Only for the use of Medical Professionals

Remophos®

Calcium Acetate

Description

Remophos® is a preparation of Calcium Acetate. Calcium acetate (Remophos®) when taken with meals combines with dietary phosphate to form insoluble calcium phosphate which is excreted in the feces.

Indications

Remophos® is indicated for the -

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

Dosage and administration

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

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.

Precautions

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. An estimate of daily calcium intake should be made initially and the intake adjusted as needed. Serum phosphorus should also be determined periodically.

Side effects

In clinical studies, patients have occasionally experienced nausea during Calcium Acetate therapy. Hypercalcemia may occur during treatment with Calcium Acetate. Mild hypercalcemia (Ca> 10.5mg/dl) may be asymptomatic or manifest itself as constipation, anorexia, nausea and vomiting. More severe hypercalcemia (Ca>12mg/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.

Contraindications

Calcium Acetate is contraindicated in 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 Calcium Acetate.

Drug interactions
Calcium Acetate may decrease the bioavailability of tetracyclines.

Over dosage
Administration of Calcium Acetate in excess of the appropriate daily dosage can cause severe hypercalcemia. Mild hypercalcemia is easily controlled by reducing the Calcium Acetate dose or temporarily discontinuing therapy. Severe hypercalcemia can be treated by acute hemodialysis and discontinuing Calcium Acetate therapy. Decreasing dialysate calcium concentration could reduce the incidence and severity of Calcium Acetate induced hypercalcemia.

Pharmaceutical precautions
Store in a cool & dry place at room temperature. Protect from light, heat & moisture.

Presentation
Remophos® tablet: Each tablet contains Calcium Acetate 667 mg USP.

Package quantities
Remophos® tablet: Carton of 50 tablets in Alu-PVC blister.

® Registerd Trade Mark

ACI Limited
Narayanganj, Bangladesh