

Sevel

Sevelamer Carbonate 800 mg
Film-Coated Tablet

DESCRIPTION

The Active Ingredient of Sevel tablet is Sevelamer Carbonate, a polymeric amine that binds phosphate and is meant for oral administration. Sevelamer Carbonate is known chemically as poly (allylamine-co-N,N'-diallyl-1,3diamino-2-hydroxypropane) carbonate salt. Sevelamer Carbonate is hygroscopic, but insoluble in water.

COMPOSITION

Each film-coated tablet contains Sevelamer Carbonate INN 800 mg.

INDICATIONS

Sevelamer Carbonate is indicated for the control of serum phosphorus in patients with chronic kidney disease (CKD) on dialysis.

DOSAGE AND ADMINISTRATION

Patients Not Taking a Phosphate Binder : The recommended starting dose of Sevelamer Carbonate is 800 to 1600 mg, which can be administered as two to four 400 mg Sevelamer Carbonate Tablets, with meals based on serum phosphorus level. Table 1 provides recommended starting doses of Sevelamer Carbonate for patients not taking a phosphate binder.

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

Serum Phosphorus	Sevelamer Carbonate 800 mg
> 5.5 and < 7.5 mg/dL	1 tablets three times daily with meals
≥7.5 and < 9.0 mg/dL	2 tablets three times daily with meals
≥9.0 mg/dL	2 tablets three times daily with meals

Switching from Sevelamer Hydrochloride tablets: For patients switching from Sevelamer Hydrochloride tablets to Sevelamer Carbonate tablets use the same dose.

Patients switching From Calcium Acetate : Table 2 gives recommended starting doses of Sevelamer Carbonate based on a patients current calcium acetate dose.

Table 2. Starting Dose for Dialysis Patients Switching from Calcium Acetate to Sevelamer Carbonate

Calcium Acetate 667 mg (Tablets per meal)	Sevelamer Carbonate 800 mg (Tablets per meal)
1 tablet	1 tablets
2 tablets	2 tablets
3 tablets	2 tablets

Dose Titration for all Patients taking Sevelamer Carbonate : Dosage should be adjusted based on the serum phosphorus concentration with a goal of lowering serum phosphorus to 5.5 mg/dL or less. The dose may be increased or decreased by one tablet per meal at two week intervals as necessary. Table 3 gives a dose titration guideline.

Table 3. Dose Titration Guideline

Serum Phosphorus	Sevelamer Carbonate
> 5.5 mg/dL	Increase 1 tablet per meal at 2 week intervals
3.5 - 5.5 mg/dL	Maintain current dose
< 3.5 mg/dL	Decrease 1 tablet per meal

OR AS DIRECTED BY THE PHYSICIAN.

CONTRAINDICATIONS

Sevelamer Carbonate is contraindicated in patients with hypophosphatemia or bowel obstruction.

SIDE EFFECTS

Side effects reported include peritonitis, diarrhoea, nausea, constipation, abdominal pain, flatulence, vomiting, fatigue, anorexia,

arthralgia, dyspepsia, pruritus, rash and uncommon cases of ileus, intestinal obstruction and intestinal perforation may occur. Appropriate medical management should be given to patients who develop constipation or have worsening of existing constipation to avoid severe complications.

PRECAUTIONS

The safety of Sevelamer Carbonate has not been established in patients with dysphagia swallowing disorders, severe gastrointestinal (GI) motility disorders including severe constipation, or major GI tract surgery. So, Sevelamer Carbonate should be used with caution in patients with gastrointestinal disorders. Serum bicarbonate and chloride levels should be monitored while using this drug. It may reduce vitamin D, E, K (clotting factors) and Folic acid levels of serum. So these should be monitored.

USE IN PREGNANCY AND LACTATION

Pregnancy category C. Sevelamer Carbonate should only be given to pregnant women if clearly needed and after a careful risk/benefit analysis has been conducted for both the mother and the foetus.

There are no data on the excretion of Sevelamer Carbonate in to breast milk. Sevelamer Carbonate should only be given to lactating women if clearly needed and after a careful risk/benefit analysis has been conducted for both the mother and the infant.

USE IN ELDERLY

There is no evidence for special considerations when Sevelamer Carbonate is administered for elderly patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range.

USE IN CHILDREN

The safety and efficacy of Sevelamer Carbonate has not been established in pediatric patients.

DRUG INTERACTIONS

Sevelamer Carbonate has been studied in human drug-drug interaction studies with ciprofloxacin, digoxin, warfarin, enalapril, metoprolol and iron.

Ciprofloxacin : Sevelamer Carbonate decreased the bioavailability of ciprofloxacin by approximately 50%.

Digoxin: Sevelamer Carbonate did not alter the pharmacokinetics of a single dose of digoxin.

Warfarin: Sevelamer Carbonate did not alter the pharmacokinetics of a single dose of warfarin.

Enalapril : Sevelamer Carbonate did not alter the pharmacokinetics of a single dose of enalapril.

Metoprolol: Sevelamer Carbonate did not alter the pharmacokinetics of a single dose of metoprolol.

Iron: Sevelamer Carbonate did not alter the absorption of a single oral dose of iron as 200 mg exsiccated ferrous sulfate tablet.

SUPPLY

Each box contains 2 x 6 tablets in Alu-Alu blister strips.

Keep all medicines out of reach of children.
Store in a cool and dry place, Protect from light.

* Further information is available on request.

FOR HEALTH, VIGOUR AND HAPPINESS



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