ELIPHOS™ Tablets
Rx Only

Description: Each white, round tablet (stamped "CYP 910") contains 667 mg of calcium acetate, USP (anhydrous; Ca(CH3COO)2; MW = 158.17 grams) equal to 169 mg (8.45 mEq) calcium, polyethylene glycol 8000, NF; sodium lauryl sulfate, NF; and crospovidone, NF. ELIPHOS™ (Calcium Acetate, USP) are administered orally for the control of hyperphosphatemia in end stage renal failure.

Clinical Pharmacology: Patients with advanced renal insufficiency (creatinine clearance less than 30 mL/min) exhibit phosphate retention and some degree of hyperphosphatemia. The retention of phosphate plays a pivotal role in causing secondary hyperparathyroidism associated with osteodystrophy, and soft-tissue calcification. The mechanism by which phosphate retention leads to hyperparathyroidism is not clearly delineated. Therapeutic efforts directed toward the control of hyperphosphatemia include reduction in the dietary intake of phosphate, inhibition of absorption of phosphate in the intestine with phosphate binders, and removal of phosphate from the body by more efficient methods of dialysis. The rate of removal of phosphate by dietary manipulation or by dialysis is insufficient. Dialysis patients absorb 40% to 80% of dietary phosphorus. Therefore, the fraction of dietary phosphate absorbed from the diet needs to be reduced by using phosphate binders in most renal failure patients on maintenance dialysis. Calcium acetate (ELIPHOS™), when taken with meals, combines with dietary phosphate to form insoluble calcium phosphate which is excreted in the feces. Maintenance of serum phosphorus below 6.0 mg/dl is generally considered as a clinically acceptable outcome of treatment with phosphate binders. ELIPHOS™ is highly soluble at neutral pH, making the calcium readily available for binding to phosphate in the proximal small intestine.

Orally administered calcium acetate from pharmaceutical dosage forms has been demonstrated to be systemically absorbed up to approximately 40% under fasting conditions and up to approximately 30% under nonfasting conditions. This range represents data from both healthy subjects and renal dialysis patients under various conditions.
Indications and Usage: ELIPHOS™ is indicated for the control of hyperphosphatemia in end stage renal failure and does not promote aluminum absorption.

Contraindications: Patients with hypercalcemia.

Warnings: Patients with end stage renal failure may develop hypercalcemia when given calcium with meals. No other calcium supplements should be given concurrently with ELIPHOS™.

Progressive hypercalcemia due to overdose of ELIPHOS™ may be severe as to require emergency measures. Chronic hypercalcemia may lead to vascular calcification, and other soft-tissue calcification. The serum calcium level should be monitored twice weekly during the early dose adjustment period.

The serum calcium times phosphate (CaXP) product should not be allowed to exceed 66. Radiographic evaluation of suspect anatomical region may be helpful in early detection of soft-tissue calcification.

Precautions: General: Excessive dosage of ELIPHOS™ induces hypercalcemia; therefore, early in the treatment during dosage adjustment serum calcium should be determined twice weekly. Should hypercalcemia develop, the dosage should be reduced or the treatment discontinued immediately depending on the severity of hypercalcemia. ELIPHOS™ should not be given to patients on digitalis, because hypercalcemia may precipitate cardiac arrhythmias. ELIPHOS™ therapy should always be started at low dose and should not be increased without careful monitoring of serum calcium. An estimate of daily dietary calcium intake should be made initially and the intake adjusted as needed. Serum phosphorus should also be determined periodically.

Information for the patient: The patient should be informed about compliance with dosage instructions, adherence to instructions about diet and avoidance of the use of nonprescription antacids. Patients should be informed about the symptoms of hypercalcemia (see ADVERSE REACTIONS section).

Drug Interactions: ELIPHOS™ may decrease the bioavailability of tetracyclines.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Long term animal studies have not been performed to evaluate the carcinogenic potential,

mutagenicity, or effect on fertility of calcium acetate tablets.

Pregnancy: Teratogenic Effects: Category C. Animal reproduction studies have not been conducted with calcium acetate tablets. It is also not known whether calcium acetate tablets can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Calcium acetate tablets should be given to a pregnant woman only if clearly needed.

Pediatric Use: Safety and efficacy of calcium acetate tablets have not been established.

Geriatric Use: Of the total number of subjects in clinical studies of calcium acetate tablets (n = 91), 25 percent were 65 and over, while 7 percent were 75 and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Adverse Reactions: In clinical studies, patients have occasionally experienced nausea during calcium acetate tablet therapy. Hypercalcemia may occur during treatment with ELIPHOS™. 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. Mild hypercalcemia is easily controlled by reducing the ELIPHOS™ dose or temporarily discontinuing therapy. Severe hypercalcemia can be treated by acute hemodialysis and discontinuing calcium acetate tablets therapy.

Decreasing dialysate calcium concentration could reduce the incidence and severity of ELIPHOS™ induced hypercalcemia. The long-term effect of calcium acetate tablets 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.

Overdosage: Administration of ELIPHOS™ in excess of the appropriate daily dosage can cause severe hypercalcemia (See ADVERSE REACTIONS).

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

How Supplied: In tablet form with “CYP 910” debossed on one side and plain on the other, for oral administration. Each white round tablet contains 667 mg of calcium acetate (anhydrous Ca(CH3COO)2; MW = 158.17 grams) equal to 169 mg (8.45 mEq) calcium, polyethylene glycol 8000, NF; sodium lauryl sulfate, NF; and crospovidone, NF.

Tablets, NDC 63717-910-02, bottles of 200.
Samples, NDC 63717-910-99, bottles of 30.

Storage: Store at 25° C (77° F); excursions permitted to 15°–30° C (59°–86° F) [See USP Controlled Room Temperature].

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Manufactured for:
Hawthorn Pharmaceuticals, Inc.
Madison, MS 39110

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