Phosphout™

Sevelamer Carbonate 400 mg,800 mg Tablets

Ease out Phosphorus

Product Description:

- Phosphout 400: Each film coated tablet contains Sevelamer Carbonate 400 mg
- Phosphout 800: Each film coated tablet contains Sevelamer Carbonate 800 mg

General Information:

Sevelamer carbonate is a phosphate binding drug used to treat hyperphosphatemiain patients with chronic kidney disease. When taken with meals, it binds to dietary phosphate and prevents its absorption.

Indication & Usage;

Sevelamer carbonateis indicated for the control of hyperphosphatemia in patients with end-stage renal disease (ESRD) undergoing dialysis.

Dosage and Administration:

- **Starting Dose:**
  - Initial Serum Phosphorus: > 1.8 and < 2.4 mmol/L: Dose should be 2.4 gm per day
  - Initial Serum Phosphorus: ≥ 2.4 mmol/L: Dose should be 4.8 gm per day
- **Maintenance**
  - Serum phosphorus should be monitored on a regular basis with the goal of maintaining serum phosphorus levels consistent with current medical standards
  - The average actual daily dose of sevelamer carbonate was approximately 6 g per day. The highest studied daily dose of sevelamer carbonate taken was 14.4 g per day in CKD patients.**:**

Mechanism of action:

Sevelamer prevents hyperphosphatemia by binding to dietary phosphate in the gut, preventing its absorption and thus lowers the phosphate concentration in the serum.

Pharmacokinetic:

Pharmacokinetic studies have not been carried out with sevelamer carbonate as sevelamer is not absorbed from the GI tract

Use in Specific Population:

Pregnancy: The safety of Sevelamer Carbonate has not been established in pregnant women. Sevelamer Carbonate should only be given to pregnant women if the benefits outweigh the risks.

Nursing Mother: There have been no adequate, well-controlled studies in nursing women; however, since sevelamer is not absorbed, excretion in breast milk is not expected.

Paediatric Use: The safety and efficacy of Sevelamer has not been established in children below the age of 18 years. Sevelamer is not recommended for use in children below the age of 18 years.

Geriatric Use: No special considerations are needed for elderly patients.

Contraindication: Sevelamer carbonate is contraindicated in

- Patients with hypophosphatemia
- Patients with bowel obstruction, or known active mucosal injury such as necrosis, perforation, ulcerative colitis or gastrointestinal bleeding
- Patients hypersensitive to sevelamer or one of the other ingredients in the product

Warning & Precaution:

General:

Patients with renal insufficiency may develop hypocalcaemia. In these patients, serum calcium levels should be monitored, and elemental calcium should be supplemented whenever considered necessary. In cases of hypocalcaemia, patients should be given an evening calcium supplement.

Sevelamer carbonate to be given with caution to avoid hypophosphatemia if serum phosphorus of < 0.8 mmol/L

Gastrointestinal:

The safety and efficacy of sevelamer carbonate in patients with dysphagia, swallowing disorders, severe GI motility disorders including severe constipation, or major GI tract surgery have not been established. In these set of patients sevelamer carbonateto be administered with caution

Drug Interaction:

- Sevelamer carbonateshould not be taken simultaneously with ciprofloxacin as bioavailability of ciprofloxacin was decreased by approximately 50%
- Reduced concentrations of cyclosporin, mycophenolate mofetil and tacrolimus have been reported in transplant patients when co-administered with sevelamer.The possibility of an interaction cannot be excluded and close monitoring of blood concentrations of cyclosporin, mycophenolate mofetil and tacrolimus or dosing these medicines apart from sevelamer to prevent GI binding is required
- There areincreased phosphate levels have been reported in patients taking proton pump inhibitors co-administered with sevelamer carbonate

Adverse Reactions:

Adverse Events in Patients with End-Stage Renal Disease undergoing Haemodialysis

Area of Affect	Adverse Effect
Gastrointestinal	Nausea, Vomiting, Abdominal pain, Constipation, Diarrhoea, Dyspepsia
Respiratory, Thoracic and Mediastinal Disorders	Dyspnoea, Cough
Skin Disorders	Pruritus
Infections and Infestations	Nasopharyngitis, Bronchitis Upper Respiratory Tract Infection
Musculoskeletal, Connective Tissue and Bone Disorders	Pain in Limb, Arthralgia, Back Pain
Nervous System Disorders	Headache