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Urophos™ 667 mg Tablet
(Calcium Acetate)

یوروفوس

COMPOSITION:
Each tablet contains:
Calcium Acetate ..... 667 mg.

Product Specs.: USP

DESCRIPTION:
Urophos acts as a phosphate binder. Its chemical name is calcium acetate. Its molecular formula is $C_4H_6CaO_4$, and its molecular weight is 158.17. Urophos are administered orally for the control of hyperphosphatemia in end-stage renal failure.

CLINICAL PHARMACOLOGY:
Patients with ESRD retain phosphorus and can develop hyperphosphatemia. High serum phosphorus can precipitate serum calcium resulting in ectopic calcification. Hyperphosphatemia also plays a role in the development of secondary hyperparathyroidism in patients with ESRD.
Mechanism of Action:
Calcium acetate when taken with meals, combines with dietary phosphate to form an insoluble calcium phosphate complex, which is excreted in the feces, resulting in decreased serum phosphorus concentration.
Pharmacodynamics:
Orally administered calcium acetate from pharmaceutical dosage forms is systemically absorbed up to approximately 40% under fasting conditions and up to approximately 30% under non fasting conditions. This range represents data from both healthy subjects and renal dialysis patients under various conditions.

DRUG INTERACTIONS:
The drug interaction is characterized by the potential of calcium to bind to drugs with anionic functions (e.g., carboxyl, and hydroxyl groups). Urophos may decrease the bioavailability of tetracycline's or fluoroquinolones via this mechanism.
There are no empirical data on avoiding drug interactions between calcium acetate or urophos and most concomitant drugs. When administering an oral medication with where a reduction in the bioavailability of that medication would have a clinically significant effect on its safety or efficacy, administer the drug one hour before or three hours after calcium acetate. Monitor blood levels of the concomitant drugs that have a narrow therapeutic range. Patients taking anti-arrhythmic medications for the control of arrhythmias and anti-seizure medications for the control of seizure disorders were excluded from the clinical trials with all forms of calcium acetate.

INDICATION & USAGE:
Urophos is a phosphate binder indicated to reduce serum phosphorus in patients with end stage renal disease (ESRD). goals.

DOSAGE AND ADMINISTRATION:
The recommended initial dose of Urophos for the adult dialysis patient is 2 tablets with each meal. Increase the dose gradually to lower serum phosphorus levels to the target. range, as long as hypercalcemia does not develop. Most patients require 3-4 Tablets with each meal.

CONTRAINDICATIONS:
Patients with hypercalcemia.

WARNINGS & PRECAUTIONS:
Hypercalcemia patients with end stage renal disease may develop hypercalcemia when treated with calcium, including calcium acetate. Avoid the use of calcium supplements, including calcium based nonprescription antacids, concurrently with calcium acetate.
An overdose, may lead to progressive hypercalcemia, which may require emergency measures. Therefore, early in the treatment phase during the dosage adjustment period, monitor serum calcium levels twice weekly. Should hypercalcemia develop, reduce the dosage, or discontinue the treatment, depending on the severity of hypercalcemia. More severe hypercalcemia (Ca >12 mg/dL) is associated with confusion, delirium, stupor and coma. Severe hypercalcemia can be treated by acute hemodialysis and discontinuing therapy. Mild hypercalcemia (10.5 to 11.9 mg/dL) may be asymptomatic or manifest as constipation, anorexia, nausea, and vomiting. Mild

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hypercalcemia is usually controlled by reducing the dose or temporarily discontinuing therapy. Decreasing or discontinuing Vitamin D therapy is recommended as well. Chronic hypercalcemia may lead to vascular calcification and other soft-tissue calcification. Radiographic evaluation of suspected anatomical regions may be helpful in early detection of soft tissue calcification. The long term effect on the progression of vascular or soft tissue calcification has not been determined.

USE IN SPECIFIC POPULATION:
Pregnancy:
Pregnancy Category C Urophos contains calcium acetate. Animal reproduction studies have not been conducted and there are no adequate and well controlled studies of use in pregnant women. Patients with end stage renal disease may develop hypercalcemia with calcium acetate treatment. Maintenance of normal serum calcium levels is important for maternal and fetal wellbeing. Hypercalcemia during pregnancy may increase the risk for maternal and neonatal complications such as stillbirth, preterm delivery, and neonatal hypocalcemia and hypoparathyroidism. treatment, as recommended, is not expected to harm a fetus if maternal calcium levels are properly monitored during and following treatment.
Labor and Delivery The effects on labor and delivery are unknown.
Nursing Mothers:
Calcium acetate is excreted in human milk. Human milk feeding by a mother receiving is not expected to harm an infant, provided maternal serum calcium levels are appropriately monitored. In pediatric patients safety have not been established.
Geriatric Use Clinical Studies:
Calcium acetate did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

DRUG INTERACTIONS:
Hypercalcemia may aggravate digitalis toxicity.

ADVERSE REACTIONS:
Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in the clinical studies of another drug and may not reflect the rates observed in clinical practice. Mild hypercalcemia may be asymptomatic or manifest itself as constipation, anorexia, nausea, and vomiting. More severe hypercalcemia is associated with confusion, delirium, stupor, and coma. Decreasing dialysate calcium concentration could reduce the incidence and severity of hypercalcemia. Isolated cases pruritus have been reported, which may represent allergic reactions. Because reactions are reported voluntarily from a population of uncertain size, it is not always possible to estimate their frequency or to establish a causal relationship to drug exposure.
The following additional adverse reactions have been identified during post-approval of calcium acetate are:
- Dizziness, edema, and weakness

OVER DOSAGE:
Administration in excess of the appropriate daily dosage may result in hypercalcemia.

INSTRUCTIONS:
Store below 30°C. Protect from heat, sunlight & moisture. Keep out of the reach of children.
To be sold on the prescription of a registered medical practitioner only.

PRESENTATION:
Urophos Tablet 667 mg : Pack of 10 x 10 tablets.

ہدایات:
۳۰ درجہ سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
گرمی، دھوپ اور نمی سے بچائیں۔
بچوں کی پہنچ سے دور رکھیں۔
صرف ڈاکٹر کے نسخہ پر فروخت کریں۔

FOR FURTHER INFORMATION PLEASE CONTACT:

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