SEVLAREN™

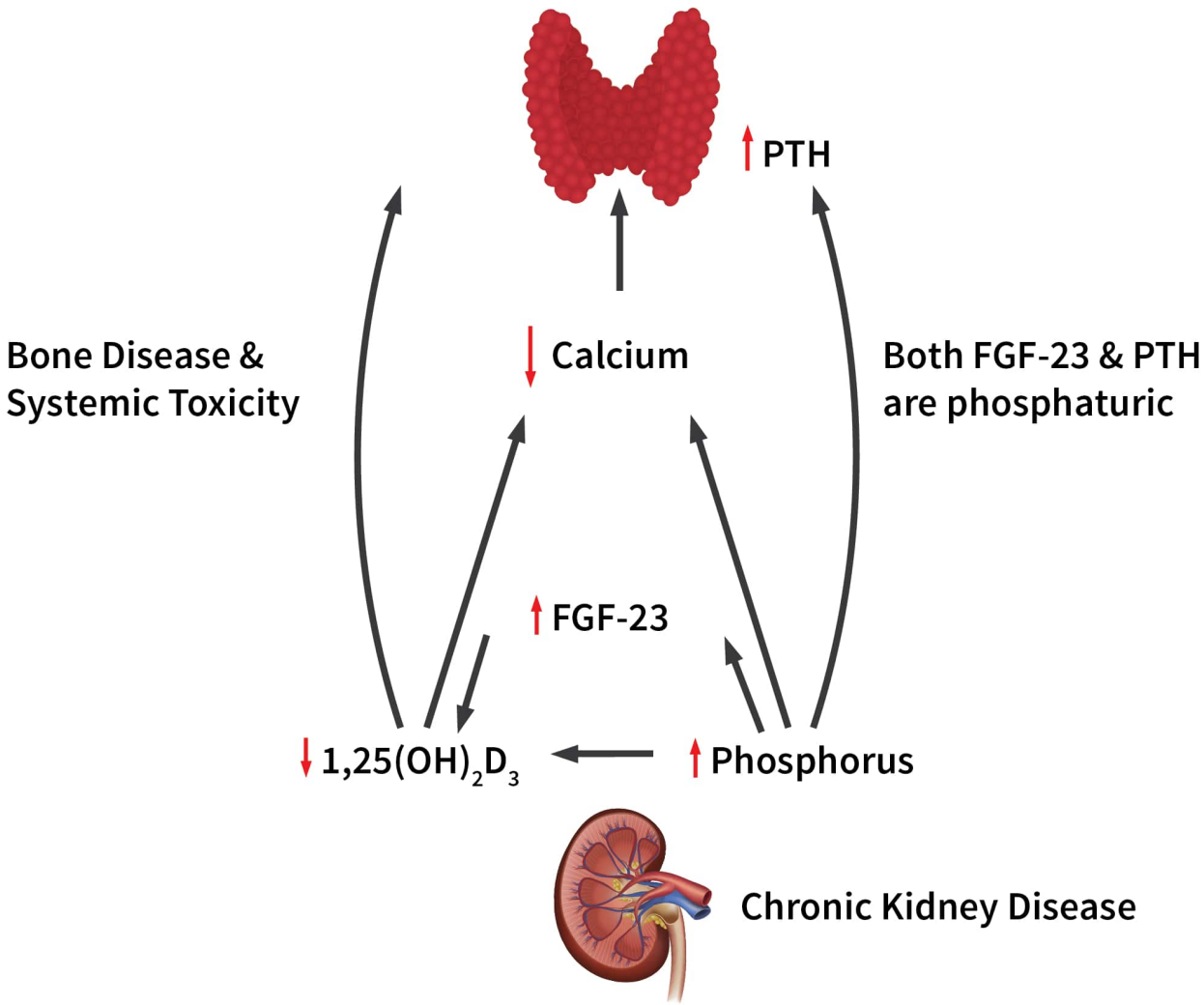
Sevelamer Carnbonate Tablets 400 mg / 800 mg

La Renon®

Background:

- Hyperphosphatemia is associated with significant pathophysiology in chronic kidney disease (CKD).
- Observational studies have determined hyperphosphatemia to be a cardiovascular risk factor in chronic kidney disease.
- This pathophysiology contributes to the high rates of mortality observed in CKD.
- Regulation of phosphorus excretion by the kidney is the key mechanism of maintaining phosphate balance in normal day to day life.
- Kidney injury impairs the ability of mammals to maintain phosphorus balance, and in human chronic kidney disease, phosphorus homeostasis is lost and positive phosphate balance occurs in the later stages (4 and 5) of kidney diseases.

