Biodal®
Vitamin D3 (cholecalciferol)

Composition:
Vitamin D3 (cholecalciferol)
Biodal tablets contain mannitol as one of the inactive ingredient.
Biodal chews chewable tablets contain sucralose, mannitol, and lactose as inactive ingredients.

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.
- Normalize vitamin D metabolism in the pregnant women and their neonates.

Dosage and administration:

BIODAL TABLETS

Treatment of vitamin D deficiency

Patient group	IU/week	Tablets/week	IU/day	Tablets/day
0 – 1 year	For 6 weeks 50,000 – 60,000 IU	N/A	For 6 weeks 2,000 IU *Then* 400 – 1,000 IU	N/A
1 – 18 years	For 6 weeks 50,000 – 60,000 IU	For 6 weeks 1 tablet Biodal 50,000 IU *Or* 1 tablet Biodal 60,000 IU *Or* 5 tablets Biodal 10,000 IU	For 6 weeks 2,000 IU *Then* 600 – 1,000 IU	For 6 weeks 1 tablet Biodal 2,000 IU *Or* 2 tablets Biodal 1,000 IU *Then* 1 tablet Biodal 1,000 IU
19 – 70+ years	For 8 – 12 weeks 50,000 – 60,000 IU	For 8 – 12 weeks 1 tablet Biodal 50,000 IU	For 8 – 12 weeks 5,000 – 6,000 IU	For 8 – 12 weeks 1 tablet Biodal 5,000 IU

		Or 1 tablet Biodal 60,000 IU *Or* 5 tablets Biodal 10,000 IU	*Then* 1,500 – 2,000 IU	*Then* 1 tablet Biodal 2,000 IU
Pregnancy	N/A	N/A	4,000 IU*	1 tablet Biodal 4,000 IU*
Lactation	N/A	N/A	4,000 – 6,000 IU	1 tablet Biodal 4,000 IU 1 tablet Biodal 5,000 IU

*Starting at 12 – 16 weeks' gestation

Prevention of vitamin D deficiency

Patient group	**IU/day**	**Tablets/day**
0 – 1 year	400 – 1,000 IU	N/A
1 – 18 years	600 – 1,000 IU	1 tablet Biodal 1,000 IU
19 – 70+ years	1,500 – 2,000 IU	1 tablet Biodal 2,000 IU
Pregnancy	4,000 IU*	1 tablet Biodal 4,000 IU*
Lactation	4,000 – 6000 IU	1 tablet Biodal 4,000 IU *Or* 1 tablet Biodal 5,000 IU

*Starting at 12 – 16 weeks' gestation

BIODAL CHEWS CHEWABLE TABLETS

Treatment of vitamin D deficiency

Patient group	**IU/day**	**Chewable Tablets/day**
0 – 1 year	For 6 weeks 2,000 IU *Then* 400 – 1,000 IU	For 6 weeks 1 chewable tablet Biodal chews 2,000 IU *Or* 2 chewable tablet Biodal chews 1,000 IU *Then* 1 chewable tablet Biodal chews 1,000 IU
1 – 18 years	For 6 weeks 2,000 IU *Then* 600 – 1,000 IU	For 6 weeks 1 chewable tablet Biodal chews 2,000 IU *Or* 2 chewable tablet Biodal chews 1,000 IU *Then* 1 chewable tablet Biodal chews 1,000 IU
19 – 70+ years	For 8 - 12 weeks 5,000 – 6,000 IU	For 8 – 12 weeks 3 chewable tablets Biodal Chews 2,000 IU

	Then 1,500 – 2,000 IU	*Then* 1 chewable tablet Biodal Chews 2,000 IU
Pregnancy	4,000 IU*	1 chewable tablet Biodal Chews 4,000 IU*
Lactation	4,000 – 6000 IU	1 chewable tablet Biodal Chews 4,000 IU

