PHOSLO Tablet
(Calcium Acetate)

فوسلو ٹیبلیٹ
(کیلشیئم ایسیٹیٹ)

COMPOSITION
Phoslo Tablet 667mg
Each tablet contains:
Calcium Acetate 667mg eq. to elemental calcium 169mg
(USP Specifications)

DESCRIPTION
Calcium acetate is the calcium salt of acetic acid. The anhydrous form is very hygroscopic, therefore the monohydrate Ca $(C_2H_3OO)_2.H_2O$ is the common form.

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 vital 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 towards 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 when taken with meals combines with dietary phosphate to form insoluble Calcium Phosphate which is excreted in the feces. Maintenance of serum phosphate below 6.0 mg/dl is generally considered as a clinically acceptable outcome of treatment with phosphate binders. Calcium acetate is highly soluble at neutral pH, making the calcium readily available for binding to phosphate in the proximal end of 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 non fasting conditions. This range represents data from both healthy subjects and renal dialysis patients under various conditions.

INDICATIONS AND USAGE
Phoslo is indicated for the control of hyperphosphatemia in end stage renal failure and does not promote aluminium 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 Calcium acetate.Progressive hypercalcemia due to overdose of Calcium acetate may be severe as to require emergency measures. Chronic hypercalcemia may leads 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 Calcium Acetate induces hypercalcemia therefore, early in the treatment during dosage adjustment serum Calcium should be determined twice weekly. If hypercalcemia develop, the dosage should be reduced or the treatment 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 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.

Drug Interactions: Calcium acetate may decrease the absorption of bisphosphonates, phenytoinquinolone, strontium, thyroid medication and tetracycline anti biotic.
Pregnancy: It is also not known weather 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.

Pediatric Use: Safety and effectiveness in pediatric patients have not been established.

Geriatric Use: In clinical studies of Calcium acetate 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 therapy. Hypercalcemia may occur during treatment with Calcium acetate. Mild hypercalcemia (Ca> 10.5mg/dl) may be a symptomatic or manifest itself as constipation, anorexia, nausea and vomiting. More severe hypercalcemia (Ca> 12mg/dl) is associated with confusion, delirium, stupor and coma. 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. 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.

OVERDOSAGE
Administration of Calcium acetate in excess of the appropriate daily dosage can cause severe hypercalcemia.

MISSED DOSE
If a patient miss the dose, skip the missed dose unless patient have just eaten.if the patient have not recently eaten or if it is near the time of next dose, skip the missed dose and resume the usual dosing schedule. Do not double the dose.

DOSAGE AND ADMINISTRATION
Tablets: The recommended initial dose of Phoslo 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.

STORAGE & INSTRUCTIONS
Store between 15-25°C.
Protect from heat, sunlight and moisture.
Keep away from the reach of children.
To be sold on prescription of registered medical practitioner only.

HOW SUPPLIED
Phoslo Tablet 667mg
30's, 100's Tablets.

خوراک وطریقہ استعمال:
ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات:
دوا کو ۱۵-۲۵ ڈگری سینٹی گریڈ درجہ حرارت کے درمیان رکھیں۔
دھوپ، گرمی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔
صرف رجسٹرڈ ڈاکٹر کے نسخے کے مطابق فروخت کریں۔

Manufactured by:
PHARMASOL
PRIVATE LIMITED
Plot # 549, Sundar Industrial Estate,
Lahore, Pakistan.