



LEAFLET

AGOCAL

CALCIUM LACTATE TABLETS BP 300 mg

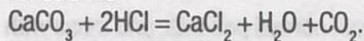
COMPOSITION

Each uncoated tablet contains :

Calcium lactate BP 300 mg.

CLINICAL PHARMACOLOGY

Antacids react with gastric acid to produce a salt and water for calcium lactate, the postulated chemical reaction is :



The doses commonly used result in a pH of over 9 when dissolve in 30-40 ml water in vitro 2 g calcium lactate will readily bring 100 ml hydrochloric acid (0.1 mol. l⁻¹) to a pH above 6. The increase in gastric pH diminishes the activity of pepsin in the gastric secretion.

In Chronic renal failure patients, calcium lactate is used as a phosphate-binding agent, alone, or in combination with an aluminium containing drug, Phosphate absorption from the gastrointestinal tract is reduced by calcium lactate subsequent to the formation of calcium phosphate in the lumen. It was found that 75 mEq. calcium bound 4.7 mEq phosphate. However their resulting reduction in serum phosphorus concentration may be due only in part to phosphate binding in the gut, as it has been suggested that increased deposition of calcium phosphate in bone and soft tissue may also be important. Up to 30% of the oral calcium load may be absorbed and therefore calcium lactate can be used to supplement the diet.

INDICATION (S)

Calcium lactate tablet is indicated for :

1. For dietary calcium supplementation
2. As a phosphate binder in chronic renal failure
3. As an antacid

DOSAGE AND ADMINISTRATION (DIRECTIONS FOR USE)

Calcium lactate always used orally and when used as on antacid the recommended doses for adults are equivalent to 540 - 2000 mg calcium lactate per 24 hr. doses for children being half of those for adults. With the advent of effective antigastric secretory and mucosal protectant drugs, antacids should not be used with the aim of healing but as an adjunct for pain relief, particularly during early treatment with the above agents, hence the antacids are best taken regularly to combat pain. As a dietary supplement, such as for the prevention of Osteoporosis, 500 - 1500 mg. calcium daily (1250-3750 mg. calcium lactate) is recommended in general, but again this will need to be tailored to the individual patient depending on any disease specificities such as specific calcium deficiency, malabsorption or parathyroid function.

In chronic renal failure the doses used vary from 2.5 - 9 g. calcium lactate per 24 hr. and need to be adjusted according to the individual patient. To maximize effective phosphate binding in this context the calcium lactate should be given with meals.

PRECAUTIONS & WARNINGS

The milk-alkali syndrome, which includes hypercalcaemia and alkalosis together with renal dysfunction,



Regd. Office & Factory : Plot No. 33, Sector II, The Vasai Taluka Industrial Co-op. Estate Ltd. Gaurai-pada, Vasai (E), Dist. Thane - 401 208. INDIA.
Tel. : 95250 - 2455801 / 2452714 / 2453525 • Fax : 95250 - 2452074 (0091 - 250 - 2452074) • Email : agog@vsnl.net & agogpharma@rediffmail.com

has occasionally occurred, usually in patients taking large doses, patients with renal impairment or dehydration and electrolyte imbalance are predisposed.

High doses or prolonged use may lead to gastric hypersecretion and acid rebound.

CONTRAINDICATIONS

1. Hypercalcemia and hyperparathyroidism
2. Renal calculi and nephrolithiasis
3. Zollinger-Ellison syndrome
4. Concomitant digoxin therapy (required careful monitoring at serum calcium level)

ADVERSE REACTION / SIDE EFFECTS

Acute hypercalcemia and life threatening renal failure have been described after antacid therapy with Bisocodel. Eleven cases of mild to severe hypercalcemia in hemodialysis patients treated with calcium lactate were noted by Stein; three of these patients needed admission to hospital for treatment of impacted feces and worsening hypertension.

Hypercalcemia associated with excess calcium lactate therapy in both normal patients, and those with renal failure is usually reversible on reduction or cessation of therapy. There is some evidence of urinary alkalization in patients treated with calcium lactate, but the clinical significance of this is unclear. There is no good evidence that calcium lactate accelerates the deterioration of renal function in pre-end state patients with chronic renal failure.

The main symptomatic adverse effects in calcium therapy relate to hypercalcemia. However constipation may be a problem with a normal serum calcium. Systemic alkalosis and hypercalcemia in patients drinking large amounts of milk as an adjunct to antacid therapy are well documented but rare in practice. 'Acid rebound' with worsening dyspeptic symptoms on cessation of calcium lactate therapy is described, possibility related to stimulation of gastric secretion by the direct action of calcium on the gastric mucosa. Eructation may occur owing to carbon dioxide production in the stomach.

STORAGE

Store under normal storage conditions. (15°C to 30°C) and in tightly closed container.
Protect from light.

Keep all medicines out of reach of children

PRESENTATION

A bulk pack of 100 / 250 / 500 / 1000 Tablets.

Blister pack of 10 x 10 Tablets.

Blister pack of 100 x 10 Tablets.

Manufactured in India by



AGOG PHARMA LTD.

Plot No. 33, Sector II, The Vasai Taluka Industrial Co-op. Estate Ltd.,
Vasai (E), Dist. Thane. INDIA