



NUBONE +D Calcium/Vitamin D 500mg/200 IU Tablet

INDICATED CLAIMS:

- Helps in the maintenance of Bones and teeth.
- Calcium intake, when combined with Sufficient vitamin D, a healthy diet, and regular exercise,
- May reduce the risk of developing osteoporosis.

GENERAL INFORMATION

Calcium is an essential mineral with a wide range of biological roles. Apart from being a major constituent of bones and teeth, calcium is crucial for muscle contraction, nerve conduction, the beating of the heart, blood coagulation, glandular secretion, the production of energy and the maintenance of immune function, among other things.

Calcium is found in bone and teeth primarily in the form of the calcium phosphate compound hydroxyapatite. Over 99% of the total body calcium is found in bone and teeth, and calcium makes up from 1% to 2% of adult body weight.

Milk products are the most calcium-dense foods. Other foods rich in calcium include the vegetables collard greens, Chinese cabbage, mustard greens, broccoli and bok choy, as well as tofu and sardines with bones included. About 25% of women in the United States take calcium supplements. The average intake of calcium in the American diet is approximately 800 milligrams daily. Calcium intake is typically higher in males than it is in females.

The active form of vitamin D is 1,25-dihydroxyvitamin D or 1,25(OH)₂D (again, when D is used without a subscript it refers to either D₂ or D₃). 1,25(OH)₂D enhance the efficiency of calcium absorption, and, to a much lesser extent, phosphorus absorption, from the small intestine. Vitamin D deficiency is characterized by inadequate mineralization or demineralization of the skeleton. Inadequate mineralization of the skeleton is the cause of rickets in children (vitamin D is also known as the antirachitic factor), while demineralization of the skeleton results in osteomalacia in adults. Further, vitamin D

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deficiency in adults can lead to osteoporosis. This results from a compensatory increase in the production of parathyroid hormone resulting in resorption of bone.

Very few foods are natural sources of vitamin D. Foods that do contain vitamin D include fatty fish, fish liver oils and eggs from hens that have been fed vitamin D. Nearly all the vitamin D intake from foods comes from fortified milk products and other foods, such as breakfast cereals, which have been fortified with vitamin D. Vitamin D is a fat-soluble vitamin and therefore its absorption is adversely affected in those with malabsorption disorders. Those with chronic liver disease, cystic fibrosis, Crohn's disease, Whipple's disease and sprue are prone to vitamin D deficiency. Others at risk for vitamin D deficiency, include those that do not drink milk and who do not receive much sunlight, those who live in regions where they receive little natural light, and alcoholics. The elderly are at risk for vitamin D deficiency for several reasons, including inadequate exposure to sunlight, consumption of low amounts of vitamin D-containing foods and the use of certain drugs, which interfere with the absorption and/or metabolism of vitamin D. In addition, older adults need higher amounts of vitamin D than younger adults because of decreased absorption of the vitamin.

PHARMACOKINETICS

Calcium is absorbed from the small intestine by both active and passive mechanisms. At low and moderate intakes of calcium, calcium is absorbed via active transfer. Active transfer depends on the action of the active form of vitamin D, 1, 25-dihydroxycholecalciferol or 1, 25(01-1)₂ D₃. Vitamin D-induced calcium transport involves the synthesis of the calcium-binding protein, calbindin. Calbindin serves as a calcium translocator. It also serves as a cytosolic calcium buffer. Calcium is typically freed from calcium complexes during digestion and is released in a soluble and probably ionized form for absorption. Low molecular weight complexes, such as calcium carbonate, may be absorbed intact.

As calcium intakes increase, the active transfer mechanism becomes saturated and an increasing proportion of calcium is absorbed via passive diffusion.

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Vitamin D absorbed from the small intestine and stored in the liver and other fat depots. Cholecalciferol (D₃) may be absorbed more rapidly and completely than ergocalciferol (D₂) since ergocalciferol requires the presence of bile salts.

Nutralife nubone+ D formulated with calcium carbonate and vitamin D₃ which pharmaceutically tested to guarantee full potency and absolute clinical purity to ensure maximal calcium absorption.

NUBONE +D Calcium/Vitamin D 500mg/200 IU Tablet

Product information

Available as 100 tablets

Each tablet contains:

Calcium 500mg and Vitamin D₃ 200 IU

Non-medicinal ingredients: Microcrystalline cellulose, Croscarmellose, M magnesium Stearate, Hydroxylpropyl methylcellulose, Carnauba Wax.

