

# Calbotol<sup>TM</sup> Tablet

Calcium Citrate USP 1200 mg &  
Calcitriol EP 0.25 mcg

## COMPOSITION:

Each tablet contains Calcium Citrate USP 1200 mg equivalent to Calcium 252 mg and Calcitriol EP 0.25 mcg

## PHARMACOLOGY:

Calcium plays a very important role in the body. It is necessary for normal functioning of nerves, cells, muscle, and bone. If there is not enough calcium in the blood, then the body will take calcium from the bones, thereby weakening bones. Having the right amount of calcium is important for building and keeping strong bones. Calcium citrate is well absorbed on an empty stomach and does not constipate. Calcium citrate is less dependent on stomach acid for absorption.

Calcitriol is the most active known form of vitamin D<sub>3</sub> in stimulating intestinal calcium transport. It is normally formed in the kidneys from its immediate precursor, 25-hydroxycholecalciferol. In physiological amounts it augments the intestinal absorption of calcium and phosphate and plays a significant part in the regulation of bone mineralization. The defective production of calcitriol in chronic renal failure contributes to the abnormalities of mineral metabolism found in that disorder.

The biological effects of calcitriol are mediated by the vitamin D receptor, a nuclear hormone receptor expressed in most cell types and functioning as a ligand-activated transcription factor that binds to DNA sites to modify the expression of target genes. Oral administration of Calcitriol to patients with chronic renal failure compensates for impaired endogenous production of calcitriol which is decreased when the glomerular filtration rate falls below 30 ml/min. Consequently, intestinal malabsorption of calcium and phosphate and the resulting hypocalcaemia are improved, thereby reversing the signs and symptoms of bone disease.

In patients with established post-menopausal osteoporosis, Calcitriol increases calcium absorption, elevates circulating levels of calcitriol and reduces vertebral fracture frequency.

## INDICATIONS:

The combination of Calcium Citrate and Calcitriol is used to prevent or treat low blood calcium levels in people who do not get enough calcium from their diets. It may be used to treat conditions caused by low calcium levels such as bone loss (osteoporosis), weak bones (osteomalacia, rickets), decreased activity of the parathyroid gland (hypoparathyroidism) and a certain muscle disease (latent tetany). It may also be used in certain patients to make sure they are getting enough calcium (e.g. postmenopausal).

## DOSAGE AND ADMINISTRATION:

1-4 tablets daily with or without food depending on clinical situation or as directed by the registered physician.

## CONTRAINDICATION:

This drug is contraindicated for the patients with hypercalcaemia, hypercalciuria, hypophosphatemia.

## SIDE EFFECT:

The side effects of this drug are-constipation, nausea, abdominal pain, hypercalcaemia, hypercalciuria, headache, muscle weakness.

## PRECAUTION AND WARNING:

This medication should be used with cautions in the following conditions- hypercalcaemia, malabsorption syndrome, heart disease, kidney disease, kidney stones, certain immune system disorder (sarcoidosis), liver disease, certain bowel diseases (Crohn's disease).

## DRUG INTERACTION:

Reduced absorption of tetracyclines, quinolones and oral biphosphates with concurrent calcium use. Calcium absorption may be reduced by corticosteroids. Increased risk of hypercalcaemia and metabolic alkalosis with thiazide diuretics. High blood calcium level may increase the effect of cardiac glycosides. Reduced erlotinib efficacy with calcium. Increased risk of hypercalcaemia with paricalcitol. Enzyme inducing antiepileptics increases the metabolism of vitamin D. Fatal encephalopathy can occur in patients with renal failure when given calcium citrate and aluminium products concurrently due to marked rise in aluminium levels.

## USE IN PREGNANCY AND LACTATION:

Pregnancy category C. It should be used as directed by the registered physician during pregnancy and lactation.

## STORAGE:

Store at a cool and dry place below 25<sup>o</sup> C protected from light and moisture. Keep out of the reach of children.

## HOW SUPPLIDE:

Each pack contains 30 tablets in double layer HDPE container.

Manufactured by



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