



ORACAL

Chewable Tablets

Composition

Each tablet contains Calcium carbonate 600 mg, equivalent to 240 mg calcium.

Action

Calcium is essential for the functional integrity of the nervous, muscular, and skeletal systems. It plays a role in normal cardiac function, renal function, respiration, blood coagulation, and cell membrane and capillary permeability. In addition, calcium helps to regulate the release and storage of neurotransmitters and hormones, the uptake and binding of amino acids, the absorption of vitamin B₁₂, and gastrin secretion.

Pharmacokinetics

Approximately one-fifth to one-third of orally administered calcium is absorbed in the small intestine, depending on presence of vitamin D metabolites, pH in lumen, and on dietary factors, such as calcium binding to fiber or phytates. Calcium absorption increased when a calcium deficiency is present or when a patient is on a low-calcium diet. In patients with achlorhydria or hypochlorhydria, calcium absorption may be reduced.

About 45% of calcium bounded to proteins in the plasma. The amount of calcium eliminated through the kidneys (about 20%) varies with degree of calcium absorption and whether there is excessive bone loss or failure of renal conservation. About 80% of calcium is eliminated through the faeces (consists mainly of nonabsorbed calcium).

Indications

Oracal indicated in the following conditions:

Hypocalcaemia

Oracal provides a source of calcium ion for treating calcium depletion occurring in conditions such as chronic hypoparathyroidism, pseudohypoparathyroidism, osteomalacia, rickets, chronic renal failure, and hypocalcaemia secondary to the administration of anticonvulsant medications. When chronic hypocalcaemia is due to vitamin D deficiency, oral calcium salts may be administered concomitantly with vitamin D analogs (Alfacal, Oral D)

Calcium Deficiency

Oracal used as dietary supplemental therapy for persons who may not get enough calcium in their regular diet. Due to increased needs, children and pregnant women are at greatest risk. Pre- and postmenopausal women; adolescents, especially girls and the elderly may not receive adequate calcium in their diets. Supplementation is necessary in patients receiving total parenteral nutrition (TPN) or undergoing rapid weight loss or in those with malnutrition, because of inadequate dietary intake.

Osteoporosis

Calcium used as part of the prevention and treatment of osteoporosis in patients with an inadequate calcium intake.



Hyperacidity

For the symptomatic relief of upset stomach associated with hyperacidity, including heartburn, acid indigestion, sour stomach, and hyperacidity associated with the diagnosis of peptic ulcer, gastritis, peptic esophagitis and hiatus hernia.

Hyperphosphatemia

Calcium carbonate is used in patients with end-stage renal failure (renal osteodystrophy) to lower serum phosphate concentrations. However, it should be used with caution in patients on chronic hemodialysis.

Contraindications

- Known hypersensitivity to the preparation.
- This preparation contraindicated in patients with hypercalcemia, hypercalciuria, calcium renal calculi or ventricular fibrillation.

Warnings & Precautions

Care should be taken in patients who are severely debilitated or suffering from kidney failure. Calcium supplement should not be used in hyperparathyroidism, unless the need for calcium supplement is high and the patient is carefully monitored.

This preparation should be used with caution if at all, in patients with severe renal disease, sarcoidosis and in patients receiving cardiac glycosides.

Hypercalcemia/hypercalciuria may result when therapeutic amounts of calcium taken for prolonged periods. This is most likely to occur in hypoparathyroid patients receiving high doses of vitamin D, its analogues or metabolites. In such cases, frequent monitoring of plasma and urine calcium levels is required.

Absorption of calcium carbonate may be impaired in patients presenting with achlorhydria or hypochlorhydria. In such cases, patients should advise to take the preparation with meals. Chronic use may cause rebound hyperacidity and may lead to milk-alkali syndrome.

Use in Geriatrics

With advancing age, intestinal calcium absorption decreases. Therefore, calcium requirements increased in the elderly, and dosages of oral supplements may need to adjust accordingly. Impaired absorption may be due to low levels of active vitamin D metabolites.

