G-Calbo™ ⊇XX

Calcium 600 mg (Algae Source) and Vitamin D₃ 400 IU Tablet

COMPOSITION:

Each tablet contains Calcium Carbonate USP 1500 mg (from Algae source) equivalent to 600 mg of elemental Calcium and Cholecalciferol USP 10 mcg equivalent to Vitamin D, 400 IU

PHARMACOLOGY:

Algae source Calcium is a plant based Algae which is hand harvested, sun dried, then milled into a powder. The Algae plant draws Calcium and 12 other essential bone supporting minerals from seawater.

The pharmacokinetic profiles of Calcium and its salts are well known. Calcium carbonate is converted to calcium chloride by gastric acid. Calcium is absorbed to the extent of about 15-25% from the gastro-intestinal tract while the remainder reverts to insoluble calcium carbonate and calcium stearate, and is excreted in the feces.

The pharmacokinetics of vitamin D, is also well known. Vitamin D, is well absorbed from the gastro-intestinal tract in the presence of bile. It is hydroxylated in the liver to form 25-hydroxycholecalciferol and then undergoes further hydroxylation in the kidney to form the active metabolite 1, 25 dihydroxycholecalciferol (calcitriol). The metabolites circulate in the blood bound to a specific α -globin. Vitamin D and its metabolites are excreted mainly in the bile and feces.

INDICATION:

Calcium and Vitamin D, is used for the treatment of Osteoporosis, Osteomalacia, Rickets, Tetany, Parathyroid disease etc.

DOSAGE AND ADMINISTRATION:

One tablet in the morning and one tablet at night or as directed by the Physician.

CONTRAINDICATION:

Absolute contra-indications are hypercalcemia resulting for example from myeloma, bone metastases or other malignant bone disease, sarcoidosis, primary hyperparathyroidism and vitamin D, over dosage. Severe renal failure. Hypersensi tivity to any of the tablet ingredients. Relative contra-indications are osteoporosis due to prolonged immobilization, renal stones, and severe hypercalciuria.

SIDE FEFECT:

Orally administered Calcium Carbonate may be irritating to the GI tract. It may also cause constipation. Hypercalcemia is rarely produced by administration of Calcium alone, but may occur when large doses are given to patients with chronic renal failure. Also there may be allergic reactions, irregular heartbeats, nausea, vomiting, decreased appetite dry mouth and drowsiness. Following administration of Vitamin D3 Supplements occasion skin rash has been reported.

PRECAUTION AND WARNING:

Patients with mild to moderate renal failure or mild hypercalciuria should be supervised carefully including periodic checks of plasma calcium levels and urinary calcium excretion. In patients with a history of renal stones, urinary calcium excretion should be measured to exclude hypercalciuria. With long-term treatment it is advisable to monitor serum and urinary calcium levels and kidney function, and reduce or stop treatment temporarily if urinary calcium exceeds 7.5 mmol/24 hours (300 mg/24 hours). Caution is required in patients receiving treatment for cardiovascular disease (thiazide diuretics and cardiac glycosides including digitalis).

DRUG INTERACTION:

It has possible interaction with digoxin, antacids containing Calcium, Aluminum or Magnesium, other Calcium supplements, Calcitriol, Tetracycline, Doxycycline, Aminocycline or Oxytetracycline etc.

USE IN PREGNANCY AND LACTATION:

It should be used as directed by the physician during Pregnancy and Lactation.

STORAGE:

Store at a cool and dry place below 30° C protected from light and moisture. Keep out of the reach of children.

HOW SUPPLIDE:

Each pack contains 30 tablets in HDPE container.

Manufactured by



PHARMACEUTICALS LTD.