

PRESENTATION

Each tablet contains Calcium Acetate USP 667 mg

INDICATION

Lofos™ is indicated for the -

- Treatment of hyperphosphatemia
- Control of hyperphosphatemia in end stage renal failure

DOSAGE AND ADMINISTRATION

The recommended initial dose of **Lofos**TM for the adult dialysis patient is 2 tablets with each meal. The dosage may be increased gradually to bring the serum phosphate level below 6 mg/dl, as long as hypercalcemia does not develop. Most patients require 3-4 tablets with each meal.

SIDE EFFECT

Patients may occasionally experience nausea during Calcium Acetate therapy. Hypercalcemia may occur during treatment with Calcium Acetate. Mild hypercalcemia (Ca >10.5 mg/dl) may be asymptomatic or manifest itself as constipation, anorexia, nausea and vomiting. More severe hypercalcemia (Ca >12 mg/dl) is associated with confusion, delirium, stupor and coma. The long-term effect of Calcium Acetate on the progression of vascular or soft-tissue calcification has not been determined. Isolated cases of pruritus have been reported which may represent allergic reactions.

CONTRAINDICATION

Calcium Acetate is contraindicated in patients with hypercalcemia.

DRUG INTERACTION

Calcium Acetate may decrease the bioavailability of tetracyclines.

PRECAUTION

Excessive dosage of Calcium Acetate induces hypercalcemia; therefore, early in the treatment during dosage adjustment serum calcium should be determined twice weekly. If hypercalcemia develops, the dosage should be reduced or the treatment should be discontinued immediately depending on the severity of hypercalcemia. Calcium Acetate should not be given to patients on digitalis, because hypercalcemia may precipitate cardiac arrhythmias. Calcium Acetate therapy should always be started at low dose and should not be increased without careful monitoring of serum calcium.

USE IN PREGNANCY & LACTATION

Animal reproduction studies have not been conducted with Calcium Acetate. It is not known whether Calcium Acetate can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Calcium Acetate should be given to a pregnant woman only if clearly needed. There are no adequate studies in women for determining infant risk when using the medication during breastfeeding. Weigh the potential benefits against the potential risks before taking this medication while breastfeeding.

STORAGE

Store below 25° C temperature, protect from light & moisture.

HOW SUPPLIED

 $\textbf{Lofos}^{\,\text{TM}}$ tablet: Box containing 60 tablets in blister pack.

Manufactured by

