Biodal®

Vitamin D3 (Cholecalciferol)

Composition:

Vitamin D3 (Cholecalciferol)
The product contains mannitol as one of the inactive ingredient.

Properties:

Vitamin D substances are well absorbed from the gastrointestinal tract. The presence of bile is essential for adequate intestinal absorption; absorption may be decreased in patients with decreased fat absorption.
Biodal® (Cholecalciferol) has a slow onset and a long duration of action. It is hydroxylated in the liver and kidneys.

Indications and uses:

- Treatment and prevention of vitamin D deficiency states and hypocalcemia in disorders such as hypoparathyroidism.
- Treatment of hypoparathyroidism in pregnancy.
- Treatment of osteomalacia and rickets
- Treatment and prevention of osteoporosis (in conjunction with calcium)
- Prevention of corticosteroid-induced osteoporosis
- Prevention of fractures
- Prevention of various cardiovascular, metabolic disorders including diabetes mellitus, multiple sclerosis and malignant disorders.

Dosage and administration:

Classification	**Serum 25-hydroxyvitamin D level**	**Dosage regimen**	**Blood testing**
Severe vitamin D deficiency	< 10 ng/ml (< 25 nmol/L)	Loading dose: 50,000 I.U. once weekly for 2 to 3 months . Maintenance dose: 800 to 2000 I.U.once daily regardless of dosing pattern.	
Vitamin D deficiency	10 – 15 ng/ml (25 – 37 nmol/L)	2000 – 5000 I.U.once daily or 5000 I.U.once daily	Every 6 months Every 2 – 3 months
Vitamin D insufficiency	15 – 30 ng/ml (37 – 75 nmol/L)	2000 – 5000 I.U.once daily or 5000 I.U.once daily	Every 6 months Every 2 – 3 months
Supplementation	-	1000-2000 I.U. once daily	-

*The variation of laboratory results from lab to lab has to be taken into account.

Biodal ®2000 I.U. Tablets: One-two tablets once daily.
Biodal ®5000 I.U. Tablets: One tablet once daily or one tablet every other day.

Biodal ®50000 I.U. Tablets: One tablet once weekly for two-three months .

Contraindications:

Vitamin D should not be given to patients with hypercalcemia .

Drug interactions:

- Thiazide diuretics, calcium, or phosphate: Increased risk of hypercalcemia. Plasma calcium concentrations should be monitored.
- Some antiepileptics (e.g., carbamazepine, Phenobarbital, phenytoin, and primidone): Increased vitamin D requirements.
- Rifampicin and isoniazide: Rifampicin and isoniazide may reduce the effectiveness of vitamin D.
- Corticosteroids: Corticosteroids may counteract the effect of vitamin D.

Precautions:

- Vitamin D should be used with caution in infants, who may have increased sensitivity to its effects, and in patients with renal impairment or calculi, or heart disease, who might be at increased risk of organ damage if hypercalcemia occurred.
- Plasma phosphate concentrations should be controlled during vitamin D therapy to reduce the risk of ectopic calcification.
- It is advised that patients receiving pharmacological doses of vitamin D should have their plasma calcium concentration monitored at regular intervals, especially initially or if symptoms suggest toxicity, and in infants if they are breast-fed by mothers receiving pharmacological doses of vitamin D.
- **Pregnancy:** Hypercalcemia during pregnancy may produce congenital disorders in the offspring, and neonatal hypoparathyroidism. However, the risks to the fetus of untreated maternal hypoparathyroidism are considered greater than the risks of hypercalcemia due to vitamin D therapy.
- **Breast feeding:** Vitamin D is distributed into breast milk, and its concentration appears to correlate with the amount of vitamin D in the serum of exclusively breast-fed infants. The American Academy of Pediatrics considers the use of vitamin D to be usually compatible with breast feeding, although they recommend, if the mother is taking pharmacological doses of vitamin D, that the infant be closely monitored for hypercalcemia or clinical manifestations of vitamin D toxicity.
- Dose should be monitored by testing for serum vitamin D level.

Overdosage:

Excessive intake of vitamin D leads to the development of hyperphosphatemia or hypercalcemia. Associated effects with hypercalcemia include hypercalciuria, ectopic calcification, renal and cardiovascular damage, muscle weakness, apathy, headache, anorexia, nausea , vomiting, bone pain, proteinuria, and hypertension.

Chronic hypercalcemia can lead to generalized vascular calcification, nephrocalcinosis, and rapid deterioration of renal function. Hypercalcemia has been reported in a patient after brief industrial exposure to cholecalciferol.

Symptoms of overdosage include anorexia, lassitude, nausea and vomiting, constipation or diarrhea, polyuria, nocturia, sweating, headache, thirst, somnolence, and vertigo. Infants and children are generally more susceptible to its toxic effects. The vitamin should be withdrawn if toxicity occurs. It has been stated that vitamin D dietary supplementation may be detrimental in persons already receiving an adequate intake through diet and exposure to sunlight, since the difference between therapeutic and toxic concentrations is relatively small.

Presentations:
Biodal ®2000 I.U. Tablets: Each film coated tablet contains 2000 I.U. Cholecalciferol calcium in bottles of 50 ,60 and100 tablets.
Biodal ®5000 I.U. Tablets: Each film coated tablet contains 5000 I.U. Cholecalciferol calcium in bottles of 50 ,60 and 100 tablets.
Biodal ®50000 I.U. Tablets: Each film coated tablet contains 50000 I.U. Cholecalciferol calcium in bottles of 10,12 , 20 and 50 tablets.

*Some presentations may not be available in certain countries.

(This is a medicament - Keep medicaments out of the reach of children)

- Medicament is a product that affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who dispensed the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

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