Renofa 800

Sevelamer Carbonate Tablet

Right Start, Another Step

Towards Victory

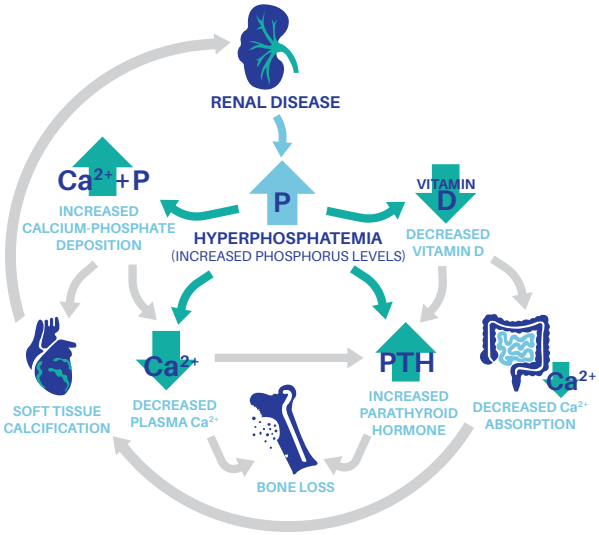
Renofa (sevelamer carbonate) is a phosphate binder indicated for the control of serum phosphorus in adults and children 6 years of age and older [1]. Hyperphosphatemia (HP) is defined by an abnormally high serum phosphorus level in the blood. HP is associated with advanced CKD (stages 4 and 5), often caused by renal failure. HP is characterized by high serum phosphorus levels that can lead to a variety of symptoms and complications [2]. More than 50% of patients on dialysis have serum phosphorus levels over the recommended range, for a variety of reasons[3].

HP due to CKD is common, with as many as

50%-74%

of patients with end stage renal disease affected[3].

Development and Consequences of HP in CKD [4]



ADAPTED FROM ENCYCLOPEDIA OF ENDOCRINE DISEASES(2018)

In the early stages of CKD, compensatory mechanisms (such as FGF23 and PTH) activate to prevent an increase in serum phosphate. As CKD progresses, these mechanisms are unable to compensate for phosphate increases from dietary intake, leading to HP.

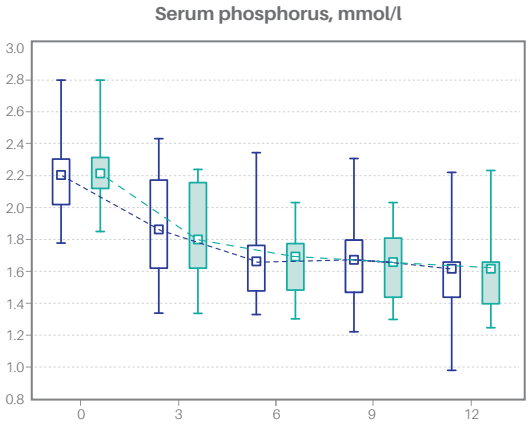
For patients with advanced CKD, loss of kidney function reduces renal phosphate excretion and fails to eliminate excess phosphate through other homeostatic mechanisms [1,3].

Sevelamer Carbonate Vs. Calcium acetate[5]

Correction of hyperphosphatemia in hemodialysis patients

An open-label, randomized, parallel study was conducted to compare the safety and effectiveness of the use of sevelamer carbonate (main group) with calcium acetate (comparison group) for hyperphosphatemia control in hemodialysis patients for 12 months. 198 patients treated with hemodialysis at the Kyiv City Center of Nephrology and dialysis in the period from 2019 to 2021 were included.

The obtained data showed the high efficiency and safety of sevelamer for hyperphosphatemia correction in hemodialysis patients, as well as a beneficial effect on important clinical outcomes.



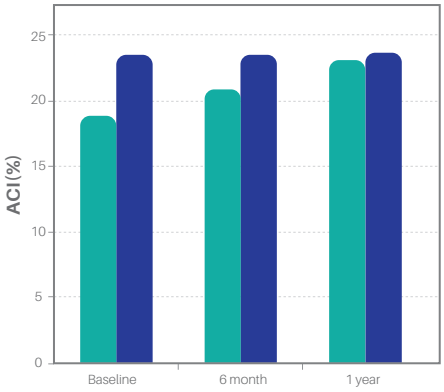
Aortic Vascular Calcification? [6]

Sevelamer Carbonate Vs. Calcium Acetate

The prevalence of vascular (abdominal aortic) calcification was 75% in patients with CKD stages 4 and 5 (69.5% in CKD stage 4 and 85.72% in CKD stage 5). Abdominal aortic calcification increased significantly in calcium acetate-treated patients during six months and one year; however, the increase was not significant in the sevelamer group.