Fertility, pregnancy and lactation

Pregnancy

Category A

During pregnancy, there is an increased need for calcium to calcify fetal bones and to increase the maternal skeletal mass in preparation for lactation. This need normally met by enhanced intestinal absorption of calcium, increased vitamin D production, and concurrent increase in calcitonin secretion, which prevents unwanted bone resorption in the maternal skeleton. The maternal parathyroid glands undergo hyperplasia, producing greater amounts of parathyroid hormone,



which acts indirectly to increase intestinal absorption of calcium, reabsorption at the distal renal tubules, and bone calcium mobilization. However, the prescribing of Oracal during pregnancy may be necessary since standard prenatal vitamins along with normal intake of dairy products may not provide sufficient elemental calcium for the average pregnant women.

Nursing Mothers

Problems in nursing babies not been documented. Although some oral supplemental calcium may be excreted in breast milk, the concentration is not sufficient to produce an adverse effect in the neonate.

Adverse Reactions

Adverse Reactions are more likely to occur if calcium was taken in much larger doses than recommended (greater than 2000 to 2500 mg a day), if it is taken for a longer period, or if patients with renal function impairment or milk -alkali syndrome, take it.

Early symptoms of hypercalcemia are

Severe constipation, dryness of mouth, headache, increased thirst, irritability, loss of appetite, mental depression, metallic taste and unusual tiredness or weakness.

Late symptoms of hypercalcemia are

Confusion, drowsiness, high blood pressure, increased sensitivity of eyes or skin to light especially in hemodialysis patients, heartburn, nausea and vomiting and increased frequency of urination.

Precautions

Drug Interactions

Calcium/ Alcohol/ Caffeine/ Tobacco

Concurrent use of excessive amounts of these substances has been reported to decrease calcium absorption.

Calcium/ Calcitonin

Concurrent use may antagonize the effect of calcitonin in the treatment of hypercalcemia; however when calcitonin is prescribed for osteoporosis or Paget's disease of the bone, calcium intake should be generous to prevent hypocalcaemia which might generate secondary hyperparathyroidism.

Calcium/ Calcium-Channel Blocking Agents

Concurrent use of calcium with these agents in quantities sufficient to raise serum calcium concentrations above normal may alter the response to Verapamil and probably other calcium-channel blockers.

Calcium/ Cellulose Sodium Phosphate

Concurrent use may decrease effectiveness of cellulose sodium phosphate in preventing hypercalciuria.



Calcium/ Ciprofloxacin/ Norfloxacin/ Ofloxacin

Concurrent use may reduce absorption by chelation of ciprofloxacin, norfloxacin, or ofloxacin, resulting in lower serum and urine concentrations of ciprofloxacin, norfloxacin, or ofloxacin; therefore, concurrent use not recommended.

Calcium/ Diuretics (Thiazide)

Concurrent use with large doses of calcium supplement may result in hypercalcemia because of reduced calcium excretion.

Calcium/ Gallium nitrate

Concurrent use may antagonize the effect of gallium nitrate.

Calcium/ Iron supplements

Concurrent use will decrease the absorption of iron; iron supplements should not be taken within 1 or 2 hours of calcium intake.

Calcium/ Milk or Milk products

Concurrent and prolonged use with calcium may result in the milk-alkali syndrome.

Calcium/ Phenytoin

Concurrent use decreases the bioavailability of both phenytoin and calcium because of possible formation of a non-absorbable complex; patients advised not to take calcium supplement within 1 to 3 hours of taking phenytoin.

Calcium/ Tetracyclines

Concurrent use decreases the absorption of tetracyclines because of possible formation of a non-absorbable complexes and increase in intragastric pH; patients should be advised not to take calcium supplement within 1 to 3 hours of taking tetracyclines.

Calcium/ Vitamin A

Excessive intake, more than 5000 I.U. per day, of vitamin A may stimulate bone loss and counteract the effect of calcium and may cause hypercalcemia.

Dosage and Administration

Antacid

1-2 tablets, to be taken after every meal or when required.

Antacids should be administered frequently, due to the rapid emptying of the gastric contents.

Calcium Supplement

Children 1-10 years of age

The recommended dosage is 800 mg of calcium daily (3 tablets daily).

Adolescents

The recommended dosage is 1,200 mg of calcium daily (5 tablets daily).



Patients over 18 years of age

The recommended dosage is 800 mg of calcium daily (3 tablets daily).

Pregnant and nursing women

The recommended dosage is 1,200 mg of calcium daily (5 tablets daily).

Presentation

Box of 40 tablets.