

DBOOST® Capsules/Sachet
[Vitamin D3 (cholecalciferol)]

COMPOSITION

Each Capsule/Sachet contains:	
Cholecalciferol	60,000 IU

PHARMACOLOGY

Vitamin D is a fat-soluble vitamin and has properties of both vitamins and minerals. Vitamin D is essential for the absorption and utilization of calcium and phosphate and aids in the mobilization of bone calcium and maintenance of serum calcium concentrations.

Cholecalciferol (Vitamin D₃) is synthesized in the skin on exposure to ultraviolet radiation. Cholecalciferol is also present in fish liver oils. Ergocalciferol (Vitamin D₂) is produced by ultraviolet irradiation of a provitamin D sterol (ergosterol) which occurs in yeast and fungi.

Both of these agents who have equal biologic activity are metabolized in the liver to calcifediol (25 hydroxycholecalciferol) which is then hydroxylated in the kidney to calcitriol (1, 25 dihydroxycholecalciferol). Calcitriol is considered the most active form. Dihyrotachysterol is produced by synthetic reduction of ergocalciferol. Patients with chronic renal disease cannot convert calcifediol to calcitriol. Alfalcidol (1 α hydroxyvitamin D₃), a synthetic analogue of calcitriol, is rapidly converted in the liver to calcitriol, bypassing the renal conversion step.

Because alfalcidol, calcitriol and dihyrotachysterol do not require renal hydroxylation, they are useful in patients with renal failure.

INDICATIONS

Vitamin D analogues are used in treatment of refractory rickets (Vitamin D-resistant rickets), familial hypophosphatemia and hypoparathyroidism, and in the management of hypocalcemia and renal osteodystrophy in patients with chronic renal failure undergoing dialysis. Vitamin D is used in conjunction with calcium in the management and prevention of primary or corticosteroid-induced osteoporosis.

Vitamin D supplementation is indicated when dietary intake is insufficient, e.g., breast-fed infants.

CONTRAINDICATIONS

Known hypersensitivity to Vitamin D or any of its analogues and derivatives. Hypercalcemia, malabsorption syndrome, abnormal sensitivity to the toxic effects of Vitamin D and hypervitaminosis D.

PRECAUTIONS

Vitamin D analogues are usually non-toxic in physiologic doses. Chronic or acute administration of excessive doses may lead to hypervitaminosis D, manifested by hyperkalemia and its sequelae.

The therapeutic index of Vitamin D analogues is narrow, and there is great interindividual variation in the dose that will lead to chronic toxicity. Daily doses of ergocalciferol ranging from 1.25 to 2.5 mg in adults and 25 µg in children may result in hypervitaminosis. Other Vitamin D analogues with shorter duration of action may have a lower propensity to accumulate and to cause hypercalcemia.

Early symptoms of hypercalcemia may include weakness, fatigue, somnolence, headache, anorexia, dry mouth, metallic taste, nausea, vomiting, vertigo, tinnitus, ataxia, hypotonia. Later and possibly more serious manifestations include nephrocalcinosis, renal dysfunction, osteoporosis in adults, impaired growth in children, anemia, metastatic calcification, pancreatitis, generalized vascular calcification and seizures.

Periodic monitoring of serum calcium, phosphate, magnesium, and alkaline phosphatase is recommended for patients taking Vitamin D analogues. Serum calcium should be maintained in the range of 2.25 to 2.5 mmol/L and not allowed to exceed 2.75 mmol/L.

DRUG INTERACTIONS

Antacids (Magnesium-containing): Hypermagnesemia may develop when these agents are used concurrently with Vitamin D, particularly in patients with chronic renal failure.

Anticonvulsants (Phenytoin, Phenobarbital): Decreased Vitamin D effects may occur when certain anticonvulsants are administered, as they may induce hepatic microsomal enzymes and accelerate the conversion of Vitamin D to inactive metabolites.

Cholestyramine. Colestipol, Mineral Oil: Intestinal absorption of Vitamin D may be impaired. Patients on cholestyramine or colestipol should be advised to allow as

much time as possible between the ingestion of these drugs and Vitamin D.

Different Vitamin D analogues should be administered concurrently.

Hypercalcemia during pregnancy may also lead to suppression of parathyroid hormone release in the neonate, resulting in hypocalcemia, tetany and seizures.

ADVERSE EFFECTS

Vitamin D analogues are well tolerated in normal daily doses. Chronic excessive dosing can lead to toxicity (see Overdose).

DOSAGE & ADMINISTRATION

1 Capsule or Sachet / week for 8 weeks followed by 1 Capsule or Sachet /month for 6 months

STORAGE AND STABILITY

Store between 15 and 30°C. Protect from light and humidity.

PRESENTATION

Dboost Granules are available in a sachet: 60,000 IU in 1 gm.

Dboost Capsules are available in a strip of 4's and box of 8's.