Inophos®

Sevelamer Hydrochloride tablet

Presentation
Inophos® 400: Each tablet contains Sevelamer Hydrochloride INN 400 mg.

Description
The active ingredient in Inophos tablets is Sevelamer Hydrochloride, a polymeric phosphate binder intended for oral administration. Sevelamer hydrochloride is hydrophilic, but insoluble in water. Sevelamer hydrochloride has been shown to decrease serum phosphorus concentrations in patients with ESRD who are on hemodialysis. Sevelamer binds phosphate to a similar extent. Since Sevelamer does not contain aluminum, it does not cause aluminum intoxication.

Indications
Sevelamer Hydrochloride is indicated for the reduction of serum phosphorus in patients with end-stage renal disease (ESRD).

Dosage and administration
Patients not taking a Phosphate Binder: The recommended starting dose of Sevelamer is 800 to 1600 mg, which can be administered as one or two 800 mg Sevelamer tablets or two to four 400 mg Sevelamer tablets, with meals based on serum phosphorus level. Table 1 provides recommended starting doses of Renagel for patients not taking a phosphate binder.

Table 1. Starting dose for dialysis patients not taking a phosphate binder

Serum phosphorus	Sevelamer 800 mg	Sevelamer 400 mg
> 5.5 and < 7.5 mg/dL	1 tablet three times daily with meals	2 tablets three times daily with meals
≥ 7.5 and < 9.0 mg/dL	2 tablets three times daily with meals	3 tablets three times daily with meals
≥ 9.0 mg/dL	2 tablets three times daily with meals	4 tablets three times daily with meals

Patients switching from Calcium Acetate: Table 2 gives recommended starting doses of Sevelamer based on a patient's current calcium acetate dose.

Table 2. Starting dose for dialysis patients switching from calcium acetate to Sevelamer

Calcium Acetate 667 mg (Tablets per meal)	Sevelamer 800 mg (Tablets per meal)	Sevelamer 400 mg (Tablets per meal)
1 tablet	1 tablet	2 tablet
2 tablets	2 tablets	3 tablets
3 tablets	3 tablets	5 tablets

Dose titration for all patients taking Sevelamer: 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 dose
> 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

Side-effects
Sevelamer may cause dyspepsia, peritonitis, diarrhea, nausea, constipation, pruritus, abdominal distension, vomiting, fatigue, anorexia, arthralgia and less commonly ileus, bowel obstruction and bowel perforation.

Use in pregnancy and lactation
Pregnancy: Pregnancy Category C.
Lactation: No adequate and controlled studies have been conducted using Sevelamer in nursing mothers. Sevelamer should be used during breastfeeding only if the potential benefit justifies the potential risks.

Precaution
The safety and efficacy of Sevelamer in patients with dysphagia, swallowing disorders, severe GI motility disorders including severe constipation, or major GI tract surgery have not been established. Caution should be exercised when Sevelamer is used in patients with these GI disorders.

Contraindications
Sevelamer is contraindicated in patients with hypophosphatemia or bowel obstruction. It is contraindicated in patients known to be hypersensitive to Sevelamer hydrochloride or any of its constituents.

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

Overdose
There are no reported overdosages of Sevelamer in patients. Since Sevelamer is not absorbed, the risk of systemic toxicity is low.

Commercial Pack
Inophos® 400: Each box contains 5 blister strips of 4 tablets.

Manufactured by
Incepta Pharmaceuticals Ltd
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