Directions for use: adult: take 1 tablet twice daily or as directed by a health care practitioner.

Benefits

- Maintains strong bones and healthy teeth
- Helps prevent osteoporosis to reduce the risk of fractures later in life
- May help reduce high blood pressure
- Relieves symptoms of PMS (Premenstrual Syndrome)
- Aids in the nervous system, especially with impulse transmission
- Supports colon health
- Good for adolescents

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CONTRAINDICATIONS

Calcium supplementation is contraindicated in those with hypercalcemia. Conditions causing hypercalcemia include sarcoidosis, hyperparathyroidism, hypervitaminosis D and cancer.

Calcium supplementation is contraindicated in those hypersensitive to any component of a calcium-containing supplement.

Vitamin D is contraindicated in those with hypercalcemia and in those with evidence of vitamin D toxicity. Vitamin D is contraindicated in those with hypersensitivity to any component of a vitamin D-containing product.

PRECAUTIONS

Supplemental calcium taken without food may increase the risk of kidney stones in women and possibly also in men. It is thought that taking supplemental calcium without food limits the opportunity for the beneficial effect that calcium may have in binding oxalate in the intestine. Therefore, it is advisable that supplemental calcium be taken with food.

Those who form calcium-containing kidney stones are generally advised not to take supplemental calcium.

Those with achlorhydria should take calcium carbonate with food.

Pregnant women and nursing mothers should avoid vitamin D supplemental intakes greater than U.S. RDA amounts of the vitamin unless higher amounts are prescribed by their physicians. The U.S. RDA for vitamin D is 400 IU or 10 micrograms daily.

Pharmaceutical use of vitamin D must only be undertaken under medical supervision.

Supplemental vitamin D should be used cautiously in those on digoxin or any cardiac glycoside. Hypercalcemia in those on digoxin may precipitate cardiac arrhythmias. Supplemental doses of

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vitamin D greater than upper limit intake levels (UL) should only be used if medically prescribed and should be avoided by those on digoxin or other cardiac glycoside. The UL for adults is 2,000 IU or 50 micrograms daily.

Concomitant use of thiazides and pharmacologic doses of vitamin D may cause hypercalcemia in some.

ADVERSE REACTIONS

Calcium supplements are generally well tolerated. Use of calcium carbonate may cause such gastrointestinal side reactions as constipation, bloating, gas and flatulence. Prolonged use of large doses of calcium carbonate-greater than 12 grams daily (about 5 grams of elemental calcium)- may lead to the milk-alkali syndrome, nephrocalcinosis and renal insufficiency.

Dosage of vitamin D up to 60 micrograms (2,400 IU)/day in healthy individuals rarely causes adverse reactions. Chronic dosage of 95 micrograms (3,800 IU)/day or greater in healthy individuals may cause hypercalcemia. Early symptoms of hypercalcemia, include nausea and vomiting, weakness, headache, somnolence, dry mouth, constipation, metallic taste, muscle pain and bone pain. Late symptoms and signs of hypercalcemia include polyuria, polydipsia, anorexia, weight loss, nocturia, conjunctivitis, pancreatitis, photophobia, rhinorrhea, pruritus, hyperthermia, decreased libido, elevated BUN, albuminuria, hypercholesterolemia, elevated ALT (SGPT) and AST (SGOT), ectopic calcification, nephrocalcinosis, hypertension and cardiac arrhythmias.

INTERACTIONS:

DRUGS

Biphosphonates (alendronate, etidronate, risedronate): Concomitant intake of a bisphosphonate and calcium may decrease the absorption of the bisphosphonate.

H₂ blockers (cimetidine, famotidine, nizatidine, ranitidine): Concomitant use of H₂ blockers and calcium carbonate or calcium phosphate can cause decreased absorption of these calcium salts.

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Levothyroxine: Concomitant intake of levothyroxine and calcium carbonate was found to reduce levothyroxine absorption and to increase serum thyrotropin levels. Levothyroxine may adsorb to calcium carbonate in an acidic environment, which may block its absorption: There is no evidence that other forms of calcium block levothyroxine absorption if taken concomitantly.

Proton Pump Inhibitors (lansoprazole, omeprazole, rabeprazole sodium): Concomitant use of proton pump inhibitors and calcium carbonate or calcium phosphate can cause decreased absorption of these calcium salts.

Quinolones (ciprofloxacin, gatifloxacin, levofloxacin, Lorne floxacin, lomefloxacin, norfloxacin, ofloxacin, sparfloxacin, trovafloxacin): Concomitant use of a quinolone and calcium may decrease the absorption of the quinolone.