*Starting at 12 – 16 weeks' gestation

Prevention of vitamin D deficiency

Patient group	IU/day	Chewable Tablets/day
0 – 1 year	400 – 1,000 IU	1 chewable tablet Biodal chews 1,000 IU
1 – 18 years	600 – 1,000 IU	1 chewable tablet Biodal Chews 1,000 IU
19 – 70+ years	1,500 – 2,000 IU	1 chewable tablet Biodal Chews 2,000 IU
Pregnancy	4,000 IU*	1 chewable tablet Biodal Chews 4,000 IU*
Lactation	4,000 – 6,000 IU	1 chewable tablet Biodal Chews 4,000 IU

*Starting at 12 – 16 weeks' gestation

BIODAL DROPS 400 IU/Drop [2000 IU/5 drops]

Treatment of vitamin D deficiency

Patient group	IU/day	Drops/day
0 – 1 year	For 6 weeks 2,000 IU *Then* 400 – 1,000 IU	For 6 weeks 5 drops *Then* 1 – 3 drops
1 – 18 years	For 6 weeks 2,000 IU *Then* 600 – 1,000 IU	For 6 weeks 5 drops *Then* 1 – 3 drops
19 – 70+ years	For 8 – 12 weeks 5,000 – 6,000 IU *Then* 1,500 – 2,000 IU	For 8 – 12 weeks 15 drops *Then* 3 – 5 drops
Pregnancy	4,000 IU*	10 drops*
Lactation	4,000 – 6,000 IU	10 – 15 drops

*Starting at 12 – 16 weeks' gestation

Prevention of vitamin D deficiency

Patient group	IU/day	Drops/day
0 – 1 year	400 – 1000 IU	1 – 2 drops
1 – 18 years	600 – 1,000 IU	1 – 3 drops
19 – 70+ years	1,500 – 2,000 IU	4 – 5 drops

Pregnancy	4,000 IU*	10 drops*
Lactation	4,000 – 6,000 IU	10 – 15 drops

*Starting at 12 – 16 weeks' gestation

Method of administration:
Biodal tablets are taken orally. Swallow with water.

Biodal Chews are taken orally. Chew or let it dissolve in your mouth.

Biodal Drops 400 IU/Drop [2000 IU/5 drops] are taken orally. The best way is to tilt the bottle and allow the drops to drip into the mouth drop by drop, or if necessary, administer with a spoon and some liquid.

If using for the first time, hold the bottle vertically and gently tap the bottom of the bottle with your finger until the first drop appears.

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® 60,000 IU Tablets: Each film coated tablet contains 60000 I.U. Cholecalciferol in bottles of 10 tablets.
Biodal® 50,000 IU Tablets: Each film coated tablet contains 50000 I.U. Cholecalciferol in bottles of 8, 10, 12, 20 and 30 tablets.
Biodal® 10,000 IU Tablets: Each film coated tablet contains 10000 I.U. Cholecalciferol in bottles of 30, and 50 tablets.
Biodal® 5,000 IU Tablets: Each film coated tablet contains 5000 I.U. Cholecalciferol in bottles of 30, 50, and 60 tablets.
Biodal® 4,000 IU Tablets: Each film coated tablet contains 4000 I.U. Cholecalciferol in bottles of 60 tablets.
Biodal® 2,000 IU Tablets: Each film coated tablet contains 2000 I.U. Cholecalciferol in bottles of 30, 50, and 60 tablets.
Biodal® Chews 4,000 IU Chewable tablets: Each chewable tablet contains 4000 I.U. Cholecalciferol in bottles of 30, and 60 tablets.
Biodal® Chews 2,000 IU Chewable tablets: Each chewable tablet contains 2000 I.U. Cholecalciferol in bottles of 60 tablets.
Biodal® Drops 400 IU/Drop [2000 IU/5 drops]: Each drop contains 400 I.U. Cholecalciferol in bottles of 15 mL.

*Some presentations may not be available in certain countries.

(This is a medicament - Keep medicaments out of 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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