Pathophysiology of Secondary Hyperparathyroidism:



Clinical Evidence:

Sevelamer carbonate lowers serum phosphorus effectively in hemodialysis patients: a randomized, double-blind, placebo-controlled, dose-titration study.

Background:

- Hyperphosphataemia in patients with advanced chronic kidney disease (CKD) is associated with adverse outcomes, including vascular calcification and higher mortality rates.
- While phosphate lowering is an integral aspect of CKD management, the efficacy and safety of phosphate binders in a contemporary cohort of Chinese hemodialysis patients (who have different genetics and dietary patterns than other populations) has not been previously described.
- Moreover, sparse data are available on strategies for optimal dose titration when transitioning from a calcium-based to a polymer-based phosphate binder.

Methods:

- This randomized, double-blind, dose-titration study compared sevelamer carbonate (starting dose 800 mg three times daily) with placebo over 8 weeks' duration in Chinese CKD patients on hemodialysis. Patients were required to be using calcium-based binders prior to study start.

Results:

- In all, 205 patients were randomized (sevelamer, n = 135; placebo, n = 70); 61% were male and the mean time on dialysis was 4.4 years.
- The mean serum phosphorus decreased significantly in patients treated with sevelamer carbonate [change −0.69 ± 0.64 mmol/L (−2.14 ± 1.98 mg/dL)] but remained persistently elevated with placebo [change −0.06 ± 0.57 mmol/L (−0.19 ± 1.76 mg/dL)].
- When compared with placebo, sevelamer carbonate treatment resulted in statistically significant greater mean reductions from baseline in serum total (−17.1 versus −3.3%) and low-density lipoprotein cholesterol (−33.5 versus −7.6%).
- Sevelamer carbonate was well tolerated with 96% adherence compared with 97% adherence in the placebo arm.
- Overall, adverse events experienced by patients in the sevelamer carbonate and placebo treatment groups were similar and consistent with their underlying renal disease.

Conclusion:

- This study demonstrated that hyperphosphataemia developed quickly following the cessation of phosphate binders and remained persistently elevated in end-stage CKD in the placebo-treated group.
- Gradually titrating up sevelamer carbonate from an initial dose of 2.4 g/day to an average daily dose of 7.1 ± 2.5 g/day was well tolerated, safe and efficacious in contemporary Chinese hemodialysis patients.

Reference:
Nephrol Dial Transplant (2014) 29: 152–160

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Description :

- Sevelamer is a polymeric amine that binds phosphate and is meant for oral administration.
- It acts like an anion exchange resin, free of metal and calcium.
- It contains multiple amines separated by one carbon from the polymer backbone.
- These amines exist in a protonated form in the intestine and interact with phosphate molecules through ionic and hydrogen bonding.
- By binding phosphate in the gastrointestinal tract and decreasing absorption, sevelamer carbonate lowers the phosphate concentration in the serum (serum phosphorus).

Composition:

- SEVALREN™ 400 and 800 contains 400mg and 800mg respectively of sevelamer carbonate on anhydrous basis.

Indication:

- SEVLAREN™ is indicated for the control of serum phosphorus in patients with Chronic Kidney Disease.

Mechanism of Action:

- SEVLAREN™, a non-absorbed phosphate-binding crosslinked polymer contains multiple amines separated by 1 carbon from the polymer backbone.
- These amines exist in a protonated form in the intestine and interact with phosphate molecules through ionic and hydrogen bonding.
- By binding phosphate in the dietary tract and decreasing absorption, sevelamer carbonate lowers the concentration in the serum.

Dosage:

- The recommended starting dose of SEVLAREN™ for Serum phosphorus greater than 5.5mg/dl but less than 7.5 mg/dl is 0.8 g thrice daily. For a serum phosphorus more than 7.5 mg/dl the recommended dosage is 1.6 g thrice daily.

Presentation:

- SEVLAREN™ is available as a strip of 10 tablets in Alu-Alu blister packing.

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