Abbreviated Prescribing Information

C: Sevelamer Carbonate (Renvela) 800 mg
P: Tablet and Powder for Oral Suspension.
IND: Control of serum P in patients w/ chronic kidney disease (CKD) on dialysis; hyperphosphatemia in adults receiving hemo-or peritoneal dialysis. Adult CKD patients not on dialysis w/serum P >1.78 mmol/L (5.5 mg/dL). Control of serum P in ped patients (for Tab: >6 yr & BSA of ≥ 0.75 m^2, Pwd: >6 yr & BSA of > 0.75 m^2) w/CKD.
D: Adult Start dose 2.4-4.8 g/day based on clinical needs & P level. To be taken TID with meals. Patient previously on phosphate binders: Give on a gram from gram basis w/ monitoring of serum P levels to ensure optimal daily doses. Monitor serum P levels & titrate dose every 2-4 wks until acceptable serum P level is reached. Continue treatment based on need to control serum P levels & expect daily dose to be average of approx. 6g/day. Pedia Start Dose – if BSA ≥ 1.2 m^2 give 1.6 g/meal, if BSA ≥ 0.75 - < 1.2 m^2 give 0.8 g/meal. May be taken TID with meals.
A: Tab: Swallow whole, do not crust/chew/break. Powd for susp: Disperse in water (30mL) prior to administration. Multiple sachets may be mixed together, as long as the appropriate amount of water is used. Patient should drink the preparation within 30 minutes. As an alternative to water, the powder may be pre-mixed with a small amount of beverage or food (e.g. 4 ounces/ 120 ml) and consumed within 30 minutes. Do not heat (e.g., microwave) or add to hot foods or liquids.
AR: Nausea, vomiting, diarrhea, dyspepsia, abdominal pain, flatulence, constipation;
C: Hypersensitivity to the active substance or to any of the excipients, hypophosphatemia or bowel obstruction.
W: Safety and efficacy have not been established in patients with dysphagia, swallowing disorders, severe gastrointestinal motility disorders, active inflammatory bowel disease, major gastrointestinal tract surgery. Treatment should be reevaluated in patients who develop severe constipation or other severe gastrointestinal symptoms. Patients with CKD may develop low levels of fat-soluble vitamins A, D, E and K, depending on dietary intake and the severity of their disease. Hypo/Hypercalcemia. Metabolic acidosis. Peritonitis. Hypothyroidism. Hyperparathyroidism. Inflammatory gastrointestinal disorders. Limited data on use in pregnant women.
INT: Dialysis. Ciprofloxacin. Ciclosporin, mycophenolate mofetil and tacrolimus in transplant patients, Levothyroxine, Anti-arrhythmics and anti-seizure medicinal products, Proton pump inhibitors.
PD: Sevelamer contains multiple amines separated by one carbon from the polymer backbone which become protonated in the stomach. These protonated amines bind negatively charged ions such as dietary phosphate in the intestine.
PK: Pharmacokinetic studies have not been carried out with sevelamer carbonate. Sevelamer hydrochloride, which contains the same active moiety as sevelamer carbonate, is not absorbed from the gastrointestinal tract, as confirmed by an absorption study in healthy volunteers.

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