



DVITA PLUS Vitamin D 1000 IU Tablet

INDICATED CLAIMS:

- Vitamin D is the principal regulator of calcium homeostasis in the body
- Vitamin D is particularly important in skeletal development and bone mineralization.

GENERAL INFORMATION

The term vitamin D refers to the secosterols ergocalciferol or vitamin D₂ and Cholecalciferol or vitamin D₃ as well as to the metabolites and analogues of these substances. All forms of vitamin D possess antirachitic activity. Vitamin D is different from all of the other vitamins in human nutrition because it is the only vitamin that is a conditional one. Vitamin D₃ is synthesized in the skin from 7-dehydrocholesterol via photochemical reactions using ultraviolet B (UV-B) radiation from sunlight. However, there are conditions where the synthesis of vitamin D₃ in the skin is not sufficient to meet physiological requirements. Humans, who are not exposed to sufficient sunlight due to reason of geography, shelter or clothing, require dietary intake of vitamin D. Under these conditions, vitamin D is an essential nutrient. Vitamin D without a subscript refers to either vitamin D₂ or vitamin D₃.

The active form of vitamin D is I alpha, 25-dihydroxyvitamin D or I,25(OH)₂D (again, when D is used without a subscript it refers to either D₂ or D₃). I, 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 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

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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, Cohn'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 (see Interactions). In addition, older adults need higher amounts of vitamin D than younger adults because of decreased absorption of the vitamin. The use of sunscreens is another factor that can negatively affect vitamin D status. However, those who spend time in the sun without using a sunscreen put themselves at risk for skin cancers.

Over the last several years, studies have indicated that vitamin D may play beneficial roles in a wide range of diseases and disorders, including osteoporosis, cancer, multiple sclerosis, heart disease, psoriasis and Alzheimer's disease.

PHARMACOKINETICS

Vitamin D is principally absorbed in the small intestine. It is absorbed from the lumen of the small intestine into the enterocytes by passive diffusion. Vitamin D is delivered to the enterocytes in micelles formed from bile acids and other substances. The efficiency of absorption of vitamin D is high. Approximately 50% to 80% of ingested vitamin D is absorbed. Vitamin D is secreted by the enterocytes into the lymphatics in the form of chylomicrons. It enters the circulation via the thoracic duct. Vitamin D is transported in the blood bound to an alpha-globulin vitamin D binding protein. This protein is also known as the vitamin D-binding protein (DBP) and the group-specific component (Gc) protein. A large fraction of circulating vitamin D is extracted by the hepatocytes. It is metabolized to 25-hydroxyvitamin D (25 (OH) D) or calcidiol in the hepatocytes, via the enzyme vitamin D 25-hydroxylase. 25(OH) D is the major circulating form

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of vitamin D. This metabolite of vitamin D, however, is not biologically active under physiological conditions. The Biologically active hormone form of vitamin D, 1, 25-dihydroxyvitamin D (1, 25(OH)₂ D) or calcitriol, is produced in the kidney via the enzyme 25-hydroxyvitamin DI-alpha-hydroxylase. This enzyme is a cytochrome P450 mixed function oxygenase also known as CYP27B1. 25(OH)D and 1,25(OH)₂ D may undergo hydroxylation catalyzed by the enzyme cytochrome P450C24 (CYP24), also a cytochrome P450 mixed function oxygenase, to form 24, 25-dihydroxyvitamin D (24, 25(OH)₂ D) and 1,24,25-trihydroxyvitamin D (1,24,25(OH)₃ D), respectively. Deactivation of 1, 25(OH)₂ D and 25 (OH) D occurs via hydroxylation at C-24 catalyzed by CYP24. Other metabolites of 1, 25 (OH)₂ D include calcitric acid and the lactone I alpha, 25R (OH)₂-26,23S-lactone cholecalciferol. Vitamin D and its metabolites are excreted primarily via the biliary route. The final degradation product of 1, 25 (OH)₂ D₃ is calcitric acid, which is excreted by the kidney.

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.

Dvita Plus with vitamin D 1000 IU formulated with vitamin D₃ which pharmaceutically tested to guarantee full potency and absolute clinical purity to ensure maximal calcium absorption.

DVITA PLUS Vitamin D 1000 IU Tablet

Product information

Available as 100 tablets, Each tablet contains:

Vitamin D₃ 1000 IU

Non-medicinal ingredients: Microcrystalline cellulose Dicalcium phosphates dehydrate, Magnesium Stearate.

Directions for use: take 1 tablet daily or as directed by your health care practitioner

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**Benefits:**

- Essential for normal development and maintenance of bones and teeth
- Helps in the absorption and use of calcium and phosphorus in the body
- Prevents rickets, osteomalacia and osteoporosis to reduce the risk of fractures later in life

CONTRAINDICATIONS

Vitamin D is contraindicated in those with hypocalcaemia 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

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.

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 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

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

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pain and bone pain. Late symptoms and signs of hypercalcemia, include polyuria, polydipsia, anorexia, weight loss, nocturia, conjunctivitis, pancreatitis, photophobia, rhino rhea, pruritus, hyperthermia, decreased libido, elevated BUN, albuminuria, hypercholesterolemia, elevated ALT (SGPT) and AST (SGOT), ectopic calcification, nephrocalcinosis, hypertension and cardiac arrhythmias.

INTERACTIONS:

DRUGS

Cholestyranine: 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 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

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

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FOODS

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

Hypocalcaemia 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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