For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

Abridged Prescribing Information

Sevelamer Carbonate Tablets and Powder for Oral Suspension

Renvela®

THERAPEUTIC CATEGORY

Phosphate Binder

COMPOSITION

Renvela Tablets : Each film coated tablet contains 800 mg of sevelamer carbonate on an anhydrous basis.

Renvela Sachets : Each sachet contains 0.8 g of sevelamer carbonate for oral suspension on anhydrous basis

THERAPEUTIC INDICATION

Renvela is indicated for control of serum phosphorous in patients with chronic kidney disease on haemodialysis or peritoneal dialysis and patients with CKD not on dialysis with serum phosphorous ≥5.5 mg/dl

DOSAGE AND ADMINISTRATION

Starting dose: The recommended starting dose is 2.4 to 4.8 g per day based on clinical needs and phosphorus level. Renvela must be taken three times per day with meals. For patients previously on phosphate binders (sevelamer hydrochloride or calcium base), Renvela should be given on a gram for gram basis with monitoring of serum phosphorus levels to ensure optimal daily doses.

Titration and Maintenance Serum phosphorus levels must be monitored and the dose of sevelamer carbonate titrated every 2-4 weeks until an acceptable serum phosphorus level is reached, with regular monitoring thereafter.

Patients taking Renvela should adhere to their prescribed diets.

Special Populations

Children The safety and efficacy of Renvela has not been established in children below the age of 18 years. Renvela is not recommended for use in children below the age of 18 years.

Elderly There is no evidence for special considerations when Renvela is administered to elderly patients

Route of administration is oral. Renvela is available as tablets or powder for oral suspension.

Renvela 800 mg tablets can be taken three times per day with meals at a dosage based on individual patient requirements to control phosphate levels. Tablets should be swallowed intact and should not be crushed, chewed, or broken into pieces prior to administration.

Renvela 800 mg powder sachet can be taken three times per day with meals individually or in combination at a dosage based on individual patient requirements to control phosphate levels. The powder should be dispersed in water (30 ml for 0.8 g powder sachet) 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 Renvela (e.g., microwave) or add to hot foods or liquids

SAFETY-RELATED INFORMATION

CONTRAINDICATIONS

Renvela is contraindicated in patients with hypophosphatemia or bowel obstruction and in patients with hypersensitivity to the active substance or to any of the excipients

WARNINGS AND PRECAUTIONS

The safety and efficacy of Renvela in patients with dysphagia, swallowing disorders, severe gastrointestinal motility disorders including severe constipation or major gastrointestinal tract surgery have not been established. Consequently, caution should be exercised when Renvela is used in patients with these disorders. Renvela treatment should be reevaluated in patients who develop severe constipation or other severe gastrointestinal symptoms.Uncommon case reports of difficulty swallowing the tablet have been report. Consider using powder for oral suspension in patients with a history of difficulty swallowing.

Treatment with sevelamer in preclinical studies, approximately at the equivalent of 6-10 times the maximum clinical trial dose, has been shown to reduce the absorption of vitamins D, E and K, and folic acid. Therefore, in patients not taking supplemental vitamins but on sevelamer, serum vitamin A, D, and E levels and vitamin K status should be assessed regularly.

Cases of serious inflammatory disorders of the gastrointestinal tract (including serious with complications such as including hemorrhage bleeding, perforation, ulceration, necrosis and colitis) associated with the presence of sevelamer crystals have been reported. However, the causality of the sevelamer crystals in initiating such disorders has not been demonstrated. Inflammatory disorders may resolve upon Renvela discontinuation. Sevelamer carbonate Treatment with Renvela should be reevaluated in patients who develop severe gastrointestinal symptoms

PREGNANCY

Pregnancy Category C The safety of Renvela has not been established in pregnant or lactating women. Renvela should only be given to pregnant or lactating women if clearly needed and after careful risk/benefit analysis has been conducted for both the mother and fetus or infant.

Studies in animals have shown minimal reproductive toxicity when sevelamer was administered to rats at high doses (see section “Impairment of Fertility” in section Reproduction toxicity).There have been no adequate well controlled studies in women undergoing labor and delivery.

ADVERSE REACTIONS

The most frequently occurring adverse reaction for Renvela 800 mg tablets and 800 mg powder sachet are hypersensitivity,rash, nausea, vomiting, constipation, diarrhea, dyspepsia, abdominal pain, flatulence, constipation, pruritus, abdominal distention, abdominal discomfort,fatigueand anorexia.

For full prescribing information, please write to: Sanofi Healthcare India Private Limited, Sanofi House, CT Survey No 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai 400072

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