In patients with CKD stages 4 and 5, sevelamer demonstrates higher efficacy and consistency in halting aortic vascular calcification progression than calcium acetate.

The beneficial effect of sevelamer in retarding vascular calcification progression beyond its phosphate-binding property may be associated with its **lipid-lowering and anti-inflammatory properties.**



Progression of aortic calcification index (ACI) in patients assigned to calcium acetate (n=25) and sevelamer (n=25) groups at six months and one year (numbers are presented as mean and SD).

■ Sevelamer ■ Calcium acetate

Dosing and Administration[7]

Table 1: Starting Dose for Adult Dialysis Patients Not Taking a Phosphate Binder.

Serum Phosphorus	Renofa 800
>5.5 and <7.5mg/dL	1 tablet three times daily
≥7.5 mg/dL	2 tablets three times daily

Table 2: Recommended Starting Dosage and Titration Increment based on Pediatric Patients Body Surface Area (m^2)

BSA(M^2)	Starting dose per meal/snack	Titration increases/decreases per dose
>0.75 to <1.2	0.8 g	Titrate by 0.4 g
≥1.2	1.6 g	Titrate by 0.8 g

Table 3: Starting Dose for Dialysis Patients Switching From Calcium Acetate to Renofa 800

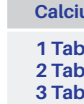
Calcium Acetate 667mg (Tablets per meal)	Renofa 800
1 Tablet	1 Tablet
2 Tablets	2 Tablets
3 Tablets	3 Tablets

*Must be administered with meals.

Hyperphosphatemia is a condition characterized by an increase in serum phosphate level above 4.5mg/100mL

Diagnosis

Blood tests
Serum phosphate measurement



Contraindications: Hypersensitivity to sevelamer or any component of the formulation/ Bowel obstruction/ Hypophosphatemia. **Warnings/Precautions:** Gastrointestinal effects: Bowel obstruction and perforation have been reported. Use with caution in patients with gastrointestinal disorders. / Vitamins: May cause reductions in vitamin D, E, K, or folic acid absorption. /Pregnancy and Breast-Feeding: Sevelamer is not absorbed systemically however, it may reduce maternal absorption of fat-soluble vitamins and folic acid; supplementation may be needed. **Drug Interactions:** Sevelamer may decrease the serum concentration of other medicines or vitamins e.g., D, E, K, or folic acid. Administer other medicine at least 2 hours before or 6 hours after sevelamer, also Consider vitamins supplementation. **Side Effects:** Vomiting, nausea, diarrhea, dyspepsia, abdominal pain, constipation, flatulence, peritonitis.

Rx Code: 66385

Reference:

1. Allart E, Benoit A, Blanchard-Dauphin A, Tiffreau V, Thevenon A, Zephir H, Outteryck O, Lacour A, Vermersch P. Sustained-released fampridine in multiple sclerosis: effects on gait parameters, arm function, fatigue, and quality of life. Journal of neurology. 2015 Aug;262(8):1936-45./ 2. Prugger M, Berger T. Assessing the long-term clinical benefit of prolonged-release fampridine tablets in a real-world setting: a review of 67 cases. Patient related outcome measures. 2013;4:75. / 3. https://www.uptodate.com/contents/dalfampridine-fampridine-drug-information. / 4. https://www.medicines.org.uk/emc/product/4763/smpc#gref. / 5. Horton L, Conger A, Conger D, Remington G, Frohman T, Frohman E, Greenberg B. Effect of 4-aminopyridine on vision in multiple sclerosis patients with optic neuropathy. Neurology. 2013 May 14;80(20):1862-6. / 6. Glasauer S, Kalla R, Büttner U, Strupp M, Brandt T. 4-aminopyridine restores visual ocular motor function in upbeat nystagmus. Journal of Neurology, Neurosurgery & Psychiatry. 2005 Mar 1;76(3):451-3. / 7. Strupp M, Kalla R, Claassen J, Adrion C, Mansmann U, Klopstock T, Freilinger T, Neugebauer H, Spiegel R, Dichgans M, Lehmann-Horn F. A randomized trial of 4-aminopyridine in EA2 and related familial episodic ataxias. Neurology. 2011 Jul 19;77(3):269-75.