Tetracycline's (doxycycline, minocycline, and tetracycline): Concomitant intake of a tetracycline and calcium may decrease the absorption of the tetracycline. Tetracyclines may form nonabsorbable complexes with calcium.

Vitamin D Analogues (calcitriol, alfacalcidol): Concomitant use of these vitamin D analogues and calcium can cause increased absorption of calcium.

Cholestyramine: Concomitant intake of cholestyramine and vitamin D may reduce the absorption of vitamin D.

Colestipol: Concomitant intake of colestipol and vitamin D may reduce the absorption of vitamin D.

HIV protease inhibitors: The HIV protease inhibitors ritonavir, indinavir and nelfinavir may impair vitamin D bioactivation to 1, 25-dihydroxyvitamin D. This is based on in vitro studies conducted in human hepatocyte and monocyte cell lines. Ritonavir had the most potent inhibitory effect.

Ketoconazole: Ketoconazole may inhibit the biosynthesis and catabolism of 1, 25-dihydroxyvitamin D. Reductions in serum 1, 25-dihydroxyvitamin D concentrations have been

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observed following the administration of 300 to 1,200 milligrams daily of ketoconazole to healthy men for seven days.

Mineral Concomitant use of mineral oil and vitamin D may reduce the absorption of vitamin D.

Orlistat: Orlistat may decrease the absorption of vitamin D.

Phenobarbital and Phenytoin: Phenobarbital and phenytoin may reduce plasma levels of 25-hydroxyvitamin D by inhibiting vitamin D 25-hydroxylase activity in the liver.

NUTRITIONAL SUPPLEMENTS

Inositol Hexaphosphate: Concomitant use of inositol hexaphosphate (phytic acid) and calcium may decrease the absorption of calcium.

Minerals (iron, fluoride, magnesium, phosphorous): Concomitant use of iron and calcium may inhibit the absorption of iron. Similarly, concomitant use of fluoride, magnesium, phosphorous or zinc and calcium may decrease the absorption of these minerals. However, these possible mineral interactions have not been shown to be of clinical significance.

Non-digestible oligosaccharides (fructo-oligosaccharides, inulin): Concomitant use of these oligosaccharides and calcium may increase the absorption of calcium in the colon.

Sodium Alginate: Concomitant intake of sodium alginate and calcium may decrease the absorption of calcium.

Vitamin D: Concomitant use of vitamin D and calcium may increase the absorption of calcium.

Calcium: Concomitant intake of calcium and vitamin D may be more effective than no therapy or calcium alone in corticosteroid-induced osteoporosis.

FOODS

Calcium may be poorly absorbed from foods rich in oxalic acid (spinach, sweet potatoes, rhubarb and beans) or phytic acid (unleavened bread, raw beans, seeds, nuts and grains and soy isolates). Concomitant intake of a calcium supplement with foods rich in oxalic acid or phytic acid may

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decrease the absorption of calcium. The phytate associated with dietary fiber appears to be the major factor involved in depressing absorption of calcium.

Olestra: The fat substitute olestra inhibits the absorption of vitamin D as well as the other fat-soluble vitamins A, E and K. Vitamins A, D, E (alpha-tocopherol) and K are added to olestra to compensate for this. Olestra contains 12 IU (0.3 micrograms) of vitamin D per gram.

OVERDOSAGE

Overdosage has not been reported with calcium supplements.

Hypercalcemia can result either from excess intakes of prescribed forms of vitamin D or from consumption of high amounts of vitamin D₂ or vitamin D₃. The hypercalcemia associated with hypervitaminosis D may cause multiple debilitating effects. Anorexia, nausea and vomiting have been observed in hypercalcemic individuals treated with 1,250 to 5,000 micrograms (50,000 to 200,000 IU)/day of vitamin D. Hypercalcemia can result in a loss of the urinary concentrating mechanism of the kidney tubule, resulting in polyuria and polydipsia. The prolonged ingestion of excessive amounts of vitamin D and the accompanying hypercalcemia can result in metastatic calcification of soft tissues, including the kidney, blood vessels, heart and lungs. Typically, chronic ingestion of 50,000 to 1100,000 IU/day of vitamin D is required to produce hypercalcemia. Since vitamin D stores in fat: may be substantial, vitamin D intoxication may persist for weeks after vitamin D ingestion is terminated. The elimination half-life of vitamin D is about 20 to 29 days.

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