CIANCAL 500
CALCIUM CARBONATE & VITAMIN D3 TABLETS

COMPOSITION:
Each film coated tablet contains:

Calcium Carbonate BP	1250 mg
Eq. to Elemental Calcium	500 mg
Vitamin D3 BP	250 IU
Excipients	q.s.
Colour: Titanium Dioxide BP	

DESCRIPTION:
CIANCAL 500 is a White, elongated, biconvex, film coated tablet having score line on one side and plain on the other side.
Calcium Carbonate & Vitamin D3 Tablets are indicated in Prevention and treatment of calcium and vitamin D3 deficiency in the elderly.

PHARMACODYNAMICS:
Pharmacotherapeutic group: Calcium, combinations with other drugs.
Vitamin D3 increases the intestinal absorption of calcium.
Administration of calcium and vitamin D3 counteracts the increase of parathyroid hormone (PTH) which is caused by calcium deficiency and which cause increased bone resorption.

PHARMACOKINETICS:
Calcium
Absorption: The amount of calcium absorbed through the gastrointestinal tract is approximately 30% of the swallowed dose.
Distribution and metabolism: 99% of the calcium in the body is concentrated in the hard structure of bones and teeth. The remaining 1% is present in the intra- and extracellular fluids. About 50% of the total blood-calcium content is in the physiologically active ionised form with approximately 10% being complexed to citrate, phosphate or other anions, the remaining 40% being bound to proteins, principally albumin. The bioavailability of calcium can be slightly increased by concomitant intake of food.
Elimination: Calcium is eliminated through faeces, urine and sweat. Renal excretion depends on glomerular filtration and calcium tubular reabsorption.
Vitamin D3:
Absorption: Vitamin D3 is easily absorbed in the small intestine.
Distribution and metabolism: Cholecalciferol and its metabolites circulate in the blood bound to a specific globulin. Cholecalciferol is converted in the liver by hydroxylation to the active form 25-hydroxycholecalciferol. It is then further converted in the kidneys to 1,25- dihydroxycholecalciferol. 1,25-dihydroxycholecalciferol is the metabolite responsible for increasing calcium absorption. Vitamin D3 which is not metabolised is stored in adipose and muscle tissues.
Elimination: Vitamin D3 is excreted in faeces and urine.

INDICATION:
Calcium Carbonate & Vitamin D3 Tablets are indicated in Prevention and treatment of Calcium and Vitamin D3 deficiency in the elderly. Vitamin D3 and Calcium Carbonate supplement in addition to specific osteoporosis treatment of patients who are at risk of Vitamin D3, Zinc and Calcium deficiency.

DOSAGE AND ADMINISTRATION:
1 tablet twice daily, preferably 1 tablet in the morning and 1 tablet in the evening or as directed by the physician. It is best taken with or just after main meals with a full glass of water.

CONTRAINDICATIONS:
Hypercalciuria and hypercalcaemia and diseases and/or conditions, which lead to hypercalcaemia and/or hypercalciuria (e.g. myeloma, bone metastases, primary hyperparathyroidism).
- Nephrolithiasis.
- Nephrocalcinosis
- Hypervitaminosis D.
- Severe renal impairment and renal failure.
- Hypersensitivity to calcium carbonate, colecalciferol.
- Hypersensitivity to any of the excipients.

SPECIAL WARNING AND PRECAUTION FOR USE:
CIANCAL 500 film-coated tablets should be prescribed with caution to patients suffering from sarcoidosis due to risk of increased metabolism of vitamin D3 into its active form. These patients should be monitored with regard to the calcium content in serum and urine.
During long-term treatment, serum calcium levels should be followed and renal function should be monitored through measurements of serum creatinine. Monitoring is especially important in elderly patients on concomitant treatment with cardiac glycosides or diuretics and in patients with a high tendency to calculus formation. In case of hypercalciuria (exceeding 300 mg (7.5 mmol)/24 hours) or signs of impaired renal function the dose should be reduced or the treatment discontinued.
Vitamin D3 should be used with caution in patients with impairment of renal function and the effect on calcium and phosphate levels should be monitored. The risk of soft tissue calcification should be taken into account. In patients with severe renal insufficiency, vitamin D3 in the form of cholecalciferol is not metabolised normally and other forms of vitamin D3 should be used.
CIANCAL 500 film-coated tablets should be used cautiously in immobilised patients with osteoporosis due to increased risk of hypercalcaemia.
The content of vitamin D3 (800 IU) in CIANCAL 500 film-coated tablets should be considered when prescribing other medicinal products containing vitamin D3. Additional doses of calcium or vitamin D3 should be taken under close medical supervision. In such cases it is necessary to monitor serum calcium levels and urinary calcium excretion frequently.

