DBOOST® DROPS
[Vitamin D3 (cholecalciferol)]

COMPOSITION

Each ml of Dboost Drops contains:	
Cholecalciferol	400 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 D_3) is synthesized in the skin on exposure to ultraviolet radiation. Cholecalciferol is also present in fish liver oils. Ergocalciferol (Vitamin D_2) 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. Dihydrotachysterol is produced by synthetic reduction of ergocalciferol. Patients with chronic renal disease cannot convert calcifediol to calcitriol. Alfacalcidol (1 α hydroxyvitamin D_3), a synthetic analogue of calcitriol, is rapidly converted in the liver to calcitriol, bypassing the renal conversion step.

Because alfacalcidol, calcitriol and dihydrotachysterol 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. Dboost Drops is recommended for premature infants as well.

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 be 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 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 microsomial enzymes and accelerate the conversion of Vitamin D to inactive metabolites.

Cholestyramine. Colestipol, Mineral OiI: Intestinal absorption of Vitamin D may be impaired. Patients on chotestyramine 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

Recommendations of Indian Association Pediatrics (IAP) on dosing of Vitamin D –

Group	**Daily regimen (8-12 weeks)**	**Weekly regimen (8-12 weeks)**	**Maintenance**
<1 mo old	1,000 IU	50,000 IU	400-1,000 IU
1-12 mo old	1,000-5000 IU	50,000 IU	400-1,000 IU
1-18 y old	5,000 IU	50,000 IU	600-1,000 IU
>18 y old	6,000 IU	50,000 IU	1,500-2,000 IU

The recommended dose of Dboost drops is 1 ml/day

STORAGE AND STABILITY

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

PRESENTATION

Dboost Drops is available in a bottle of 30 ml with calibrated dropper.