CALCIUM ACETATE - calcium acetate capsule
State of Florida DOH Central Pharmacy

Calcium Acetate Capsules

RX Only

DESCRIPTION

Each white opaque/blue opaque gelcap contains 667 mg of calcium acetate, (anhydrous; Ca(CH3COO)2; MW=158.17 grams) equal to 169 mg (8.45 mEq) calcium. Each capsule also contains FD&C blue #1, FD&C red #3, gelatin, magnesium stearate, polyethylene glycol 8000, and titanium dioxide. In addition to the ingredients listed above, each capsule contains Opacode (Black) monogrammingink. Opacode (Black) contains ethanol, FD&C blue #2, FD&C red #40, FD&C yellow #6, iron oxide black, Nbutyl alcohol, propylene glycol, and shellac. Calcium Acetate Capsules 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 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. Calcium acetate 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

Calcium Acetate Capsules are indicated for the control of hyperphosphatemia in end stage renal failure and do 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 calcium acetate capsules. Progressive

hypercalcemia due to overdose of calcium acetate 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. **Theserum calcium times phosphate(CaXP) product should not be allowedto 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. Should 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 calcium intake should be made initially and the intake adjusted as needed. Serum phosphorus should also be determined periodically.

Information for patients

The patients 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**).

Drug interactions

Calcium acetate may decrease the bioavailability of tetracyclines.

Carcinogenesis, mutagenesis, impairment of fertility

Long-term animal studies have notbeen performed to evaluate the carcinogenic potential, mutagenicity, or effect on fertility of calcium acetate.

Pregnancy

Teratogenic effects: Category C:

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.

Pediatric use

Safety and effectiveness in pediatric patients have not been established.

Geriatric use

Of the total number of subjects in clinical studies of calcium acetate (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 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. 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 (see **ADVERSE REACTIONS**).

DOSAGE AND ADMINISTRATION

The recommended initial dose of calcium acetate capsules for the adult dialysis patient is 2 capsules 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 to 4 capsules with each meal.

HOW SUPPLIED

Calcium Acetate Capsules are supplied as white opaque/blue opaque capsules imprinted with “54 215” on the cap and body.

They are supplied by **State of Florida DOH Central Pharmacy** as follows:

NDC	Strength	Quantity/Form	Color	Source NDC
53808-0216-1	667 mg	30 Capsule	Blue Opaque	0054-0088-26

STORAGE

Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.]

This product was Manufactured By:

Roxane Laboratories, Inc.

And Repackaged By:

State of Florida DOH Central Pharmacy
104-2 Hamilton Park Drive
Tallahassee, FL 32304
United States

Package Label - Calcium Acetate Capsules, 667 mg

53808-0216-1 - 30 Capsules

Rx Only

Roxane Laboratories, Inc.

CALCIUM ACETATE

calcium acetate capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:53808-0216(NDC:0054-0088)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CALCIUM ACETATE (UNII: Y882YXF34X) (CALCIUM - UNII:SY7Q814VUP)	CALCIUM ACETATE	667 mg

Inactive Ingredients	
Ingredient Name	**Strength**
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
GELATIN (UNII: 2G86QN327L)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ALCOHOL (UNII: 3K9958V90M)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	

Product Characteristics

Color	WHITE (Blue Opaque)	**Score**	no score
Shape	CAPSULE	**Size**	1mm
Flavor		**Imprint Code**	54215
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53808-0216-1	30 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077728	07/01/2009	

Labeler - State of Florida DOH Central Pharmacy (829348114)

Establishment

Name	Address	ID/FEI	Business Operations
State of Florida DOH Central Pharmacy		829348114	repack

Revised: 3/2010 State of Florida DOH Central Pharmacy