INTERACTION WITH OTHER MEDICINE AND CONCOMITANT USE:
Thiazide diuretics reduce the urinary excretion of calcium. Due to increased risk of hypercalcaemia, serum calcium should be regularly monitored during concomitant use of thiazide diuretics.
Concomitant use of phenytoin or barbiturates may reduce the effect of vitamin D3 since the metabolism increases.
Systemic corticosteroids reduce calcium absorption. During concomitant use, it may be necessary to increase the dose of CIANCAL 500.
Hypercalcaemia may increase the toxicity of cardiac glycosides during treatment with calcium and vitamin D3. Patients should be monitored with regard to electrocardiogram (ECG) and serum calcium levels.
The efficacy of levothyroxine can be reduced by the concurrent use of calcium, due to decreased levothyroxine absorption. Administration of calcium and levothyroxine should be separated by at least four hours.
If a bisphosphonate is used concomitantly, this preparation should be administered at least one hour before the intake of CIANCAL 500 since gastrointestinal absorption may be reduced.
Calcium may also reduce absorption of sodium fluoride and iron salts, and such preparations should be administered at least three hours before the intake of CIANCAL 500.
Simultaneous treatment with ion exchange resins such as cholestyramine or laxatives such as paraffin oil may reduce the gastrointestinal absorption of vitamin D3.
Calcium carbonate may interfere with the absorption of concomitantly administered tetracycline preparations. For this reason, tetracycline preparations should be administered at least two hours before or four to six hours after oral intake of calcium.
The absorption of quinolone antibiotics may be impaired if administered concomitantly with calcium. Quinolone antibiotics should be taken two hours before or six hours after intake of calcium.
Oxalic acid (found in spinach and rhubarb) and phytic acid (found in whole cereals) may inhibit calcium absorption through formation of insoluble compounds with calcium ions. The patient should not take calcium products within two hours of eating foods high in oxalic acid and phytic acid.

PREGNANCY AND LACTATION:
Pregnancy
During pregnancy the daily intake should not exceed 1500 mg Calcium and 600 IU Vitamin D. CIANCAL 500 is not recommended during pregnancy. Studies in animals have shown reproductive toxicity of high doses of Vitamin D. In pregnant women, overdoses of Calcium and Vitamin D should be avoided as permanent hypercalcaemia has been related to adverse effects on the developing foetus. CIANCAL 500 can be used during pregnancy, in case of a Calcium and Vitamin D deficiency.
Breast-feeding
CIANCAL 500 can be used during breast-feeding. Calcium and Vitamin D3 pass into breast milk. This should be considered when giving additional Vitamin D3 to the child.
Fertility
Normal endogenous levels of Calcium and Vitamin D3 are not expected to have any adverse effects on fertility.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:
Not available.

UNDESIRABLE EFFECTS:
Adverse reactions frequencies are defined as: uncommon (⩾ 1/1,000, <1/100), rare (>1/10,000, <1/1,000) or not known (cannot be estimated from the available data)
Immune system disorders
Not known: Hypersensitivity reactions such as angioedema or laryngeal oedema.
Metabolism and nutrition disorders
Uncommon: Hypercalcaemia and hypercalciuria.
Gastrointestinal disorders
Rare: Constipation, flatulence, nausea, abdominal pain, and diarrhoea.
Skin and subcutaneous disorders
Rare: Pruritus, rash and urticaria.

OVERDOSE:
Overdose can lead to hypervitaminosis and hypercalcaemia. Symptoms of hypercalcaemia may include anorexia, thirst, nausea, vomiting, constipation, abdominal pain, muscle weakness, fatigue, mental disturbances, polydipsia, polyuria, bone pain, nephrocalcinosis, renal calculi and in severe cases, cardiac arrhythmias. Extreme hypercalcaemia may result in coma and death. Persistently high calcium levels may lead to irreversible renal damage and soft tissue calcification.
Treatment of hypercalcaemia: The treatment with Calcium and Vitamin D3 must be discontinued. Treatment with Thiazide diuretics, Lithium, Vitamin A, Vitamin D3 and Cardiac glycosides must also be discontinued. Rehydration, and, according to severity, isolated or combined treatment with loop diuretics, bisphosphonates, calcitonin and corticosteroids. Serum electrolytes, renal function and diuresis must be monitored. In severe cases, ECG and CVP should be followed.

SHELF LIFE:
3 years

PACKAGING:
10 tablets are packed in the Alu–Alu Blister Pack. Such 3 blisters are packed in printed carton along with pack insert.

STORAGE CONDITION:
Store in dry place below 30°C. Keep out of reach of children.

Marketed by:

Slim Pharmaceuticals (Pvt) Ltd,
No: 98/10, Namal Mawatha,
Kahanthota Road, Malabe,Sri Lanka.

Manufactured by :

CIAN HEALTH CARE PVT. LTD.
(An ISO 9001 : 2015 & WHO GMP Certified Co.)
Kh. No. : 248, Village Sisona, Bhagwanpur,
Roorkee, Haridwar, Uttarakhand, India.
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