide) – Expanded indication

- On July 1, 2024, the [FDA approved](#) Fresenius' [Velphoro \(sucroferric oxyhydroxide\)](#), for the control of serum phosphorus levels in **adults and pediatric patients 9 years of age and older** with chronic kidney disease (CKD) on dialysis.
  - Velphoro was previously approved for the control of serum phosphorus levels in patients with CKD on dialysis and the labeling did not include data in pediatric patients.
- The approval of Velphoro for the expanded indication was based on a study in pediatric patients with hyperphosphatemia and advanced CKD. Following a washout period of up to 3 weeks, 78 patients 6 to 18 years of age were randomized to Velphoro or active control calcium acetate (Phoslyra) for a 10-week dose titration period, followed by a 24-week safety extension.
  - The least squares mean reduction in serum phosphorus levels from baseline to the end of the dose titration period in the Velphoro group was -0.52 mg/dL (95% CI: -0.97, -0.07). The percentage of patients with serum phosphorus levels within normal ranges increased from 39% at baseline to 64% at the end of the dose titration period.
  - Velphoro is not approved in pediatric patients 6 years to less than 9 years of age because of the lack of an appropriate dosage strength.
- The recommended starting dose of Velphoro in adults and pediatric patients 12 years of age and older is one 500 mg tablet three times daily with meals. The recommended starting dose of Velphoro in pediatric patients 9 to < 12 years of age is one 500 mg tablet two times daily with meals.
- Serum phosphorus levels should be monitored, and the dose should be titrated in decrements or increments of one 500 mg tablet per day as needed until an acceptable serum phosphorus level is reached, with regular monitoring afterwards. The dose should be titrated as often as weekly. If the recommended daily dose cannot be divided equally among meals, the larger dose should be administered with the largest meal of the day.